Migration of Stent Grafts Following an Endovascular Aneurysm Repair, A Reappraisal of Current Definitions: An analysis of prevalence, prognosis, and review of surveillance strategies

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Declaration of Originality

I hereby declare that the work in this thesis is my own, any individuals who have collaborated are credited and all else is appropriately referenced.

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In the name of the Lord, the Most Gracious, the Most Merciful

"….Whoever saves a single life, is it as if he has saved the whole of mankind"

This work is dedicated to all my patients who have given me the privilege of caring for them.

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Praise be to You eternally, and gratitude forever is due to You for Your endless bounties."

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Abstract

The introduction of endovascular aneurysm repair (EVAR) has transformed the treatment of abdominal aortic aneurysms, yet stent graft migration remains a complication driven by intrinsic aortic changes. A lack of standardisation complicates reporting; a systematic review identified 18 definitions, with only "≥10mm or intervention" showing robust historical validity. This study assessed migration rates across two tertiary vascular centres using a standardised protocol. Migration prevalence varied by definition: 20.7% (≥5mm), 11.3% (≥10mm), and 14.7% (≥10mm or intervention). Migration ≥10mm was associated with a significantly higher risk of proximal seal failure compared to migration at 5-9.9mm (27% vs 5%, p=0.001). The average time to migration was 63.6 months, confirming it as a long-term complication. Crucially, "early migration" (≥5mm within 18 months) was identified as a powerful predictor of eventual ≥10mm migration (OR 139.3, CI 39.15-495.6, p<0.001). This provides a practical, accessible screening tool for identifying high-risk patients. Additionally, freehand electromagnetic 3D ultrasound successfully reconstructed a phantom aorta to measure EndoAnchor positions. This demonstrates a foundation for future non-invasive, radiation-free post-operative surveillance despite current challenges with EndoAnchor visualisation.

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Presentations

Oral Presentation

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Developing a Pulsatile Flow Model. Abdullah A, Hanna L, Riga C, Bicknell C. London Surgical Symposium. London, UK (2021).

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Abbreviations

3D	3-dimensional
AAA	Abdominal Aortic Aneurysm
AP	Anterior to Posterior
BMF	Blood mimicking fluid
CFD	Contralateral fabric distance
CIA	Common iliac artery
CI	Confidence interval
CM	Clinical migration
COPD	Chronic obstructive pulmonary disorder
CSM	Clinically significant migration
CTA	Computed tomography angiography
CT	Computed tomography
DOF	Degrees of freedom
EM	Electromagnetic
EMT	Electromagnetic tracking
ESVS	European Society of Vascular Surgery
EVAR	Endovascular Aneurysm Repair
FEVAR	Fenestrated endovascular aneurysm repair
FOV	Field of view
GP	General practitioner
GREAT	Global Registry for Endovascular Aortic Treatment
HR	Hazard ratio
IHD	Ischaemic heart disease
IFU	Instructions for use
IIA	Internal iliac artery
IMU	Inertial measurement units
LRA	Lowest renal artery
MG	Migratory group
NHS	National Health Organisation
NMG	Non-migratory group
NVR	National Vascular Database
OR	Odds ratio

OSR	Open surgical repair
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RM	Radiological migration
ROI	Region of interest
ROC	Receiver operator characteristics
SFD	Shortest fabric distance
SG	Stent graft
SMA	Superior mesenteric artery
SD	Standard deviation
SVS	Society of Vascular Surgery
UK	United Kingdom
US	Ultrasound
USS	Ultrasound scan

1 Introduction

1.1 Aetiology, Pathophysiology and Prevalence of AAA

1.1.1 Aetiology

Abdominal Aortic Aneurysm (AAA) is a pathological condition characterised by localised dilation of the abdominal aorta, typically involving the infrarenal segment. The aetiology of AAA is multifaceted, encompassing genetic, environmental, and lifestyle factors. Evidence of genetic predisposition is apparent through familial clustering of AAA cases and the identification of polymorphisms in genes associated with extracellular matrix regulation and inflammation. Environmental risk factors, particularly smoking, are significant contributors. A comprehensive understanding of these factors is essential for personalised risk assessment and the formulation of effective preventative strategies [1].

1.1.2 Pathophysiology:

AAA manifests as a localised dilation of the abdominal aorta. It is understood that the typical, although not exclusive central pathological driver is atherosclerosis, a chronic condition characterised by the deposition of lipid-rich plaques along the arterial wall. This initiates a cascade of events, including chronic inflammation, leading to the degradation of extracellular matrix components. The arterial wall weakens under the influence of biomechanical stress and hemodynamic forces, ultimately resulting in the dilation of the aorta and the formation of an AAA. Inflammatory cascades, involving cytokines, proteases, and immune cell activation, play a pivotal role in perpetuating the vascular remodelling process associated with AAA development. If left untreated, the enlarged and weakened aortic wall is at an increased risk of rupture, posing a severe and likely life-threatening complication [2].

1.1.3 Prevalence:

The prevalence of AAA displays distinct demographic patterns closely tied to age, gender, and various risk factors. The incidence rises exponentially with age, predominantly affecting individuals over 65, with a higher occurrence in men. Global estimates of AAA prevalence

range from between 1.3% and 12.5%, in individuals over 65, with variations influenced by geographical, ethnic, and socio-economic factors [3]. Screening programs, particularly those targeting high-risk populations such as elderly men with a history of smoking, have proven effective in early detection. However, as the majority of AAA remain asymptomatic which underscores the importance of proactive screening efforts for at-risk populations. The global prevalence of AAA among persons aged 30 to 79 years was 0.92% (95% CI, 0.65–1.30), translating to a total of 35.12 million (95% CI, 24.94–49.80) AAA cases in 2019 [4].

1.2 Defining treatment options for AAA

Abdominal Aortic Aneurysm (AAA) repair can involve various treatment options, each tailored to the specific characteristics of the aneurysm and the patient's overall health. However, the two primary approaches include open surgical repair (OSR) and endovascular aneurysm repair (EVAR).

1.2.1 Open Surgical Repair (OSR)

The purpose of OSR aims to eliminate the risk of AAA rupture by replacing the weakened aortic wall with a synthetic graft. This is carried out under general anaesthesia with extensive patient monitoring. The abdominal aorta is accessed through a midline, subcostal incision, or a retroperitoneal approach. The choice depends on surgeon preference and patient factors. A proximal clamp is positioned below renal arteries, followed by distal clamps on the common iliac arteries. The aneurysmal segment is excised, replaced with a tube graft usually made from polyester based material. The choice of a straight tube graft or bifurcated graft will depend on the patients' anatomy and concurrent aneurysms within the iliac systems. Patients typically require postoperative care on the high dependency unit [5].

1.2.2 Endovascular Aneurysm Repair

The aim of an endovascular approach, is to exclude the aneurysm sac from systemic circulation, diverting blood beyond the renal arteries through a prosthetic conduit (SG) into the iliac system. The procedure is carried out under fluoroscopic guidance and can be performed under local, regional, or general anaesthesia. Surgical access is typically gained

through both common femoral arteries, with either a surgical cut down or percutaneously. Vascular sheaths are introduced into the femoral arteries, to facilitate the passage of guidewires, catheters, and the endograft. An angiogram is then taken to aid in the deployment of the stent, before the main body at the level of the renal arteries is deployed, followed by two limbs into each common iliac vessel [5].

Since the inception of EVAR technology, there has been a shift in treatment from OSR to EVAR, whereby in some institutions, the number of EVAR's far outweigh the number of OSR in contemporary practice [6].

Extensive works have been published comparing the two approaches in the treatment of AAA, both in the elective and emergency setting. Four major randomised controlled trials have provided the primary evidence base for EVAR versus OSR outcomes: the UK EVAR-1 trial comparing EVAR with open repair in patients fit for either procedure, the UK EVAR-2 trial comparing EVAR with best medical therapy in patients unfit for open repair, the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial, and the US Open Versus Endovascular Repair (OVER) trial conducted in the Veterans Affairs healthcare system [7-10]. A meta-analysis of individual patient data from these four trials demonstrated an early survival advantage for EVAR that eroded over time, with no significant difference in aneurysm-related mortality at 5 years [11]. All trials consistently showed higher reintervention rates following EVAR compared to open repair, reflecting the ongoing surveillance and secondary procedure burden associated with endovascular treatment. It is therefore pertinent to continue to evaluate this relatively new treatment and the long-term implications of this continuously evolving technology.

1.3 The Evolution of Stent Grafts

Since the initial inception of EVAR, using primitive physician made stents, there has been a drastic evolution in the stent design, material, deployment systems, experience and 'instructions for use' (IFU) from manufacturers, reducing the mortality and morbidity first associated with this procedure, with eventual comparable outcomes to OSR, which has been shown to converge with OSR in extended follow-up. However, this equivalence in survival masks a trade-off, in which EVAR is associated with a significantly higher rate of late,

device-related complications and re-interventions, which necessitates lifelong surveillance [12]. The conception and subsequent development of EVAR technology was ensuing on two fronts: in modern day Ukraine, and in South America.

Nicolai Leontyevich Volodos, a cardiovascular surgeon in Kharkov, USSR, was part of a team which, in 1980 fashioned fenestrations in aortic dissection cases using an endovascular approach. In 1987, his team together with *The Technical Physical Institute for Low Temperature in Kharkov*, published the first comprehensive works on the employment of graft technology within arteries, based on testing which had started in 1983. Voldos' team deployed their first endovascular stent in 1985, to treat a patient with a common iliac artery stenosis. Following on from this he undertook the first EVAR in 1987, by deploying a SG in a post-traumatic aneurysm in the distal thoracic aorta, Figure 1. A further 9 patients were treated with SG in his published case series in 1987. In 1993, Voldos' team deployed their first successful EVAR, for the treatment of an AAA, following unsuccessful attempts with a bifurcated device dating back to 1989 [13].

Figure 1: Words first EVAR, Voldos 1987

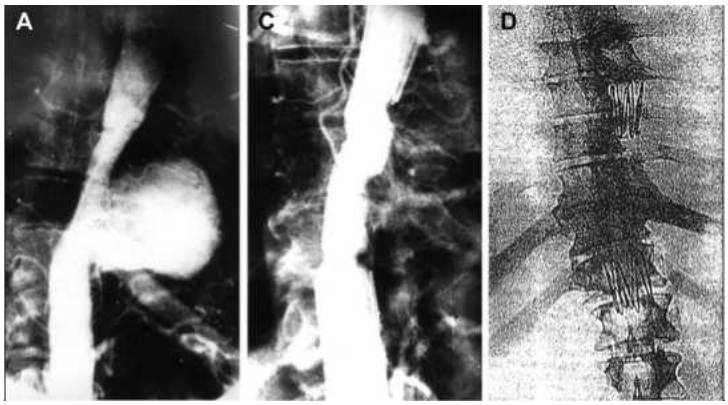


Figure 1: The world's first patient treated by Nicolai L. Volodos with an aortic stent graft for a post-traumatic thoracic aortic aneurysm in March, 1987. Published in Russian [13].

Concurrently, in the west Juan Parodi, an Argentinian surgeon first developed two prototypes, for AAA repairs, which failed to translate into any successful attempts and remained unpublished in 1976. Following ongoing benchtop and animal testing, he then collaborated with Julio Palmaz, who had designed a balloon expandable stent. This allowed Parodi to revisit his original design and with the aid of a Palmaz stent attached to a knitted

straight polyester dacron graft (Figure 2), this was successfully deployed in a patient in 1990 and led to the treatment of several more in their published case series in 1991 [14].

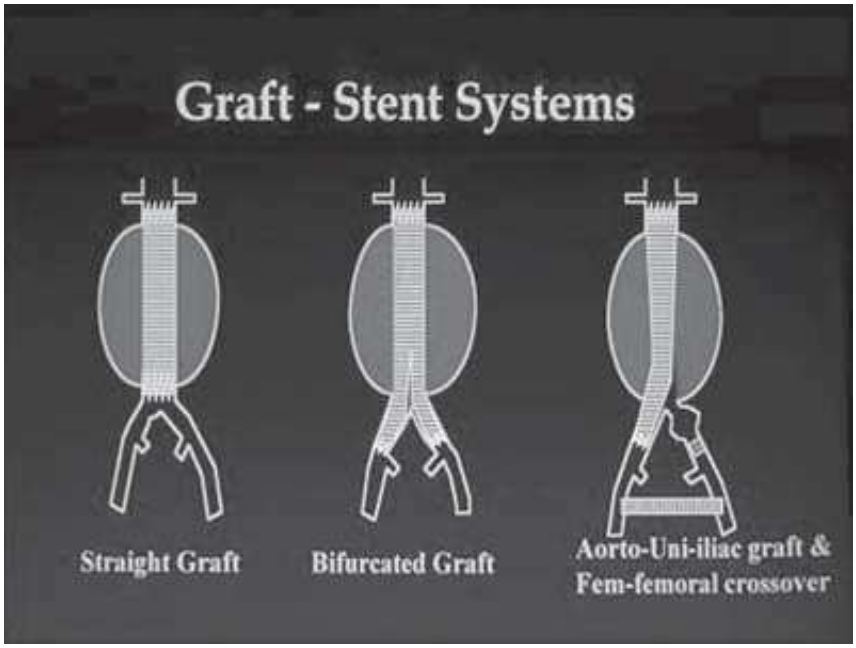
Figure 2: Parodi tubular endostent graft used in his treatment of AAA, 1991



[13]

By the mid 1990's commercially manufactured devices began to emerge on the market and physicians also became better equipped with manufacturing their own devices. Despite these improvements the EUROSTAR registry highlighted the particularly high levels of reinterventions which followed EVARs, 40 percent over 4 years [15]. The design of SG evolved to extend into the iliac arteries as this was found to provide a better purchase with a reduced incidence of migration and type 1 endoleaks, Figure 3 ([12]

Figure 3: EVAR configurations in the early treatment of AAA



[12]

To avoid grafts collapsing and kinking a supporting scaffolding stent was incorporated within the stent design. The first such stent was based on Gianturco's Z-based stainless-steel stent (which was originally designed for oesophageal strictures), this allowed the SG to be inserted into a smaller catheter and then deployed within the aorta, acting as a self-expanding stent [12]. Other alloys such as nitinol or elgiloy, in addition to stainless steel make up the composition of other stent graft scaffolding materials used by commercial manufacturers to date [16].

Graft material in OSR was initially developed from parachutes by Voorhees (N-vinyon by Vorhees in 1952). However early grafts were beset with issues regarding their durability. Over time, stent designs were refined to resist degradation, be less porous, less thrombogenic and hold sutures without unravelling. Ultimately, two distinct fabrics were eventually favoured in OSR, woven polyester (Dacron) and expanded polytetrafluoroethylene (ePTFE) [12]. EVAR fabric designs have similarly also evolved over time: the Gore Excluder and Vanguard, used ultra-thin ePTFE so that they may be easily housed within the delivery systems however this came at the cost of increased porosity and subsequent AAA sac size increase. These designs were revisited in 2004, W. L. Gore & Associates introduced a new version of the Gore Excluder device made from a low permeability ePTFE fabric. The

original ultra-thin ePTFE was porous, allowing blood plasma to seep through the graft wall. This fluid tansudation into the aneurysm sac could lead to persistent pressure, creating endotension. The new low-permeability material was specifically engineered to reduce this transudation, which was proven in subsequent studies which showed similar sac size regression as the standard polyester grafts such as the Zenith (Cook) [17].

1.3.1 Stent Graft Eras

Tadros et al (2014) conducted a review of EVAR outcomes in accordance to SG generations. They stratified all SG since their inception into four distinct generations or eras, Table 1: EVAR stent Era's, Tadros et al [18].

1.3.2 Era 1 (1986-2003)

Related to the very first primitive physician made grafts as those created by Parodi and Marin, who were some of the first to experiment with this novel method.

1.3.3 Eras 2 and 3 (1994-2012)

These SG relate to the those which were first introduced by commercial companies that required refinement over time and different iterations. None of these stent grafts are currently being used routinely.

1.3.4 Era 4 (2008- present)

These are the SG which are currently being used and have their own registries which publish their outcomes at different time intervals.

Table 1: EVAR stent Era's, Tadros et al [18]

Device and manufacturer	Dates used
Era 1: Physician made	
Juan Parodi	11/92-01/95
Michael Marin	06/94-06/03
Era 2: Early industry	
Endovascular Technologies (EVT)	06/94-05/96
Boston Scientific (Vanguard)	08/97-03/00
Guidant (Ancure)	05/00-03/01
Teramed (Ariba)	07/00-08/00
Cordis (Quantum LP)	04/02-04/03
Early Gore (Excluder)	05/98-06/03
Early Medtronic (Talent)a	04/98-03/11
Early AneuRx (AAAdvantage)	11/99-06/03
Era 3: Intermediary industry	
Aptus Endovascular (Aptus)a	12/07-02/08
Powerlink (Endologix)a	12/06-05/12
Intermediary Gore (Excluder)	06/03-01/08
Late Medtronic (Talent)a	04/98-03/11
Late AneuRx (AAAdvantage) a	06/03-10/10
Early Cook (Zenith)	12/03-01/08
Era 4: Modern industry	
Late Cook (Zenith)	01/08-02/12
Medtronic (Endurant)	09/08-07/12
Late Gore (Excluder)	01/08-07/12

Eras were defined generally to categorize the various endografts as best as possible by the time periods: era 1, all physician-made devices; era 2, June 1994 to June 2003; era 3, June 2003 to January 2008; era 4, January 2008 to July 2012.
EVT (Endovascular Technologies, Menlo Park, Calif); Vanguard (Boston Scientific, Natick, Mass); Ancure (Guidant, Indianapolis, Ind); Ariba (Teramed, Maple Grove, Minn); Quantum LP (Cordis, Waterloo, Belgium); Excluder (Gore, Flagstaff, Ariz); Talent (Medtronic, Minneapolis, Minn); AAAdvantage (AneuRx; Medtronic, Santa Rosa, Calif); Aptus (Aptus Endovascular, Sunnyvale, Calif); Endologix (Powerlink, Irvine, Calif); Zenith (Cook, Bloomington, Ind); and Endurant (Medtronic, Minneapolis, Minn).
a: These devices were used outside of the date range defined by the eras because of case-by-case circumstances.

Tadros et al found that complications, rates of reintervention and mortality significantly improved with each generation of SG. This in part is due to both improved clinician experience with EVAR and improved design of the SG. Such findings would concur with industry registries which have published reassuring outcomes [19].

Proponents of EVAR have routinely highlighted that there has been a continuous improvement in outcomes despite the short history of this technique. Consequently, EVAR outcomes cannot be accurately represented using historic data taken from earlier generation stents to represent the current treatment standards [20]. Therefore, an adequate assessment of EVAR can only be made on current practice, a rationale which has prompted the need to evaluate the outcomes of 4th generation SG in the subsequent chapters.

1.4 EVAR specific Complications

EVAR has become an established technique for the treatment of infrarenal aortic aneurysms. While EVAR is notably less invasive than traditional open surgical repair, it is not devoid of complications. These complications have the potential to lead to significant morbidity or, in severe cases, mortality. These may be categorised into:

1.4.1 Surgical complications

Local wound complications from the access site, most notably the groins, have a 1-10% incidence. These include, groin hematoma, infection and lymphocele [21]. The access artery is also at risk of injury in the form of acute thrombosis, dissection and pseudoaneurysm formation in up to 3% of cases [22].

1.4.2 Contrast nephropathy

The accurate deployment of SG during an EVAR is contingent on the use of digital subtraction angiography, which is best achieved with iodine-based contrast. An average of 50-100mls is used during an EVAR with a resulting incidence of contrast-induced nephropathy and subsequent acute renal failure in up to 6.7% of cases [23]. To mitigate this risk, particularly in patients with pre-existing renal impairment, carbon dioxide (CO_2) can be used as an alternative contrast agent. A propensity-score matched study has shown that CO_2-guided EVAR significantly reduces the incidence of post-operative contrast-induced nephropathy in this high-risk population. However, this renal-sparing benefit comes with the significant limitation of inferior image resolution compared to standard angiography, which can make precise visualisation of visceral anatomy more challenging for the operator [24].

1.4.3 Ischaemic events

Ischaemic complications may occur secondary to thrombo-embolic events following instrumentation of the arteries during an EVAR. This may occur at any site of the vascular tree where wires have been introduced, including the supra-aortic segments, in the form of a stroke or upper limb ischemia. where the stiff wire is placed. There is also a risk of visceral ischaemia, (coeliac, superior mesenteric, renal, and inferior mesenteric vessels as the source) and lower limb ischaemia.

Ischaemia can also occur secondary to the occlusion of feeding vessels, notably colonic ischaemia (1-3%) following coverage of the inferior mesenteric artery [25], renal ischaemia (<5%) following the inadvertent coverage of the renal arteries [26] or spinal ischemia (0.21%) due to the coverage of lumbar vessels [27], originating from the infra-renal abdominal aorta. Occlusion of the internal iliac artery, whether planned or not can contribute to pelvic ischaemia, colonic or rectal ischaemia and spinal cord ischaemia. An Occlusion of the endograft or its distal limbs, at any time following its deployment can result in lower limb ischaemia [28].

Acute limb ischaemia (ALI) is another well-recognised ischaemic complication, typically occurring in the immediate post-operative period. This is often caused by thromboembolism

or arterial dissection related to the passage of large-bore delivery systems through the iliofemoral access vessels. Recent studies have identified several key risk factors for developing ALI within 30 days of EVAR, including female sex (often associated with smaller vessel calibre), extensive iliofemoral calcification, and narrow access artery diameter [29].

1.4.4 Endoleaks

Endoleaks represent the most frequent complication following EVAR, manifesting in 15-30% of patients within the initial 30 days post-procedure. The classification system comprises five distinct categories, differentiated by anatomical location and underlying pathophysiological mechanism (Table 2). Each type carries discrete implications for stent graft stability and the potential for subsequent migration [30].

1.4.5 Endograft migration

Device migration, a frequent complication necessitating secondary intervention (when identified) following an EVAR, is characterised by the displacement of the endograft by more than 5–10 mm from its initial position. This can lead to a loss of proximal seal and lead to a type 1a endoleak [31].

1.4.6 Limb retraction

Limb retraction is an important late complication of the distal limb. This is defined as an increase of ≥ 5 mm in the distance between the iliac bifurcation and the distal sealing point of the endograft limb. This type of retraction is particularly associated with an increased risk of Type Ib endoleaks during long-term follow-up. Risk factors for this complication include the use of large diameter (≥ 24 mm) and 'bell-bottom' style iliac limbs, with a sufficient initial length of seal being the only protective factor against it [32]

1.4.7 Endograft kinking or occlusion

Endograft kinking and limb occlusion are serious complications that can lead to acute or chronic lower extremity ischemia. A recent large, dual-centre UK study of 787 patients identified an overall limb occlusion rate of 6.35% [33].

While kinking is a contributing factor, the study found that the most significant independent predictor for limb occlusion was excessive oversizing of the iliac limb relative to the native vessel diameter. Oversizing by more than 20% was present in half of all patients who experienced a limb occlusion. The proposed mechanism is that excessive oversizing causes "pleating" of the graft fabric, which disturbs blood flow and promotes thrombus formation. The study also noted that different endografts had varying occlusion rates, with the Cook Zenith graft demonstrating a higher rate (9%) compared to the Medtronic (2.4%) and Vascutek (2.5%) devices in the cohort. This analysis, however, found no significant correlation with iliac tortuosity, inferring that judicious limb sizing is the most critical modifiable factor for preventing this complication [33].

1.4.8 Endograft infection

Infection of the endograft has been documented in 0.4–3.0% of cases following endovascular repair (EVAR) of the abdominal aorta. This condition is linked to elevated mortality rates, ranging from 25% to 50%, primarily attributable to septic shock [34].

1.4.9 Post-implantation syndrome

Post-implantation syndrome may manifest following EVAR, with a reported incidence ranging from 13–60%. It is believed to signify a typically self-limiting inflammatory immune-mediated reaction, triggered by endothelial activation in response to the endograft material, resulting in the release of inflammatory cytokines. Clinically, symptoms resemble those of the flu and present as a systemic inflammatory response, characterized by fever, leukocytosis, and elevated levels of inflammatory markers such as C-reactive protein (CRP), tumor necrosis factor (TNF)-alpha, and interleukin (IL)-6 [35].

1.5 Stent Graft Migration Pathophysiology and Prevalence

The phenomenon of stent graft migration involves a nuanced interplay of mechanical and biological forces. The process of migration may result, as a consequence of both biomechanical stresses and biological responses, ultimately influencing the configuration of the implanted stent graft within the native aorta [36].

The main driving mechanical displacing force results from the pulsatile nature of blood flow within the aorta, imposing dynamic forces upon the stent graft and its fixation system. These continuous hemodynamic pressures, coupled with the inherent variability in aortic anatomy, can predispose the graft to displacement. Furthermore, anatomical irregularities, such as neck angulation or tortuosity, may further pose challenges to graft conformity and stability, potentially compromising the efficacy of fixation mechanisms [37].

The integrity of the stent graft's fixation system therefore plays a crucial factor in maintaining an effective long-term seal. Anchoring mechanisms, ranging from hooks to suprarenal stents, serve to reinforce this proximal seal against migration. However, any compromise in the integrity of these mechanisms, whether through mechanical failure or anatomical mismatch, weakens the graft stability, leaving it vulnerable to displacement [38].

Following the deployment of a SG, the biological interface between the device and the vascular wall may also be influenced by cellular and molecular interactions. Inflammatory cascades, tissue ingrowth, and subsequent vascular remodelling may alter the mechanical properties of the interface over time. These biological metamorphoses, though intended to fortify the graft-host junction, can inadvertently contribute to migration through alterations in tissue characteristics. In addition, the presence of preoperative thrombus or peri/postoperative thrombus formation as a result of instrumentation, may further contribute to adverse remodelling around the SG, serving as an additional risk factor for migration [39].

Moreover, the inherent properties of the graft material, including flexibility, durability, and biocompatibility, will determine the SG’s resilience against the displacing forces over time. Material degradation, fatigue, or deformation may contribute to the onset of migration [36].

1.5.1 Aortic graft fixation

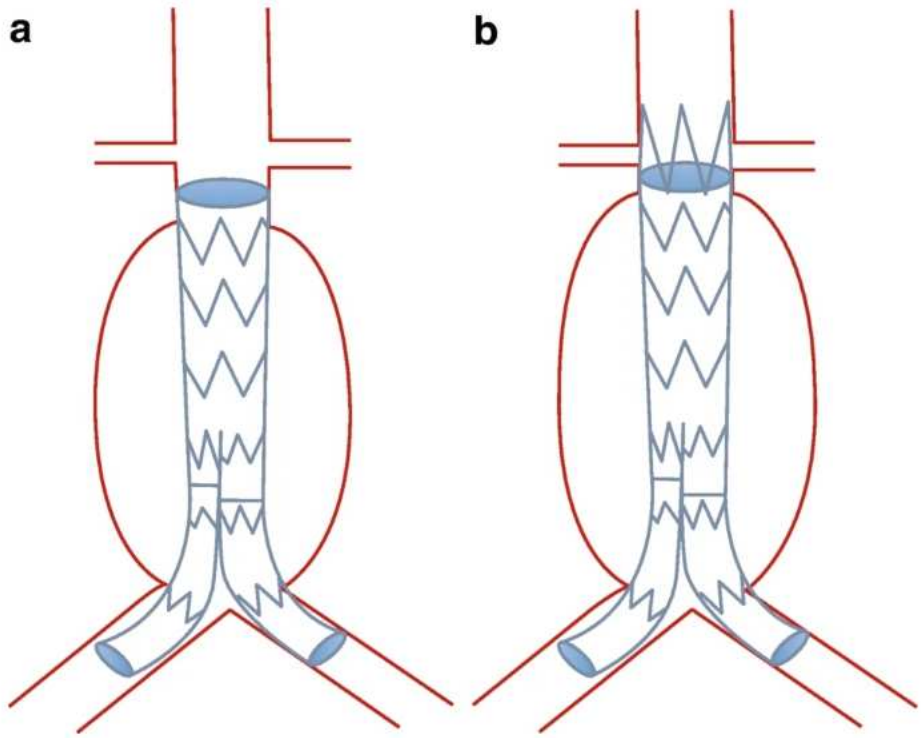
Stent graft migration is thought to occur when the device stabilisation forces are overcome by displacement forces. Longitudinal displacement forces originate from caudal blood flow, cross-sectional area reductions in graft diameter, angulation, gravitational forces and those attributable to morphological changes. The SG fixation forces mainly rely on radial forces, which can be influenced by aortic anatomy such as, vascular wall compliance and affect the stent-graft dynamically throughout the cardiac cycle in regions where there is close apposition of the device to the arterial wall, such as the proximal and distal fixation sites [36].

1.5.2 Inadequate Fixation

Fixation in EVAR denotes the secure attachment of the endograft within the aortic wall, ensuring its stability, functionality, and long-term success to establish a robust seal. In order to achieve this seal, the deployment of stents, hooks, or other anchoring mechanisms that intimately engage with the aortic anatomy, have been employed [38].

Two primary philosophies of proximal fixation have emerged, which are well-exemplified by the designs of the Medtronic and Gore endograft systems. Suprarenal Fixation such as the Medtronic Endurant, employ active suprarenal fixation. This design features a bare metal stent with small hooks or barbs that extends above the lowest renal artery. These hooks anchor directly into the healthy aortic wall, providing a secure mechanical grip intended to resist the downward forces that cause migration. Gore Excluder however in contrast utilises infrarenal fixation. This mechanism sits entirely below the renal arteries and relies on the stent's strong radial force to press outwards against the aortic wall, creating a tight friction seal, in addition to infrarenal hooks. This design avoids placing any material across the renal arteries (Figure 4).

Figure 4: Schematic diagram comparing infrarenal and supra renal fixation.



Schematic models of aortic endoprostheses: (a) infrarenal fixation endoprosthesis; (b) suprarenal fixation endoprosthesis [40]

The anchoring mechanism serves as the architectural foundation, determining the resistance of the endograft against the relentless forces exerted by the pulsatile blood flow within the aorta. A failure in achieving proper fixation can set the stage for a cascade of complications, with migration standing as a prominent concern. Various factors contribute to inadequate fixation: device structural integrity to withstand the biomechanical stresses within the aorta and deployment technique plays a pivotal role; ensuring the anchoring components are appropriately engaged with the aortic wall. Complications arising from inadequate fixation are often gradual, unfolding over time as the forces acting on the endograft persist. The consequences can manifest as a subtle shift or movement of the device within the aorta, ultimately leading to migration and subsequently compromises seal zone [30].

1.5.3 Pre-operative aortic neck anatomy and mechanisms of failure:

The long-term success of an EVAR is critically dependent on achieving a durable seal in the proximal aortic neck. Manufacturer Instructions for Use (IFU) define an "ideal" neck as

having adequate length (typically ≥15 mm, but not exclusively), a diameter between 18-32 mm, and minimal angulation (<60°) or calcification/thrombus. Anatomy that fails to meet these criteria is termed "hostile neck anatomy." [41] The clinical significance of hostile neck anatomy is substantial, with large-scale registry data demonstrating that approximately 34% of patients undergoing EVAR have at least one hostile neck characteristic [42].

Treating such patients is common in real-world practice but is unequivocally associated with significantly poorer outcomes. A meta-analysis by Antoniou et al. (2013) analysing 1,559 patients across seven studies found that patients with hostile anatomy had a four-fold increased risk of developing Type I endoleak (OR 4.563; 95% CI, 1.430-14.558) and a nine-fold increased risk of aneurysm-related mortality within one year of treatment (OR 9.378; 95% CI, 1.595-55.137) compared to those with favourable anatomy [43]. These findings have been corroborated by more recent large database studies, including analysis of 14,739 patients in the Vascular Quality Initiative (VQI), which confirmed that hostile neck characteristics are independently associated with perioperative Type Ia endoleaks and reduced long-term survival [44].

1.5.3.1 Neck Length

Neck length represents one of the most critical determinants of endograft success. A minimum sealing zone of 10-15 mm is mandated for adequate seal between the proximal stent graft and healthy infrarenal aortic tissue [45, 46]. Short necks (<15 mm) provide insufficient surface area for both radial and active fixation forces to counteract the constant downward hemodynamic displacement forces acting on the endograft. Registry data from the VQI demonstrates that 19.6% of EVAR patients have neck lengths <15 mm [44]. Consequently, short neck length is one of the strongest independent predictors of late stent graft migration and subsequent device failure [43, 47, 48]. Mathlouthi et al. (2022) demonstrated a significant correlation between shorter aortic neck lengths and late outcomes in their analysis of the Ovation stent graft, reinforcing the critical importance of adequate neck length for long-term durability [49].

1.5.3.2 Neck Shape

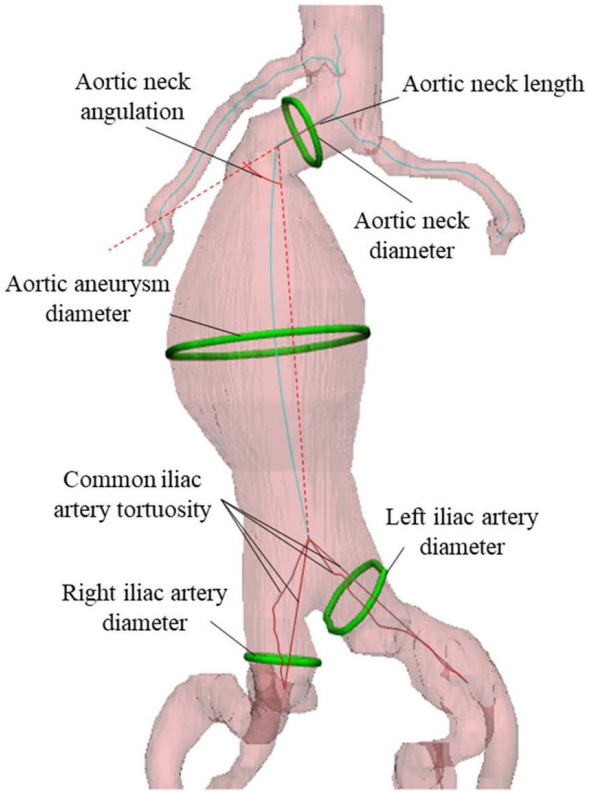
Neck morphology significantly influences the apposition of stent graft material with the aortic wall. When a straight parallel tube graft is deployed within a conical, reverse conical, or "double bubble" neck configuration, this reduces the surface area of aortic wall contact and compromises the radial force required to maintain an adequate seal [41]. Such morphological variants are classified as hostile and are recognised precipitants of graft failure manifesting as migration and endoleaks [43]. A Delphi Consensus Group has formally recognised these morphological variants as hostile characteristics requiring special consideration during treatment planning [41].

1.5.3.3 Aortic neck diameter

Contemporary guidelines recommend stent graft oversizing by 10-25% to accommodate aortic diameter variations during the cardiac cycle and ensure adequate radial force for wall apposition [50, 51]. However, necks exceeding 28-30 mm present distinct challenges. VQI data shows that 9.1% of EVAR patients have neck diameters >30 mm [44].
Wide or aneurysmal necks pose two fundamental problems. First, they reduce the effectiveness of endograft radial force, making stable friction seal achievement difficult. Second, wide necks are often part of the aneurysmal disease process itself and prone to progressive dilatation over time, leading to loss of seal years after initial deployment and resulting in late Type Ia endoleaks [42, 52]. Howard et al. (2018) demonstrated in their analysis of the Gore Global Registry that proximal aortic neck diameter significantly influences durability of aneurysm sealing and overall survival [53].

1.5.3.4 Aortic neck angulation

Figure 5:Aortic anatomy



[50]

Severe neck angulation, defined as infrarenal neck angulation exceeding 60 degrees, occurs in 6.3% of EVAR patients according to VQI data [3, 41, 44]. The irregular geometry of significantly angulated necks creates multiple challenges for endovascular repair. It poses difficulties in appropriate stent graft deployment and conformity to the vessel wall, potentially resulting in gaps or areas of inadequate apposition that increase susceptibility to endoleaks [45].

The mechanical forces acting on stent grafts within highly angulated necks are unevenly distributed, predisposing devices to migration. Pulsatile blood flow and dynamic movements of adjacent anatomical structures exert varying degrees of stress on different graft regions, which may exceed fixation system tolerances and compromise device stability [48]. Furthermore, the cyclic loading from pulsatile flow combined with non-linear neck geometry

may accelerate fatigue-related failure mechanisms, including material degradation and fixation system loosening [45].

Seike et al. (2020) demonstrated that preoperative neck angulation is independently associated with aneurysm sac growth due to persistent Type Ia endoleak after EVAR, with poor apposition serving as a powerful predictor of proximal seal failure [45]. This relationship has been quantified in recent studies developing novel morphological predictors, such as the "neck hostility index," which incorporates the combined effect of angulation distance and neck length [54].

1.5.3.5 Clinical implications

The clinical significance of hostile neck anatomy is dependent on the summation of the individual anatomical parameters. Kontopodis et al. (2020) demonstrated in their systematic review and meta-analysis that the combined effect of multiple hostile features is more threatening to proximal seal integrity than individual characteristics alone [55]. Data from large registries consistently shows that EVARs performed in patients with hostile neck anatomy require increased numbers of adjunctive procedures, with Antoniou's meta-analysis revealing a three-fold increase in requirement for adjunctive procedures to achieve proximal seal (OR 3.050; 95% CI, 1.884-4.938) [43], a concept which was further quantified by the ‘Hostile Neck Index’ [54]

Contemporary practice patterns reveal that a significant proportion of real-world EVAR procedures are performed in patients with anatomy outside manufacturer IFU parameters, underscoring the clinical importance of understanding these failure mechanisms for appropriate patient selection and intensified post-operative surveillance [42, 56]. This reality necessitates careful consideration of alternative treatment strategies, including complex endovascular techniques, hybrid procedures, or open surgical repair in patients with multiple hostile characteristics.

1.5.4 Graft Design

The design of the endograft influences its interaction with the aortic anatomy. Factors such as the flexibility, conformability, and radial force of the graft play a role. Grafts that do not conform well to the aortic contours may be more prone to migration over time.
In the realm of EVAR, the intricacies of graft design emerge as a paramount facet dictating the procedural dynamics and long-term outcomes. The graft, serving as the architectural linchpin of the endovascular intervention, undergoes meticulous scrutiny, with its structural nuances intricately woven into the fabric of procedural success and patient well-being [57].

A requirement for SG design is the consideration of optimal conformance to the dynamic vascular anatomy. The endograft, typically crafted from textile polyester material – notably polyethylene terephthalate, is one preferred material for its role in withstanding biomechanical and pulsatile forces in addition to its properties of integration within the native aortic anatomy [58]. The SG is also required to be flexible to adapt to the contours of the aorta. The graft's inherent flexibility is a key determinant in ensuring a conformal fit, minimising the risk of endograft migration, and optimising the sealing capacity at the proximal attachment site [59]. However, a delicate balance is required, as excessive flexibility may compromise the graft's radial force, potentially compromising its efficacy .

The radial force, an elemental facet of graft design, relates to the graft's inherent ability to exert outward pressure against the aortic wall. This characteristic requires careful calibration to maintain graft patency while averting complications such as kinking or collapse.
Achieving an optimal radial force is pivotal, as inadequate force may predispose the graft to deformation, while excessive force may inflict undue stress on the aortic wall.

Moreover, the graft's deployment mechanism also plays a role in ensuring it long term durability. The controlled and precise deployment of the endograft is paramount, ensuring its apposition to the aortic wall and, consequently, the adequacy of fixation and therefore averting complications such as endoleaks and graft migration [60].

1.5.5 Post-operative changes

1.5.5.1 Aneurysm Sac Changes

Dynamic changes in the size and shape of the aneurysm sac post-EVAR can impact the stability of the endograft. If the sac increases in size, there may be a loss of contact between the graft and the aortic wall, potentially leading to migration. An increase in aneurysm sac post SG deployment can not only lead to rupture but is also an independent risk factor for graft failure [61]. Aneurysmal sac growth may be due to number of causes, most notably an endoleak. However, regardless of the cause, routine surveillance of the aneurysmal sac diameter is necessary in the postoperative surveillance of patients who have undergone an EVAR, to monitor the graft position and pre-empt intervention for impending SG failure [62].

1.5.5.2 Endoleaks

Endoleaks post implantation of the SG may compromise its ultimate durability. Changes may be categorised as dynamic biological changes within the aneurysmal sac resulting in in-direct forces on the SG or an increase in high pressure forces contributing to direct forces on the SG position [60]. Endoleaks represent the most frequent complication following EVAR, manifesting in 15-30% of patients within the initial 30 days post-procedure. The classification system comprises five distinct categories, differentiated by anatomical location and underlying pathophysiological mechanism, each carrying discrete implications for stent graft migration risk (Table 2).

Table 2: Endoleak catagories

Endoleak Type	**Definition**	**Mechanism**	**Relationship to migration**
Type I	Blood Flow into the aneurysm sac due to inadequate seal at attachment sites		
1a (Proximal)	Leak at Proximal attachement zone	Inadequate proximal seal, neck dilatation, graft undersizing	High Migration risk: promoting caudal displacement
1b (Distal)	Leak at distal attachment zone	Inadequate distal seal, iliac dilatation	Low migration risk - affects distal fixation

Type II	Reterograde flow from branch vessels		
IIa	Single vessel (IMA, lumbar)	Collateral circulation with the potential to maintain pressure	Indirect migration risk – sac enlargement may alter mechanics
IIb	Multiple vessels	Complex collateral network	Moderate migration risk- persistent sac pressurisation
Type III	Graft structure failure		
IIIa	Fabric tears/holes	Material fatigue, manufacturing defect	High migration risk -Loss of structural integrity
IIIb	Modular disconnection	Component separation, inadequate overlap	Variable migration risk – Depends on location
Type IV	Graft porosity	Flow through intact graft fabric	No migration risk – Usually self-limiting
Type V	Endotension	Sac enlargement without visible leak	Unknown migration risk – Mechanism unclear

Classification of endoleaks, mechanisms, and relationship with stent graft migration (adapted from White et al. [63, 64]and Veith et al [64].

The pathophysiological relationship between endoleaks and stent graft migration operates through multiple interconnected mechanisms.The presence of an endoleak may allow increased pressure within the aneurysm sac, creating a hydraulic force that acts on the stent graft. This force can exert pressure on the graft and its fixation system, potentially causing it to shift or migrate over time. Endoleaks may also disrupt the normal flow patterns within the aneurysm sac and around the stent graft. These altered hemodynamic conditions can create turbulent flow or currents that impose additional mechanical stresses on the graft and increase the risk of migration [65]. Furthermore, persistent endoleaks can lead to the accumulation of blood or other fluids within the aneurysm sac. The presence of fluid may create a slippery environment that reduces friction between the graft and the vessel wall, making it easier for the graft to migrate . Endoleaks may also trigger a chronic inflammatory response within the aneurysm sac, leading to tissue remodelling and degradation of the surrounding vascular tissues. These inflammatory changes may alter the mechanical properties of the vessel wall and the interface with the stent graft, contributing to graft migration over time [66].

High pressure direct endoleaks such as Type Ia, Ib or III may compromise the stability of the interface between the stent graft and the vessel wall. The presence of persistent flow into the aneurysm sac can disrupt the seal between the graft and the vessel wall, weakening the fixation and increasing the likelihood of migration [62]. Type I endoleaks, particularly Type Ia occurring at the proximal attachment site, establish the highest risk environment for migration due to their direct impact on the primary fixation zone. Conversely, Type II endoleaks, whilst contributing to sac pressurisation, carry a lower immediate migration risk but may facilitate displacement through chronic sac enlargement and altered device-aorta interface mechanics over extended follow-up periods.

1.5.6 Summary of migratory causes

The cause of SG migration is a multifactorial phenomenon. Established risk factors for SG migration have been identified within the pre-operative planning in accordance with the patient's aortic anatomy, the SG design, deployment of the SG and post-operative phase following an EVAR.

1.6 Defining Migration within scientific literature.

The initial reporting standards for EVAR published by The American Association of Vascular Surgery in 1997, provided one of the first guidelines on EVAR reporting, in order to standardise the reporting methods and provide an objective narrative of both the procedure and important anatomical variances which may influence the outcome of the intervention [67]. Within this document migration is briefly mentioned: with the requirement that it be reported on, rather than providing a definition. With the increased uptake of EVAR, experience in using this novel technology grew and a more substantive tool was required to evaluate the success or failure of this intervention. This prompted the second iteration of the guidelines published in 2002 which provided a significantly more substantial review of its reporting standards [68]. This report addressed migration in slightly more detail, defining migration as: 'migration of the SG of 10mm relative to an anatomical landmark or migration leading to symptoms or requiring therapy' [68]. These reporting standards published in 2002,

continue to be the most current guidelines published by the Society of Vascular Surgery (SVS) in America.

The European Society of Vascular Surgery's most recent guidelines on the management of Abdominal Aorto-iliac Aneurysm (2019), again reiterates the SVS's definition of migration as 10mm. However whilst they acknowledge, that continued aortic dilation is a recognised phenomenon following intervention and the possible role in oversizing stents in the contribution to the development of migration, they have stated that 'the active supra- or infrarenal fixation in modern stents has reduced its prevalence' [69]. The guidelines fall short of any further examination on how to further define migration or assess the orientation of a SG during post-operative surveillance.

Since the inception of EVAR, studies evaluating such repairs, particularly those recording the prevalence of post-operative migration have developed their own specific protocols in defining and recording cases of migration. Defining and measuring the caudal displacement of these grafts has varied dramatically between published literature.

1.6.1 Choice of imaging in determining migration

The limitations, risks and benefits of each form of imaging with regards to postoperative surveillance of EVAR's will be discussed in subsequent chapters. However, described below is a brief outline of existing imaging modalities specific to detecting SG migration.

A contrast enhanced CT scan performed in the arterial phase, is seen as the gold standard in assessing graft integrity and orientation. In the case of determining migration, images are typically assessed using axial, sagittal and coronal views, this allows the operator to manipulate the images to visualise and account for angulation when taking measurements, both parallel to and within the aorta. The process of manipulating the images along different axis, is dependent on the operator and is therefore vulnerable to both intra and inter observer error [70]. Centreline technology such as Terarecon ® and 3mensio® reconstruct images around the contrast and therefore vessel, generating the same image each time using an integrated algorithm. This allows for reproducible, accurate imaging of the vessel from which reliable measurements may be made [71].

Lateral and AP (anterior-posterior) abdominal x-rays are a key component in several post-operative surveillance protocols within the UK [72]. X-rays provide an overview of the stent graft position and integrity over time. Such imaging has been utilised in detecting SG migration, wire frame fracture, and kinking of the graft. Measurements of the SG are made to neighbouring bony landmarks on the film, however, are susceptible to geometric distortion and mandate centring of the image to ensure adequate comparability to subsequent films [70]. Furthermore, the use of vertebral bodies may be unreliable particularly over time, as any changes due to osteoporosis or other bony or spinal conditions may lead to inaccurate measurements [73]

Ultrasound imaging has not been recommended for assessing graft position and integrity due to its poor visibility [71, 72]. The use of percutaneous arterial angiogram provides an accurate understanding of graft position, flow rate, endoleak detection and also allows simultaneous treatment of issues identified. Unfortunately, this can be a lengthy and invasive procedure associated with morbidity to the patient and is therefore unsuitable as a routine surveillance tool [70].

To date up to 39% of UK vascular institutions, included abdominal X-rays in their post-operative surveillance programmes. This is typically in combination with other modalities such as ultrasound [72]. However, such practice falls short of providing a valid assessment of graft migration, despite covering a number of anticipated potential complications following an EVAR [74].

1.6.2 5mm Vs 10mm

Bastos et al (2012), Abbruzzese et al (2008) and Litwinski et al (2006) chose to determine migration at two distances, 5mm and 10mm. They acknowledged the need to have a more conservative definition as migration beyond 5mm in cases with particularly short necks, as they are expected to have an increased likelihood of complications, in contrast to the SVS and ESVS guidance [75-77]. Despite the two definitions, within several studies, some studies have chosen to include only SG's that had migrated 10mm when determining the incidence of migration, in accordance with SVS guidance [77].

1.6.3 Migration protocols

Different protocols amongst authors as to how to determine or measure caudal SG migration below are listed below:

Bastos (2012)

Excluder endoprosthesis (W. L. Gore and Associates, Flagstaff, Ariz).

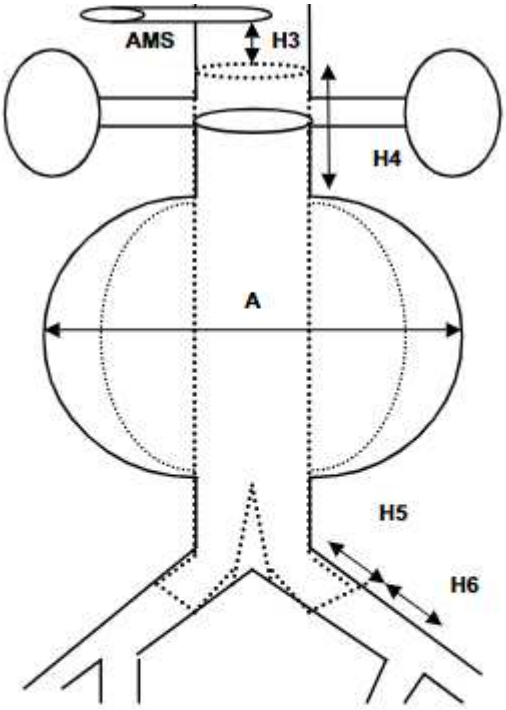
Definition: The distance from the lowermost renal artery to the start of the endoprosthesis was serially measured and migration calculated using the first postoperative measurement as baseline, using centre line technology. [76]

Waasdrop (2009)

Talent device (Medtronic Vascular, Santa Rosa, CA, USA)

Definition: Distal border of SMA to circumferential top of bare metal stent (minimum distance to migration - 10mm) [78]

Figure 6: Anatomical measurements for EVAR



AMS	Superior mesenteric artery
H3	Distance AMS to top of stent graft
H4	Proximal stent graft fixation
A	AAA diameter
H5	Distal stent graft fixation
H6	Distance bottom of stent graft to hypogastric artery

van Heerwarden (2007)

AneuRx device (Medtronic Vascular, Santa Rosa, CA, USA)

Definition: most proximal part of device to lowest renal (minimum distance to migration - 10mm) [79]

Liwinski (2006)

AneuRx device (Medtronic Vascular, Santa Rosa, CA, USA)

Definition: Lowest renal to stent (threshold length to determine migration - not defined) [77]

Fulton (2006)

AneuRx device (Medtronic Vascular, Santa Rosa, CA, USA)

Definition: lowest renal to complete ring of stent [80]

The definitions listed above, are as published by the respective authors in determining migration. Evidently, there exists a great deal of variation in both the quality of the descriptions and methods used. Authors have used either the lowest most renal or the SMA as their landmark reference. There is also a variation in which segment of the artery they have taken as their landmark. Variations also exist in what part of the SG measurements are taken: using single measurement ranging from the first point of the stent graft, to the first time a circumferential ring is seen.

1.7 Limitations of current definitions

1.7.1 Length

The arbitrary use of 10mm migratory distance to meet the definition for migration is precarious. The majority of IFU's have stated a minimum 15mm sealing zone is required in the proximal neck, should the device migrate 8-9 mm, this would have lost more than half the seal and therefore more than half the stabilising force required to keep the SG in place. However, this would not meet the definition of migration. Furthermore, more contemporary grafts on the market, advise the minimum neck length to be even shorter at 10 mm, with the potential of increasing the risk of a type 1a endoleak should the graft migrate [49].

1.7.2 Choice of anatomical landmarks

The limitations of using bony landmarks as reference point in measuring the migration of an intra-arterial stent have been discussed above. Particularly with the use of CT scans, visceral branches are more commonly used, typically the SMA or the lowest most renal [76, 78]. Depending on the specific aortic anatomy of the patient, taking measurements to either of the SMA or lowest renal to the SG may have an element of unreliability depending on where the aorta angulates. However, the employment of centreline technology would limit possible variations in taking such measurements [81]. Aortic elongation is a natural age-related phenomenon. The aorta is reported to elongate 66mm on average in males over the course of their adult life [82]. Therefore, in choosing a reference point (a visceral branch), choosing a

branch closest to the stent, should be associated with least possible variation in distances which would be secondary to aortic elongation rather than SG migration.

1.7.3 Orientation

A SG is a 3-dimensional (3D) structure, which may move in a variety of vectors. If a SG tilts anteriorly-posteriorly with the left and right sealing zones remaining in contact with the aortic wall, this may be missed with the above definitions.

1.8 Summary of existing literature:

Stent graft migration is a recognised complication of EVAR, irrespective of the device implanted. Its aetiology is multifactorial, stemming from the progressive nature of aneurysmal disease, subsequent anatomical changes in the aortic neck, and hemodynamic forces. Since the inception of EVAR, understanding of graft failure risks, such as what constitutes a "hostile neck", has improved, and greater emphasis has been placed on treating patients within the Instructions for Use (IFU).

Despite this progress, the literature demonstrates considerable variability in how migration is quantified. This lack of methodological uniformity contributes to a heterogeneous definition of migration, which consequently obscures its true incidence.

To accurately assess migration rates and temporal trends, it is first essential to understand the various definitions and protocols used in the literature. Establishing which definitions are most common, or if a consensus exists, is a prerequisite for any valid comparison across studies. Only by employing a consistent definition can we reliably determine whether technological advancements have genuinely reduced this complication.

2 Systematic Review

2.1 Introduction

Stent graft migration is a recognised complication following EVAR, yet its reported incidence in the scientific literature is marked by considerable variability [76-80]. This inconsistency presents a significant challenge, making it difficult to ascertain the true prevalence of migration and to evaluate the impact of technological advancements in stent graft design over time.

It is hypothesised that this variation stems from two principal sources: a lack of a standardised definition for migration, and the significant technological evolution of stent grafts across several decades [83]. Consequently, a direct comparison of outcomes between studies is often precarious.

Therefore, the purpose of this systematic review is twofold: first, to systematically identify and categorise the various definitions of migration employed within the scientific literature; and second, to quantify the reported incidence of migration over time, stratified by distinct stent graft 'eras'. This will help to determine whether there has been a demonstrable reduction in this complication. This chapter will provide a critical appraisal of the existing evidence base, establishing the foundation for the original research presented in subsequent chapters which seeks to develop and validate a standardised protocol for measuring migration.

2.2 Aim

This study aims to perform a systematic review and metanalysis to determine the:

2.2.1 Primary question

1. What methods are being used to determine stent migration?

2.2.2 Secondary question

1. The incidence of stent migration in patients who have undergone an infra-renal EVAR using a 1st, 2nd, 3rd and 4th generation stent grafts?

2.3 Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the protocol was registered on the international prospective register of systematic reviews (PROSPERO ID CRD42024574429).

The population of interest was patients undergoing EVAR for an infrarenal abdominal aortic aneurysm. There were no comparator groups. The outcome measured was radiological evidence of graft migration according to the authors' published definition.

The Ovid MEDLINE® and Embase (EMBASE Classic+Embase) were searched until 14th December 2020 using a combination of search terms relating endovascular abdominal aortic repair, EVAR, abdominal aortic aneurysm, abdominal aorta, and migration, outcome. The search was limited to human studies and studies in English only

Below is the full search string used for the systematic review. The search combines subject headings (e.g., MeSH terms, indicated by /) with keyword searches of titles, abstracts, and other text fields (indicated by .mp.). Truncation (*) was used to capture variations of word endings.

Search Strategy

1. abdo* aort* aneurysm*.mp.
2. abdominal aorta aneurysm/ or endovascular aneurysm repair/
3. 1 or 2
4. evar.mp.
5. endovascular surgery/ or endovascular aneurysm repair/ or abdominal aorta aneurysm/
6. endovascular aneurysm repair.mp.
7. abdominal aorta aneurysm/ or endovascular aneurysm repair/
8. 4 or 5 or 6 or 7

9. migrat*.mp.
10. migration/
11. follow up.mp.
12. follow up/
13. outcome.mp.
14. adverse outcome/ or clinical outcome/ or treatment outcome/
15. 9 or 10 or 11 or 12 or 13 or 14
16. 3 and 8 and 15
17. 3 and 8
18. 9 or 10
19. 17 and 18

A second-level hand search of the reference lists of retrieved articles was also undertaken to increase sensitivity. Full text articles were obtained through institutional access and through the British Library.

2.3.1 Selection criteria

- All randomised control trials, observational studies, case cohort studies, as defined using the Cochrane Handbook List of study design features were eligible
- Participants of all ages that had undergone an EVAR for AAA, studies need to have a minimum of 16-month follow up and reported migration rate of stents, in accordance with Spanos et al's previous systematic review which identified migration was most likely to occur between the 16 and 36 months [31].
- Patients undergoing EVAR for both elective and emergency will be included, as will bifurcated and uni-iliac devices.
- The year of stent implantation, type of stent and time of migration from implantation need to have been reported.
- Articles reporting on migration as a secondary outcome will also be included: papers where the primary focus of the article is not to study migration but where migration is clearly documented.
- No restriction on publication type and date.

2.3.1.1 Exclusion criteria

- EVARs placed for non-aneurysmal pathologies, such as trauma will not be included.
- Case histories and reports, industry registries and systematic reviews
- Articles reporting on migration data with less than 16-month follow up, as per Spanos et al's systematic review which demonstrated migration was likely to occur between 16 and 36 months. [31]
- Articles reporting on less than 50 patients within their analysis.
- Articles failing to mention the type of device implanted, time of implantation and migration will not be included unless this information can be gathered by contacting the authors.
- Cases where adjuncts to the EVAR were used at the proximal seal (e.g. chimneys, EndoAnchors, palmaz stents).

2.3.2 Data extraction and analysis

Two independent PhD research students (Mr Ammar Abdullah and Ms Lydia Hanna) performed a screening of the title and abstract of the identified articles, using the COVIDENCE platform against the above inclusion and exclusion criteria. Any disagreements were resolved initially through discussion or by a third independent reviewer Professor Colin Bicknell. Data was extracted independently by the two research students on a prespecified proforma using Microsoft excel. Where only abstracts have been published, attempts were made to contact authors to determine methodology and results. If this was not possible, then the study was excluded. For each study, data extraction included study design, patient demographics, dates of EVAR insertion, migration definition, the number of participants in the study, the number determined to have graft migration, whether the grafts were deployed in accordance with the manufacturers IFU.

To address potential patient population, overlap between included studies, a systematic duplicate analysis was conducted following established methodological frameworks for systematic reviews. This analysis was essential to ensure the integrity of the meta-analysis and prevent double-counting of patients across multiple publications. The duplicate assessment employed a multi-stage approach examining: (1) identical DOIs indicating data entry errors, (2) same lead authors with overlapping timeframes and patient populations, (3)

sequential publications from identical institutions using similar cohorts, and (4) industry-sponsored device trials with potentially overlapping recruitment periods. Each suspected duplicate pair was evaluated based on author names, institutional affiliations, study timeframes, patient numbers, device types, and methodology descriptions.

For each duplicate pair, the study with the larger patient cohort was retained to maximise statistical power and provide the most comprehensive data. In cases where patient numbers were similar, preference was given to the more recent publication with longer follow-up duration. Studies addressing distinctly different research questions or endpoints were retained despite author overlap. The retained studies were cross-referenced to ensure no remaining methodological descriptions, patient demographics, or statistical results suggested further population overlap. Where uncertainty remained regarding potential patient overlap, this was noted in the limitations section of the review.

2.3.3 Statistical Analysis

A definition-stratified meta-analysis was conducted to assess temporal trends in stent graft migration rates across four technological eras (1-4). The higher-quality studies, once identified, were then stratified into their respected groups based on the definition of migration employed within the study. Each group analysed independently to control for measurement heterogeneity that could confound genuine temporal trends. The midpoint of the data collection period for each study was calculated to determine the 'study period'. Studies were then allocated to graft eras based on this calculated midpoint in accordance with Tadros et al.'s classification [18]: Era 1 (1990-1996), Era 2 (1996-2003), Era 3 (2004-2007), and Era 4 (2008-2020). This temporal stratification formed the basis for subsequent meta-regression analysis to test whether migration rates declined systematically across technological eras. Era was modelled as a continuous linear predictor (1-4) in meta-regression models. While this assumes linear temporal change, sensitivity analyses treating era as categorical were not feasible due to sparse data distribution. The continuous approach maximises statistical power while acknowledging that technological improvements may not be strictly linear.

For each definition group, random-effects meta-analysis was performed using the DerSimonian-Laird method with inverse variance weighting to calculate pooled migration rates [84]. In the presence of zero-event studies, a continuity correction of 0.5 was applied to all cells to enable transformation [85]. The logit transformation (PLOGIT) was employed to stabilise variance and normalise the sampling distribution of proportions, in keeping with accepted practice in meta-analysis of event rates, particularly when proportions approach boundary values of 0% or 100% [86]. Confidence intervals for individual studies were calculated using the Clopper-Pearson exact method [87].

Between-study heterogeneity was quantified using the I^2 statistic, representing the percentage of total variation attributable to true differences between studies rather than sampling error [88]. Thresholds for interpretation followed Cochrane guidelines: I^2 values of 0-40% indicate low heterogeneity, 30-60% moderate, 50-90% substantial, and 75-100% considerable heterogeneity. The between-study variance (τ^2) and Cochran's Q test (with associated p-value) were calculated to complement I^2 interpretation [89].

Forest plots were generated for each definition group, with studies sorted by era to enable visual assessment of temporal clustering. Each plot displayed individual study effect sizes (represented as squares proportional to study weight), 95% confidence intervals (horizontal lines), the random-effects pooled estimate (diamond), and prediction intervals to indicate the expected range [90].

To investigate temporal trends the primary analysis was a meta-regression model with era as a continuous predictor variable using the restricted maximum likelihood (REML) method [90, 91]

Meta-regression coefficients on the logit scale were back-transformed to proportions to provide clinically interpretable estimates. Predicted migration rates were calculated for each era represented in the data by substituting era values into the regression equation and applying the inverse logit transformation. Absolute change (percentage point difference) and relative change (percentage reduction) between relevant eras were calculated to quantify the magnitude of in change of migration rates between eras.

Leave-one-out analysis was conducted by sequentially removing each study and re-fitting the meta-regression model to identify whether any single study disproportionately influenced the temporal trend estimate [92]. Robustness was defined as the temporal trend remaining statistically significant ($p < 0.05$). Substantial variation in coefficients or p-values crossing the significance threshold indicated instability and lack of robustness.

A meta-analysis of proportions was conducted utilising R Studio running R version 4.2.3. The analysis was conducted using the meta package alongside other relevant packages such as metafor. A funnel plot was created to assess potential publication bias. The plot visually examined the symmetry of the study estimates and their standard errors. Additionally, an Egger's test was performed to statistically assess for publication bias.

A meta-regression was performed to explore the influence of moderators (e.g., year of publication, study characteristics) on the effect size. The metareg() function from the meta package was used for this purpose. The results of the meta-analysis were interpreted based on the pooled effect size, confidence intervals, and heterogeneity statistics. The findings were summarised with emphasis on the clinical significance of the pooled estimates [93].

To determine the rate of migration over time, a staged approach to sorting the data was carried out. The mid-point of the data collection period for each study was calculated to determine the 'study period'. The study was then allocated to the graft era based on the calculated 'study period' in accordance to Tadros et al's classification [18]: Era 1(1990-1996), Era 2 (1996-2003), Era 3 (2004-2007) and Era 4 (2008-2020). A meta-regression was then performed by 'study period'. In the event were the I^2 was found to be < 50%, uni- and multi- variable meta-regression would be used to explore the effects of sex, and patient anatomical features on the primary outcome (migration). For all analyses, a p value < 0.05 was significant.

2.3.4 Risk of bias

Based on Cochrane recommendations, publication bias was assessed only for groups, which contained a minimum of 10 studies. Funnel plots and formal statistical tests for publication

bias (Egger's test, Begg's test) require a minimum of 10 studies to provide meaningful interpretation, with optimal assessment requiring ≥15 studies [94, 95].

2.3.5 Comparative Synthesis

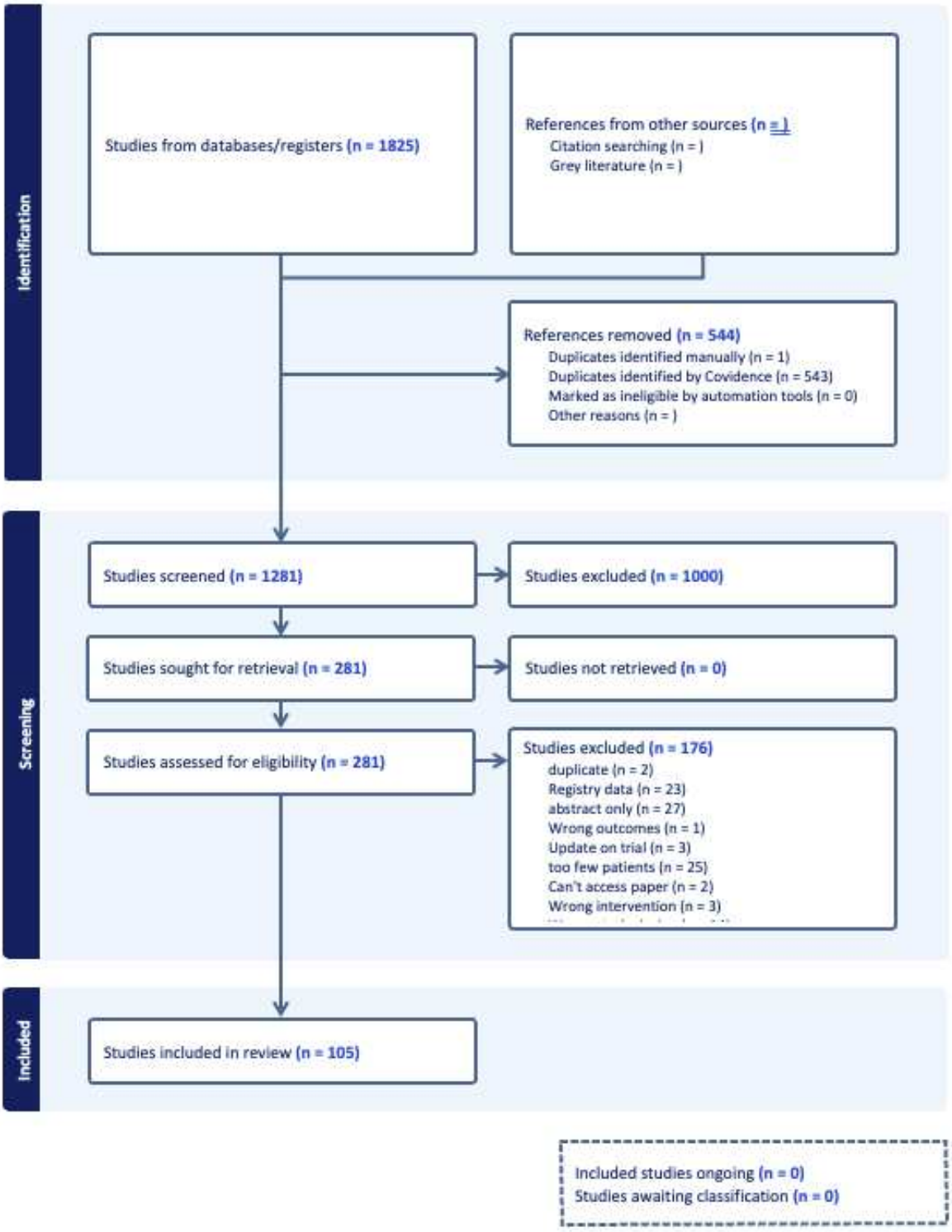
Quality assessment of each study was performed using a modification of the National Institute of Health (NIH) quality assessment tool for case series [96] and the Newcastle-Ottawa Scale (NOS) [97] because the majority of studies included in this review were case series and both tools had appropriate domains for assessment. Studies scoring between 7-9 were judged to be high quality, 4-6 high risk of bias, and 0-3 very high risk of bias. The quality of the evidence was graded using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach based on risk of bias (individual study limitations), inconsistency (heterogeneity in the meta-analysis), indirectness (external validity), imprecision (small sample size, wide confidence interval), and publication bias.

2.4 Results

The electronic database search yielded 1825 studies. The PRISMA flow chart is detailed in Figure 7.

2.4.1 Prisma Flow chart

Figure 7: PRISMA flow chart



2.4.2 Duplication of Data

From the initial database of 105 studies, 8 studies were identified to have duplicate data and

excluded from further analysis, leaving 97 remaining studies. The following duplicates were identified:

1. Oliveira-Pinto Studies: One study was removed due to identical DOI (https://dx.doi.org/10.1016/j.jvs.2019.03.039), representing a data entry duplication rather than separate publications. The entry "Oliveira-Pinto et al 2019" (277 patients) was removed, retaining "Oliveira-Pinto 2020" (277 patients) [98].
2. Jim Studies: Two publications from the same institution (Washington University) studying identical Talent endograft cohorts with overlapping data collection periods (2002-2003) were identified. Jim 2010 (137 patients) [99] was removed, retaining Jim 2011 (156 patients) [100] as the more comprehensive publication with larger patient cohort.
3. Tonnessen Publications: Two studies from the same author with overlapping timeframes (1997-2001 vs 1997-2004) studying AneuRx endografts were identified. Given the substantial temporal overlap and identical device focus, the AneuRx patients from the 2002 study [101] were likely included in the comparative analysis of the 2005 study. Tonnessen 2002 (101 patients) was removed, retaining Tonnessen 2005 (130 patients) [102] as the larger comparative study.
4. Carpenter Publications: Two industry-sponsored studies of the Powerlink endograft from the same investigator, representing feasibility followed by pivotal trial phases with likely overlapping patients. Carpenter 2002 (118 patients) [103] was removed, retaining Carpenter 2004 (188 patients) [104] as the larger pivotal study.
5. Bastos Goncalves Studies: Following the initial duplicate screening, a secondary analysis identified potential patient overlap between two studies from the same lead author with overlapping data collection periods. Bastos Goncalves (2012) [105] examined 144 patients (2000-2007) [106] focusing on Excluder endograft outcomes, while Bastos Goncalves 2012 analysed 396 patients (2004-2008) examining multiple endografts with neck thrombus analysis. Risk assessment using established systematic review criteria [89, 107] identified multiple high-risk indicators: identical lead investigator, three-year temporal overlap (2004-2007) representing 75% of the smaller study's timeframe, likely identical institutional setting, and similar methodological approaches. Following Cochrane Handbook guidance [89] and applying the precautionary principle recommended for systematic reviews when patient overlap cannot be definitively excluded [108], the smaller study (Bastos

Goncalves 2012, 144 patients) was removed to prevent potential double-counting. BastosGoncalves 2012 (396 patients) [106] was retained based on larger sample size, broader analytical scope, and extended follow-up period.

6. Abdulrasak 2020 study [109]: Secondary duplicate analysis identified Abdulrasak 2020 as utilising an identical national registry dataset to Baderkhan 2020 [110]. Both studies analyzed 863 patients from the Swedish Vascular Registry (Swedvasc) covering identical data collection periods (1998-2012). The Swedish Vascular Registry represents a comprehensive national database maintaining near-complete coverage of all vascular surgical procedures performed in Sweden since 1994, making patient population overlap highly probable. Following established systematic review methodology prohibiting multiple inclusion of identical patient cohorts [108], Abdulrasak 2020 (863 patients, 84 months follow-up) was removed, while Baderkhan 2020 (863 patients, 120 months follow-up) was retained as having the most comprehensive follow-up analysis.
7. Broos (2016) study: Similarly, Broos (2016) [111] was identified as analysing the same 863 patients from the Swedish Vascular Registry (Swedvasc) over the identical 1998-2012 data collection period as Baderkhan 2020 [110]. This represents "salami slicing" where multiple publications analyse the same underlying dataset with different analytical approaches [112]. To prevent artificial inflation of sample sizes and maintain meta-analysis validity, Broos 2016 (863 patients, 96 months follow-up) was excluded while retaining Baderkhan 2020 as the study with longest follow-up duration.
8. Oliveira-Pinto studies: Secondary analysis revealed potential subset publication between two studies by the same lead author published in the same year. One Oliveira-Pinto 2020 [98] study included 277 patients with data collection from 2004-2011, while a second Oliveira-Pinto 2020 study analysed 565 patients with data collection from 2000-2015 [113]. The data collection period of the smaller study was entirely encompassed within the timeframe of the larger study, creating high probability that the 277-patient cohort represented subset analysis of the broader population. Applying conservative systematic review principles to prevent double-counting, the smaller subset study (277 patients) was excluded while retaining the comprehensive analysis of 565 patients.

Following comprehensive primary and secondary duplicate analysis, 8 studies were excluded from the original database of 105 studies, resulting in a final systematic review of 97 studies.

2.4.3 Migration definition

Of the 97 included studies, 25 (25.8%) provided no definition on how migration was determined. Of the remaining 72 studies, there were eighteen different documented methods of how migration was measured, outlined in Table 3

Table 3: Migration Definitions

Definition of migration	**Number of studies (%)**
1. No definition	25 (25.8%)
2. Device migration >10mm or any migration necessitating intervention	14 (14.4%)
3. Device migration of more than 5 mm	21 (21.6%)
4. Device migration of more than 10 mm	22 (22.7%)
5. Inferior aspect of the most caudad renal artery to the first axial cut with any appreciable endograft was measured, 5mm cut off	1 (1%)
6. Any displacement of the graft detected by CT during follow-up	1 (1%)
7. A change of > 10 mm in the distance between the reference vessel (celiac axis or superior mesenteric artery) and the first visible portion of the stent-graft on a sagittal multiplanar CT re- construction	1 (1%)
8. Changes of 10 mm or more in the distance between the lower renal artery and the first visible portion of the endograft on the axial reconstruction of the CT scan were defined as migration	1 (1%)
9. Distance of the first axial CT slice containing half of the proximal attachment system to the most caudal renal artery. A movement of two or more slices was considered significant	1 (1%)

10. Migration was defined as a movement of 5 mm or 10 mm, with the latter aligned with endovascular reporting standards.	1 (1%)
11. Migration was defined as renal artery to stent-graft (fabric) distance increase of >0.5 cm	1 (1%)
12. An increase >2 mm in the distance between the lowest renal artery and the proximal end of the stent-graft	1 (1%)
13. The difference between the distance from the bottom of the lower renal artery to the edge of the proximal stent on the centreline immediately after EVAR and 2 years later, 3mm used as the cut off	1 (1%)
14. An increase of ≥3 mm in the distance between the lowest renal artery and the proximal end of the stent graft in comparing the first with the last follow-up CT images.	1 (1%)
15. Stent graft migration >1 cm associated with a Type 1 endoleak or aortic neck seal zone <1 cm	1 (1%)
16. If the proximal or distal sealing zones became clearly shorter than specified in the instructions for use for the respective stent graft.	1 (1%)
17. Migration was reported if it required intervention or if adequate seal was lost	1 (1%)
18. Migration defined only as those identified as requiring intervention due to type 1 endoleak, sac enlargement or rupture	1 (1%)
19. A change between the reference level of an anatomical landmark and the attachment system level exceeding the maximum slice thickness (2-10 mm).	1 (1%)

Of the remaining 72 studies which did document a definition for migration, definitions 2-4, accounted for 79% (57/72). With 14 defining migration as >10mm or any migration necessitating intervention, 21 defining migration as movement of >5mm and 22 defining migration as movement of >10mm.

2.4.4 Migration over time

In allocating each study to a specific era in accordance with Tadros et al's classification, using the midpoint of the data collection period to determine the 'study period', five studies covered 1st era, forty-six studies covered 2nd era, eighteen studies covered the 3rd era and

twenty eight studies covered the 4th era (Table 4). There was a general trend of reduced reported migration rates over this period with an average percentage of migration recorded of 7.5%, in the 1st era of stent grafts. 5.7% in the 2nd era, 2.7% in the 3rd era and 3.5% in the 4th era (Table 4, Table 5).

Table 4: Migration over time for all studies

Author	Publication year	Data Collection period	Midpoint of data collection period	Allocated stent graft era	Number of patients	Number of migrators	Follow-up time (months)	% migration within the study
May [114]	2003	1992-1996	1994	1	51	5	48	9.8
Blum [115]	2001	1994-1997	1995.5	1	263	10	36	3.8
Schlensak [116]	2001	1994-1998	1996	1	114	4	24	3.5
Broeders [117]	1999	1993-1996	1994.5	1	170	4	18	2.4
Resch [118]	1999	1993-1997	1995	1	58	26	24	44.8
TOTAL ERA 1					**656**	**49**		**7.5%**
Ramirez [119]	2019	1998-2005	2001.5	2	89	0	60	0.0
tMannetje [120]	2016	1999-2005	2002	2	149	5	84	3.4
Chung [121]	2015	1992-2012	2002	2	1247	1	48	0.1
Droc [122]	2011	1997-2007	2002	2	89	0	60	0.0
Jim [100]	2011	2002-2003	2002.5	2	156	5	48	3.2
Pintoux [123]	2011	1999-2007	2003	2	58	9	60	15.5
Waasdorp [124]	2011	1997-2007	2002	2	144	38	48	26.4
Oberhuber [125]	2010	1998-2007	2002.5	2	103	3	36	2.9
Turnbull [126]	2010	2002-2003	2002.5	2	166	5	48	3.0
Conrad [127]	2009	1997-2007	2002	2	592	10	72	1.7
Pitoulias [128]	2009	1997-2005	2001	2	617	60	84	9.7
Pitton [129]	2009	1997-2007	2002	2	127	32	48	25.2
Abbruzzese [75]	2008	1999-2005	2002	2	113	2	36	1.8
Coppi [130]	2008	1999-2007	2003	2	128	5	48	3.9
Greenberg [131]	2008	2000-2003	2001.5	2	736	21	60	2.9
Wang [132]	2008	2000-2003	2001.5	2	140	3	36	2.1
Dalainas [133]	2007	1999-2004	2001.5	2	242	52	48	21.5

Author	Publication year	Data Collection period	Midpoint of data collection period	Allocated stent graft era	Number of patients	Number of migrators	Follow-up time (months)	% migration within the study
Goodman [134]	2007	1999-2004	2001.5	2	133	2	36	1.5
vanHerwaarden [79]	2007	1996-2003	1999.5	2	211	26	60	12.3
Brewster [135]	2006	1994-2005	1999.5	2	653	19	72	2.9
Fulton [80]	2006	1999-2001	2000	2	84	14	48	16.7
Heikkinen [136]	2006	1996-2003	1999.5	2	305	30	84	9.8
Litwinski [77]	2006	1996-2004	2000	2	308	73	60	23.7
Seriki [137]	2006	1998-2002	2000	2	119	7	36	5.9
Steingruber [138]	2006	1995-2005	2000	2	70	14	48	20.0
Torsello [139]	2006	1996-1998	1997	2	165	7	60	4.2
Albertini [140]	2005	2000-2001	2000.5	2	123	6	24	4.9
Malas [141]	2005	1997-2002	1999.5	2	190	0	36	0.0
Tonnessen [102]	2005	1997-2004	2000.5	2	130	41	48	31.5
Carpenter [104]	2004	2000-2003	2001.5	2	188	3	36	1.6
England [142]	2004	1998-2001	1999.5	2	102	13	24	12.7
Greenberg [143]	2004	2000-2001	2000.5	2	200	4	36	2.0
Verhoeven [144]	2004	1996-2003	1999.5	2	173	14	48	8.1
Clouse [145]	2003	1996-1998	1997	2	118	2	36	1.7
Dillavou [146]	2003	1999-2002	2000.5	2	79	0	24	0.0
Kibbe [147]	2003	2003	2003	2	110	1	18	0.9
Zarins [59]	2003	1997-2007	2002	2	1192	0	60	0.0
Alric [148]	2002	1996-2002	1999	2	94	1	36	1.1
Cao [149]	2002	1997-1999	1998	2	113	17	48	15.0
Pereira [150]	2002	1995-2001	1998	2	84	0	24	0.0
Resch [151]	2002	2002	2002	2	164	31	36	18.9
Sternbergh III [152]	2002	1995-2001	1998	2	163	14	48	8.6
Greenberg [153]	2001	1995-2000	1997.5	2	528	8	36	1.5

Author	Publication year	Data Collection period	Midpoint of data collection period	Allocated stent graft era	Number of patients	Number of migrators	Follow-up time (months)	% migration within the study
Resch [154]	2001	1993-2000	1996.5	2	158	8	24	5.1
TOTAL ERA 2					**9,933**	**564**		**5.7%**
Baderkhan [110]	2020	1998-2012	2005	3	863	6	120	0.7
Mateo [155]	2016	2000-2014	2007	3	128	0	72	0.0
Walker [156]	2015	2000-2010	2005	3	118	2	60	1.7
Lee [157]	2013	2004-2007	2005.5	3	179	1	48	0.5
Mehta [158]	2013	2002-2011	2006.5	3	123	1	84	0.8
Nyheim [159]	2013	2001-2006	2003.5	3	56	4	60	7.1
BastosGoncalves [106]	2012	2004-2008	2006	3	396	28	60	7.1
Hager [160]	2012	2002-2009	2005.5	3	155	0	72	0.0
Kaladji [161]	2012	2003-2007	2005	3	61	1	48	1.6
Majumder [162]	2012	2005-2009	2007	3	106	2	36	1.9
Stather [163]	2012	1999-2010	2004.5	3	298	8	84	2.7
Kalteis [164]	2011	2001-2010	2005.5	3	157	3	60	1.9
Mehta [165]	2011	2002-2009	2005.5	3	98	1	48	1.0
Cao [166]	2009	2002-2006	2004	3	102	5	36	4.9
Rodel [167]	2009	2002-2005	2003.5	3	92	0	24	0.0
Stella [168]	2009	2005-2008	2006.5	3	60	0	18	0.0
Waasdrop [78]	2009	2000-2007	2003.5	3	48	10	36	20.8
Sternbergh [169]	2008	2000-2007	2003.5	3	349	1	48	0.3
TOTAL ERA 3					**2,731**	**73**		**2.7%**
Barleben [170]	2020	2009-2011	2010	4	161	0	36	0.0
Chinsakchai [171]	2020	2010-2013	2011.5	4	118	6	48	5.1
Midy [172]	2020	2012-2013	2012.5	4	177	3	24	1.7
Mufty [173]	2020	2012-2019	2015.5	4	96	0	72	0.0
Oliveira-Pinto [113]	2020	2000-2015	2007.5	4	565	46	96	8.1

Author	Publication year	Data Collection period	Midpoint of data collection period	Allocated stent graft era	Number of patients	Number of migrators	Follow-up time (months)	% migration within the study
Reina [174]	2020	2016-2019	2017.5	4	119	0	24	0.0
Sirignano [175]	2020	2008-2015	2011.5	4	509	1	60	0.2
Asenbaum [66]	2019	2002-2014	2008	4	97	28	72	28.9
McFarland [176]	2019	2000-2016	2008	4	113	7	96	6.2
Torsello [177]	2019	2010-2011	2010.5	4	60	0	48	0.0
Herman [178]	2018	2005-2014	2009.5	4	87	4	72	4.6
Healy [179]	2017	2006-2015	2010.5	4	138	4	84	2.9
Malas [180]	2017	2006-2011	2008.5	4	219	7	60	3.2
Oliveira [181]	2017	2008-2012	2010	4	106	5	48	4.7
Poublon [182]	2017	2000-2015	2007.5	4	249	3	96	1.2
Pratesi [183]	2017	2010-2011	2010.5	4	60	0	36	0.0
tMannetje [184]	2017	2005-2010	2007.5	4	221	8	72	3.6
Tokunga [48]	2017	2007-2010	2008.5	4	80	8	48	10.0
DeDonato [185]	2016	2009-2011	2010	4	161	0	24	0.0
Kim [186]	2016	2007-2010	2008.5	4	126	5	48	4.0
Roos [187]	2016	2005-2013	2009	4	272	6	84	2.2
Singh [188]	2016	2008-2009	2008.5	4	128	0	36	0.0
Torsello [189]	2015	2010-2011	2010.5	4	60	0	48	0.0
Bisdas [190]	2014	2007-2010	2008.5	4	79	0	36	0.0
Speziale [191]	2014	2010-2011	2010.5	4	96	3	24	3.1
Zandvoort [192]	2014	2007-2009	2008	4	85	0	48	0.0
Fossaceca [193]	2013	2005-2011	2008	4	105	0	60	0.0
Ghotbi [194]	2010	2006-2009	2007.5	4	100	1	36	1.0
TOTAL ERA 4					**4,386**	**155**		**3.5%**
OVERALL TOTAL					**17,706**	**841**		**4.7%**

Table 5: Summary of migration across all studies (by Era)

Era	Number of Studies	Total Patients	Total Migrators	Overall Migration Rate	Mean Follow-up (months)
Era 1 (1990-1996)	5	656	49	7.5%	30
Era 2 (1996-2003)	46	9,933	564	5.7%	48
Era 3 (2004-2007)	18	2,731	73	2.7%	62
Era 4 (2008-2020)	28	4,386	155	3.5%	56

2.4.5 Reducing heterogeneity

In an attempt to reduce heterogeneity in the assessment of migration over time, studies with a clearly documented definition of migration, length of follow up (which would include a more complete time frame of migration, as per Spanos et al [31]) of more than 36 months and using CT scans in their follow up protocol were reassessed separately, in Table 6. 28 studies were identified, including 5589 patients and an overall 8.3% reported rate of migration. Again, the migration rates were shown to decrease over time. Only one study was included covering Era 1, with a 9.8% rate of migration, 16 studies covering Era 2, with an 10.2% rate of migration, 4 studies covering Era 3 with a 5.7% rate of migration and 7 studies covering Era 4, with a 4.1% rate of migration. There were however 7 different migration definitions used within these 27 studies (Table 6 and Table 7).

Table 6: Migration over time, in studies with follow up >36 months, using CT scan follow up and a prescribed definition

Study	Study Period	Era	Migration Definition	Number of Patients	Number of Migrators	% Migrators per Study
ERA 1						
May	1994	1	2	51	5	9.8%
TOTAL ERA 1				**51**	**5**	**9.8%**
ERA 2						
Jim	2002.5	2	3	156	5	3.2%
Pintoux	2003	2	3	58	9	15.5%
Waasdorp	2002	2	1	144	38	26.4%
Oberhuber	2002.5	2	11	103	3	2.9%
Turnbull	2002.5	2	3	166	5	3.0%
Pitoulias	2001	2	2	617	60	9.7%
Pitton	2002	2	3	127	32	25.2%
Greenberg	2001.5	2	9	736	21	2.9%
Dalainas	2001.5	2	2	242	52	21.5%
vanHerwaarden	1999.5	2	3	211	26	12.3%
Fulton	2000	2	1	84	14	16.7%
Litwinski	2000	2	2	308	73	23.7%
Torsello	1997	2	3	165	7	4.2%
Cao et al	1998	2	7	113	17	15.0%
Makaroun	1996.5	2	8	242	2	0.8%
TOTAL ERA 2				**3,609**	**369**	**10.2%**
ERA 3						
Nyheim	2003.5	3	3	56	4	7.1%
BastosGoncalves	2006	3	3	396	28	7.1%
Kaladji	2005	3	3	61	1	1.6%
Majumder	2007	3	3	106	2	1.9%
TOTAL ERA 3				**619**	**35**	**5.7%**
ERA 4						
Barleben	2010	4	1	161	0	0.0%
Midy	2012.5	4	1	177	3	1.7%

Study	Study Period	Era	Migration Definition	Number of Patients	Number of Migrators	% Migrators per Study
Oliveira-Pinto	2007.5	4	2	565	46	8.1%
Torsello	2010.5	4	3	60	0	0.0%
Pratesi	2010.5	4	3	60	0	0.0%
DeDonato	2010	4	13	161	0	0.0%
Kim	2008.5	4	2	126	5	4.0%
TOTAL ERA 4				**1,310**	**54**	**4.1%**
TOTAL ALL ERAS				**5,589**	**463**	**8.3%**

Table 7: Summary of migration over time, in studies with follow up >36 months, using CT scan follow up and a prescribed definition

Era	Time Period	Studies (n)	Patients (n)	Migrators (n)	Migration Rate (%)	Definition Categories Used
Era 1	1990-1996	1	51	5	9.8%	Definition 2
Era 2	1996-2003	16	3,609	369	10.2%	Definitions 1,2,3,7,8,9,11
Era 3	2004-2007	4	619	35	5.7%	Definition 3
Era 4	2008-2020	7	1,310	54	4.1%	Definitions 1,2,3,13
Overall	1990-2020	**28**	**5,589**	**463**	**8.3%**	**7 different definitions**

2.4.6 Preparation for Metanalysis

2.4.6.1 Definition-Based Stratification for Meta-Analytical Synthesis

Tables 4-8 demonstrate the raw extracted data from the studies' analysed and provide an overview and insight into migration rates over the distinct era periods. Despite attempts to refine these studies, we can see from the raw data the persistence of heterogeneity - seven different migration definitions within the 27 higher-quality studies necessitated a definition stratified analytical approach to enable valid meta-analytical pooling. Studies were therefore grouped according to their respective definitions, with three common groups identified (accounting for 23/27, 85% of all definitions used):

1. Device migration >10mm or any migration necessitating intervention
2. Device migration of more than 5 mm
3. Device migration of more than 10 mm

4 studies would be removed (Makaroun, Greenberg, Oberhuber and DeDonato), as there was only one study per definition and thus cannot be subject to metanalysis. Cao's definition included specific anatomical landmarks, however used 10mm as his cut off and therefore could be included into group 3. This stratification process resulted in 23 studies suitable for meta-analytical synthesis, representing 4,210 patients and 347 migration events (Table 8).

Table 8: Definition-based stratification of migrations rates by era

Study	Study Period	Era	Migration Definition	Number of Patients	Number of Migrators	% Migrators per Study
ERA 1						
May (2003)	1994	1	2	51	5	9.8%
TOTAL ERA 1				**51**	**5**	**9.8%**
ERA 2						
Jim(2011)	2002.5	2	3	156	5	3.2%
Pintoux (2011)	2003	2	3	58	9	15.5%
Waasdorp (2011)	2002	2	1	144	38	26.4%
Turnbull (2010)	2002.5	2	3	166	5	3.0%
Pitoulias (2009)	2001	2	2	617	60	9.7%
Pitton (2009)	2002	2	3	127	32	25.2%
Dalainas (2007)	2001.5	2	2	242	52	21.5%
vanHerwaarden (2007)	1999.5	2	3	211	26	12.3%
Fulton (2006)	2000	2	1	84	14	16.7%
Litwinski (2006)	2000	2	2	308	73	23.7%
Torsello (2006)	1997	2	3	165	7	4.2%
Cao et al (2002)	1998	2	3	113	17	15.0%
TOTAL ERA 2				**2,391**	**338**	**14.1%**

Study	Study Period	Era	Migration Definition	Number of Patients	Number of Migrators	% Migrators per Study
ERA 3						
Nyheim (2013)	2003.5	3	3	56	4	7.1%
BastosGoncalves (2012)	2006	3	3	396	28	7.1%
Kaladji (2012)	2005	3	3	61	1	1.6%
Majumder (2012)	2007	3	3	106	2	1.9%
TOTAL ERA 3				**619**	**35**	**5.7%**
ERA 4						
Barleben (2020)	2010	4	1	161	0	0.0%
Midy (2020)	2012.5	4	1	177	3	1.7%
Oliveira-Pinto (2020)	2007.5	4	2	565	46	8.1%
Torsello (2019)	2010.5	4	3	60	0	0.0%
Pratesi(2017)	2010.5	4	3	60	0	0.0%
Kim (2016)	2008.5	4	2	126	5	4.0%
TOTAL ERA 4				**1,149**	**54**	**4.7%**
TOTAL ALL ERAS				**4,210**	**432**	**10.3%**

Figure 9, graphically displays the crude trend in migration over time (according to era), for each of the three definitions.

Definition 1: employing the definition of migration as >10mm or requiring intervention, encompasses 4 studies with 566 patients distributed across Era 2 (2 studies, 228 patients) and Era 4 (2 studies, 338 patients). Descriptive examination reveals crude migration rates of 22.8% in Era 2 and 0.9% in Era 4, demonstrating a 96% reduction and suggesting substantial temporal variation, that requires further analytical testing.

Definition 2, employing a definition of migration as >5mm, includes 6 studies with 1,909 patients spanning Era 1 (1 study, 51 patients), Era 2 (3 studies, 1,167 patients), and Era 4 (2 studies, 691 patients). Crude rates demonstrate 9.8% in Era 1, 15.9% in Era 2, and 7.4% in

Era 4, indicating a 53% reduction from Era 2 to Era 4 and again, warranting further analysis to assess temporal trends.

Definition 3, employing the definition of migration as >10mm, represents the largest group with 13 studies encompassing 1,802 patients across Era 2 (7 studies, 1,063 patients), Era 3 (4 studies, 619 patients), and Era 4 (2 studies, 120 patients). Crude rates show 9.5% in Era 2, 5.7% in Era 3, and 0.0% in Era 4, demonstrating progressive improvement over time with complete elimination of migration in the most recent era.

Figure 8: Summary of migration rate over time (era), by definition

Definition	Era 1	Era 2	Era 3	Era 4
Definition 1	—	52/228 (22.8%)	—	3/338 (0.9%)
Definition 2	5/51 (9.8%)	185/1,167 (15.9%)	—	51/691 (7.4%)
Definition 3	—	101/1,063 (9.5%)	35/619 (5.7%)	0/120 (0.0%)

Figure 9: Migration rate over time (era), by definition.



The preliminary descriptive findings demonstrate apparent temporal patterns across all three definition groups, with Era 2 consistently showing higher migration rates and subsequent eras demonstrating variable degrees of improvement. These crude migration rates, however, represent unadjusted descriptive estimates and therefore require formal meta-analytical assessment to account for between-study heterogeneity, study-level characteristics, and potential confounding factors. Meta-regression analysis by era will be essential to statistically validate these apparent temporal trends and quantify the magnitude in total reduction of migration across the four time periods.

2.4.7 Metanalysis approach: definition-stratifies temporal trend analysis.

2.4.7.1 Rationale for Analytical Approach

The primary objective of this meta-analysis is to determine whether stent graft migration rates have decreased over time across four technological eras. However, a critical methodological challenge exists: the 23 included studies employed three different migration definitions, which could introduce significant heterogeneity confounding genuine temporal trends. To address this, a definition-stratified approach was adopted with meta-regression, analysing each definition group independently.

An initial consideration was to perform separate meta-analyses for each era-definition combination (e.g., Definition 1 in Era 2, Definition 1 in Era 4) and compare pooled estimates across eras. However, examination of the data distribution revealed this approach to be infeasible. Table 9 shows the distribution of studies across era-definition combinations, revealing numerous empty cells and small sample sizes that preclude meaningful between-era comparisons.

Table 9: Distribution of studies across era-definition combinations

Definition	Era 1 (1990-1996)	Era 2 (1996-2003)	Era 3 (2004-2007)	Era 4 (2008-2020)	Total
Definition 1 (>10mm or intervention)	0	2	0	2	4
Definition 2 (>5mm)	1	3	0	2	6
Definition 3 (>10mm)	0	7	4	2	13

Definition 1 has no studies in Eras 1 or 3, creating structural gaps that prevent assessment of temporal trends across all four eras through direct comparison. Definition 2 similarly lacks Era 3 representation. Where studies exist, they would need to be further subdivided (e.g., 2 studies in Era 2, 2 studies in Era 4 for Definition 1), preventing any assessment of whether changes are gradual or step-wise, and eliminating the ability to test for linear temporal trends.

Furthermore, with multiple missing cells, there is no consistent analytical framework: Definition 1 could only compare Era 2 vs Era 4, Definition 2 could compare Era 1 vs Era 2 vs Era 4, and Definition 3 could compare Era 2 vs Era 3 vs Era 4. This inconsistency across definitions would make comparative interpretation impossible as each definition would be testing fundamentally different era contrasts [195].

Meta-regression addresses these limitations by treating era as a continuous predictor, which requires only that studies span multiple era values, not that all eras are represented [196]. This approach utilises all available studies simultaneously within each definition while testing for linear temporal relationships that accommodate missing cells. A study from Era 4 contributes information about the temporal trend even if no Era 3 studies exist, because the regression line is fitted across all available era values.

The era is therefore treated as a continuous predictor rather than categorical groupings, thereby utilising all available studies simultaneously within each definition. This approach models migration rate as a function of era:

$$\text{Migration Rate} = \beta_0 + \beta_1(\text{Era}) + \varepsilon$$

β_1 represents the change in migration rate per era unit. A negative β_1 coefficient with $p < 0.05$ indicates statistically significant temporal decline.

This method therefore addresses the previous cited limitations by allowing the use of all studies within a definition simultaneously rather than fragmenting them across era subgroups, testing for linear temporal trends without requiring complete era representation. This allows for the calculation of R^2 showing what proportion of between-study variation is explained by temporal factors, and provides a single coefficient quantifying the magnitude of temporal change rather than multiple pairwise comparisons [91, 196].

By analysing each definition separately using meta-regression, we control for measurement heterogeneity while maximising statistical efficiency given the uneven distribution of studies across eras.

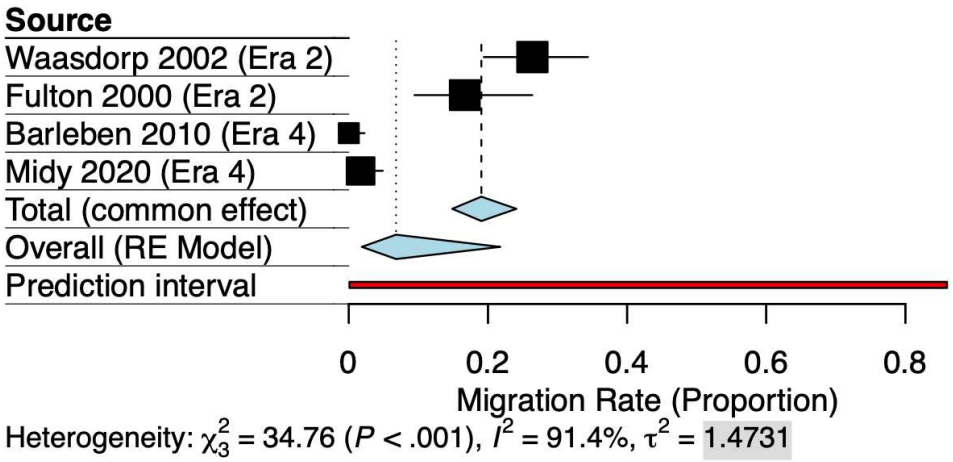
2.4.8 Definition-Stratified Meta-Analysis and Meta-Regression

The 23 higher-quality studies were stratified into three groups based on migration definition criteria, with each group analysed independently using random-effects meta-analysis followed by meta-regression with era as a continuous predictor.

2.4.8.1 Definition 1: Migration >10mm or Requiring Intervention

Definition 1 comprised 4 studies with 566 patients distributed across Era 2 (2 studies, 228 patients) and Era 4 (2 studies, 338 patients), with no representation in Eras 1 or 3. Individual study migration rates ranged from 0% (Barleben 2010) to 26.4% (Waasdorp 2002). Random-effects meta-analysis yielded a pooled migration rate of 6.8% (95% CI: 1.9-21.8%). There was considerable between-study heterogeneity ($I^2 = 91.4\%$, $\tau^2 = 1.473$, $Q = 34.76$, $df = 3$, $p < 0.001$).

Figure 10: Forest plot: Definition 1



The forest plot for Definition 1(Figure 10) displays this significant heterogeneity, with the prediction interval extending beyond the plotted range, indicating high uncertainty in where future studies might fall.

Meta-regression analysis revealed a highly significant temporal decline (β = -1.544, 95% CI: -2.212 to -0.876, $p < 0.0001$). The test of moderators confirmed era as a highly significant predictor of migration rates (QM = 20.51, df = 1, $p < 0.0001$). Critically, era explained 91.9% of the between-study heterogeneity ($R^2 = 91.9\%$), reducing residual heterogeneity to moderate levels (residual $I^2 = 50.7\%$, $\tau^2 = 0.119$). This exceptionally high R^2 demonstrates that temporal factors are the dominant driver of variation between studies, with remaining heterogeneity likely attributable to differences in patient selection or follow-up protocols.

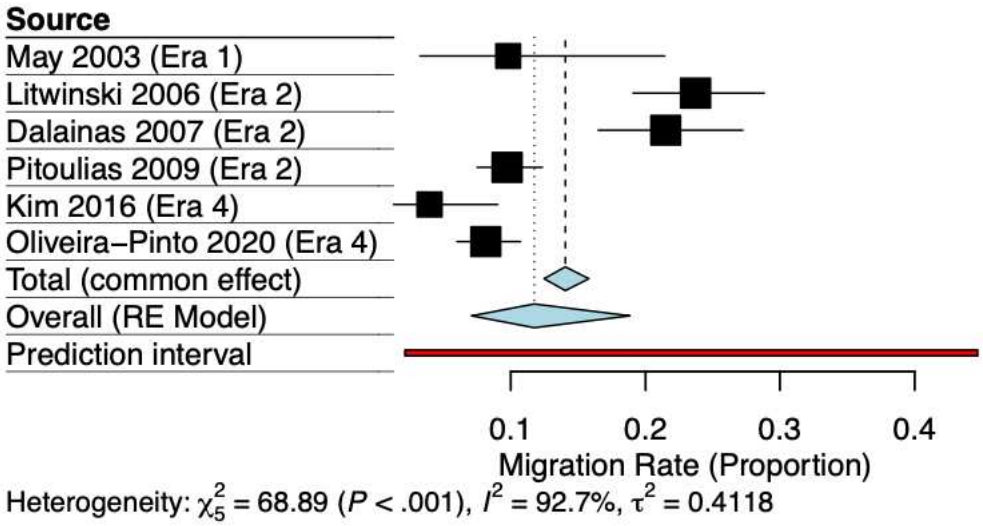
Back-transformation of regression coefficients to clinically interpretable proportions revealed predicted migration rates of 21.8% in Era 2 declining to 1.3% in Era 4, with an absolute reduction of 20.5 percentage points representing a 94.2% relative reduction. This dramatic decline provides evidence of a significant reduction in migration rates over time.

Furthermore, 'leave-one-out' analysis confirmed the robustness of the temporal trend. Across all four iterations, the era coefficient remained negative and highly significant: without Waasdorp, 2011 (β = -1.412, $p = 0.003$), without Fulton, 2006 (β = -1.704, $p < 0.001$), without Barleben, 2020 (β = -1.393, $p < 0.001$), and without Midy, 2020 (β = -2.251, $p = 0.002$). The consistency of these results, with all p-values remaining well below 0.05 and coefficients ranging from -1.39 to -2.25, demonstrates that no single study drives the observed temporal decline.

2.4.8.2 Definition 2: Migration >5mm

Definition 2, employing the more sensitive threshold of >5mm, comprised 6 studies with 1,909 patients distributed across Era 1 (n=1 study, 51 patients), Era 2 (n=3 studies, 1,167 patients), and Era 4 (n=2 studies, 691 patients), with no representation in Era 3. Individual study migration rates demonstrated substantial variation ranging from 4.0% (Kim, 2016) to 23.7% (Litwinski, 2006). Random-effects meta-analysis yielded a pooled migration rate of 11.7% (95% CI: 7.1-18.8%). Considerable between-study heterogeneity was observed ($I^2 = 92.7\%$, $\tau^2 = 0.412$, Q = 68.89, df = 5, $p < 0.0001$), consistent with the pattern observed in Definition 1: Migration >10mm or Requiring Intervention.

Figure 11: Forest plot: Definition 2



The forest plot for Definition 2 (Figure 11) illustrates this high heterogeneity with widely dispersed confidence intervals across studies.

Meta-regression with era as predictor revealed a non-significant temporal trend (β = -0.380, 95% CI: -0.861 to 0.102, p = 0.122). While the negative coefficient suggests a declining pattern, this failed to reach statistical significance. Critically, era explained only 18.8% of between-study heterogeneity (R^2 = 18.8%), with substantial residual heterogeneity remaining (residual I^2 = 90.7%, τ^2 = 0.335). This contrasts markedly with Definition 1 and indicates that temporal factors play a far less dominant role in explaining variation for the >5mm threshold.

Despite the non-significant statistical test, predicted migration rates showed a descending pattern from 19.2% in Era 1, to 14.0% in Era 2, to 7.1% in Era 4, representing an absolute reduction of 6.9 percentage points and relative reduction of 49.4% between Era 2 and Era 4. However, the wide confidence intervals and non-significant p-value indicate this apparent pattern could plausibly be due to chance variation or unmeasured confounding factors.

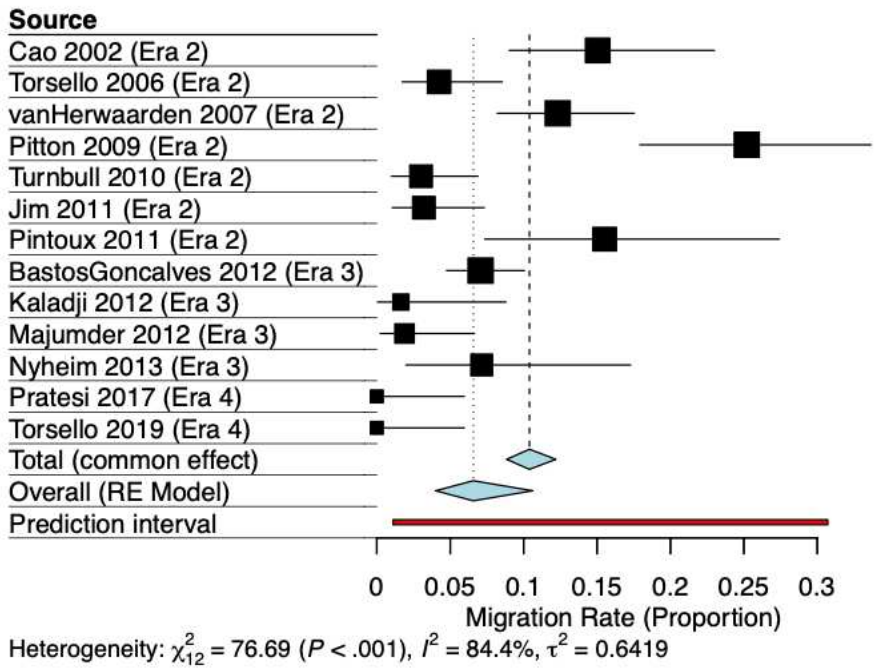
The 'leave-one-out' sensitivity analysis revealed variability in the temporal trend estimate. Removal of certain studies yielded statistically significant results: without May, 2003 (β = -0.579, p = 0.042) and without Pitoulias, 2009 (β = -0.449, p = 0.021). Conversely, removal of other studies eliminated any temporal signal: without Kim, 2016 (β = -0.216, p = 0.462) and without Litwinski 2006 (β = -0.307, p = 0.226). This marked sensitivity to individual study

inclusion indicates lack of robustness, the apparent declining pattern appears to be driven by specific study characteristics rather than representing a consistent era related reduction.

2.4.8.3 Definition 3: Migration >10mm

Definition 3 represented the largest group with 13 studies including 1,735 patients across Era 2 (7 studies, 1,063 patients), Era 3 (4 studies, 619 patients), and Era 4 (2 studies, 120 patients), with no representation in Era 1. This group provided the most complete temporal coverage with consecutive era representation. Individual study migration rates ranged from 0% (Torsello 2019 and Pratesi 2017) to 25.2% (Pitton, 2009). Random-effects meta-analysis yielded a pooled migration rate of 6.6% (95% CI: 4.0-10.6%), with significant heterogeneity ($I^2 = 84.4\%$, $\tau^2 = 0.642$, $Q = 76.69$, $df = 12$, $p < 0.001$).

Figure 12: Forest plot: Definition 3



The forest plot for Definition 3 (Figure 12) demonstrates this heterogeneity, though notably less extreme than Definitions 1 and 2.

Meta-regression analysis revealed a statistically significant temporal decline ($\beta = -1.018$, 95% CI: -1.869 to -0.167, $p = 0.019$). The test of moderators confirmed era as a significant predictor ($QM = 5.49$, $df = 1$, $p = 0.019$). However, era explained only 14.6% of between-

study heterogeneity (R^2 = 14.6%), with high residual heterogeneity remaining (residual I^2 = 80.5%, τ^2 = 0.548). This low R^2 indicates that temporal factors account for only a minority of between-study variation.

Predicted migration rates decreased from 9.6% in Era 2, to 3.7% in Era 3, to 1.4% in Era 4, representing an absolute reduction of 8.3 percentage points and relative reduction of 85.7% between Era 2 and Era 4. While this demonstrates clinically meaningful improvement, the low R^2 suggests substantial unmeasured sources of heterogeneity persist.

The 'leave-one-out' analysis revealed borderline robustness. While most iterations maintained statistical significance, removal of either Torsello, 2019 or Pratesi, 2017 resulted in p = 0.054, approaching non-significance. Given that both studies reported zero migration events in Era 4, their inclusion substantially influences the temporal trend estimate. The coefficient ranged from -0.82 to -1.19 across iterations, showing moderate variability but consistent negative direction.

2.4.8.3.1 Publication Bias Assessment

Given that Definition 3 contained 13 studies, approaching the threshold for meaningful funnel plot assessment, a funnel plot was generated (Figure 13).

Figure 13: Funnel Plot: Definition 3

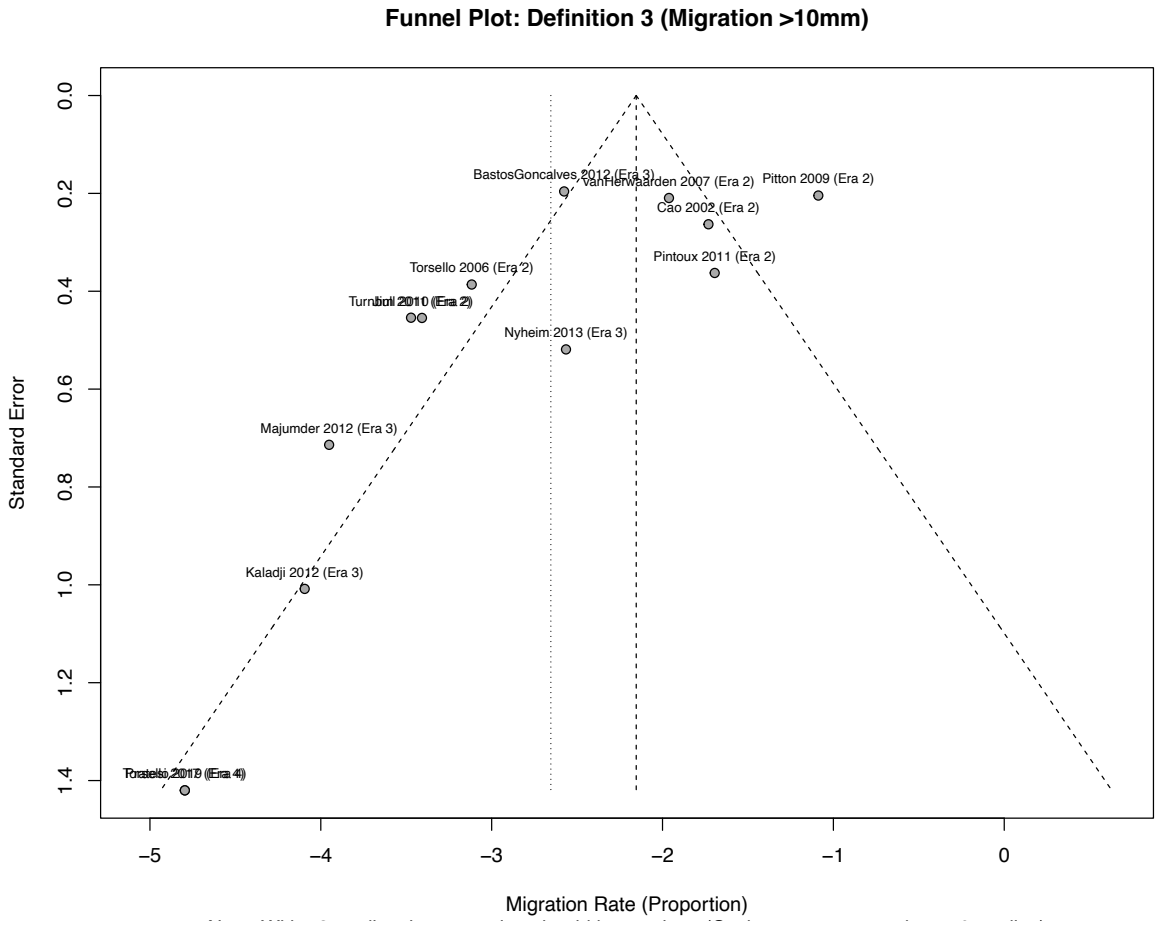


Figure 13 allows you to visually inspect for potential publication bias. While Cochrane guidelines recommend ≥10 studies for funnel plot interpretation, caution is warranted with samples below 15 studies [95]. Visual inspection revealed some asymmetry with studies dispersed across the funnel, though no clear pattern of small-study effects was evident. The two zero-event studies appear in the lower region of the funnel, which could suggest either genuine temporal reduction or potential reporting bias favouring positive findings in recent eras. Formal statistical tests for publication bias (Egger's test, Begg's test) were not performed given the borderline sample size and established limitations of these tests with <15 studies [94].

2.4.9 Comparative Analysis Across Definitions

2.4.9.1 Summary of Meta-Regression Findings

Table 10 represents a comprehensive comparison of meta-regression results across all three definitions, showing a stark differences in temporal trends and explanatory power.

Table 10: Comparative summary of meta-regression results across three migration definitions

Characteristic	Definition 1: >10mm or Intervention	Definition 2: >5mm	Definition 3: >10mm
Study Characteristics			
Number of studies (k)	4	6	13
Total patients (n)	566	1,909	1,735
Era distribution	2, 4	1, 2, 4	2, 3, 4
Pooled Estimates			
Overall migration rate (%)	6.8 (1.9-21.8)	11.7 (7.1-18.8)	6.6 (4.0-10.6)
Initial heterogeneity (I^2)	91.4%	92.7%	84.4%
Meta-Regression Results			
Era coefficient (β)	-1.544	-0.380	-1.018
95% Confidence interval	-2.212 to -0.876	-0.861 to 0.102	-1.869 to -0.167
P-value	<0.0001	0.122	0.019
Statistical significance	Highly significant	Not significant	Significant
Heterogeneity Explained			
R^2 (% explained by era)	91.9%	18.8%	14.6%
Residual I^2	50.7%	90.7%	80.5%
Residual τ^2	0.119	0.335	0.548
Predicted Migration Rates			
Era 1	—	19.2%	—
Era 2	21.8%	14.0%	9.6%
Era 3	—	—	3.7%
Era 4	1.3%	7.1%	1.4%
Clinical Impact (Era 2→4)			
Absolute change	-20.5 %	-6.9 %	-8.3 %

Characteristic	Definition 1: >10mm or Intervention	Definition 2: >5mm	Definition 3: >10mm
Relative reduction	94.2%	49.4%	85.7%
Sensitivity Analysis			
Robustness	Strong (all p<0.003)	Weak (p=0.02-0.46)	Marginal (p=0.007-0.054)
Range of β coefficients	-1.39 to -2.25	-0.22 to -0.58	-0.82 to -1.19
Interpretation			
Temporal trend	Robust decline	No significant trend	Weak decline
Era as explanator	Dominant factor	Minor factor	Minor factor

Key: β = regression coefficient (logit scale); R^2 = proportion of heterogeneity explained by era; — = no studies in this era

Figure 14: Meta-regression coefficeints across migration definitions

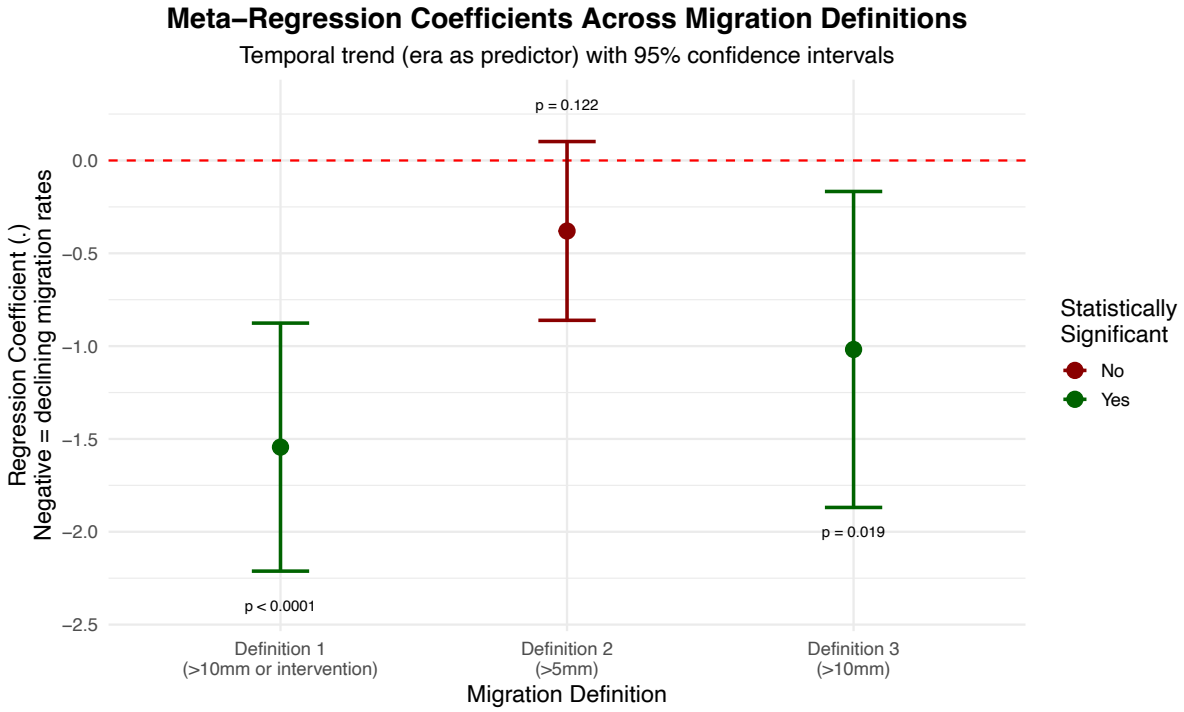


Figure 14 presents a comparison of the meta-regression coefficients across all three definitions. Both Definition 1 and Definition 3 have confidence intervals entirely below zero, indicating statistically significant temporal declines, while Definition 2's confidence interval

crosses zero (non-significant). Definition 1 demonstrates the most pronounced decline with a narrow confidence interval ($\beta = -1.544$, $p < 0.0001$), while Definition 3 shows a significant but less certain decline with a wider confidence interval ($\beta = -1.018$, $p = 0.019$). In understanding this results, the reliance should not be dependent on on the statistical significance alone, but in conjunction with explanatory power: Definition 1's temporal trend accounts for the vast majority of heterogeneity, while Definition 3's significant p-value may mask the limited explanatory capacity.

Figure 15: Heterogeneity explained by era

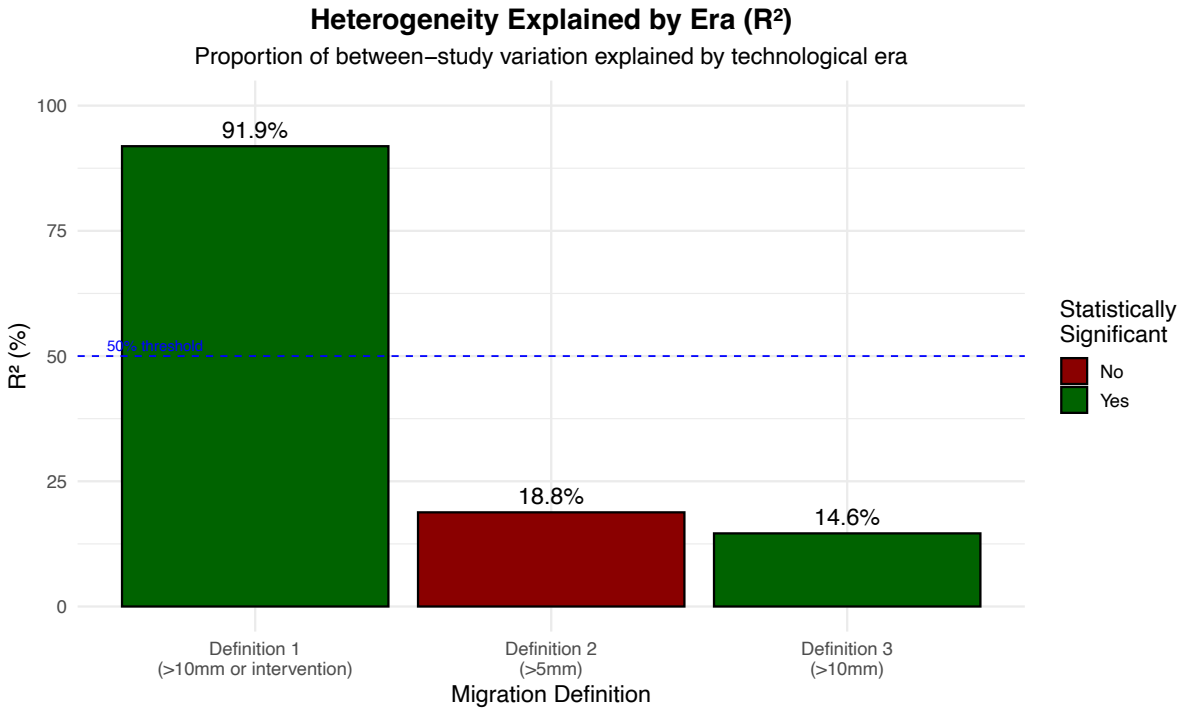


Figure 15 displays the difference in explanatory power across definitions. Definition 1's R^2 of 91.9% far exceeds the 50% threshold (marked with a dashed line), while Definitions 2 (18.8%) and 3 (14.6%) fall well below, indicating the limitations of temporal factors explaining their heterogeneity.

Figure 16: Relative reduction over time

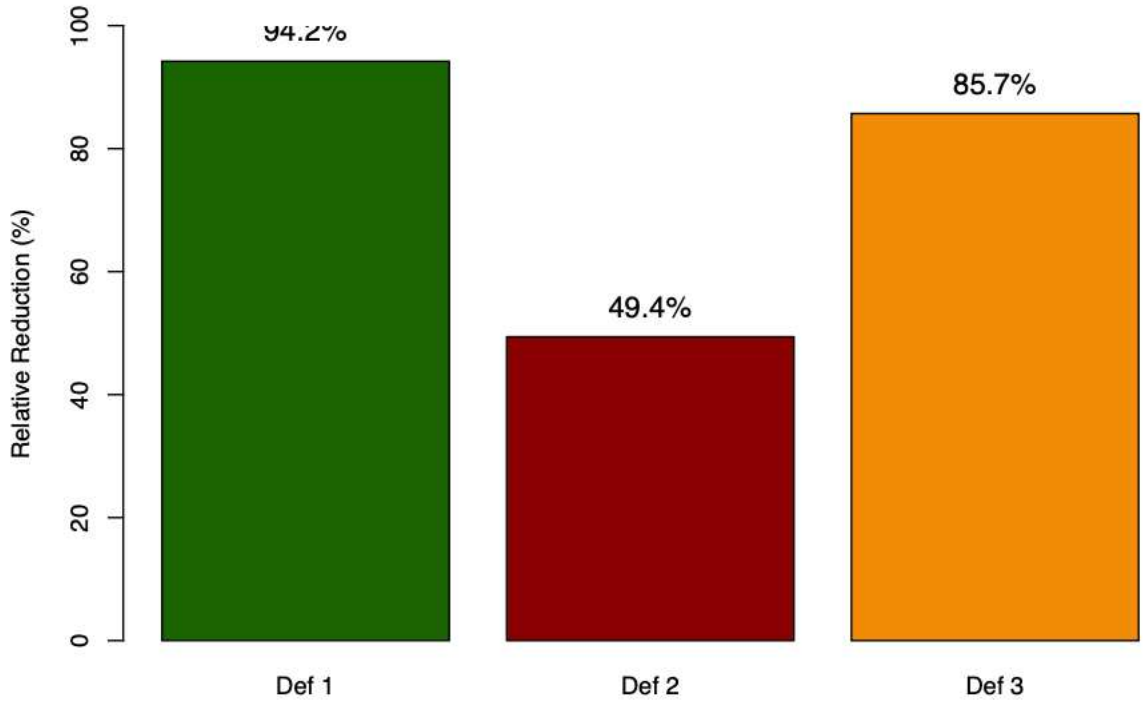


Figure 16 illustrates the relative reduction in migratory rates over the defined study period for each definition. The combined figures demonstrate that while all definitions show some degree of clinical reduction, only Definition 1 achieves statistical robustness with high explanatory power.

Only Definition 1, combining radiological threshold (>10mm) or a functional endpoint (intervention requirement), demonstrated robust temporal decline with era explaining >90% of heterogeneity. Both radiological thresholds alone—whether more sensitive (>5mm, Definition 2) or standard (>10mm, Definition 3), showed absent or weak relative temporal patterns with era explaining <20% of heterogeneity.

This pattern suggests that Definition 1, (in keeping with the SVS and ESVS definitions of migration) has substantially decreased over the different stent graft eras, while radiological measurements alone show inconsistent temporal patterns. The >5mm threshold may be too sensitive, capturing subclinical movements, measurement variability, or normal graft settling that have not changed substantially across eras. The >10mm threshold without the functional

criterion may miss earlier interventions that prevent progression to this magnitude, particularly in modern practice with intensive surveillance protocols.

2.4.10 Meta-regression and sensitivity analysis

Given the significant heterogeneity identified amongst the studies, univariate analysis of possible risk factors for migration such as anatomical features or an analysis of the grafts used, was not carried out.

2.4.11 Risk of bias

A comprehensive assessment of each study's risk of bias and justification is outlined in the Appendix List, as Newcastle-Ottawa assessment and Newcastle-Ottawa justification in Table 59: Systematic Review: Risk of bias assessment using modified Newcastle-Ottawa quality assessment score. and Table 60: Systematic Review: justification for risk of bias. The eventual 23 studies which were included in the subsequent metanalysis all scored ≥5 on quality assessment tool and the Newcastle-Ottawa Scale (NOS). The included studies were predominantly retrospective case series reporting migration as a secondary outcome rather than prospective studies with migration as the primary endpoint. This introduces inherent methodological limitations including potential selection bias, inconsistent follow-up protocols, and non-systematic migration assessment (where they truly looking for migration? did they have a protocol in place on how to assess for migration?). While the NOS scores indicate acceptable quality within the constraints of observational device literature, all studies carried substantial risk of bias characteristic of retrospective surgical series.

2.4.11.1 GRADE assessment

2.4.11.1.1 Quality of Evidence Assessment

The quality of evidence for migration rates after EVAR was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [197]. GRADE was applied to the 23 studies included in the definition-stratified meta-analysis, representing the pooled quantitative estimates that directly address the secondary research question regarding migration incidence over time. The primary research question regarding

definitional heterogeneity is addressed through descriptive analysis in the Migration definition results section and narrative discussion below. Table 11 presents the GRADE assessment for migration rates stratified by definition. A summary of the findings and meta-regression results examining temporal trends across stent graft eras are integrated into this assessment, as these analyses utilise the same 23 studies and address the temporal component of the incidence question. This is followed by Table 12, which outlines the parameters and criterion on which the final GRADE assessment was made.

Table 11: Summary of findings and final GRADE assessment for migration rates after EVAR by definition

Migration Definition	Studies (n)	Patients (n)	Follow-up (months)	Pooled Migration Rate (95% CI)	Risk of Bias	Overall Certainty	Temporal Trend (Meta-regression)
Definition 1: ≥10mm displacement or requiring intervention	4	566	36-60	6.8% (1.9-21.8%)	Serious	VERY LOW	Significant decline across eras (β=-1.544, p<0.0001, R^2=91.9%). Robust in sensitivity analysis. Era 2: 21.8% → Era 4: 1.3%
Definition 2: ≥5mm displacement	6	1,909	36-96	11.7% (7.1-18.8%)	Serious	VERY LOW	No significant temporal trend (β=-0.380, p=0.122, R^2=18.8%). Non-robust in sensitivity analysis. Era 1: 19.2% → Era 4: 7.1%
Definition 3: ≥10mm displacement only	13	1,735	36-84	6.6% (4.0-10.6%)	Serious	VERY LOW	Marginally significant decline (β=-1.018, p=0.019, R^2=14.6%). Sensitivity analysis approached non-significance (p=0.054). Era 2: 9.6% → Era 4: 1.4%

Table 12: Formal GRADE assessment for migration rates after EVAR by definition

Migration Definition	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Certainty	Temporal Trend (Meta-regression)
Definition 1: ≥10mm displacement or requiring intervention	Serious	Serious	Not serious	Serious	Suspected	VERY LOW	Significant decline across eras (β=-1.544, p<0.0001, R^2=91.9%). Robust in sensitivity analysis. Era 2: 21.8% → Era 4: 1.3%

Migration Definition	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Overall Certainty	Temporal Trend (Meta-regression)
Definition 2: ≥5mm displacement	Serious	Serious	Not serious	Serious	Suspected	VERY LOW	No significant temporal trend (β=-0.380, p=0.122, R^2=18.8%). Non-robust in sensitivity analysis. Era 1: 19.2% → Era 4: 7.1%
Definition 3: ≥10mm displacement only	Serious	Serious	Not serious	Not serious	Suspected	VERY LOW	Marginally significant decline (β=-1.018, p=0.019, R^2=14.6%). Sensitivity analysis approached non-significance (p=0.054). Era 2: 9.6% → Era 4: 1.4%

2.4.11.1.2 Serious risk of bias (all definitions)

All included studies were observational in design, predominantly retrospective case series (modified Newcastle-Ottawa Scale scores 2-5 out of 9). Migration was reported as a secondary outcome in most studies rather than the primary endpoint, with non-systematic or ambiguous assessment protocols. No randomised controlled trials were identified. Patient selection criteria, stent graft deployment techniques, and surveillance protocols varied substantially across studies. Temporal trends were therefore potentially confounded by:

(i) Changes in patient selection with increasing adherence to instructions for use over time.
(ii) Operator learning curve effects during early eras.
(iii) Survivor bias with longer follow-up in earlier eras.
(iv) Improvements in imaging quality and measurement precision in recent eras.

These sources of bias were consistent across all definition groups, warranting downgrading by one level.

2.4.11.1.3 Serious inconsistency (all definitions)

Very high statistical heterogeneity observed across all definition groups (I^2 = 84.4-92.7%) despite definition-based stratification intended to reduce methodological heterogeneity. Prediction intervals extended well beyond pooled estimate confidence intervals, indicating substantial uncertainty about the expected migration rate in a new setting even when using standardised definitions. Between-study variation in migration rates remains large and largely unexplained by definition alone. Residual heterogeneity after meta-regression remained moderate to high (residual I^2 = 50.7-90.7%), suggesting that patient characteristics, anatomical features, stent graft types, operator experience, and other unmeasured factors are likely to contribute substantially to variation. Therefore, downgrading by one level was warranted for serious inconsistency across all groups.

2.4.11.1.4 Serious imprecision (Definition 1):

Very wide 95% confidence interval (1.9% to 21.8%) representing an 11-fold range between lower and upper bounds. This degree of imprecision makes the estimate of limited utility for clinical decision-making or comparative effectiveness assessment, as the true rate could plausibly be very low (near 2%) or concerningly high (over 20%). Small number of studies (4 studies) with total sample size of only 566 patients contributes to imprecision. Meta-regression with only 4 studies may therefore be exploratory and hypothesis-generating rather than definitive, as conventional guidance recommends ≥10 studies per predictor variable for reliable estimates [196]. This was therefore downgraded one level for serious imprecision.

2.4.11.1.5 Suspected publication bias (all definitions):

Multiple sources of potential publication bias were identified:

1. The funnel plot asymmetry was observed for Definition 3 (13 studies), the only group with sufficient studies for visual assessment; formal statistical tests (Egger's, Begg's) were not performed due to insufficient study numbers (<15) in all groups.
2. Several included studies were industry-sponsored device trials conducted for regulatory approval, potentially subject to selective outcome reporting favouring specific device outcomes.

3. The temporal trend analyses showing improvement over time are susceptible to differential publication bias if early-era studies with unfavourable results remained unpublished while contemporary studies with better outcomes were more likely published.
4. A shift from physician-initiated research in early eras to industry-sponsored trials in recent eras may introduce systematic bias in reported outcomes. The direction and magnitude of publication bias cannot be precisely quantified but is sufficient to warrant downgrading, which was applied to all definition groups.

2.4.11.1.6 Serious imprecision (Definition 2):

The outcome of a wide 95% confidence interval (7.1% to 18.8%), representing a 2.6-fold range, introduces concern regarding imprecisions. Despite substantially larger sample size (n=1,909) compared to Definition 1, the substantial between-study heterogeneity (I^2=92.7%) contributes to imprecision in the pooled estimate. The non-significant meta-regression finding (p=0.122) with confidence interval crossing zero (-0.861 to 0.102) and non-robust sensitivity analysis further indicate imprecision in characterising temporal trends for this definition. This was therefore downgraded one level for serious imprecision.

2.4.11.1.7 Not serious imprecision (Definition 3):

Relatively narrow 95% confidence interval (4.0% to 10.6%) with 2.7-fold range, which is the narrowest among the three definition groups. Largest number of studies (13 studies) providing the most stable pooled estimate. Adequate total sample size (n=1,735). While the confidence interval is not negligible, it is sufficiently narrow that it would not substantially alter clinical decision-making compared to a point estimate. Meta-regression confidence interval excludes the null (-1.869 to -0.167), indicating a statistically significant temporal trend despite marginal robustness in sensitivity analysis. No downgrading for imprecision.

All studies were observational (case series), which begin at Low certainty in GRADE framework [198]. Downgrading was applied to all three definition groups: one level for serious risk of bias (observational design with multiple confounding sources), one level for serious inconsistency (very high I^2 despite stratification), one level for serious imprecision

(Definitions 1 and 2) or no downgrading (Definition 3). In addition to consideration for suspected publication bias (serious concern across all groups)

2.4.12 Interpreting the final GRADE assessment

All three definition groups rated as Very Low certainty. This rating reflects methodological limitations inherent to observational studies, small study numbers in some definition groups, high residual heterogeneity, and the presence of mixed residual confounding. However, the Very Low certainty rating should not reflect doubt regarding whether migration rates have genuinely declined over time. Rather, uncertainty about the precise magnitude of decline and the relative contribution of different causal mechanisms.

Definition 1 (≥10mm or requiring intervention) demonstrated a large magnitude of effect (94% relative reduction from Era 2 to Era 4), robust sensitivity analysis, and high explanatory power (R^2=91.9%). Despite these strengths, formal upgrading from Very Low to Low certainty was not applied according to GRADE criteria. GRADE upgrading requires evidence that all plausible residual confounding would work against the observed effect rather than explaining it. In this analysis, there are mixed confounding effects: some factors (improved imaging detection capability, longer follow-up in earlier eras) work against the observed decline and suggest the true improvement may be even larger, while other factors (publication bias favouring recent studies, industry sponsorship of contemporary trials) may work with the decline and potentially inflate its apparent magnitude. This mixed confounding pattern, combined with small study numbers (4 studies) and observational study design, does not meet GRADE criteria for formal upgrading.

Nevertheless, the temporal decline observed with Definition 1 appears genuine and clinically meaningful for several reasons. First, the decline demonstrates robust consistency across all leave-one-out sensitivity analysis iterations (all $p<0.003$), indicating the finding is not driven by any single influential study. Second, the high explanatory power (R^2=91.9%) indicates temporal factors explain the overwhelming majority of between-study variance, suggesting this is a true signal rather than random variation. Third, the consistency of direction across all three definition groups, supports the plausibility of genuine improvement. Fourth, the temporal trend aligns with documented evolution in stent graft technology, operator

experience, patient selection criteria, and deployment techniques, providing mechanistic support for the observed decline [199].

The temporal improvement likely represents the combined effect of multiple concurrent advancements: evolution of stent graft fixation mechanisms and materials, accumulation of operator experience and refinement of deployment techniques, improved adherence to anatomical suitability criteria and patient selection, and enhanced surveillance protocols. From a patient perspective, these factors collectively constitute genuine advancement in EVAR safety and durability, regardless of their relative contributions. A patient undergoing EVAR in 2020 faces genuinely lower migration risk than a patient in 2000, whether this stems primarily from superior devices, more experienced operators, better patient selection, or some combination thereof [31, 83].

2.5 Discussion

2.5.1 Principle Findings

This systematic review of 97 studies encompassing 17,706 patients revealed three critical findings regarding stent graft migration following EVAR. First, substantial definitional heterogeneity characterises the published literature: one-quarter of studies (25.8%, 25/97) provided no definition of migration, while the remaining 72 studies employed 18 distinct definitions with varying radiological thresholds (5mm vs 10mm), anatomical reference points (lowest renal artery vs superior mesenteric artery vs celiac axis), measurement techniques (axial CT vs centreline reconstruction vs plain radiography), and functional criteria (some requiring intervention, others purely radiological). This fundamental methodological inconsistency prevents direct comparison of migration rates across studies and obscures the true incidence of this complication.

Second, definition-stratified meta-analysis of 23 higher-quality studies with clearly documented migration definitions, ≥36 months follow-up, and CT-based surveillance yielded pooled migration rates varying from 6.6% to 11.7% depending on the definition employed. All three common definition groups demonstrated very low certainty of evidence. Even after definition-based stratification to reduce methodological heterogeneity, substantial

unexplained variation persisted (I^2 84-93%), indicating that factors beyond measurement method, including patient selection, stent graft type and generation, operator experience, anatomical characteristics, and follow-up duration, may contribute substantially to variation in reported migration rates.

Third, meta-regression analyses examining temporal trends across four stent graft eras (1990-2020) demonstrated marked heterogeneity in findings across definition groups. Definition 1 (≥10mm displacement or requiring intervention), which aligns with SVS and ESVS reporting standards [69, 200], showed robust temporal decline explaining 91.9% of between-study variance. Leave-one-out sensitivity analysis confirmed stability of this finding (all iterations $p<0.003$). Predicted migration rates decreased from 21.8% in Era 2 (1996-2003) to 1.3% in Era 4 (2008-2020), representing a 94.2% relative reduction. In contrast, Definition 2 (≥5mm displacement) showed no significant temporal trend ($\beta=-0.380$, $p=0.122$, $R^2=18.8\%$) with non-robust sensitivity analysis, suggesting this threshold may be overly sensitive and capture movements that have not decreased despite technological improvements. Definition 3 (≥10mm displacement without functional criteria) showed statistically significant but marginally robust decline ($p=0.019$, but $p=0.054$ in sensitivity analysis when studies with zero events were removed) with weak explanatory power ($R^2=14.6\%$). These disparate findings suggest that composite endpoints incorporating both radiological displacement and functional consequences (intervention requirement) may better capture clinically meaningful improvements in stent graft performance than purely anatomical thresholds.

2.5.2 Interpretation of Findings

2.5.2.1 Heterogeniety in the definition of migration

The identification of 18 distinct definitions across 72 studies, in addition to the 25 studies with no definition, represents a profound implication for evidence synthesis, clinical practice guideline development, and future research. The employment of different measurement methods, anatomical landmarks, radiological thresholds, and functional criteria would infer that pooled meta-analysis of migration rates becomes methodologically questionable without stratification. The persistently high heterogeneity observed even after definition-based

stratification (I^2 84-93%) confirms that definitional variation is a major but not sole contributor to between-study differences.

There is plausibility in understanding that the inconsistencies in definitions may have arisen from the absence of validated migration assessment protocols during the early development of EVAR technology. The SVS published initial reporting standards in 1997 [67] but provided minimal guidance on migration definition. The updated 2002 standards [200] specified ≥10mm displacement "relative to an anatomical landmark" or "migration leading to symptoms or requiring therapy," but left considerable autonomy in implementation. The ESVS 2019 guidelines [69] reiterated this definition but acknowledged that "the active supra- or infrarenal fixation in modern stents has reduced its prevalence" without substantively revising measurement standards or thresholds.

The practical consequences of this definitional heterogeneity are expected to be substantial. Surveillance protocols cannot be evidence-based when the evidence employs non-comparable measurement methods. Comparative effectiveness research examining migration rates across different stent graft devices becomes uninterpretable when studies use different definitions. Device manufacturers' pivotal trials and post-market registries may employ definition choices that optimise reported outcomes, potentially introducing systematic bias. Clinical practice guidelines attempting to synthesise this literature face the challenge of providing recommendations based on very low certainty evidence with unclear applicability.

2.5.2.2 Superiority of Definition 1 (≥10mm or requiring intervention)

Of the three definitions, the performance of Definition 1 demonstrated robust temporal decline with high explanatory power (R^2=91.9%). Several factors may contribute to this finding. First, the composite endpoint combining radiological displacement (≥10mm) with functional consequence (requiring intervention) captures both anatomical and clinical dimensions of stent graft failure. Early-generation stent grafts with inadequate fixation mechanisms may have migrated substantially (exceeding 10mm threshold) and frequently required secondary intervention due to resulting type Ia endoleaks or seal compromise. Contemporary devices with improved fixation, enhanced radial force, and optimised

deployment systems may genuinely migrate less and less frequently require intervention even when minor displacement occurs.

Furthermore, Definition 1 may be less susceptible to measurement bias compared to purely radiological thresholds. The "requiring intervention" component introduces a clinical adjudication that is less dependent on imaging technique, measurement precision, or observer interpretation than purely anatomical assessments. An intervention for migration-related complications is a discrete, unambiguous event that is consistently reported across studies and eras, whereas measuring displacement on imaging can vary substantially based on image quality, reconstruction technique, and measurement methodology.

Moreover, the definition aligns with clinical outcomes. Migration that does not require intervention and does not compromise seal may represent clinically insignificant displacement or normal graft settling rather than true failure. The incorporation of intervention requirement inherently filters for clinically consequential migration, potentially explaining why this definition better tracks genuine improvements in stent graft durability over time.

However, alternative explanations must be considered. The high R^2 could reflect changing intervention thresholds over time rather than actual reduction in migration. If operators in early eras were more aggressive in intervening for minor displacement (defensive practice during EVAR's learning curve) [64] while contemporary operators tolerate more displacement with intensive surveillance (maturity and confidence in the technology), the apparent decline in "migration requiring intervention" might partially reflect changing clinical practice rather than improved device performance. Additionally, the small number of studies (4 studies) in Definition 1 means that any outliers or influential studies have disproportionate impact, though the robust sensitivity analysis argues against this concern.

2.5.2.3 Temporal trends in EVAR outcomes

The observed temporal decline in migration rates does not occur in isolation but forms part of a well-documented pattern of improvement across multiple EVAR outcomes. Registry data provide evidence of genuine advancement over time. The EUROSTAR registry,

encompassing multiple early-generation devices (Era 2), reported 40% reintervention rates at 4 years [15], representing the challenges of early EVAR technology and practice. In stark contrast, the GREAT (Gore) registry for the more contemporary Excluder device (Era 4) reported re-intervention rates 7.2% at 5 years [201], demonstrating the magnitude of improvement achievable with modern devices, refined patient selection, and mature operator experience. This dramatic reduction represents a relative improvement and cannot be dismissed as methodological artifact or bias.

The consistent direction toward improved durability across independent registry sources, different outcome definitions, and diverse geographical settings strengthens confidence that temporal improvement is genuine [199].nThe temporal decline in migration observed in this systematic review aligns closely with this broader evidence base. The finding of 21.8% predicted migration (Definition 1) in Era 2 declining to 1.3% in Era 4, a 94% relative reduction, is concordant in both magnitude and direction with registry data comparing EUROSTAR and GREAT registry [201]. The convergence of evidence from this meta-analysis of 23 studies with existing published temporal trends provides strong corroborative support that the observed improvements represent a genuine reduction in migration rates over time, rather than statistical artifact or selective reporting.

2.5.2.4 Bias within temporal trends

Observed temporal trends require cautious interpretation due to multiple confounding factors that cannot be controlled in this study-level meta-analysis. Individual patient data would be needed to adequately adjust for these factors.

Stent graft technology evolved substantially across four eras (1990-2020). First-generation physician-made devices progressed through early commercial models with suboptimal fixation to contemporary devices with enhanced fixation mechanisms (hooks, barbs, suprarenal stents), improved materials (low-permeability grafts), refined metallurgy, and sophisticated deployment systems [18] . These advances likely genuinely reduced migration rates. Simultaneously, adherence to anatomical suitability criteria improved markedly[178]. Early EVAR often treated challenging anatomy (short necks, large diameters, severe angulation, heavy calcification) unsuitable by current standards. Contemporary practice

shows better patient selection, recognising that hostile neck anatomy predicts poor outcomes [54]. This improvement likely contributes to better results independent of device technology. The EVAR learning curve was traversed during early eras, with contemporary operators benefiting from accumulated experience, refined techniques, and better anatomical understanding. This maturation likely contributes to temporal improvement [154]. Additionally, imaging quality improved dramatically from early plain radiography (subject to parallax error) to contemporary centreline technology with 3D reconstruction and automated measurement [202]. The improved imaging has likely increased migration detection or decreased it through better initial deployment.

Systematic bias likely affects temporal trend estimates. Early studies with unfavorable results may have remained unpublished, while manufacturer-sponsored recent studies introduce potential selective reporting [94]. Funnel plot asymmetry supports this concern (Figure 13). Longer follow-up in earlier-era studies could reveal more late migration, though meta-regression adjusts for this.

These factors cannot be disentangled from study-level data, reflected in very low certainty of evidence. Nevertheless, robust temporal decline with Definition 1, documented technological improvements, and corroborative publications documenting a reduction in reintervention rates suggest a genuine reduction in migration rates. From a patient-centred perspective, migration-related complication risk has genuinely declined, regardless of whether improvement stems primarily from technology, technique, or patient selection.

2.5.2.5 Comparison to existing evidence

This systematic review updates and substantially extends the 2016 meta-analysis by Spanos et al. [31], which reported an overall migration rate of 4.47% (95% CI 3.30-5.93%) across 33 studies with 8,892 patients and median follow-up of 24 months. That review reported I^2=76.7% heterogeneity but did not stratify by definition or examine temporal trends, analysing migration as a homogeneous outcome despite methodological variation across included studies.

The current meta-analysis of 23 higher-quality studies with 4,210 patients yielded pooled rates of 6.6-11.7% depending on definition, with substantial heterogeneity (I^2=84-93%). While the number of studies in the meta-analysis is comparable to Spanos et al (23 vs 33 studies), this review encompasses a broader systematic search of 97 studies with 17,706 patients, enabling identification of definitional heterogeneity and era-stratified analysis not performed in prior reviews. Several factors may explain this discrepancy. First, Spanos et al. included studies with shorter follow-up (median 24 months vs ≥36 months required in the current meta-analysis), potentially underestimating late migration [77]. Second, the current analysis included more recent studies from Eras 3-4 with longer surveillance periods, allowing detection of delayed migration. Third, definition-stratified analysis in the current review may more accurately capture true variation rather than averaging across heterogeneous measurement methods.

2.5.3 Strengths and Limitations

2.5.3.1 Strengths

This systematic review possesses several methodological strengths. First, the search extended from database inception through December 2020, capturing three decades of EVAR literature.

Furthermore, the definition-stratified analytical approach represents a methodological contribution. Rather than pooling studies with heterogeneous migration definitions, which produces uninterpretable results with artifactually inflated heterogeneity, this review separately analysed each common definition group. This approach controls for measurement heterogeneity and allows examination of whether apparent temporal trends are definition-dependent, a question not previously addressed in the literature.

The comprehensive assessment of study quality using a modified Newcastle-Ottawa Scale adapted for case series provided transparent evaluation of risk of bias. While quality scores were not used as inclusion criteria, they informed interpretation and sensitivity analyses restricting to higher-quality studies with ≥36 months follow-up, clear definitions, and CT surveillance.

Moreover, multiple sensitivity analyses enhanced confidence in findings. Leave-one-out meta-regression examined whether any single study drove temporal trend estimates. Restriction to higher-quality studies assessed robustness across quality thresholds. Meta-regression examining era as a continuous predictor complemented era-stratified descriptive analyses and accommodated the uneven distribution of studies across eras without requiring complete representation in all era-definition combinations.

2.5.3.2 Limitations

Several important limitations must be considered when interpreting these findings. All included studies were observational, predominantly retrospective case series, with no randomised controlled trials identified. This fundamentally limits causal inference and is reflected in the starting point of low certainty in the GRADE framework, subsequently downgraded to very low certainty. Observational studies cannot fully adjust for confounding variables, which is particularly problematic in temporal trend analyses where secular changes in patient selection, technology, and practice patterns occur simultaneously. While individual patient data meta-analysis with adjustment for patient-level confounders would provide stronger evidence, this was not feasible with the available data [196].

Assignment of studies to eras based on data collection midpoint represents a necessary but imperfect simplification. Studies with data spanning multiple eras (e.g., 2000-2012 encompassing Eras 2, 3, and 4) were assigned to a single era, potentially misclassifying patients treated with different-generation devices [203]. This limitation is inherent when examining temporal trends from published aggregate data, and sensitivity analyses using alternative assignment methods were not feasible. Importantly, this misclassification probably attenuates observed temporal trends toward the null, suggesting true improvements may be more pronounced than detected.

Substantial residual heterogeneity persisted even after definition-based stratification (I^2 84-93%, residual I^2 51-91% after meta-regression). Beyond measurement method, numerous

factors contribute to between-study variation: patient characteristics (age, comorbidity, anatomy), stent graft types and specific devices, operator and institutional experience, deployment techniques, and surveillance protocols. Meta-regression with study-level covariates such as mean patient age, proportion with hostile neck anatomy, or specific stent graft proportions was considered but deemed unreliable. Small study numbers (4-13) and incomplete reporting across studies made this approach unsuitable. These unmeasured confounders limit confidence in estimates and explain the serious inconsistency in GRADE assessment. Furthermore, the underlying the question of this systematic review was to address, whether there had been a reduction in migration rates over time. Whilst an understanding of the underlying cause of this anticipated reduction may help understand why this reduction may have occurred, stratifying the overall effects of the multiple possible underlying causes, was not integral in addressing this underlying question.

The meta-regression analyses themselves would need to be interpreted with caution. With only 4 to 13 studies per definition group, statistical power is limited and results should be considered exploratory. Conventional guidance recommends ≥10 studies per predictor for reliable meta-regression [88, 196], a threshold met only by Definition 3 (13 studies). Definitions 1 (4 studies) and 2 (6 studies) are particularly underpowered and vulnerable to influential studies, though robust sensitivity analysis for Definition 1 provides some reassurance. These analyses generate hypotheses rather than provide definitive evidence. Publication bias almost certainly affects the evidence base but could not be comprehensively assessed. Funnel plot asymmetry tests and Egger's regression require ≥10-15 studies for reliable interpretation, achievable only for Definition 3 where visual asymmetry was observed. Small-study effects may inflate pooled estimates. Moreover, industry sponsorship of many contemporary device trials introduces potential selective outcome reporting. While the direction and magnitude of publication bias cannot be precisely quantified, it may exaggerate apparent temporal improvement if early-era negative studies remained unpublished while contemporary industry-sponsored trials preferentially published favourable results.

The search was limited to English-language publications and concluded in December 2020. Non-English studies from regions with active EVAR programs (e.g., German, French, Italian, Japanese literature) were excluded, a common but potentially problematic limitation if these studies report systematically different results. The 2020 cut-off means recent publications

with Era 4 devices and extended follow-up are not represented, though this likely affects absolute numbers rather than conclusions about temporal trends and definitional heterogeneity.

More fundamentally, this review examined migration as an isolated outcome without comprehensive assessment of subsequent clinical consequences. Migration is a surrogate endpoint; its correlation with patient-important outcomes: type Ia endoleak, sac expansion, rupture, aneurysm-related mortality, and reintervention, these remain incompletely characterised. Definition 1's incorporation of "requiring intervention" partially addresses this by selecting clinically consequential migration, but comprehensive outcome data linking migration to ultimate patient outcomes were not systematically extractable across the heterogeneous studies. Future research should examine not merely whether migration occurs but what clinical consequences ensue and at what thresholds intervention improves outcomes.

Finally, the distinction between radiological migration (image-based detection, e.g. 5 or 10mm) and clinical migration (displacement requiring intervention) was inconsistently reported across studies. Some reported all radiologically detected migration ≥10mm regardless of clinical consequence; others reported only migration prompting intervention. Definition 1 attempts to capture both, but heterogeneity within this definition group may exist based on institutional thresholds for intervention. This reflects the broader definitional inconsistency in the literature and reinforces the need for standardisation.

2.5.4 Clinical Implications

The finding that Definition 1 (≥10mm or requiring intervention) demonstrates the most robust temporal trend with highest explanatory power supports current SVS [67, 212] and ESVS [213] guidelines recommending this composite endpoint for migration assessment. Clinicians conducting post-EVAR surveillance should document migration using this standardised definition: ≥10mm displacement from baseline (measured using centreline reconstruction) or displacement of any magnitude requiring intervention due to seal compromise i.e. type Ia endoleak, or clinical compromise. This approach captures both anatomical and functional dimensions of graft failure.

The apparent reduction in migration rates with contemporary devices (Era 4 predicted rate 1.3% for Definition 1) must be interpreted cautiously. Migration following EVAR is recognised as a late complication [77, 120, 125] yet the median follow-up in this analysis was only 36 months, potentially insufficient to capture the true incidence. Despite this limitation, even at 1.3%, migration represents a meaningful source of late morbidity given the substantial volume of EVAR procedures performed annually [204]. Long-term surveillance remains essential. The very low certainty of current evidence means true migration rates could be considerably higher than contemporary estimates suggest, particularly with extended follow-up beyond the 36-60 month range typical of recent studies.

Lastly, patient counselling regarding EVAR risks should acknowledge that while stent graft durability has improved over time, late complications including migration remain possible and necessitate lifelong surveillance.

2.6 Future research

This systematic review highlights several critical priorities for future research.

2.6.1 Standardisation of migration definitions

The most pressing need is a universal adoption of a standardised migration definition. The SVS/ESVS composite endpoint (≥10mm displacement or requiring intervention) demonstrated the most robust temporal trend and highest explanatory power in this analysis, supporting its designation as the reference standard. Future studies should uniformly adopt this definition, measured using centreline technology on CT angiography at standardised time points. Without this, the field will continue to generate evidence that cannot be meaningfully synthesised.

2.6.2 Standardised measurement protocols should be device specific.

Different stent grafts have distinct anatomical fixation points: infrarenal versus suprarenal fixation, varying barb lengths, different radio-opaque marker positions, etc. Recommendations should also specify anatomical landmarks (e.g., lowest renal artery or

superior mesenteric artery) and measurement points tailored to each device type, yet such guidance remains largely absent from current literature.

The shift toward ultrasound-based surveillance complicates this further. Current ESVS guidance recommends duplex ultrasound as the primary surveillance modality for uncomplicated repairs to reduce cumulative radiation exposure [205-207]. Migration, however, has traditionally been measured using CT or x-ray. Patients now receive CT only when ultrasound reveals inconsistencies or complications. While this reduces radiation exposure, serial measurements to track progressive displacement become difficult when the gold standard imaging modality is reserved for problem cases. We lack robust data on how early ultrasound changes correlate with CT-detected migration.

The 2024 ESVS guidelines recommend CT imaging at 1 month and 12 months post-procedure, with subsequent annual duplex ultrasound in uncomplicated cases [205]. These two CT scans present an opportunity. A standardised approach comparing stent position and orientation between baseline and 12-month imaging could identify early changes predictive of future migration, though this would require retrospective analysis of existing cohorts, cohorts that may become increasingly rare as ultrasound-based protocols are adopted. Such predictive models could enable more targeted surveillance strategies. Without this development, we risk either over-imaging low-risk patients or under-detecting migration in the ultrasound era.

2.6.3 Elevating migration as a primary outcome

Migration should become a primary outcome in device trials and registries. The current analysis was limited by migration's secondary status in most included studies, resulting in non-systematic assessment, incomplete reporting, and heterogeneous measurement methods. Device pivotal trials for regulatory approval should include migration as a co-primary outcome alongside traditional endpoints (aneurysm-related mortality, reintervention), with pre-specified non-inferiority margins based on contemporary benchmarks.

2.6.4 Understanding migration's natural history

The relationship between migration magnitude, progression rate, and clinical consequences remains poorly characterised. Critical questions persist: Is 5-9mm displacement with stable seal clinically equivalent to no migration, or does it predict subsequent progression? Does migration velocity (mm/year) predict eventual failure better than absolute displacement at a single time point? Is migration gradual or are there more abrupt migratory phases in relation to the failure of the stent graft? What thresholds mandate intervention versus intensified surveillance?

Answering these questions requires prospective natural history studies with serial imaging, standardised measurement protocols, and long-term follow-up linking migration to subsequent outcomes including type Ia endoleak, sac expansion, rupture, and aneurysm-related mortality. This represents perhaps the most significant knowledge gap identified by this review.

2.6.5 Individual patient data meta-analysis

Study-level meta-analysis cannot adequately adjust for patient-level confounders. Variables including neck length, diameter, angle, conicity, calcification burden, thrombus presence, oversizing percentage, device-specific characteristics, operator experience, and institutional volume should be systematically collected and analysed to identify independent predictors of migration beyond temporal trends. The Vascular Quality Initiative (VQI) [204] and similar large registries provide potential infrastructure for such analysis, though coordinating multi-registry individual patient data remains challenging.

2.7 Conclusion

This systematic review of 97 studies (17,706 patients) reveals pervasive definitional heterogeneity in how stent graft migration after EVAR is recorded, with 18 distinct definitions identified. For the three most common definitions, pooled migration rates ranged from 6.6-11.7%, showing a decline in all three definitions over 4 different technological eras. The SVS/ESVS composite definition (≥10mm displacement or requiring intervention) showed the most robust temporal decline, with a 94% relative reduction from Era 2 (1996-2003) to Era 4 (2008-2020).

This review highlighted, that the field requires the use of standardised definitions and protocols, with migration recorded as a primary outcome in device trials, and individual patient data meta-analysis. Until better evidence emerges, clinicians should interpret published migration rates cautiously. This review establishes the foundation for developing standardised measurement protocols in subsequent chapters.

3 Determining Stent Migration in Contemporary Practice

3.1 Introduction

Systematic Review, highlighted the heterogeneity amongst practice in both defining and measuring migration. Of the evaluated three definitions of migration, Definition 1 (≥10mm displacement or requiring intervention), showed a the most robust temporal decline over the different eras. Furthermore, the review was unable to provide any evidence of a similar reduction in migration rates for studies document migration at 5-9mm. However, given the heterogeneity identified from the studies' protocols making a definitive inference on threshold distances, to determine migration was not possible.

Nevertheless, the systematic review in Chapter 2, was able to demonstrate a temporal reduction in migration rates over time, although the risk of migration itself was not entirely mitigated by Era 4.

Understanding the relationship between migration distance and associated clinical sequalae remains outstanding and therefore which threshold is superior in determining both stent graft failure and patient implications remains unknown. This is particularly relevant within contemporary practice, in the post Era 3period, where the relevance of migration has been challenged [208-210].

3.2 Objectives

The aim of this chapter will therefore focus on:

i) Identifying and choosing a reproducible, valid and reliable method of calculating migration
ii) Employing this single method in determining the rate of migration in the use of 4th generation SG
iii) Determining the clinical relevance of migration at 5 and 10mm within contemporary SG.

3.3 Methods

3.3.1 Determine a valid definition of stent migration.

Following on from the findings of the systematic review and limitations of previous publications in determining a valid understanding of SG migration in EVARs, several issues will need to be addressed.

To determine a valid screening tool which acknowledges the:

1. 3-dimensional structure of SG
2. to a relevant and reliable landmark
3. over time using a reliable imaging modality
4. reproducibility of this technique, by health care professionals, to ensure it is practical.

3.3.2 Choosing the relevant landmark

The origin of a visceral branch would be best suited for this as it a structure easily identifiable (particularly with contrast enhanced scans), is intimately related and close to the SG and less susceptible to changes over time. In terms of which visceral branch, the lowest renal artery was preferred as it is typically the reference point used by clinicians when determining where to place the SG. The lowest renal artery is the also the closest identifiable structure to the SG and is therefore least likely to be susceptible to erroneous measurements secondary to aortic elongation. In order to standardise measurements, the most distal part of the ostium of the lowest renal artery was used as the reference point: using axial images, the first slice (moving in a caudo-cranial direction) in which the artery first joins the aorta and is no longer a separate entity [202].

3.3.3 Accounting for the 3-dimensional structure

Typically, much the publications have used a single point of the graft from which measurements were made, to determine migration. As highlighted previously a single measurement may not adequately represent the orientation or tilt of the graft and therefore fail to capture migration in the event this has occurred above (Chapter 1: Issues with current definition: orientation). Several measurements to distinct areas to the SG from a single

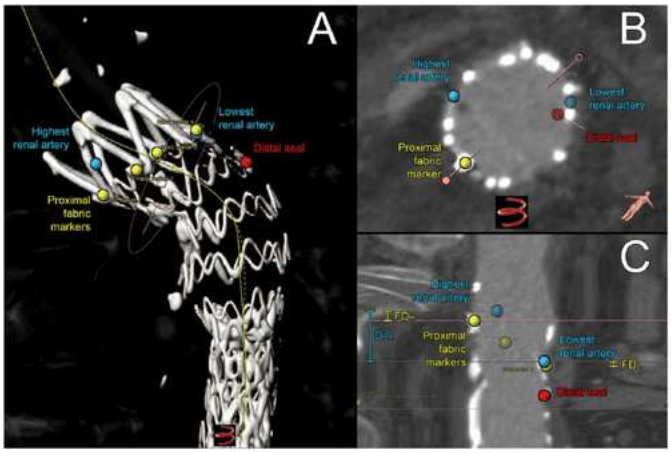
landmark (lowest renal) would therefore need to be made to capture a true representation of the proximal portion of the graph.

3.3.3.1 Defining SG position 1: Schuurmann et al (2017)

Shuurmann et al (2017) proposed a novel way of establishing a semi-automated method for measuring the 3-dimensional fabric to renal artery distances in determining an endograft position following EVAR. [211]

Using reconstructions of the aorta from contrast enhanced CT scans (with centre line technology) and an understanding of how far the supra-renal fixation prongs are from the fabric (Endurant 1.3 mm, Zenith 1.3 mm, Excluder 1.5 mm, and Talent 1.3 mm, information gathered directed from respective manufacturers), the radio opaque markers are marked and used to infer the most proximal portion of graft fabric following deployment.

Figure 17: Schuurman et al, semi-automated method to measure graft to renal artery (1)

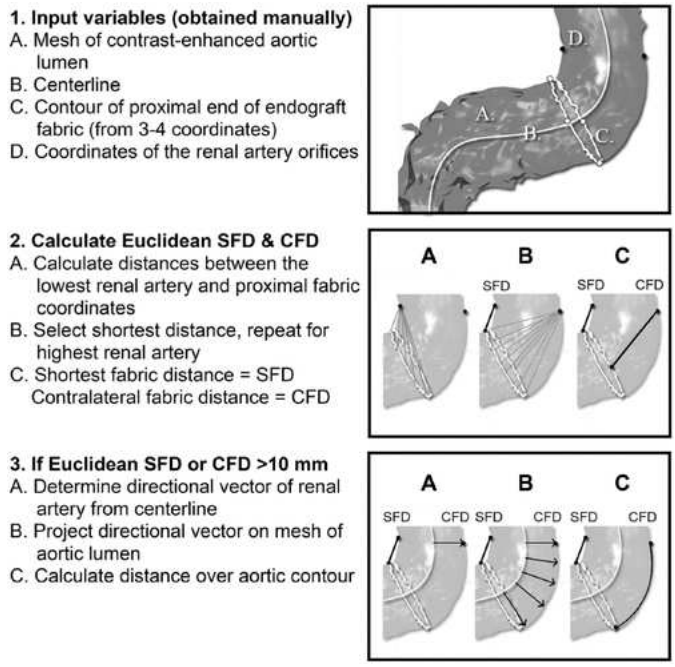


Post repair computed tomography measurements on the 3mensio workstation displayed in (A) a 3-dimensional, (B) perpendicular to the centreline, and (C) stretched vessel views. Coordinates of the renal arteries, the 4 proximal fabric markers, and the distal end of the seal are displayed, as well as the centreline distances between the renal artery orifices (D_{RA}) and the fabric distances below the lower (FD_L) and higher (FD_H) renal arteries [211].

In order to generate an understanding of the position of the 3-dimensional graft within the aorta, several measurements are made:

1. The shortest distances between both renal arteries and the endograft fabric, (fabric distances), are automatically calculated as the minimal Euclidean distances between the distal boundaries of the orifices of the respective renal arteries and the proximal boundary circumference of the endograft fabric (Figure 2).
2. The Euclidean distance describes the straight-line distance between 2 coordinates in a 3D space. If the Euclidean fabric distance was >10 mm, the fabric distance was calculated over the outer contours of the aortic lumen to account for curved morphology of the aortic segment.
3. The fabric distances are then calculated for both left and right renal arteries (and a preserved accessory renal artery if applicable). The shortest distance between the fabric and one of the renal arteries is referred to as the shortest fabric distance (SFD) and the distance to the contralateral renal artery is referred to as the contralateral fabric distance (CFD).
4. These distances are independent of which renal artery is defined as the lower renal artery on the preoperative CT scan. The coordinates of the renal arteries and the proximal graft boundary (Figure 17: Schuurman et al, semi-automated method to measure graft to renal artery) were obtained from the first postoperative 3D CT volumes on the 3mensio vascular workstation (version 8.1 research edition; Pie Medical Imaging BV, Bilthoven, the Netherlands).

Figure 18: Schuurman et al, semi-automated method to measure graft to renal artery (2)



Step-by-step explanation of the methodology of calculating the shortest fabric distance (SFD) and contralateral fabric distance (CFD): (1) obtain the coordinates, centerline, and mesh from a vascular workstation; (2) calculate Euclidean fabric distances; and (3) if a Euclidean distance is >10 mm, the fabric distance is calculated over the curve of the aorta. [211]

Shuurmann et al, attempted to test this new method on 150 patients from the Aortic Securement System Global Registry (ANCHOR). 69 (46%) had to be excluded for a variety of reason. Importantly, 53 patients did not meet the inclusion criteria, a further 6 were excluded because the scanned trajectory was too short, or the trajectory was not sufficiently enhanced with contrast agent and 11 were excluded as they had no clear proximal boundary of the graft fabric. Therefore, out of 98 eligible patients this method could only be carried out on 81 (87%) as they were unable to reliably identify the relevant landmarks to generate measurements. Of those successfully measured, Schuurmann was able to reliably project the position of SG relevant within 3mm in relation to the renal arteries. Whilst this approach appears to be rather comprehensive and acknowledges the 3-dimensional character of the stents within the aorta, it does have limitations in terms of reproducibility:

1. 6% of patients had to be excluded as the graft position did not allow for adequate measurements or the image did not enhance adequately enough for measurements to be taken

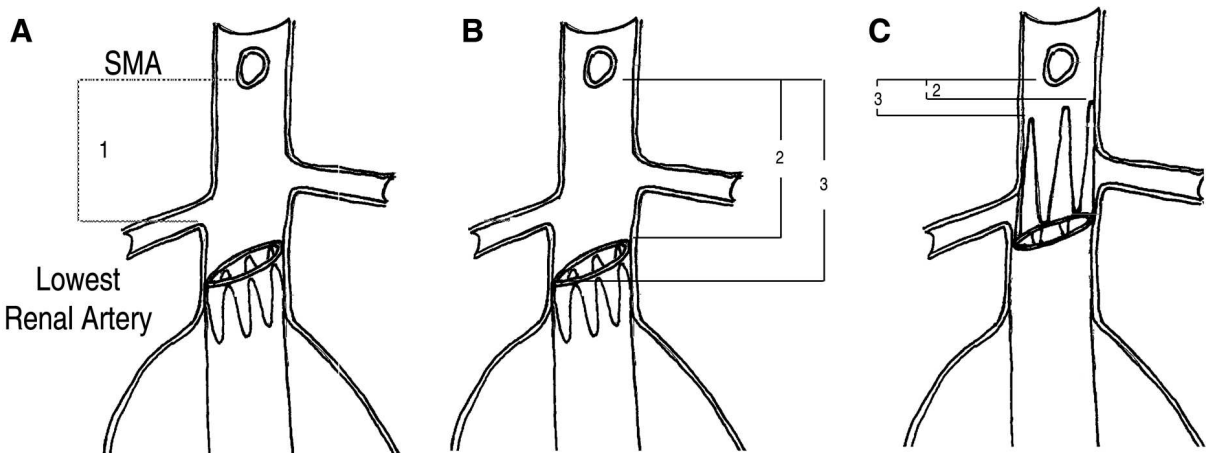
2. 11% of patients were excluded as the authors were unable to identify were the graft fabric started, this means that they were unable to identify this on the CT scan. The use of graft fabric – to determine stent graft position, is not always reproducible.
3. There are significant limitations in terms of reproducibility: This method was presented to 5 vascular trainees, 80% (four out five) were unable to follow the steps published using centreline technology and reproduce outcomes similar to that of the authors', which would suggest that this method is rather complicated and would require a certain amount of training, in order to reproduce similar results.

The combination of a high exclusion cohort, complexity and difficulty in reproducing the measurement protocols would preclude Schuurmann's method from being employed as surveillance tool.

3.3.3.2 Defining SG position 2: Greenberg et al (2004)

Greenberg et al (2004), sought to reappraise the radiographic definition of SG migration that accurately describes a specific failure mode of an aortic SG. He assessed 24 cases of documented SG migration on which he built a radiographic protocol on how this may be measured (Figure 19: Greenberg et al, defining) [74]

Figure 19: Greenberg et al, defining migration.



The protocol to assess for SG migration:

1. To assess CT interscan variability, the distance between the SMA and lowest renal artery was measured (1A) in each scan. If this distance changed significantly between the various studies, additional measures, such as centreline of flow studies, would be employed.
2. The SMA was chosen as a focal point, given the possibility of late problems with the lowest renal artery.
3. The method remained the same whether the device was an infrarenal device (B) or a suprarenal device (C): However, in the setting of a suprarenal device, the proximal portion of the stent may extend beyond the SMA; thus, if the device were to migrate, the distance between the proximal stent and SMA would decrease and eventually become zero or a negative value. This possibility must be accounted for when assessing devices with suprarenal stents.
4. If one aspect of the device were to move without the entire device position shifting, this would be considered angulation. For this reason, the distance from the SMA to the first visible stent (B2) on the CT scan would be assessed with the first appearance of the circumferential stent (B3) on the CT scan.
5. This is similarly accomplished with a suprarenal stent (C2 and C3, respectively).

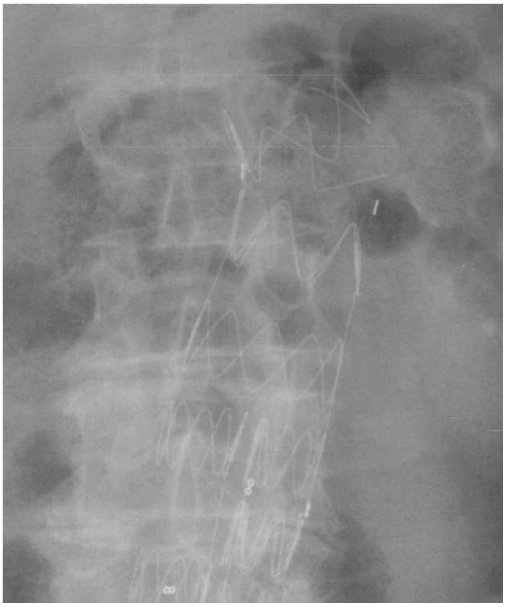
Greenberg successfully applied this method to all cases assessed and identified that the existing definitions, particularly that set by the SVS guidelines are inadequate. The benefits of this method allow for:

1. Less complicated process for others to replicate and are therefore easily reproducible: This process was again presented to 5 vascular trainees: all of which were able to replicate and provide similar results between them.
2. Acknowledges and incorporates the 3-dimensional structure of the SG within the aorta improving the validity of the assessment.
3. Uses readily identifiable landmarks (SMA and proximal metallic stent prongs) from which to take measurements.

Whilst Greenberg's' protocol is able to overcome much of the limitations seen with Schuurmann's analysis, Greenberg's protocols focus solely on identifying the position of the stent graft within the aorta in relation to the SMA, rather than study the contact of the fabric

(active part of the graft) with the aorta. Greenberg's method may allow one to infer the fabric position (as did Shuurman) by subtracting the distance of the supra-renal fixation prongs (Endurant 1.3 mm, Zenith 1.3 mm, Excluder 1.5 mm, and Talent 1.3 mm) from their measurements, relying on the integrity of the metallic prongs. The proximal metallic metal prongs are fairly robust structures; a literature search found a single example of proximal prong fracture, occurring in a case study describing, a fracture of the proximal prong (Figure 20) and the loss of the integrity of the SG leading to a contained rupture [212].

Figure 20: Suprarenal fixation fracture



Such fractures are very easily identifiable on CT scans and if identified would warrant intervention or closer surveillance, regardless of any migration detected.

A radiographic protocol based on Greenberg's method would meet much of the requirements needed in detecting SG migration and may provide a platform on which future surveillance methods could be built.

It is worth noting however Greenberg's protocol did not employ centreline technology. Furthermore, Greenberg chose to differentiate between migration and angulation: the term angulation would be used, when only one of the prongs would be displaced, and migration

when both prongs would be displaced. In line with the European and American guidelines, wherein migration would be defined as any displacement of the SG necessitating proximal aortic intervention, the differentiation between angulation and migration will not be employed, rather only the term migration would be adopted in the event any of the prongs where identified to be displaced.

3.4 Developing a radiographic protocol to define and measure migration.

In developing a radiographic protocol to determine and measure stent migration an acknowledgment of the characteristics of patient anatomy, stent profile and imaging modalities needs to acknowledged:

3.4.1.1 Imaging modality

1. Arterial phase enhance CT scan's have shown to produce the clearest images in identifying both the aorta and its visceral branches. [202]
2. This modality is routinely used in pre-operative planning and post-operative surveillance particularly when other image modalities (e.g. ultrasound and x-rays) may show a discrepancy or possible complication. [213, 214]
3. Clinicians are well versed in analysing such images and in using complimentary software such as centre line technology and developing image reconstructions.[215]
4. The arterial post-contrast phases are typically acquired with 0.625-mm slice collimation. This can limit an over/under estimation of measurements taken in reconstructions. [214]

3.4.1.2 Choice of anatomical landmarks

1. The lowest renal artery (LRA) will be used as a reference point rather than the SMA as it is closer to the SG. This will possibly help limit the effect of aortic elongation when taking subsequent measurements over time. Furthermore, it is the reference point traditionally used in planning the deployment of the SG

2. The use of the inferior border of the visceral branch is used as the anatomical landmark, due to its intimate relationship with the aorta and is readily identifiable in an arterial phase CT. [216]

3.4.1.3 Choice of SG landmarks:

In order to determine whether a SG has migrated, measurements from the chosen anatomical landmark (LRA) will need to be made to the SG to provide reliable measurements over time. Ideally the SG landmark would need to be close to the LRA, in order to minimise the risk of erroneous measurements and be reliably identified by the clinician to ensure measurements are taken between the two landmarks each time. [217]

Commonly used SG for EVAR's, typically have radio-opaque markers placed throughout the SG and in particular, within the proximal portion of the SG's fabric, to aid the clinician in ensuring the device is deployed in the correct orientation and as close to the LRA as possible (Figure 21). However, whether these markers would be a suitable and reliable marker to use a reference point for subsequent measurements on CT, would need to be determined. Alternative landmarks to use would be to use the proximal prongs of the SG, as used by Greenberg. To identify which of the two is more readily and reliably identified on CT imaging, the following experiment was carried out:

3.4.1.4 Experiment: identifying suitable SG landmarks

Using 3 patients (with different brand stent grafts: Cook, Endurant and Gore) who had undergone an EVAR, three years prior, with 3 subsequent postoperative CT scans performed on an annual basis, we began to experiment with the best method of identifying and measuring a reliable method of mapping out the orientation of the stent graft. Analysis was commenced using workstations: Aquarius (TeraRecon, San Mateo, CA, USA), which had been previously independently validated to create reconstructions of aorta using centre-line technology [218]. Identifying the radio opaque markers on CT, to determine the fabric was not always reliable.

Using the Terarecon station, 5 vascular trainees were requested to identify all the radio-opaque markers for the different stents (Figure 21), which sit at the proximal part of the stent fabric, and help clinicians determine the fabrics upper limits during deployment.

Figure 21: Proximal EVAR stent graft

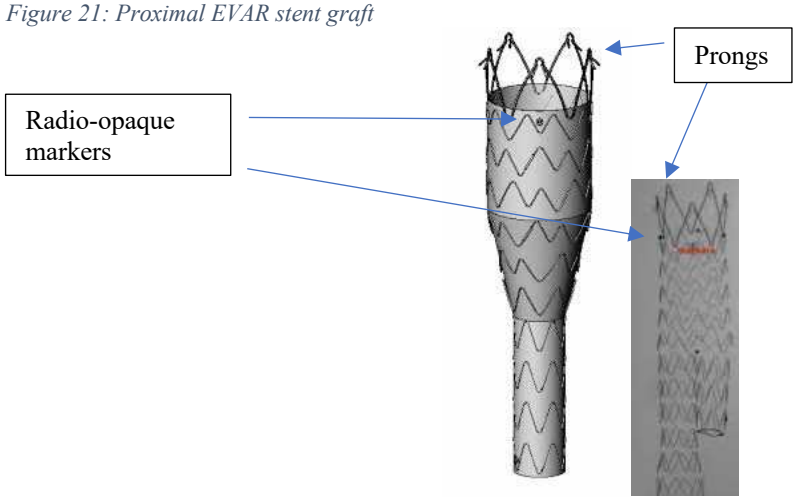


Figure 21: Proximal EVAR stent graft, shows a diagrammatic and xray picture of an Endurant graft with the visible markers at the fabric edge and prongs identified

Trainees had to identify all radio opaque markers (3-4 depending on the brand) confidently and independent from the metallic struts in order to be deemed successful.

Table 13: EXPERIMENT: identifying radio-opaque markers on CT

Trainee	endurant	cook	gore
1	-	-	-
2	x	-	-
3	x	x	-
4	-	x	x
5	-	-	-

x = success

- = failure

From 15 attempts only 5 (33%) were confident in confidently identifying the radio-opaque markers

The trainees were then requested to confidently identify all proximal prongs of the respective stent (5-12 depending on the stent brand).

Table 14: EXPERIMENT, identifying SG prongs on CT

Trainee	endurant	cook	gore
1	x	x	x
2	x	x	x
3	x	x	x
4	x	x	x
5	x	x	x

In this attempt all trainees were able to reliably identify the proximal prongs for each manufacturer.

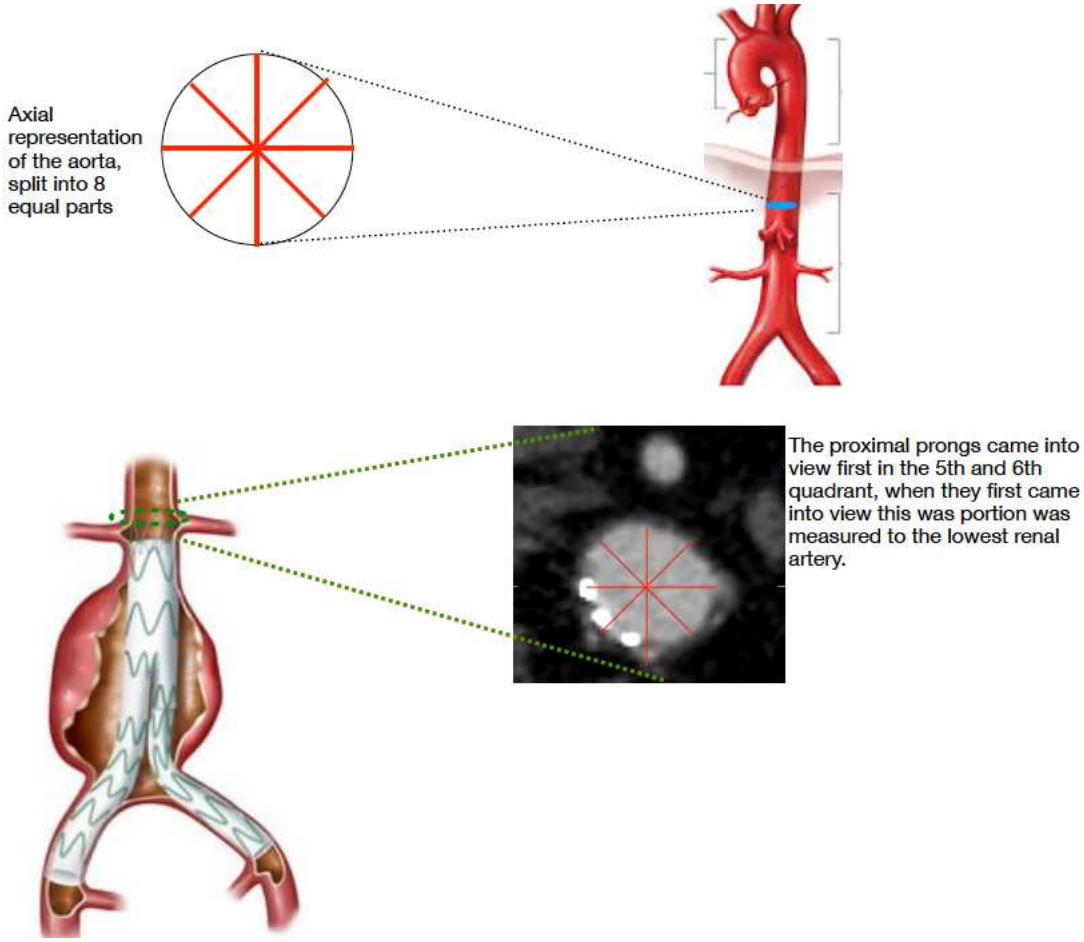
A decision to use the proximal prongs as reference points for measurements was made.

3.4.1.5 Measuring SG position and distance in relation to LRA:

3.4.1.5.1 1st iteration of measuring protocols

To identify each specific prong, axial images (using centreline software) of the aorta were initially split into 8 octants. Starting at the level of the coeliac axis, the assessor would scroll down slice by slice, noting at which point (distance from the LRA) and in which octant, SG material could be seen. The distance (from LRA) at which each octant first showed stent material would be noted. This would be used to map out the position of the stent graft (Figure 22: EXPERIMENT, capturing SG prongs on CT).

Figure 22: EXPERIMENT, capturing SG prongs on CT, 1st iteration.



Steps of this method using the terarecon workstation:

1. Ensure the image provided has a maximum of 1mm slice collimation.
2. Select an arterial enhanced CT scan.
3. Identify lowest renal artery (LRA) and place a marker.
4. Scroll up to the metallic prongs and count them, ensuring they are still intact
5. Scroll down slice by slice, setting a marker at each time an octant is occupied with a new prong and measuring to the Lowest renal artery as well as aortic diameter. Until all prongs are accounted for. Corroboration of the correct position can be made with

sagittal and coronal images, simultaneously following the markers using the workstation.

6. Measurements from the LRA and the aortic diameter measurements can demonstrate the position of the stent within the aorta.
7. The same process is carried out for the same patient on subsequent scans to generate a comprehensive understanding of the SG position over time.

In the next experiment, 3 vascular trainees were informed of the above process and provided with a tutorial and then written guide on how to record the distance of each prong within their respective octant. Participants were given three attempts at reviewing a CT scan of an anonymised patient who had previously undergone an EVAR with an endurant SG for a 6cm uncomplicated AAA. Their performance was measured as to whether they were able to accurately record the distance of each prong from the LRA, each prong would be identified according to which octant they occupied within the cross-sectional aorta. The time taken to complete the task was also recorded.
Table 15: EXPERIMENT, measuring prongs within octants to the LRA, summarises the results of this experiment.

Table 15: EXPERIMENT, measuring prongs within octants to the LRA

	Did participant correctly calculate position of the prong within 1mm and in the correct octant?							
Participant	Prong 1	Prong 2	Prong 3	Prong 4	Prong 5	Prong 6	Time taken (minutes)	% correct
A (1st attempt)	y	y	n	n	y	y	48	67%
A (2nd attempt)	y	y	y	y	y	y	45	100%
A (3rd attempt)	y	y	y	y	y	y	42	100%
B (1st attempt)	n	y	y	n	n	n	38	33%

B (2nd attempt)	y	y	y	y	n	y	38	83%
B (3rd attempt)	y	y	y	y	y	y	37	100%
C (1st attempt)	y	y	y	y	y	y	41	100%
C (2nd attempt)	y	y	y	y	y	y	42	100%
C (3rd attempt)	y	y	y	y	y	y	35	100%
Average correction recording	89%	100%	89%	78%	78%	89%	41 minutes	87%

There is a clear learning curve with implementing this measuring protocol, before all participants were able to produce 100% accuracy.

3.4.1.5.1.1 Limitations

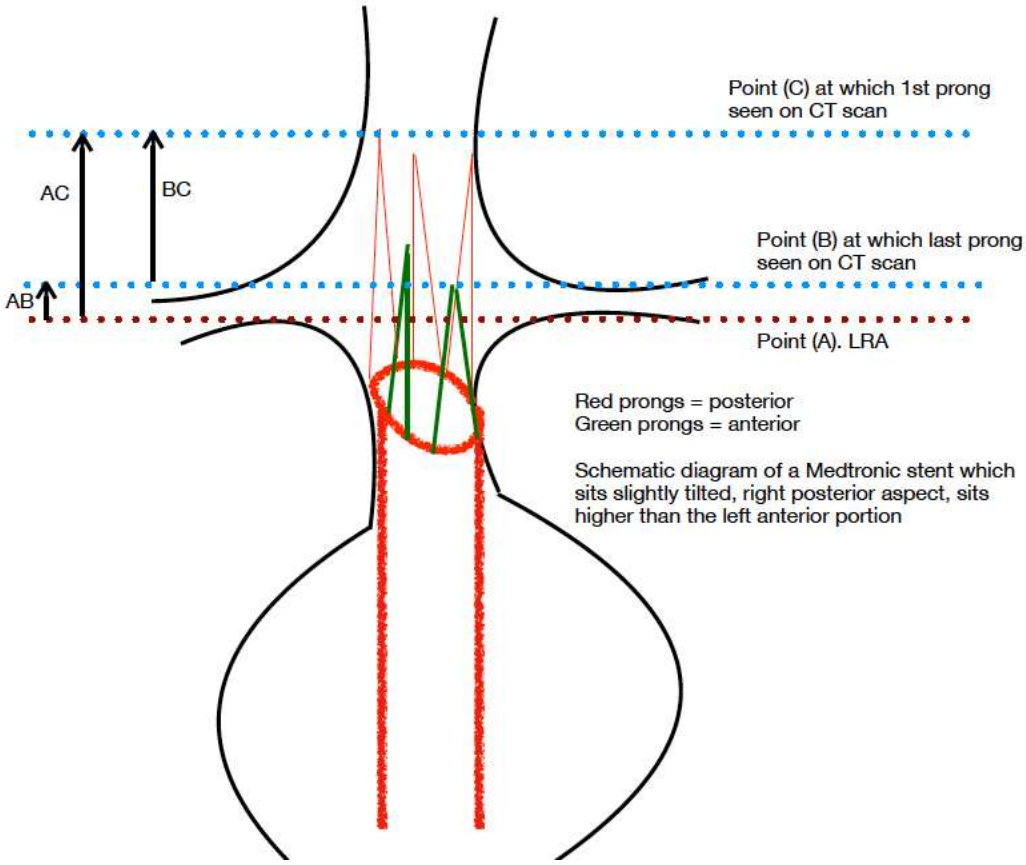
1. Each octant may have more than one prong which may cause the operator to overlook more distal prongs within the same octant. However as the collective prongs, create a circle, it is not possible to have the most proximal and distal prong within the same octant, unless all prongs lie adjacent to the arterial wall and therefore at the same level.
2. Some prongs may lie on the borders of the quadrants creating confusion as to which octant they should be placed in
3. This method generates multiple manual measurements which then need to be compared and subtracted from those in subsequent scans. A trial of 3 vascular trainees performing this process for a single scan found it took an average time of 41 minutes to perform all the necessary measurements. Whilst in an academic realm this may be feasible, it is unlikely to be routinely replicated in the real-life practice.
4. Participants also commented that the process felt over complicated, with multiple measurements and equations required, thereby introducing the possibility of error.

Whilst this method provided a plausible understanding of the SG positions over time, it was fairly complicated and was subject to operator bias and confusion amongst participants. A more streamline method, to screen all postoperative EVAR for evidence of migration, incorporating all the prongs was needed.

3.4.1.5.2 2nd iteration of measuring protocols

A more easily applicable tool for measuring migration is required as a screening tool in assessing post-operative scans. Greenberg et al's (2004) methods, provide a promising platform which may be adapted in light of the previously identified limitations of previous protocols [74].

Figure 23: measuring SG prongs to LRA



Following the steps below (Figure 23: measuring SG prongs to LRA)

1. Ensure the image provided has a maximum of 1mm slice collimation
2. Select an arterial enhanced CT scan
3. Identify lowest renal artery (LRA) and place a marker
4. Scroll up to the metallic prongs and count them, ensuring they are still intact
5. Start just above the coeliac axis, scroll down slice by slice, setting a marker at the first prong seen (C)
6. Continue scrolling down to the first time the last prong is seen and set a marker (B)
7. Continue scrolling down until you reach the most distal aspect of the lowest renal artery and set the final marker
8. Corroboration of the correct position of each of the three markers can be made with sagittal and coronal images, simultaneously following the markers using the workstation.
9. Measure from point A to B (AB). To give the lower limit of the lower of the proximal stent graft prongs
10. Measure from Point A to C (AC). To give the lower limit of the upper limit of the proximal stent graft prongs
11. The distance between B and C should be recorded allowing one to calculate the tilt of the graft within the aorta, using the aortic diameter. Should this change over time this will determine whether the tilt of the SG has changed.
12. Measurements AB and AC from the first postoperative scan should be noted and then compared to the most recent surveillance scans, to determine whether there has been any change in the position of the SG.
13. Should either AB or AC change more than 5mm, than this will determine that migration has occurred, and further evaluation of the images will need to be undertaken.

In a subsequent experiment. the same three participants where then provided with a different anonymised CT scan of a 6 cm uncomplicated AAA, having undergone an EVAR with an Endurant SG. The 3 participants were then informed of the above process and provided with a tutorial and then written guide on how to record the distance of the most proximal and distal prongs, from the LRA. Participants were given three attempts at reviewing the CT scan of the new anonymised patient Their performance was measured as to whether they were able to accurately record the distance of each prong from the LRA. The time taken to complete the task was also recorded. The results of this experiment are summarised in

Table 16.

Table 16:EXPERIMENT measuring prongs to LRA, using the Greenberg method.

	Correctly measured distance of the prong to LRA			
Participant	Proximal prong	Distal prong	% successfully recorded	Time taken (minutes)
A (1st attempt)	y	y	100	7
A (2nd attempt)	y	y	100	7
A (3rd attempt)	y	y	100	5
B (1st attempt)	y	y	100	6
B (2nd attempt)	y	y	100	5
B (3rd attempt)	y	y	100	5
C (1st attempt)	y	y	100	5
C (2nd attempt)	y	y	100	4
C (3rd attempt)	y	y	100	4
Average	100%	100%	100%	5 minutes

With this second attempt, participants were able to calculate the distance of both the proximal and distal prongs from the LRA with a 100% success rate. They also took a significantly shorter time in proving this information with a shorter learning curve. Participants also expressed their preference over the previous measuring iteration as it was more straightforward, easier to complete and had less room for error.

This second iteration will serve as the screening tool for determining whether migration has occurred. Of those cases in which migration is confirmed further evaluation of all images are to be undertaken to map out the possible pattern of migration over time

Using Greenberg's method to measure SG migration in patients who have undergone an EVAR for AAA, I will be retrospectively reviewing the cases and scans of patients who have undergone an EVAR for an AAA, using a 4th generation SG.

3.5 Application of ethical approval

In order to determine the incidence of SG migration and assessing for evidence of specific patterns, an evaluation of patients pre and post-operative imaging was required. As this would require handling of confidential information, an ethics request was completed and approved, with the Integrated Research Applications System, IRAS Project ID: 251364.

3.6 Determining the rate of migration in 4th generation stent grafts, in the UK since 2008:

3.6.1 Compiling a database of patients who have undergone an EVAR

From the previous chapters several questions have remained unanswered:

1. Is there evidence of migration in 4th generation SG?
2. If there is, are there any risk factors associated with this subgroup to migrate?
3. At what point is migration likely to occur in 4th generation SG?
4. Can we predict which cases are more likely to migrate?

To address the limitations of previous studies evaluating migration of SG following EVAR a more comprehensive analysis was required by implementing a standardised and accepted method of calculating migration over a long enough period to detect when this is likely to occur, using an adaptation of Greenberg's methods.[74] Again, this analysis would need to be relevant to contemporary practice and therefore this analysis should avoid evaluating outdated technology, ensuring 4th generation SG and more contemporary grafts are included. Furthermore, to reduce the risk of publication bias, data from additional, independent and non-related vascular surgery centres would need to included.[219]

3.6.2 Identifying relevant vascular centres for data collection

Imperial College Health Trust, an established vascular centre is where the author currently practices. In 2018 Imperial College Health Trust, were within the top quartile amongst

vascular centres in the UK for number of AAA repairs, according to the National Vascular Database (NVR), having carried out 103 abdominal aortic aneurysm repairs, of which 72% were recorded as EVAR. This would therefore be suitable as a centre to provide data for the proposed project. [220]

Recruiting an international centre for a more diverse and representable population was considered however, recent publications have found little differences in overall outcomes in patients who have undergone AAA repair between the UK and another European country, Sweden. [221] It was therefore felt that recruiting from an alternative vascular centre from the UK would be sufficient. To identify an additional suitable recruiting centre, a list of all centres within the top three quartiles (in terms of volume) was assembled and a member of the clinical team was contacted to ascertain their routine post-operative surveillance programmes and whether they would grant permission to access their data. Taking into account the shift in practice in moving from CT to USS in post-operative surveillance following an EVAR [72], the recruited centre would have needed to employ CT scanning as part of their routine surveillance (at least up to one year post-operatively) in at least 50% of their patients. Of the 10 centres successfully contacted, University Hospitals Coventry and Warwickshire NHS trust, had both granted access and met the post-operative surveillance requirements. In 2018 they had carried out 52 AAA repairs of which 56% were repaired using EVAR.[220] Whilst this may not have been regarded as a high volume centre, the additional data extracted from this centre would have provided for a total of approximately 90 EVARs per year, from two vascular tertiary referral centres. A retrospective database, recruiting patients over a 9-year period between 2008-2017 would theoretically yield 630 cases for analysis.

3.7 Designing the proforma and database for data capture

Data from CT scans, patient demographics and postoperative surveillance would be collected for each patient that underwent an EVAR since 2008 (the year in which 4th Generations were commonly used) at Imperial College Trust Hospitals and University Hospitals Coventry and Warwickshire NHS trust.

3.7.1 Identifying patients within the trust

A comprehensive and inclusive list of all patients who have undergone an EVAR from 2008-2017 would need to be created. To achieve this several data sources were reviewed: the NVR database, local databases held by research fellows, local departmental lists (compiled for governance and audits), hospital coding database and the ultrasound angiology department's EVAR surveillance list. Patient information from all these individual sources were compiled onto a single list and duplicates removed. Where there was a discrepancy in the data, e.g. the type of operation a patient had, this was cross referenced with the patient's medical notes and either amended within the main database or removed (e.g. should the patient have had a fenestrated EVAR rather than an EVAR).

Following the identification of all patients who had an EVAR at both institutions, I established the inclusion and exclusion.

3.7.2 The inclusion criteria:

1. An infrarenal EVAR with no addition neck adjuncts, such as Chimneys, or cuffs – to reduce risk of heterogeneity of assessed intervention
2. Patients needed to have a pre-operative CT scan (within 6 months of procedure) – to adequately assess the patients anatomy and suitability for the intervention.
3. All patients needed to have a post-operative CT scan following the EVAR (within 4 months) – this would act as the initial base-line investigation from which subsequent migration may be determined
4. All patients require to have had a minimum one-year interval period between their initial post-operative CT scan and subsequent surveillance scan/s – allowing for measurements to be compared over time.
5. Patients which have undergone a proximal neck intervention postoperatively will only be included until the date of their secondary intervention – as including such patient would introduce heterogeneity of the assessed intervention.

3.7.3 Exclusion Criteria:

1. Fenestrated EVAR's (FEVAR), extension cuffs or chimneys

2. Less than one year follow up with CT

3.7.4 Data Extraction and Database Headings

Patients' medical records were reviewed to ascertain their demographics,

The database headings were compiled based on the lessons learned from previous studies and theory (as discussed in the introduction). Listed below are the headings within the proforma and subsequent database for each EVAR case meeting the inclusion criteria:

3.7.4.1 Demographics

1. Date of Birth
2. Age at operation
3. Gender

3.7.4.2 Operation and follow-up

4. Date of death/most recent follow-up.
5. Date of EVAR?

3.7.4.3 Co-morbidities

6. Smoking status
7. Age at operation
8. Hypertensive?
9. Diabetic?
10. Chronic obstructive pulmonary disorder (COPD)?
11. Ischaemic heart disease?

3.7.4.4 Medications

12. On antiplatet therapy e.g aspirin/clopidogrel at time of operation?

13. On statin therapy at time of operation?
14. Receiving anticoagulation at time of operation?

3.7.4.5 Graft Specifics

15. Stent brand
16. Graft size?
17. Supra renal fixation?
18. Number of supra-fabric prongs?

3.7.4.6 Aneurysm Anatomy

19. AAA preop size?
20. Aortic length 1: Superior Mesenteric Artery (SMA) to LRA distance
21. Aortic length 2: SMA to Right Internal Iliac Artery (RIIA)
22. Neck shape
23. Neck length
24. Aortic diameter 10mm below LRA
25. Aortic diameter 5mm below LRA
26. Aortic Diameter at the level of LRA
27. Aortic Diameter 5mm above LRA
28. Thrombus neck %
29. Calcium neck %
30. Distal aortic diameter

3.7.4.7 Procedural variables

31. Peri-operative adjuncts (e.g. vessel embolization, distal extension)
32. Perioperative and immediate postoperative complications (within first week).

3.7.4.8 1st post-operative CT scan data

33. 1st post-operative CT scan date
34. SMA to LRA distance

35. SMA to RIIA distance
36. AAA sac diameter
37. Neck length
38. Aortic diameter 10mm below LRA
39. Aortic diameter 5mm below LRA
40. Aortic Diameter at the level of LRA
41. Aortic Diameter 5mm above LRA
42. Distance from LRA to most proximal (supra-renal*) prong: distance AC, Figure 23
43. Distance from LRA to most distal (supra-renal*) prong: distance AB, Figure 23
44. Calculate the tilt of the graph: $\tan^{-1}$ (AC-AB)/aortic diameter.
45. Leak channel?
46. Endoleak classification
47. Intervention following first CT?

3.7.4.9 Most recent CT scan data

48. Most recent CT date
49. Time from first post-op CT scan to most Recent CT
50. SMA to LRA distance
51. SMA to RIIA distance
52. AAA sac diameter
53. Neck length
54. Aortic diameter 10mm below LRA
55. Aortic diameter 5mm below LRA
56. Aortic Diameter at the level of LRA
57. Aortic Diameter 5mm above LRA
58. Distance from LRA to most proximal (supra-renal*) prong: distance AC, Figure 23
59. Distance from LRA to most distal (supra-renal*) prong: distance AB, Figure 23
60. Calculate the tilt of the graph: $\tan^{-1}$ (AC-AB)/aortic diameter
61. Leak channel?
62. Endoleak classification
63. Intervention following most recent CT?

3.7.4.10 Measuring outcomes

From the raw data gathered above the following calculations could be made for each included EVAR case

1. Length of follow up
2. Change in neck length
3. Change in AAA sac size
4. Change in graft tilt
5. Evidence of aortic elongation:
    a) Change in length between SMA and LRA
    b) Change in length between SMA and RIIA
6. Change in aortic diameter at:
    a) 10mm below LRA
    b) 5mm below LRA
    c) At level of LRA
    d) 5mm above LRA
7. Evidence of migration:

a) Distance of proximal prong to LRA
b) Distance of distal prong LRA

3.7.5 Radiological vs Clinical Migration

Migration has been defined by both the American [200] and European [222] reporting standards as SG migration of ≥10mm or any migration leading to aortic neck re-intervention. However, the SG displacement of ≥ 5mm as a definition for migration has also been introduced by several authors [31, 102], especially, as newer devices have recommended a sealing zone of only 10mm. [223] A direct comparison of migratory distance of ≥ 5mm vs ≥10mm in 4th generation SG, comparing outcomes has not yet been undertaken. Two separate definitions of migration have therefore been considered:

1. **Clinical migration (CM)**: migration of ≥10mm or any migration leading to aortic neck re-intervention

2. **Radiological migration (RM)**: if either of the proximal or distal prongs migrated 5mm or more, in accordance with Greenberg's method [74]

3.7.6 Follow up

Follow up will be recorded as either:

1. Radiological follow up: the time from the patients first postoperative CT to their most recent. Or until the patients most recent CT prior to their secondary intervention to the aortic neck (if the patient required one).
2. Clinical follow up: the time from the patient's operation to their most recent interaction with a clinician or death. If the patient had a secondary intervention to their aortic neck, the follow up would be until their secondary procedure.

3.7.7 Anatomical measurements

All CT images were processed and reconstructed into three-dimensional images using Aquarius NET software (TeraRecon Inc., San Mateo, CA, USA), with the centre line technology employed.

3.7.7.1 Aortic Diameter

The proximal aortic diameter at four locations (at the level of the lowest renal artery and then 5mm above, 5mm below and 10 mm below) using the maximal orthogonal measured diameters to the vessel centreline using the inner edge to inner edge technique.[224] The distal aortic diameter was taken 2mm proximal to the aortic bifurcation.

3.7.7.2 Aneurysm neck

The aneurysm neck was defined as the distance between the lower edge of the lowest renal artery (LRA) and the beginning of the aneurysm sac.

3.7.7.3 Neck angulation

Neck angulation was calculated in accordance to Van Keulen et al's method,[225] and the aortic neck was deemed to be angulated should the angulation exceed 60 degrees.

3.7.7.4 Neck Shape

Neck shape was defined in accordance with McDonell et al's classification. The classification system categorises abdominal aortic aneurysm necks by morphology. The six types are Flared (most common at 46%), Parallel (34%), Irregular (9%), Conical (6%), Barrel (3%), and Hourglass (3%). [226]

3.7.7.5 Aortic neck thrombus and calcification

Aortic neck thrombus and calcification was calculated as the average surface area occupied within the lumen at 2,4 and 6mm below the LRA.

3.7.7.6 Sac diameter

The sac diameter was calculated as the maximum corrected anteroposterior length.

3.7.7.7 Aortic length

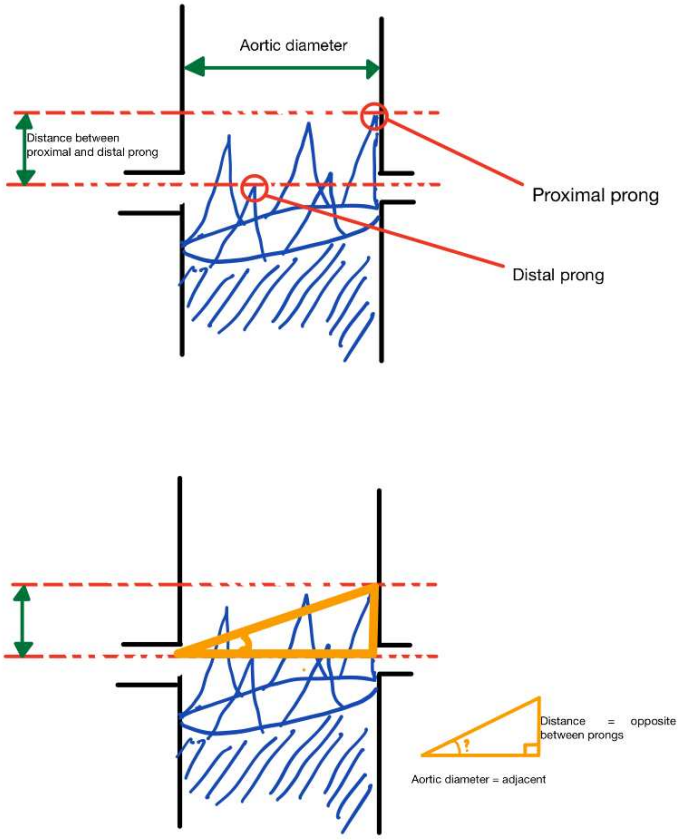
To determine any evidence of aortic elongation, serial centre-line measurements were taken from the origin of the superior mesenteric artery to two landmarks: 1) inferior border of the origin of the LRA and 2) to the superior border of the origin of the right internal iliac artery.

3.7.7.8 SG tilt

SG tilt was determined, by measuring the distance of the most proximal from the most distal prong to calculate the angulation of the stent graft within the aorta (Figure 24). This is based on two assumptions:

1. The prongs maintain contact with the vessel wall – which would be expected as they as SG are typically oversized and exude a constant radial force.
2. The prongs maintain their shape- without fracturing or bending, which can be assessed on the CT prior to starting the measurements.

Figure 24: measuring tilt



Tan(θ) = Opposite / Adjacent

Tan(θ) = Distance between prongs/aortic diameter

θ or ? = $\tan^{-1}$ (Distance between prongs/aortic diameter)

θ = degree of tilt

3.7.7.9 Instructions for use (IFU)

Since gathered anatomical variables, compliance requirements with the manufacturer's instructions for use (IFU) were analysed and rated as within or outside the IFU.

3.7.8 Statistical analysis

Continuous variables that followed a normal distribution were expressed as the mean ± standard deviation (SD), and group differences were assessed using the t-test. For data that did not meet normal distribution assumptions, medians and interquartile ranges (IQRs) were reported, with differences between groups evaluated using the Wilcoxon-Mann-Whitney U test. Categorical variables were presented as absolute counts and percentages, with

comparisons between groups made using either the chi-square test or Fisher's exact test, depending on the data structure.

A univariate Cox proportional hazards model was used to explore how baseline clinical and morphological factors influenced the likelihood of stent-graft surface movement-free survival. Hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated. A multivariate Cox proportional hazards model was constructed using backward selection, with a p-value threshold of 0.1 for variables to enter or remain in the model. Proportional hazards assumptions were checked for each variable using the time-dependent covariate method, with no significant violations detected. Interaction terms were tested with the partial likelihood ratio test, revealing no significant interactions [227].

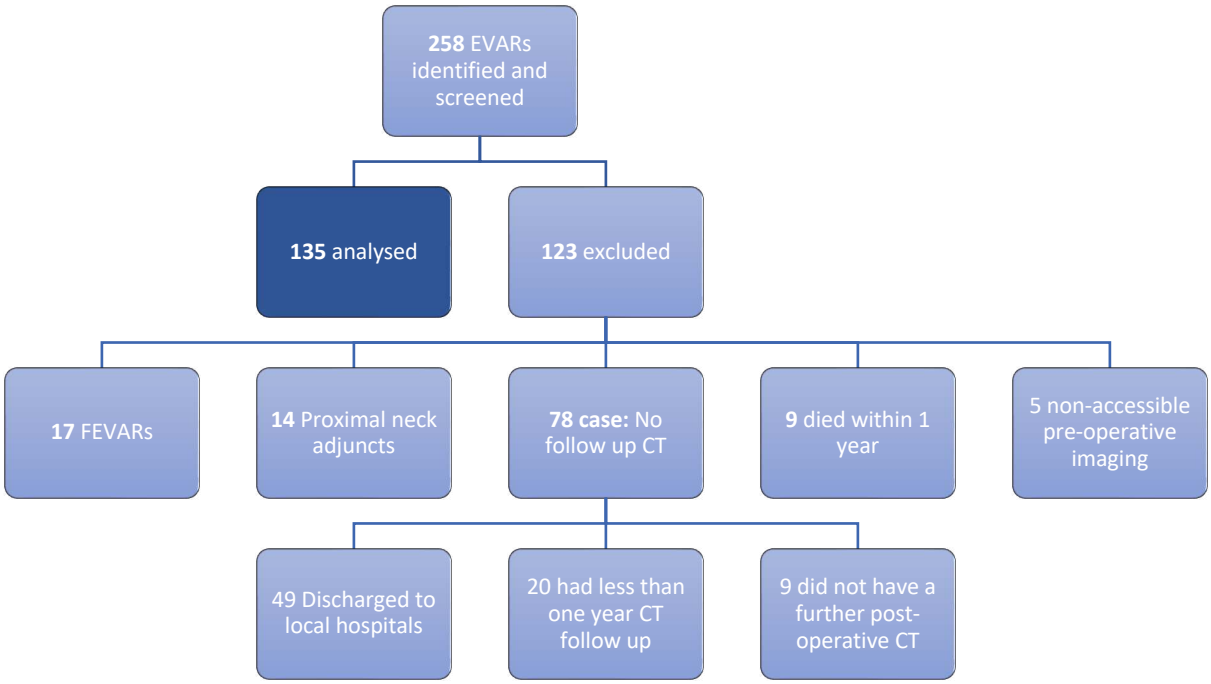
Receiver operating characteristic (ROC) analysis was applied to variables identified as significant in the multivariate model, with optimal cut-off values determined using the Youden J statistic. Kaplan-Meier survival analysis was performed to estimate freedom from stent-graft surface movement, migration, and stent-graft-related endoleaks. Survival data were censored at the time of the patient's last computed tomography angiography (CTA) scan. All statistical tests were two-sided, with a significance level set at $p < 0.05$. Analyses were conducted using SPSS for Windows (version 24.0, IBM Corp).

3.8 Preliminary results: Excluded cases

3.8.1 Imperial College London Data

Out of a possible 258 EVARs carried out at Imperial College London Health Trust between 2008-2018, 135 met the eligibility criteria for inclusion for analysis. 123 were excluded for analysis. 17 had been mis-coded as EVAR when in fact they had undergone a FEVAR. 14 cases had had a proximal neck adjunct such as endostapling or a proximal neck extension, 9 had died within a year and 5 had a missing preoperative CT scans. 78 cases did not have a follow up CT scan at least 1 year following their initial postoperative CT scan: 49 had been discharged to the patients' local hospitals, where they had their follow up arrangements, 20 had their subsequent CT scan within a year and 9 had not had one at all (Figure 25).

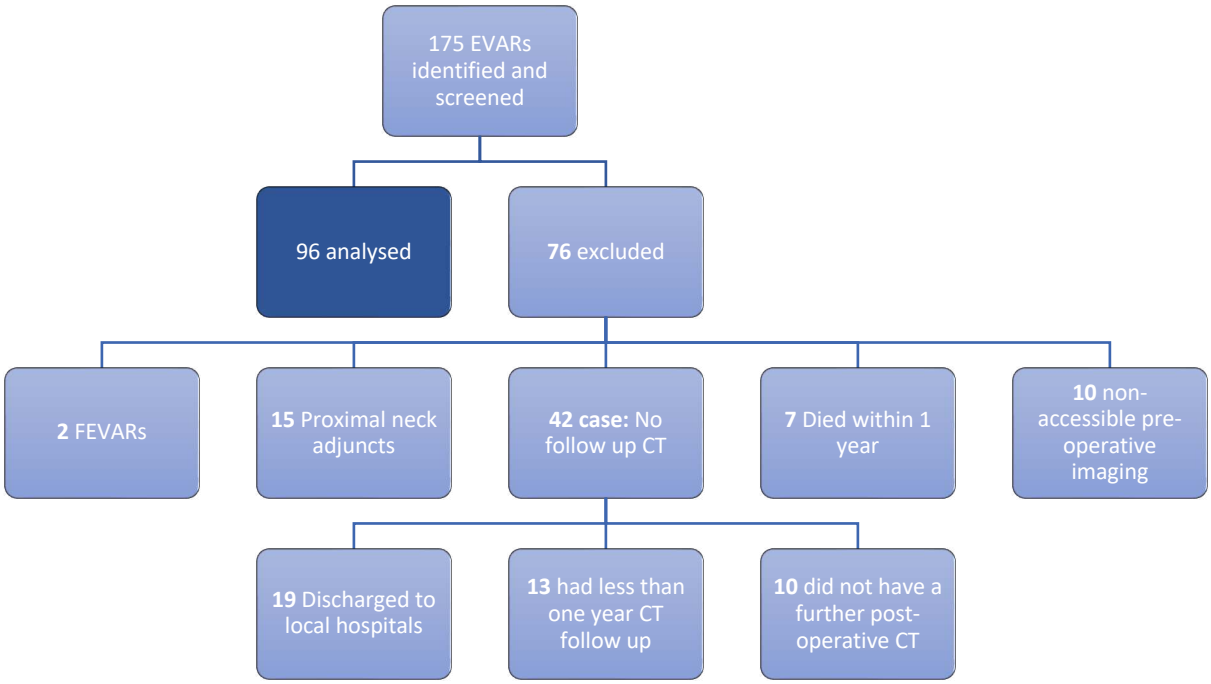
Figure 25: Imperial College London: excluded EVAR cases



3.8.2 University Hospitals Coventry and Warwickshire Exclusion Data

Out of a possible 175 EVARs carried out at University Hospitals Coventry and Warwickshire Health Trust between 2008-2018, 96 met the eligibility criteria for inclusion for analysis. 76 were excluded for analysis. 2 had been mis-coded as EVAR when in fact they had undergone a FEVAR. 15 cases had had a proximal neck adjunct such as endostapling or a proximal neck extension, 7 had died within a year and 10 had a missing preoperative CT scan. 42 cases did not have a follow up CT scan at least 1 year following their initial postoperative CT scan: 19 had been discharged to the patients' local hospitals, were they had their follow up arrangements and 13 had not their subsequent CT scan within a year and 10 had not had one at all

Figure 26: University Hospitals Coventry and Warwickshire: Excluded EVAR cases

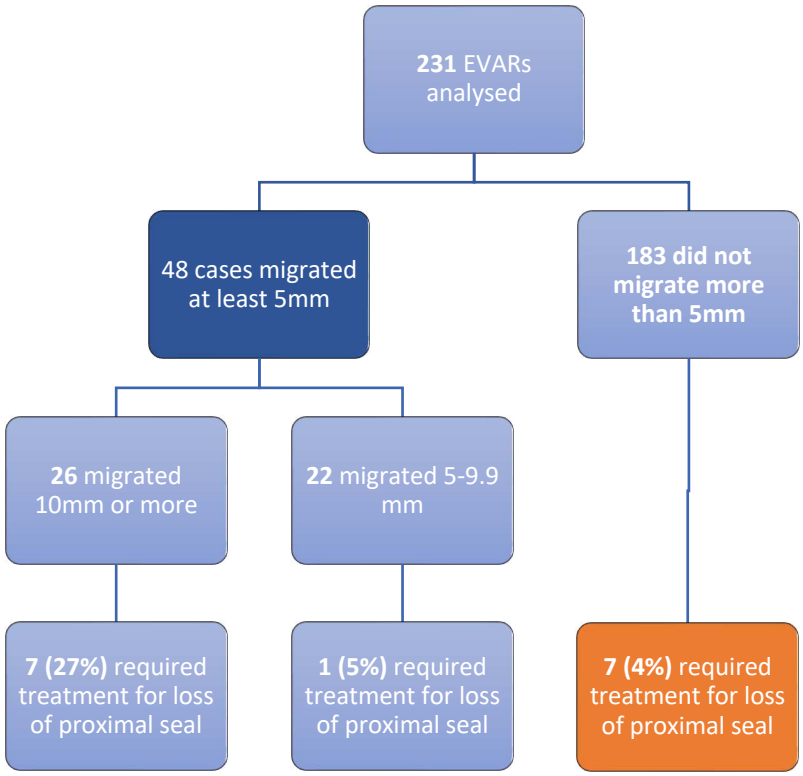


3.9 Preliminary Results: Migratory Cases

Collectively 231 cases over a ten-year period were included for analysis from two vascular tertiary referral centres. 48 cases were found to have migrated at least 5mm over their respective follow up period: 26 cases had caudally migrated 10mm or more and 22 cases had migrated 5-9.9mm. There were an additional 7 cases that had migrated less than 5mm (but more than 0.5mm), however developed a type 1a endoleaks, requiring surgical intervention, thereby meeting the SVS and European standards technical definition for migration (Figure 27). The migratory rates are therefore as follows according to following definition:

1. Radiological significant (5mm or more): 20.7% (48/231)
2. Clinically significant (according to the SVS and European guidance): 14.7% (34/231)

Figure 27:Total number of migratory cases



3.9.1 Follow up

3.9.1.1 Radiological Significant Migration (RM)

When assessing for radiologically significant migration (5mm or more), the median clinical follow up was 7.3 years (1.6-14.0) for the non-migratory group compared to 8.6 years (5.1-13.9) for the migratory group (p=0.03). The median radiological follow up was 3.3 years (1-10.3) for the non-migratory group compared to the 5.5 years (1.1-11.9) for the migratory group (p=0.02). There was significantly longer clinical and radiological follow up for the migratory group, compared to the non-migratory group (Table 17).

3.9.1.2 Clinically Significant Migration (CM)

When assessing for clinically significant migration (in accordance to the European and American guidance definitions), the median clinical follow up was 7.2 years (1.6-14.0) for the non-migratory group compared to the 8.2 years (5.1-13.9) for the migratory group (p=0.03). The median radiological follow up was 3.3 years (1-10.3) for the non-migratory

group compared to the 5.2 years (1.1-11.9) for the migratory group (p=0.02). There was significantly longer clinical and radiological follow up for the migratory group, compared to the non-migratory group (Table 17).

Table 17: Follow up

Type of follow up (median)	**Radiologically significant migration (RM)**			**Clinically significant migration (CM)**		
	Non-migratory group	Migratory group	Significance	Non-migratory group	Migratory group	Significance
Clinical	**7.3** years (1.6-10)	**8.6** years (5.1-10)	p = 0.03	**7.2** years (1.6-14.3)	**8.2** years (5.1-10)	p = 0.03
Radiological	**3.3** years (1-10)	**5.5** years (1.1-10)	p = 0.02	**3.3** years (1-10.3)	**5.2** years (1.1-10)	p = 0.02
Number of patients	**183**/231	**48**/231		**197**/231	**34**/231	

3.9.2 Patient Demographics

As is expected with AAA pathology, there were significantly higher number of males than females treated with EVAR. There was however no significant difference in the number of female patients in the migratory group (MG) compared to the non-migratory groups (NMG) for both the CM (2/48 vs 9/183, p = 0.43) and RM cohorts (2/34 vs 9/197, p = 0.43). Whilst the MG group tended to be a year younger, there was no statistical difference between the MG and NMG groups (
Table 18).

Table 18: Age and Gender Migration

	Radiologically significant migration (RM)	**Clinically significant migration (CM)**

	Non-migratory group	Migratory group	Significance (p)	Non-migratory group	Migratory group	Significance (p)
Age	75	74	0.3	75	74	0.3
Males	174	46	0.39	188	32	0.36
Females	9	2	0.43	9	2	0.42

In the RM cohort, there was a higher percentage of active smokers in the MG (45% vs 9%) this did not reach statistical significance (p = 0.07). As oppose to the CM cohort where there was a significant statistical difference between the MG and NMG (50% vs 10%, p = 0.04).

There was no statistical difference between the MG and NMG for both the RM and CM cohorts in patients diagnosed with hypertension, diabetes, chronic obstructive pulmonary disease (COPD) and ischaemic heart disease (IHD). Neither was there a statistical difference in those prescribed an Aspirin statin or on any formal anticoagulation regimes (Table 19).

Table 19: Co-morbidities and Medications

	Radiologically significant migration (RM)			**Clinically significant migration (CM)**			
	Non-migratory group	Migratory group	Significance (p)	Non-migratory group	Migratory group	Significance (p)	Missing Data
Active smoker	14/157	18/40	0.07	17/167	15/30	0.04	34/231
Hypertension	32/157	7/40	0.71	30/167	9/30	0.74	34/231
Diabetes	35/157	4/40	0.58	34/167	5/30	0.565	34/231
COPD	37/157	4/40	0.32	37/167	4/30		34/231
IHD	108/157	13/40	0.23	107/167	14/30	0.165	34/231
Aspirin	109/157	12/40	0.74	109/167	12/30	0.679	34/231
Statin	64/75	20/21	0.31	65/81	19/20	0.225	135/231
Anti-coagulation	16/75	5/21	0.82	16/81	05/20	0.808	135/231

3.9.2.1 Statistical evaluation

A chi-square (χ^2) statistic test was used to compare the two categorical observed data sets. As the data used was random, not correlated, drawn from independent variables and large enough to allow this test to be undertaken. [228]

3.9.2.2 Missing data

It is worth noting that there was incomplete data recorded for all patients, within this analysis. A thorough review of both digital and paper-based medical notes was carried out. Regarding documenting patient co-morbidities and medication history, 34 (out of the 231) and 135 (out 231) patients' data was either missing, or not documented consistently, respectively. Attempts were made to overcome this by contacting the patient or general practitioner (GP) to gain further information, however this would rarely yield a successful outcome as either the patient was not contactable or unable to recall the medical history from ten years ago or the GP would not keep records of patients that had moved relocated or passed away.

3.9.3 Pre operative Anatomy

Table 20 displays the pre-operative anatomical differences between the NMG and MG for the RM and CM cohorts.

3.9.3.1 Radiologically Significant Migration

Patients in the NMG tended to have a smaller aneurysm (62.6 vs 69.9mm), a longer neck (36 vs 32mm), less thrombus within the aortic neck (6.4% vs 7.4%), more calcification within the aortic neck (2.6% vs 2.3%) and a slightly shorter distance between the SMA and LRA (12.2 vs 12.7mm). These differences, however, where all noted to be statistically insignificant.

Multiple measurements of the aortic diameter however revealed a significant difference between the two groups. At 10mm and 5mm below the LRA, the MG were found to have

significantly wider necks, 25.6 vs 24.5mm (p = 0.049) and 25.4 vs 24mm (p = 0.032), respectively. Whilst the other diameter measurements also showed a similar patter, whereby the NMG had a slightly smaller diameter at the level of the LRA, 5mm above the LRA and in the distal aorta, none of these differences had shown a significant statistical significance.

Table 20: Preoperative Anatomy

	Radiologically significant migration (RM)			**Clinically significant migration (CM)**		
	Non-migratory group	Migratory group	Significance (p)	Non-migratory group	Migratory group	Significance (p)
AAA size	62.6	69.9	0.12	**61.2**	**66.7**	**0.021**
Neck length (mm)	36	32	0.067	**35**	**28.3**	**0.03**
Thrombus %	6.40%	7.40%	0.5	6.4%	7.3%	0.795
Calcium %	2.60%	2.30%	0.75	2.5%	2.4%	0.8
Aortic length SMA – LRA (mm)	12.2	12.7	0.6	17.8	16.2	0
Aortic diameter (10 mm below LRA) (mm)	**24.5**	**25.6**	**0.049**	**24.4**	**27**	**0.000**
Aortic diameter (5mm below LRA) (mm)	**24**	**25.4**	**0.032**	**24**	**26**	**0.004**
Aortic diameter (5mm above LRA) (mm)	24.3	25.2	0.206	24.5	25.2	0.336
Aortic diameter (at LRA) (mm)	24.3	25	0.558	24	24.6	0.578
Distal Aortic Diameter (mm)	37.8	41.5	0.119	36	38.2	0.67

3.9.3.2 Clinically Significant Migration

In the CSM cohort, we continue to a see a similar pattern in differences in pre-operative anatomy. However, when comparing the MG and NMG, we find there is a significant difference in both the Pre-operative AAA size (66.7 vs 61.2, p = 0.021) and neck length (28.3 vs 35mm. p = 0.03), not seen when grouping the data according the RM definition. The significance in aortic diameter is also more pronounced: at 10mm below the LRA (27 vs 24.4mm, p = 0.00) and 5mm below the LRA (26 vs 24mm, p = 0.004). The other aortic diameter measurements did not show a significant difference between the two groups.

3.9.3.3 Statistical analysis

An initial test for normality to determine the distribution of the results was calculated using the Shapiro-Wilk test. This identified that the results of all the tested variables were equally distributed other than two: measurements 5mm below the renal arteries and measurements 5mm above the renal arteries. For the parametric data a paired t-test was used and for the non-parametric data a Mann-Whitney U test was applied. [229]

3.9.3.4 Stent Brand Deployed

6 different stent brands were used for the 231 EVAR cases analysed seen in Table 21. The Endurant (39.8%) and Zenith Flex (41.6%) accounted for the majority of stents deployed within the analysis, both of which rely on suprarenal fixation. A further two devices, with suprarenal fixation used later within the study the Cordis (Incraft) and the Jotec (GMBH) accounted for only 4 (1.7%) further suprarenal devices within our analysis. The two infrarenal fixation devices: the Excluder (Gore) and Anaconda (Vascutek) accounted for 17% of all devices used.

Table 21: Stent graft devices used

Stent brand	Year of use	Fixation	Number
Medtronic: Endurant II/IIs [230]	2011. 2014	Suprarenal	92
Cook: Zenith Flex [231]	2008 onwards	Suprarenal	96
Gore: Excluder, Excluder C3[232]	2008, 2010	Infrarenal	14

Vascutek: Anaconda[233]	2009 onwards	Infrarenal	25
Incraft: Cordis[234]	2016 onwards	Suprarenal	3
GMBH: Jotec	2014 onwards	Supra renal	1

Table 22: RM according to stent brand

Radiologically Significant Migration (RM)					
Brand	**Number of stents migrated**	**Number of non-migrating stents**	**Total number of stents deployed**	**Number of stents used as % of total deployed**	**Percentage of stents that migrated**
Medtronic	14	78	92	39.8	15.2
Cook	25	71	96	41.6	26.0
Gore	1	13	14	6.1	7.1
Anaconda	8	17	25	10.8	32.0
Cordis	0	3	3	1.3	0.0
Jotec	0	1	1	0.4	0.0
Total	**48**	**183**	**231**	**100**	

The commonest device used was the Cook Zenith Flex, with 96 deployed over the period of analysis. 25 (26%) were found to have migrated at least 5mm. This was followed by the Endurant device, where 92 were deployed, 14 (15.2%) had been found to migrate.

Table 23: CM according to stent brand

Clinically Significant Migration (CM)					
Brand	**Number of stents migrated**	**Number of non-migrating stents**	**Total number of stents deployed**	**Number of stents used as % of total deployed**	**% of stents migrated according to brand**
Medtronic	9	83	92	39.8	9.8
Cook	17	79	96	41.6	17.7
Gore	1	13	14	6.1	7.1
Anaconda	7	18	25	10.8	28.0
Cordis	0	3	3	1.3	0.0

Jotec	0	1	1	0.4	0.0
Total	**34**	**197**	**231**	**100**	

For the CM migratory group, similar results can be found, whereby 96 Cook grafts had been deployed with a witnessed 17 (17.7%) cases of migration, followed by 92 Medtronic grafts with a recorded 9 (9.8%) cases of migration.

3.9.3.5 Supra/infra renal fixation, adjunctive procedures and immediate endoleak channels

Table 24: Intra-operative Variables

	Radiologically significant migration (RM)			**Clinically significant migration (CM)**		
	Non-migratory group	Migratory group	Significance (p)	Non-migratory group	Migratory group	Significance (p)
Stent brand			needs regression			
Supra renal fixation	168/183	47/48	0.33	182/197	33/34	0.67
Adjunctive procedure			needs regression			
Immediate endo-leak	**28/183**	**16/48**	**0.005**	**31/197**	**13/34**	**0**
Tilt	**11**	**17**	**0.035**	**9.4**	**18.2**	**0.03**

The majority of SG's used within this analysis, employed suprarenal fixation. There was only one case of migration in which no supra-renal fixation was employed for both RM and CM. Nevertheless, no significant differences in RM ($p = 0.33$) or CM ($p = 0.67$) rates were identified between the two forms of fixation.

Table 25 Adjunct Procedures during EVAR

	Radiologically significant migration (RM)		**Clinically significant migration (CM)**	
	Non-migratory group	Migratory group	Non-migratory group	Migratory group
Internal iliac embolisation	19	9	21	7
Common Iliac Artery embolisation	3	1	3	1
Femoral to Femoral artery bypass	3	1	3	1
Iliac angioplasty	3	1	2	2
Unplanned limb extension	6	0	6	0
Surgical internal iliac ligation	1	2	1	2
Renal accessory artery embolisation	1	0	1	0
IVC filter	0	1	0	1
Aorto-uni iliac EVAR	3	1	3	1
Unplanned renal artery stenting	1	0	1	0

Adjunctive procedures to the index EVAR procedures, such as internal iliac artery embolisation or iliac angioplasty were documented and displayed in

Table 25 Adjunct Procedures during EVAR. Given the heterogeneity in the adjuncts employed and small numbers, meaningful statistical analysis in comparing groups was not feasible. It is worth noting however that there was a higher proportion of internal iliac artery embolisations in the migratory groups compared to the non-migratory groups. RSM (10.3% vs 18.8%), CSM (10.7% vs 20.5%).

3.9.3.5.1 Endoleaks

In looking at endoleak rates between the two groups, the type and incidence of endoleak was recorded in the first postoperative CT scan, which would have occurred within the first 6 months, postoperative. The second postoperative scan would be the most recent scan available for the patient and would have been a minimum of 12 months later.

Table 26:Documented endoleaks, in the 1st postoperative and most recent CT scan

	RSM			CSM		
Type of Endoleak	NMG	MG	P value	NMG	MG	P value
Documented Endoleak on 1st CT scan (within 6 months)						
Type 1a	2	1	0.473	2	1	0.482
Type 2	26	11	0.002	26	11	0.000
Type 1b	2	1	0.473	2	1	0.482
Type 4	0	0	1	0	0	1
Type 5	1	0	0.041	1	0	0.229
Type 3	0	0	1	0	0	1
Documented Endoleak in most recent CT scan						
Type 1a	7	9	0.229	0	16	0.000
Type 2	9	2	0.001	10	1	0.006
Type 1b	3	2	0.771	3	2	0.725
Type 4	0	0	1	0	0	1
Type 5	0	0	1	0	0	1
Type 3	2	0	0.075	2	0	0.093

3.9.3.5.2 Radiologically significant migratory groups

When reviewing the data for the RSM group. the second postoperative scan, would be the most recent scan available for the patient and would have been a minimum of 12 months later, with a median of 3.3 years later for the RSM NMG and 5.5 years later for the RSM MG.

Table 27: Endoleak type and rate in the RSM groups

Endoleak type	RSM NMG				RSM MG			
	1st Post operative Scan (within 6 months)	As a % (183 cases)	2nd Post operative Scan (most recent)	As a % (183 cases)	1st Post operative Scan (within 6 months)	As a % (48 cases)	2nd Post operative Scan (most recent)	As a % (48 cases)
Type 1a	2	1.1	7	3.8	1	2.1	9	18.8
Type 1b	2	1.1	3	1.6	1	2.1	2	4.2
Type 2	26	14.2	9	4.9	11	22.9	2	4.2
Type 3	0	0.0	2	1.1	0	0.0	0	0.0
Type 4	0	0.0	0	0.0	0	0.0	0	0.0
Type 5	1	0.5	0	0.0	0	0.0	0	0.0

Table 27, outlines the prevalence and types of endoleaks found within the RSM groups.

3.9.3.5.3 Type 1a endoleaks

There appear to be a slight but significant difference in recorded initial type 1a endoleaks in the first postoperative scans for both NMG (1.1%) and the MG (2.1%), however the number of type 1a endoleaks increases significantly in the MG in their most recent scan to 18.8% of cases in comparison to the NMG (3.8%).

3.9.3.5.4 Type 2 endoleaks

Of note there was a significantly higher percentage of type 2 endoleak in the MG (22.9%) in the initial CT in comparison to the NMG (14.2%). However, over time the prevalence of type 2 endoleak was comparative at 4.9% for the NMG and 4.2% for the MG.

3.9.3.5.5 Type 1b endoleaks

In the initial postoperative scan there appears to be evidence of a slightly higher incidence of type 1b endoleaks in the MG (1.6%) compared to the NMG (1.1%), however this did not amount to a statistical significance. Over time there does not appear to be a significant difference in the incidence of type 1b endoleaks, although the percentage incidence in the MG had climbed to 4.2%

3.9.3.5.6 Type 3/4/5 endoleaks

Only two type 3 endoleaks are identified in all groups, with both being found in the NMG in their most recent scan. No type 4 endoleaks were found and a single type 5 endoleak was identified in the NMG, which had resolved in subsequent imaging, and required no intervention.

3.9.3.5.7 Clinically significant migratory groups

In the case of CSM groups, again the initial scan would have been within 6 months of the index EVAR procedure and the second postoperative scan, would be the most recent scan available for the patient and would have been a minimum of 12 months later, with a median of 3.3 years later for the CSM NMG and 5.2 years later for the CSM MG.

Table 28:Endoleak type and rate in the CSM groups

Endoleak type	CSM NMG				CSM MG			
	1st Post operative Scan (within 6 months)	As a % (197 cases)	2nd Post operative Scan (most recent)	As a % (197 cases)	1st Post operative Scan (within 6 months)	As a % (34 cases)	2nd Post operative Scan (most recent)	As a % (34 cases)
Type 1a	2	1.0	0.0	0.0	1.0	2.9	16	47.1
Type 1b	2	1.0	3	1.5	1.0	2.9	2	5.9

Type 2	26	13.2	10	5.1	11.0	32.4	1.0	2.9
Type 3	0	0.0	2	1.5	0.0	0.0	0	0
Type 4	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Type 5	1	0.5	0.0	0.0	0.0	0.0	0.0	0.0

When stratifying the data in accordance with to CSM, we see some variations (Table 28):

3.9.3.5.8 Type 1a endoleaks

Again there appears to be a similar picture in the first post operative CT scan where there are 2 cases of type 1 endoleaks seen in the NMG compared to only 1 seen in the MG, however over time this relationship is reversed and greatly exaggerated, where the 2 type 1a endoleaks seen in the initial post operative CT scans in the NMG resolve and 16 new cases are seen in the MG.

3.9.3.5.9 Type 2 endoleaks

As with the RSM group, there is a significantly higher proportion of type 2 endoleaks seen within the MG (32.4%), compared to the NMG (13.2%) in the first CT scan. However a higher proportion of these appear to resolve in the MG group, with eventually only one patient showing evidence of a type 2 endoleak on their final imaging in the MG, compared ten (5.1%) in the NMG.

3.9.3.5.10 Type 1b endoleak

There appear to be similar number of type1b endoleaks between the two groups, with no statistical difference established between the two.

3.9.3.5.11 Type 3/4/5 endoleaks

Similar results to the RSM group, with very little event rates and thus difficulty in establishing a true inference.

3.9.4 Post operative anatomical changes over time

Table 20, outlined the preoperative anatomical measurements of the NMG and MG, for both RSM and CSM. It identified a significant difference in the neck diameter, with patients in the MG more likely to have a slightly wider neck. In the CSM group however there was the additional difference in measurements, between the NMG and MG in AAA sac size and neck length. An analysis was therefore undertaken to examine the changes over time between all measurements to ascertain whether, changes in anatomical measurements were likely to be different over time, this is displayed in Table 29.

Table 29: Anatomical changes over time (mm)

Anatomical measurements (mm)	RSM			CSM		
	NMG	MG	P value	NMG	MG	P Value
Aortic length change	+ 0.1	+ 2	0.35	0	+ 2	0.87
Sac size change	-5.3	-3.9	0.99	-5.5	0.5	0.001
neck length change	+2	+0.5	0.002	+2.3	0	0.096
aortic diameter (10mm below renal)	+2.9	+5.15	0	+3.5	+4.8	0
Aortic diameter (5mm below renal)	+2.3	+4.2	0.005	+2.4	+4	0
Aortic diameter (at renals)	+1.6	+2.65	0.54	+1.6	+3.7	0
Aortic diameter	+1.3	+2.3	0.005	+1.2	+2.8	0.1

(5mm above renal)						

3.9.4.1.1 RSM

Similar to preoperative measurements the aortic sac size between the NMG and MG did not show a statistical difference, although there was a trend towards increased sac regression in the NMG. There was however a global increase in aortic neck diameter with a more pronounced and significant expansion in the MG compared to the NMG. There was an increase of 5.15mm vs 2.9mm (p=0.000) 10mm below the lowest renal and 4.2mm vs 2.3mm (p=0.005) at 5mm below the lowest renal. There was also a subtle but significant difference in change in neck length between the two groups with aortic neck remodelling and lengthening by 2mm in the NMG compered to 0.5mm inn MG.

3.9.4.1.2 CSM

The initial differences between the NMG and MG in the preoperative measurements, appear to become more pronounced over time. With a significant change in aortic sac size between the NMG and MG. Sac regression of 5.5mm is found in the NMG with an overall sac increase of 0.5mm in the CSM, which is to be expected as the CSM group would include more cases with type 1a endoleak and loss of proximal seal. There is also a pronounced difference in aortic neck measurement diameter with a larger increase of aortic neck diameter over time in MG compared to the non migratory group, at the level of the lowest renal 3.7mm vs 1.6mm, 5mm below the lowest renal 3.7mm vs 1.6mm and 10mm below the lowest renal, 4.8mm vs 3.5mm.

3.9.4.2 Aortic neck measurements

When further scrutinising the aortic neck diameters over time, there is global trend of aortic neck dilation in all groups. Table 30 and Table 31 outline the changes over time of the aortic neck diameters in RSM and CSM groups, respectively. When comparing NMG to MG, patients within the MG, tend to have slightly larger necks to start with and will have a larger increase in diameter over time. This is most pronounced at 10mm below the lowest renal arteries, in which there is an average increase of 3.9 mm in MG neck diameters compared to 2.6mm in the NMG for RSM. For CSM this is more exaggerated, with an average increase of 4.6mm (MG) compared to 2.8mm (NMG) over time.

Whilst there are significant differences identified, it is worth noting the difference in radiological follow up time between the two groups. Where the NMG were followed up radiologically for approximately 2 years less than the MG and therefore possible subsequent dilation beyond that may have been missed.

Table 30:RSM- Aortic neck measurements, comparing preoperative measurements to most recent CT scan.

Aortic neck measurements (mm)	RSM					
	NMG			MG		
	Preop	Latest	Change (mm)	Preop	Latest	Change (mm)
10mms below renal	24.5	27.1	2.6	25.6	29.5	3.9
5mms below renal	24	26.3	2.3	25.4	28.8	3.4
at renal	24.3	25.6	1.3	25	26.5	1.5
5mm above renal	24.3	25.7	1.4	25.2	27.8	2.6

Table 31: CSM- Aortic neck measurements, comparing preoperative measurements to most recent CT scan.

Aortic neck measurements (mm)	CSM					
	NMG			MG		
	Preop	Latest	Change (mm)	Pre op	Latest	Change (mm)
10mms below renal	24.4	27.2	2.8	27	31.6	4.6
5mms below renal	24	26.5	2.5	26	29.6	3.6

At renal	24	25.6	1.6	24.6	28.1	3.5
5mm above renal	24.5	25.7	1.2	25.2	28.3	3.1

3.9.5 Clinical outcomes.

3.9.5.1 Post operative complications

Table 32 documents the number of post operative complications following the EVAR procedure.

Table 32: Post operative complications recorded over the follow up period for both RSM and CSM groups

Complication	RSM			CSM		
	NMG	MG	P value	NMG	MG	P value
Thrombosed limb	3	3	1	5	1	0.003
Type 1a endoleak	5	7	0.668	0	12	0.000
Type 2 endoleak – with sac expansion	6	3	0.229	9	0	0.000
CIA rupture	1	1	1	2	0	0.067
AAA Rupture, secondary to 1a	2	2	1	0	4	0.000
Type 1b endoleak	9	3	0.0047	10	2	0.000
Limb stenosis	7	0	0.000	7	0	0.000
Type 3 endoleak	2	0	0.021	2	0	0.067

3.9.5.1.1 RSM group

Within the RSM group there appeared to be similar rates of complications between the NMG and MG, with higher rates of type 1b endoleaks, limb stenosis and type 3 endoleak seen in the NMG.

3.9.5.1.2 CSM

The dynamics however appear slightly different, with an expected significantly higher incidence of type 1a endoleaks and ruptures (secondary to type 1a endoleak) seen in the MG. again there was a higher incidence of limb stenosis and type 1b endoleaks seen in the NMG.

3.9.5.2 Evaluating outcomes RSM vs CSM

From the outset of this chapter, the relevance of migratory distance was raised: 5mm vs 10mm. Given the evolution of stent grafts with a minimum sealing zone required of 10-15mm [46], an acknowledgment of contemporary publications using the 5mm migratory distance as a threshold over 10mm as recommended by the ESVS and SVS has been missing.

By grouping the data as RSM and CSM we attempt to answer the question as to whether 5mm may be employed as the threshold for migration. In order to determine this, radiological identification of SGs migrating at least 5mm would need have a clinical implication, rather than a theoretical one, to influence practice and reporting standards [235].

The RSM groupings are divided only by the variable of whether SG migrated 5mm or more. In doing so we identify that we are unable to establish a statistically significant difference in type 1a endoleaks and loss of proximal seal between the MG and NMG groups, there is also no difference in rupture rates. These two clinical outcomes are the feared outcomes from graft migration and subsequent loss of proximal seal.

However when grouping the data in accordance to the ESVS and SVS definition of migration, namely migration of 10mm or mor or any migration necessitating interventions, as has been done for the CSM, the outcomes differ significantly. Within the CSM group, there were 12 type 1a endoleaks identified, without rupture and 4 with an associated rupture. 16/34 (47%) of those that met the definition, had lost their proximal seal and had pressurised aneurysmal sac. It also appears that other EVAR related complications were more prevalent in the non-migratory groups.

On this basis it may be concluded that the use of 5-9.9mm as the threshold to determine migration is not supported by clinical outcomes i.e., the loss of proximal seal.

3.9.6 Postoperative interventions

Table 33 outlines the postoperative reinterventions carried out for patients following their EVAR, comparing the NMG and MG for RSM and CSM. These interventions can be correlated to the post operative complications outlined in Table 32.

Table 33: Summary of post-operative interventions for all patients in the RSM and CSM groups

Intervention	RSM		CSM	
	NMG	MG	NMG	MG
Limb thrombosis: lysis/angioplasty	7	1	9	1
Limb extension	7	1	7	1
Lumbar artery embolization	6	1	7	0
Iliac artery stenting	1	0	1	0
AUI and fem-fem bypass	0	2	1	0
IMA embolization	0	0	2	0
Realigning	1	1	1	1
Proximal extension cuff	2	2	0	4
Fenestrated EVAR	3	1	0	4
Open repair	2	2	1	3
Not fit for intervention	2	2	0	4
Internal iliac embolization	1	0	1	0
Femoral-femoral bypass	3	0	3	0
Axillary bifemoral bypass (occlusion)	2	0	2	0
Limb extension with IIA embolisation	1	1	1	1

In line with the findings from Table 32, there is an increased number of interventions for loss of proximal seal in the CSM MG group compared to the RSM MG group (16 vs 8) and between the CSM MG and CSM NMG (16 vs 0).

As the definition for migration has now been determined to be in line with that published by the ESVS and SVS, further evaluation of the of the CSM MG will continue.

Table 34 summarises all those within the CSM MG, summarising the migratory distance, changes in sac size, final neck diameter, post-operative complication, intervention and time taken for reintervention.

Table 34: Combined results of the CSM group: migration distance, change in sac size, final neck diameter, complication, intervention and time to reintervention since EVAR

Patient	proximal barb (mm)	distal barb (mm)	change in sac size	Final neck diameter (mm)	Recorded complication	proximal aortic complication	Intervention	Time to reintervention (years)
1	-6.3	-10.01	+4	36	Type 1a endoleak	Yes	Fenestrated repair	9.5
2	-15.7	-21.42	-13	38	Type 1a endoleak	Yes	Fenestrated repair	9.2
3	-8.7	-10.2	+21	29				
4	-8.7	-10	0	34.5	Type 1a endoleak	Yes	Proximal cuff extension	5.5
5	-9.6	-6.2	-14.6	24.4	Thrombosed limb		Lytic therapy and angioplasty	2.7
6	-13.1	-7.8	+18	46.5	Type 1a endoleak	Yes	Not Fit	**2.0**
7	-10	-5.8	+1	24	Type 1b endoleak		Limb extension	6.7
8	-6.9	-10.1	+8	33				
9	-10.2	-5.9	-33	24				
10	-13.48	-2.5	-10	27				
11	-7.7	-10.3	+8	32				
12	-40.6	-53.07	+12.2	28.2	Type 1a endoleak	Yes	Proximal cuff extension	5.0
13	-73.64	-58.1	+6.7	29.6	Type 1a endoleak	Yes	Not Fit	2.2
14	-18.04	6.7	-4	29.5	Type 1b endoleak		Limb extension	7.4
15	-9.2	-10.5	-8	33.8				
16	-37.8	-34.6	-7	41				
17	-23.37	-23.9	+51	44	Type 1a endoleak	Yes	Fenestrated repair	10.5
18	-14.8	-8.9	+4	32				

19	-14.6	-21.3	+7	46	Type 1a endoleak	Yes	Open repair	7.9
20	-8	-12	-10	24				
21	-1.8	-2.8	+30	35	Rupture + type 1a	Yes	Not Fit	7.1
22	-1.04	-2.16	+15.7	29.6	Type 1a endoleak	Yes	Proximal cuff extension	2.5
23	-3.9	-1.8	-2.9	27.5	Rupture + type 1a	Yes	Not Fit	7.9
24	-2.5	-4.8	+22	39	Rupture + type 1a	Yes	Open repair	9.4
25	-5	1.2	-53	31	Type 1a endoleak	Yes	Open repair	7.8
26	-16.9	-5	-15.2	34.6				
27	-10	5	-34.1	28.4				
28	-6.2	-15.6	+10	26.5				
29	-8.1	10.1	-16	34				
30	-10.5	2.5	-22.7	25				
31	-8	-13	-10	24.7				
32	-6.2	-1.3	-3.9	28.6	Type 1a endoleak	Yes	Proximal cuff extension	4.6
33	-2.5	3.1	+30.5	24.7	Rupture + type 1a	Yes	Realigning	7.4
34	-4.3	3.8	+8.4	29.2	Type 1a endoleak	Yes	Fenestrated repair	3.5
Median	**-8.7**	**-8.8**	**+0.5**	**29.6**		**16/34**		**7.3**

Proximal and distal barb migratory distance from lowest renal artery since deployment (mm), change in sac size compared to measurements taken following initial deployment of EVAR (mm), neck diameter measurements 5mm below the lowest renal artery (mm), recorded complications, recorded re-interventions and time to re-intervention since initial EVAR deployment (years)

This table demonstrates that there was an average caudal migratory distance of 8.7-8.8mm in between the proximal and distal barb at the proximal portion of the stent. There was an overall increase in sac size of 0.5mm and neck length diameter was 29.6mm. 16 out of the 34 migrators had lost their proximal seal, leading to a quarter of them having a rupture (4/16).

Table 35, extracts the 16 cases which lost their seal, and the outcomes are further summarised in Table 36. In this cohort, whilst migration still exists, the average migratory distance is reduced to 6.3-5.9mm. This is because we have included both those who have, migrated a minimum of 10mm (with loss of proximal seal (8 cases) and those who had migrated less than 5mm with loss of seal). The average neck diameter also increases to 32.8 mm, which can be explained by the multifactorial nature of the development of type1a endoleaks, including aortic neck dilatation [52].

Table 35: Combined results of the CSM group required proximal aortic intervention: migration distance, change in sac size, final neck diameter, complication, intervention and time to reintervention since EVAR

Patient	proximal barb (mm)	distal barb (mm)	change in sac size	Final neck diameter (mm)	complication	proximal aortic complication	Intervention	Time to reintervention (years)
1	-6.3	-10.2	+4	36	Type 1a endoleak	Yes	Fenestrated repair	9.5
2	-15.7	-21.42	-13	38	Type 1a endoleak	Yes	Fenestrated repair	9.2
4	-8.7	-10	0	34.5	Type 1a endoleak	Yes	Proximal cuff extension	5.5
6	-13.1	-7.8	+18	46.5	Type 1a endoleak	Yes	Not Fit	2.0
12	-40.6	-53.07	+12.2	28.2	Type 1a endoleak	Yes	Proximal cuff extension	5.0
13	-73.64	-58.1	+6.7	29.6	Type 1a endoleak	Yes	Not Fit	2.2
17	-23.37	-23.9	+51	44	Type 1a endoleak	Yes	Fenestrated repair	10.5
19	-14.6	-21.3	+7	46	Type 1a endoleak	Yes	Open repair	7.9
21	-1.8	-2.8	+30	35	Rupture + type 1a	Yes	Not Fit	7.1
22	-1.04	-2.16	+15.7	29.6	Type 1a endoleak	Yes	Proximal cuff extension	2.5
23	-3.9	-1.8	-2.9	27.5	Rupture + type 1a	Yes	Not Fit	7.9
24	-2.5	-4.8	+22	39	Rupture + type 1a	Yes	Open repair	9.4
25	-5	1.2	-53	31	Type 1a endoleak	Yes	Open repair	7.8
32	-6.2	-1.3	-3.9	28.6	Type 1a endoleak	Yes	Proximal cuff extension	4.6
33	-2.5	3.1	+30.5	24.7	Rupture + type 1a	Yes	Realigning	7.4
34	-4.3	3.8	+8.4	29.2	Type 1a endoleak	Yes	Fenestrated repair	3.5
Average (median)	**-6.3**	**-5.9**	**-3.9**	**32.8**				**7.3**

Proximal and distal barb migratory distance from lowest renal artery since deployment (mm), change in sac size compared to measurements taken following initial deployment of EVAR (mm), neck diameter measurements 5mm below the lowest renal artery (mm), recorded complications, recorded re-interventions and time to re-intervention since initial EVAR deployment (years)

Table 36: summary of the number of proximal aortic interventions for clinical migrators in the CSM group

Reintervention	**number**	**As a percentage**
Fenestrated Repair	4	25%
Proximal Cuff Extension	4	25%
Realigning	1	6%
Open Repair	3	19%
Deemed not fit for repair	4	25%

The significance of a type 1a endoleak and its sequalae can be seen from Table 36, in which a quarter of patients had ruptured. In this group of patients there was no prior knowledge of their endoleak, despite being on routine ultrasound surveillance. Furthermore, a quarter of patients who were identified to have a type 1a endoleak were not offered any further intervention as they were not deemed fit enough to withstand further surgery. A quarter were suitable for a proximal cuff extension, however half required a more substantive repair with a quarter (4 cases) requiring a fenestrated repair, 19% (3 cases) requiring an open repair and 6% (1 case) requiring realigning of the EVAR with the placement of the main body placed more proximally.

Patients identified to have a type 1a endoleak were typically treated within 1 month of diagnosis, or turned down unless they presented acutely (rupture) in which case they were either turned down or treated immediately. The results from the time to reintervention highlight a median time of 7.3 years following their initial EVAR. Confirming that the development of a type1a endoleak, secondary to migration is a long-term issue.

3.9.6.1 Migrating 10mm or more

An evaluation of migratory cases in which, only a migratory distance of 10mm or more identifies 26 cases from 231 evaluated – 11.3%. This is a significant number, higher than that recorded in registries. 8 (30.8%) of these patients developed a loss of proximal seal and type 1a endoleak. None had ruptured, 3 had a FEVAR, 1 had an open repair, 2 had a proximal cuff

extension and 2 were turned down for further intervention. The time to intervention is slightly lower (7.1 years) than when including those that had not migrated more than 10mm, therefore supports the statement that the loss of seal secondary to migration is a long-term complication.

Table 37: Summary of outcomes in all patients that had migrated at 10mm from lowest left renal artery

Patient	proximal barb (mm)	distal barb (mm)	change in sac size	Final neck diameter (mm)	complication	proximal aortic complication	Intervention	Time to reintervention (years)
1	-6.3	-10	+4	36	Type 1a endoleak	Yes	Fenestrated repair	9.5
2	-15.7	-21.42	-13	38	Type 1a endoleak	Yes	Fenestrated repair	9.2
3	-8.7	-10.2	+21	29				
4	-8.7	-10	0	34.5	Type 1a endoleak	Yes	Proximal cuff extension	5.5
5	-10.2	-6.2	-14.6	24.4	Thrombosed limb		Lytic therapy and angioplasty	2.7
6	-13.1	-7.8	+18	46.5	Type 1a endoleak	Yes	Not Fit	
7	-10.3	-5.8	+1	24	Type 1b endoleak		Limb extension	6.7
8	-6.9	-9.7	+8	33				
9	-10.4	-5.9	-33	24				
10	-13.48	-2.5	-10	27				
11	-7.7	-10.5	+8	32				
12	-40.6	-53.07	+12.2	28.2	Type 1a endoleak	Yes	Proximal cuff extension	5.0
13	-73.64	-58.1	+6.7	29.6	Type 1a endoleak	Yes	Not Fit	2.2
14	-18.04	6.7	-4	29.5	Type 1b endoleak		Limb extension	7.4
15	-9.2	-10.9	-8	33.8				
16	-37.8	-34.6	-7	41				
17	-23.37	-23.9	+51	44	Type 1a endoleak	Yes	Fenestrated repair	10.5
18	-14.8	-8.9	+4	32				

19	-14.6	-21.3	+7	46	Type 1a endoleak	Yes	Open repair	7.9
20	-8	-12	-10	24				
26	-16.9	-5	-15.2	34.6				
27	-10	5	-34.1	28.4				
28	-6.2	-15.6	+10	26.5				
29	-8.1	-10.2	-16	34				
30	-10.5	2.5	-22.7	25				
31	-8	-13	-10	24.7				
Average (median)	**-10.4**	**-10.1**	**-11.5**	**30.8**				**7.1**

3.9.7 Predicting migration: Classification Analysis Using Stratified Shuffle Split and Leave-One-Out

In an attempt to create a predictive model based on the data gathered for the two NMG and MG, we compare various machine learning algorithms and their performance using both Stratified Shuffle Split and Leave-One-Out Cross-Validation (LOOCV). These methods used in machine learning allow for splitting data into training and testing sets to evaluate model performance [236].

4 pre-operative characteristics and 2 perioperative characteristics were found to be significantly different between the two groups in our initial evaluation of the two groups.

1. 1st CT sac size
2. 1st CT: neck length
3. 1st CT: diameter 10mm below renal
4. 1st CT: diameter 5mm below renal
5. Tilt
6. 1st CT leak channel?

3.9.7.1 Stratified Shuffle Split Analysis

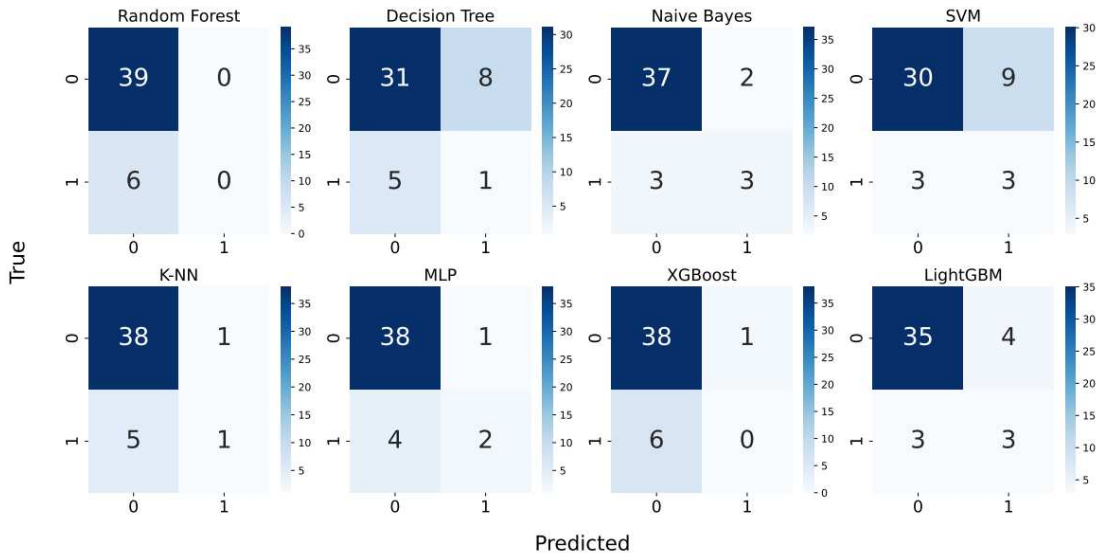
When comparing two groups, NMG and MG, with six predictive factors (1st CT sac size, 1st CT neck length, 1st CT diameter 10mm below renal, 1st CT diameter 5mm below renal, tilt, and 1st CT leak channel), it is necessary to ensure that the training and testing datasets reflect

the same distribution of these groups. First, the dataset containing data for both NMG and MG are shuffled to randomise the order. This prevents any potential bias due to the order of the data. When splitting the shuffled data into training and testing sets, this is done in a way that maintains the same proportion of NMG and MG in both sets. For example, in the overall dataset has 85.2% NMG and 14.7% MG, both the training and testing sets will reflect these proportions. Therefore, each subset accurately represents the distribution of the groups.

Table 38 displays the stratified shuffle split analysis.

Table 38: Stratified Shuffle Split Analysis

Classifier						**AUC-ROC**
	Acc.	**B Acc.**	**F1-score**	**MCC**	**Avg P-R**	
Random Forrest	0.87	0.5	0	0	0.52	0.9
Decision Tree	0.71	0.48	0.13	-0.03	0.13	0.48
Naïve Bayes	0.89	0.72	0.55	0.49	0.66	0.89
SVM	0.73	0.63	0.33	0.21	0.32	0.77
K-NN	0.87	0.57	0.25	0.23	0.35	0.84
MLP	0.89	0.65	0.44	0.42	0.49	0.73
XGBoost	0.84	0.49	0	-0.06	0.34	0.82
LightGBM	0.84	0.7	0.46	0.37	0.42	0.85

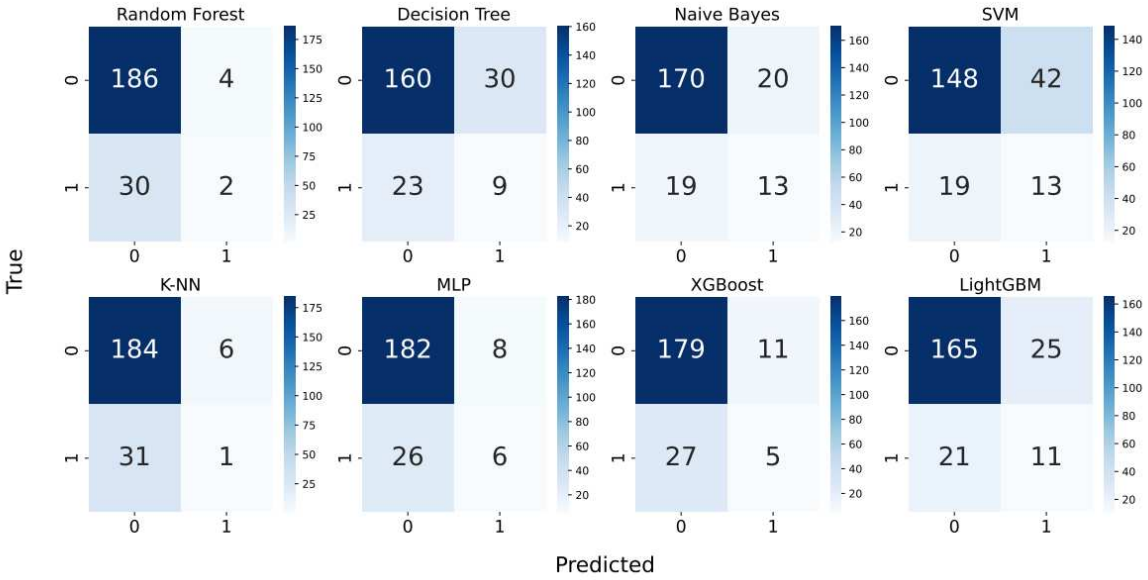


3.9.7.2 Leave-One-Out Cross-Validation Analysis

In this analysis, we aim to determine whether specific characteristics, such as 1st CT sac size, neck length, diameter measurements, tilt, and leak channel, can predict group membership between MG and NMG. The dataset comprises 34 cases in the MG group and 197 cases in the NMG group, each with numerous data points. Leave-One-Out Cross-Validation (LOOCV) involves treating each individual data point as a separate test case. In each iteration, one data point is excluded from the training set and used as the test case. The model is then trained on the remaining data points. This is followed by the iteration process in which this process is repeated for every data point in the dataset. With hundreds of data points, the model is trained and evaluated as many times as there are data points. Each iteration assesses the model's performance by predicting the group membership (MG or NMG) of the excluded data point based on the trained model. Through these iterations, the analysis evaluates how effectively the model, using the specified characteristics, can classify data points into the correct group. This comprehensive approach helps determine the significance of each characteristic in distinguishing between MG and NMG. Table 39 displays the Leave-One-Out Cross-Validation analysis

Table 39: Leave-One-Out Cross-Validation analysis

Classifier	**Balanced**					**AUC-ROC**
	Acc.	**Acc.**	**F1-score**	**MCC**	**Avg P-R**	
Random Forrest	0.85	0.52	0.11	0.09	0.29	0.71
Decision Tree	0.76	0.56	0.25	0.11	0.17	0.56
Naïve Bayes	0.82	0.65	0.4	0.3	0.37	0.75
SVM	0.73	0.59	0.3	0.15	0.21	0.65
K-NN	0.83	0.5	0.05	0	0.22	0.63
MLP	0.85	0.57	0.26	0.21	0.33	0.67
XGBoost	0.83	0.55	0.21	0.13	0.27	0.7
LightGBM	0.79	0.61	0.32	0.2	0.28	0.71



A full breakdown of the model descriptors is outline in Appendix 2: Predictive model descriptors.

Based on the performance metrics and confusion matrices, it does not appear the models tested provide much predictor power, in particular whilst the accuracy might be particularly high this is due to the imbalance of the two outcomes.

3.9.8 Discussion

SG migration is a complication which has been recorded following EVAR. The purpose of this chapter was to identify whether migration still occurred, especially in light of published registry data for contemporary stent grafts, in which migration rates had either dropped significantly or not recorded to have occurred at all [53, 83]. Furthermore, there was a great deal of heterogeneity in how migration was both measured and the distance needed to migrate before the definition of migration could be applied.

The aim of utilising a valid, reliable and reproducible method in determining if any migration had occurred was of greatest importance. Greenberg [74] and Schuurman's [211] validated methods were both initially employed. Schuurman's method utilised multiple steps and employed the use of specialised software to establish his euclidean lines from the graft's fabric. This allowed for a comprehensive and valid measurements from the covered part of the stent to the lowest renal artery, allowing for accurate measurements particularly in SG's

with supra-renal fixation. Whilst Schuurman was able to demonstrate excellent intra and interobserver variability in his study, experiments carried out within this chapter, Defining SG position 1: Schuurmann et al (2017), failed to replicate his findings amongst vascular surgeons, fluent in vascular image interpretation. These findings were replicated on three separate occasions and therefore, restricted its implementation in subsequent analysis of migration, as complicated and lengthy protocols are likely to be abandoned or misused particularly as screening tools [237]. Greenberg's method which was introduced 2 decades ago, took advantage of its reproducibility and applicability to devices with both infra and supra renal fixation. His methods were easily reproducible, with excellent intra and interobserver variability (Defining SG position 2: Greenberg et al (2004)). His protocol was easy to understand and provided valid and reproducible results within minutes. His method did however rely on the metallic prongs and not the graft fabric, which is where the proximal seal is formed. However, the fabric line is often inferred, in the context of a CT scan, in relation to the metallic components and radio opaque markers as with Schuurman. Furthermore, as the length of supra renal prongs are fixed according the manufacturers, one could therefore infer the position of the fabric based on these calculations. Moreover, Greenberg's methods rely on the distance between the SMA and renal arteries to remain unchanged. The longterm data over a period of ten years collected within this chapter affirms this to be the case and therefore permits the use of Greenberg's method as a surveillance tool during EVAR surveillance.

Greenberg's method however was introduced in the absence of centre-line technology, which he acknowledged and recommended the use of such technology to overcome the limitations caused by aortic angulation, which was used for this analysis. Furthermore, all cases were carried out within IFU and therefore the cases analysed were not subject to distortions caused by extreme angulation.

Within this chapter EVAR cases were reviewed from two separate vascular tertiary referral centres in the UK. This would allow for a more representable sample for analysis rather than relying on a single institution. There is however a bias in the terms of follow up imaging surveillance employed. Within the UK there has been a shift towards ultrasound imaging modality for post operative surveillance rather than CT, with no uniform surveillance protocol followed nationally. The surveillance imaging is therefore determined by a number of factors including, surgeon preference, patient adherence and local guidance [207].

Furthermore, over the course of a decade, the surveillance protocol had changed twice within both institutions, with variations in the number of routine postoperative CT scans prior to patient being switched to ultrasound surveillance. The institutions did however recommend a single CT scan once every five years as part of the routine surveillance, in addition to annual ultrasound scans. The use of CT scanning, in the post operative phase, once a patient had been designated to an ultrasound pathway surveillance strategy was typically, although not exclusively based on any inconsistencies or concerns identified, either clinically or on the ultrasound scan assessment. The lack of regular and routine CT scanning therefore introduces a bias, in which those at most risk, were more likely to be included within the study and followed up long-term with a CT scan. Furthermore, those deemed to be at a higher risk, will likely have more frequent CT scans, followed up for longer and therefore may be more likely to be identified with a complication. This is seen in the median follow up times between the groups (Table 17: Follow up), where there was a significant difference in the radiological (CT scans only) and clinical follow up. For the RSM definition, clinical follow up was 7.3 years (NMG) vs 8.6 years in the MG ($p=0.03$) with radiological follow-up 3.3 years (NMG) vs 5.5 years in the MG ($p=0.02$). A similar picture could be seen in the CSM definition with clinical follow up was 7.3 years (NMG) vs 8.2 years in the MG ($p=0.03$) with radiological follow-up 3.3 years (NMG) vs 5.2 years in the MG ($p=0.02$).

Such differences between the two groups for both definitions may bias and favour the outcomes in the MG. However, given the considerable length of clinical follow up in both groups, in which ultrasound was routinely carried out as part of their surveillance protocol, this notion may be challenged. Whilst annual ultrasound scans would not have identified evidence of independent graft migration, aortic sac size stability or regression would have inferred the absence of a consequence of migration, namely type 1a endoleak.

The difference in radiological follow-up is significant, with an average of two years between the two groups. It may be argued that migration is a long-term phenomenon and therefore those in the NMG, could not be deemed to have ‘not-migrated’ as they did not benefit form a CT scan beyond 3.3 years. Whilst such arguments may present a significant limitation on the findings of this study, Spanos et al’s systematic review identified that the mean time to migration in 22 studies was 10-36 months [31]. The median CT follow up time of 3.3 years (40 months) would suffice based on this finding. However, the findings from this study would suggest that Spanos et al’s study did not follow up patients long enough and therefore

it is likely he may have underestimated the true incidence of migration. A more plausible response, in remedying the difference in follow-up and its effect on the outcomes of this assessment is to consider the fact that these patients were followed up for over 7 years clinically and any clinical consequence of migration (namely sac expansion secondary to a type Ia endoleak) would have been identified during this period, thereby addressing the notion that should non-clinically relavent migration have taken place, this would not have been detected. Furthermore, the average time to intervention was 7.1 years in the CSM group. Any subsequent follow up to their intervention was not included within the analysis and therefore reduced the overall radiological follow up for such patients.

Migration is best identified using cross-sectional imaging in the form of a CT scan. To best appreciate and understand the process of migration over time, this would require routine and regular CT scans as part of a surveillance protocol for all post operative EVAR patients. This would mean deviating from the standard surveillance protocols, which recommend ultrasound in the first instance and a CT scan reserved, for further evaluation [207]. Furthermore, the employment of routine CT scan for surveillance purposes would expose the patient to an increased risk of renal injury [238] and cancer [239]. In the context of multiple registries recording significantly lower rates of migration, challenging this with a randomised control trial in which the adverse outcomes (of multiple CT scans) are already recognised, without evidence contrary to registry data, would not be acceptable. Therefore, the analysis of this data, despite the discrepancy in follow-up length periods, should provide enough evidence to advise on future research should this be required.

In keeping with previous publications, no demographic differences could be identified between the NMG and MG for both definitions of migration [31, 36, 80, 102]. The additional inclusion of medications data as part of best medical therapy, again did not show any difference between the two groups [240].

Evaluation of preoperative anatomy identified a trend toward bigger aneurysms and shorter neck in the MG for RSM, which was not clinically significant. However, in the CSM, patients in the MG had larger aneurysms (66.7 vs 61.2 mm, p=0.02) and shorter necks (35 vs 28.3mm, p=0.03), in keeping with previous literature [31]. There was no statistical significance in thrombus burden, calcium burden or neck shape. Spannos's systematic review identified that larger aneurysms with shorter necks were more susceptible to

migration. Although our cohort adhered to the manufacturer's instructions for use (IFU) and excluded cases with hostile neck anatomies, our findings were consistent with Spannos's general conclusions . This further supports the observed correlation between increased aneurysm size and neck length and the risk of stent-graft migration. There was a significant difference in the neck diameter (both at 5 and 10mm below the lowest renal artery (LRA)) for both RSM and CSM definitions. When comparing the NMG with the MG, diameters at the aortic neck were 24 and 24.5mm vs 25.4 and 25.6mm, at 5 and 10mm below LRA for the RSM definition. When comparing the NMG with the MG, diameters at the aortic neck were 24 and 24.4mm vs 26 and 27mm, at 5 and 10mm below LRA for the CSM definition. A pre-operative larger neck diameter is an independent risk factor for future reinterventions and has been highlighted following the outcomes of the GREAT (Global Registry for Endovascular Aortic Treatment) study, during which, over 3,000 consecutive patients were treated with the Gore Excluder graft. It was found that patients with proximal neck diameters exceeding 25 mm, constituting 37.6% of the cohort, experienced higher rates of re-intervention and lower five-year survival compared to those with initial neck diameters below 25 mm (64.6% and 76.5%, respectively) [53].

In terms of stent brand used, Table 21: Stent graft devices used, details that in 81% of all EVARs, either Medtronic: Endurant II/IIs (92 cases) or Cook: Zenith Flex (96 cases), the remaining 19% of cases used a combination of 4 different stents. With such disparities in numbers, making a meaningful analysis between the six stent brands, not possible. However 26% of all Cook devices deployed, migrated at least 5mm in comparison to Medtronic in which 16% had migrated a minimum of 5mm. When comparing, outcomes for infra-renal and suprarenal fixation only, only one case with infra-renal fixation had migrated. However, only 16 (7%) cases (compared to 215 cases, with supra renal fixation) used infrarenal fixation and therefore makes comparing the two groups challenging. Nevertheless, there was no difference between the groups for stents that used suprarenal fixation and infrarenal fixation (RSM: p=0.33, CSM: p=0.67). Suprarenal fixation was an evolution to SG's over the years, to help mitigate the incidence of migration [12], however this analysis has not been able to support that suprarenal fixation, reduces the incidence of migration.

Schuurman's scrutiny of 150 EVAR cases, identified that the deployed SG's had a median slope of 2.5^{o}, however failed to correlate the severity of the slope or tilt with clinical outcomes. Within our analysis we identified a more significant degree of tilt which was

significantly higher within the MG compared to the NMG for both definitions, 11 º vs 17 º (p=0.03) in the RSM and 9.4 º vs 18.2 º (p=0.03) in the CSM. Tilting of the deployed SG, may on occasion be strategically employed to position part of the SG higher than the lowest renal artery in order to gain maximum apposition between the fabric and aortic wall. However, having read the operative notes, this was not documented as a strategy, leading one to infer the tilting was coincidental. In the CSM MG there is nearly double the degree of tilt, at 18 º compared to the CSM NMG and in stark contrast to Schuurman's 2.5 º. SG deployed at an angle within the aorta may in theory introduce crumpling and loss of aortic wall apposition and therefore weaken the engaging sealing forces [211].

In summary, patients that showed evidence of RSM were more likely to have a wider aortic neck, and more severe tilt on deployment. Whereas those who showed evidence of CSM were more likely to have a larger aneurysm, a shorter aortic neck, a wider aortic neck, and more severe tilt on SG deployment.

3.9.8.1 Postoperative anatomical changes

Given the preoperative differences between the two groups for both definitions, it would be pertinent to understand how these anatomical measurements would change over time and whether these treated aneurysms would behave differently. The same anatomical measurements were taken at the patients most recent CT scan which was a minimum of 12 months following the initial post operative CT and a maximum of 10 years following the EVAR. There was no evidence of overall aortic elongation for both definitions.

For the RSM definition, there was no evidence of aortic elongation, nor was there a significance in the aortic sac remodelling, with overall shrinkage seen between the NMG and MG group (-5.3 vs -3.9mm, p=0.35). There was however a significant reduction in aortic neck remodelling, with the aortic neck, growing longer in the NMG compared to the MG (2 vs 0.5mm, p=0.002). There was a global increase in aortic neck diameter for both groups. However the MG, had a significant difference in the increase in aortic neck diameter at 10mm (+2.9 vs +5.15, p=0.000) and 5mm (+2.3 vs +4.2mm, p=0.005) below the LRA and 5mm above the LRA (+1.3 vs 2.3mm, p=0.005).

For the CSM definition the findings are very similar with the exception of no statistical significance of aortic diameter 5mm above the LRA and eventual aortic sac size in which there is an overall increase in aortic sac diameter for the MG group (-5.5 vs +0.5mm, p=0.001).

Patients within the MG for the CSM definition were less likely to have aortic neck and sac remodelling, this would be in keeping with the higher rate of type 1a endoleaks - 47% (16/34). This can be explained by the increased sac pressure secondary to a type 1a endoleak which has been known to prevent remodelling and increase the risk of aortic rupture [65].

Nevertheless, patients within both migratory groups were more likely to have an aortic neck diameter >25mm and dilate over time to a greater degree than non-migratory groups. The 25mm cut off identified within this analysis is in keeping with the outcomes of the GREAT (Global Registry for Endovascular Aortic Treatment) study, whereby those greater than 25mm were associated with worse outcomes.

Anatomical remodelling following EVAR is the desired effect following intervention. However progressive aortic neck dilation, independent of the type of fixation is a recognised phenomenon (in patients without complications) and thought due to several factors including age, continued aortic degeneration, and persistent radial force exerted by the self-expanding SG [241]. Therefore, the introduction of additional variables, including larger pre-operative neck diameters, larger aneurysms, shorter necks and higher propensity for tissue degeneration (elderly patients) may further influence an existing phenomenon following EVAR, as seen with this data.

The decision to define two separate definitions of migration and subsequently compare these groups was established around the notion that there existed some contention regarding what constituted migration – namely the distance migrated. The identification of a late type 1a endoleak independent from any evidence of migration, necessitates intervention owing to the high risk of rupture [65]. In accordance with the ESVS guidelines, the estimated 5- year incidence of migration was 0-9%, with an associated high risk of rupture only if there is an associated type1a endoleak. The significance and need for intervention for a type 1a endoleak is therefore established. However, the distance at which migration is defined and subsequently intervened on, remains debatable. The ESVS guidelines, continues to employ

the >10mm threshold in their most recent guidelines on the management of abdominal aorto-iliac artery aneurysms published in 2024 [205]. Over the last two decades this distance has been challenged with the likes of Mohan and Tonnessen publishing evidence of adverse outcomes in patients who had migrated less than 10mm [36, 102].

The two groups: radiological significant migration (RSM) definition was predicated on caudal migration of 5mm or more and the clinically significant migration (CSM) definition on the ESVS definition of migration more than 10mm, or any migration leading to a loss of proximal seal. Given that the Endurant device (Medtronic, Inc., Minneapolis, MN) gained approval for use in aneurysms with a minimum proximal neck length of 10 mm in 2012, the migration of 5mm would ultimately lead to a 50% loss of sealing zone, in the event the device was placed perfectly, in theory, thereby challenging the ESVS's 10mm threshold.

Differentiating between the clinical outcomes of the two definitions and therefore clinical utility, will help determine which of the two should be utilised in clinical practice. In reviewing the EVAR related complications (Table 32: Post operative complications recorded over the follow up period for both RSM and CSM groups), for the RSM definition there were significantly more events as a proportion in the MG group 39.6% (18/48) vs 19% (35/183)in the NMG ($p = 0.005$). This difference is even more pronounced when looking at the CSM definition with 53% (18/34) in the MG compared to 17.8% (35/197). Of note however when reviewing specific proximal seal loss complications – namely type 1a endoleaks and ruptures secondary to type 1a endoleaks, no statistical difference between the NMG and MG could be found in the RSM definition, however were significant in the CSM definition.

In reviewing other complications such as limb stenosis, type 3 and type 1b endoleaks, these appeared to be significantly higher in the NMG for both migratory definitions. Of note, however complicated type 2 endoleaks (requiring intervention) were not witnessed at all within the CSM MG, and only within the NMG.

Whilst it is understood that direct comparison of the significance of the endoleak (which leads to sac expansion) would not be apt, particularly within this cohort given the heterogeneity of an endoleak and its effects, paired with the patients' specific anatomical traits and relatively low event numbers, a broad comparison of the outcomes in relation to the anatomical changes over time may be helpful in appreciating how MG's pose a unique

challenge. The NMG had a higher number of high pressures endoleaks, namely type 1b, 2 (with sac expansion) and 3 endoleaks all of which contribute to a pressurised sac and subsequent sac expansion and risk of rupture (nine type 2, ten type 1b and two type 3), in contrast to the MG's, particularly for the CSM definition which predominantly had type 1a endoleaks (16 type 1a and 2 type 1b). Despite this the adverse anatomical changes post operatively (overall sac size and neck diameter) were significantly higher in the MG than the NMG.

Such findings would be in keeping with the concerning sequalae of type 1a endoleaks, in the context of SG migration. Furthermore, in this analysis, one may infer that whilst the RSM definition may be used to help infer which patients are at a higher risk of overall EVAR related complications, it does not differentiate between those at risk of developing complications specific to migration – namely type 1a endoleaks. In contrast however the CSM definition incorporates all patients with a type 1a endoleak and provides a good understanding in keeping with previously published literature regarding both the pre and intra operative risk factors associated with CSM as well as the anticipated changes seen in follow up imaging [30, 31, 73, 77, 80].

It may be argued that 6 cases of type 1a endoleaks identified in the CSM MG had not migrated, failing to even meet the RSM definition and whether migration was the actual cause of the type 1a endoleak, rather than a loss of seal secondary to progressive aortic dilation or degeneration despite the ESVS and SVS guidelines and therefore the 14.7% (34/231) incidence is likely to be conflated. When separating the data to include only those cases that had migrated a minimum distance of 10mm (Table 37: Summary of outcomes in all patients that had migrated at 10mm from lowest left renal artery) 26 cases are identified, with 31% (8/26) having developed a type 1a endoleak. This equates to an 11% rate of migration over time, should we only include those migrating >10mm.

Furthermore should one argue given the inclusion criteria only allowed those with CT scans to be included and therefore would bias the results towards a higher risk patient cohort, we may include all those excluded due to failure to image or follow up, and those with inaccessible preoperative data (83 in Imperial College and in 52 Coventry) that would bring the total number of patients to 366, changing the rate of migration to 9.2% (34/366). We are therefore able to show that the rates of migration, in accordance with the most modest

estimates remain higher than those published over a 5.5-year radiological follow-up and 8.2 year clinical follow up.

3.9.8.1.1 Time to migration

The median time to migration, 10mm or more was 5.3 years (range 1.1-10 years). 38% (10/26) were found to have a clinically significant event at the proximal neck (i.e. rupture or type Ia endoleak). Median time to all complications in the CSM group (i.e. type 1a endoleak or rupture) was 7.3 years (range, 2-10 years). This contrasts with previous findings by Spanos in his systematic review (15-36 months). This is likely to due to several factors, including follow up length, the sole use of 4th generation stent grafts, patient selection and more importantly a unified specific definition and methodology in assessing post-operative surveillance scans. These findings also confirm that migration is a late complication following EVAR and introduces the dilemma of employing postoperative surveillance, in the form of annual CT scans, and its associated radiation-based morbidity. Further evaluation would therefore be necessary to determine whether this migratory group could be identified early in the post-operative period and offered a more robust surveillance strategy, rather than a blanket protocol, exposing low risk groups to unnecessary radiation-based imaging.

4 Migratory Patterns of Stent Grafts following EVAR

4.1 Introduction

The findings from the evaluated database, concur with existing literature as to the risk factors associated with SG's migration. Furthermore, provided a better understanding of anatomical changes within the aorta and provided evidence on the preference of the ESVS definition of migration over the 5mm definition of migration.

Currently the incidence of migration remains a binary outcome, as to whether the SG has migrated >10mm or migrated with evidence of a type 1a endoleak. This is a long-term complication with re-interventions for this occurring at an average of 7.3 years post implantation of an EVAR. Given the possible calamitous complications associated with a type 1a endoleak, it would be pertinent to identify which of these patients are at most risk of developing stent migration.

The current preoperative risk factors associated with migration include: aortic neck diameter above 25mm, larger abdominal aortic aneurysms (67mm) shorter necks (28mm). Placing the endograft at a more tilted angle and the presence of an immediate endoleak contribute to the intraoperative risk factors for migration.

On review of larger registry data: Vascular Quality Initiative (VQI), ENGAGE registry and EUROSTAR registry, the average neck diameter of people undergoing an EVAR were, 23-27mm, 24mm and 24-26mm, respectively. The aortic neck diameters within our cohort of patients is in keeping with wider practice and includes those with aortic neck diameters above 25mm. Furthermore both neck and aneurysmal sac diameters are within IFU's of the devices employed and these anatomical variations do not preclude treatment using this technology [204].

As such, it may be argued that restricting the use of EVAR to a narrow group (excluding larger aneurysms, and wider necks), may not be entirely practical, especially in the context of the particularly long-term complication (7.3 years), where the average survival following EVAR in the UK is 3-8 years [15, 83, 242].

However, given the information available, detailing the dynamic changes within the aortic neck and an understanding of the change of orientation of the SG within the aorta over time, it would be pertinent to further understand how SG's migrate within the aorta and whether this can be anticipated in the early postoperative surveillance phase to prevent the disastrous complications associated with migration.

4.2 Objectives

1. To evaluate the migratory patterns of SGs within the aorta over time.
2. To propose a sensitive and specific surveillance protocol in the early post operative period which identifies SG's likely to migrate.

4.2.1 **Method:**

4.2.2 Inclusion of data

We have established that the more clinically relevant definition of migration to be utilised was that published in the ESVS guidelines. However as 8 of the 34 cases within the CSM cohort did not migrate more than 5mm, mapping out their migration over time would have little benefit, as all cases showed evidence of some form of displacement over time, and attempting to determine nuanced differences of 1-3mm over time would prove challenging.

It would therefore be beneficial to evaluate all cases that were shown to migrate at least 5mm over time for the benefits of this analysis. One may then correlate the pattern and distance to clinical outcomes, to determine whether any relevance may be attributed to this.

4.2.3 Choice of landmarks

From the screening process (Post operative anatomical changes over time), it was noted over time that the distance between the SMA and renal arteries did not change significantly and therefore aortic elongation was unlikely to affect the outcomes should one choose to use the SMA over the LRA. Furthermore, the use of LRA at times was challenging, this was because of smaller accessory renal arteries which at times were difficult to identify. No issues however were identified when locating the SMA. therefore, when choosing to further evaluate the migrators the SMA was chosen as the reference point over the LRA.

All cases that migrated a minimum of 5mms (Migrators), were subject to the following assessment.

1. The first post-operative scan is analysed in a similar method to the 1st iteration.
2. The brand of the SG and number of prongs is recorded
3. Each prong is then allocated a number according to a clock face i.e. 1-12 o'clock
4. A marker is placed at the SMA and then a marker at the first time each of the named prongs is seen (cranial-caudally). The aortic diameter is measured at each marker.
5. A distance for each prong from the SMA is then generated along with the aortic diameter to provide the position of the SG within the aorta
6. Every subsequent postoperative CT scan is then analysed in the same way to generate a table of prong positions over time in relation to the SMA.

Below is an example (

Table 40) of a migrator identified from the screening process which then underwent a more rigorous assessment. The final row demonstrates eventual migratory distance of each prong at the final scan

Table 40: example of mapping out migratory process (Cook Zentih stent graft)

Scan Date		**Prongs according to clock face positions** *(in a Cook graft with 12 prongs)*												**Neck L**	**DND**	**PND**	**Angle**
		1	2	3	4	5	6	7	8	9	10	11	12				
12/08 /2008	maxD	30	30	30	30	30	30	30	30	30	30	30	30	35	29	24	20
	dSMA	11	11	11	11	11	13	13	13	13	13	13	13				
15/01 /2009	maxD	30	30	30	30	30	30	30	30	30	30	30	30	36	29	25	21
	dSMA	5	5	5	5	6.2	6.2	5	8.7	8.7	7.5	6.2	5				
05/08 /2010	maxD	30	30	30	30	30	30	30	30	30	30	30	30	34	28	25	28
	dSMA	4	4	4	6	6	8	9	9	9	6	6	5				
09/08 /2012	maxD	31	31	31	31	31	31	31	31	31	31	31	31	32	28	28	29
	dSMA	6.2	4.4	4.4	5.6	5.6	10.6	11.9	11.9	11.9	10.6	9.4	8.1				
29/08 /2013	maxD	32	32	32	32	32	32	32	32	32	32	32	32	32	28	28	19
	dSMA	5	5	5	6.2	8.7	8.7	10	8.7	10	8.7	8.7	10				
Migrati -on D		**-6**	**-6**	**-6**	**-4.8**	**-2.3**	**-4.3**	**-3**	**-4.3**	**-3**	**-4.3**	**-4.3**	**-3**				

maxD= Maximum aortic diameter

dSMA= Distance of the prong to the SMA

Neck L = neck length (mm)

DND = distal neck diameter (mm)

PND = proximal neck diameter (mm)

Angle = Angle of radio-opaque markers from renal artery (as per

Rotation), degrees

Migration D = eventual migration distance between first and last scan

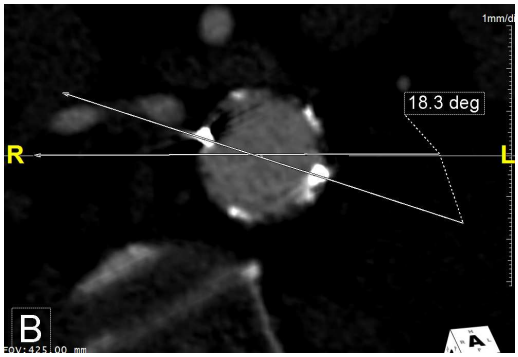
This assessment measures the caudal displacement of 12 areas in the proximal portion of the graft. To simplify the representation of migration, we will focus on the largest distance travelled or the greatest drop at any part of the graft, rather than considering all 12 areas individually. This point is likely to be the most vulnerable and prone to a loss of seal, which could lead to a type 1A endoleak. Therefore, the most significant drop in the graft will be used as our measurement point over time. In the above example the migratory distance would be determined as 6mm.

Further assessment of the anatomy of the migrators over time was also carried out measuring: changes in the neck length, aneurysm sack size, neck diameter and supra renal aortic diameter.

4.2.4 Rotation

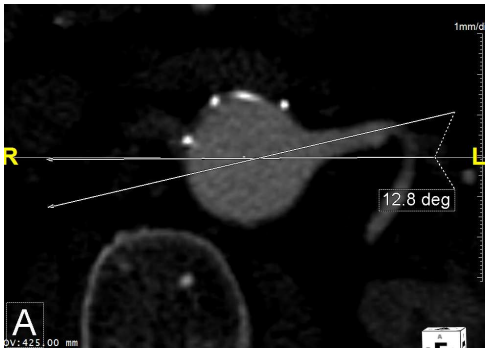
The position of the most visible radio-opaque marker was noted and marked on an axial plane. The image was reset to ensure the position of the vertebrae was positioned posteriorly and to the right. A horizontal line was drawn through the centre of the aorta, using the centre line as reference. A further line was drawn from the centre of the designated radio-opaque marker to the centre of the aorta to generate an angle (Figure 28).

Figure 28: assessing rotation in migrators (1).



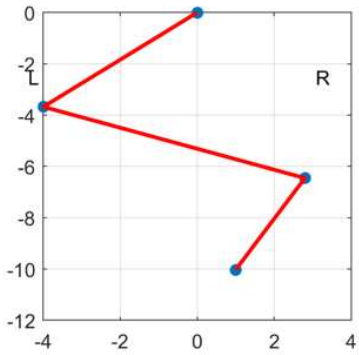
The operator than scrolls up through the images until the lowest renal artery is identified. A line is then drawn from the centre of the LRA ostium to the centre of the artery (Figure 29). The two figures are added to give the angle of the radio-opaque marker in relation to the LRA. i.e. 12.8 º + 18.3 º = 31.1º.

Figure 29:assessing rotation in migrators (2).



This process is repeated for all post-operative scans to determine the change in rotation of the graft within the aorta. Figure 30 shows an example of change in angle between the radio-opaque marker and LRA to infer rotation of the device over time in four post-operative scans.

Figure 30: mapping rotation over time



The evaluation of rotation in stent grafts has previously been undertaken for FEVAR's to investigate the cause for occluded fenestrated stents. Analysis however has been carried out on angiographic images during the deployment of the main body with supportive software to determine whether the fenestration lined up adequately or were rotated [243]. To our

knowledge the assessment for rotation in standard EVAR's in the post operative phase has not been carried out.

Further evaluation of this method to assess for inter and intra observer variability was carried out amongst 3 vascular surgeons.

Table 41: Graft rotation: assessing for intra and inter observer variability.

Did participant correctly calculate the change in rotation of the graft within 2º ?								
	Change in degrees (º)							
Participant	4 º	10 º	18 º	0 º	25 º	30 º	Time taken (minutes)	% correct
A (1st attempt)	y	y	y	n	y	y	8	83%
A (2nd attempt)	y	y	y	y	n	y	3	83%
A (3rd attempt)	y	y	y	y	y	y	3	100%
B (1st attempt)	n	y	y	y	y	n	7	67%
B (2nd attempt)	y	y	y	y	n	y	3	83%
B (3rd attempt)	y	y	y	y	y	y	3	100%
C (1st attempt)	y	y	y	y	y	y	6	100%
C (2nd attempt)	y	y	y	y	y	y	2	100%
C (3rd attempt)	y	y	y	y	y	y	2	100%
Average correction recording	89%	100%	100%	89%	78%	89%	4.1 minutes	91%

Intra observer reliability was found to be 92% and interobserver reliability was found to be 91%, with an average time of 4 minutes to calculate rotation.

The initial post operative CT scan will act as the baseline of the grafts orientation and all subsequent scans will be measured in comparison to the base line position.

4.2.5 Visualisation of migration

The migratory databases as exemplified in

Table 40 (full database can be accessed in Appendix 3: Migratory patterns), were used to assess the proximal stent graft over time within the aorta. To better visualise the migratory process, CT scan phantom images of the aorta from the Aquarius system (TeraRecon, San Mateo, CA, USA) were obtained and the graft struts superimposed on them and cross-validated using our measurements. Displayed below are images of visual representation of migration over time.

4.2.6 Assessing for patterns of migration.

An assessment of how we will determine the patterns of migration and evaluate accordingly will be based on the initial results on the distance, trajectory and follow up intervals of the migrated stents. Given the information collected to date, an assessment of early behaviour of stents would need to be appreciated to determine whether we can pre-empt migration.

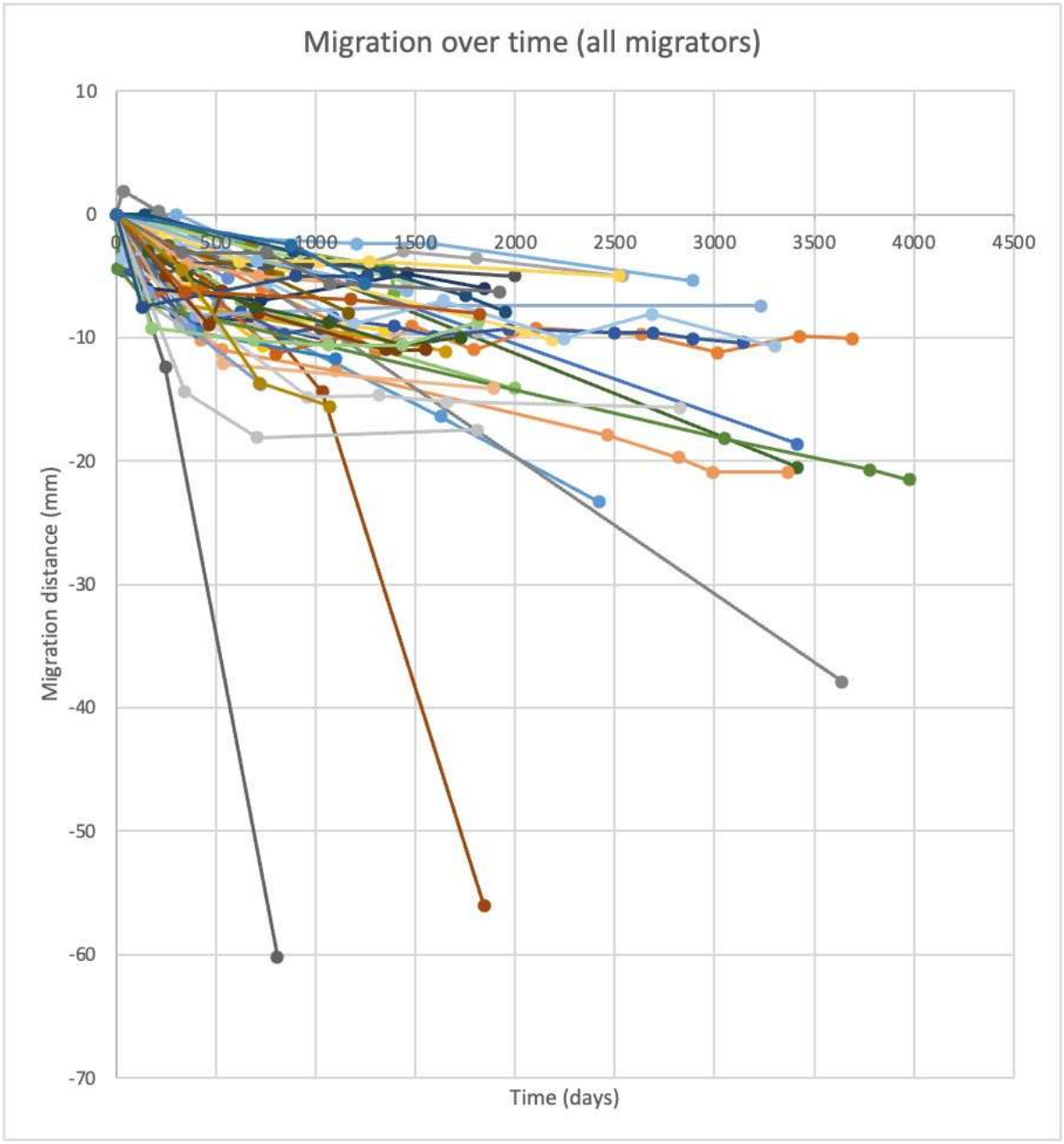
4.3 Results

4.3.1 All migrators

The average (mean) follow-up time for all migrators was 91 months (7.6 years). The average migratory distance was 7.2mm, with a maximum migratory distance of 21.5mm and a minimum of 5mm. The comprehensive tables containing all the data analysing migratory patterns can be found in Appendix 3: Migratory patterns.

Figure 31 displays a graph outlining the greatest migratory distance for all migratory graphs over time

Figure 31: Graph displaying migration over time for all migrators



4.3.2 Visualisation of migration

Displayed below are images of visual representation of migration over time. These have been grouped into those migrating <10mm (

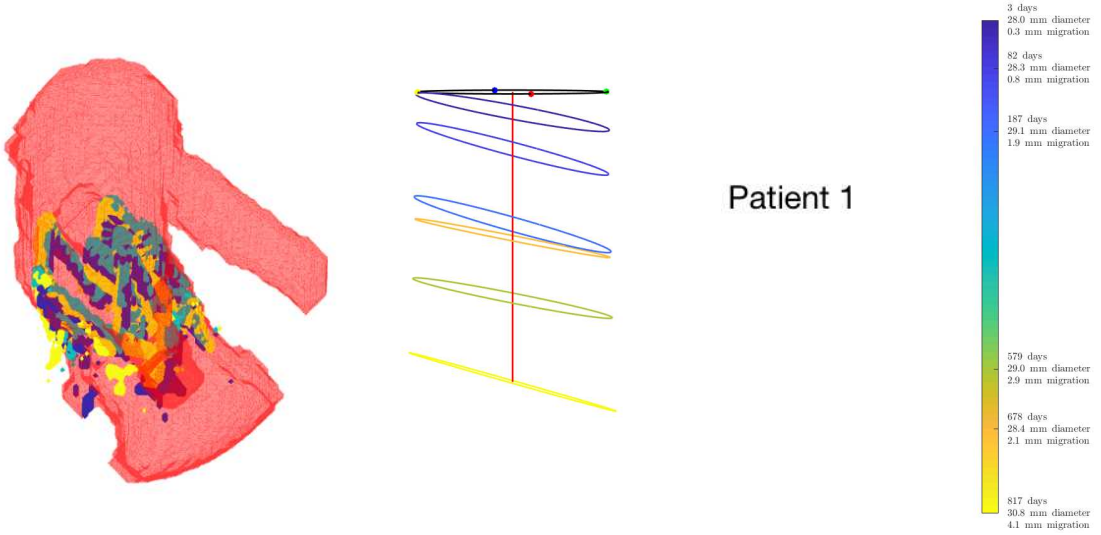
Figure 32 and Figure 33, representing patients 1-4) and those migrating more than >10mm (

Figure 34 and

Figure 35, representing patients 5-8). These images show (right to left): the timeline with corresponding colours, the movement of the proximal barbs over time (represented as a circle, based on the measurements taken from the migratory database,

Table 40) within an aortic phantom with the stent struts migrating over time, to the corresponding timeline on the right.

Figure 32: <10mm migration displayed on reconstructed aortic phantom, patients 1 and 2



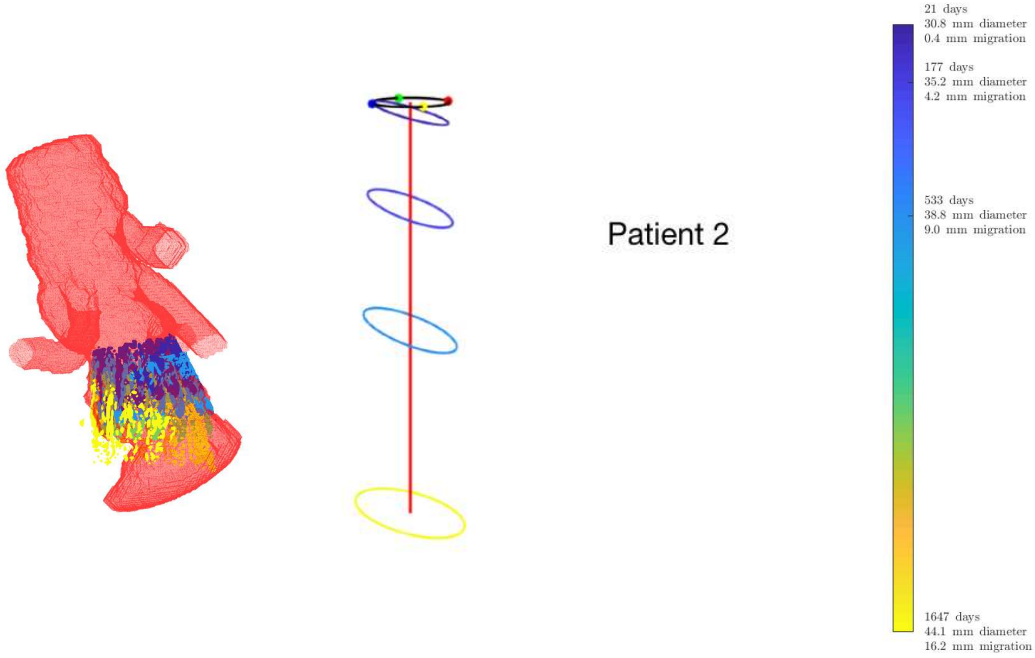
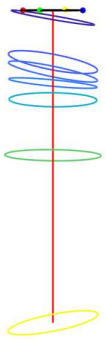
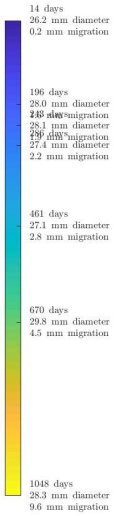


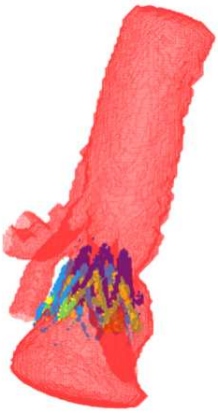
Figure 33:<10mm migration displayed on reconstructed aortic phantom, patients 3 and 4

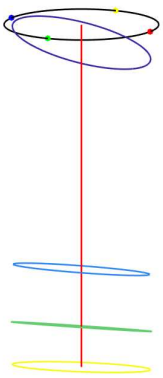




Patient 3







Patient 4

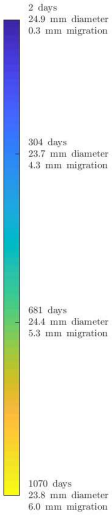
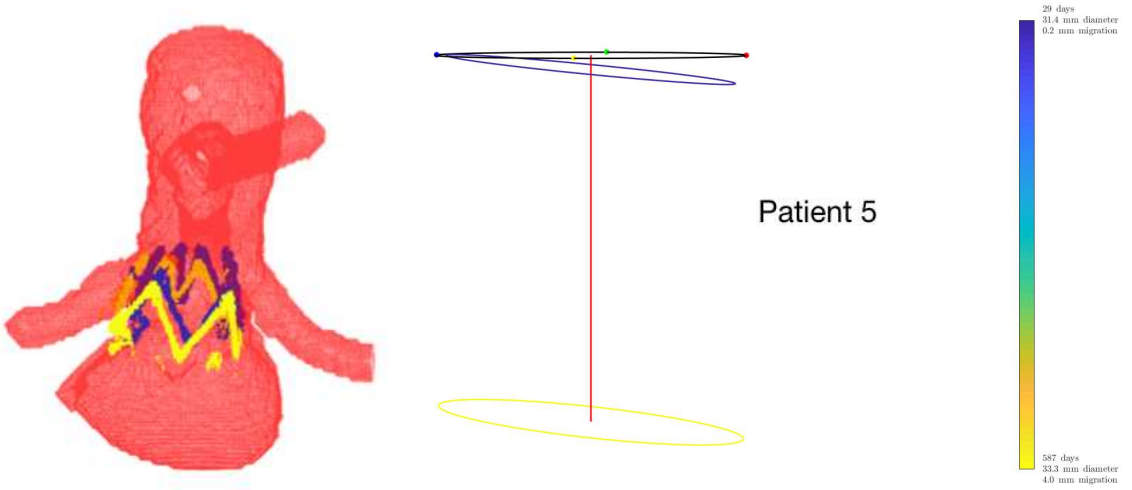


Figure 34: >10mm migration displayed on reconstructed aortic phantom, patients 5 and 6



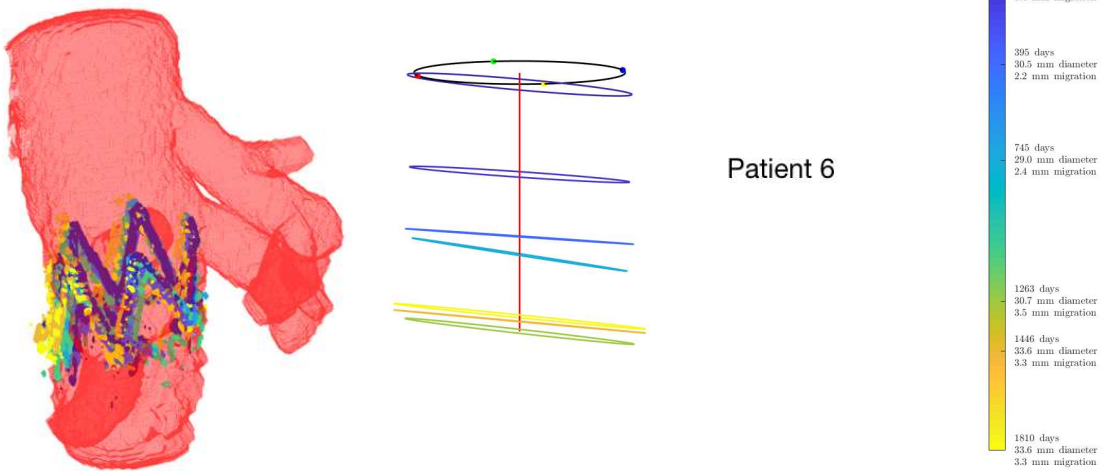
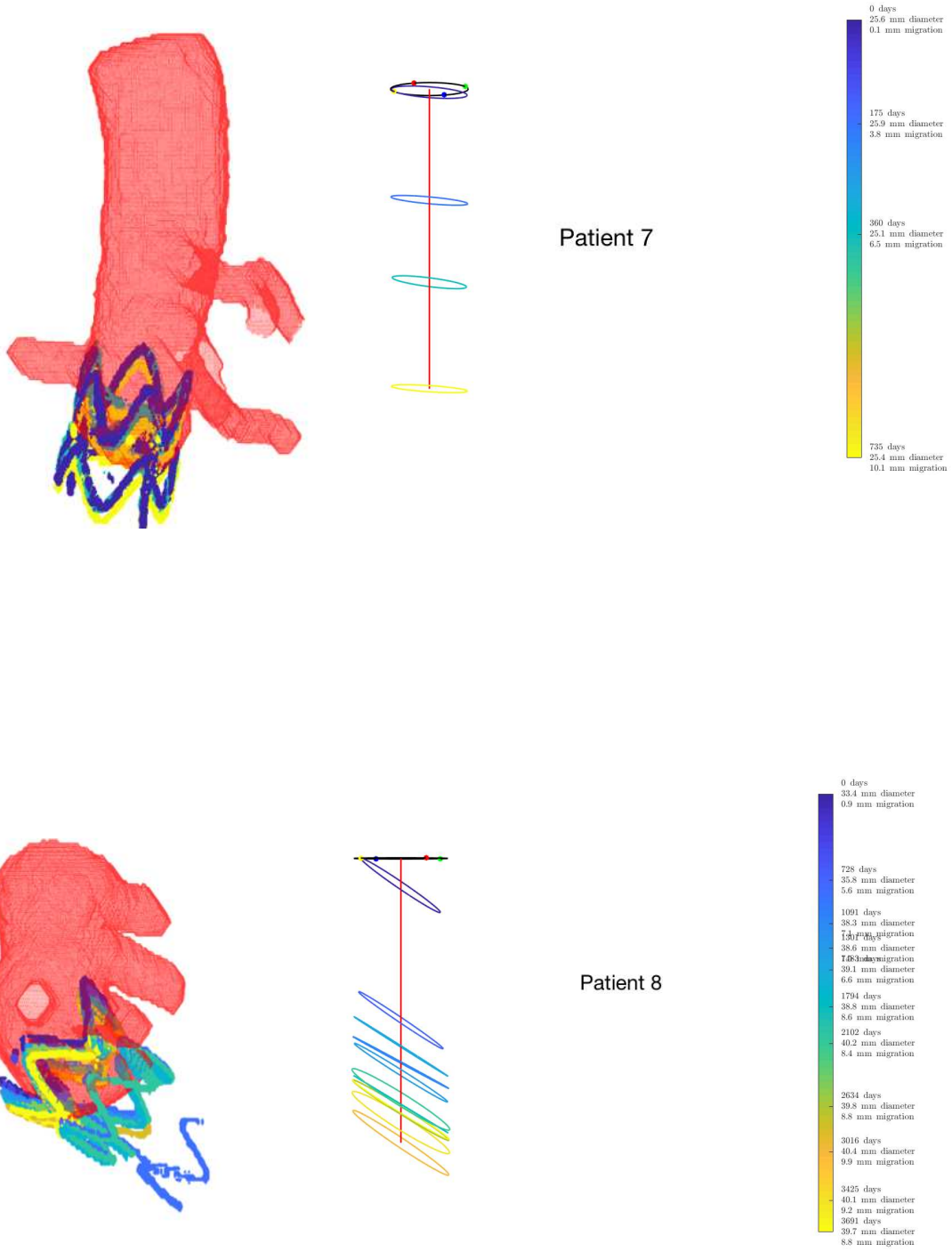


Figure 35:>10mm migration displayed on reconstructed aortic phantom, patients 7 and 8



4.3.3 Early vs late migration

Patients in whom stents migrate 10mm or more have already met the definition for migration and are at significant risk of losing their proximal seal and developing a type 1a endoleak. The focus should therefore be placed on the behaviour of stent grafts within the early post

operative period - the first two post operative scans, one year apart. As this was a retrospective study, the interval between the first two post-operative scans varied from 11-18 months. The concept of early migration was therefore proposed as evidence of a minimum 5mm of migration, within the first 18 months, postoperatively.

4.3.4 5 vs 10mm migration

In accordance with the findings from the previous chapter, in that <10mm was not found to be clinically significant, and that the definition of migration would revolve around a minimum displacement of 10mm, the data from the assessed migrators was further categorised into additional groups of < 10mm (5-9.9mm) and >10mm migration.

4.3.5 Continuous vs stable migration.

Based on the graph above (Figure 31), the distance migrated between each scan differs. Certain grafts appear to continue to migrate throughout the follow up period (patient 7 and 8,

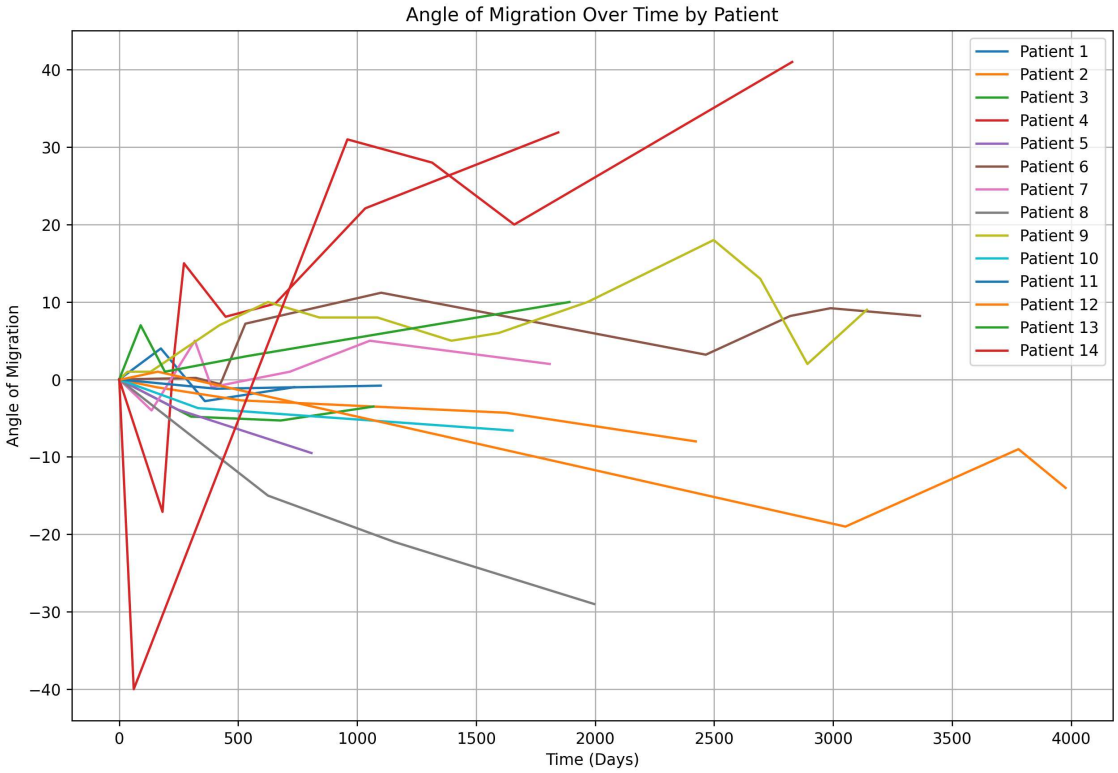
Figure 35) whereas others appear to migrate to a certain point and settle (patient 6,

Figure 34). Based on this observation, an assessment was made on the patients' last two CT scans at least 12 months apart. If there was evidence of more than 2mm between the two scans the migratory pattern would be termed as continuous, if it was 2mm or less, the migratory pattern would have been termed as stable.

4.3.6 Rotation of stent graft in migratory cases.

A review of rotation of the stent graft within the aorta in the St Mary's migratory cases cohort. The data gathered from Coventry hospital, was corrupted and lost. All grafts assessed showed varying degrees of rotation within the aorta, typically staying within 20 degrees of the baseline (-40 to 40 degrees). These grafts tended to oscillate back and forth without overlapping or returning to the baseline, except in one case. In the more extreme cases of rotation, the graft usually slipped out of the neck and lay freely within the sac. At this stage, correlating the graft's position to migration was unlikely to provide reliable information relevant to migration in general. Figure 36, displays the changes in angulation over time amongst the early >10mm migrators.

Figure 36: Graph displaying angle of displacement in migrating grafts (>10mm) over time



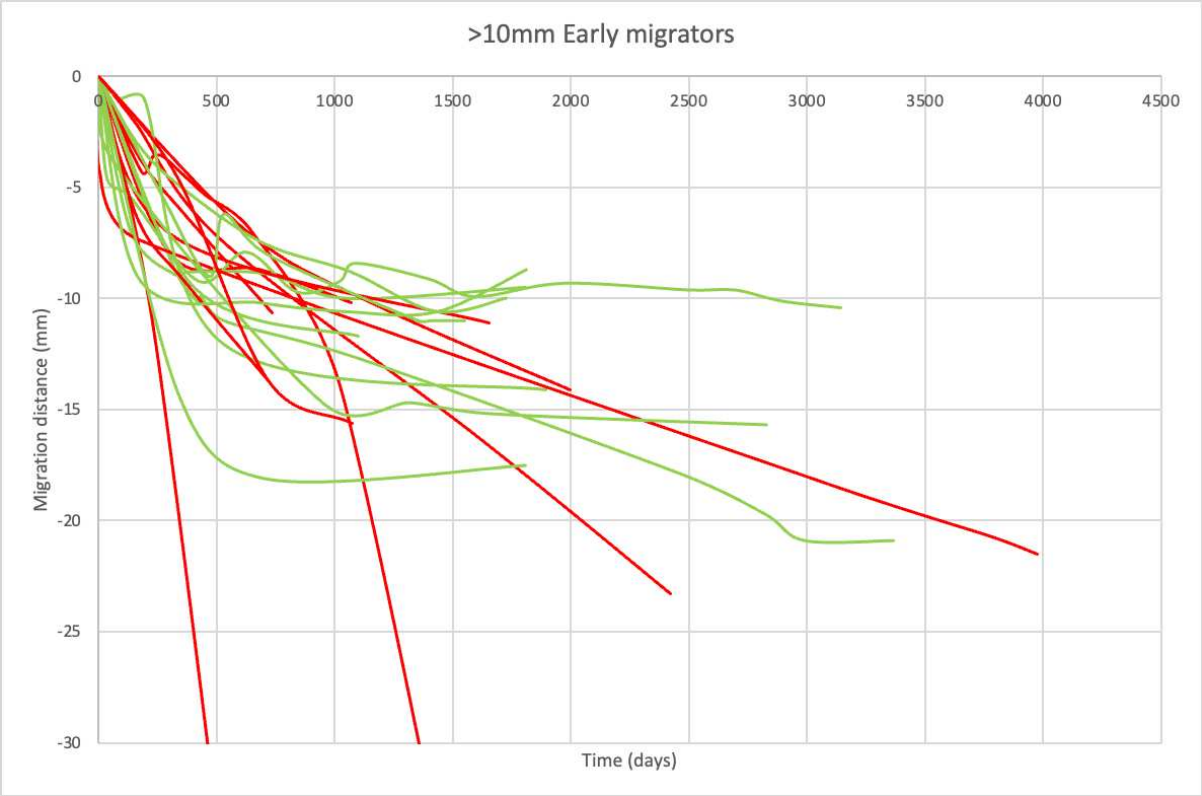
4.3.7 An analysis of patterns

Based on these proposed migratory patterns there are 4 preliminary groups listed below, with an additional assessment of continuous and stable migratory patterns.

1. ≥**10mm early migrators**: those eventually migrating a minimum of 10mm, exhibiting evidence of at least 5mm within the first 18 months postoperatively.
2. ≥**10mm late migrators**: those eventually migrating a minimum of 10mm, migrating less than 5mm within the first 18 months postoperatively.
3. **<10mm early migrators**: those eventually migrating a maximum of 9.9mm, exhibiting evidence of at least 5mm within the first 18 months postoperatively.
4. **<10mm late migrators**: those eventually migrating a maximum of 9.9mm, migrating less than 5mm within the first 18 months postoperatively.

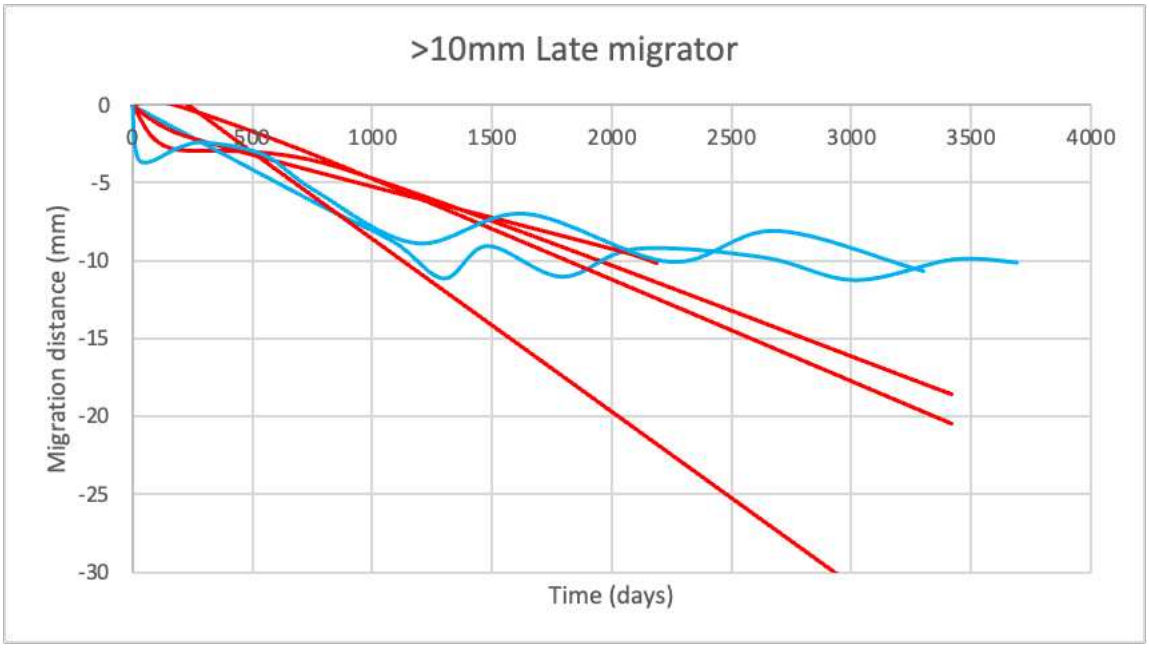
4 subsequent graphs were generated to reflect these groups:

Figure 37: Graph displaying >10mm early migrators.



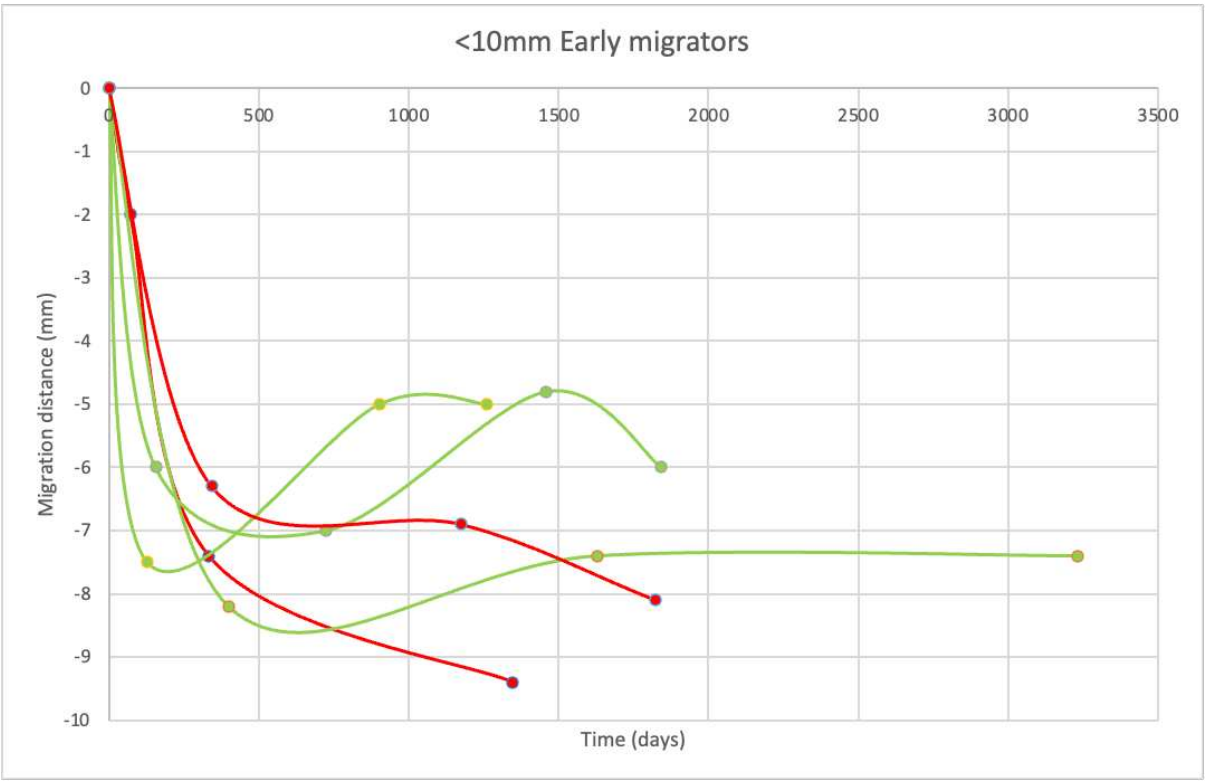
Green lines depict those grafts which stabilised, red lines depict grafts with continuous migration.

Figure 38: Graph displaying >10mm late migrators.



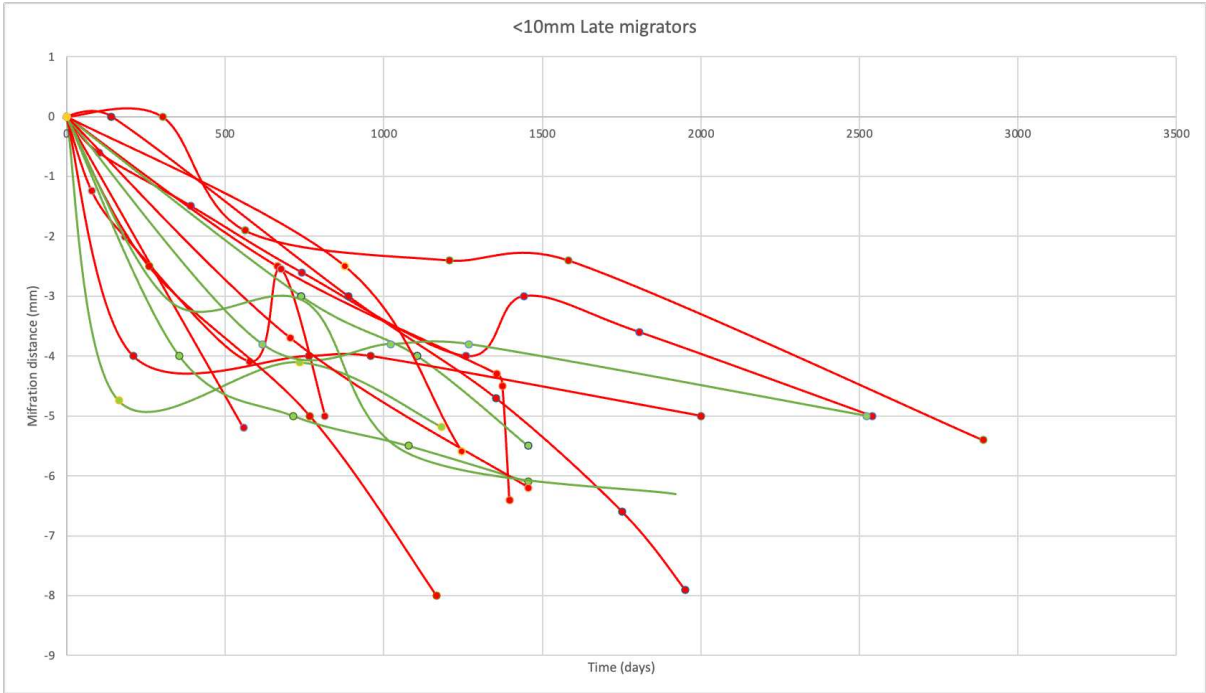
Blue lines depict those grafts which stabilised, red lines depict grafts with continuous migration.

Figure 39: Graph displaying <10mm early migrators.



Green lines depict those grafts which stabilised, red lines depict grafts with continuous migration.

Figure 40: Graph displaying <10mm late migrators.



Green lines depict those grafts which stabilised, red lines depict grafts with continuous migration.

Fischer's exact test was used to calculate whether there was a significant difference between the groups.

Table 42:A summary of migration patterns amongst all migrators

Migratory pattern	**Migrating >10mm**	**Requiring proximal neck intervention**	**Migrating <10mm (5-9.9)**	**Requiring proximal neck intervention**	**P value for >10 vs <10mm**
Late	19% (5/26)	20% (1/5)	73% (16/22)	0%	0.013
Early	81% (21/26)	33% (7/21)	27% (6/22)	4.5% (1/22)	0.000
Significance Late vs Early: P value		0.195			
Continuous	58% (15/26)	40% (6/15)	45% (10/22)	0%	0.356
Stable	42% (11/26)	18% (2/11)	55% (12/22)	4.5% (1/22)	0.758
Significance Continuous vs stable: P =		0.104			

In comparing the different groups, there is a clear statistical difference in the early behaviour of the grafts between those that eventually migrate >10mm compared to those that do not. 81% (21/26) showed evidence of at least 5mm of migration within the first 18 months compared to 27% (6/22) in the <10mm migratory group (p = <0.001). There were comparable numbers when comparing continuous vs late migratory patterns in the two groups, with no statistically significant difference between the two: for the continuous

pattern, 15/26 in the >10mm group vs to 10/22 in the <10mm group (p = 0.36), for the stable pattern 11/26 for the >10mm group vs 12/22 in the <10mm group (p= 0.758).

Further analysis on whether these two migratory patterns, early vs late and continuous vs stable found there to be no significant statistical difference in the likelihood of requiring intervention to the proximal sealing zone.

Additional analysis of graft patterns was carried out to determine whether the migratory patterns could be stratified into specific patterns over the entire course of their surveillance period, based on an analysis of the graph in Figure 31. An attempt to group these migrators into Early Migrators (which settle), Early Migrators (which are continuous) and Late migrators was undertaken, however this analysis was unable to provide any clinical relevance or reliably in predicting the clinical outcome given the variations in long term follow up intervals beyond 18 months. A more detailed description of this analysis is outline in Appendix 3: Migratory patterns.

4.3.8 Calculating sensitivity, specificity, and predictive values

4.3.8.1 Comparing all migrators >10mms vs <10mms – 48 cases

The comparative summary between the various migratory patterns outlined in Table 42, identified that of the grafts that go on to migrate a minimum of 10mm, 81% of them will show evidence of at least 5mm of migration within the first 18 months. An assessment was made to examine whether this finding may be used as a screening tool to identify a possible higher risk cohort (for migration) from the first post postoperative CT scans.

Figure 41: Sensitivity, specificity and predictive values comparing >10 and <10mm migratory groups: early migration as a screening tool.

	Migrated more than 10mm	Migrated less than 10mms	
Early migration (5mms within 18 months)	21	6	PPV = 78%
Late migration	5	16	NPV = 76%

Total	26	22	
	Sensitivity = 81%	Specificity = 73%	

The odds ratio for early stent migration (5mm) predicting eventual stent graft migration of >10mm is 11.2, with a 95% confidence interval ranging from 2.89 to 43.35 (p =<0.001)

4.3.8.2 Comparing >10mm migration with entire EVAR cohort – 231 cases

Further analysis applying this finding to the entire EVAR cohort of 231 patients to determine its applicability, specific to grafts migrating >10mms.

Figure 42: Statistical test of significance evaluating early migration in the entire EVAR cohort, using Fisher's exact test.

Migratory pattern	**Migrating >10mm**	**Not migrating >10mm**	**P value**
Early migration	21	6	<0.001
No early migration	5	199	<0.001

Figure 43: Sensitivity, specificity and predictive values comparing >10mm migration and those that did not groups with the entire EVAR cohort: early migration as a screening tool

	Migrated more than 10mm	Did not migrate 10mms	
Early migration (5mms within 18 months)	21	6	PPV = 78%
No evidence of Early migration	5	199	NPV = 97%
Total	26	205	

	Sensitivity = 81%	Specificity = 97%

The positive likelihood ratio (LR+) is calculated

Sensitivity = 0.807
Specificity = 0.970

$LR+ = 0.8077/(1-0.9707) \approx 27.57$

The resulting LR+ of 27.57, indicates patients that show evidence of early migration are much more likely to migrate than those who do not.

$LR- = (1-0.8077)/0.9707 = 0.20$

A resulting low LR- of 0.20 indicates that if early migration is not seen, the likelihood of migration is much lower.

The odds ratio for early stent migration (≥ 5mm) predicting eventual stent graft migration of >10mm is 139.3, with a 95% confidence interval ranging from 39.15 to 495.62 (p =<0.001)

4.3.8.3 Comparing European definition of migration with non-migrators – 231 cases

In this final analysis we will compare the European definition of migration (all >10mm + any migration requiring intervention to the proximal seal) with the non-migrating EVAR cohort.

Figure 44:statistical test of significance evaluating early migration in the entire EVAR cohort, against the European definition of migration using Fischer's exact test

Migratory pattern	**European definition of migration**	**Not meeting European definition of migration**	**P value**
Early migration	22	5	0.000
No early migration	12	192	0.000

Table 43: sensitivity, specificity and predictive values comparing early migration amongst the entire EVAR cohort and those meeting the European definition of migration.

	Meeting the European definition of migration	Not meeting the European definition of migration	
Early migration (5mms within 18 months)	22	5	PPV = 81%
No evidence of Early migration	12	192	NPV = 94%
Total	26	205	
	Sensitivity = 65%	Specificity = 97%	

A positive likelihood ratio of (LR+) of 25.49 and a negative likelihood ratio (LR-) of 0.36 indicate early migration strongly increase the likelihood of migration and the absence of early migration reduces the likelihood of migration according to the European definition.

The odds ratio for early stent migration (5mm) predicting eventual stent graft migration (in line with the European definition of migration) is 70.4, with a 95% confidence interval ranging from 22.68 to 218.53 (p =<0.001)

4.4 Discussion

A review of different approaches for determining whether graft migration can be anticipated in high-risk groups—defined as more than 10 mm of migration—has shown that assessing graft movement within the first 18 postoperative months provides sufficient data to identify this high-risk cohort. This method has demonstrated a sensitivity of 81% and a specificity of 97%, particularly when focusing on migration greater than 10 mm. When additional cases with less than 5 mm of migration accompanied by a type 1a endoleak (meeting the European and American definitions of migration or clinically significant migration [CSM]) were included, the sensitivity decreased slightly to 65%.

The calculated odds ratio of 70.4 (95% confidence interval: 22.68 to 218.53, $p < 0.001$), although large, is accompanied by a wide range, likely due to the small sample size. Despite this, the odds ratio remains significant in predicting migration risk.

Reliance on CT imaging continues to be the gold standard for measuring migration in the postoperative period. However, this method presents a potential limitation, particularly as clinical practice is increasingly moving away from radiation-based imaging. Given these developments, exploring alternative methods for postoperative surveillance to detect migration would be beneficial. While we have successfully identified a possible high-risk group within the first 18 months following EVAR, reducing the morbidity associated with radiation-based surveillance for this group during the postoperative phase could significantly benefit patient outcomes. Introducing alternative surveillance methods, which could identify migration, especially for high-risk patients, will need to be further explored to better align existing practice in reducing radiation exposure in long-term patient management.

5 Exploring surveillance methods of graft migration using ultrasound in the post operative period

5.1 Introduction

The evidence thus far has established a significant rate of migration in patients following EVAR, with interventions typically scheduled following the identification of a type 1a endoleak at an average of 7.3 years following implantation. The data has also shown that 80% of grafts that eventually migrate a distance greater than 10mm, will migrate at least 5mm within the first 18-month post-implantation. The exact timing as to when patients meet the prescribed threshold of migration remains unknown, with surrogate markers used to help identify an abnormality during the postoperative period such as sac expansion on surveillance ultrasound imaging [244]. However, such surrogate markers, will only highlight a complication of migration, such as a type Ia endoleak, rather than determine a migratory distance, at which point patients are at particularly high risk of morbidity and mortality as is evidence by the findings that 12% of CSM were only identified following a rupture.

Current surveillance practice employs the use of ultrasound duplex, which would report at the very minimum graft patency and maximum anterior-posterior (AP) diameter of the aortic sac. Additional information may be provided such as the possibility of an endoleak, however the availability of this additional information, depends on the operator's ability to both look for these parameters and their confidence in identifying them [206]. An increase in sac size may be used as a surrogate marker to infer an endoleak, secondary to a repressurised sac. However, by this stage, migration has already occurred leading to a complication and patients have been placed at risk of an increased rupture rate.

Employing a surveillance method, utilising the information so far gathered regarding the patterns of migration may help earlier identify higher risk patients from developing type 1a endoleaks and subsequently reduce their future risk of rupture.

5.1.1 Surveillance programmes

Following the treatment of patients with EVAR for an AAA, post operative surveillance is deemed mandatory in accordance with European and American guidance, due to increased rates of reinterventions when compared to open surgical repair [205, 213, 245]. The aim of such surveillance programmes is to identify symptomatic and asymptomatic complications following treatment, which may contribute to adverse patient outcomes. The complications associated following an EVAR procedure have been discussed in earlier chapters (EVAR specific Complications) [246].

The European Society of Vascular Surgery (ESVS) provides a structured surveillance programme following a standard uncomplicated EVAR. The first postoperative imaging should be performed within 30 days in the form of a CT angiogram (CTA) to assess the position and deployment of the graft, detecting any early endoleaks, and measuring the aneurysm sac size. At 6 months and 12 months, the patient should have either an ultrasound duplex with Doppler or another CTA. Following this annual surveillance is advised, with ultrasound duplex as the primary modality. This modality is preferred as it is non-invasive and does not expose the patient to radiation. In addition a CTA every 5 years is recommended [205]. Surveillance protocols may be tailored in accordance to the patient's risk factors, co-morbidities and needs. The Society for Vascular Surgery in the US have published similar recommendations and provides similar rationales [247]. More recently there has been a push to further stratify patients following their aneurysm repair and initial CTA into high and low risk for future complications, with a view to reduce the scanning interval to up to 5 years post operatively in low risk patients [244].

The employment of duplex ultrasound (DUS) is thought to provide enough information in non-complicated patients during their follow up period to infer the absence of major complications, namely graft patency and sac stability and regression [72]. Additional information may be gained such as identification of endoleaks, stent integrity, thrombus formation, and adjacent vessel patency. However, this additional information if recorded would trigger the need for further imaging and not be relied on for future management decisions [206].

5.1.2 Imaging modalities

An array of existing imaging modalities are employed either in isolation or as in combination in the post-operative period following an EVAR. These range from simple abdominal x-rays to more invasive aortic angiograms. The imaging modality preferred will depend on the patients' specific circumstances and the information the clinician is seeking. These modalities have previously been discussed at length in numerous publications, with the ESVS providing a summary in 2024, which has been reproduced below, Table 44 [205, 244].

Table 44: Imaging modalities following EVAR

Table 22. Pros and cons of different follow up imaging modalities after endovascular abdominal aortic aneurysm repair.

	CTA	CT	DUS	CEUS	MRA
Availability	+++	+++	+++	+	+
Cost	++	++	+	+++	+++
Capacity to detect complications	+++	+	++	+++	+++
Assessment of aortic branches	+++	+	++	++	+++
Operator dependency	−	−	+++	+++	++
Nephrotoxicity	+++	−	−	−	+
Radiation exposure	+++	+++	−	−	−

+/- indicate different degrees of importance for the respective characteristics.

EVAR = endovascular aneurysm repair; CTA = computed tomography angiography; CT = computed tomography; DUS = duplex ultrasound; CEUS = contrast enhanced ultrasound; MRA = magnetic resonance angiography.

Whilst CTA is recognised as the gold standard in terms of information provided following an EVAR, the morbidity (increased radiation exposure and nephrotoxicity) associated with such imaging, reduces its general applicability for routine use. MRA also has a limited role given it's high costs and constrained capacity at many institutions. Ultrasound, however, is readily available, cost effective, and effective and therefore routinely used [207]. There have been significant advancements in ultrasound technology, notably the use of contrast ultrasound and 3-dimensional developments. There is therefore a rationale to explore this modality further in the context of the new evidence identified in defining migration.

5.2 Objective

1. Evaluate the use of ultrasound technologies as a viable option to monitor stent migration.

5.3 Methods

5.3.1 Exploring the use of ultrasound in measuring graft migration

DUS, whilst easily accessible, relatively cheap, free from significant complications and portable the use of USS is limited in delineating existing complications or pre-empting the need to intervene [206]. Certainly, the implication and information extrapolated from the images generated by an USS will vary, as this is very much an operator dependant imaging modality. Nevertheless, there is a consensus on the expected information, which may be gathered from USS for the purposes of surveillance.

Currently, USS provides the following routine information:

- Maximum measured diameter of the infra renal aorta
- Maximum measured diameter of common iliac arteries
- Thrombus within the infra renal aorta and common iliac arteries
- Patency of the graft
- Type of blood flow within the aorta and common iliac arteries [206]

The rate of identification of possible endoleaks and leak channels, is limited with the sole use of a doppler USS. Furthermore, an evaluation of the stent position and orientation within the aorta is particularly challenging due to the use of 2 dimensional measurements and difficulty in detecting the stent using this modality. This is particularly relevant in the context of determining migration.

As discussed in Chapter 1, particularly in the section "Accounting for the 3-dimensional structure," current protocols for diagnosing stent migration have significant limitations. To accurately assess the 3-dimensional orientation of the proximal stent graft and ensure the

integrity of its seal, it is imperative to establish a protocol for taking multiple reliable measurements from the stent to a consistent anatomical landmark.

Ultimately, the goal is therefore to reliably visualise the metallic proximal supra-renal prongs/barbs of an aortic stent using ultrasound and take valid and reliable measurements to ascertain the orientation and subsequent migration using USS. Providing a comprehensive assessment of the orientation of the proximal stent graft will rely on the following:

1. visualising the stent
2. taking reliable and valid measurements from the stent to existing landmarks, to determine the position and orientation of the stent graft within the aorta.

5.4 Experiment 1: Visualising the stent using USS

Visualisation of the stent graft is essential in determining the orientation or possible displacement of a stent graft. The graft will either need to be constructed from an USS opaque material or have an USS opaque marker, so that it may be tracked, and the position inferred. At present there is no consensus on the reliability of identifying independent facets of the stent grafts. More recent ultrasound machines, in the hands of experienced individuals have yielded valid images from which inferences can be made. However, the reliability in detecting the individual aspects of the graft to determine the orientation of the proximal seal poses a limitation in its routine use [248].

Most aortic grafts (Medtronic, cook, anaconda and gore) have two main components to the graft. The underlying metallic scaffolding (provides radial force, and infrastructure), which may take on several arrangements, depending on the manufacturer and are typically made of nitinol or steel. The covered portion of the stent, which is not obviously seen is made of fabric (typically ePTFE, Dacron or polyester variants) [12].

We have established that the graft position is determined following the identification and measurements of the proximal metallic components (barb/prongs) of the stent graft on a CT scan. To replicate such measurements the barbs would need to be adequately visualised on ultrasound.

An experiment was set up to visualise the barbs of a Medtronic aortic graft (Figure 45) within a silicone tube representing an aorta.

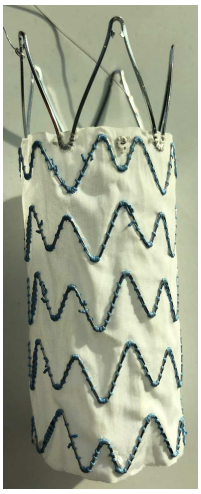
5.4.1 Aim:

Can the proximal metallic prongs of an aortic graft be reliably visualised using USS?

5.4.2 Methods:

A 22mm x 50mm Endurant Medtronic cuff was sourced and chosen as the stent graft for experimentation. This graft best represented the current practice from the database in which the majority of grafts used during EVAR procedures had suprarenal fixation. The focus of this study is on the proximal seal and incorporating the distal limbs or flow divider portion of the EVAR stent graft was felt not necessary. The sharp hooks attached to the apex of the prongs (used to aid fixation to the aortic wall) were removed, for safety and to allow for easier manipulation of the SG during the experiment, Figure 45.

Figure 45: Medtronic Endurant proximal aortic cuff stent graft



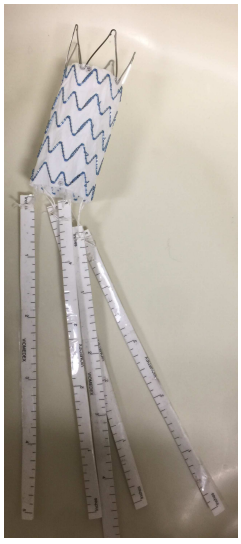
Silicone can be visualised with ultrasound, accurately, it is also transparent and would allow manual measurements to be taken independent of the ultrasound, using callipers [249]. Therefore, a silicone tube representing the aorta was used measuring 21mm in diameter (inner to inner) with a thickness of 3mm, Figure 46.

Figure 46: Silicone tube representing aorta



Five measuring tapes were placed at the distal end of the stent, corresponding to each of the proximal metallic prongs/barbs, in order to record the distance of the stent graft from the distal aspect of the silicone tube, Figure 47.

Figure 47: SG with attached measuring device



The stent graft was placed in the silicone tube and placed in a water tube Figure 48

Figure 48: SG within aortic model, and water bath



Two separate assessors imaged the stent graft using standard abdominal probe: low-frequency curved transducer with a frequency of 5 MHz. Five separate attempts were made by each individual assessor to visualise each independent prong/barb, with a time limit of five minutes for each assessment and no restrictions on the technique employed.

Assessors were asked:

1. How many barbs/prongs they were able to visualise from a possible 5, with the stents position manipulated in between each attempt.
2. To take measurements of the silicone tubing thickness and diameter.

5.4.2.1.1 Results:

Table 45: Experiment, visualising proximal prongs

	Number of prongs visualised	
	Assessor 1	Assessor 2

1st attempt	3	3
2nd attempt	4	4
3rd attempt	4	4
4th attempt	4	4
5th attempt	4	4

Table 46: Experiment, Visualising aortic model wall

	Correct measurement of tube diameter to within 2mm	
	Assessor 1	Assessor 2
1st attempt	yes	yes
2nd attempt	yes	yes
3rd attempt	yes	yes
4th attempt	yes	yes
5th attempt	yes	yes

Table 47: Experiment, measuring aortic model wall thickness

	Correct measurement of tube thickness to within 1mm	
	Assessor 1	Assessor 2

1st attempt	yes	yes
2nd attempt	yes	yes
3rd attempt	yes	yes
4th attempt	yes	yes
5th attempt	yes	yes

The maximum number of prongs which were visible by the assessors were 4 out a possible 5 in an experimental setting - sensitivity rate of 80% in the detection of barbs/prongs. Measurements of the silicone's tube and thickness were reliably and accurately measured by both assessors with a sensitivity rate of 100%.

5.4.3 Discussion:

Based on these results the silicone tubing could be reliably visualised with accurate measurements taken, with 100% sensitivity. However, the prongs/barbs could only be detected with 80% sensitivity. Sensitivity rates are likely to be lower in real-life setting and with such low sensitivity rates in an experimental setting, a reliance on taking measurements from the prongs/barbs cannot be made.

5.4.4 Conclusion:

The proximal prongs/barbs of the Medtronic endurant stent could not be reliably detected using USS.

5.5 Exploring alternative markers on the stent graft to measure migration.

As barbs/prongs cannot be reliable detected using ultrasound, methods of calculating the stents orientation with the aorta from a USS cannot be used.

To detect the stents accurate position with the aorta, the stent would need to be either:

1. Constructed from different material for more optimum visualisation

   or

2. Have an inbuilt tracking system, which may interact with an interface to inform the clinician of the stents position within the aorta, or contact with the aortic wall

   or

3. An USS opaque marker may be placed on the stent to allow accurate measurements of the stent from existing landmarks

As described in Stent Graft Eras, stents have evolved radically since their inception by Parodi in 1991, and are now commercially available as 'off the shelf' device. Redesigning a stent for the purposes of ultrasound imaging would require a phenomenal undertaking beyond the scope of this project.

The use of an inbuilt tracking system may be feasible but requires advanced technology and engineering innovations, again beyond the scope of this project [250].

With regards to the third option several materials have been described in the literature as having USS opaque properties, ranging from air, glass and chromium [251]. However before experimenting with such materials, one must appreciate the ultimate aim of such experiments would be to place these trackers within a patient's aorta. Therefore, the product would need to be safe, reliable, and resistant to decomposition. Furthermore, there exist several existing adjuncts used by clinicians, which have been tested and approved by both the FDA and MHRA in the use of proximal neck fixation. It would be pertinent to explore their feasibility in the context of ultrasound imaging, prior to developing a customised tracker.

Multiple comprehensive reviews of existing proximal seal adjuncts have previously been published [252]. However the majority of these adjuncts such as additional cuffs, bare metal stents and chimneys, would possibly distort the and obscure the proximal neck, introduce a

new realm of complications (associated with these adjuncts) and fail to act as a tracking means [46]. The Heli-FX EndoAnchor System (Medtronic Vascular, Santa Rosa, CA, USA) however, are small, low-profile adjuncts, which may be placed inside the fabric of the stent graft. Endoanchors pierce the fabric of the stent graft and become integrated as part of the stent graft [253]. Should the EndoAnchor prove visible on ultrasound, they may also act as markers on the stent graft during USS, allowing for the clinician to calculate the orientation of the graft using landmarks reliably and accurately.

5.6 Employing Helix EndoAnchors as markers for migration

5.6.1 Introduction:

The Heli-FX EndoAnchor System (Medtronic Vascular, Santa Rosa, Calif) is becoming a more commonly used adjunct during endovascular aneurysm surgery [254]. The premise of this technology centres on the use of small helical 'screws' (EndoAnchors) which are used to 'fix' the stent graft to the aortic wall.

An EndoAnchor is deployed through a disposable deployment system using a steerable sheath (16/18Fr OD). An individual EndoAnchor is helical in shape and measures 3mm (diameter) x 4.5mm (length), Figure 49: Helix Endoanchor system. These are introduced intraluminal through a delivery system within the aorta. The EndoAnchor then essentially pierces both the endograft and the aortic wall to fixate the graft to the aortic wall, aiding in fixation and wall apposition [253].

Results from the initial EndoAnchor registry, introduced the use of EndoAnchors for an array of treatment options: as adjuncts to more challenging infrarenal abdominal aortic aneurysms (AAA), with EVAR, prophylactic use to reduce the risk of migration and type 1a endoleaks and in revision surgery. The use of EndoAnchors can be seen in practice, with the recruitment of such technologies being employed in more complex cases as can be seen with the UK Compass trial [255].

The ability to identify and evaluate the EndoAnchors following their deployment, using existing imaging modalities is therefore vital to ensure the safety and efficacy of their use in practice. Furthermore, recent publications have highlighted the relationship between the mal

deployment of the EndoAnchor (and subsequent failure of penetration of the EndoAnchor with the aortic wall) with an increased risk of type 1a endoleaks [256].

Whilst the mainstay of image-based evaluation of the EndoAnchors has been reported using CT modalities, ultrasound duplex remains the overwhelming imaging modality in post-operative EVAR surveillance. To date, no research has yet to describe the appearance of EndoAnchors using ultrasound and to what extent EndoAnchors maybe used in the continued post-operative surveillance of these patients.

5.6.2 Aim:

The aim of this experiment is therefore to describe the appearance of EndoAnchors (Medtronic Vascular, Santa Rosa, CA, USA) using ultrasound imaging and determine if EndoAnchors may be a helpful adjunct in determining the position of the proximal stent graft within an aortic phantom.

5.6.3 Objectives:

1. Describe the appearance of the EndoAnchor, using ultrasound in a conventional setting: the EndoAnchor delivered intraluminally, piercing the proximal portion of the stent graft and aortic model.
2. Describe the appearance of mal-deployed EndoAnchors
3. Determine whether the use of EndoAnchors can be used to measure the position the stent graft within the aortic phantom

5.6.4 Method and Materials

Using the Heli-FX EndoAnchor System (Medtronic Vascular, Santa Rosa, CA, USA) delivery system, and EndoAnchor was delivered through the aortic phantom, 2cm from the proximal end.

Figure 49: Helix Endoanchor system



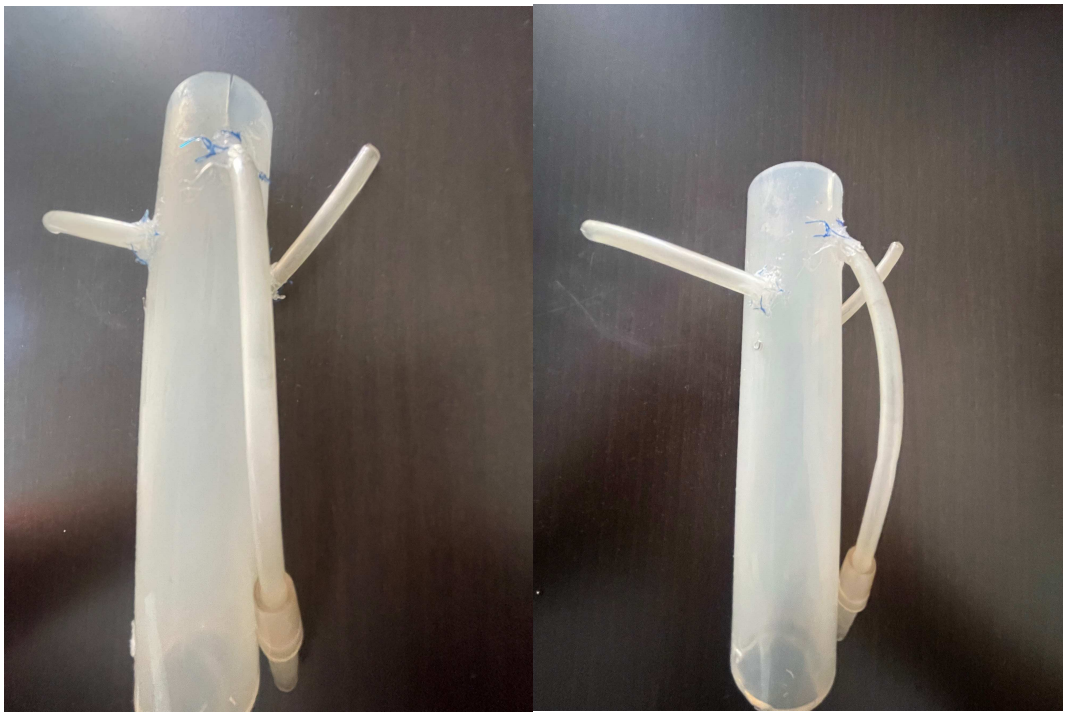
5.6.4.1 Ultrasound and position

Examination of the aortic model was conducted in accordance to standardised method of AAA scanning surveillance [248]. The model was placed in a supine position, with the cranial end slightly elevated, a high-resolution duplex ultrasound scanner (GE LOGIQ-e) with a curved linear transducer (5 MHz) was used to image the model from the coeliac axis to the aortic bifurcation. Multiple transverse and longitudinal B-mode ultrasound images were viewed to ascertain aortic diameter (anterior to posterior) and to identify the anatomy, ensuring they orientate the image plane perpendicular to the axis of the aorta.

5.6.4.2 Phantom

An aortic phantom with renal and superior mesenteric (SMA) arteries was required so that measurements to suitable landmarks could be made. A phantom was therefore fashioned from a silicone tubing: 2mm thick, 160mm long with a luminal diameter of 24mm. Narrower silicone tubing, with a diameter of 5mm served as visceral arteries and the first was implanted into the main larger silicone tube at the 12 o'clock position, 21mm from the proximal edge to represent the SMA, another 5mm tube was placed at the 10 o'clock position 35 mm from the edge to represent the right renal artery, and the last tube was placed at the 3 o'clock position 43mm from the edge to represent the left renal artery. These were secured into place using 4/0 prolene sutures and an epoxy resin, Figure 50.

Figure 50: Aortic Phantom with SMA and renals



A prosthetic silicone skin covering (5mm thick) was used to cover the model, blinding the operator from the position and presence of the EndoAnchor and stent within the aortic model.

5.6.4.3 Stent and EndoAnchors

Examination of EndoAnchors within the proximal aortic neck was required for this study. Therefore, a Medtronic aortic cuff extension (ETCF 28 28 C 49; Medtronic Inc, Minneapolis, Minn) in place of the main body was used as the stent graft. Stainless steel wires where attached to each of the proximal prongs and a 1/0 nylon suture to the distal main body, to allow manipulation of the graft within the aorta, Figure 51.

Figure 51:Medtronic aortic stent graft with attached wires

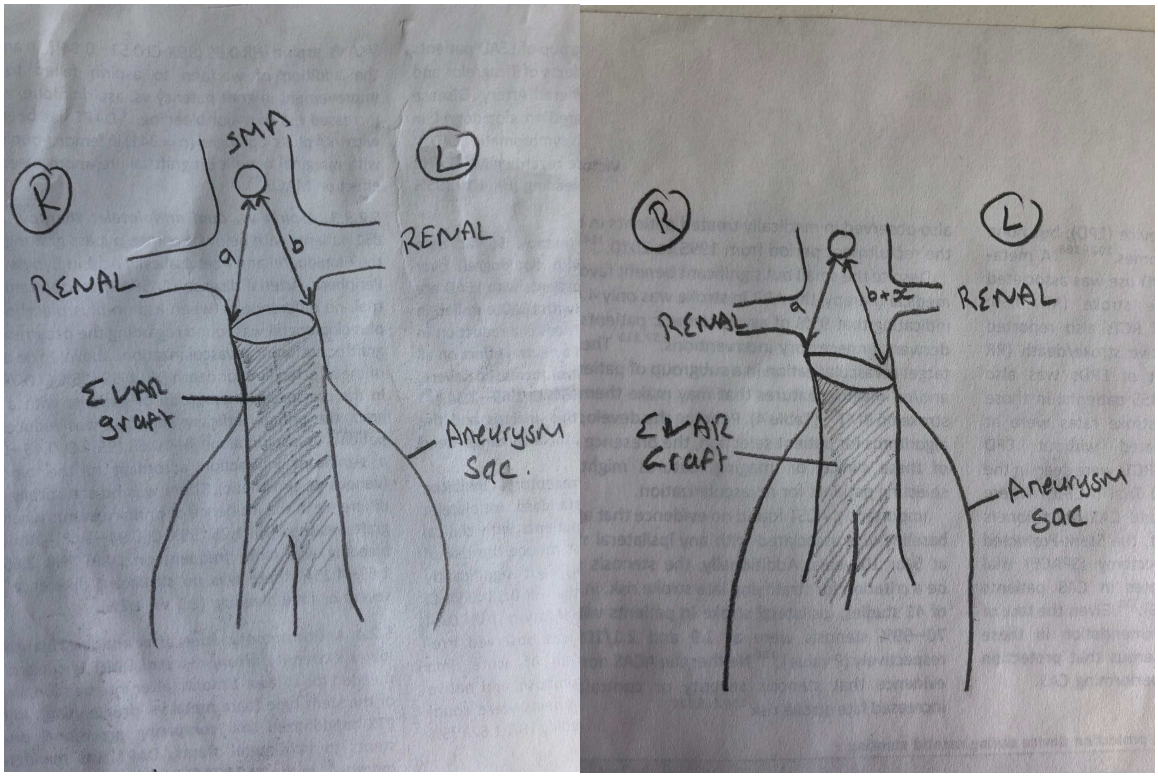


The Heli-FX EndoAnchor System (Medtronic Vascular, Santa Rosa, Calif) was used to deploy EndoAnchors.

5.6.4.4 Positioning of EndoAnchors as markers

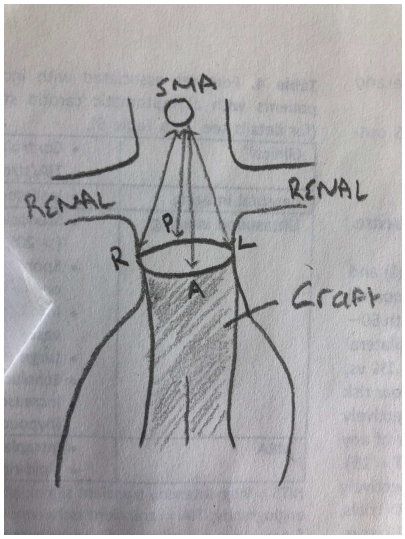
Stent graft migration is typically detected and measured, using serial CT scans following the procedure. However, acknowledging that post-EVAR surveillance has shifted from CT scanning to ultrasound imaging due to the morbidity associated with the former, the previous perceived limitations of US will need to be overcome to be better utilised in the assessment of migration. The evaluation of the position of the proximal infrarenal seal remains a challenge due to the translucency of the fabric material on the stent graft and varied position and orientation in which the proximal prongs are placed within the aortic neck and therefore makes determining reliable measurements from separate regions of the stent graft to a single reference point, challenging [257]. This becomes particularly problematic should the stent graft tilt over time, maintaining its position in one area (e.g. on the right side), whilst migrating on the left (Figure 52)

Figure 52: schematic diagram of SG tilting



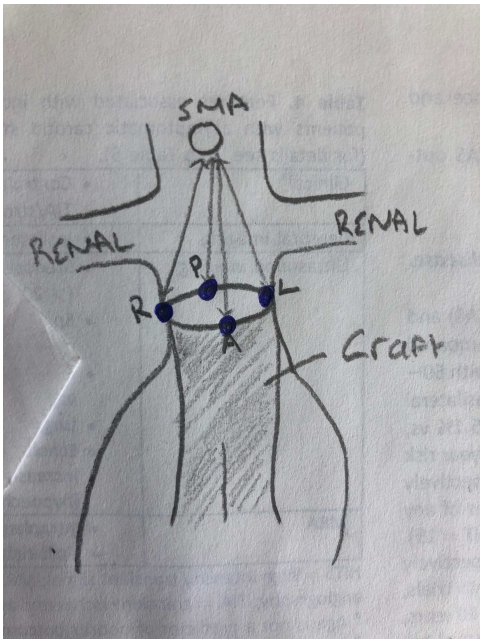
A minimum of 4 separate independent measurements from different regions on the proximal graft to a landmark is therefore required, to ascertain a valid representation of the grafts position within the aorta. We propose measuring the graft to a single reference point - the origin of the superior mesenteric artery (SMA). Measurements from four separate regions of the graft: anterior (A), posterior (P), left (L) and right (R) are to be made to the origin of the SMA (Figure 53).

Figure 53: proposal of the placement of EndoAnchors in 4 quadrants



The same separate regions of the graft will need to be identified when taking measurements to the SMA in each subsequent surveillance ultrasound scan. Furthermore, reliably visualising the different components of the stent graft on ultrasound is highly variable [258]. Ultrasound opaque trackers (placed in the four regions – A,P,R and L), within the stent will aid in identification of the same region of the graft for measurements to the SMA (Figure 54).

Figure 54: Schematic diagram of the placement of the EndoAnchors in the four quadrants



Following a review of existing literature in identifying a suitable material as a tracker the Helix-FX EndoAnchor ® will be evaluated in the following experiments to identify whether it may be used as a suitable marker which can be identified on ultrasound and fixed to the stent graft.

The proposed experimentation relies on taking several measurements from a single reference point (SMA) to separate regions on the stent graft. This may prove unreliable as obtaining long axis views which have both the origins of the SMA (an anterior structure) and reference points (on the posterior wall) may prove challenging. Theoretically, a more reliable method of measuring several placed reference points to the SMA would be to do so from a 3D reconstruction of the aorta (such as CT imaging). However, if the first instance, the feasibility of applying these EndoAnchors in the correct position and then reliably identifying them on US is required. Following this one may then attempt to overcome the challenges of 2D ultrasound scanning by employing 3D ultrasound technology to develop reconstructed images in the later part of experimentation to determine whether this will improve the validity and reliability of determining the orientation of the stent graft within the aorta.

5.7 Visualising EndoAnchors and defining characteristics using USS

The proximal metallic prongs of contemporary stent grafts cannot be reliably visualised using ultrasound. EndoAnchors represent a potential alternative, small, highly echogenic devices already used clinically for fixation, which may serve as ultrasound-visible markers for tracking stent graft position. However, their actual appearance on ultrasound, the features distinguishing appropriate from inappropriate deployment, and whether multiple operators can reliably identify them in practice, all require systematic investigation.

Three experiments were designed to address the following issues:

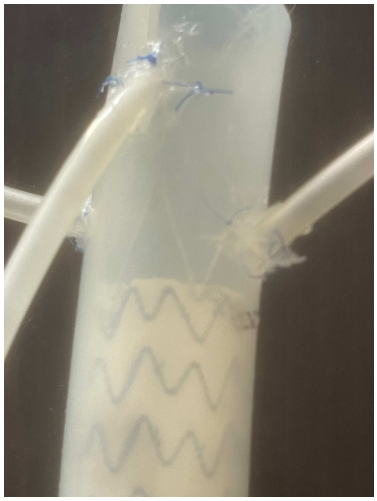
1. To characterise the ultrasound appearance of appropriately deployed EndoAnchors.
2. Examine mal-deployed configurations.
3. Assess whether multiple operators, blinded to stent position, could reliably identify EndoAnchors and measure distances to anatomical landmarks.

A standardised aortic phantom with incorporated visceral branches allowed controlled manipulation of stent graft position whilst maintaining anatomical fidelity. Should EndoAnchors prove reliably identifiable, they may offer a practical solution to the limitations of current ultrasound-based migration assessment.

5.7.1 Experiment 1: Appearance of EndoAnchor deployed appropriately in accordance with IFU

A stent graft was deployed into the model and manipulated into position using the stainless teel wires by two experienced vascular surgeons, landing the stent graft 2mm below the lowest renal artery under visual guidance. EndoAnchors were then placed within 4mm of the proximal fabric edge at 4 points 90^{o} to one another and determined to be anterior, posterior, right and left, Figure 55. Using callipers (Johnson 500mm) the short distance from each of EndoAnchors to SMA ostium was taken.

Figure 55: position 1 SG within the aorta and deployed EndoAnchor



Independent assessments using ultrasound by the two vascular surgeons were made: an assessment of the stent graft and EndoAnchors was conducted recording whether the EndoAnchors could be visualised, and their characteristics in relation to the stent and aortic wall.

5.7.2 Experiment 2: Appearance of mal-deployed EndoAnchor

A new stent graft (ETCF 28 28 C 49; Medtronic Inc, Minneapolis, Minn) was deployed 2mm below the lowest renal artery in the aortic silicone model. The EndoAnchors were placed at the following three positions, under direct vison:

1. 2mm below the proximal edge of the fabric, piercing only the fabric
2. 2 mm below the proximal edge of the fabric piercing the fabric completely and partially piercing the aortic wall
3. 2mm below the proximal edge of the fabric, entirely piercing the fabric and aortic model wall

Using ultrasound, an assessment of the stent graft and EndoAnchors was conducted recording whether the EndoAnchors could be visualised, and their characteristics in relation to the stent and aortic wall.

5.7.3 Experiment 3: Reliability of identifying EndoAnchors

Still ultrasound images of the appearance of EndoAnchors (from Experiment 2: Appearance of mal-deployed EndoAnchor) accompanied with a description of their appearance was provided to 3 operators (three vascular surgeons) who were then invited to scan the model using ultrasound and requested to identify:

1) how many anchors they could identify?
2) determine both their position in relation to the SMA and the distance from the SMA.

The SG was placed in the aorta and fixed using four EndoAnchors (as per Experiment 1: Appearance of EndoAnchor deployed appropriately in accordance with IFU). The model was then covered with synthetic silicone skin, blinding the operators to the position and presence of both the stent graft and EndoAnchors.

The operators were requested to scan three different orientations of the SG within the aortic model:
1) 0.2 cm below the lowest renal with no tilt;
2) 0.2 cm below the lowest renal with 20 degree till from anterior to posterior;
3) 0.2 cm below the lowest renal artery with 20 degree tilt from left to right (pic4).

The operators were blinded to the position and orientation of the SG and requested to scan each orientation five times. Each operator would therefore perform 15 scans in total. As there were three operators performing 15 scans each, a total of forty-five scans would be performed in total.

5.7.4 Results

5.7.4.1 Experiment 1

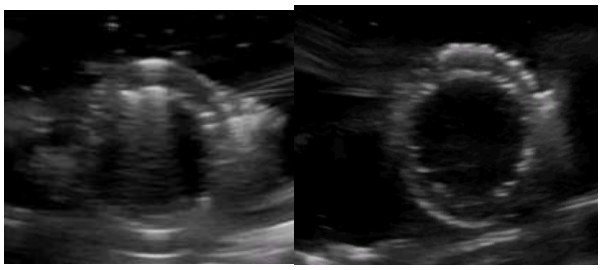
The two operators were able to view all four EndoAnchors.

A summation of the agreed ultrasound appearance between the two operators:

1. Highly echogenic, material traversing the stent graft and all layers of the aorta;
2. A sharp appearance measuring approximately 3-5mm in length 3mm in diameter.

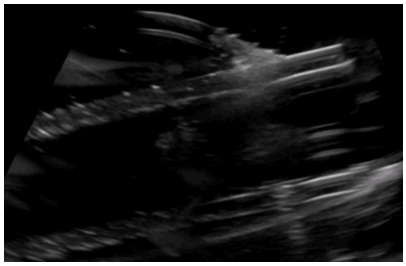
3. A distinguishing feature is that echogenic material could be seen both outside and inside of the aortic wall
4. On occasion can present as 2 separate echogenic circular ‘dots’ (1-2mm) outside the aorta with a parallel single circular echogenic projection within the aorta.
5. Can be distinguished from stent material and aortic calcification as traverses’ layers of the aortic wall
6. No overt shadowing seen

Figure 56: USS appearance of EndoAnchor - axial views



EndoAnchor seen at the 2 o’clock position

Figure 57:USS appearance of EndoAnchor - sagittal view



EndoAnchor seen posteriorly, opposite the LRA origin

5.7.4.2 Experiment 2

The two operators were able to view all four EndoAnchors.

A summation of the agreed ultrasound appearance between the two operators:

Configuration 1: EndoAnchor piercing only the stent graft, Figure 58

1. Sharp appearance of highly echogenic material extending from the graft/aortic wall into the lumen
2. Measuring 3-5mm in length
3. At times difficult distinguishing from stent material
4. No overt shadowing

Figure 58: penetration of stent only, not involving the aortic wall



Configuration 2: EndoAnchor piercing the stent graft and partial piercing of the aortic wall

1. Difficult to differentiate from EndoAnchors only piercing the SG intraluminally
2. The absence of the EndoAnchor outside the aortic wall was indicative of its mal-deployment.

Configuration 3: EndoAnchor Piercing the stent graft and aortic wall in its entirety, Figure 56. Figure 59 displays an appropriately placed EndoAnchor, in which the EndoAnchor has fully pierced the aortic wall and extends beyond it

Figure 59: An appropriately placed EndoAnchor, which has fully penetrated the aortic wall, below the left renal artery



Appearances of the EndoAnchor, as described in Experiment 1.

5.7.4.3 Experiment 3:

Table 48 summarises the results of Experiment 3. All three operators were able to correctly identify all 4 EndoAnchors in each of the set orientations. Assessments of whether they were successful in making accurate measurements of the EndoAnchors to the SMA within 2mm were assessed. No accurate measurements could be made, whilst the probe was horizontal, using axial images as they were unable to ensure both the origin of the SMA and EndoAnchor could be caught within the same image. Measurements could only be taken when images where taken in the sagittal projection, when both the origin of the SMA and the EndoAnchor could be seen on the same image, as was the case with the anterior and posteriorly positioned EndoAnchors.

Table 48: Experiment 3 results, measuring EndoAnchors to SMA in aortic model

	operator 1	operator 2	operator 3
SG position 1: 0.2 cm below the lowest renal with no tilt			
Identify all 4 EndoAnchors	1	1	1

correct measurement from SMA to EndoAnchor -anterior	1	1	1
correct measurement from SMA to EndoAnchor - posterior	1	1	1
correct measurement from SMA to EndoAnchor - left	0	0	0
correct measurement from SMA to EndoAnchor - right	0	0	0
SG position 2: 0.2 cm below the lowest renal with 20-degree tilt from anterior to posterior			
Identify all 4 anchors	1	1	1
correct measurement from SMA to EndoAnchor -anterior	1	1	1
correct measurement from SMA to EndoAnchor - posterior	1	1	1
correct measurement from SMA to EndoAnchor - left	0	0	0
correct measurement from SMA to EndoAnchor - right	0	0	0
SG position 3: 0.2 cm below the lowest renal artery with 20-degree tilt from left to right			
Identify all 4 EndoAnchor	1	1	1
correct measurement from SMA to EndoAnchor -anterior	1	1	1
correct measurement from SMA to EndoAnchor - posterior	1	1	1
correct measurement from SMA to EndoAnchor - left	0	0	0
correct measurement from SMA to EndoAnchor - right	0	0	0

Summary of results from Experiment 3. 1 = successful, 0 = not successful

5.7.5 Conclusion

Using USS, EndoAnchors could be correctly and reliably identified. Furthermore, a clear description of adequately place EndoAnchors could be determined using USS. Valid measurements of the EndoAnchors to a landmark (SMA) could only be made in the event the EndoAnchor was placed parallel to the origin of the SMA, Endoanchors placed out of the line of sight could not be reliably measured using USS.

5.7.6 Discussion

These experiments have demonstrated that EndoAnchors may be readily identified using ultrasound. However, ascertaining reliable measurements from appropriate landmarks (such as the SMA) to EndoAnchors are limited to those EndoAnchors placed in parallel to the SMA. Whilst this may be helpful in monitoring the position of the graft's migration and orientation only in anteriorly and posterior portion, it is not possible to comment on left and right position of the graft. The assessment of multiple collated axial images, to generate a reconstructed image of the aorta may be helpful in mapping out a valid reconstruction on which valid measurements may take place.

5.8 Identifying a suitable 3-dimensional ultrasound platform

Advances in software and technology attempt to take advantage of the benefits of existing familiar two-dimensional ultrasound, in providing more information. 3D ultrasound continues to be an innovative and developing technique, which has grown since the late 1980's. The approach in the development of 3D ultrasound systems revolves around the ability in augmenting 2-dimentional images into a third dimension. This has typically involved two main methods. The first involves dedicated probes with a 2D arrangement of transducer elements, as opposed to simple 1D arrays. These probes can either form a full 2D matrix or combine perpendicular rows. In such systems the 3D data is acquired immediately to form the 3D image. The disadvantage of such methods are higher costs, larger footprints that make scanning more cumbersome, and decreased image quality due to the rectangular arrangement of transducer elements[259].

The second is the freehand method, which has several advantages over using a 3D US transducer, such as lower cost, higher volume quality, and an improved field of view (FOV) [260]. However, capturing a 3D US volume with the freehand technique is challenging due to localisation sensor errors, low calibration accuracy, delays in the reconstruction algorithm and the need for high-performance computing systems like GPU (Graphics Processing Unit) based visualization [261]. Nevertheless, several benefits of the freehand method have been published including providing comprehensive visualisation, reducing operator dependence, providing orientation-independent images viewing, measuring quantitatively, reliability of 'region of interest' (ROI) and fusing with other 3D modalities [262].

5.8.1 Benefits of 3-dimensional USS

In the context of vascular imaging, the entire abdominal aorta may be visualised as a 3D surface or volume using interpolation, segmentation, and registration methods. By automatically generating 3D images, this permits direct screening of anatomy during diagnostic exams on the user interface, eliminating the need for operators to mentally transform 2D B-scans into a 3D view and makes the acquisition step easier and less reliant on operator expertise, i.e once the aorta is scanned, the 3D image of the aorta is automatically generated, without the need for the operator to interpret the images based on their interpretation of their 2D assessment. The 3D images enable viewing of any plane, regardless of orientation, including those not possible with conventional ultrasound methods (coronal), allowing the operator to re-examine and depict the aorta from different viewpoints after the patient has left, and share data with other experts to enhance diagnosis [259]. 3D images can also provide accurate quantitative measurements to measure the aortic volume, at different segments, rather than relying solely on diameter measurements. More accurate comparisons may also be made between serial imaging, as the dependence on operator's to replicate the exact image are not as necessary, i.e. during AAA surveillance the operator is expected to provide the largest diameter of AAA, and may not measure the exact cross-section each time, by generating a 3D image, one may configure their repeated measurements to a particular segment, reducing intra and inter assessor variability. Lastly, there have been attempts to fuse 3D imaging from different modalities, using specific software, which would allow direct comparison of anatomy between modalities [262].

5.8.2 Freehand 3-dimensional ultrasound

With freehand 3D ultrasound an operator manoeuvres the traditional 2D transducer probe which has a tracking device attached to it over the region of interest (ROI). The acquired 2D B-scan US images are then arranged in accordance to their corresponding positions and orientation (using data from the tracking device) and then transmitted to a computer for further processing and volume reconstruction, creating a 3D image [259]. As the 2D images generated from the US machine are similar to that obtained from a traditional US scan, the difference in technologies will revolve around the tracking system employed.

Tracking systems may comprise various technologies, either singly or in combination such as electromagnetic sensors, acoustic or optical sensors, mechanical arms, fibre-optic cables, inertial measurement units (IMUs), or skin feature tracking using cameras or laser sensors [263]. An accurate tracking system requires tracking of the US transducer's position and orientation with six degrees of freedom (6 DOF) be utilised [262].

Since the tracking system only specifies the US transducer's positions and orientations and not the image output, spatial calibration is necessary to map each pixel of the B-scans to the corresponding voxel in the 3-D volume. Additionally, temporal calibration and filtering steps, which remove unnecessary data, are required to synchronise the B-scans with the location data [264].

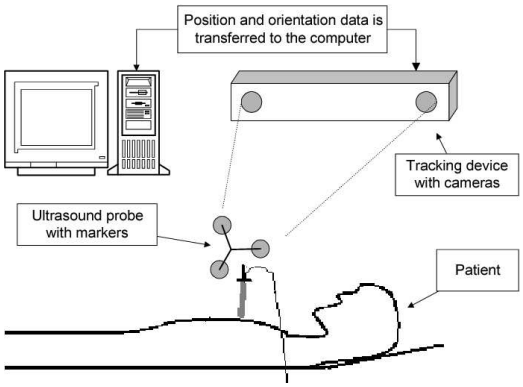
Within freehand systems, electromagnetic and optical sensors are frequently used in research due to their high precision; however, may be limited by sensitivity to metal and line-of-sight requirements, respectively. Electromagnetic sensors are the most cost-effective and convenient localisation method, using AC or DC magnetic fields. DC magnetic sensors are less affected by metallic materials, whereas AC types are more accurate [262].

Mozafferi et al's systematic review of 3D US technologies, identified that using freehand technologies allowed operators to achieve higher quality B-slices by utilizing images from multiple insonation angles. Furthermore the field of view (FOV) of the ultrasound volume can be expanded using a 3-D probe equipped with an optical tracking system and a block-based registration of the ROI sections [262]. Given these collective findings the use of freehand 3D US technology will be evaluated in the context of SG migration within the aorta.

5.8.3 Electromagnetic vs Optical sight freehand 3D US

Optical sensors have been employed through various approaches, using an optical tracking system with optical markers to measure the US probe's position. Studies have shown that commercial optical tracking systems can achieve position errors of less than 1 mm and orientation errors of less than 1°. However, direct line of sight must be maintained between the marker on the probe and the optical positioner to ensure continuous focus is maintained on the marker on the US probe. The line of sight may be easily interrupted as the probe or examiner moves. Moreover, the lighting conditions could also affect the registration of the marker and subsequently further complicate the valid tracking ability, Figure 60 [265]. Alternatively, mounting a camera onto the probe may help mitigate this issue, by recording its position relative to the patient's skin. This however requires complicated algorithms to estimate the probe's motion and is hampered by its lack of accuracy as it is highly dependent on external factors such as light variations and the visibility of skin features [261].

Figure 60: Schematic image of optic tracking using freehand US.

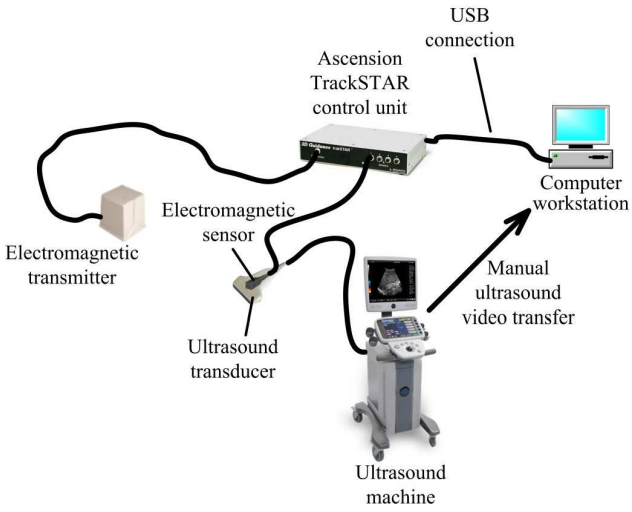


Szabo et al (2004). [265]

Electromagnetic tracking employs electromagnetic (EM) sensors that are small, flexible, and resistant to visual obstruction. The sensor is positioned and calibrated to the US transducer, and the electromagnetic generator is placed in close proximity to determine the position and orientation of the transducer, in relation to the generated 2D images, Figure 61. However, their tracking precision can be compromised by EM interference and the presence of metal

objects, leading to distortion. Position sensors possess the properties resilient to such issues, however, exhibit relatively low accuracy and can be easily affected by environmental factors like sound, temperature, and humidity. To overcome this combining the different currents can help overcome the respective limitations [266].

Figure 61: Schematic diagram of electromagnetic tracking in freehand US



Daoud et al (2015), [267]

An evaluation of both freehand technologies will therefore be evaluated to ascertain the feasibility of employing such technologies in the evaluation of SG migration within the aorta. An initial assessment of accurately delineating aorta, its branches and EndoAnchors was attempted.

5.8.3.1 Experiment: an assessment of the feasibility of using optical sight tracking in assessing the aortic anatomy in an aortic phantom

5.8.3.1.1 Aim:

To determine the feasibility of 3D ultrasound, using optical sight in making reliable measurement from the EndoAnchors to a designated landmark (representing the SMA)

5.8.3.1.2 Methods:

Outlined are the steps to design an optical tracking system for an ultrasound transducer. The system uses a QR code affixed to the transducer (Figure 62) and a camera placed at a distance to track the position and orientation of the probe. The accuracy and reliability essential for tracking will be assessed to determine the feasibility of employing such technology

Figure 62: QR code affixed to the transducer for optical tracking



5.8.3.1.2.1 Materials and Equipment

1. Ultrasound transducer: GE LOGIQ-e, with a curved linear transducer (5 MHz)
2. QR code image: (https://me-qr.com/saving-high-res-codes)
3. High-resolution camera: Canon MB2000
4. Mounting stand for the camera
5. Computer with image processing software: Visp auto tracker
6. Calibration grid or object

5.8.3.1.2.2 Procedure

The methodological process was planned as below to determine a suitable protocol to generate reliable and valid 3D US images from which valid measurements may be taken.

1. QR Code Generation and Placement

- Generate a high-contrast QR code using an online generator or software, using Visp Auto tracker .
- Print the QR code onto non-reflective, waterproof card

- Affix the QR code securely to a visible, flat surface on the ultrasound transducer.

2. Camera Setup

- Position the camera on a stable mounting stand approximately 1-1.5 meters away from the transducer.
- Ensure the camera has a clear, unobstructed view of the QR code on the transducer.
- Connect the camera to a computer for live feed and data processing.

3. Calibration

- Place a calibration grid or object at the location where the transducer will be used.
- Capture multiple images of the calibration grid from the camera's perspective.
- Use these images to calibrate the camera, ensuring accurate measurement of distances and angles.

4. Image Capture and Processing

- Employ the visp autotracker as image processing software to detect the QR code and extracting positional data.
- Set up the software to process live video feed from the camera.
- Implement algorithms to detect the QR code, decode its information, and calculate the position and orientation of the transducer based on the QR code's geometry.

5. Position and Orientation Calculation

- Use the positional data extracted from the QR code to determine the transducer's exact location and orientation in 3D space.
- Apply mathematical models to convert the 2D image coordinates into 3D spatial coordinates, using auto tracker software.

6. Validation and Testing

- Compare images generated and measurements taken form the scan to physical measurements of the phantom using calliper, to determine validity.
- Repeat the process using different assessors and phantoms to test reliability.

5.8.3.1.3 Results

The designed optical tracking system effectively tracked the position and orientation of an ultrasound transducer using a QR code and a camera, whilst the transducer remained in the line of site and not angulated beyond 5 degrees. This allowed images to be generated and tracked within a single trajectory only. A complete scan of the proximal aortic model was not possible. The transducer was required to remain completely perpendicular to the model and manoeuvring the transducer across the 'y'or'z' axis or changes to the angle of insonsation resulted in the interruption of line of sight and therefore unable to produce valid or reliable images, representing the entire proximal aortic model or region of interest (aortic neck)

5.8.3.1.4 Conclusion

The limitations of the optical tracking in generating 3D ultrasound images could not be overcome within the lab setting. Tracking of the images relied heavily on maintaining line of sight. In a setting where the transducer probe is required to be manipulated constantly across the different axis, the use of optical tracking is not feasible. Translating this to 'real-life' setting would likely prove more challenging and therefore the decision not to proceed with optical tracking was made.

5.8.3.2 Experiment: an assessment of the feasibility of using electromagnetic tracking in assessing the aortic anatomy in an aortic phantom

5.8.3.2.1 Aim:

To determine the feasibility of 3D ultrasound, using electromagnetic tracking in making reliable measurement from the EndoAnchors to a designated landmark (representing the SMA)

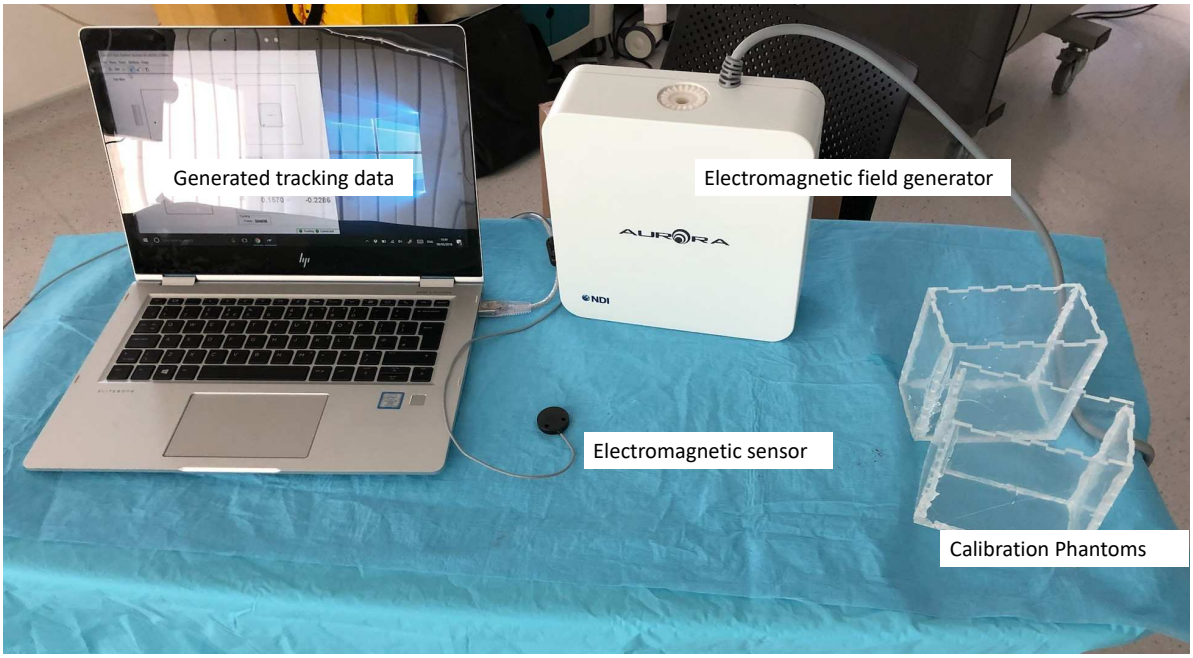
5.8.3.2.2 Materials and Methods

Outlined is the proposed methods and protocols to determine whether reliable and valid measurements may be taken from 3D generated images using electromagnetic tracking (EMT).

5.8.3.2.2.1 Equipment

- 3D Ultrasound System: GE LOGIQ-e, with a curved linear transducer (5 MHz).
- Electromagnetic Tracking System: Aurora system by Northern Digital Inc. (NDI): Aurora Field Generator Tabletop 50-70, Aurora 6DOF Reference, 25 mm Disc, Standard and AURORA FG Connection Cable, Figure 63.
- Aortic Model: Synthetic aortic model, as used in previous experiments, Figure 50.
- Callipers: Precision callipers from Johnson & Johnson for manual measurements Model #: 1889-0600
- Calibration Phantom: For calibrating the ultrasound and EMT systems, created using 3D printer, with predefined measurements, Figure 63.
- Data Acquisition Software: Custom-developed software for capturing and processing ultrasound and EMT data.

Figure 63: EMT setup



5.8.3.2.2.2 Experimental Setup

5.8.3.2.2.2.1 Calibration:

5.8.3.2.2.2.1.1 Calibration of the Electromagnetic Tracking (EMT) System:

The NDI Aurora calibration was carried out in line with the manufacturers guidelines to perform system calibration. This involves placing the calibration phantom within the

electromagnetic field and running the calibration, which adjusts the system to minimize tracking errors. Following the manufacturer's guidelines to ensure accurate tracking.

5.8.3.2.2.2.1.2 Calibration of the 3D Ultrasound System:

A multi-modal calibration phantom was 3D printed with predefined dimensions, that can be imaged using both ultrasound and tracked by the EMT system, Figure 63. A cross-modality calibration was carried out by imaging the phantom with the ultrasound system while simultaneously tracking its position with the EMT system. The manufacturers software package would then be used (NDI Cygna-6D™) to correlate the ultrasound images with the tracked positions, ensuring that the spatial coordinates in the ultrasound images match the EMT data.

5.8.3.2.2.2.2 Model Preparation

The model would be positioned within 1 metre of the EMT to ensure it remained within the EMT electromagnetic field, whilst being able to view the images on the US machine to guide the manipulation of the transducer. The EM sensor would be fixated to the transducer prober, Figure 64. Aortic model dimensions were made manually using callipers prior, to compare to those generated by the EMT system.

Figure 64: EM sensor to transducer



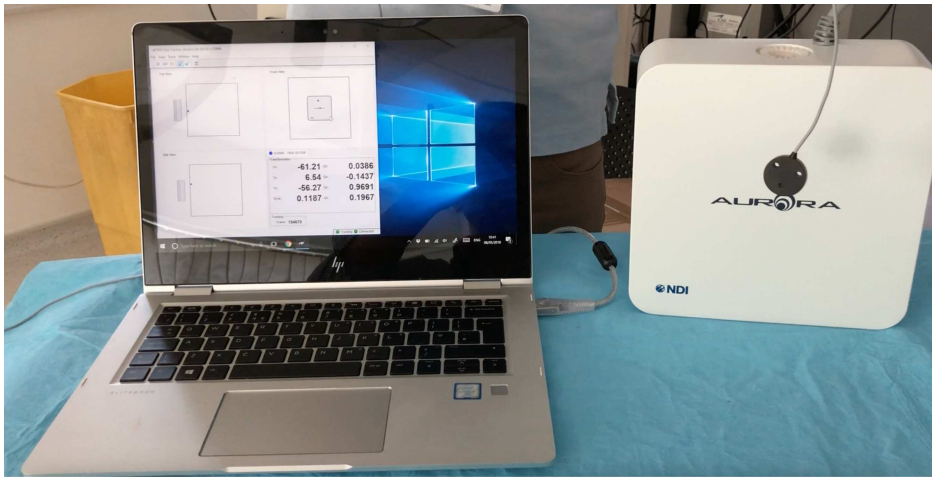
5.8.3.2.2.2.3 Data Acquisition:

5.8.3.2.2.2.3.1 Development of Data Acquisition Software:

Custom software would need to be developed to integrate ultrasound image capture with EMT data recording. The software should generate an interface with the ultrasound system to acquire 3D images and a further interface with the Aurora system to receive real-time tracking data. Further synchronisation would be required of the ultrasound images with the corresponding EMT data. With the ultimate aim of creating a user interface for real-time visualisation and control.

Scanning Procedure:
The scan of the aortic model would be carried out using the set up described above ensuring the EMT system accurately tracks the probe's position and orientation. With the aim of acquiring multiple measurements of key parameters (diameter, length, of aorta and landmarks) at predefined locations along the aortic model. Record the EMT data for each ultrasound image, Figure 65. Repeat the ultrasound scans multiple times to assess reproducibility.

Figure 65: data recordings of EMT, using Aurora NDI



The spatial data is captured from the sensor and recorded

For the data processing stage, the extraction of the 3D ultrasound images and EMT data from the acquisition software, using custom software to reconstruct 3D models from the ultrasound data; incorporating the EMT data for spatial accuracy, would be required. Aligning the ultrasound-derived measurements with manual measurements using fiducial markers for reference.

5.8.3.2.3 Results

In utilising this method, the spatial data of the sensor was calibrated and subsequently adequately recorded. At the same time images generated by the transducer were also captured and had to be manually correlated with the spatial data. An interfaced was required to integrate ultrasound images captured with EMT data recordings – to produce a 3-dimensional image. A software engineer was consulted, as to how best to develop such software. The development of this software interface would require several months to develop and would demand an initial fee of £15,000 and subsequent validation.

5.8.3.2.4 Conclusion

This experiment displayed the feasibility and preference of using EMT over optical tracking. Tracking was uninterrupted and ultrasound images could be correlated to spatial data, to provide the base data from which a 3D ultrasound image may be created. This however could not be carried out as an interface was not created. As the development of this interface was beyond the scope of this project, it was felt employing an existing validated EMT system, would be more appropriate.

5.8.3.3 Identifying an electromagnetic tracking 3D ultrasound system

The PIUR tUS tomographic ultrasound system was identified and selected for further evaluation [259]. This system was preferred due to its integration of external electromagnetic tracking, which we have identified is preferred in obtaining precise and accurate 3D imaging. This system combines high-resolution tomographic ultrasound capabilities with refined electromagnetic tracking to provide real-time spatial data of the ultrasound probe's position and orientation. The dual modality of tomographic imaging and electromagnetic tracking allows for a detailed and reliable measurements of the aortic model. Following a review of various systems, it was felt the PIUR tUS system was preferred due to its user-friendly interface, robust data acquisition capabilities, and image reconstruction algorithms. Additionally, the system's effectiveness and reliability have been validated in previous published studies, corroborating its validity and reliability [259, 264, 268, 269].

When compared to other systems on the market, such as the Clarius HD3 with its wireless ultrasound probes, the GE LOGIQ E10 with its cSound Architecture, and the Philips Lumify,

the PIUR tUS system offered us a distinct advantage. This system could be attached to our existing ultrasound machine as an adjunct and did not need to replace our existing hardware. Rather this would be an additional component to the existing machines we are familiar with. Furthermore, some of the alternative systems employ optical tracking or do not provide integrated electromagnetic tracking, which can result in less accurate spatial localisation and increased susceptibility to line-of-sight issues or environmental interferences. It was felt the PIUR tUS system's incorporation of external electromagnetic tracking is likely to provide a more robust and precise probe localisation without the constraints associated with optical systems, thereby enhancing the accuracy and repeatability of measurements.

5.8.3.4 PIUR Tomographic Ultrasound (tUS) for 3D vessel analysis

PIUR tUS has been advertised to allow rapid scanning and 3D visualisation of arteries and veins to assess optimal vessel analysis including measurements and volume, to accurately plan intervention. Its integrated software and interface aims to reduce operator dependency in acquiring such measurements and may help identify complications at early stage. This system employs the same technology as mentioned in the previous Experiment: an assessment of the feasibility of using electromagnetic tracking in assessing the aortic anatomy in an aortic phantom. Using EM field generator, which picks up the spatial data from a sensor which can be attached to an US transducer probe (this is not a specific probe and can be one already in use by the department for routine duplex assessment) and is calibrated accordingly, Figure 66. The manufacturer have their own integrated software and interface which combines the spatial data with images generated from the US scan to create a 3D image, with axial, coronal and sagittal planes, Figure 67 [270, 271] :

Figure 66:Schematic PIUR tUS, © piur imaging GmbH 2018

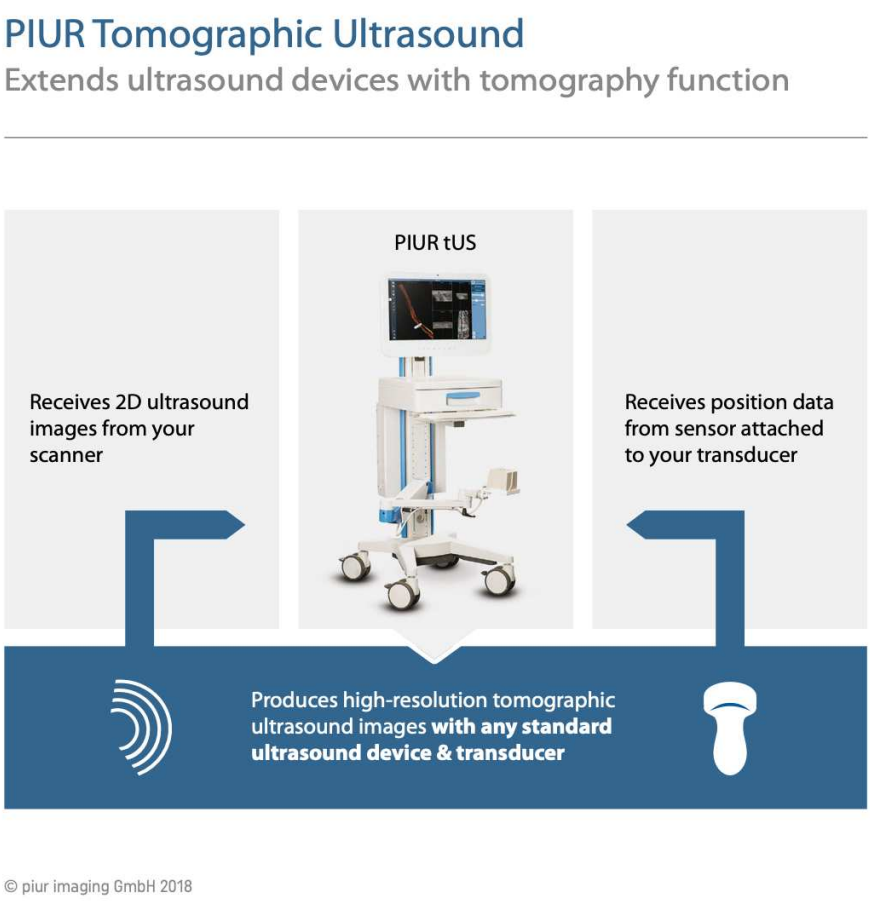
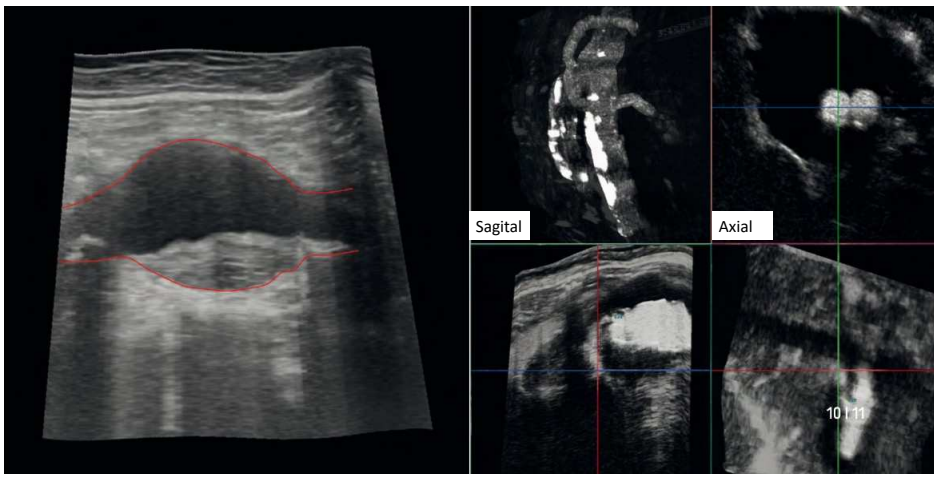


Figure 67: PIUR tUS aortic reconstructions of a patient during EVAR surveillance, © piur imaging GmbH 2018



5.8.3.5 Experiment: Validating PIUR tUS for Aortic Model Measurements, an assessment of feasibility

5.8.3.5.1 Objective

To determine the feasibility and accuracy of using the PIUR tUS tomographic ultrasound system to measure the dimensions of an aortic model, including the distance from the EndoAnchor of an EVAR stent graft to the superior mesenteric artery (SMA).

5.8.3.5.2 Equipment

- PIUR tUS tomographic ultrasound system
- GE LOGIQ-e, with a curved linear transducer (5 MHz)
- Aortic model with an EVAR stent graft and EndoAnchor

5.8.3.5.3 Methodology

5.8.3.5.3.1 System Calibration

A 3D printed sensor mount was created and placed on to the probe to ensure fixed location for the sensor. The ultrasound images where then calibrated with the tUS system for each of the 0.5cm depth intervals from 0.5 – 20cm, by the manufacturer, for the GE LOGIQ-e, with a curved linear transducer (5 MHz) in our lab, to ensure the electromagnetic tracking system is accurately aligned with the ultrasound probe. The calibration was verified by measuring known distances within the manufacturers calibration phantom and comparing them to expected values.

5.8.3.5.3.2 Preparation of the Aortic Model

The aortic model was prepared in the same manner as with the EMT experiment, Model Preparation, Figure 68.

Figure 68: Model preparation within a water-bath for EMT US evaluation



5.8.3.5.3.3 Data Acquisition

The transducer was placed approximately 3-6 cm above and perpendicular to the aortic model, providing axial images and scanned with one sweep, along the length of aortic model to capture comprehensive multiple US still images, which would be transferred to the PUIR tUS system to generate 3D tomographic images.
Multiple scans would then be performed to capture the entire length of the aorta at different angles to ensure the ensure the regions of interest around the stent graft, landmarks and EndoAnchor, were captured.

The generated reconstructed images would then need to be manually processed, in each of the 3 views (axial, coronal and sagittal) to inform the interface of vessel and areas of interest. This would require identifying the inner and outer parts of the vessel, delineate the length of the vessel, branches of aorta and EndoAnchor. Following this manual insertion of data, a 3D image is generated.

5.8.3.5.3.4 Measurement Validation:

1. Identify key anatomical landmarks on the 3D images: aortic diameter, and the SMA and EndoAnchor.
2. Use the PIUR tUS software to measure the aortic dimensions and the distance from the EndoAnchor to the SMA.

3. Compare these measurements to those obtained using manual callipers as the reference standard.

5.8.3.5.3.5 Data Analysis

1. Analyse the consistency and accuracy of the measurements obtained from the PIUR tUS system.
2. Calculate the mean, standard deviation, and measurement error relative to the manual calliper measurements.
3. Perform statistical analysis to determine the validity and reliability of the PIUR tUS measurements.

5.8.3.5.4 Results

The initial sweep of the transducer across the length of the aorta, generated the following stacked images in an coronal (Figure 69), sagittal (Figure 70) and axial (
Figure 71) plane.

Figure 69: Stacked images projecting appearance in a coronal plane

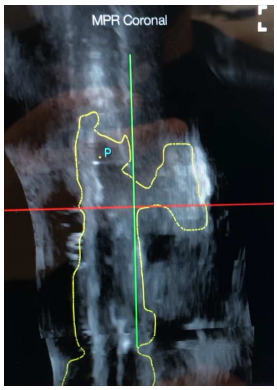


Figure 70: Stacked images projecting appearance in a sagittal plane

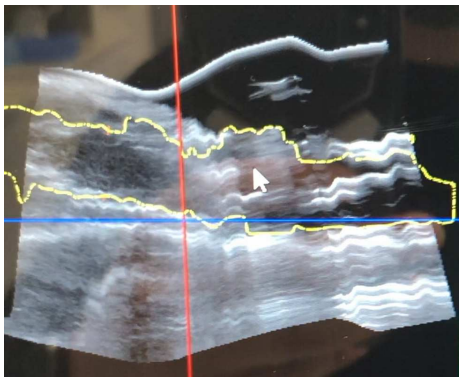
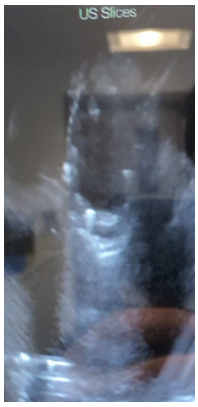
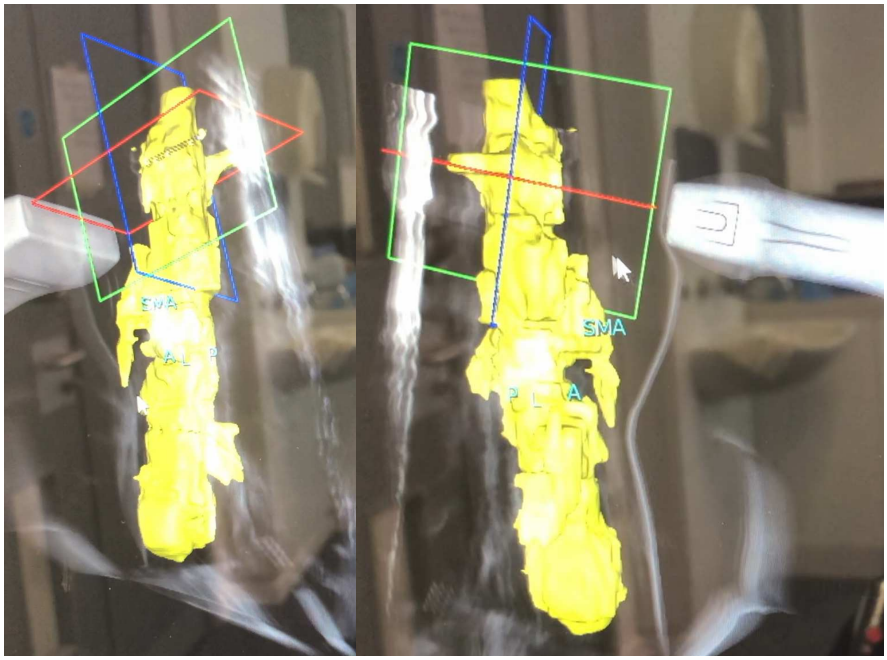


Figure 71: Axial image of proximal aortic model displaying the anterior (A), posterior (P), left (L) and right (endoAnchor)



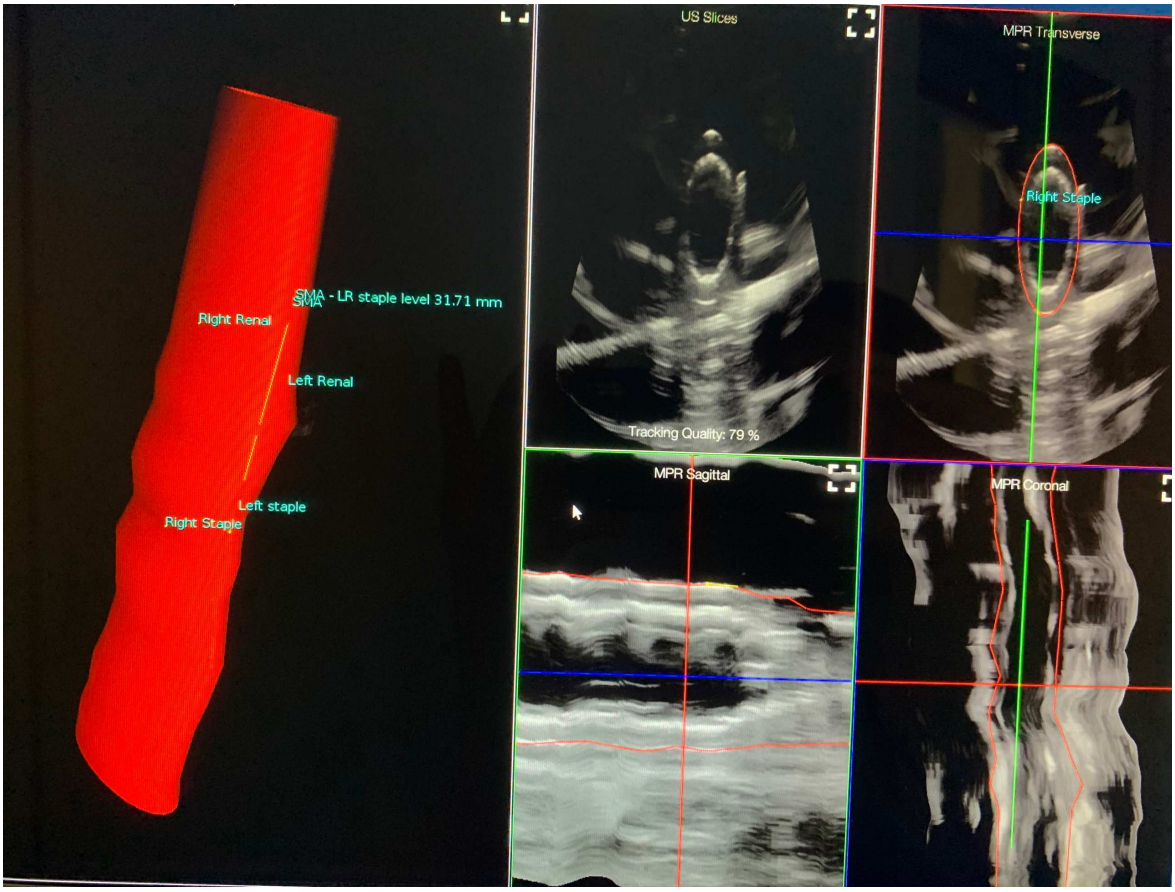
The puir tUS system has an inbuilt algorithm in which it attempts to capture what it believes is the vessel out line (yellow line). This was invariably incorrect and required a lengthy process of attempting to rectify this to the correct dimensions. Figure 72 displays the 3D image of the imaged aorta. This is the initial image in which attempts were made to correct the actual vessel wall, however, as can be seen the image does not adequately represent the aortic vessel and as such valid measurements could not be made by measuring the outline of the phantom (in yellow). What was possible however, was to accurately mark the position of the 4 EndoAnchors and the origin of the SMA. The 4 EndoAnchors were marked as anterior (A), posterior (P), left (L) and right (R). Direct linear measurements were then made from the SMA to each of the EndoAnchors within 1mm.

Figure 72:generated 3D image of aortic model



Further refinement of the image was carried out using the product software to better represent the aortic anatomy, for a more aesthetic visual appearance of the aortic model. Figure 73, displays a clearer 3D image with the same markers placed to represent the visceral origins and measurements taken. The refinement process took a further 55 minutes to achieve however had no bearing on the measurements taken, as these were based on the markers placed and not the image generated.

Figure 73: Refined 3D generated image of the aortic model



5.8.3.6 Experiment: Validating PIUR tUS for Aortic Model Measurements, an assessment of reliability and validity

5.8.3.6.1 Objective

To validate the accuracy of the PIUR tUS tomographic ultrasound system in measuring the dimensions of an aortic model and the distance from an EVAR stent graft EndoAnchor to the superior mesenteric artery (SMA).

5.8.3.6.2 Materials and Methods

5.8.3.6.2.1 Equipment:

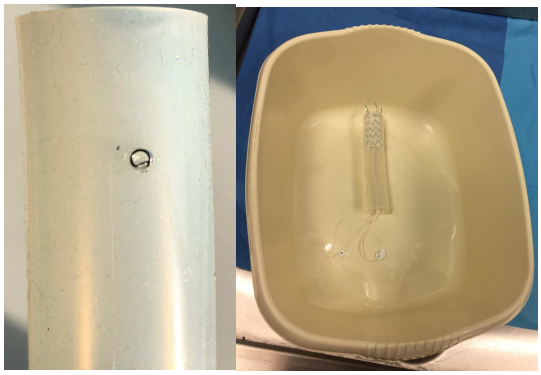
- PIUR tUS tomographic ultrasound system
- Aortic model with EVAR stent graft and EndoAnchor

- Manual callipers for reference measurements

5.8.3.6.2.2 Operators and instructions

3 vascular surgeons were employed to perform blinded measurements of the aorta. An initial 90-minute lesson was first delivered to explain the software, requirements and to practice on an alternative phantom containing an EVAR endograft and EndoAnchor (Figure 74), to aid in familiarity.

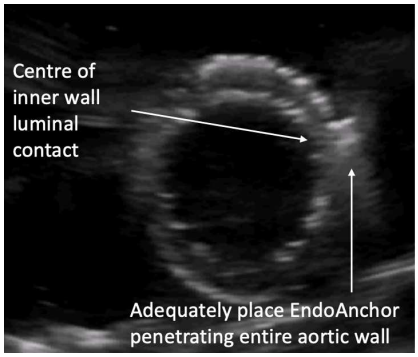
Figure 74: Alternative aortic model for operator practice and familiarity



5.8.3.6.2.3 Instructions

- Identify 4 EndoAnchors and correctly label them as anterior, posterior, left and right.
- Identify the origin of the SMA and correctly label it
- Generate a 3D image using the software – without the need to generate a proportional image, given the inherent difficulties with the PUIR imaging software, which is very labour intensive.
- Use the markers set to measure the distance between the SMA and anterior EndoAnchor, the SMA and posterior EndoAnchor, the SMA and left EndoAnchor and the SMA and right EndoAnchor.
- Measurements to the endo anchor should be made from the level of the centre inner luminal contact (Figure 75), to ensure a standardised point for measurements.

Figure 75: Measurement to be taken from centre of inner wall luminal contact



5.8.3.6.2.4 Operator Blinding and Repetition

Operators were blinded to the measurements of the aortic model and informed the EndoAnchors would be placed at different locations for their different scans. Each operator performed three independent scans, resulting in a total of nine measurements per parameter.

5.8.3.6.2.5 Data Analysis

An analysis of the consistency and accuracy of measurements from the PIUR tUS system was calculated based on mean values, standard deviations, and measurement errors compared to manual calliper measurement, using statistical analysis to determine the validity and reliability of the PIUR tUS measurements.

5.8.3.6.3 Results

Table 49: Results table, using PUIR tUS to measure EndoAnchors to SMA

Measurement	**Manual (Ref)**	**Operator 1**	**Operator 2**	**Operator 3**	**Mean PIUR**	**Difference (Mean PIUR - Ref)**
SMA to A	30	29, 31, 31	32, 30, 29	29, 30, 30	30.0	0.0
SMA to P	40	42, 41, 39	42, 41, 42	42, 41, 41	41.4	1.4
SMA to L	35	34, 35, 35	36, 36, 34	36, 36, 36	35.4	0.4
SMA to R	36	36, 36, 37	36, 37, 36	36, 37, 36	36.3	0.3

Mean Absolute Error (MAE):

SMA to A: 0.67 mm
SMA to P: 1.33 mm
SMA to L: 0.67 mm
SMA to R: 0.33 mm

Standard Deviation (SD):

SMA to A: 1.0 mm
SMA to P: 0.8 mm
SMA to L: 0.7 mm
SMA to R: 0.5 mm

The average measurements obtained by the PIUR tUS system across all operators and attempts were very close to the manual reference values, with minimal differences. The differences between the PIUR tUS measurements and manual measurements were within 1.4 mm, indicating high accuracy. The low MAE values (ranging from 0.33 mm to 1.33 mm) show that the PIUR tUS system consistently produces measurements close to the manual reference. The low SD values indicate that the measurements were consistent among the different operators and attempts, demonstrating the reproducibility and reliability of the PIUR tUS system.

5.8.3.6.4 Conclusion

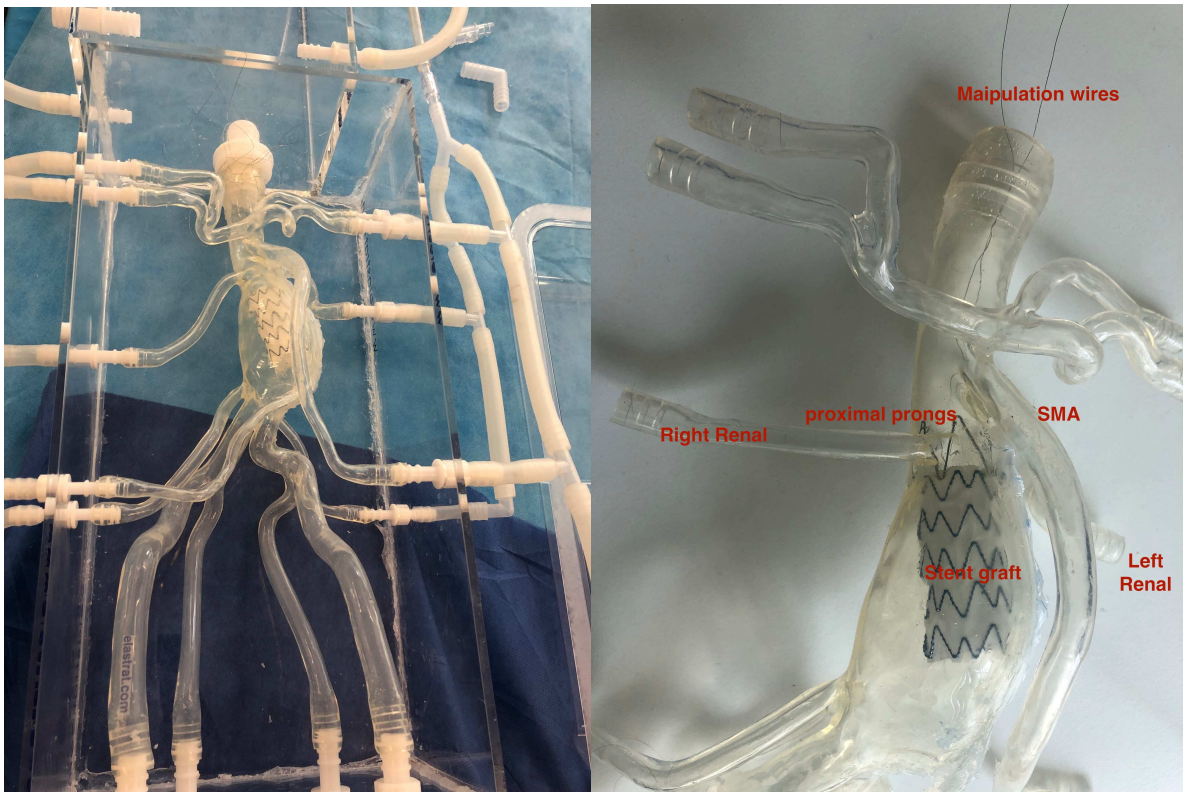
The PIUR tUS tomographic ultrasound system provided highly accurate and consistent measurements of the aortic model when compared to manual calliper measurements. The system's measurements were within 1.4 mm of the manual reference values, with low mean absolute errors and standard deviations, confirming its validity and possible clinical applications in measuring SG markers from the SMA. Prior to the evaluation of the PUIR tUS system in clinical practice a better understanding of the validity of this technology within a more clinically relevant setting.

5.9 Developing an aortic model representing human anatomical and physiological properties.

5.9.1.1 Model Anatomy

A silicone aortic model was purchased from Elastrat® (Gneva, Switzerland) which contained a 5.5cm abdominal aortic aneurysm, visceral and iliac branches, which was thought to better simulate patient anatomy for further experimentation and enhance the validity of subsequent testing. The dimensions are outlined in
Table 50: Complete aortic model dimensions

Figure 76: Complete aortic model, Elastrat®



Aortic graft inserted within the model. Superiorly the stainless-steel wires attached to the suprarenal prongs (from which the hooks had been cut) can be seen which were used to manipulate the position of the graft within the aortic neck.

Table 50: Complete aortic model dimensions

Aortic Model Geometry	
Parameters	**Measurements**

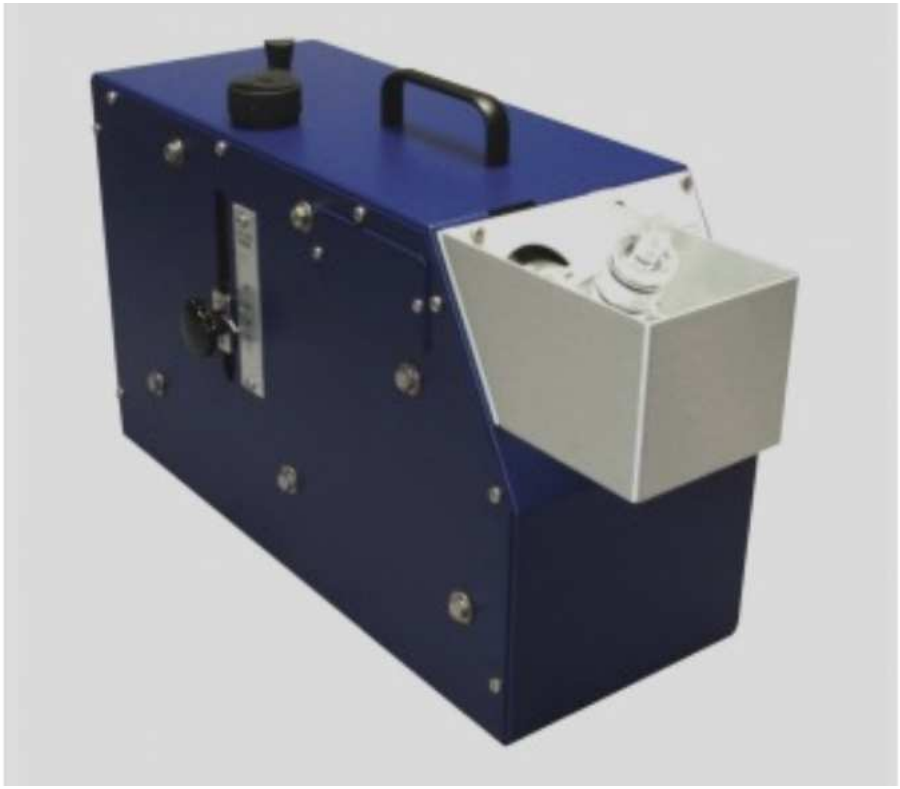
Suprarenal Aorta	
Diameter (mm)	25
Length (mm)	74
Angulation (degrees)	0
SMA	
Diameter mm)	9
Length (mm)	150
Take off Angle (degrees)	55
Right Renal Artery	
Diameter mm)	6
Length (mm)	110
Take off Angle (degrees)	110
Left Renal Artery	
Diameter mm)	6
Length (mm)	110
Take off Angle (degrees)	120
Infra renal aorta	
Diameter (mm)	27
Infrarenal neck (mm)	10
Diameter 15mm distal to renal arteries	36
Maximum AAA (mm)	55
Aortic bifurcation (mm)	35
Length (mm)	115
Angulation (degrees)	30
Right Common iliac artery	
Diameter (mm)	13
Length (mm)	110
Take off Angle (degrees)	30

Left Common Iliac Artery	
Diameter (mm)	13
Length (mm)	120
Take off Angle (degrees)	30

5.9.1.2 Model Physiology

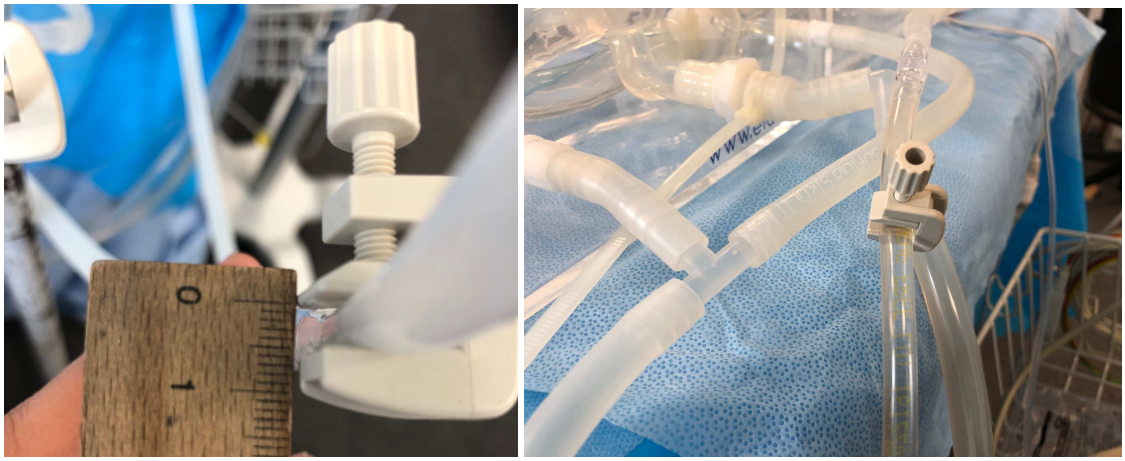
To generate pulsatile flow through the aortic model, a Harvard pulsatile pump (Figure 77: Harvard pulsatile pump) was used to circulate blood mimicking fluid (BMF) through the system [272]. The Harvard pump is able to generate physiological flow rates akin to that produced by the human heart rates via a piston mechanism[273]. Antegrade perfusion was generated, with BMF entering the supra renal aorta and being returned back to the pump via the visceral and iliac branches.

Figure 77: Harvard pulsatile pump



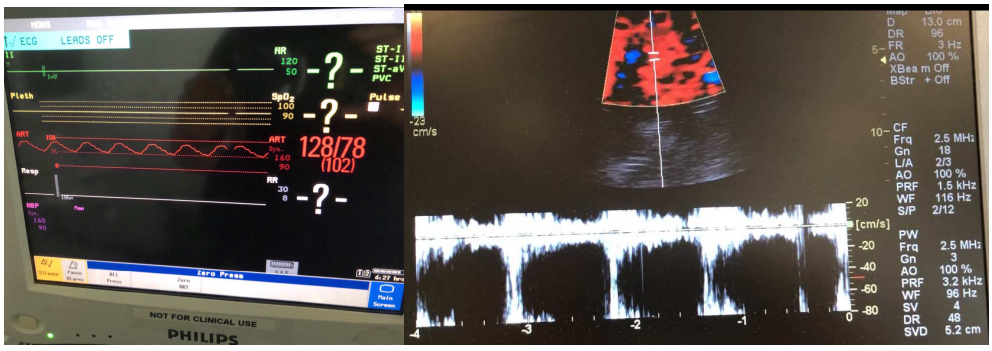
An intra-arterial 18G catheter was inserted via the iliac limb and calibrated, it was then connected to a cardiac monitor to measure the blood pressure, and heart rate. The heart rate and stroke volume may be set from the Harvard pump. This allowed the cardiac output to be calculated (heart rate x stroke volume = cardiac output). The blood pressure however is dependent on peripheral resistance (blood pressure = cardiac output x peripheral resistance). Multiple callipers were applied to the each of the outflow limbs to generate peripheral resistance, Figure 78. The calliper's resistance was increased by 1mm increments until a physiological blood pressure of 128/78 mmHg was achieved, Figure 79.

Figure 78: Peripheral callipers to adjust blood pressure in complete aortic model



Pressure and arterial waveform validation was also carried out by an experienced senior sonographer from the Irvine vascular lab, Imperial College London, by placement of an ultrasound probe over the aortic model to display arterial waveforms at the supra renal aorta, infra renal aorta, renal arteries, SMA, and common iliac arteries, Figure 79. The stroke rate was controlled to maintain a flow rate of 6l/minute.

Figure 79:Blood pressure measurements and wave form of aortic model within the supra renal aortic segment



The flow model was filled with Model 046 Blood Mimicking Fluid (BMF) made by CIRS (Model 046 Blood Mimicking Fluid, CIRS, Inc., VA, USA) at a temperature of 37 degrees. This fluid was developed for use with aortic phantoms, utilising any form of circulation/pump mechanism . The BMF has a viscosity of 4mPa (human blood is 4.4mPa), density of 1037kgm3 (human blood 1053), velocity of 1548 ms-1 (human blood 1583), acoustic attenuation 0.05 dB/cm-1MHz (human blood 0.15 dB/cm MHz). These properties

allow for simulation of blood acoustic and physical properties to provide a stable and reliable fluid for Doppler studies and system evaluations [274].

Once the model was adequately prepared as described, a 9mm synthetic silicone abdominal wall, replicated a patient's skin was placed over the model. The navel was positioned at the level of bifurcation to aid with orientation, Figure 80 and Figure 81. This provides two functions: an additional barrier, more representative of patient anatomy and blinded the operator to the position of the graft and EndoAnchors.

Figure 80: Abdominal wall placement (operator's view) over aortic model



Figure 81: Side view of the aortic model with abdominal wall in place



Once the model was prepared a further experiment were carried out to determine the validity and reliability of the PUIR tUS system in a more realistic model. This model will be referred to as the physiological aortic model.

5.9.1.3 Experiment: Validating PIUR tUS system in obtaining accurate measurements in a physiological and anatomical representative aortic model, an assessment of reliability and validity

5.9.1.3.1 Objective

To validate the accuracy of the PIUR tUS tomographic ultrasound system in measuring the dimensions of a physiological aortic model, better representative of real-life conditions and the distance from an EVAR stent graft EndoAnchor to the superior mesenteric artery (SMA).

5.9.1.3.2 Materials and Methods

Similar set up to Experiment: Validating PIUR tUS for Aortic Model Measurements, an assessment of reliability and validity.

5.9.1.3.2.1 Equipment:

- PIUR tUS tomographic ultrasound system
- Physiological aortic model with EVAR stent graft and EndoAnchor
- Manual callipers for reference measurements

5.9.1.3.2.2 Operators and instructions

3 vascular surgeons were employed to perform blinded measurements of the physiological aortic model. An initial 90-minute lesson was first delivered to explain the software, requirements and to practice on the phantom containing an EVAR endograft with a single EndoAnchor at the level of and posterior to the origin of the SMA, to aid in familiarity.

5.9.1.3.2.3 EndoAnchor Orientation

Three separate orientations of the EndoAnchors were devised as below:

Table 51: Orientation of EndoAnchors within physiological aortic model

	SMA to anterior EndoAnchor (mm)	SMA to posterior EndoAnchor (mm)	SMA to left EndoAnchor (mm)	SMA to right EndoAnchor (mm)
Orientation 1	15	31	22	22
Orientation 2	18	33	24	25
Orientation 3	20	27	26	35

5.9.1.3.2.4 Instructions

- Identify 4 EndoAnchors and correctly label them as anterior, posterior, left and right.
- Identify the origin of the SMA and correctly label it
- Generate a 3D image using the software – without the need to generate a proportional image, given the inherent difficulties with the PUIR imaging software, which is very labour intensive.
- Use the markers set, to measure the distance between the SMA and anterior EndoAnchor, the SMA and posterior EndoAnchor, the SMA and left EndoAnchor and the SMA and right EndoAnchor.

- Measurements to the endo anchor should be made from the level of the centre inner luminal contact (Figure 75), to ensure a standardised point for measurments.

5.9.1.3.2.5 Operator Blinding and Repetition

Operators were blinded to the measurements of the aortic model and informed the EndoAnchors would be placed at different locations for their different scans. Each operator performed three independent scans for the three different orientations, resulting in a total of twenty-seven measurements.

5.9.1.3.2.6 Data Analysis

An analysis of the consistency and accuracy of measurements from the PIUR tUS system was calculated based on mean values, standard deviations, and measurement errors compared to manual calliper measurement, using statistical analysis to determine the validity and reliability of the PIUR tUS measurements.

5.9.1.3.3 Results

Table 52 outlines the measurements recorded by the operators in this experiment.

Table 52: Results, PUIR tUS of EndAnchor positions in physiological aortic model

Endo-Anchor orientation	Measurement	Actual measurement (mm)	Operator 1	Operator 2	Operator 3	Mean operator measurement	Difference (Mean - Ref)
Orientation 1	SMA to A	15	16, 16, 15	15, 16, 16	15, 16, 15	15.5	0.5
	SMA to P	31	32, 33, 33	32, 32, 33	32, 32, 33	32.4	1.4
	SMA to L	22	22, 21, 22	24, 24, 24	22, 23, 23	22.3	0.3
	SMA to R	22	23, 23, 22	22, 22, 23	23, 23, 23	22.6	0.6
Orientation 2	SMA to A	18	18, 18, 18	18, 17, 18	18, 19, 18	18.0	0.0

	SMA to P	33	34, 35, 34	33, 34, 33	34, 33, 33	33.6	0.6
	SMA to L	24	25, 25, 25	24, 26, 25	26, 25, 25	25.0	1.0
	SMA to R	25	26, 26, 25	24, 24, 25	25, 24, 24	24.8	-0.2
Orientation 3	SMA to A	20	21, 21, 20	19, 19, 20	20, 21, 21	20.3	0.3
	SMA to P	35	37, 37, 37	36, 36, 38	37, 35, 37	36.6	1.6
	SMA to L	26	27, 28, 27	29, 26, 27	28, 27, 28	27.4	1.4
	SMA to R	27	28, 28, 27	29, 29, 30	28, 29, 29	28.3	1.3

All operators were able to identify and mark out all four markers and the SMA. 3D generated images from the stacked 2D B-mode ultrasound images were successfully generated, Figure 82. Subsequent measurements using the PUIR tUS software were reliably made.

Figure 82: 3D generated image of the physiological aortic model

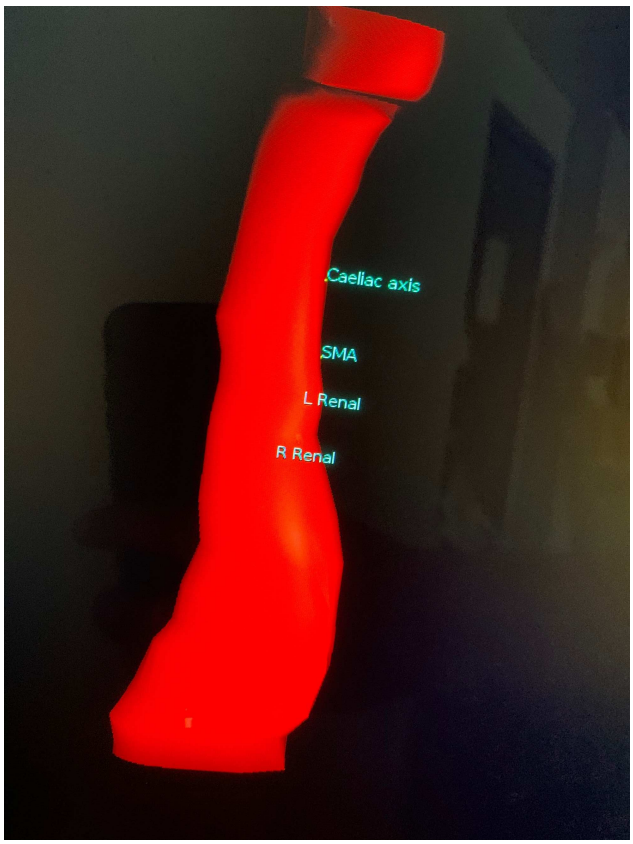


Table 53, combines the mean absolute error and standard deviation for all measurements and standard deviation across all orientations.

Table 53: Mean Absolute Error and Standard deviation for all measurements across the three orientations

Measurement	Overall Mean Absolute Error, MAE (mm)	Overall Standard Deviation, SD (mm)
SMA to A	0.27	0.46
SMA to P	1.20	0.70
SMA to L	0.90	0.77
SMA to R	0.57	0.63

In combining the results of the recorded measurements, the PIUR tUS tomographic ultrasound system appears to be accurate and reliable. The mean absolute error (MAE) across all orientations is less than 1.2 mm for all measurements, with the highest MAE observed for the SMA to posterior EndoAnchor distance. All standard deviation (SD) values are below 0.8 mm, which would indicate high consistency in repeated measurements. These findings would suggest the use of the PUIR tUS for the measurement of EndoAnchors to the SMA in clinical practice may be feasible.

5.10 Proposed imaging protocol for the surveillance of stent graft migration

Using these findings a proposed protocol for aortic imaging, in the post operative period to detect stent graft migration has been outlined below.

5.10.1 Intraoperative

- Deployment of 4 EndoAnchors, 2mm below the line of the proximal fabric at the 3,6,9 and 12 o'clock position during the index EVAR procedure, in line with manufacturers IFU.

5.10.2 Postoperative

- An assessment of the EndoAnchor position on patients' routine post operative CT to confirm adequate deployment.
- An initial US to determine the visibility and adequate deployment of the 4 EndoAnchors.
- Employment of the PUIR tUS system to scan patient within the first 30 days, post EVAR.
- Using the PUIR tUS system, mark the origin of the SMA and 4 EndoAnchors
- Using the generated 3D image, record the distance between the SMA and 4 EndoAnchors
- Repeat imaging and serial measurements of SMA to EndoAnchors at interval surveillance scans.
- An increase in any of the measurements of 5mm or more should trigger an alternative surveillance modality, preferably in the form of a CT scan to further evaluate the EVAR graft and position.
- The reliability and validity of this protocol may be further evaluated at 10 years.

5.11 Discussion

The purpose of this chapter was to explore how we may incorporate an evaluation of SG position within the aorta during the post-operative surveillance period. Given the morbidity and complexity associated with alternative surveillance modalities to ultrasound, a more extensive evaluation of the US modality was conducted to determine whether this may be better utilised, given its existing advantages.

We have identified the EndoAnchor as a suitable marker and established a criterion for its adequate deployment. The use of 3D technology has enabled operators to measure the distance reliably and accurately from the SMA (used as a landmark) to the graft and its markers (EndoAnchors). This allows for precise monitoring of any changes in these measurements over time using postoperative imaging, facilitating the detection of potential migration.

This chapter provides 'proof of concept', in which USS may be used to visualise

EndoAnchors within an aorta. This however relies on the assumption that the EndoAnchor will migrate with the stent graft, in the event of migration and therefore may aide in measuring migration. EndoAnchors however are by definition 'anchored' within the aorta, using an entirely different mechanism to stent graft anchoring mechanisms (typically hooks and radial force). One may therefore argue that the presence of EndoAnchors mitigates the risk of migration and therefore such stringent or alternative methods of post operative surveillance are obsolete based on systematic reviews conducted evaluating migration following EndoAnchor placement, with migration rates recorded as no larger than 0.04% over a mean follow up of less than 12 months [254, 275]. Furthermore, this chapter does not address how frequently these proposed scans should take place, nor is the placement of an expensive and invasive adjuncts such as EndoAnchors (with its own associated complications) superior to MRI surveillance.

Such concerns are valid should the conclusion of this chapter recommend the adoption of EndoAnchors for all EVAR's as a form of surveillance. This chapter however, demonstrated how 3D USS maybe used to clearly identify a marker made from a nickel-cobalt-chromium alloy (specifically MP35N-LT), which pieces the aorta, from which reliable measurements can be made. The inference and recommendation can therefore be made that subsequent stent designs incorporate the positive findings from the above experiments into future stent grafts to aid in non-radiation-based imaging modalities to better detect stent migration. An example of which would be to incorporate such materials within the fixation barbs (be they supra or infra renal devices) and determine an ultrasound-based protocol on how these may be assessed and followed up.

Furthermore, the use of MRI for post-operative surveillance has significant limitations. A considerable number of patients are ineligible due to implanted devices like pacemakers. Additionally, older stainless steel stent grafts create significant metallic artefacts, preventing an adequate assessment of the graft's position. The scan's long duration is also a factor; patients are required to stay still, and common movement creates artefacts that hinder interpretation. Finally, many patients are claustrophobic and unable to tolerate the scan [276]. It is therefore beneficial to better utilise and exhaust existing modalities such USS which overcome much of these limitations.

6 Discussion, conclusion, and future work

6.1 General Discussion

Since the inception of EVAR, migration has been recognised as a post-operative complication. Although the frequency of migration has decreased with advancements from early physician-made stent grafts, originally used in patients unsuitable for open surgical repair, it continues to be a significant concern. 'Introduction' detailed the underlying pathophysiology of EVAR migration, emphasising how it can lead to catastrophic complications. Despite technological improvements in EVAR stents, these advancements have not necessarily addressed the intrinsic changes in a patient's aorta, such as ongoing aortic dilatation, which can contribute to migration. Additionally, the lack of standardisation in measuring migration introduces ambiguity and variability in reporting, making it challenging to accurately determine its true prevalence. These observations are particularly relevant in light of claims made by industry and registry publications, which often assert minimal or no rates of migration with the newer generation stent grafts [53, 83].

The systematic review presented in 'Systematic Review' confirmed substantial variation in how migration is both measured and reported within the literature, identifying 18 different definitions. This inconsistency was further emphasised by the heterogeneity across studies and the overall low quality of evidence in the meta-analysis. Nevertheless, a general trend emerged showing a reduction in reported migration rates over time, correlating with the different stent graft eras (1-4). The identification of a significant and robust reduction in migratory case with good explanatory power for Definition 1 (migration of >10mm or any migration requiring intervention), in contrast to Definitions 2(migration >5mm), further supports the inconsistencies in how the heterogeneity in reporting migration can lead to different clinical inferences. Additionally, a clear distinction was observed in the number of reported migratory cases between studies that included migration as part of a broader EVAR protocol and those that specifically focused on migration, with detailed measurements of graft positioning over time. These findings suggest that the true prevalence of migration may be underreported. The discrepancy between studies specifically monitoring for migration and those that include it as a secondary observation raises concerns that the true incidence of migration with newer stent grafts could be higher than reported [77, 102, 129].

Chapter 3 aimed to address the challenges of measuring stent graft (SG) migration identified in Chapters 1 and 2, particularly concerning newer-generation stent grafts. Greenberg's published method for determining migration was initially employed, then applied to contemporary clinical practice using CT scans [74]. This approach identified a migration rate of 20.7% at a threshold of 5mm or more, with a median follow-up of 43.2 months. However, uncertainty remained regarding a more clinically relevant definition of migration, particularly its impact on patient outcomes.

Further analysis correlating migration distance with clinical outcomes (specifically type 1a endoleak) showed that migration of ≥ 5mm did not significantly increase the risk of proximal seal failure (14.7% ≥ 5mm migration vs 3% with no migration, p = 0.668), in keeping with previously published literature [102]. In contrast, migration of ≥ 10mm was associated with a significantly higher risk of proximal seal failure (42.3% ≥ 10mm migration vs 4% ≤ 10mm migration, p = 0.001). By adopting the ≥ 10mm threshold as the definition of clinically relevant migration, the prevalence rate was revised to 11.3% (26/231). Including the SVS and ESVS definitions increased the prevalence to 14.7% (34/231). These figures contrast with previously published data, which report significantly lower migration rates [31].

Several factors explain these discrepancies, including the longer follow-up period in this analysis, particularly for patients who experienced migration (66 months), compared to other studies. Additionally, a defined protocol was used to measure migration across the entire proximal stent rather than focusing on a single point, ensuring that even cases of stent tilt were recorded. The average time to migration was found to be 63.6 months (range 13-120), confirming migration as a long-term complication occurring later than Spanos's systematic review, which reported a time to migration of 15-36 months. This difference is likely due to more contemporary graft technology, better patient selection (adherence to IFU), and the longer follow-up period in this study, which allowed for more migration events to be detected [31].

The risk factors identified in the migratory group align with previous literature, including shorter neck length, larger aneurysms, and wider necks [31, 73, 80]. These findings reaffirm that stent graft migration remains a significant issue, even with the newer, contemporary grafts currently in use. A multitude of factors contribute to this, ranging from preoperative

risk factors such as wider and shorter necks, to perioperative factors like graft placement at an increased tilt or the presence of an intraoperative endoleak. While these grafts are typically deployed within the manufacturer's instructions for use (IFU), they continue to show evidence of migration. One of the most notable anatomical changes over time in those who experienced migration was neck widening, suggesting that the ongoing degenerative process leading to neck dilation may still be a key contributor to migration, even in patients initially considered low-risk [277].

The findings from Chapter 3, where by cases migrating 10mm or more, were more likely to be associated with adverse clinical outcomes and therefore an adequate threshold to determine migration in contrast to using 5mm supports the findings of the systematic review in Chapter 2, in which no significant reduction of migration rates over time were identified.

A limitation of this retrospective analysis is the discrepancy in the length of radiological follow-up between the migratory (66 months) and non-migratory groups (39.6 months). This likely underestimates the true prevalence of migration in the non-migratory group, as the time to migration was found to be 63.6 months for newer-generation stent grafts.

Subsequent these findings, identifying a high-risk cohort, those likely to experience stent graft migration of ≥10mm—during their postoperative phase was necessary. Given the limitations inherent in retrospective analyses and the variability in follow-up protocols, the most valid and reliable assessment was focused on the first 18 months post-EVAR. During this period, patients typically undergo two early postoperative CT scans, providing more consistent data for analysis. Beyond this time, the timing of CT scans varies due to multiple factors, making it difficult to extrapolate reliable patterns based on migration trends from later scans.

Chapter 4 undertook a comprehensive analysis of graft movement over time, confirming that patients who experience early migration (≥5mm within the first 18 months) are 81% likely to experience eventual migration of ≥10mm. The odds ratio for early stent migration predicting later significant migration was 139.3, with a 95% confidence interval of 39.15 to 495.62 ($p < 0.001$). Although the wide confidence interval reflects some variability, likely due to a smaller sample size, this finding remains statistically significant and underscores the robust association between early and later migration.

To the best of my knowledge, this is a novel finding in the context of identifying high-risk, asymptomatic patients during postoperative surveillance. This early identification can be leveraged as a practical screening tool, where detecting ≥5mm of migration within 18 months could serve as a strong predictor of future complications. Importantly, this method does not require complex mathematical models or specialised software, making it easily adoptable by institutions performing EVAR procedures [211]. In contrast those found migrating less than 5mm within the first 18 months following an EVAR may be enrolled in less intensive surveillance programmes, similar to existing low-risk cohorts in which longer surveillance intervals have been recommended [244].

In contemporary post-operative practice, much of the focus is on the information reliably deduced from duplex ultrasound, primarily concerning the residual AAA sac size (to infer a repressurised system), graft patency, and the presence of endoleaks. The aim of my final chapter was to further explore this modality, with the goal of providing positional data that could be utilised during the postoperative period. Through a series of experiments, the use of freehand electromagnetic 3D ultrasound successfully reconstructed a phantom aorta, allowing for reliable and valid measurements. To my knowledge, this has not been previously demonstrated and offers a promising platform for future research to further evaluate and refine the use of such techniques in the post-operative setting.

To achieve this, additional markers in the form of EndoAnchors were employed to serve as reference points, based on the assumption that the EndoAnchor would remain fixed to the same point on the graft over time, without compromising the integrity of the graft (although rare cases of fracture have been reported) [254]. However, the routine use of EndoAnchors in all EVAR patients introduces significant challenges, including increased costs, longer procedure times, and perioperative complications [278]. It is therefore recommended that the findings of this chapter, namely to use of 3D USS to identify markers within a stent graft be better utilised to aide in surveying possible stent graft migration. Despite these issues, this chapter presents a proof of concept demonstrating that valid and reliable positional measurements can be obtained. Serial imaging may then be employed to detect stent graft migration over time.

6.2 Future Work

The limitations of each study have been outlined within their respective chapters. Further research should be undertaken to address each of these highlighted issues.

6.2.1 Identifying occult migration:

Greenberg introduced his method for measuring migration in 2004, yet, despite its introduction nearly 20 years ago, various definitions and methodologies continue to be used without a standardised approach in the literature. By applying this screening method, we identified a significant number of cases with ≥10mm migration that had not previously been diagnosed, notifying the respective clinical teams for appropriate intervention.

Using Greenberg's method, vascular centres could retrospectively review their existing patients to determine whether early migration (within the first 18 months) or occult migration of ≥10mm has occurred and manage these cases accordingly.

Collating the outcomes of these steps across multiple vascular institutions could help validate the findings from this research, improve patient outcomes, and potentially prevent the development of type 1a endoleaks or the more severe complication of rupture.

6.2.2 3D ultrasound in monitoring migration

Building on the findings from Chapter 5, an opportunistic trial could be conducted to evaluate the accuracy and reliability of this modality on existing patients who have had EndoAnchors placed as part of their index procedures. These patients could be scanned using the 3D ultrasound system, and the recorded graft position compared to their surveillance CT scans. This approach would further validate the findings from my research and help establish the utility of 3D ultrasound as a reliable tool in post-EVAR monitoring.

This modality could be expanded to include other areas of the aorta, such as the thoracic aorta. Significant progress has been made in using ultrasound to assess the thoracic aorta, and further evaluation of stent orientation within this region may be especially beneficial. This is particularly relevant for younger patients with connective tissue disorders who have previously undergone vascular interventions and would benefit from reduced radiation

exposure, which they might otherwise receive from multiple CT scans. Exploring the use of 3D ultrasound in this context could offer a safer, more sustainable method for long-term monitoring [279].

7 Appendix List

7.1 Appendix 1: Systematic Review tables

7.1.1 Author, year and DOI

Table 54: systematic review - author, year and DOI

Study	year published	DOI/PMID
Abdulrasak	2020	https://doi.org/10.1016/j.jvs.2019.09.061
Baderkhan et al	2020	https://dx.doi.org/10.1016/j.ejvs.2020.02.021
Barleben	2020	https://dx.doi.org/10.1016/j.jvs.2020.01.066
Chinsakchai	2020	https://dx.doi.org/10.1177/1708538120924552
Midy	2020	https://dx.doi.org/10.1016/j.ejvs.2020.02.005
Mufty	2020	https://dx.doi.org/10.1016/j.avsg.2019.06.045
Oliveira-Pinto	2020	https://dx.doi.org/10.1016/j.jvs.2019.03.039
Oliveira-Pinto	2020	https://dx.doi.org/10.1016/j.jvs.2019.07.091
Reina	2020	https://dx.doi.org/10.23736/S0392-9590.20.04336-9
Sirignano	2020	https://dx.doi.org/10.1016/j.avsg.2020.03.012
Asenbaum	2019	https://dx.doi.org/10.1007/s00330-019-06282-w
McFarland	2019	https://dx.doi.org/10.1016/j.jvs.2018.02.054
Oliveira-Pinto et al	2019	https://dx.doi.org/10.1016/j.jvs.2019.03.039
Ramirez	2019	https://dx.doi.org/10.1016/j.jvs.2019.02.047
Torsello	2019	https://dx.doi.org/10.1016/j.jvs.2018.09.059
Herman	2018	https://dx.doi.org/10.1016/j.jvs.2017.05.095
Healy	2017	https://dx.doi.org/10.1177/1538574417703268
Malas	2017	https://dx.doi.org/10.1016/j.jvs.2016.10.120
Oliveira	2017	https://dx.doi.org/10.1016/j.jvs.2016.09.052
Poublon	2017	https://dx.doi.org/10.1016/j.jvir.2017.01.012
Pratesi	2017	https://dx.doi.org/10.23736/S0021-9509.17.09305-3
tMannetje	2017	https://dx.doi.org/10.1016/j.jvs.2017.01.022
Tokunga	2017	https://dx.doi.org/10.1016/j.avsg.2016.05.128
Broos	2016	https://dx.doi.org/10.1177/1526602816649371
DeDonato	2016	https://dx.doi.org/10.1016/j.jvs.2015.07.099
Kim	2016	https://dx.doi.org/10.1016/j.jvs.2016.02.057
Mateo	2016	https://dx.doi.org/10.1177/1526602816646550
Roos	2016	https://dx.doi.org/10.1186/s12872-016-0309-0
Singh	2016	https://dx.doi.org/10.1016/j.jvs.2015.12.048

tMannetje	2016	https://dx.doi.org/10.1016/j.jvs.2016.01.035
Chung	2015	https://dx.doi.org/10.1016/j.jvs.2014.11.006
Torsello	2015	https://dx.doi.org/10.1016/j.jvs.2014.06.007
Walker	2015	https://dx.doi.org/10.1016/j.jvs.2015.04.389
Bisdas	2014	https://dx.doi.org/10.1016/j.jvs.2014.04.070
Speziale	2014	https://dx.doi.org/10.1016/j.avsg.2014.06.057
Zandvoort	2014	https://dx.doi.org/10.1016/j.jvs.2013.12.031
Fossaceca	2013	https://dx.doi.org/10.1007/s11547-012-0905-8
Lee	2013	https://dx.doi.org/10.1016/j.ejvs.2013.03.027
Mehta	2013	https://dx.doi.org/10.1016/j.jvs.2012.09.003
Nyheim	2013	https://dx.doi.org/10.1258/ar.2012.110291
Bastos Goncalves	2012	https://dx.doi.org/10.1016/j.jvs.2012.03.263
BastosGoncalves	2012	https://dx.doi.org/10.1016/j.jvs.2011.12.062
Hager	2012	https://dx.doi.org/10.1016/j.jvs.2011.11.088
Kaladji	2012	https://dx.doi.org/10.1016/j.jvs.2011.07.067
Majumder	2012	https://dx.doi.org/10.1258/smj.2012.012001
Stather	2012	https://dx.doi.org/10.1016/j.ejvs.2012.10.003
Droc	2011	https://dx.doi.org/10.3109/13645706.2011.554842
Jim	2011	https://dx.doi.org/10.1016/j.avsg.2010.09.007
Kalteis	2011	https://dx.doi.org/10.1016/j.avsg.2011.06.012
Mehta	2011	https://dx.doi.org/10.1016/j.jvs.2010.07.052
Pintoux	2011	https://dx.doi.org/10.1016/j.avsg.2010.08.013
Waasdorp	2011	https://dx.doi.org/10.1016/j.jvs.2011.10.093
Ghotbi	2010	20671631
Jim	2010	https://dx.doi.org/10.1016/j.avsg.2010.05.015
Oberhuber	2010	https://dx.doi.org/10.1583/10-3172.1
Turnbull	2010	https://dx.doi.org/10.1016/j.jvs.2009.09.039
Cao	2009	https://dx.doi.org/10.1016/j.jvs.2008.11.044
Conrad	2009	https://dx.doi.org/10.1097/SLA.0b013e3181b365bd
Pitoulias	2009	https://dx.doi.org/10.2310/6670.2009.00004
Pitton	2009	https://dx.doi.org/10.1007/s00270-009-9599-2
Rodel	2009	https://dx.doi.org/10.1016/j.ejvs.2009.08.007
Stella	2009	19329910
Waasdrop	2009	https://doi.org/10.1016/j.ejvs.2009.03.001
Abbruzzese	2008	https://dx.doi.org/10.1016/j.jvs.2008.02.003
Coppi	2008	https://dx.doi.org/10.1016/j.jvs.2008.05.011
Greenberg	2008	https://dx.doi.org/10.1016/j.jvs.2008.02.051
Sternbergh	2008	https://dx.doi.org/10.1016/j.jvs.2008.02.075
Wang	2008	https://dx.doi.org/10.1016/j.jvs.2008.04.031

Dalainas	2007	https://dx.doi.org/10.1583/06-2007.1
Goodman	2007	https://doi.org/10.1583/06-1918.1
vanHerwaarden	2007	https://doi.org/10.1583/06-1993.1
Brewster	2006	https://dx.doi.org/10.1097/01.sla.0000234893.88045.dc
Fulton	2006	https://dx.doi.org/10.1016/j.jvs.2006.06.034
Heikkinen	2006	https://doi.org/10.1016/j.jvs.2006.01.031
Litwinski	2006	https://dx.doi.org/10.1016/j.jvs.2006.08.028
Seriki	2006	https://dx.doi.org/10.1097/01.RVI.0000222661.64390.3e
Steingruber	2006	https://dx.doi.org/10.1016/j.ejrad.2006.04.002
Torsello	2006	https://doi.org/10.1016/j.jvs.2005.09.037
Albertini	2005	https://doi.org/10.1583/05-1629r.1
Malas	2005	https://dx.doi.org/10.1016/j.jvs.2005.06.017
Tonnessen	2005	https://doi.org/10.1016/j.jvs.2005.05.040
Carpenter	2004	https://dx.doi.org/10.1016/j.jvs.2004.08.051
England et al	2004	https://dx.doi.org/10.1097/01.RVI.0000142601.10673.00
Greenberg	2004	https://dx.doi.org/10.1016/j.jvs.2004.02.032
Verhoeven	2004	https://dx.doi.org/10.1016/j.ejvs.2004.06.013
Clouse	2003	https://doi.org/10.1016/s0741-5214(03)00327-6
Dillavou	2003	https://doi.org/10.1016/s0741-5214(03)00738-9
Kibbe	2003	https://dx.doi.org/10.1016/S0895-7967(03)00012-7
May	2003	https://dx.doi.org/10.1067/mva.2003.109
Zarins	2003	https://doi.org/10.1016/s0741-5214(03)00946-7
Alric et al	2002	https://doi.org/10.1177/152660280200900602
Cao et al	2002	https://dx.doi.org/10.1067/mva.2002.120045
Connors III	2002	https://dx.doi.org/10.1067/mva.2002.126561
Carpenter	2002	https://dx.doi.org/10.1067/mva.2002.129641
Makaroun	2002	https://dx.doi.org/10.1067/mva.2002.120377
Pereira	2002	https://doi.org/10.1177/152660280200900608
Resch	2002	https://doi-org.iclibezp1.cc.ic.ac.uk/10.1016/S1072-7515(01)01102-4
Sternbergh III	2002	https://dx.doi.org/10.1067/mva.2002.119506
Tonnessen	2002	https://dx.doi.org/10.1016/S0002-9610
Blum	2001	https://doi.org/10.1007/s002680020382
Greenberg	2001	https://doi.org/10.1067/mva.2001.111683
Resch	2001	https://dx.doi.org/10.1053/ejvs.2001.1401
Schlensak	2001	https://doi.org/10.1067/mva.2001.116975
Broeders	1999	https://doi.org/10.1053/ejvs.1999.0900
Resch	1999	https://doi.org/10.1016/S1051-0443(99)70027-8

7.1.2 Follow up data

Table 55: Systematic Review - follow up data

Study	Year published	Data collection period	Length of F/U (months)	Follow up range	Follow up protocol (months)	*Imaging
Abdulrasak	2020	1998-2012	60	36-96	1,6,12, annually	2
Baderkhan et al	2020	1998-2012	62.4	29-84	1,6,12, annually	2
Barleben	2020	2009-2011	60		1,6,12, annually	1
Chinsakchai	2020	2010-2013	54.9	1-82.9	1,6,12, annually	2
Midy	2020	2012-2013	59	43-62	1,6,12, annually	1
Mufty	2020	2012-2019	31.6	0-72	1,3,12, annually	2
Oliveira-Pinto	2020	2004-2011	5.9	2-148	3,6,12, annually	2
Oliveira-Pinto	2020	2000-2015	52	6-84	1,6,12, annually	1
Reina	2020	2016-2019	19.6	1-42	1,6,12, annually	2
Sirignano	2020	2008-2015	53	1-120	1,3,6,12, annually	3
Asenbaum	2019	2002-2014	33.5	6-60	1 then 6 months	1
McFarland	2019	2000-2016	34.1	1-60	1,6, annually	1
Oliveira-Pinto et al	2019	2004-2011	68	3-148	1,6,12, annually	2
Ramirez	2019	1998-2005	67.2	1-196	1,6,12, annually	1
Torsello	2019	2010-2011	60	1-60	1,6,12, annually	1
Herman	2018	2005-2014	25		1,6,12, annually	2
Healy	2017	2006-2015	34.4	1-113	3, annually	3

Malas	2017	2006-2011	60		1,6,12, annually	2
Oliveira	2017	2008-2012	46.8	14-67	1, annually	2
Poublon	2017	2000-2015	25.6	1-190	1, annually	1
Pratesi	2017	2010-2011	60	1-60	1,6,12, annually	1
tMannetje	2017	2005-2010	61	30-92	1,6,12, annually	2
Tokunga	2017	2007-2010	24		1, annually	1
Broos	2016	1998-2012	37.8	3-78	1,6,12, annually	1
DeDonato	2016	2009-2011	60		1,6,12, annually	1
Kim	2016	2007-2010	55	0-91	1,3,6,12, annually	1
Mateo	2016	2000-2014	34.3	1-176	1,annually	1
Roos	2016	2005-2013	29	0-108	1, annually	1
Singh	2016	2008-2009	60		1,6,12, annually	2
tMannetje	2016	1999-2005	84		1,6,12, annually	3
Chung	2015	1992-2012	20.9	0-154	1,6, annually	1
Torsello	2015	2010-2011	24		1,6,12,24	1
Walker	2015	2000-2010	32.2	14.2-52.8	1, then varied	1
Bisdas	2014	2007-2010	42	30-50	1,6,12, annually	3
Speziale	2014	2010-2011	24		3,6,12, annually	3
Zandvoort	2014	2007-2009	48	1-62	1,12,annually	1

Fossaceca	2013	2005-2011	29.6		1,6,12, annually	2
Lee	2013	2004-2007	35	12-74	1,6,annually	3
Mehta	2013	2002-2011	35	12-72	1,6,12, annually	1
Nyheim	2013	2001-2006	41.5	2-94	1,6,12, annually	1
Bastos Goncalves	2012	2000-2007	60	36-134	1, then most recent	1
BastosGoncalves	2012	2004-2008	39	23-57	1, annually	1
Hager	2012	2002-2009	18.6	1-24	1,12,annually	3
Kaladji	2012	2003-2007	39	24-84	1 then most recent	1
Majumder	2012	2005-2009	39	24-84	1,6,12, annually	1
Stather	2012	1999-2010	49		3,6,12, annually	2
Droc	2011	1997-2007	41	1-98	1,3,6,12, annually	1
Jim	2011	2002-2003	60		1,6,12, annually	1
Kalteis	2011	2001-2010	52	13-106	1, then most recent	1
Mehta	2011	2002-2009	29	14-111	1,6,12, annually	1
Pintoux	2011	1999-2007	62	40-79	3,6,12,18,24,annually	1
Waasdorp	2011	1997-2007	43.3	6-108	1,6,12,annually	1
Ghotbi	2010	2006-2009	20		1,3, annually	0
Jim	2010	2002-2003	60		1,6,12, annually	1
Oberhuber	2010	1998-2007	39.4	3-109	3,6,12, annually	1

Turnbull	2010	2002-2003	60		1,6,12, annually	1
Cao	2009	2002-2006	25	12-60	1, annually	1
Conrad	2009	1997-2007	35	0-113	1, annually	1
Pitoulias	2009	1997-2005	46.7	1-94	1,6,12,18,24, annually	1
Pitton	2009	1997-2007	47.7	0-123	3,6,12, annaually	1
Rodel	2009	2002-2005	24		3,6,12,24	1
Stella	2009	2005-2008	23.2	1.4-38.6	1,3,6,12, annually	1
Waasdrop	2009	2000-2007	32	12-58	12, then varied	1
Abbruzzese	2008	1999-2005	29.6		1,6,12, annually	1
Coppi	2008	1999-2007	42.4	6-94	1,6,12,bianually	2
Greenberg	2008	2000-2003	43	1-60	1,6, annually	1
Sternbergh	2008	2000-2007	29.9	1-84	1,6,12, annually	1
Wang	2008	2000-2003	49	11-72	1,6,12, annually	1
Dalainas	2007	1999-2004	54	6-74	1,3,6,annually	1
Goodman	2007	1999-2004	26.9	2-66	6, annually	1
vanHerwaarden	2007	1996-2003	52	1-109	1,3,12,annually	1
Brewster	2006	1994-2005	27		1,3,6,12, annually	1
Fulton	2006	1999-2001	40.3	30-55	1,6,12, annually	1
Heikkinen	2006	1996-2003	23	4-42	1 then most recent	1

Litwinski	2006	1996-2004	84		1 and then annually	1
Seriki	2006	1998-2002	39	24-72	3,12, annually	1
Steingruber	2006	1995-2005	23.9	0-86	3,6,12, annually	1
Torsello	2006	1996-1998	53.2	1-84	1,6,12, annually	1
Albertini	2005	2000-2001	40.6	1-51	1,3,6,12, 18, 24, annually	1
Malas	2005	1997-2002	31	12-66	1,6,12, annually	1
Tonnessen	2005	1997-2004	39	12-72	1,6,12, annually	1
Carpenter	2004	2000-2003	24		1,6,12, annually	1
England et al	2004	1998-2001	36	24-60	1,3,6,18, annually	1
Greenberg	2004	2000-2001	24		1,6,12,24	1
Verhoeven	2004	1996-2003	36	12-87	1,3,6,12,18,24, annually	1
Clouse	2003	1996-1998	38	20-52	1,6, annually	1
Dillavou	2003	1999-2002	18	1-43	1, annaully	1
Kibbe	2003		24		1,6,12, annually	1
May	2003	1992-1996	60		1,6, annually	1
Zarins	2003	1997-2007	41.1	1-98	1,3,6,12, annually	1
Alric et al	2002	1996-2002	20.6	6-68	3,6,12, annually	1
Cao et al	2002	1997-1999	28	24-46	1,6,12, annually	1
Connors III	2002	1997-2000	33.2	32.1-34.3	1,6,12, annually	1
Carpenter	2002	1999-2000	16	10-25	1,6,12, annually	1

Makaroun	2002	1995-1998	36		1,6,12, annually	1
Pereira	2002	1995-2001	35	1-66	3,6, annually	1
Resch	2002		39	25-55	1,3,6, biannually	1
Sternbergh III	2002	1995-2001	26.6		1,6,12, annually	1
Tonnessen	2002	1997-2001	20.7		1,6,12, annually	1
Blum	2001	1994-1997	35	30-50		1
Greenberg	2001	1995-2000	18		1,6,12, annually	1
Resch	2001	1993-2000	21	1-36	1,3,6, biannually	1
Schlensak	2001	1994-1998	49	26-74	1,6,12, annually	1
Broeders	1999	1993-1996	24	12-48	1, annually	1
Resch	1999	1993-1997	29	1-49	1,3,6, biannually	1

*CT used annually (1), Combined CT and USS (2), USS (3) or unknown (0)

7.1.3 Study domains and grafts

Table 56: Systematic Review - study domains and grafts

Study	year published	Method	Aim	Type of endograft
Abdulrasak	2020	Prospectively collective data, clinical trial	To assess the long-term outcomes of elective infrarenal EVAR of AAA with the **Cook-Zenith stent graft** at a tertiary referral center.	Cook-Zenith stent graft
Baderkhan et al	2020	Retrospective analysis of prospectively collected	to identify how post-EVAR complications were detected, assess	Endurant, Zenith, Excluder, Talent and others

		nonrandomized data in a tertiary institution	their timing and frequency, and compare the effectiveness of **DUS vs. CTA** for complication detection.	
Barleben	2020	**Prospective, non-randomized, multicenter clinical trial**.	o evaluate the long-term safety and efficacy of the **Ovation Abdominal Stent Graft System** for treating infrarenal AAA.	Ovation Abdominal Stent Graft System
Chinsakchai	2020	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	To investigate the early and late outcomes of EVAR in treating AAA, comparing patients with severe (>60°) and non-severe (≤60°) infrarenal neck angulation.	**Endurant**, **Zenith**, and **Excluder** were used, with **Zenith** and **Endurant**
Midy	2020	prospective observational study	evaluate the results of the third-generation Anaconda endograft for treating unruptured AAAs under real-life conditions.	Anaconda™ AAA Stent Graft System
Mufty	2020	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	o evaluate the **mid-term to long-term outcomes** of using the **Ovation, Ovation Prime, and Ovation iX stent-graft**	**Ovation, Ovation Prime, and Ovation iX Abdominal stent-graft systems**.

			systems for EVAR in a single-center university hospital.	
Oliveira-Pinto	2020	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	To report long-term outcomes of the Endurant and Excluder stent grafts for EVAR and evaluate their performance, particularly in anatomically challenging cases.	Endurant Stent Graft System and Low Porosity Excluder Abdominal Stent Graft.
Oliveira-Pinto	2020	Retrospective cohort study based on a prospectively maintained database	compare midterm outcomes between patients undergoing r-EVAR and el-EVAR.	Endurant, Excluder, Talent,
Reina	2020	retrospective study with a retrospective analysis of data	describe the initial experience and evaluate the outcomes of using the TREO endoprosthesis in treating infrarenal aortic aneurysms	Treo
Sirignano	2020	Retrospective study using a prospectively compiled database.	To evaluate early-, mid-, and long-term outcomes in patients treated for AAAs by EVAR with various commercially available devices	Excluder, Zenith Flex, Endurant, Ovation, AFX, Treovance, Nellix, Incraft, Jotec, Anaconda, and Talent
Asenbaum	2019	Retrospective single-center, cross-sectional study.	To evaluate the influence of baseline clinical and morphological parameters on stent-graft surface movement and its	Talent (Medtronic), Excluder (W.L. Gore & Associates), Zenith (Cook Medical), Endurant (Medtronic), Anaconda (Vascutek), Aorfix (Lombard Medical

			association with migration and stent-graft-related endoleaks after EVAR.	Technologies), Powerlink (Endologix, Inc.), and Treovance (Bolton Medical).
McFarland	2019	Retrospective review of a prospectively maintained database	To determine the outcomes of repair of dilated infrarenal neck aneurysms with standard EVAR using large proximal diameter devices (34-36 mm)	Excluder, Zenith, Talent, Endurant I and II, Ovation, and AFX
Oliveira-Pinto et al	2019	Retrospective study based on a prospectively maintained database	eport long-term outcomes of the Endurant and Excluder stent grafts, focusing on primary clinical success, secondary interventions, and neck-related events	Endurant and Excluder
Ramirez	2019	retrospective single-center study.	examine the long-term outcomes and performance of the Zenith stent graft over 15 years in high-risk patients undergoing EVAR.	Zenith
Torsello	2019	prospective, single-arm trial	evaluate the long-term outcome of the INCRAFT AAA stent graft, focusing on its adaptability to aortoiliac remodeling over a 5-year follow-up period	INCRAFT AAA stent graft (Cordis Corporation)
Herman	2018	Retrospective cohort design.	o determine if device-specific	Endurant, Talent, and Zenith Flex

			instructions for use (IFU) nonadherence is associated with worse short-term outcomes in patients undergoing elective endovascular aneurysm repair (EVAR)	
Healy	2017	reterospective study	assess the rates of complications, secondary intervention, survival, and causes of death during medium-term follow-up in a modern EVAR program	talent, endurant I, endurant II, Zenith, Excluder
Malas	2017	Multicenter, nonrandomized regulatory study.	safety and effectiveness of the Aorfix endograft for the treatment of abdominal aortic aneurysms (AAAs) with highly angulated or tortuous aortoiliac anatomy, specifically in patients with aortic neck angles between 0 and 90 degrees.	Aorfix
Oliveira	2017	Retrospective cohort study based on a prospectively maintained database	determine midterm outcomes following EVAR with a single endograft in patients with large diameter aneurysm necks and	Endurant

			to assess the risk of neck-related complications associated with an infrarenal neck diameter of ≥30 mm.	
Poublon	2017	reterospective study	To evaluate long-term outcome of GORE EXCLUDER AAA Endoprosthesis (W.L. Gore & Associates, Inc, Flagstaff, Arizona) for elective treatment of infrarenal aortic aneurysms and to evaluate performance of different generations of the device	Gore Excluder and AneuRx
Pratesi	2017	prospective, single-arm trial	evaluate the long-term outcome of the INCRAFT AAA stent graft, focusing on its adaptability to aortoiliac remodeling over a 5-year follow-up period	INCRAFT AAA stent graft (Cordis Corporation)
tMannetje	2017	reterospective study	compare two widely used stent graft systems, the Endurant AAA Stent Graft and the Talent Abdominal Stent Graft, in terms	Endrant and Talent

			of durability and midterm outcomes.	
Tokunga	2017	retrospective study	examine temporal changes in proximal neck angulation and its relationship to stent graft migration after EVAR	Excluder and Zenith
Broos	2016	reterospective study	evaluate the short- and long-term outcomes of EVAR in a consecutive cohort of patients treated in a high-volume center, comparing the differences between elective EVAR (el-EVAR) and EVAR for ruptured AAA (r-EVAR)	AneuRx, Excluder, Zenith, PowerLink, LofePath, Fortron
DeDonato	2016	Prospective, nonrandomized, multicenter clinical trial	report 5 year data of trial	Ovation
Kim	2016	reterospective study	aim of the study was to assess the midterm outcomes of abdominal EVAR using the first-generation Seal stent graft.	Seal stent graft (S & G Biotech Inc, Seong-nam, Gyeonggi-do, Korea)
Mateo	2016	reterospective study	to analyze midterm clinical outcomes among patients with favorable and unfavorable neck morphology and determine any impact of the C3	Excluder and excluder C3

			Excluder repositionable system on outcomes in patients undergoing EVAR with unfavorable neck anatomy.	
Roos	2016	reterospective study	describe the incidence, indications, procedures, and outcomes of re-interventions after EVAR, with a special focus on non-access-related re-interventions.	Endurant® (Medtronic), Zenith Flex® (Cook Inc.), Excluder® (W. L. Gore), Talent® (Medtronic), Zenith LP® (Cook Inc.), and Ovation® (Trivascular).
Singh	2016	Multicenter single-arm study.	eport the 5-year long-term outcomes of the Endurant Stent Graft	Endurant
tMannetje	2016	reterospective study	assess the occurrence of stent graft-related complications and secondary interventions during a minimum of 10 years of follow-up	Talent
Chung	2015	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	investigate the relationship between gender and outcomes after EVAR, comparing perioperative and late outcomes between men and women.	Talent Endurant, Excluder
Torsello	2015	multicenter, open-label, prospective,	evaluate the safety and efficacy of the	INCRAFT AAA Stent Graft System

		non-randomized study	INCRAFT Stent Graft System for the treatment of patients with infrarenal abdominal aortic aneurysms (AAAs)	
Walker	2015	reterospective study	long-term experience with T2L management in a large multicenter centre	Gore, medtronic, Zenith and other
Bisdas	2014	Prospective two-center single-arm study.	assess the late outcomes of the Endurant endograft in patients undergoing abdominal aortic aneurysm (AAA) repair.	Endurant
Speziale	2014	double-center, retrospective analysis using a prospectively compiled database.	evaluate the 2-year outcome of unselected, real-world patients treated with EVAR in challenging aortic neck morphologies using commercially available stent-graft systems.	Endurant I and II Excluder and C3, Zenith
Zandvoort	2014	prospective follow up study	analyze the 4-year results of the first 100 consecutive patients treated with an Endurant graft for an abdominal aortic aneurysm (AAA).	Endurant
Fossaceca	2013	reterospective study	assess the effectiveness of endovascular	Zenith (Cook), Excluder (W.L. Gore), Le Maitre Endofit, Talent

			abdominal aortic aneurysm (AAA)	(Medtronic), Aorfix (Lombard Medical), Endurant (Medtronic), and Evita (Jotec).
Lee	2013	reterospective study	examine the mid-term results of endovascular aneurysm repair (EVAR) using different commercially available endografts in treating abdominal aortic aneurysms (AAAs) with short angled necks	AneuRx (Medtronic Vascular), Excluder (W.L.Gore & Associates), and Zenith (Cook Medical)
Mehta	2013	reterospective study	to determine if Endovascular Aneurysm Repair (EVAR) resulted in lower 30-day mortality compared to open surgical repair (OSR) and to assess long-term survival outcomes in patients with ruptured abdominal aortic aneurysms (r-AAAs)	Gore Excluder and AneuRx
Nyheim	2013	prospective study	assess whether CT and US were comparable and to evaluate a modified follow-up protocol for safety and reduction in the number of CT scans after EVAR.	

Bastos Goncalves	2012	retrospective study using prospectively collected data	aimed to analyze long-term results and morphological changes after EVAR using the Excluder endoprosthesis, assessing its durability and complications.	excluder
BastosGoncalves	2012	reterospective study	compare clinical success after EVAR in patients with and without significant neck thrombus and to analyze technical success, changes in renal function, and morphologic neck changes over time	Talent, Excluder, Zenith and Endurant
Hager	2012	retrospective cohort study	evaluate the performance of two different endograft systems, the Gore Excluder (infrarenal fixation) and the Cook Zenith (suprarenal fixation), in patients with short straight aortic necks undergoing EVAR.	
Kaladji	2012	reterospective study	examine the correlation between diameter increases at the proximal and distal necks of abdominal aortic aneurysms (AAA) after endovascular	Talent, Excluder, Zenith and Endurant

			aneurysm repair (EVAR), specifically focusing on anchor zones and adjacent vascular segments, and to observe clinical events such as endoleaks.	
Majumder	2012	prospective study	evaluate the initial clinical experience with the Anaconda endoluminal graft in the treatment of patients with abdominal aortic aneurysm (AAA).	anaconda
Stather	2012	Retrospective cohort study based on a prospectively maintained database	evaluate outcomes following EVAR in patients with hostile neck anatomy (HNA) over an 11-year period.	Cook Zenith, Medtronic Talent, Gore Excluder, Medtronic Endurant, Edwards Lifepath, Endologix Powerlink, Lombard Aorfix, and Jotec.
Droc	2011	reterospective study	evaluate the safety, effectiveness, and durability of EVAR for infrarenal aortic aneurysms with suitable anatomy.	Powerlink, Anaconda, Talent, and EVITA
Jim	2011	**nonrandomized multicenter prospective Investigator Device Exemption trial**.	evaluate the outcomes of EVAR in patients with small versus large AAAs, particularly focusing on the safety and effectiveness of the Medtronic Talent eLPS graft.	talent

Kalteis	2011	retrospective cohort study	report clinical long-term results and technical success rates after EVAR, based on routine clinical use at a non–university-based vascular center.	zenith, excluder
Mehta	2011	reterospective study	evaluate the frequency, etiology, and outcomes of delayed AAA rupture following EVAR and to identify treatment options that facilitate improved survival.	EVT, Corvita, Aneurex, Zenith, and Gore.
Pintoux	2011	reterospective study	analyze the long-term influence of stent graft proximal fixation systems on inter-renal and infrarenal aneurysm neck dilatation after endovascular aneurysm repair (EVAR).	AneuRx (Medtronic) and Talent (Medtronic)
Waasdorp	2011	retrospective cohort study.	to determine whether sideways movement of the endograft within the aneurysm sac is related to endograft migration and late clinical adverse events in a large patient population	Talent or AneuRx

			with long-term follow-up	
Ghotbi	2010	reterospective study	report the outcome of EVAR using EXCLUDER endoprosthesis	Gore Excluder and AneuRx
Jim	2010	prospective, multicenter clinical trial (nonrandomized)	evaluate the outcomes of EVAR using the Medtronic Talent endograft for aneurysms with short aortic necks (10-15 mm)	Talent
Oberhuber	2010	retrospective study based on data from a prospectively maintained database.	primary aim was to evaluate aortic neck changes, specifically aortic neck dilatation, over a 10-year period in patients treated with three self-expanding stent-grafts. Secondary endpoints included assessing changes in aneurysm diameter and incidence of stent-graft migration and endoleaks.	Excluder (W. L. Gore & Associates), Talent (Medtronic Vascular), and Zenith Trifab (Cook Inc.)
Turnbull	2010	**nonrandomized multicenter prospective Investigator Device Exemption trial**.	evaluate the outcomes of EVAR in patients with small versus large AAAs, particularly focusing on the safety and effectiveness of the Medtronic Talent eLPS graft.	talent

Cao	2009	reterospective study	evaluate midterm morphological changes after using the new generation Talent Unidoc device through core lab analysis of data	Talent Unidoc
Conrad	2009	reterospective study	to analyze the frequency and nature of secondary interventions required after EVAR and to evaluate their impact on overall clinical outcomes	Cook Zenith, Gore Excluder, Medtronic AneuRx, and Endologix Powerlink.
Pitoulias	2009	prospective study	analyze the outcomes of secondary procedures and especially of conversion surgery in patients with failing EVAR.	Vanguard, Lifepath, Talent, AneuRx, Zenith, Excluder, and other commercially available stent grafts
Pitton	2009	prospective, single-center study.	analyze the long-term clinical and radiological outcomes of patients treated with the Talent bifurcated stent-graft, focusing on technical results, the incidence of secondary procedures, and the impact of endoleaks on aneurysm shrinkage.	Talent

Rodel	2009	multicenter, prospective, non-randomized controlled study	examine the technical and clinical success of the Anaconda™ AAA Stent Graft System for the treatment of AAA	Anaconda™ AAA Stent Graft System
Stella	2009	reterospective study	toevaluate the mid-term outcomes of the anaconda stent graft	anaconda
Waasdrop	2009	retrospective, based on prospectively collected data	analyze the long-term association between iliac fixation and proximal endograft migration in patients treated with the Talent stent-graft.	Talent
Abbruzzese	2008	reterospective study	to perform an anatomically and device-specific analysis of EVAR to determine the effects of device type on early and late clinical outcomes.	Cook Zenith, Gore Excluder, and Medtronic AneuRx.
Coppi	2008	prospective multicentre study	o analyze the best deployment technique for the unibody bifurcated Powerlink endograft in primary, elective EVAR for selected low- and high-risk patients, and its impact on	Powerlink unibody bifurcated endograft.

			immediate and late outcomes.	
Greenberg	2008	non-randomized, controlled trial involving retrospective analysis of both a pivotal study and a continued access study	eport on the long-term durability and outcomes of the Zenith AAA Endovascular Graft, evaluating its effectiveness and complications in treating infrarenal abdominal aortic aneurysms.	Zenith (Cook)
Sternbergh	2008	reterospective study	To examine the correlation of early endoleaks with the long-term outcomes in patients treated with the Zenith endograft, and to assess the possible need for changes in current surveillance regimens.	Zenith endograft (Cook Inc, Bloomington, Ind).
Wang	2008	prospective nonrandomized concurrently controlled trial.	To evaluate the safety and efficacy of the Endologix Powerlink bifurcated system for the repair of abdominal aortic aneurysms.	Powerlink bifurcated system
Dalainas	2007	reterospective study	To compare self-expanding and balloon-expandable stent-grafts in terms of aortic neck dilatation and endograft migration	Lifepath, Excluder, endologix, Vanguard, anaconda, talent, excluder

Goodman	2007	reterospective study	To evaluate the outcome of treating infrarenal abdominal aortic aneurysms with unfavorable necks using the 36-mm Zenith endograft.	Zenith
vanHerwaarden	2007	Retrospective cohort study based on a prospectively maintained database	To evaluate the long-term single-center results with the AneuRx stent-graft in endovascular abdominal aortic aneurysm (AAA) repair (EVAR)	Aneurx
Brewster	2006	reterospective study	To document late outcome data of EVAR to aid decision-making regarding its long-term effectiveness and durability.	
Fulton	2006	reterospective study	o establish the effect of challenging neck anatomy on the mid-term incidence of migration using the AneuRx bifurcated device.	AneuRx bifurcated stent graft.
Heikkinen	2006	reterospective study	To determine the importance of iliac fixation in preventing migration using an endovascular device fully supported by an exoskeleton for	Aneurx

			meaningful longitudinal columnar support.	
Litwinski	2006	reterospective study	to determine whether stent graft migration always signifies a real phenomenon involving the loss of the proximal stent graft seal or whether it can be attributed to aortic neck elongation.	Aneurx
Seriki	2006	reterospective study	The aim was to assess the midterm benefits regarding the technical success rate and low morbidity and mortality rates initially observed with the EVAR procedure.	Talent
Steingruber	2006	reterospective study	To report a single-center experience with EVAR, focusing on patient selection and stent-graft devices.	Vanguard, Excluder, Talent, Zenith, and Quantum.
Torsello	2006	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	long-term clinical and radiographic results after the implantation of the Talent endograft	Talent
Albertini	2005	prospective, multicenter investigational	To report the results of a prospective multicenter study on	Powerlink unibody bifurcated endograft.

		device exemption (IDE) clinical trial.	endovascular repair of abdominal aortic aneurysms (AAA) using the bifurcated Powerlink stent-graft.	
Malas	2005	reterospective study	To evaluate the long-term outcome of the Montefiore Endografting System (MEGS), particularly in terms of graft migration and proximal neck dilatation (PND).	Montefiore Endografting System (MEGS) with a balloon-expanding stent (BES).
Tonnessen	2005	reterospective study	To evaluate the mid- and long-term incidence of migration with two commercially available endografts and examine risk factors for migration and selective treatment options.	AneuRx (Medtronic/AVE Inc) and Zenith (Cook Inc) endografts.
Carpenter	2004	Prospective nonrandomized concurrently controlled trial.	To evaluate the safety and efficacy of the Endologix Powerlink bifurcated system for abdominal aortic aneurysms (AAAs) repair in comparison with open AAA repair.	Powerlink bifurcated endovascular graft.
England et al	2004	Retrospective analysis of prospectively collected	Predict migration?	Talent

		nonrandomized data in a tertiary institution		
Greenberg	2004	Prospective, non-randomized, concurrently controlled clinical trial.	To assess the safety and effectiveness of the Zenith AAA Endovascular Graft compared with conventional open surgical repair in patients with similar pathophysiologic features.	Zenith AAA Endovascular Graft.
Verhoeven	2004	prospective cohort study	To describe the long-term results of EVAR in a consecutive cohort and report the frequency, type, and outcomes of re-interventions.	Vanguard, Talent, Zenith, Excluder, and Quantum.
Clouse	2003	prospective cohort study	To evaluate the long-term success and durability of the EVT/Guidant AI device in overcoming complex iliac artery anatomy constraints.	EVT/Guidant AI device
Dillavou	2003	reterospective study	To review the experience with the Ancure graft in patients with compromised necks after its commercial release.	Ancure
Kibbe	2003	Prospective controlled clinical trial	summarise the 2-year outcomes of the FDA-approved	Excluder

			Excluder endograft in the treatment of abdominal aortic aneurysms (AAA) and compare it to standard open surgical repair.	
May	2003	reterospective study	document changes in the diameter of the proximal neck of AAA in patients who underwent endoluminal repair over a period of 5 to 9 years,	modified Parodi (n = 4), Endovascular Technologies (EVT) (n = 14) (Menlo Park, Calif), White-Yu (n = 10), Stentor/Vanguard (n = 21) (Boston Scientific, Natick, Mass), and Bard 1996 prototype (n = 2) (Haverhill, Mass).
Zarins	2003	reterospective study	evaluate the safety, effectiveness, and durability of EVAR for infrarenal aortic aneurysms with suitable anatomy.	Powerlink, Anaconda, Talent, and EVITA
Alric et al	2002	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	Evaluate the efficacy and midterm results of the Zenith stent-graft in the treat-ment of abdominal aortic aneurysms	Zenith
Cao et al	2002	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	incidence rate and the predictive factors of distal migration of the proximal portion of the endograft	Aneurx
Connors III	2002	Retrospective analysis of prospectively	Rate of migration at 1 year	Aneurx

		collected nonrandomized data in a tertiary institution		
Carpenter	2002	Prospectively collective data, clinical trial	Assess the results of abdominal aortic aneurysm repair with the PowerLink bifurcated endovascular graft (Endologix, Inc, Irvine, Calif).	powerlink
Makaroun	2002	prspective study evaluating efficacy of graft	analyze the long-term results of the Ancure bifurcated endovascular graft, focusing on parameters favoring endovascular repair over open surgery.	Ancure
Pereira	2002	reterospective study	To analyze the outcome of endovascular exclusion of abdominal aortic aneurysm (AAA) using aortomonoiliac stent-grafts.	conical ELLA stent-graft
Resch	2002	reterospective study	to **analyze the evolution of the Gianturco Z stent–based stent-graft and its effect on short- and midterm outcomes**of endovascular aneurysm repair.	Ivancev-Malmö monoiliac stent-graft (first and second generation), Chuter bifurcated SG, Zenith SG

Sternbergh III	2002	Retrospective analysis of prospectively collected nonrandomized data in a tertiary institution	aortic neck angulation, on the incidence of acute and delayed adverse events after EAAA repair	Aneurx, Zenith
Tonnessen	2002	retrospective study	define the mid-term results from EVAR performed with the AneuRx	AneuRx
Blum	2001	reterospective study	To examine the clinical utility of polyester-covered nitinol stents and PTFE-covered endoprostheses for treating infrarenal AAAs.	Mialhe Stentor, Vanguard, and Excluder devices.
Greenberg	2001	prospective study	To evaluate the initial and mid-term results of the Zenith endovascular grafting system for infrarenal abdominal aortic aneurysms.	Zenith
Resch	2001	prospective study	to **analyze the impact of newer stent-grafts (SG) and improved operator skills** on short- and mid-term outcomes of AAA SG repair over a **7-year experience**.	Ivancev-Malmö monoiliac stent-graft (first and second generation), Chuter bifurcated SG, Vanguard SG, Zenith SG
Schlensak	2001	reterospective study	To summarize experiences with explantation of stent-grafts due to	Stentor and Vanguard

			complications requiring surgical intervention.	
Broeders	1999	Prospective study	To investigate the long-term efficacy of the EVT endograft system in preventing endograft migration and the morphological changes in the abdominal aorta during follow-up.	EVT endografts, first and second generation.
Resch	1999	prospective study	To analyze the causes of distal migration of stent-grafts after endovascular AAA repair.	Ivancev-Malmo system, Chuter system, and Vanguard system.

7.1.4 Migration specific data

Table 57: Systematic Review - migration details

Study	year published	Definition of migration	centre line technology 1= yes	number of patients	migration at 10mm	migration at 5mm	type 1a endoleak
Abdulrasak	2020	3	1	543	3		13
Baderkhan et al	2020	1	1	439	3		42
Barleben	2020	1	1	161	0	0	4
Chinsakchai	2020	0	1	198	10	0	12
Midy	2020	1	1	177	3		6
Mufty	2020	0	0	74	0		4
Oliveira-Pinto	2020	2	1	277		16	23
Oliveira-Pinto	2020	2	1	565		46	35
Reina	2020	1	1	71	0		2
Sirignano	2020	0	1	479	1		6
Asenbaum	2019	10	1	187	54		4
McFarland	2019	3	1	500	31		30

Oliveira-Pinto et al	2019	2	1	277		17	14
Ramirez	2019	0	0	325	0	0	3
Torsello	2019	3	1	60	0	0	2
Herman	2018	1	1	461	21		39
Healy	2017	0	0	175	5		9
Malas	2017	3	1	218	7		0
Oliveira	2017	1	0	427	20		17
Poublon	2017	2	0	248	2	1	5
Pratesi	2017	3	1	60	0	0	2
tMannetje	2017	1	1	221	8		16
Tokunga	2017	12	1	80		8	
Broos	2016	1	0	863	8		23
DeDonato	2016	13	1	161	0		4
Kim	2016	2	0	126	1	4	
Mateo	2016	5	0	249	0	0	11
Roos	2016	15	0	405	9		19
Singh	2016	0	1	150	0	0	2
tMannetje	2016	3	0	149	5		
Chung	2015	0	0	1380	1		140
Torsello	2015	2	0	60			2
Walker	2015	16	0	1595	27		
Bisdas	2014	0	1	273	0		5
Speziale	2014	2	1	196		6	1
Zandvoort	2014	0	1	100			2
Fossaceca	2013	0	0	222	0		4
Lee	2013	3	1	218	1		5
Mehta	2013	0	0	120	1		3
Nyheim	2013	3	0	56	4		2
Bastos Goncalves	2012	3	1	144	5	15	7
BastosGoncalves	2012	3	1	396	12	16	1
Hager	2012	3	0	84	0	0	2
Kaladji	2012	3	1	61	1		1
Majumder	2012	3	0	106	2		0
Stather	2012	1	0	552	15		
Droc	2011	0	0	1502	0		
Jim	2011	3	0	156	5		3
Kalteis	2011	0	0	106	2		4
Mehta	2011	14	0	1768	17		20

Pintoux	2011	3	0	58	9		3
Waasdorp	2011	1	1	144	38		18
Ghotbi	2010	3	0	100	1		3
Jim	2010	3	0	137	5	0	3
Oberhuber	2010	11	1	103	1	2	11
Turnbull	2010	3	0	166	5		3
Cao	2009	3	1	349	17		
Conrad	2009	2	1	832	14		
Pitoulias	2009	2	0	617	41	19	29
Pitton	2009	3	1	127	32		
Rodel	2009	0	0	61			1
Stella	2009	1	0	100	0		1
Waasdrop	2009	3	1	154	32		
Abbruzzese	2008	2	0	565	7	3	
Coppi	2008	2	0	205		8	21
Greenberg	2008	9	0	736	2	19	
Sternbergh	2008	1	0	714	2		
Wang	2008	0	0	145	3		
Dalainas	2007	2	1	242		52	10
Goodman	2007	0	0	65	1		3
vanHerwaarden	2007	3	1	211	26		17
Brewster	2006	0	1	873	25		
Fulton	2006	1	1	84	14		7
Heikkinen	2006	1	1	173	17		
Litwinski	2006	2	1	308	25	48	5
Seriki	2006	17	1	68	4		5
Steingruber	2006	2	1	70		14	
Torsello	2006	3	0	165	7		6
Albertini	2005	0	0	61	3		3
Malas	2005	2	0	77	0	0	1
Tonnessen	2005	1	0	130	15	26	
Carpenter	2004	3	0	188	3		
England et al	2004	6	0	55	6	1	
Greenberg	2004	2	0	200		4	
Verhoeven	2004	0	0	308	25		
Clouse	2003	0	0	121	2		
Dillavou	2003	0	0	206			
Kibbe	2003	0	0	235	2		47
May	2003	2	0	51	2	3	5

Zarins	2003	0	0	1502	0		
Alric et al	2002	2	0	88		1	3
Cao et al	2002	7	0	113	17		7
Connors III	2002	4	0	69		15	2
Carpenter	2002	0	0	118	1		3
Makaroun	2002	8	0	242	2		0
Pereira	2002	1	0	57	0		
Resch	2002	0	0	164		31	8
Sternbergh III	2002	2	0	81		7	
Tonnessen	2002	2	0	101		15	9
Blum	2001	0	0	159	5	1	
Greenberg	2001	2	0	528		8	
Resch	2001	2	0	158		8	
Schlensak	2001	0	0	144	5		
Broeders	1999	18	0	125	3		3
Resch	1999	2	0	58	15	11	

7.1.5 Anatomical data

Table 58: Systematic Review: anatomical data

Study	year published	AAA diameter	neck length	neck diameter	neck angulation	Sex
Abdulrasak	2020	58				87.8
Baderkhan et al	2020	63.6				80.8
Barleben	2020	54	22.9	22.5	19.1	87.6
Chinsakchai	2020	64.9	26.5		47.75	78.3
Midy	2020	53.9	20	23	6	90.4
Mufty	2020	60	32	23	33	93
Oliveira-Pinto	2020	60	26.5	27	38.5	87
Oliveira-Pinto	2020	61.6	27.2	25	21	90.1
Reina	2020	55.6	17.7	22	27.7	96
Sirignano	2020	52.02				86.3
Asenbaum	2019	59.9	30.8	24.2	34.7	92.5
McFarland	2019	62.1	25.86	23.94		84.5
Oliveira-Pinto et al	2019	61	28.3	25.5	36	87
Ramirez	2019	59.5				92
Torsello	2019	52.6		23	34.4	94
Herman	2018					
Healy	2017	61				85

Malas	2017	57.5	22.6	22.6	71	71
Oliveira	2017	60	27	26	25	89
Poublon	2017	59.1	32.2	22.9	23.9	87.1
Pratesi	2017	52.6		23	34.4	94
tMannetje	2017	58	35	23	48	90
Tokunga	2017		28.1		34	85
Broos	2016	61.4				89
DeDonato	2016	54.9	22.1	22.1	19.1	87.6
Kim	2016	61	34	22		83
Mateo	2016	57.5	18.5	23.35	35.75	96.8
Roos	2016					84
Singh	2016	57	26.5			
tMannetje	2016	59				91.9
Chung	2015	57	25	24.5	32	84.5
Torsello	2015	52.6				95
Walker	2015	56				86.5
Bisdas	2014	57	9	26	65	90
Speziale	2014	60.2	24.9	22.5	22.1	79
Zandvoort	2014	58	34	27	23	88
Fossaceca	2013	59	60			95.9
Lee	2013	58.5	20			90.4
Mehta	2013	64				71.1
Nyheim	2013	60				89
Bastos Goncalves	2012	60	28.5	24	27	88.2
BastosGoncalves	2012	60	32	25		90.6
Hager	2012	58.5	11.7			85
Kaladji	2012			24.3		93
Majumder	2012	63	25	31.5		85
Stather	2012	64				93
Droc	2011	52.4				
Jim	2011	54	22	25	31	91
Kalteis	2011	58	25.5	23	24	94.3
Mehta	2011	56				81
Pintoux	2011	55	24.3	23	20	100
Waasdorp	2011	58.5	22.5	26.7		91
Ghotbi	2010	56.1				91
Jim	2010	56.3	24.2	25.6	30	92.5
Oberhuber	2010	57.6	28.1			93.2
Turnbull	2010	54	22	25	31	91

Cao	2009	56	20	25		93
Conrad	2009	59	24	23.4	43	80
Pitoulias	2009	53.5	13.1	27.4	42.5	86.4
Pitton	2009	59.6		29.1		91%
Rodel	2009					98.4
Stella	2009	55.2	26.5	36		94
Waasdrop	2009	61	24	27	30	92.5
Abbruzzese	2008	56.1	24.6	23.4	22.7	80
Coppi	2008	53.8	26.5	23.9		93.7
Greenberg	2008					
Sternbergh	2008					
Wang	2008	51	29.3	22.4		88
Dalainas	2007			25.5	30	73
Goodman	2007			32		
vanHerwaarden	2007					
Brewster	2006	56.8				81.4
Fulton	2006	57	25.6		26.5	84
Heikkinen	2006	56	26	22		88
Litwinski	2006					
Seriki	2006	63				91.2
Steingruber	2006					91.4
Torsello	2006	55.9	27.9	24.6		97.6
Albertini	2005	55			16.3	95
Malas	2005	23	24			74
Tonnessen	2005	55.7	30	33.7		91.5
Carpenter	2004	50				87
England et al	2004					
Greenberg	2004					
Verhoeven	2004	59.9				94
Clouse	2003	54.4				92.6
Dillavou	2003	54.8				
Kibbe	2003	55.6	28.9	22.3	22	87
May	2003			25		94.7
Zarins	2003	52.4				
Alric et al	2002					
Cao et al	2002					
Connors III	2002					
Carpenter	2002					
Makaroun	2002					

Pereira	2002					
Resch	2002					87
Sternbergh III	2002	59	24	22	20	
Tonnessen	2002	56				87
Blum	2001					
Greenberg	2001					88
Resch	2001	55				88.6
Schlensak	2001					95
Broeders	1999	53				89
Resch	1999	54				91

7.1.6 Newcastle-Ottawa assessment

Table 59: Systematic Review: Risk of bias assessment using modified Newcastle-Ottawa quality assessment score.

	Selection				Comparability	Outcome			
Study	Adequacy of the case	Representativeness of the cases	Selection of Controls	Definition of Controls	Comparability of Cohorts Based on Design or Analysis	Assessment of Outcome	Was Follow-Up Long	Adequacy of Follow-Up of	Total
Abdulrasak	1	1	N/A	N/A	0	1	1	0	4
Baderkhan et al	1	1	N/A	N/A	0	1	1	0	4
Barleben	1	1	N/A	N/A	0	1	1	1	5
Chinsakchai	1	1	N/A	N/A	0	1	1	0	4
Midy	1	1	N/A	N/A	0	1	1	1	5
Mufty	1	1	N/A	N/A	0	0	0	0	2
Oliveira-Pinto	1	1	N/A	N/A	0	1	1	0	4
Oliveira-Pinto	1	1	N/A	N/A	0	1	1	1	5
Reina	1	1	N/A	N/A	0	1	0	0	3
Sirignano	1	1	N/A	N/A	0	0	1	0	3
Asenbaum	1	1	N/A	N/A	0	1	0	1	4
McFarland	1	1	N/A	N/A	0	1	0	1	4
Oliveira-Pinto et al	1	1	N/A	N/A	0	1	1	0	4
Ramirez	1	1	N/A	N/A	0	0	1	0	3
Torsello	1	1	N/A	N/A	0	1	1	1	5
Herman	1	1	N/A	N/A	0	1	0	1	4
Healy	1	1	N/A	N/A	0	0	0	0	2
Malas	1	1	N/A	N/A	0	1	1	1	5
Oliveira	1	1	N/A	N/A	0	1	1	0	4

Poublon	1	1	N/A	N/A	0	1	0	1	4
Pratesi	1	1	N/A	N/A	0	1	1	1	5
tMannetje	1	1	N/A	N/A	0	1	1	0	4
Tokunga	1	1	N/A	N/A	0	1	0	1	4
Broos	1	1	N/A	N/A	0	1	1	1	5
DeDonato	1	1	N/A	N/A	0	1	1	1	5
Kim	1	1	N/A	N/A	0	1	1	1	5
Mateo	1	1	N/A	N/A	0	1	0	1	4
Roos	1	1	N/A	N/A	0	1	0	1	4
Singh	1	1	N/A	N/A	0	0	1	0	3
tMannetje	1	1	N/A	N/A	0	1	1	0	4
Chung	1	1	N/A	N/A	0	0	0	1	3
Torsello	1	1	N/A	N/A	0	1	0	1	4
Walker	1	1	N/A	N/A	0	1	0	0	3
Bisdas	1	1	N/A	N/A	0	0	1	0	3
Speziale	1	1	N/A	N/A	0	1	0	0	3
Zandvoort	1	1	N/A	N/A	0	0	1	0	3
Fossaceca	1	1	N/A	N/A	0	0	0	0	2
Lee	1	1	N/A	N/A	0	1	0	0	3
Mehta	1	1	N/A	N/A	0	0	0	1	3
Nyheim	1	1	N/A	N/A	0	1	1	1	5
Bastos Goncalves	1	1	N/A	N/A	0	1	1	1	5
BastosGoncalves	1	1	N/A	N/A	0	1	1	1	5
Hager	1	1	N/A	N/A	0	1	0	0	3
Kaladji	1	1	N/A	N/A	0	1	1	1	5
Majumder	1	1	N/A	N/A	0	1	1	1	5
Stather	1	1	N/A	N/A	0	1	1	0	4
Droc	1	1	N/A	N/A	0	0	1	1	4
Jim	1	1	N/A	N/A	0	1	1	1	5
Kalteis	1	1	N/A	N/A	0	0	1	1	4
Mehta	1	1	N/A	N/A	0	0	0	1	3
Pintoux	1	1	N/A	N/A	0	1	1	1	5
Waasdorp	1	1	N/A	N/A	0	1	1	1	5
Ghotbi	1	1	N/A	N/A	0	1	0	0	3
Jim	1	1	N/A	N/A	0	1	1	1	5
Oberhuber	1	1	N/A	N/A	0	1	1	1	5
Turnbull	1	1	N/A	N/A	0	1	1	1	5
Cao	1	1	N/A	N/A	0	1	0	1	4

Conrad	1	1	N/A	N/A	0	1	0	1	4
Pitoulias	1	1	N/A	N/A	0	1	1	1	5
Pitton	1	1	N/A	N/A	0	1	1	1	5
Rodel	1	1	N/A	N/A	0	0	0	1	3
Stella	1	1	N/A	N/A	0	1	0	1	4
Waasdrop	1	1	N/A	N/A	0	1	0	1	4
Abbruzzese	1	1	N/A	N/A	0	1	0	1	4
Coppi	1	1	N/A	N/A	0	1	1	0	4
Greenberg	1	1	N/A	N/A	0	1	1	1	5
Sternbergh	1	1	N/A	N/A	0	1	0	1	4
Wang	1	1	N/A	N/A	0	0	1	1	4
Dalainas	1	1	N/A	N/A	0	1	1	1	5
Goodman	1	1	N/A	N/A	0	0	0	1	3
vanHerwaarden	1	1	N/A	N/A	0	1	1	1	5
Brewster	1	1	N/A	N/A	0	0	0	1	3
Fulton	1	1	N/A	N/A	0	1	1	1	5
Heikkinen	1	1	N/A	N/A	0	1	0	1	4
Litwinski	1	1	N/A	N/A	0	1	1	1	5
Seriki	1	1	N/A	N/A	0	0	1	1	4
Steingruber	1	1	N/A	N/A	0	1	0	1	4
Torsello	1	1	N/A	N/A	0	1	1	1	5
Albertini	1	1	N/A	N/A	0	0	1	1	4
Malas	1	1	N/A	N/A	0	1	0	1	4
Tonnessen	1	1	N/A	N/A	0	1	1	1	5
Carpenter	1	1	N/A	N/A	0	1	0	1	4
England et al	1	1	N/A	N/A	0	1	0	1	4
Greenberg	1	1	N/A	N/A	0	1	0	1	4
Verhoeven	1	1	N/A	N/A	0	0	1	1	4
Clouse	1	1	N/A	N/A	0	0	1	1	4
Dillavou	1	1	N/A	N/A	0	0	0	1	3
Kibbe	1	1	N/A	N/A	0	0	0	1	3
May	1	1	N/A	N/A	0	1	1	1	5
Zarins	1	1	N/A	N/A	0	0	1	1	4
Alric et al	1	1	N/A	N/A	0	1	0	1	4
Cao et al	1	1	N/A	N/A	0	1	1	1	5
Connors III	1	1	N/A	N/A	0	1	0	1	4
Carpenter	1	1	N/A	N/A	0	0	0	1	3
Makaroun	1	1	N/A	N/A	0	1	1	1	5
Pereira	1	1	N/A	N/A	0	0	0	1	3

Resch	1	1	N/A	N/A	0	0	1	1	4
Sternbergh III	1	1	N/A	N/A	0	1	0	1	4
Tonnessen	1	1	N/A	N/A	0	1	0	1	4
Blum	1	1	N/A	N/A	0	0	0	0	2
Greenberg	1	1	N/A	N/A	0	1	0	1	4
Resch	1	1	N/A	N/A	0	1	0	1	4
Schlensak	1	1	N/A	N/A	0	0	1	1	4
Broeders	1	1	N/A	N/A	0	1	0	1	4
Resch	1	1	N/A	N/A	0	1	0	1	4

7.1.7 Newcastle-Ottawa justification

Table 60: Systematic Review: justification for risk of bias

	Selection				**Comparability**	**Outcome**		
Study	**Adequacy of the case**	**Representativeness of the cases**	**Selection of Controls**	**Definition of Controls**	**Comparability of Cohorts**	**Assessment of Outcome**	**Was Follow-Up**	**Adequacy of Follow-Up of**
Abdulrasak	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixed USS and CT follow up
Baderkhan et al	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixed USS and CT follow up
Barleben	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)

Chinsakchai	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixed USS and CT follow up
Midy	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Mufty	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition	Short follow up	mixed USS and CT follow up
Oliveira-Pinto	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixed USS and CT follow up
Oliveira-Pinto	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Reina	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with	too short	mixed USS and CT follow up

						a definition		
Sirignano	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	USS f/u
Asenbaum	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
McFarland	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Oliveira-Pinto et al	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixed USS and CT follow up
Ramirez	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Torsello	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with	>36 months	Follow-up was adequate (regular intervals)

						a definition		
Herman	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)
Healy	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	USS f/u
Malas	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Oliveira	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixture of USS and CT
Poublon	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Pratesi	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with	>36 months	Follow-up was adequate (regular intervals)

						a definition		
tMannetje	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixture of USS and CT
Tokunga	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Broos	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
DeDonato	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Kim	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)

Mateo	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Roos	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Singh	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	mixed USS and CT follow up
tMannetje	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	USS f/u
Chung	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)
Torsello	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)

Walker	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	variable follow up lengths
Bisdas	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	USS f/u
Speziale	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	USS f/u
Zandvoort	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	mixture of USS and CT
Fossaceca	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	mixed USS and CT follow up
Lee	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	USS f/u

Mehta	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)
Nyheim	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Bastos Goncalves	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
BastosGoncalves	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Hager	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	USS f/u
Kaladji	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with	>36 months	Follow-up was adequate (regular intervals)

						a definition		
Majumder	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Stather	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixture of USS and CT
Droc	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Jim	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Kalteis	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Mehta	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	defined only in context of rupture	too short	Follow-up was adequate (regular intervals)

Pintoux	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Waasdorp	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Ghotbi	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	unsure if CT follow up employed
Jim	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Oberhuber	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Turnbull	AAA patients with infra	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is	>36 months	Follow-up was adequate

	renal EVAR					explicitly assed with a definition		(regular intervals)
Cao	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Conrad	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Pitoulias	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Pitton	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Rodel	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)

Stella	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Waasdrop	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Abbruzzese	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Coppi	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	mixture of USS and CT
Greenberg	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Sternbergh	AAA patients with infra	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is	too short	Follow-up was adequate

	renal EVAR					explicitly assed with a definition		(regular intervals)
Wang	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Dalainas	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Goodman	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)
vanHerwaarden	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Brewster	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	Migration only determined if led to type 1a endoleak	too short	Follow-up was adequate (regular intervals)
Fulton	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with	>36 months	Follow-up was adequate (regular intervals)

						a definition		
Heikkinen	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Litwinski	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Seriki	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	inadequate definition for migration	>36 months	Follow-up was adequate (regular intervals)
Steingruber	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Torsello	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Albertini	AAA patients with infra	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate

	renal EVAR							(regular intervals)
Malas	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Tonnessen	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Carpenter	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
England et al	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	Short follow up	Follow-up was adequate (regular intervals)
Greenberg	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)

Verhoeven	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Clouse	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Dillavou	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)
Kibbe	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	Follow-up was adequate (regular intervals)
May	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Zarins	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)
Alric et al	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	Short follow up	Follow-up was adequate (regular intervals)

Cao et al	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	Short follow up	Follow-up was adequate (regular intervals)
Connors III	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	Short follow up	Follow-up was adequate (regular intervals)
Carpenter	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	Short follow up	Follow-up was adequate (regular intervals)
Makaroun	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	>36 months	Follow-up was adequate (regular intervals)
Pereira	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Resch	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)

Sternbergh III	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Tonnessen	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Blum	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	too short	interval follow up not clear
Greenberg	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Resch	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Schlensak	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	no definition for migration	>36 months	Follow-up was adequate (regular intervals)

Broeders	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)
Resch	AAA patients with infra renal EVAR	representative of AAA for EVAR	N/A	N/A	N/A	outcome of interest (migration) is explicitly assed with a definition	too short	Follow-up was adequate (regular intervals)

7.2 Appendix 2: Predictive model descriptors

7.2.1 2.1 Random Forest

Random Forest is an ensemble learning method that constructs multiple decision trees during training and outputs the class that is the mode of the classes (classification) of the individual trees. It uses bagging and feature randomness when building each tree to create an uncorrelated forest of trees whose prediction is more accurate than that of any individual tree.

7.2.2 2.2 Decision Tree

A Decision Tree is a flowchart-like structure where each internal node represents a feature (or attribute), each branch represents a decision rule, and each leaf node represents an outcome. The topmost node in a decision tree is known as the root node. It learns to partition on the basis of the attribute value. It partitions the tree in a recursive manner called recursive partitioning.

7.2.3 2.3 Naive Bayes

Naive Bayes is a probabilistic classifier based on applying Bayes' theorem with strong (naive) independence assumptions between the features. Despite its simplicity, Naive Bayes can often outperform more sophisticated classification methods, especially in text classification and spam filtering.

7.2.4 2.4 Support Vector Machine (SVM)

SVM is a supervised machine learning algorithm which can be used for both classification and regression challenges. However, it is mostly used in classification problems. In this algorithm, we plot each data item as a point in n-dimensional space (where n is number of features you have) with the value of each feature being the value of a particular coordinate. Then, we perform classification by finding the hyper-plane that differentiates the two classes very well.

7.2.5 2.5 K-Nearest Neighbors (K-NN)

K-NN is a simple, easy-to-implement supervised machine learning algorithm that can be used to solve both classification and regression problems. It assumes that similar things exist in close proximity. In other words, similar things are near to each other. K-NN captures the idea of similarity by calculating the distance between points on a graph.

7.2.6 2.6 Multi-Layer Perceptron (MLP)

MLP is a class of feedforward artificial neural network. An MLP consists of at least three layers of nodes: an input layer, a hidden layer and an output layer. Except for the input nodes, each node is a neuron that uses a nonlinear activation function. MLP utilizes a supervised learning technique called backpropagation for training.

7.2.7 2.7 XGBoost

XGBoost (Extreme Gradient Boosting) is an optimized distributed gradient boosting library designed to be highly efficient, flexible and portable. It implements machine learning algorithms under the Gradient Boosting framework. XGBoost provides a parallel tree boosting that solve many data science problems in a fast and accurate way.

7.2.8 2.8 LightGBM

LightGBM is a gradient boosting framework that uses tree based learning algorithms. It is designed to be distributed and efficient with the following advantages: faster training speed and higher efficiency, lower memory usage, better accuracy, support of parallel and GPU learning, and capable of handling large-scale data.

7.2.9 Performance Metrics

7.2.9.1 Accuracy

Accuracy is the ratio of correct predictions to the total number of cases evaluated. Mathematically, it can be expressed as:

$$\text{Accuracy} = \frac{\text{TP} + \text{TN}}{\text{TP} + \text{TN} + \text{FP} + \text{FN}}$$

where TP = True Positives, TN = True Negatives, FP = False Positives, and FN = False Negatives.

7.2.9.2 Balanced Accuracy

Balanced Accuracy is the average of recall obtained on each class. It's especially useful when dealing with imbalanced datasets. It's defined as:

$$\text{Balanced Accuracy} = \frac{1}{2}\left(\frac{\text{TP}}{\text{TP} + \text{FN}} + \frac{\text{TN}}{\text{TN} + \text{FP}}\right)$$

7.2.9.3 F1-score

The F1-score is the harmonic mean of precision and recall. It provides a single score that balances both the precision and the recall. Mathematically:

$$\text{F1-score} = 2 \cdot \frac{\text{Precision} \cdot \text{Recall}}{\text{Precision} + \text{Recall}}$$

where Precision = TP / (TP + FP) and Recall = TP / (TP + FN).

7.2.9.4 Matthews Correlation Coefficient (MCC)

MCC is a balanced measure which can be used even if the classes are of very different sizes. It's essentially a correlation coefficient between the observed and predicted binary classifications. It returns a value between −1 and +1, where +1 represents a perfect prediction, 0 no better than random prediction and −1 indicates total disagreement between prediction and observation.

$$\text{MCC} = \frac{\text{TP} \cdot \text{TN} - \text{FP} \cdot \text{FN}}{\sqrt{(\text{TP} + \text{FP})(\text{TP} + \text{FN})(\text{TN} + \text{FP})(\text{TN} + \text{FN})}}$$

7.2.9.5 Average Precision-Recall Score

The Average Precision-Recall Score summarizes a precision-recall curve as the weighted mean of precisions achieved at each threshold, with the increase in recall from the previous threshold used as the weight. Mathematically:

$$\mathrm{AP} = \sum_n (R_n - R_{n-1}) P_n$$

where R_n and P_n are the recall and precision at the n-th threshold.
This metric is particularly useful for imbalanced datasets as it focuses on the minority class (typically the positive class).

7.2.9.6 Area Under the Receiver Operating Characteristic Curve (AUC-ROC)

The AUC-ROC is a performance measurement for classification problems at various threshold settings. ROC is a probability curve and AUC represents the degree or measure of separability. It tells how much the model is capable of distinguishing between classes. The higher the AUC, the better the model is at predicting 0s as 0s and 1s as 1s. The ROC curve is plotted with True Positive Rate (TPR) against the False Positive Rate (FPR) where TPR is on the y-axis and FPR is on the x-axis. Mathematically, AUC can be expressed as:

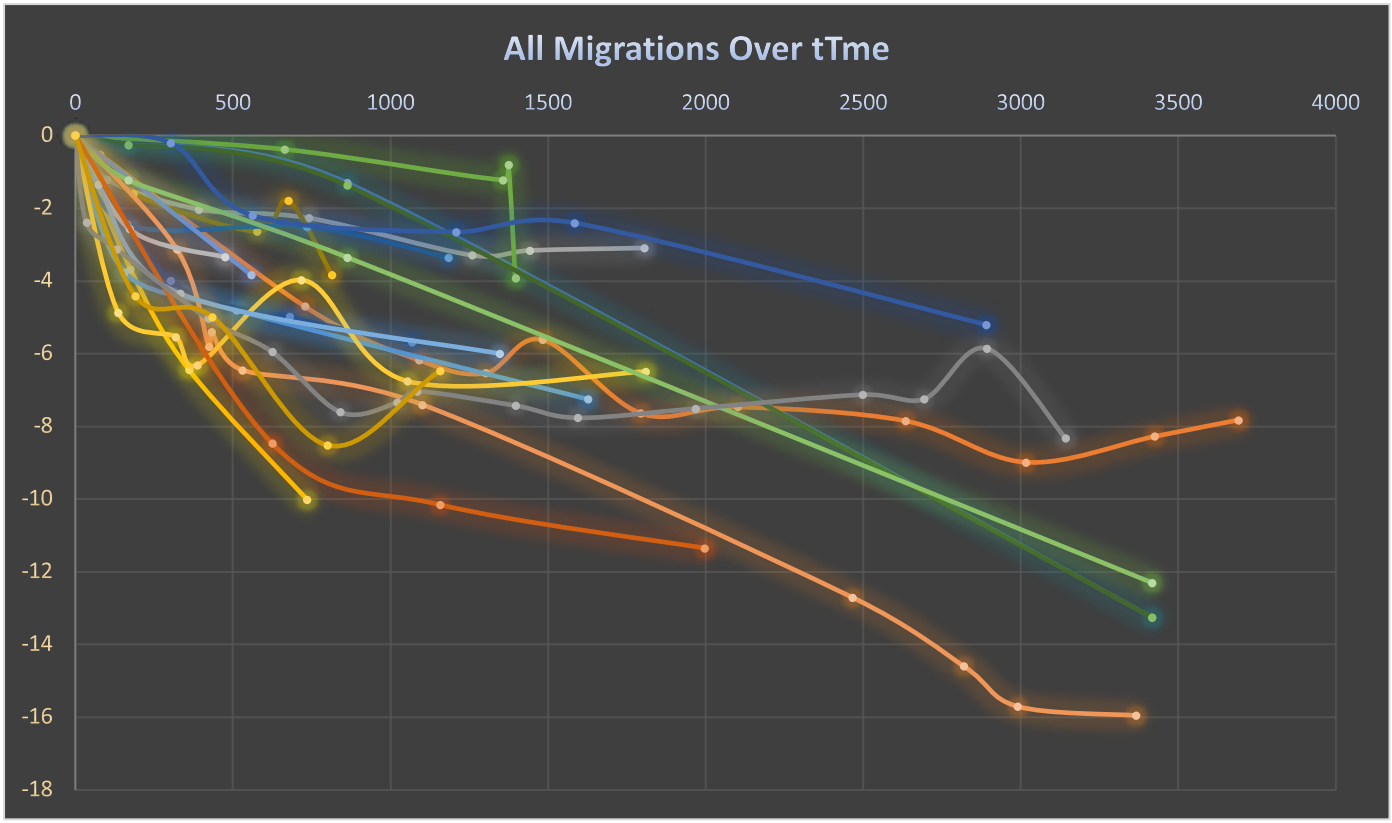
$$\mathrm{AUC} = \int_0^1 \mathrm{TPR}(\mathrm{FPR}^{-1}(t))dt$$

$$\text{where } \mathrm{TPR} = \frac{\mathrm{TP}}{\mathrm{TP+FN}} \text{ and } \mathrm{FPR} = \frac{\mathrm{FP}}{\mathrm{TN+FP}}.$$

AUC-ROC is scale-invariant and classification-threshold-invariant. It measures how well pre-dictions are ranked, rather than their absolute values. This makes it especially useful in cases of imbalanced datasets, as it's not affected by the choice of the decision threshold.

7.3 Appendix 3: Migratory patterns

Graph 1 displays all migration over time



X axis distance in mm

Y axis time in days

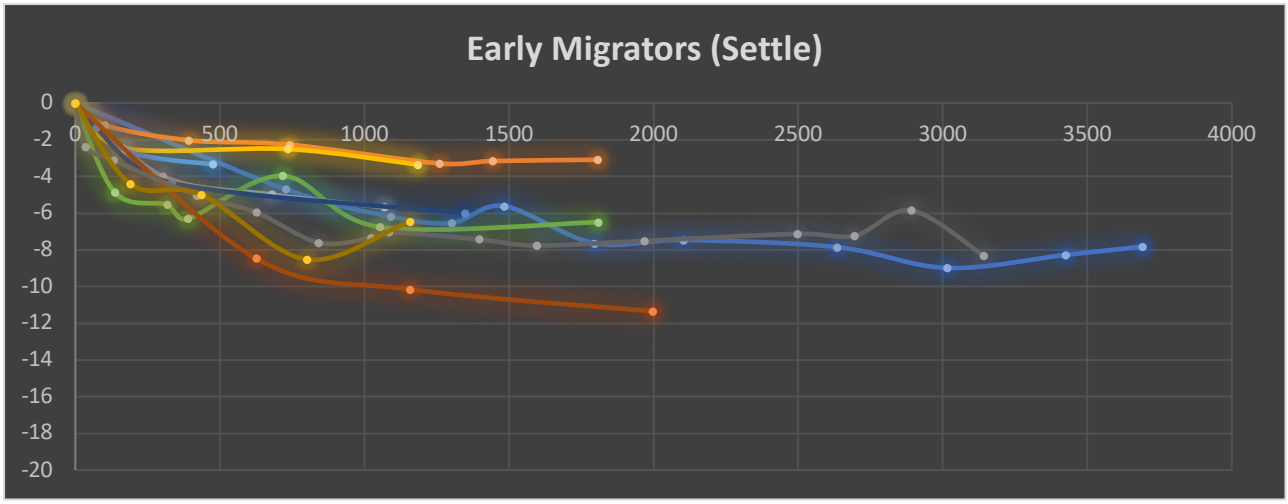
Graph 1

In order to determine a particular pattern of migration individual cases were separated into 3 separate groups:

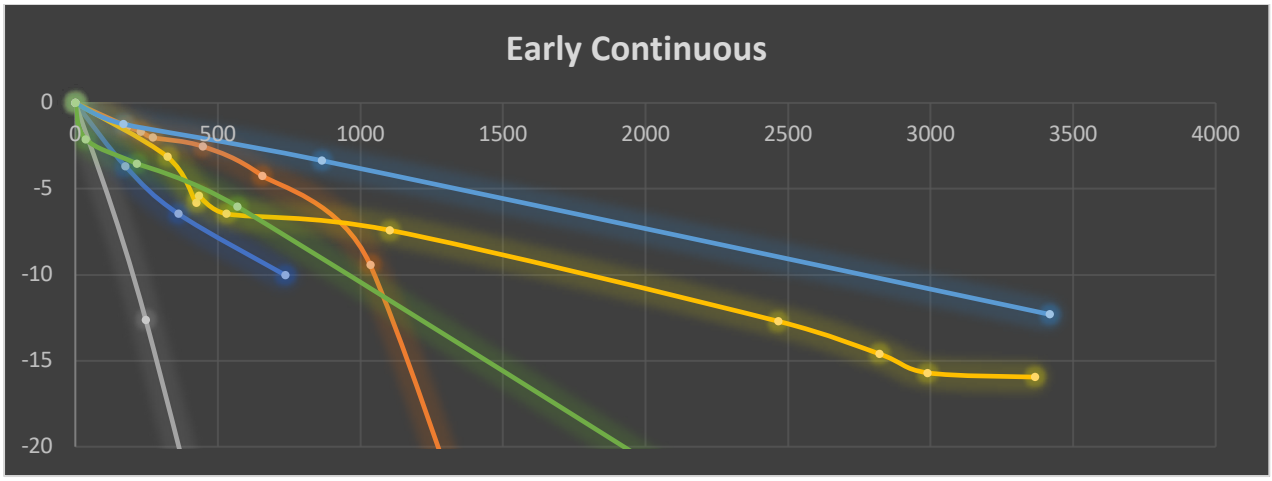
1. Early Migrators (settle) (graph 2)
2. Early Continuous (graph 3)
3. Late migrators (graph 4)

The definitions of the above migratory patterns are based on the two factors:

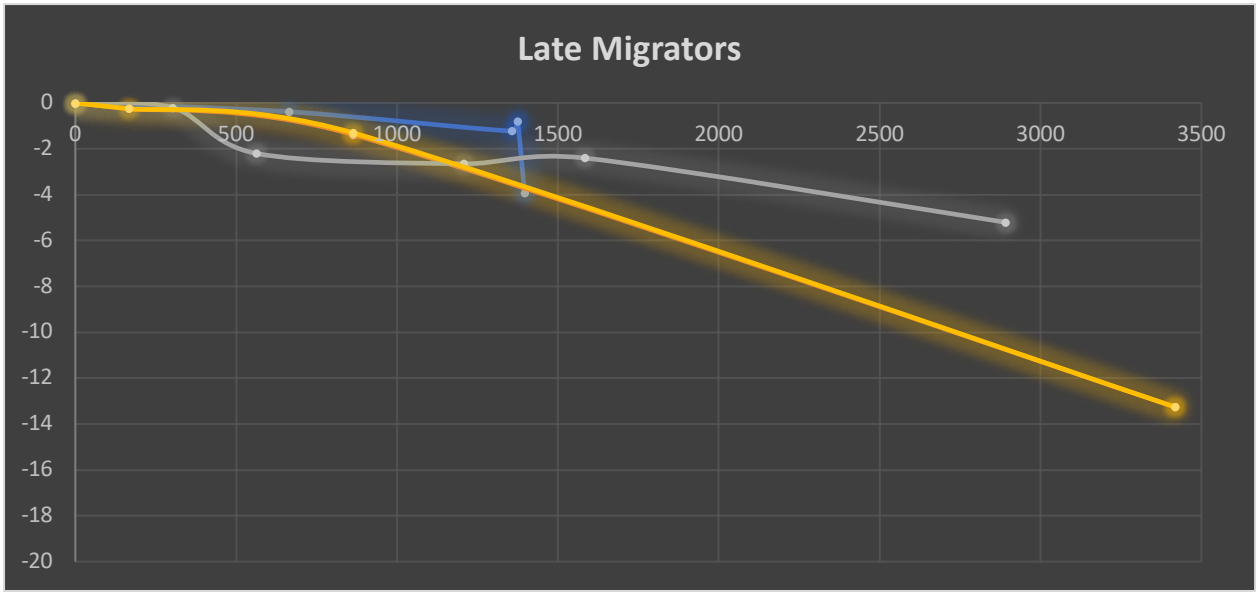
1. The timing at which migration was not (beyond 1 year: late)
2. The persistence of migration



Graph 2



Graph 3



Graph 4

No correlation between clinical outcome and these patterns could be made. Furthermore, given the varied intervals in follow up beyond 18 months and the last scan, the behaviour of the grafts during this period where this information was sparse, could only be inferred (yellow line on graph 4).

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