‘An Investigation Into The Function, Accuracy And Technology Associated With Arthroplasty Of The Hip’

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Declaration of Originality

I declare that all material in this thesis which is not my own work has been identified and that no material has previously been submitted and approved for the award of a degree by this or any other University.

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Abstract

Hip arthroplasty is a successful intervention for symptomatic end stage arthritis of the hip. However it remains an imperfect procedure due in many respects to the difficulty in reproducing biomechanics for each individual patient. Reproduction of femoral offset and leg length ensures appropriate muscle balancing which allows for hip biomechanics to be restored. In addition adequate soft tissue balancing reduces the risk of complications such as dislocations and nerve injuries. Post-operative functional performance may also be affected by the implant technology being used as well as surgical accuracy. However little is known as to what functional performance is to be expected following hip arthroplasty, especially when function is measured at fast speeds and walking inclines.

This thesis will explore the gait of patients prospectively through pre to post-operative stages, in an attempt to ascertain what gait changes can be expected following hip arthroplasty. Furthermore the gait assessments will focus on higher end function, when walking at fast speeds. Following this, this thesis aims to assess whether gait differences are evident when different implants are used, and judge whether they may be a functional advantage to using different implants in hip reconstruction.

Surgical accuracy is paramount, when avoiding complications alluded to earlier. This thesis explores whether rapid prototyping technology can be utilised to aid accurate insertion a femoral stem as part of a pre-clinical test.

Finally this thesis will also test the association of implant size and failures that has been alluded to from national joint registries.
List Of Publications From Or Related To This Thesis

Peer Reviewed Papers


Collaboration Papers


Oral Presentations And Abstracts


AQIL A, DRABU R, WIIK A, ZANNOTTO M, MANNING V, COBB J. Hip Arthroplasty Protects The Good Leg: A Blinded Prospective Controlled Study at Fast Walking Speeds. British Hip Society 05/03/2014 (BEST PAPER PRIZE WON)


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Achievements come at an expense, and are the culmination of ones efforts, opportunities, and experiences gained from other people. I must acknowledge the main people who have supported and influenced me in the production of this thesis.

To my father – who instilled in me that all is possible when one works to a level, that you thought was impossible. I recount stories he told me of how he and his sister studied by candle light for twelve hours a day, every day to gain entry to university and pass exams. His efforts enabled him to educate himself and drag his family out of poverty and in the face of adversities and lack of opportunities I could not imagine.

To Professor Justin Cobb – Whom I would describe as the father of orthopaedic computer aided surgery in the UK. He has taught me many lessons, including how to conduct oneself with decorum even in the face of ignorance and prejudice. His doctrine of ‘you can achieve much more when working together as a group, than when working individually’ is now permanently etched into my psyche and has served me well in my clinical, academic and personal life. I consider myself privileged to have worked so closely with and for him. I will be eternally grateful for his tutelage. I am certainly aware that the fruits of my labours are the result of seeds of opportunities he has bestowed on me.

To my wife Naureen – I will never be able to repay her for everything she has done for our three children and me. She has been utterly selfless, sacrificing all so that our children flourish. All the papers, presentations and even this thesis, are poor excuses for all the missed times we would have had together. The dedication of this thesis is therefore to you, my dear wife. It is the more the product of your sacrifices than mine that this thesis came to completion.
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<td>Total hip arthroplasty</td>
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<td>Hip resurfacing arthroplasty</td>
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<td>PROMS</td>
<td>Patient reported outcome scores</td>
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<td>Leg length discrepancy</td>
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<td>Patient specific instruments</td>
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<td>NJR</td>
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Chapter 1
Thesis Introduction

1.1 Background
Hip arthroplasty is a successful intervention for arthritis of the hip. It aims to alleviate pain and improve function. It exists in two main forms, total hip arthroplasty (THA) and hip resurfacing arthroplasty (HRA). HRA as a concept has been around for many years, but gained a resurgence of its popularity in recent times, fueled in part by improvements in material science and manufacturing technology which allowed for the fabrication of highly congruent metal bearing surfaces. In HRA, the articular surfaces of the femoral head are removed but the neck left in situ, and a metal ‘cap’ impacted over the patients’ own femoral neck. In total hip arthroplasty (THA), the femoral head is removed, along with most of the femoral neck. The femoral shaft is exposed and prepared to accept a femoral stem. In either case, the acetabulum is also prepared to accept a suitable cup to articulate with the chosen femoral component. Whilst HRA head size is limited by femoral neck anatomy and compromised by acetabulum cup size, according to registry data the most common sizes vary between 48 and 52mm in diameter, whilst the most common THA head sizes are between 28 and 36mm. (1, 2) When one considers that actual femoral head sizes are also around 50mm, then HRA offers a more natural reconstruction of normal anatomy. (3)

It is not only head size that HRA seems to restore more effectively. In a study comparing postoperative offset and leg length in THA and HRA subjects, authors found HRA to be superior in their ability to restore femoral offset and leg length when compared to large head metal-on-metal and conventional total hip replacement. (4) From these results it may be reasonable to assume that HRA would result in better patient functional outcomes. However these clinical differences have not been universally evident when assessed using patient reported outcome scores (PROMS), which are limited by their well-documented ceiling effects. (5-7) However, walking ability measured by gait analysis, acting as a surrogate assessment of global function, may be a more responsive outcome measure, which could distinguish between higher functional levels.

There are a number of ways of assessing the outcome of hip arthroplasty surgery. These usually include postoperative radiographic, clinical examination, and functional scores assessments. Motion
analysis, however allows for collection of kinematic and kinetic data. These quantifiable variables, allow for an objective assessment of walking ability.

**Gait Analysis Using Instrumented Treadmills**

Treadmills instrumented with force plates are a reliable and validated gait assessment tool, which allow subjects to walk at self determined top speeds. They require less floor space and have the use of a harness. This provides a welcome safety measure when assessing gait under potentially difficult conditions, such as during fast or incline walking. Although treadmills assess walking under artificial settings, studies have found gait measurements to be very similar to those obtained during over-ground walking. These machines also have the advantage of providing very standardized conditions, where times and speeds can be controlled very precisely, making the treadmill ideal for pre- and post gait testing.

**The Effect THA On High End Function**

One must first determine the effects of an intervention (in this case hip replacement surgery) on function in order to assess whether modifying the intervention has an advantage. Whilst there are retrospective studies comparing post-operative gait of osteoarthritis (OA) and asymptomatic normal controls, prospective studies are lacking. In addition, tools, which assess function, have traditionally been limited by ceiling effects. Treadmills instrumented with force plates have long been used in gait assessment. Whilst they lack the ability to provide spatio-temporal outcome information, they have the ability to assess subjects function under more challenging conditions, such as walking at variable speeds and inclines. Thus treadmills may more likely be able to identify gait differences than traditional methods of measuring function.

We therefore aimed to quantify the effect of hip arthroplasty on the walking gait of patients with unilateral hip arthritis. We will endeavor to address this in chapter 2 of this thesis. I aim to firstly assess whether there is a change in gait following this surgical intervention, and secondly see whether surgery results in a more normal effect in gait. Clearly the gait of one limb with affect the other and this thesis will also examine the effect of hip arthroplasty on the gait of the other limb at top walking speeds, which are determined by the patient and not limited by the equipment.
Can Implants Influence Walking Gait?

A number of retrospective case controlled studies have examined post-operative gait in subjects who have had either a THA or HRA. Mont found that patients with a THA, compared similarly to an age and sex matched osteoarthritic (OA) group in terms of walking speed, abductor and extension moments. However, significant and functionally advantageous gait differences were observed in those patients who had a HRA. These patients appeared to have gait characteristics, which more closely resembled that of symptomatic individuals. (12) Authors had postulated that the functional advantages of HRA resulted from the fact that resurfacing arthroplasty preserved more femoral bone stock and allowed a closer approximation of femoral anatomy. Specifically, HRA may have allowed a closer reconstruction of femoral offset and leg length and preserved abductor and extensor moment arm distances (12). Shrader et al, later demonstrated hip abduction and extension motions were significantly less for total hip arthroplasty subjects compared to controls but similar between controls and post-operative HRA subjects.(13)

Nantel et al, found no difference in gait velocity or stride length between HRA and THA subjects.(14) They also found that both operative groups had deficiencies in abduction post-operatively.(14) These findings contrast those from Mont et al. (12)

The lack of concordance between studies in these observations may be explained by heterogeneity of their design. Most were retrospective and observations generally taken at a single time point post-operatively. In addition observed differences may have been the result of patient, rather than implant factors, in that younger or more active patients may have been offered or self selected to have HRA rather than THA. Prospective studies with a pre-operative assessment of gait and a randomized selection to HRA and THA would certainly have ensured a more robust study design.

Prospective studies evaluating THA gait have been performed. Kyriazis has demonstrated that THA resulted in female patients being able to bare more weight on the affected limb, as demonstrated by increased single leg support and a reduction of double support time compared to pre-operative values. (15). This study demonstrated an improvement in gait following THA, but conclusions are still limited by the lack of a comparison group.

Costa et al. conducted a prospective randomized controlled trial to compare HRA and THA gait. (16)
Similarly Lavigne et al. also conducted a prospective controlled and double-blinded study to compare HRA and large head THA gait. He used a static 10 meter walkway and an eight camera Vicon system (Oxford Metrics Limited, Oxford, UK) to assess gait at preferred (PWS) and top walking speeds (TWS) at 3, 6 and 12 months post-operatively. (17) Interestingly, any difference between THA and HRA groups failed to reach statistical significance (6.6 km/hr versus 6.2 km/hr). Whilst one might argue that this difference might be clinically significant, the interesting fact is that it would appear that both groups seemed to outperform the control group who only managed to achieve top speeds of 6.15km/hr. It is therefore likely that the confines of the experiment prevented any group, be it control or study groups from showing superiority. Perhaps the limitation of the static 10-meter walkway prevented subjects from reaching their actual top walking speed, and that differences seen between HRA and THA would have been accentuated, under different conditions. Perhaps this is the ceiling effect of gait analysis that has been seen all too often in PROMS.

Hence in this thesis we also aim to examine for the first time, the gait of patients with one HRA and one THA head to head. The gait parameters collected will be compared with matched controls in order to examine whether one implant confers a possible functional advantage to the subject. In conducting the experiment in this way, we potentially remove the potential confounding of all systemic patient related covariate factors, which could influence walking performance, as they as they should affect both limbs equally.

Is Accurate Surgery Important?

Accurate reconstructive arthroplasty of the hip results in fewer complications, improved implant longevity, and better patient functional outcomes resulting from optimal biomechanics. Pre- and post-operatively, surgeons commonly measure femoral offset and leg lengths in order to plan and assess surgical accuracy.

Femoral offset is the distance from the center of rotation of the femoral head to a line bisecting the long axis of the femur. There are strong correlations between femoral offset, abductor lever arm and hip abductor strength. (18). Thus reconstructing the femoral offset is important to post-operative function. Furthermore, inadvertent increases in femoral offset can result in higher stresses being
applied to the fixation interface, which can affect implant longevity.\(^{(19)}\) In a study examining survivorship of high and normal offset stems, authors found that whilst high offset stems reproduced the preoperative femoral offset in the majority of cases, survival was 95.1% at seven years. This was significantly lower than non-lateralised stems 98% at 7 years.\(^{(5)}\) Presumably the increased offset led to higher stresses being transferred to the fixation interfaces, which in turn may have lead to an increase risk of aseptic losing and need for revision.

Achieving accurate leg length reconstruction following THA can be challenging. Leg length discrepancies (LLD) can actually worsen hip pain and can exacerbate lower lumber back pain.\(^{(20-22)}\) Leg lengthening can also result in neurological injuries, which manifest as persistent pain, numbness or even a foot drop.\(^{(23-25)}\) Dissatisfaction is higher in these patients and thus it is hardly surprising that LLDs are a common reason for successful litigation.\(^{(26)}\)

**Technology and Surgical Accuracy**

Accurate reconstruction of femoral offset and leg length is therefore essential to improving function, ensuring patient satisfaction, avoiding complications and increasing implant longevity. Currently, there are a number of pre-operative templating tools, which can assist in planning surgery. However, intra-operatively, the surgeon still needs to achieve the pre-determined plan. Conventional guides available on most THA kits can be used, to aid osteotomy cuts. However it is accepted that these are crude and fail to prevent implantation outliers. Robotic surgery has been used to improve accuracy in hip resurfacing arthroplasty to good effect. However its application in THA is limited. In addition robotic surgery requires a robot, which can be expensive, and may also add time to surgery. The use of patient specific instruments (PSI) has reduced surgical time in knee arthroplasty, while providing the accuracy that is seen in other computer aided surgery methods. PSI has been shown to efficacious in knee arthroplasty and for implant placement in hip resurfacing arthroplasty. PSI has even been used with success for placing the acetabular component in THA, but its role in assisting in a total hip femoral stem implantation remains relatively unexplored. Therefore this thesis will attempt to assess the potential role of PSI in improving surgical errors in THA surgery as part of a preclinical test.
Patient specific instruments are manufactured from a rapid prototyping process (RP), whereby physical objects are built from three-dimensional (3D) surface model data. RP or additive manufacturing (AM) as it is also known, occurs when a material is layered upon itself till the 3D model has been built. This is in contrast to subtractive manufacturing, where material is removed from a larger block to reproduce the 3D model.

Advances in AM techniques have enabled the development of medical interventions, which are specific to each patients’ own anatomy. AM can be a lengthy process, which requires co-operation between medical and engineering specialists. First one must obtain a patient’s 3D scan data. This is then segmented to create 3D surface models the area of interest. Surgery is then planned including guides/ tool structures and trajectories using 3D modeling software. The assembly process includes: choosing the appropriate material, building the PSI using rapid prototyping equipment, and finally cleaning and sterilizing the unit prior to its use. However lengthy, this pre-operative process promises the possibility of increasing intra-operative surgical accuracy, whilst reducing surgical time and reducing costs.

There are a number of areas of applications of this technology already in practice and within orthopaedic surgery. PSI can be invaluable when encountering aberrant anatomy such as in trauma and deformity correction surgery when 3D planar osteotomies are required. (27-30)

In spinal surgery where precision accuracy is required, PSI has been successfully used to guide pedicle screws placement.(31-33) PSIs have also been used to guide knee arthroplasty surgery.(34, 35) Indeed, PSI has also been used in the field of hip arthroplasty. Specifically, it has aided orientation acetabular cups, or resurfacing stems. Its usefulness in assisting with femoral total hip stem implantation, is largely unexplored.(36-39) Thus there is a gap in the literature regarding the potential usefulness of PSIs in assisting the surgeon to accurately implant a femoral stem. This thesis will aim to address this question as part of a preclinical laboratory study and in order to ascertain whether future in vivo studies would be feasible.

National Joint Registries

The first national joint registry was established in Sweden in 1975 and collected data on total knee replacement data only.(40) Registries now exist in many countries including the Finland, Norway,
Denmark, New Zealand, Australia, Canada, and the UK to name a few. Data collected has expanded in some of these to include hip, shoulder and ankle replacements.

The Capital hip implant was introduced in 1991 in the UK (3M Health Care Ltd, Londonborough, UK). It was marketed as a low cost alternative to the successful market leaders of the time. By 1997, thousands of patients had a Capital hip and over ninety centers were using the implant nationally. Unfortunately, this poorly designed implant had disastrous consequences with one fifth of implants having failed in only 5 years. (41) It was argued that the use of a national registry would identify failing implants early and therefore serve to protect the public from such instances again and hence in 2002, the National joint Registry of England and Wales (NJR) was set up. Three years later, the NJR was able to issue an alert concerning high failure rates of the Articular Surface Replacement (ASR), which was another poor copy of a successful implant, the Birmingham Hip Resurfacing (BHR). Unfortunately, it was not till 2010 that the implant was withdrawn from the market, but the alert had the effects of curtailing its use from informed surgeons, who changed their practice and stopped using it even before the implants removal from the market.

However, although registries adjust for sex and age in their analysis, they often lack consideration of comorbidities and socioeconomic status, which are well known to be associated with poorer outcomes. (42) So the question arises as to whether the role of registries can be safely expanded to identify potential trends, which are associated with failure and make recommendations based on this observational data.

**Can Registries Identify Risk Factors to Failure?**

A registry level multivariate analysis performed using National Joint Registry data (NJR), between 2003 and 2010 investigated risk factors to revision of 27,971 implanted hip resurfacing arthroplasties. Only 3.6% of these underwent revision surgery (1003 cases). Risk to revision was found to be associated with implant brand, with the BHR (Birmingham Hip Resurfacing; Smith and Nephew, Memphis, Tennessee, USA) faring the best, and the ASR (Articular Surface Replacement; Depuy, Leeds, UK) faring the worst (HR= 2.82, p<0.001). Smaller femoral head components were also significantly more likely to require revision (≤ 40mm: HR=1.43, p=0.001), as was the case if surgery was performed in females (HR= 1.3, p=0.007). (43) Some have suggested that smaller component sizes are associated with adverse wear, which induce a greater soft tissue reaction. (44, 
45) This hypothesis however lacks supportive evidence, which is anything more than circumstantial in nature. According to the analysis of registry data by Jameson et al. component size and revision from adverse tissue reactions are not the real cause of the majority of revisions. Adverse soft-tissue reaction to metal debris comprised only 71 cases out of the 1003 revisions (7.1%), and only 0.25% of all the 27971 analysed.(43) Incidentally, sex was not been listed as a reason for failure. It is merely an associated risk factor.(43) Looking at all the revisions as a group, one can actually see, that the most common cause for revision, was actually a femoral neck fracture, with 203 cases (20.2%), followed by acetabular aseptic loosening with 132 cases (13.2%). So if small head sizes are really causal to the need to revision, then they should be associated with periprosthetic fractures. There are already a number of laboratory studies, which have demonstrated the link between femoral notching and fracture during HRA, but none which have explored the relationship between resurfacing head size and risk to periprosthetic fracture directly. This thesis will again address this gap in the literature by investigating this potential mechanical association between implant head size and risk of fracture.

1.2 Thesis Aims

This thesis aims to explore four areas surrounding hip arthroplasty surgery:

1: The effect of hip arthroplasty on osteoarthritic gait, when walking at fast speeds.
2: The effect of different types of arthroplasty on gait and the conditions in which they are most obvious.
3: The potential association highlighted between hip resurfacing implant size and surgery failure from fracture.
4. The impact of PSI (patient specific instrumentation), accuracy in hip arthroplasty.
2.1 Abstract

Background: Painful unilateral cox-arthrosis results in excessive forces passing through the ‘good leg’. The impact of hip arthroplasty on contralateral leg gait has not been fully explored. We measured patients gait before and after arthroplasty, to answer three questions: (1) Are peak forces for the good legs outside the normal range? (2) Does arthroplasty protect contralateral limbs by reducing peak forces, and (3) Does arthroplasty result in a more symmetric and normal gait at fast walking speeds?

Methods: This prospective, controlled study, assessed ground reaction forces (GRFs) prior to and 13 months (range: 6-21 months) following hip arthroplasty.

Results: Peak GRF in contralateral hips fell (1.45 to 1.38 times body weight, p=0.04), whilst symmetry index maximum weight acceptance improved post-operatively (12.2±11 versus 1.3±6, p<0.001. Conclusion: Although gait becomes more symmetrical, patients still experience higher peak loads than matched controls. These high forces may offer an explanation for the progression of arthrosis in lower limbs.

2.2 Peer review evidence:

1. The contents in this chapter have been published in a peer-reviewed journal. A copy of which can be found in the Appendix (Appendix A). A copy is also available on pubmed (PMID: 27062351).

2. The contents in this chapter has been peer-reviewed as an oral presentation in the British hip society meeting (BHS) 2014. It also won the prize for best scientific paper at that time. Evidence of this can be found in the appendix labeled Appendix B.
2.3 Introduction
Osteoarthritis develops when the mechanical stresses exerted upon a joint exceed its ability to withstand and repair damage(46). End stage hip disease can now be treated effectively with arthroplasty, however research continues into interventions which may prevent or reverse early pathological structural changes(47). Weight loss is an effective way of reducing symptoms, and slowing the progression of OA, presumably by reducing the forces exerted across a joint (48). Patients with osteoarthritis in one limb are at risk of disease progression in the other limb, as it will be exposed to compensatory high peak forces and asymmetrical walking patterns(49-51). Indeed patients are likely to develop OA in the ‘good’ leg than in the ipsilateral knee OA following hip arthroplasty (50, 52, 53). Weight loss has been shown to reduce OA symptoms, presumably from reducing the peak forces experienced through these affected joints (54). Therefore, it may be reasonable to hypothesize that the high peak loads, and asymmetrical gait patterns also may also contribute to disease progression in the compensating leg. Opinion remains divided as to whether surgery reverses these gait changes (55-57). However previous gait studies have examined patients walking at slow walking speeds or failed to look at the peak forces on contralateral limbs (55-57). Between leg differences become more apparent with increasing speed for a number of gait variables both after surgery (58), and in patients who are not yet to candidates for it (59, 60). Restricting any analysis to low speeds may therefore miss the real extent of any asymmetry, and underreport the actual improvement in gait following surgery (55).

In this prospective, single blinded controlled study, we investigated whether arthroplasty: (1) Had a protective effect on the ‘good’ leg by reducing peak forces, (2) resulted in improved gait symmetry and (3) restored a normal gait at fast walking speeds

2.4 Material and Methods

Participant inclusion/exclusion criteria
Ethical approval was sought and gained prior to the study. We prospectively identified patients with painful unilateral cox-arthrosis who were deemed suitable for total hip arthroplasty from the operating waiting lists of one surgeon. Patients had unilateral hip pain with otherwise asymptomatic lower limbs. Patients were excluded if they could not walk unaided. There were nine males and eight females with an average age of 59 (range of 32- 73). Seventeen previously tested
asymptomatic control subjects were also selected from a database. They were sex matched and of similar ages (average 54, range 33-83). The sample size calculation was performed based on a study, which successfully documented the impact of intervention on the affected hip (56).

**Outcome Measures**

Our primary outcome measure was maximum weight acceptance as the greatest peak forces are seen at this point during fast walking on flat ground (58). Secondary outcome measures included gait symmetry index values for weight acceptance rate, maximum weight acceptance, mid support, push off rate and maximum push-off force. Previous studies have suggested a plateau of gait recovery at 6 months following hip arthroplasty; hence we used this as our minimum postoperative assessment time (56, 61, 62). Assessment was taken in the month before surgery, and at an average of 13 months postoperatively (range 6-21months).

**Arthroplasty surgery**

All surgical cases were carried out by the senior author using a posterior approach with a capsular and muscular inter-osseous repair. Three different implants were used, including the Furlong Evolution Hip, and Furlong HAC (Joint Replacement Instruments, Sheffield, England), and the Birmingham Hip Resurfacing, (Smith and Nephew, Memphis, Tenessee).

**Equipment/ Assessment**

Subjects were tested using a treadmill instrumented with force plates beneath the tread (Kistler Gaitway®, Kistler Instrument Corporation, Amherst NY). Ethical approval had been granted prior to the commencement of this study (Appendix C). Treadmills have been used previously as a gait assessment tool in patients with a variety of medical conditions as well as with post arthroplasty gait assessment(58, 63-66). They have also been validated as a reasonable alternative to over-ground gait analysis, whilst allowing assessment at faster walking speeds (67). Gait data was normalized for weight and height using previously published and acceptable techniques (68). Testing followed a six- minute warm up at 4 km/hr where subjects acclimatized themselves to the treadmill. This warm up period has been shown to reduce gait data inconsistencies (58, 66, 69). Assessment was performed with two trained blinded observers, using a standardized testing protocol, which began at 4km/hr and increased in 0.5km/hr increments until the patients self determined top walking speed (TWS) was reached. TWS was defined as the maximum speed subjects could walk comfortably without pain or needing to run (58, 66).
Theory And Calculation

All GRF data were appropriately body weight and or height normalized, to enable cross group comparison (68). A paired t-test was used to compare peak forces before and after surgery. Significance was judged at the 5% level. Gait data was examined at the fastest speed subjects could walk prior surgery to and at the same speed postoperatively to allow a like for like comparison. The symmetry index (SI) was calculated using a previously described and accepted method (70, 71).

\[
SI = \frac{(X_R - X_L) \times 100}{0.5(X_R + X_L)}
\]

Values closer to zero indicated a tendency to greater symmetry. We compared pre- and post surgery SIs using a paired T-test assessing for statistical significance at the 5% level.

In order to assess whether surgery resulted in a more ‘normal’ gait we compared pre and post surgery symmetry indexes to that of an age and sex matched group of normal controls. Control group GRFs were sampled at 6km/hr to match the subject group average speed. As data was normally distributed, an independent sample t-test was used to compare results between groups. Analysis was performed using IBM SPSS Statistics Version 21.

2.5 Results

All patients were able to walk faster following surgery, increasing from an average top speed of 6km/hr beforehand (range: 4-8km/hr) to 7.6 km/hr (range: 5.5-9.5) postoperatively. There were no drop- outs, and all patients were tested at a minimum of 6 months following surgery. In all subjects, the highest peak forces were seen at maximum weight acceptance (MWA), with the forces seen at push off being 30% lower.
Our primary aim was to establish whether hip replacement surgery induced a change in gait, which would culminate in a reduction of peak forces in the non-operated leg. As the greatest peak forces occur at MWA during flat ground walking, this was our primary point of interest. Prior to surgery, and at MWA, the ‘good’ leg experienced peak loads, which were 12% greater than in the arthritic limb (1.45 ± 0.23 versus 1.29 ± 0.22, p=0.03). These forces were significantly reduced, following surgery (1.45 ± 0.23 to 1.38 ± 0.15, p=0.04) (Figures 1 and 2).

**Figure 1:** Ground reaction forces in arthritic and asymptomatic limbs prior to surgery and at top walking speed

**Figure 2:** Ground reaction forces in arthroplasty and asymptomatic limbs following surgery at 6km/hr.
Secondly we wished to ascertain whether surgery resulted in a more symmetrical gait pattern and then establish whether it was more normal by comparing it to that of healthy subjects. Following surgery, gait was more symmetrical (Figure 2). Pre-operatively the poorest between leg symmetry was seen in the rate that patients could bare weight. The weight acceptance rate of both legs improved following surgery, however the symmetry index, did not improve enough to reach statistical significance. Following surgery the symmetry index did significantly improve in the remaining four key gait variables, with all symmetry index values approaching zero (Table 1).

The control group walked with near perfect symmetry at 6km/hr (Figure 3).

![Control Group at 6km/hr](image)

**Figure 3: Ground reaction forces for both limbs of control subjects at 6km/hr.**

Symmetry indexes were near zero for all five GRF variables (Table 2). Whilst post surgery peak forces were closer to those of the control group, they were still over 10% greater. As the post arthroplasty group walked more symmetrically, their gait more closely resembled that of the normal health controls (Figure 2 and 3). Again differences still persisted, particularly with the surgical groups lack of ability to accept weight quickly and equally between the operated and non-operated legs.
Table 1. Table showing ground reaction forces at top walking speeds, prior to and following surgery

<table>
<thead>
<tr>
<th>Surgery Group at TWS</th>
<th>Normalised Weight Acceptance Rate</th>
<th>Maximum Normalised Weight Acceptance</th>
<th>Normalised Mid-support Force</th>
<th>Normalised Push-off Rate</th>
<th>Maximum Normalised Push-off Force</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PRE - Arthroplasty</td>
<td>POST - Arthroplasty</td>
<td>PRE - Arthroplasty</td>
<td>POST - Arthroplasty</td>
<td>PRE - Arthroplasty</td>
</tr>
<tr>
<td></td>
<td>N  OA</td>
<td>N  OA</td>
<td>N  OA</td>
<td>N  OA</td>
<td>N  OA</td>
</tr>
<tr>
<td>Mean</td>
<td>26.80 20.40</td>
<td>20.55 18.48</td>
<td>1.45 1.29</td>
<td>1.38 1.36</td>
<td>0.56 0.64</td>
</tr>
<tr>
<td>SD</td>
<td>22.36 7.64</td>
<td>8.64 6.43</td>
<td>0.23 0.22</td>
<td>0.15 0.16</td>
<td>0.14 0.13</td>
</tr>
<tr>
<td>Min</td>
<td>10.15 8.58</td>
<td>5.73 6.53</td>
<td>1.05 0.82</td>
<td>1.02 1.00</td>
<td>0.32 0.41</td>
</tr>
<tr>
<td>Max</td>
<td>110.81 38.89</td>
<td>39.06 28.86</td>
<td>2.01 1.71</td>
<td>1.58 1.64</td>
<td>0.83 0.84</td>
</tr>
<tr>
<td>Mean Symmetry Index</td>
<td>18.0 7.1</td>
<td>12.2 6.0</td>
<td>-13.6 0.3</td>
<td>11.5 0.7</td>
<td>6.2 0.0</td>
</tr>
<tr>
<td>SD Symmetry Index</td>
<td>31.6 22.0</td>
<td>11.0 6.0</td>
<td>15.1 10.3</td>
<td>14.6 9.1</td>
<td>9.6 5.9</td>
</tr>
<tr>
<td>Min SI</td>
<td>-42.8 -28.4</td>
<td>-10.3 -13.2</td>
<td>-42.6 -20.0</td>
<td>-15.1 -18.6</td>
<td>-9.5 -8.9</td>
</tr>
<tr>
<td>Max SI</td>
<td>96.1 66.1</td>
<td>40.5 9.5</td>
<td>5.5 22.8</td>
<td>34.3 14.6</td>
<td>24.9 11.8</td>
</tr>
<tr>
<td>t.test</td>
<td>0.139 &lt;0.001</td>
<td>&lt;0.001 0.001</td>
<td>0.001 0.006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

KEY: TWS= Top walking speed, SI= Symmetry index, (where 0=perfectly symmetrical gait), N= Normal leg, OA= Osteoarthritis affected leg, t.test=Paired t-test, Values given are dimensionless and therefore without units.
Table 2: Table showing ground reaction forces for both limbs of the control group when walking at 6 km/hr

<table>
<thead>
<tr>
<th></th>
<th>N. Wt. Acceptance Rate</th>
<th>Max. N. Wt. Acceptance</th>
<th>N. Mid-support Force</th>
<th>N. Push-off Rate</th>
<th>Max. N. Push-off Force</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
<td>Right</td>
<td>Left</td>
</tr>
<tr>
<td>Mean</td>
<td>13.94</td>
<td>13.87</td>
<td>1.30</td>
<td>1.30</td>
<td>0.64</td>
</tr>
<tr>
<td>SD</td>
<td>3.02</td>
<td>3.09</td>
<td>0.08</td>
<td>0.06</td>
<td>0.05</td>
</tr>
<tr>
<td>Min</td>
<td>7.18</td>
<td>7.31</td>
<td>1.19</td>
<td>1.20</td>
<td>0.54</td>
</tr>
<tr>
<td>Max</td>
<td>20.19</td>
<td>19.43</td>
<td>1.48</td>
<td>1.39</td>
<td>0.75</td>
</tr>
<tr>
<td>Mean Symmetry Index</td>
<td>0.7</td>
<td>0.0</td>
<td>-0.4</td>
<td>-0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>SD Symmetry Index</td>
<td>12.4</td>
<td>4.6</td>
<td>5.9</td>
<td>7.2</td>
<td>2.9</td>
</tr>
<tr>
<td>Min SI</td>
<td>-27.4</td>
<td>-8.2</td>
<td>-19.6</td>
<td>-12.9</td>
<td>-4.6</td>
</tr>
<tr>
<td>Max SI</td>
<td>19.2</td>
<td>12.2</td>
<td>6.9</td>
<td>10.9</td>
<td>5.2</td>
</tr>
</tbody>
</table>

KEY: GRFs= Ground reaction forces, SI= Symmetry index, (where 0=perfectly symmetrical gait), N=Normalised, Wt=Weight, SD= Standard Deviation, Max=Maximum, Min=Minimum. Values given are dimensionless and therefore without units.

2.6 Discussion

Despite suffering from painful end-stage arthritic hips, subjects were able to walk at an average of 6km/hr, even prior to surgery. Hip arthroplasty surgery enabled all subjects to walk at significantly higher speeds. This study therefore demonstrates that it is possible to examine arthritic gait at faster speeds than in previous studies, which have used static walkways. We have previously demonstrated strong correlations between increasing walking speed and between leg gait differences (58). Thus using an instrumented treadmill and examining gait at high walking speeds is justified (55, 56).

Individuals, who are free from disease, demonstrate a symmetrical between-leg gait pattern, even at fast walking speeds. This study has shown that patients with painful unilateral cox arthrosis, expose their opposite asymptomatic legs to peak forces which are significantly higher than that seen in normal individuals. Conversely lower peak forces were observed in the arthritic limb pre-operatively, which were lower than the peak forces in normal individuals. This pattern was consistent across all of the arthroplasty subjects. It would appear that painful unilateral hip OA, may have resulted in a lowering of peak forces, presumably as a result of anticipation of or actual pain. The knock-on effect appears to be that the asymptomatic limbs take more of the burden and experience significantly higher peak forces. Following surgery however, patients are more able to
accept weight through the operated leg and experience a reduction of peak forces in their better, non-operated limb. This represented a change towards normalization, as the post-operative gait more closely resembled that of normal healthy controls. In another prospective study, which examined temporospatial gait parameters, authors also found that hip arthroplasty resulted in a more symmetrical gait. Whilst they lacked a control group and failed to measure ground reaction forces, their findings do corroborate that of our own (72). Thus it would be reasonable to conclude that in the setting of unilateral painful cox arthrosis, hip replacement surgery resulted in the ability of patients to walk and bear weight more normally and symmetrically.

The reduction and normalization of peak forces may be of further importance when one realizes that peak forces were as much as 12% greater in the good legs of arthritic subjects, than control group limbs. This compensatory overloading of ‘good legs’ may be a predisposing factor expediting OA progression, which has been alluded to in other studies (56, 59, 60).

Surgery resulted in a substantial lowering of the peak forces in the ‘good leg’ and a significant improvement in gait symmetry, more closely resembling the normal controls. Weight reduction is accepted as a way of reducing the risk of developing OA (73-77). Similarly, exercise and bariatric surgical interventions have been shown to reduce skeletal strain, and thereby improve musculoskeletal pain symptoms (54, 78-82). Some orthoses have also been shown to reduce joint loads and OA associated pain (83, 84). One therefore, might reasonably hypothesize that the reduced peak forces seen following hip arthroplasty may also help reduce pain and disease progression associated with overloaded joints. Whilst timely surgery as a way of reducing risk of OA development in contralateral limbs has not been proven here, it clearly would need to be examined in future studies. The impact of this potentially modifiable risk factor may have a significant effect on the burden of arthroplasty services, given the high frequency of patients who develop symptomatic OA in contralateral limbs so soon following their index procedure (50-52, 85).
Chapter 3

The Gait Of Patients With One Resurfacing And One Replacement Hip:
A Single Blinded Controlled Study

3.1 Abstract

Purposes: Post arthroplasty gait analysis has up till now been performed on subjects walking slowly on flat ground rather than challenging them at faster speeds or walking uphill. We therefore asked: (1) Is there a measurable difference in the performance of HRA and THA limbs at patients’ self-determined fastest walking speeds and steepest inclines? (2) Is there a relationship between the observed differences between the gait of HRA and THA implanted limbs and patient walking speeds and inclines.

Methods: In an ethically approved study we recruited patients with bilateral hip arthroplasties: one HRA and one THA. Nine subjects were assessed using an instrumented treadmill at a range of speeds and inclines by a blinded observer. The ground reaction forces of subjects were recorded and an age, sex and BMI matched control group was used for comparison.

Results: Increasing walking speed correlated strongly with between leg differences in weight acceptance (r=0.9, p=0.000) and push off force (r=0.79, p=0.002). HRA implanted limbs accepted significantly more weight at top walking speeds (1208N ± 320 versus 1279N ± 370, p=0.026) and pushed off with greater force when walking uphill (818N ± 163 versus 855 ± 166, p=0.012). HRA limbs more closely approximated to the gait of the normal control group.

Conclusions: Arthroplasty implants do have an impact on the gait characteristics of patients. Differences in gait are more likely to be evident when assessment is made at fast speeds and walking uphill. This study suggests that HRA may enable a more normal gait.

3.2 Peer review evidence:

1. The contents in this chapter have been published in a peer-reviewed journal. A copy of which can be found in the Appendix (Appendix D). A copy is also available on PubMed (PMID: 23443980).
2. The contents in this chapter has been peer-reviewed as an oral presentation in the British Hip Society meeting (BHS) 2013. (Appendix E)
3.3 Introduction

Hip Resurfacing Arthroplasty (HRA) was introduced to provide superior function for the more active patient, however selection bias may have skewed these results in favor of HRA (12, 86, 87). Three recent prospective randomized controlled trials have failed to detect a difference between HRA and Total Hip Arthroplasty (THA). All were only powered to detect a 10% difference in slow walking speeds or used conventional functional scores, which have well documented ceiling effects (17, 88, 89).

Instrumented treadmills have the advantage of allowing subjects to be tested at a range of speeds and walking inclines. They have been used and validated as a tool for gait assessment (90-92), with increasing speed being used to demonstrate clinically important differences that are not detectable at slower speeds (93, 94). As HRA has been advocated for the more active patient, in whom higher walking speeds are particularly relevant, the use of this technology seemed appropriate. We have used this faster walking metric to distinguish HRA from THA, but in a cohort study where selection bias might still occur (95).

Patients with both one resurfacing and one total hip replacement who have high functional scores should overcome this presumed selection bias, as both implants would have an equal opportunity to be loaded by the same weight in the same person. Thus potential gait differences could then be attributed to the implants.

We therefore asked two relevant questions.

1. Is there a measurable difference in the performance of HRA and THA limbs at patients’ self-determined fastest walking speeds and steepest inclines?

2. Is there a relationship between the observed differences between the gait of THA and HRA implanted limbs and patient walking speed and inclines.
3.4 Participants and Methods

Ethical approval was sought and gained prior to commencement of the study. We retrospectively identified all patients who had one THA and one HRA on the contralateral side. Patients at least 6 months following most recent surgery were identified from the surgical logs of two surgeons, JPC and SMA. Both surgeons used a posterior approach to the hip and repaired the external rotators on closure. Patients were assessed using the Oxford Hip Score (OHS) to ensure they had good functioning hips. Some patients had a THA first presumably because this was prior to HRA increasing in popularity or availability. Some had a THA as their second procedure, perhaps due to increasing subject age and concerns over bone strength. A brief and careful medical history was obtained from patients to ensure they were free from confounding disease in their lower limbs.

Twelve candidate patients were identified, but on questioning three patients were excluded. One patient had hallux rigidus on the side of the resurfacing arthroplasty. One patient had osteoarthritis of the ankle on the side of the THA. The last excluded patient had a knee arthroplasty on the side of the total hip replacement. In total this left 9 patients who all consented to have their gait analyzed. A further group of 9 controls were obtained from a database of already tested asymptomatic normal subjects. There were 3 females and 6 males in both the study and control groups. The study group was slightly older (mean 67 years, range 55-76 versus control 64 years, range 53-82, p=0.52). The mean Body Mass Index (BMI) of the study group was slightly higher (28 kg/m² v 25 kg/m², p=0.11).

Participants had a range of THA bearing couples from metal on polyethylene to ceramic on ceramic with a range of head sizes (28 to 38). All subjects were content with both hips and pain free. The mean average oxford score of included patients was 44 (36-48). Radiographs of all subjects were examined to ensure that implanted components were well fixed without signs of loosening.

The mean time from THA operation to gait assessment was 4 years (1-17 years) and that for HRA was 6 years (0.7-10 years, p=0.31).

Patients were assessed using a treadmill instrumented with piezo-electric force plates underneath the tread (Kistler Gaitway®, Kistler Instrument Corporation, Amherst NY). Data was collected from the force plates during the stance phase of the gait cycle generating 4 variables for analysis: maximum weight acceptance, mid support, maximum push-off force and impulse (Figure 4).
‘Maximum weight acceptance’ and ‘maximum push off’ were the first and second peaks of the gait cycle with the ‘mid-support’ force being the lowest point between the peaks. Impulse was defined as the total force throughout the stance phase of the gait cycle, or the area under the curve in Figure 4.

Testing followed a 6-minute acclimatization period where patients walked at a gentle 4km/hr. This acclimatization period has previously been shown to be sufficient to remove inconsistencies in recorded ground reaction forces encountered due to a lack of warming up (69). The average of each step was used for each speed and inclination.

Flat ground walking was assessed at a range of speeds starting at 4km/hr up to the patients self determined top walking speed (TWS). Following completion of flat walking, subjects were asked to walk uphill at a fixed speed of 4km/hr, at inclinations increasing at 5° increments until they wished to stop. This final inclination was called their top walking incline (TWI).

Assessment was performed with two trained observers using a standardized testing protocol. Assessors were blinded to the sides of the different types of arthroplasty, and patients were tested with their surgical scars covered.
Force differences were normalized for weight and averaged across speeds for comparison. A Kolmogorov-Smirnov test showed data was normally distributed. A paired t-test was used to assess the significance of any detectable difference at TWS and TWI for means of each of the four key GRF variables. A paired t-test was also conducted for the 4 km/hr walking speed and zero incline to determine if there are differences at baseline. Pearson product-moment correlations were computed to assess the relationship between increasing speeds and the differences between the implanted legs for the key variables. SPSS (IBM SPSS Statistics, version 20) was used to perform all the statistical analyses.

Gait curves of normal and arthroplasty limbs were plotted for visual comparison. The control group left and right legs were averaged to create a single force curve to make visual comparison easier.
3.5 Results

At slow speeds weight acceptance of both legs was similar (HRA 913 N ± 216 vs THA 919 N ± 194, p =0.6), as were the other ground reaction forces (see Table 3).

<table>
<thead>
<tr>
<th>Table 3: Showing ground reaction forces on the flat at 4 km/hr between THA and HRA implanted limbs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Weight Acceptance (N)</td>
</tr>
<tr>
<td>Mid Stance Force (N)</td>
</tr>
<tr>
<td>Max Push Off Force (N)</td>
</tr>
<tr>
<td>Impulse (Ns)</td>
</tr>
</tbody>
</table>

THA= Total Hip Arthroplasty, HRA= Hip Resurfacing Arthroplasty

Figure 5: Showing the ground reaction forces for HRA, THA and Control limbs at Top Walking Speed

The impulse force difference also reached significance (HRA 364 Ns ± 110 vs THA 348 Ns ± 95 p=0.034). The gait cycle of THA and HRA implanted legs were visually compared with those of the age, sex and BMI matched control group. In all these four measured key gait GRFs, the HRA
implanted legs more closely resembled the control group (Figure 5). As arthroplasty subjects walked faster, gait differences became more apparent (Figure 6).

Figure 6: A-C Graphs showing the effect of increasing speeds on the observed ground reaction forces with HRA and THA implanted limbs
Pearson’s $r$ data analysis revealed a strongly positive correlation between increasing speed and ground reaction force differences between the types of arthroplasty in 3 GRFs: maximum weight acceptance ($r=0.9$, $p=0.000$), maximum push off ($r=0.79$, $p=0.002$) and impulse ($r=0.75$, $p=0.005$). With increasing speed, the greatest differences were observed in maximum weight acceptance (Figure 7).

Key: Correlations were calculated using Pearson’s $r$ data analysis

Figure 7: A-C Graphs show the differences between the ground reaction forces between limbs with increasing speeds
At their steepest achievable incline, differences between the implanted legs were also marked (figure 8).

Figure 8: Showing the ground reaction forces for HRA, THA and Control limbs at Top Walking Incline

The difference in maximum push off was most significant (HRA 855 N ± 166 vs THA 818 N ± 163 p =0.012) (Table 4).

<table>
<thead>
<tr>
<th>Ground reaction forces at TWS</th>
<th>Ground reaction forces at TWI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Weight Acceptance (N)</td>
<td>Maximum Weight Acceptance (N)</td>
</tr>
<tr>
<td>Mid Stance Force (N)</td>
<td>Mid Stance Force (N)</td>
</tr>
<tr>
<td>Maximum Push Off Force (N)</td>
<td>Maximum Push Off Force (N)</td>
</tr>
<tr>
<td>Impulse (N*s)</td>
<td>Impulse (N*s)</td>
</tr>
<tr>
<td>THA</td>
<td>HRA</td>
</tr>
<tr>
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</tr>
<tr>
<td>Standard Deviation</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Max. Force</td>
<td>175 1</td>
</tr>
<tr>
<td>Paired T-Test</td>
<td>0.026*</td>
</tr>
</tbody>
</table>

*Statistical significance at 95% CI, TWS= Top Walking Speed, TWI= Top Walking Incline, THA= Total hip arthroplasty, HRA= Hip resurfacing arthroplasty

Table 4. Showing between leg differences in ground reaction forces for arthroplasty subjects at TWS and TWI
Pearson’s $r$ data analysis revealed a moderate positive correlation between increasing steepness and difference in impulse, which just failed to reach significance ($r=0.34$, $n=5$, $p=0.051$). There were no significant differences between limb ground reaction forces of control subjects (Table 5).

<table>
<thead>
<tr>
<th>Ground reaction forces at TWS</th>
<th>Ground reaction forces at TWI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Weight Acceptance (N)</td>
<td>Maximum Weight Acceptance (N)</td>
</tr>
<tr>
<td>Mid Stance Force (N)</td>
<td>Mid Stance Force (N)</td>
</tr>
<tr>
<td>Maximum Push Off Force (N)</td>
<td>Maximum Push Off Force (N)</td>
</tr>
<tr>
<td>Impulse (N*s)</td>
<td>Impulse (N*s)</td>
</tr>
<tr>
<td>L R L R L R L R L R L R L R</td>
<td>L R L R L R L R L R L R L R</td>
</tr>
<tr>
<td>Mean</td>
<td>1178 1164 399 388 788 780 337 336</td>
</tr>
<tr>
<td>Min. Force</td>
<td>816 781 257 255 623 567 233 232</td>
</tr>
<tr>
<td>Max. Force</td>
<td>1848 1792 594 513 1052 1059 475 495</td>
</tr>
<tr>
<td>SD</td>
<td>350 348 113 89 142 159 83 87</td>
</tr>
<tr>
<td>Paired T-Test</td>
<td>0.479 0.640 0.628 0.795 0.595 0.831 0.185 0.617</td>
</tr>
</tbody>
</table>

Table 5. Showing between leg differences in ground reaction forces for control subjects at TWS and TWI

### 3.6 Discussion

This small study set out to detect significant differences in the gait that might exist between THA and HRA by using patients with one of each device in situ. The principle limitation is that of sample size: we were only able to find 9 subjects with high hip scores and no co-morbidities that might invalidate the comparison. However, despite the small sample size, our primary hypothesis was confirmed: there do appear to be measurable and significant differences in the performance of HRA and THA at higher speeds and on inclines. Furthermore, the strong correlations between observed differences and increasing speed confirms that this difference does not exist at a single speed but is a pattern as speed increases. Out of the 9 patients only 7 were able to walk uphill. Uphill walking took place after the fast walking trial. Tiredness may therefore have been the reason why two of the patients did not consent to carry on and this further reduction of numbers may have been a reason for just failing to reach significance with correlating force differences with increasing steepness.

The self determined top walking speeds (TWS) of subjects were considerably higher than that of other studies testing arthroplasty subjects (6.8km/hr, range: 5.5- 9.5km/hr). At TWS, the weight
acceptance was 71N or 8% of body mass greater in HRA implanted limbs. There were strong correlations between the differences in weight acceptance, push-off and impulse as speed increased, confirming the supposition that by testing at low speeds, differences might be missed (96).

Speed dependent gait variability is not a new subject in the medical field and has been highlighted in the field of cerebral ataxia (93). It is therefore reasonable to assume that faster speeds may distinguish the good from the very good arthroplasty in functional terms. The data concurs with previous studies, which failed to detect any significant difference between THA and HRA at slow speeds (up to 5.5km/hr) (17). For more active patients who wish to return to an active lifestyle, this 8% of body weight difference in performance at higher speeds may be clinically relevant.

This is the first report of the performance of hip arthroplasty patients on steep inclines. The median incline managed by these patients with bilateral hip arthroplasty was 20°(10-25°). At TWI, the maximum weight acceptance was 4kg, or 5% of body weight more in the HRA implanted limbs. This size of difference may also be clinically relevant in those patients who wish to return to walking on variable terrain. This small study could not demonstrate a linear correlation between increasing gradient and increasing difference in gait between THA and HRA. However when testing people at their TWI at 4km/hr, the difference in their maximum push off reached significance, while on flat ground it was undetected.

The age and sex matched, asymptomatic control group walked faster on flat ground, and achieved steeper inclines than the arthroplasty group. The ‘normal’ gait cycle curve was visibly different from that of either arthroplasty limb. So while subjects were satisfied with their surgery and had quite good functional scores, as surgeons we should not be complacent in assuming that arthroplasty restores normal function, particularly at higher speeds or on inclines. However the gait cycle of HRA implanted limbs was closer to ‘normal’ at TWS and TWIs. This suggests that the statistically detected differences in gait between types of arthroplasty were in favor of HRA. Hip resurfacing in its current state remains a controversial surgical option for the active patient. This small study, which appears to be free from selection bias, suggests that HRA does indeed enable superior levels of function when treadmill walking at variable speeds and gradients are used as a surrogate for global function. These activities are not unreasonable expectations for all patients who wish to remain active. The decision of which implant to use however should not be based on
potential gait advantages alone and must be joint decision made between surgeon and patient based on safety as well as function aspirations of the patient.
Chapter 4

Resurfacing Head Size And Femoral Fracture: Are Registry Conclusions Justified?

4.1 Abstract

*Background:* Joint registries report that peri-prosthetic fractures are the most common reason for early revision of a hip resurfacing arthroplasty (HRA) and are twice as likely with small implant sizes. However, a national survey found peri-prosthetic fracture to be strongly associated with surgical accuracy rather than implant size.

We therefore asked whether, the force required to induce a peri-prosthetic fracture: 1) Was significantly lower when using smaller implants and 2) Correlated to the size of implant used, when surgery was performed accurately.

*Methods:* To ensure an adequate power we calculated our sample size from pilot data. Forty-four femurs were tested in two experiments. The first experiment tested femurs with either a small (48mm) or a large (54mm) HRA implant. The second involved testing femurs with a range of implant sizes. A rapid prototyped femur specific guide ensured accurate implantation. Specimens were then vertically loaded in a servo-hydraulic testing machine till fracture. Displacement (mm) and force (N) required for fracture were recorded.

*Results:* A median force of 1081 N was required to fracture specimens implanted with small 48mm heads, while 1134N was required when a 54 head was used (U=77, z=-0.054, p=0.957). Implant head size and force required to fracture were not related, r= 0.12, p= 0.63.

*Conclusions:* The force required to induce a resurfacing peri-prosthetic fracture was not related to the size of the implant. The increased failure rate seen in all registries is unlikely to be directly the result of this single variable. Correctly performed resurfacing arthroplasty is highly resistant to fracture.

4.2 Peer review evidence:

1. Much of contents in this chapter have been published in a peer-reviewed journal. A copy of which can be found in the Appendix (Appendix F). A copy is also available on PubMed (PMID:26407614).
4.3 Introduction

Hip resurfacing arthroplasty may offer some advantages over hip replacement, such as superior function (97), and reduced risk of perioperative mortality (98). However, resurfacing is reported to have a higher reoperation rate than replacement in most joint registries (1, 2, 99). The reasons why resurfacings should be revised more often than replacement remain contentious. Periprosthetic fracture is the most common reason for revision of a hip resurfacing arthroplasty (HRA) in the first two postoperative years, and at twelve years post implantation it is still the second most common reason, accounting for 23% of revisions (1). Every joint registry has identified a greater risk of revision with smaller femoral sizes (1, 2, 99). The Australian registry has also identified HRA 12 year revision rates from periprosthetic fractures, to be more than double when small head sizes were used (1). However, a national survey of a well performing HRA implant, showed there to be no correlation between HRA head size and the incidence of periprosthetic fracture (100). Instead, fracture was strongly associated with notching 46.6%, and a varus femoral neck-shaft angle greater than 5° (71.1%). This retrospective analysis implies that periprosthetic HRA fracture to be mainly a surgeon related complication. However, neither retrospective analysis, nor joint registries allow causation to be established. So far, only one hypothesis has been advanced to explain why resurfacing fails more often in smaller sized patients. Acetabular coverage reduces with smaller sizes in most implants so edge loading owing to technical error may be a factor (101). Neck notching may also be harder to avoid in smaller sizes, and smaller and more female patients may have weaker bone than larger heavier males.

The role of head size in HRA failure remains a topic of real clinical relevance as it is easy to record, while surgical accuracy is hard to measure and is unreported in many registries (1, 2, 99). This has lead to registries making firm conclusions on head size alone when the real variable may be surgical accuracy.

We therefore asked, whether the force required to induce a periprosthetic fracture:

1) Was significantly different when using small and large implants and

2) Correlated to the size of implant used, when surgery was performed accurately.
4.4 Materials and Methods

Specimens

Forty-four synthetic femurs (Large left femurs, model number 1130; Sawbones Europe AB, Sweden) were used because of their consistency of geometry and strength. They were dual density with a polyurethane shell, to mimic cortical bone. Femurs from the same batch and manufacture date were used to avoid potential inter-batch variation in mechanical properties. These specimens were chosen for the good correlation between their mechanical properties that of cadaveric femurs (102-104). One specimen was CT scanned to generate a digital three-dimensional model, which was later used for planning and validation of correct implant positioning.

Sample Size Calculation

We conducted a pilot study of seven non-implanted synthetic femurs and axially loaded them to fracture. This sample yielded a standard deviation of 72.9N. With an expected difference of 51.8N (5% difference), we calculated that we had to test sixteen specimens (eight in each group), to power the study adequately at the 95% confidence interval. However we aimed to test thirteen specimens in each group to account for possible outliers, which would have to be excluded from later analysis.

Prostheses

This study evaluated the relationship between the head size, of a successful hip resurfacing implant (BHR, Smith and Nephew), and the force required to induce a peri-prosthetic fracture. In order to ascertain whether there was a difference in fracture resistance with small and large head sizes, we implanted femurs with either a 48mm or 54mm HRA head.

Later we separately tested specimens with a range of head sizes (46, 48, 50, 52, 54, 58mm), to determine whether implant size correlated to the force required to induce a peri-prosthetic fracture. Three specimens were tested at each size.
Specimen Preparation

As this study focused on establishing whether failure was related to implant size, we attempted to standardize all other potential contributing factors. This included eliminating potential implantation errors.

A single specimen was 3D laser scanned (NextEngine 3D Scanner HD, California, USA), to derive a surface model, which was saved in the stereolithography (STL) file format. This was used to plan the ideal position of the implants and design a specimen specific guide which was later 3D printed (Embody Orthopaedic LTD, London, UK). The position of the stem was planned to be in 5° of valgus in the coronal plane and in the centre of the neck in the axial plane. This is consistent with previous studies, which have confirmed this position to reduce the risk of peri-prosthetic fracture (100, 105, 106). The use of a specimen specific guide ensured an accurate and reproducible position of the guide wire, which is the most important determinant of implant positioning. The remaining femoral preparation, used equipment, which was routinely available in clinical practice. Implanted specimens were 3D laser scanned and generated STL models were compared with the original plans to ensure accuracy prior to testing.

Implants were mounted in a 3D printed customised block (Embody Orthopaedic LTD, London, UK), at a standard distance from the top of the greater trochanter. The mounted specimens were all tested on the same day to avoid discrepancies from specimens, which may have degraded with time.

Testing Protocol

The mounted proximal femurs were fixed under a servohydraulic testing machine (MultiTest 10-I (10kN), Mecmesin, Slinfold, UK) in a standardised position, so that the head was directly under it. A customised pusher, (Embody Orthopaedic LTD, London, UK) was designed to mimic an acetabulum, so that when pressure was applied from above, the head was not able to deform out of position (see Figure 9).
Figure 9: Figure showing vertical loading set up before and after an induced peri-prosthetic fracture

Force was then applied vertically until fracture, which was defined as an increase in displacement by more than 25% in one second. Force (N) and displacement (mm) data was recorded at a rate of 50hz.

Statistical analysis

As data was not parametric, we used a Mann-Whitney test for between group analysis. One outlier was identified in the 48mm head size group (See Figure 10).
Figure 10: Box plot showing forces required to induce a peri-prosthetic fracture in large (54mm) and small (48mm) hip resurfacing implanted femurs

This was excluded from the analysis to avoid skewing the results. To assess whether there was any correlation between head size and fracture force, we conducted a spearman rank test. Data analysis was performed using SPSS (IBM SPSS Statistics, version 21).

4.5 Results

In total, this study tested 43 implanted specimens. There were 25 samples in the between group test and a further 18 implanted specimens in the correlation test. Examination of the 3-dimentional steriolithography images of scanned implanted femurs, revealed appropriate implant positioning, with no notches and a valgus stem-neck angle in all cases (see Figure 11).
Figure 11: Coronal (A) and oblique (B) images of a 3D scanned prepared specimen showing the center of the femoral neck (black dashed line) and the planned ideal stem position (solid white line).

Visual inspection revealed no cortical breaches of the stem. Therefore all specimens were suitable for testing.

Between Group Test

The load needed to fracture these hips was very similar in the two groups: the 48mm head hips fractured at a median 1081 N (range 834-1215 N), while 54mm head hips fractures at a median 1134 N (range 876.0 -1204 N). No real difference between these two groups was detectable (U=77, z=-0.054, p=0.957 (see Figure 10 and table 6).

<table>
<thead>
<tr>
<th>Table 6.</th>
<th>Head Size</th>
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<tbody>
<tr>
<td></td>
<td>48mm</td>
</tr>
<tr>
<td>Median</td>
<td>1081</td>
</tr>
<tr>
<td>SD</td>
<td>99.4</td>
</tr>
<tr>
<td>Min</td>
<td>834</td>
</tr>
<tr>
<td>Max</td>
<td>1215</td>
</tr>
<tr>
<td>n</td>
<td>12*</td>
</tr>
<tr>
<td>p-value</td>
<td></td>
</tr>
</tbody>
</table>

Key

* One outlier removed from analysis

** Analysis performed using Mann-Whitney test

Table 6. Showing Forces required to induce a peri-prosthetic fracture with large and small implant sizes
Correlation Test

The load to failure across all femoral components was broadly the same, with no clear evidence of increasing load to failure with increasing size, (Spearman’s $r=0.122$, $p=0.629$ see Figure 12).

Figure 12: Figure showing the force required to induce a peri-prosthetic fracture with a range of implant sizes.

4.6 Discussion

This study set out to ask a simple question: is the size of the component used related to the force needed to create a peri-prosthetic fracture as is suggested by registry data?

It is of course limited by using dry bones rather than cadavers. Fracture patterns seen in this study seem to be different from those seen clinically when fractures mostly emanate from the femoral neck rather than the per-trochanteric region. This difference may be due to surgery being performed more accurately in our study as we used anatomy specific instrumentation to aid bone cuts and avoid femoral notching, which has been strongly associated with neck fractures, or may be due to dissimilarities of our synthetic bone models from real bone. However the predictability of geometry and strength of these synthetic bones is an advantage over cadaveric bones, which vary greatly with respect to gender, age and bone quality. These synthetic femora have been
found to be reasonable surrogates for cadaveric bone in previous studies, so their use may be justifiable (102-104).

We also used one size of femur for all sizes of implants, trying to minimise the variables. However, altering femoral size as well as head size would leave one questioning whether the results obtained were due to differences in femurs or implants. Thus our use of a single size specimen allows us to be confident with the interpretation of our results.

This study does not make inferences on the likely effects, if any, of head size on the need for revision from metal debris associated lesions. The role of the study was purely to assess the impact of head size on peri-prosthetic fracture, which is the most common reason for revision in the first two years following HRA (1, 2, 99). As we have only used one size of femur, we cannot make inferences on the effect of different sizes or densities of femur on the force required to induce a fracture.

We found that the force required to cause a peri-prosthetic fracture when the same femur has a small HRA implant is broadly the same as that required with a large implant. Furthermore, when testing a range of head sizes we have failed to identify any correlation between implant size and force required for fracture. These results exactly reflect the findings of a national survey, but are at odds with national registry data, which can only report on variables that are collected (100). They report a relationship between peri-prosthetic fractures with smaller head sizes (1, 99, 100), but have no data regarding surgical accuracy and therefore cannot comment on this element.

Two elements of HRA surgery may influence outcome in ways that are not immediately apparent to registries, which do not report on surgical accuracy. The acetabular components of most commercially available prostheses are not uniform across the sizes, with smaller sizes having reduced coverage angles. This design variation means that smaller prostheses have a narrower ‘safe’ range of surgical implantation (101), making the prosthesis less forgiving of surgical error. On the femoral side, most implant ranges are not scaled in terms of instrumentation, so smaller femurs are easier to notch and technically more demanding to obtain the ideal stem-neck angle. These two factors would corroborate previously published literature, which have identified these as the main risk factors for peri-prosthetic fracture (105-108). Thus, the higher failure rates are
likely the result of sensitivity to surgical error when using smaller implants rather than because of the implants themselves.

This dry bone study therefore offers an explanation for the conflicting results of registries and surgical surveys for the surgeon considering resurfacing in patients with smaller neck geometries. In our model, peri-prosthetic fracture appears to be an avoidable complication when surgery is performed accurately, whatever the head size. Technologies that increase surgical accuracy may be worth considering in smaller cases, which are technically demanding with smaller margins for error.
Chapter 5

Can Patient Specific Guides Improve Hip Arthroplasty Surgical Accuracy?

5.1 Abstract

*Purpose:* The role of patient specific (PS) technology in total hip arthroplasty remains relatively unexplored.

We asked whether PS guides (1) Reduced average surgical errors? (2) Reduced outlier error frequencies? (3) Could predict the size of implants used?

*Methods:* A single surgeon implanted femurs using either standard or PS guides and was blinded to the pre-operative plans.

*Results:* There were no differences in median offset errors for standard (1.3mm) or PS groups (1.5mm), $U=182.5$, $z=-2.1$, $p=0.83$. There were 3 outlier errors in the standard and 2 in the PS group. There were differences in median leg length errors between standard (3.3mm) and PS groups (1.4mm), $U=110$, $z=-2.3$, $p=0.02$. There were 7 outlier errors in the standard group and 2 in the PS group. The standard group undersized implants 70% of the time. The PS group always implanted the correct size.

*Conclusions:* PS guides improve hip arthroplasty surgical accuracy.

5.2 Peer review evidence:

1: The contents in this chapter has been peer-reviewed as an oral presentation in the British hip society meeting (BHS) 2016. (Appendix G)

2: The contents in this chapter was presented as an oral presentation in the Royal Society of Medicine and won the prize in December 2015.
5.3 Introduction

When performing any implant aided joint reconstruction, one aims to improve pain and function, whilst minimizing the risks of surgical complications. Unfortunately THA can worsen hip and back pain if limbs are lengthened excessively (20-22, 109). In terms of function, surgical errors leading to leg length discrepancies (LLD) or offset errors have been found to impact on walking gait, with greater errors resulting in more profound abnormalities (110-113). When walking, LLDs increase oxygen consumption, heart rates and quadriceps activities in the longer legs whilst increasing plantar flexion activities in the shorter limbs. The result is an asymmetrical and inefficient gait, which leads to early tiring (110).

LLD can also result in nerve injuries, which manifest clinically as foot drops or persistent symptoms of pain or para-asthesia (23-25). Failure to accurately reconstruct the hip offset or leg length can also impact on joint stability and range of motion (113, 114). These surgical errors can lead to dissatisfied patients who may seek financial retribution through the legal system. According to data retrieved from the National Health Service Litigation Authority (NHSLA), of all the litigation cases involving hip replacement surgery, 16% were due to unacceptable leg length discrepancies (26). The resulting average case payouts were steep ($139,840), and even greater if accompanied with a nerve injury (26, 115, 116).

It is therefore paramount to be able to consistently perform accurate surgery in order to minimize the risk of these adverse events. Patient specific technology has been proposed as one possible solution. In the context of knee replacement surgery, PS guides have been found to be as accurate as robotic surgery, whilst reducing operative times (117). Its use has also been associated with an increase accuracy of predicting implant size, which has the added benefit of being able to plan for the need of non-standard implants (118). When performing hip resurfacing arthroplasty (HRA), PS guides improve the accuracy of guide-wire insertion, and in total hip arthroplasty (THA) surgery they can assist in cup orientation (36, 38, 39, 119-122). However, its use in improving placement accuracy of a total hip stem, is largely unexplored (37).

In the context of performing a THA, we asked whether PS guides (1) Reduced average leg length and offset errors? (2) Reduced the frequency of the most severe errors? (3) Improved the predictability of the size of implants used?
5.4 Materials and Methods

Sample Size Calculation

We conducted a pilot study using ten femurs. The calculated leg length error SD and means were 3.14, and 4.3mm respectively. Setting the power at 0.8 and using 95% confidence intervals, we calculated a minimum sample size of 9 would be required in each subgroup. In order to account for errors in preparation or testing which might preclude the use of some samples we aimed to test ten implanted femurs in each subgroup to ensure an adequately powered study. As we were examining the performance of two surgical guides for two different implant types, and to account for drop-outs, we aimed test 40 specimens in total.

Surgical Planning

A single specimen was 3D laser scanned (NextEngine 3D Scanner HD, California, USA), to derive a surface model, which was saved in the stereolithography (STL) file format. This was used to plan the ideal position of the implants and design a specimen specific guide which was later 3D printed (Embody Orthopaedic LTD, London, UK). The femoral stem implant was templated to be in neutral femoral anatomical alignment in both coronal and sagittal planes. Based on this ideal implant position a single implant size, offset, and neck angle was chosen which restored femoral offset and leg length. Although implant size was allowed to vary as the surgeon saw fit, implant offset and neck angle was standardised throughout, in order to allow for a fair between group comparison.

Specimen Preparation

Forty synthetic femurs (Large left femurs, model number 1130; Sawbones Europe AB, Sweden) were used because of their consistency and realistic geometry. They were dual density with a polyurethane shell, to mimic cortical bone. Femurs from the same batch and manufacture date were used to avoid potential inter-batch variation in properties. Femurs were first mounted in a 3D printed customised block (Embody Orthopaedic LTD, London, UK), at a standard distance from the top of the greater trochanter ready for preparation.
A patient specific cutting guide was used in one group, while routinely available osteotomy cutting guides were used in the conventional group (Figure 13).

The rapid prototyped PS guide directed the proximal femoral osteotomy cut level and orientation as well as directing the entry point of the femoral rasp (Figure 13). Femurs were rasped up to the desired size as dictated by the ‘feel for the implant fit’ (as is under normal clinical circumstances). A single, and senior orthopaedic surgical registrar performed all surgery. The two different stems used in the study, (Furlong HAC and Furlong Evolution, Joint Replacement Instruments Ltd, UK) varied greatly in their proximal geometry, surface coating, and length, but were both uncemented and collared in design (Figure 14).

Fig. 14: Figure showing long (Furlong HAC, JRI Orthopaedic LTD) and short stems (Furlong Evolution, JRI Orthopaedic LTD) used.
**Error Measurement**

Implanted specimens from both groups were 3D laser scanned to generate further STL models, which were then compared with pre-surgery plans to assess accuracy of surgery (Fig. 15).

![Fig. 15: Figure showing examples of 3D surface models of specimens (grey) being compared to pre-operative plans (blue) to determine accuracy of surgery](image)

A single student blinded to the type of guide used, calculated femoral offset and leg length errors. As the risk of complications increase with worsening errors, we also calculated the frequency of outlying offset and leg length errors (taken as errors >5mm). Finally, we also noted the size of the implant used in each case, in an attempt to assess whether standard or PS guides were better at predicting the pre-operative size planned.

**Statistical Analysis**

As data was not parametric, we used a Mann-Whitney test for between group analyses. One specimen in the PS group failed quality assessment due to damage unrelated to surgery and was thus discarded prior to analysis. However, the remaining thirty-nine specimens were of good quality and were included for analysis. The loss of only one specimen was not too injurious, as we had already accounted for its potential loss from pilot study derived sample size. Data analysis was performed using SPSS (IBM SPSS Statistics, version 20).
5.5 Results

In total, this study analysed 39 implanted specimens. Twenty specimens were prepared and implanted using conventional guides, and nineteen specimens using rapid prototyped patient specific guides.

**Offset Errors**

Analysis by Mann-Whitney indicated that there were no significant differences in median offset errors for standard (1.3mm) or PS groups (1.5mm), U=182.5, z=-2.1, p=0.83). There were only 3 outliers (15% of the sample) in the standard group and 2 outliers in the PS group (10%) (Table 7).

<table>
<thead>
<tr>
<th></th>
<th>Leg Length Errors</th>
<th>Offset Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PS</td>
<td>STD</td>
</tr>
<tr>
<td>No. Outliers</td>
<td>2(10%)</td>
<td>7(35%)</td>
</tr>
<tr>
<td>Median</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Max</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>

Key: PS= Patient Specific guide group, STD= Standard guide group

Table 7: Table showing leg length and offset errors in standard and PS groups

Subgroup analysis according to implant type revealed no significant differences in offset errors between long (2mm) and short (1mm) implants (U=48, z=-0.15, p=0.88). There were also similar numbers of outliers in the long (1), and short stem (2) groups when using standard guides (Table 8).
Table 8: Table Showing leg length and offset errors when using standard guides and different implant sizes

<table>
<thead>
<tr>
<th>Standard Instruments</th>
<th>Leg Length Error</th>
<th>Offset Error</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Evo</td>
<td>Furlong</td>
</tr>
<tr>
<td>Femur No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
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<td>9</td>
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<td>8</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

| No. Outliers | 4 | 3 | 2 | 1 |
| Median       | 4 | 3 | 1 | 2 |

Key: Values given are in mm and rounded to the nearest whole number, Evo= Furlong Evolution (short stem), Furlong= Furlong HAC (Long stem), Dif.= error difference

Theses results indicating that the type of stem used had little effect on the accuracy of stem placement in terms of the average offset error or frequency of outliers seen.

**Leg length Errors**

Analysis by Mann-Whitney indicated that there were statistically significant differences in median leg length errors for standard (3.3mm) and PS groups (1.4mm), U=110, z=-2.3, p=0.02). There were 7 outliers (35% of the sample) in the standard guide group and only 2 outliers in the PS group (10%). Thus there were more than 3.5 times as many leg length outliers in standard group as compared to the PS group (Table 7).

Subgroup analysis according to implant type revealed no significant differences in leg length errors between long (3mm) and short (4mm) implants (U=36.5, z=-1.02, p=0.31). There were also similar numbers of outliers in the long (3), and short stem (4) groups when using standard guides, indicating that the type stem used had little effect on average leg length errors or frequency of outliers seen.
Implant Size Predictability

In the standard guide group the pre-planned size of implant was used only 30% of the time, whilst in the PS group the pre-planned implant size was used 100% of the time. In the standard group, where the pre-planned size was not used, the all implants were undersized by one size only. There were no peri-prosthetic fractures, which can occur as a result of oversizing or an excessively aggressive femoral preparation, in either group.

5.6 Discussion

This study addresses a gap in the understanding of the potential role of PS guides in THA. We asked whether PS guides (1) Reduced average leg length and offset errors? (2) Reduced the frequency of the most severe errors? (3) Improved the predictability of the size of implants used?

We found that PS guides were not associated with a significant improvement in average offset errors or frequency of offset outlier errors. In contrast, PS guides did lead to a statistically significant improvement in average leg length errors. One may argue that an average error improvement of 2mm is unlikely to represent a meaningful difference. The finding that conventional guides were associated with 3.5 times as many outlying leg length errors, presents a convincing argument in favor of this technologies’ potential clinical usefulness.

It is difficult to contrast our results with those from the literature due to the paucity of evidence available. Whilst enviable in vivo coronal and axial alignment errors have been reported, studies have been limited to investigating the effect of PS guides on guide-wire placement in HRA or on cup orientation in THA (36, 38, 39, 119-121). However, PS guide use in these studies do seem to agree with our findings that their use is beneficial in improving component alignment, and reducing outlier errors (36). Only one other published study has assessed the use of PS guides for performing the femoral osteotomy and aligning the femoral stem in THA (37). Their sample was calculated based on a power of 0.6 and examined only 8 pairs of fresh cadaveric hips. They calculated accuracy based on the differences from pre-operative plans but unfortunately had no control group to compare to. This study did however highlight important information about the effect of guide design on accuracy, and again our study results are in general concordance with their findings that PS guides can aid accurate osteotomies and implant placement.
This is the first study to assess the PS guide effect on the accuracy of predicting femoral stem size. We found use of standard guides resulted in under-sizing of the femoral component 70% of the time, although under-sizing was by one size only on all occasions. However the pre-planned size was used in all PS guide implanted specimens. The under-sizing seen with conventional group is likely to be due to suboptimal stem orientation and cortical abutment of the stem tip. This theory cannot be proved from our data however as we have taken surface models of specimens and can not accurately assess the stem position within the femur. Never-the-less, the theory is reasonable as others have found PS guides to have an influence on coronal plane valgus/varus errors and flexion extension errors in the sagittal plane (37). The ability to more accurately plan the required implant size is useful when trying to preempt when more extreme ‘off shelf” sizes require ordering, when managing implant inventories, and streamlining storage space and costs. Many of the strengths of this study lay in its robustness of methodology. The calculation of minimum sample size requirements from pilot data has led to an adequately powered study. Similarly a post hoc leg length error effect size of 0.8 gives credibility to the conclusions we have drawn from our results. This study is limited however by its use of dry bones rather than cadavers. However the predictability of geometry of these synthetic bones was an advantage over cadaveric bones, which can vary greatly with respect to gender, age and bone quality. In any case, these synthetic femora have been found to be reasonable surrogates for cadaveric bone in previous studies, so their use may be justifiable (102-104, 123, 124). Whilst we have established a difference in surgical accuracy in using the different types of guides, we cannot make inferences of the effect of surgeon experience on surgical accuracy. However, as this study used a single senior orthopaedic surgeon to perform surgery, it is perhaps more likely that the differences seen between two groups are likely to be more pronounced with more junior surgeons. Future research could assess affect of PS guides on accuracy and with different levels of surgical experience. Given the results presented here, it would also be reasonable to assess the use of this technology in vivo, as part of an ethically approved prospective study.
Acknowledgements

I would like to thank Embody Orthopaedic LTD and Joint Replacement Instruments LTD for kindly providing free of charge, and without condition, implants used in this study.
Chapter 6:

Summary

Currently registries are limited by the fact they only collect and record one end-point, time to revision. Some clinicians argue that this means other important end points such as, change in patient functional outcomes, morbidity not leading to revision (e.g. infection or dislocation), and the cost of revision surgery are being overlooked (125).

In addition, as only variables of convenience are collected (mainly demographic and implant related data), there is a lack of comorbidity and functional data. Thus inferences of causality in trends cannot be reliably drawn. Registry data, no matter how large, is still non-randomized. As such, studies, which use this data, cannot be of the highest quality. This is highlighted by the fact that in terms of performance one registry can place one implant as having the best survival in one part of the world, but in a different registry, the same implant may not fare as well, despite all apparent variables being similar. Thus whilst registries are useful in identifying potential implants that are faring disastrously, their role should not exceed this specific mandate, to which they were created.

Many now believe that any trends seen in the data, should instead, be investigated as part of separate and controlled studies. It was to this end that we aimed to investigate the trend of increased fractures in HRA with smaller implant sizes. We failed to find a relationship between the use of smaller implants and the forces required to induce a peri-prosthetic fracture. Other studies instead have shown that the risk of periprosthetic fracture is greatly increased by the phenomenon of notching, or varus placement of the femoral component. This is more likely to occur in the patient with smaller anatomy as surgery is more technically challenging. Thus we believe, from this and other evidence, that it is likely that surgeon error is responsible for the increase fracture rates seen in HRA when smaller implants are required. Rather that being directly relating to the implants themselves, when surgery is performed accurately, the risk of fracture is equal across all sizes.

Surgical accuracy however is as important in THA as it is in HRA. In this thesis we have already highlighted the literature, which shows that anatomical reconstruction is more difficult to achieve when performing a THA. Hence this thesis also investigated the potential usefulness of PSI when performing a THA. Whilst this preclinical study did not show an advantage of PSI in aiding the femoral offset reconstruction, it did improve leg length reconstruction accuracy and reduce the
frequency of outlier errors. Clearly clinical studies are now required to ensure that this perceived improvement in accuracy bears out in vivo. This is a promising area for future research and the popularity for PSI applications seem to be spreading in other surgical specialties and not just orthopaedic subspecialties.

When performed well and with patients who are satisfied with their surgery, function and biomechanics are improved following hip arthroplasty. This thesis has demonstrated that patient can walk at fast speeds following surgery. Most are able to walk at speeds in excess of 7km/hr, six to twelve months following surgery. This level of activity, in this group of patients has not been demonstrated before. We have also shown as part of a prospective study, that gait symmetry is markedly improved following hip arthroplasty, and that surgery not only normalizes gait in the operated leg, but also changes the gait in the contralateral limb. These post operative gait alterations we found to be closer to gait patterns seen in health individuals. Therefore, whilst it is know that hip arthroplasty improves pain for arthritis, we have demonstrated it can also result in a more normal and symmetrical gait even at fast walking speeds.

This thesis has shown that fast and incline walking on a treadmill can be used to assess the effect of interventions on high-end function. We demonstrated strong correlations between increasing speed and walking incline and between leg gait differences in patients implanted with different hip implants. Previous studies may have failed to demonstrate these findings, as patients assessment were performed with tasks, which were easily achievable by all. Our findings suggest that new technology or techniques, which claim superior high-end function, can and should be proven using the challenging gait assessments techniques we have demonstrated. It is clear that if we cannot discriminate between those who can and cannot achieve higher-end function, techniques and equipment, which promote this, are unlikely to emerge or be appreciated. Whilst PROMS will always have a role, in identifying patients performing poorly, following surgery. A fast or uphill walking gait assessment using a treadmill, may be the best way of discriminating between higher-end performing patients. We now know that PSI has the ability of improving surgical accuracy and potentially reduce complication rates. The ramifications of this would be better and more predictable patient experiences, and outcomes with a reduction in costs associated with expensive revision surgery. Therefore PSI may be a very good way of adhering to the ethos of the GRIFT (getting it right first time) report, which share these aims through accurate and safe arthroplasty
surgery (126). As we have also demonstrated HRA to enable patients to achieve higher levels of function. The logical progression and area of future research would be to assess the post-operative gait of patients with PSI implanted hip resurfacing at fast walking speeds and inclines. This would determine whether PSI could further impact on high-end function, as it seems to impact on surgical accuracy.

It may be that centers, which have the equipment and expertise to perform these assessments, will naturally become regional hubs where clinical trials are run and evaluate future implants and techniques.
References


123. Jones C, Aqil A, Clarke S, Cobb JP. Short uncemented stems allow greater femoral flexibility and may reduce peri-prosthetic fracture risk: a dry bone and cadaveric study. Journal of


Appendix

Appendix A

The Effect of Hip Arthroplasty on Osteoarthritic Gait: A Blinded, Prospective and Controlled Gait Study at Fast Walking Speeds

Adeel Agil, MRCS, *, Anatole Wilk, MRCS, Michela Zanotto, MSc, Victoria Manning, PhD, Milad Masjedi, PhD, Justin P. Cobb, FRCS

MEX Lab, Charing Cross Hospital, Imperial College London, London, UK

ABSTRACT

Background: Painful unilateral coxarthrosis results in excessive forces passing through the "good leg." The impact of hip arthroplasty on contralateral leg gait has not been fully explored. We measured patients' gait before and after arthroplasty to answer 3 questions: (1) Are peak forces for the good legs outside the normal range? (2) Does arthroplasty protect contralateral limbs by reducing peak forces? and (3) Does arthroplasty result in a more symmetric and normal gait at fast walking speeds?

Methods: This prospective, controlled study, assessed ground reaction forces before and 13 months (range, 6-21 months) after hip arthroplasty.

Results: Peak ground reaction force in contralateral hips fell (145-138 times body weight, P = .04), whereas symmetry index maximum weight acceptance improved postoperatively (12.2 ± 11 vs 13 ± 6, P < .001).

Conclusion: Although gait becomes more symmetrical, patients still experience higher peak loads than matched controls. These high forces may offer an explanation to the progression of arthritis in lower limbs.

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Appendix B:

Orthopaedic Research UK would like to acknowledge that the presentation by

Mr. Adeel Agil

was awarded

THE BEST PODIUM PRESENTATION PRIZE

at

THE 2014 BRITISH ORTHOPAEDIC RESEARCH SOCIETY/BRITISH HIP SOCIETY JOINT RESEARCH SESSION

which took place at

THE BRITISH HIP SOCIETY ANNUAL SCIENTIFIC MEETING,

EXETER, 5TH MARCH 2014.

Mr. Brian Jones
Chief Executive
Orthopaedic Research UK

Mr. Robert Vallings
Chairman
of the Board of Trustees

Furlong House 10a Chandos Street London W1G 9DQ England
www.oruk.org
Appendix C:

Imperial College

Joint Research Office
Academic Health Science Centre
Imperial College London and Imperial College Healthcare NHS Trust
St Mary's Hospital
Faculty of Medicine
Room G7A1
Ground Mezzanine Floor,
Praed Street Wing
(ex Diagnostic Radiology Suite)
V1.1 PG

8 April 2011
Prof. Justin P Cobb
Room 7E08
Department of Surgery and Cancer
Charing Cross Hospital,
London W6 8RF

Dear Professor Justin Cobb

Project Title: Gait Analysis Using An Instrumented Treadmill

Short Title: Gait Analysis Using An Instrumented Treadmill

Joint Research Office Reference number: JROHH00208

Ethics reference number: 10/H0607/104

Principal Investigator: Prof. Justin P Cobb

I confirm that this project has now been approved by the Joint Research Office. The project may now start at Imperial College Healthcare NHS Trust sites. Please note that the start date of the project is the date of this letter and the duration is the same as that provided in your application form.

The list of documents reviewed and approved by the Joint Research Office under requirements of the Research Governance Framework are as follows:

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<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<td>31/01/2011</td>
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<td>04/01/2011</td>
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<tr>
<td>Participant information sheet,  research patient</td>
<td>2</td>
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<tr>
<td>Participant consent form, instrument measurement for gait analysis</td>
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Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the Research Governance indicators 17 (Data Protection), 25 (Health and Safety) and 22 (Financial)

JRC Ref: JROHH00208

Rec Ref: 10/H0607/104

81
Prob(y). Details of the requirements to be met can be found in the Research Governance Framework available on www.dr.gov.uk.

Under the Research Governance regulations, Serious Adverse Event Reports, Adverse Reactions and amendments to the protocol or other supporting documents must be forwarded to the Joint Research Office and Ethics Committees.

In accordance with the Research Governance Framework, research projects carried out in the Trust will be randomly chosen by the Joint Research Office for auditing. Please see the attached checklist for documentation that will be required during the audit.

I wish you well in your research.

Yours sincerely,

BLAIR

Mrs Becky Ward
Research Governance Manager
Academic Health Science Centre
Joint Research Office
Imperial College London and Imperial College Healthcare NHS Trust
Hammersmith Hospital
Appendix D:

The gait of patients with one resurfacing and one replacement hip: a single blinded controlled study


Received: 1 January 2013/Accepted: 29 January 2013
© Springer-Verlag Berlin Heidelberg 2013

Abstract
Purpose Post arthroplasty gait analysis has up till now been performed on subjects walking slowly on flat ground rather than challenging them at faster speeds or walking uphill. We therefore asked: (1) Is there a measurable difference in the performance of hip resurfacing arthroplasty (HRA) and total hip arthroplasty (THA) limbs at patients' self-determined fastest walking speeds and steepest inclines? and (2) Is there a relationship between the observed differences between the gait of HRA and THA implanted limbs and patient walking speeds and inclines?
Methods In an ethically approved study we recruited patients with bilateral hip arthroplasties: one HRA and one THA. Nine subjects were assessed using an instrumented treadmill at a range of speeds and inclines by a blinded observer. The ground reaction forces of subjects were recorded and an age, sex and BMI matched control group was used for comparison.
Results Increasing walking speed correlated strongly with between leg differences in weight acceptance ($r=0.9$, $p=0.006$) and push-off force ($r=0.79$, $p=0.002$). HRA implanted limbs accepted significantly more weight at top walking speeds (1208 N±320 versus 1279 N±370, $p=0.026$) and pushed off with greater force when walking uphill (818 N±163 versus 855±166, $p=0.012$). HRA limbs more closely approximated to the gait of the normal control group.
Conclusions Arthroplasty implants do have an impact on the gait characteristics of patients. Differences in gait are more likely to be evident when assessment is made at fast speeds and walking uphill. This study suggests that HRA may enable a more normal gait.

Introduction
Hip resurfacing arthroplasty (HRA) was introduced to provide superior function for the more active patient, however selection bias may have skewed results in favour of HRA [1–3]. Three recent prospective randomised controlled trials have failed to detect a difference between HRA and total hip arthroplasty (THA). All were only powered to detect a 10% difference in slow walking speeds or used conventional functional scores, which have well documented ceiling effects [4–6].

Instrumented treadmills have the advantage of allowing
11.18 THE GAIT OF PATIENTS WITH ONE RESURFACING AND ONE REPLACEMENT HIP. (113)
A Aqil1, R Drabu2, J Bergmann1, M Masjedi1, B Andrews1, S Muirhead-Allwood2, J Cobb1

1 MSK Lab, Imperial College London, Charing Cross Campus, London, UK, 2 London Hip Unit, London, UK

11.27 PRIMARY TOTAL HIP ARTHROPLASTY WITH A FULLY COMPARED TO A PARTIALLY HYDROXYAPATITE COATED TITANIUM FEMORAL COMPONENT: RESULTS OF A PROSPECTIVE RANDOMISED CONTROLLED TRIAL WITH A MINIMUM FOLLOW-UP OF TEN YEARS. (10)
N Sandiford, J Davidson, A Butler-Manuel, HD Aphthorp, DJ East, K Miles, JAN Shepperd

Department of Orthopaedics, Conquest Hospital, The Ridge, St Leonards-on-Sea, UK

11.35 THE FIFTEEN-YEAR SURVIVAL OF TITANIUM, HYDROXYAPATITE COATED STEMS IN FEMORAL REVISION: AN INDEPENDENT ANALYSIS OF 161 STEMS. (263)
TN Board

The Centre for Hip Surgery, Wrightington Hospital, UK

11.45 PRIMARY TOTAL HIP ARTHROPLASTY WITH A FULLY HYDROXYAPATITE COATED TITANIUM FEMORAL COMPONENT: RESULTS AT AN AVERAGE FOLLOW-UP OF TWENTY TWO YEARS. (29)
N Sandiford, C Doctor, S Ahmed, DJ East, K Miles, A Butler-Manuel, S Rajaratnam, JAN Shepperd

Department of Orthopaedics, Conquest Hospital, The Ridge, St Leonards-on-Sea, UK

11.54 CLINICAL AND RADIOLOGICAL RESULTS OF THE OPERA FLANGED ACETABULAR COMPONENT AT 10 YEARS FOLLOW-UP. (136)
JE Oakley, JP Hodgkinson

Wrightington Hospital, Wigan, UK

12.03 HIGH FAILURE RATE OF THE R3 METAL ON METAL HIP ARTHROPLASTY. (79)
A Dramis, E Clatworthy, SJ Jones, A John

Hip Unit, Department of Trauma & Orthopaedics, University Hospital of Wales, Cardiff, UK
Resurfacing head size and femoral fracture: Are registry conclusions on head size justified?

Abdel Aziz 1, Amato Wulk 1, Summamul Chater 1, Milad Manjek 1, Justin Cobb 1

Received: 27 June 2015/Accepted: 20 September 2015
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Abstract
Background Joint registries report that peri-prosthetic fractures are the most common reason for early revision of a hip resurfacing arthroplasty (HRA) and are twice as likely with small implant sizes. However, a national survey found peri-prosthetic fracture to be strongly associated with surgical accuracy. We therefore asked whether the force required to induce a peri-prosthetic fracture: (1) was significantly lower when using smaller implants and (2) correlated to the size of implant used, when surgery was performed accurately.

Methods To ensure an adequate power, we calculated our sample size from pilot data. Forty-four femurs were tested in two experiments. The first experiment tested femurs with either a small (48 mm) or a large (54 mm) HRA implant. The second involved testing femurs with a range of implant sizes. A rapid prototyped femur-specific guide ensured accurate implantation. Specimens were then vertically loaded in a servo-hydraulic testing machine till fracture. Displacement (mm) and force (N) required for fracture were recorded.

Results A median force of 1081 N was required to fracture specimens implanted with small 48-mm heads, while 1134 N was required when a 54-mm head was used (U = 77, z = -0.054, p = 0.957). Implant head size and force required to fracture were not related, r = 0.12, p = 0.63.

Conclusions The force required to induce a resurfacing peri-prosthetic fracture was not related to the size of the implant. The increased failure rate seen in all registries is unlikely to be directly the result of this single variable. Correctly performed resurfacing arthroplasty is highly resistant to fracture.

Keywords Resurfacing • Head size • Failure • Femoral fracture

Introduction
Hip resurfacing arthroplasty (HRA) may offer some advantages over hip replacement, such as superior function (1), and reduced risk of perioperative mortality (2). However, resurfacing is reported to have a higher reoperation rate than replacement in most joint registries (3–5). The reasons why resurfacings should be revised more often than replacement remain contentious. Peri-prosthetic fracture is the most common reason for revision of a HRA in the first two post-operative years, and at 12 years post-implantation, it is still the second most common reason, accounting for 23% of revisions (4). Every joint registry has identified a greater risk of revision with smaller femoral sizes (3–5). The Australian registry has also identified HRA 12-year revision rates from peri-prosthetic fractures, to be more than double when small head sizes were used (4). However, a national survey of a well-performing HRA implant showed there to be no correlation between HRA head size and the incidence of peri-prosthetic fracture (6). Instead,


Appendix G:

BRITISH HIP SOCIETY
Annual Scientific Meeting 2016
St Andrew’s Hall, Norwich

THURSDAY 17th MARCH

Registration from 07.15

08.15 – 08.30 WELCOME TO NORWICH: John Nolan (President, British Hip Society)

08.30 – 08.45 CONSULTANT CONTRACT NEGOTIATIONS UPDATE
Dr Rob Harwood, Consultant Anaesthetist at the Norfolk and Norwich University Hospital and Senior BMA Negotiator on the Consultant Contract Variation Negotiations.

08.45 – 09.30 PODIUM PRESENTATIONS OF SCIENTIFIC PAPERS
(PRIMARY THR: IMPLANT ALIGNMENT ACCURACY)
Six Papers (5 Minutes Presentation + 2 ½ Minutes Q&A)

Chairs: Jonathan Howell and Dominic Merk

A RANDOMISED CONTROLLED STUDY INVESTIGATING THE EFFECT OF PATIENT PELVIC POSITIONING ON RADIOLOGICAL ACETABULAR INCLINATION DURING TOTAL HIP ARTHROPLASTY (THA) (42)
CKJ O’Neil1, D Molloy1, C Patterson2, DE Beverland1
1Primary Joint Unit, Musgrave Park Hospital, Belfast, 2Centre for Public Health, Queens University Belfast

IMPROVING ACETABULAR COMPONENT INCLINATION IN TOTAL HIP ARTHROPLASTY BY USING A DIGITAL PROTRACTOR (26)
G Meerman, W Poots, WJ Van Doorn, J Katz
Department of Orthopaedics, Lievensberg Hospital, Bergen op Zoom, The Netherlands

PATIENT SPECIFIC GUIDES IMPROVE HIP ARTHROPLASTY SURGICAL ACCURACY (102)
A Aquil, S Patel, G Jones, A Lewis, JP Cobb
Imperial College London, Department of Surgery and Cancer, Charing Cross Hospital, London, UK

DOES CUP DESIGN EFFECT DISLOCATION RATE AFTER PRIMARY TOTAL HIP REPLACEMENT: RETROSPECTIVE COHORT STUDY COMPARING THE EXETER LOW PROFILE VS CONTEMPORARY FLANGED CUP (80)
1Partridge1, M Closa1, S Jameson2, P Partington1, I Cartlidge1, M Reed1
1Northumbria Healthcare NHS Foundation Trust, 2South Tees NHS Foundation Trust