Investigations into the ability of Piezoelectric Sensors to Monitor the Integrity of the Cemented Bond between Bone and Implant

By

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Declaration of Originality

I hereby declare that all work contained in this thesis has been produced by the author and that all else has been appropriately referenced.

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ABSTRACT

This study investigates the utility of piezoelectric transduction to assess the structural health of a system through impedance analysis, with application to the field of ‘smart’ orthopaedic implants. The work is motivated by the high proportion of orthopaedic implant failures that occur due to loosening of the bond between the implant and the corresponding bone surface. The ultimate aim is to prove that piezoelectric sensors embedded within orthopaedic implants have the potential identify implant loosing before it would be shown in imaging techniques.

Orthopaedic knee implants were selected as a case study for proof of concept for the proposed health monitoring system. Three distinct experiments were conducted: 1) Small piezoelectric sensors are attached to model tibial trays which are in turn attached with bone cement to sawbone blocks. The measured sensor impedance over a range of input frequencies is measured and analysis of the frequency impedance traces is carried out to determine what changes in the trace are indicative of the bone cement between the sawbone and aluminium curing; 2) Commercially available tibial trays cemented to sawbone tibias are progressively loosened under a fatigue load in a compressive testing rig. Results from three Linear Variable Differential Transducers (LVDTs) measuring the micromotion between the implant and sawbone are compared with frequency-impedance traces taken from a piezoelectric sensor attached to the top side of the tibial tray; and 3) Varying amounts of bone cement is used to cover the surface between a sawbone block and model tibial tray. Frequency-impedance readings are taken from a piezoelectric sensor adhered to the top side of the tray. Support vector machines are used to classify between the varying amounts of cement on each test sample.

Experimental results and data analysis demonstrate the potential of piezoelectric sensors ability to provide information on the integrity of bone cement bond. Findings include: 1) Piezoelectric sensors can determine at what point bone cement bond between sawbone and an aluminium plate has cured; and 2) It is possible to identify different levels of cement coverage between sawbone and aluminium plate with an accuracy of up to 92 % with piezoelectric sensors. These findings establish the veracity of piezoelectric transduction as a means of identifying orthopaedic implant loosening in vivo. This investigation provides a firm basis for future work bringing the ideal of using piezoelectric sensors as a technique for detecting loose implants in vivo closer to becoming a reality.
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A total knee arthroplasty (TKA) is a surgical procedure where damaged or painful knees are replaced with artificial materials. In general, TKAs are used as a last resort for patients with severely damaged and painful knee joints, and approximately 70,000 of these procedures are performed annually in the UK. The most common reason for a TKA to be suggested is as a solution to end stage osteoarthritis (OA), and the average age of a TKA patient is 69 years. OA is a disease characterised by the deterioration of cartilage; particularly within the load bearing joints of the body. One of the causes of OA is adverse biomechanics of the joint, which can be caused by a natural deformity like a varus knee, or an injury like an anterior cruciate ligament tear. In both cases the loading at the knee is affected and some cartilage experiences higher load than a healthy knee, which can subsequently lead to deterioration. The main function of this cartilage is to provide a very low friction surface through boundary lubrication that enables the joint to rotate throughout its range of motion for many years. When the cartilage is damaged the underlying subchondral bone surfaces can come into contact and create pain for the patient. The fundamental purpose of the TKA is to provide artificial knee surfaces to the bones in the knee and reduce the patient’s pain.

Although highly successful in reducing pain, a TKA can fail and cause increased pain for the patient, together with the morbidity and mortality risk associated with a revision operation. Failure can happen due to numerous reasons; those that fail early on are often caused by inadequate initial fixation of the implant and/or poor surgical procedure[1]. However, even with good initial results following surgery the implant can loosen in the bone over time and lead to progressively worse pain for the patient[1]. Current diagnosis for this loosening includes mostly imaging techniques with the recent development of instrumented implants.

Through in depth research into the current techniques used to establish implant loosening and extensive experimental work on a newly proposed method of detection, this thesis demonstrates the potential of using piezoelectric sensors to unobtrusively characterise the integrity of the cement bond between bone and implant.

This chapter outlines both the objectives of this study and the structure of the rest of the thesis.
1.1 OBJECTIVES

The overall aim of this work is to investigate, through the use of both experimental and simple modelling work, the potential materials and methods that can be utilised in the design of an instrumented orthopaedic implant. The main objectives are:

1. To review existing methods to predict loosening (and or bond integrity) of an orthopaedic implant
2. To perform experimental testing and analysis of a sensing materials ability to detect dynamic progressive and static deterioration of a bone implant cemented bond
3. To perform experimental testing and analysis to determine if sensor unit can detect curing of bone cement
4. To compare predictions obtained through simple numerical models with those gained from experimental work and to interpret the findings.

1.2 STRUCTURE OF THESIS

The thesis begins, in chapter 2, with an extensive review of the current literature and work being performed in industry and healthcare into the development of instrumented implants and how they can be used in the diagnosis of implant loosening. Comparisons are made between current techniques and both their pros and cons are addressed. This chapter concludes with a section relating to piezoelectric sensing systems and why this will be used in the study. Chapter 3 goes on to look at the development of a simplified mathematical model used to predict the experimental impedance output of piezoelectric sensor. This allows for a smaller frequency range to be focused upon. Initial cement curing experiments are described in chapter 4. These investigate the sensors ability to determine the curing behaviour of bone cement as it cures between a block of artificial bone (Sawbone, Pacific Research Laboratories Inc.) and a tibial tray modelled by an aluminium plate. The results from the sensor are analysed and compared to the comments on cure time made by a trained orthopaedic surgeon.

Having established the ability of the sensors to respond to cement curing, chapter 5 looks into developing methods to classify the amount of cement covering between implant and bone. The classification method, Support Vector Machines, SVM, is used to develop a computer system capable of distinguishing between different levels of cement coverage between sawbone and aluminium. Chapter 6 uses tibia shaped sawbone blocks to establish
changes in the impedance response as the interface between sawbone and implant is progressively loosened. Here impedance readings are taken alongside micromotion measurements as a crack between bone and implant is increased in size. Finally, chapter 7 will discuss the main findings of this thesis, its relevance to the clinical community and potential future work.
2 REVIEW OF CURRENT DIAGNOSIS TOOLS FOR IMPLANT LOOSENING

This chapter is presented in four distinct sections: clinical background, TKA failure, loosening diagnosis, and summary.

The clinical background section addresses the basic science behind total knee replacements; what they are, why they are prescribed, alternatives treatments and their prevalence. This section is included to emphasise the need for a new loosening detection device in the context of total knee arthroplasty. It discusses the prevalence of and reason behind total knee replacement surgeries.

Section two looks specifically at the failure of total knee arthroplasty, investigating how it happens, why it happens, its effects on the patient and its consequences in terms of further treatment. It builds on the basic science and statistics of failure from section one and allows a further understanding as to why earlier detection of loosening would be beneficial to all parties involved, such as patients, surgeons and implant manufacturers.

Section three discusses the techniques currently used to detect loosening of orthopaedic implants. It reviews the commonly used imaging techniques that are in clinical use and explores the use of instrumented implants. Many instrumented implants are yet to be used clinically, and are either still being developed, or those that are implanted in patients are used to collect data for clinical investigations rather than for diagnosis. There are also other instrumented implants that focus on the measurement of forces in the joint rather than loosening. However, these implants are still important to investigate in this review as they provide information on the process of incorporating electrical components into orthopaedic implants, providing details on power, data transmission and miniaturisation and sterilisation of electronic components. All this information will aid in the design and evaluation of the new techniques to measure loosening, which is the focus of this thesis.

Finally, section four brings together all the information collected in the three previous parts of this chapter in order to justify the work performed in the remainder of this thesis.

2.1 CLINICAL BACKGROUND

2.1.1 REASONS FOR TKA

In general, TKAs are used as a last resort for patients with severely damaged and painful knee joints[2]. The most common reason for a TKA to be suggested is as a solution
to osteoarthritis[2]. However, there are other reasons for a TKA to be implanted. This section will give an overview of osteoarthritis and other pathologies that require TKAs.

### 2.1.2 OSTEOARTHRITIS

Osteoarthritis accounted for 97% of primary cemented TKA operations last year (NJR 2014). It is a disease characterised by the deterioration of cartilage, particularly within the load bearing joints of the body and can be caused by biological phenomena, mechanical factors or dysregulation of tissue homeostasis [3]. Figure 2.1 shows a diagrammatic image of a healthy and diseased knee. The function of this cartilage is to provide a smooth surface that prevents the bones that make up synovial joints from rubbing against each other as well as to provide some shock absorption. When the cartilage is damaged the ends of the bones (the bone condyles) rub against one another resulting in pain for the patient. The purpose of the TKA is to provide new surfaces to the bones in the knee and reduce the patient’s pain[2].

![Diagram of healthy and diseased knee](image)

Figure 2.1 Gross pathologic changes observed in OA joints during many years of degenerative change [4].

### 2.1.3 OTHER REASONS BEHIND THE NEED FOR TKAS

As mentioned, osteoarthritis is the most common reason behind a patient being prescribed TKA surgery, however, there are other reasons too. The more common alternative reasons are summarised here:
RHEUMATOID ARTHRITIS

Rheumatoid arthritis is a chronic progressive disease causing inflammation of joints causing pain, deformation and immobility. It mainly affects the smaller joints of the hands and feet and hence is not often the cause for total knee replacements. Last year the national joint registry reported roughly 2% of primary total knee replacements were due to rheumatoid arthritis[1].

AVASCULAR NECROSIS

Avascular necrosis is the death of bone in the knee joint following blood supply problems. It accounts for less than 1% of the total number of cemented primary knee replacements[1].

TRAUMATIC KNEE INJURY

Traumatic knee injuries can occur through various methods ranging from sporting accidents to road traffic accidents. Last year approximately 1% of cemented primary knee replacements were performed to correct knee injuries[1].

2.1.4 OTHER TREATMENTS USED TO MANAGE OSTEOARTHRITIS

ARTHROSCOPIC WASHOUT AND DEBRIDEMENT

This is another technique used in the treatment of osteoarthritis. Performed under general anaesthetic, a small incision is made at the knee joint in order to introduce an arthroscope to the joint such that visualisation of the joint can be seen as a further arthroscopic cannula is inserted within the joint through which saline is introduced. Loose debris is expelled through the cannula. Damaged cartilage of bone that is still intact is debrided at the same time.

Many randomised control trials (RCT) have been completed to determine the efficacy of this technique, the results of which have been mixed[5-9]. A trial comparing 180 patients with arthroscopic lavage, debridement or placebo found no significant differences between the three at a 2 year follow up in terms of reduced pain or knee function[5]. Another RCT investigated the effects of the amount of washout that 90 patients received, with those receiving 3 litres reporting significantly better pain relief, but no difference in stiffness or function after 12 months than those who received 0.25 litre washouts[6]. Two further RCT studies found no significant difference between slightly varying techniques of washout. One found no difference between the clinical and functional outcomes at 12 months between
arthroscopic and closed-needle washout[8] and the other reported no significant difference in pain or function also at 12 months between hyaluronic acid injections and arthroscopic washout[9]. However it is difficult to fully conclude on these two studies that a difference doesn’t exist due to the small sample size in each study, 32 and 38 patients were investigated respectively.

Often, even if initially successful further interventions are required following arthroscopic washout and debridement. Many of these interventions include repeat arthroscopy and often after 6-7 years, approximately 12% require full knee replacements [10, 11].

**MICROFRACTURE (MF)**

Microfracture is advocated as a first line of treatment for cartilage repair techniques [12]. The procedure has been taking place in a large cohort of patients since 1998[13]. It takes advantage of the body’s natural healing ability, small closely packed perforations are made in the subchondral bone from which marrow is released along with mesenchymal stem cells and growth factors, creating an enriched environment for fresh tissue formation[14].

Advantages of this technique are its technical simplicity and relative low cost [12]. Early follow up results for small lesions (1-5mm2) show 17/26 patients having significant improvements in functionality of the knee [15, 16] at 2 year follow up. Similar results were found in studies that investigated patients at 3 year follow up, where patients with small lesions also showed significant improvements[17-20]. It can be concluded from these studies that the use of MF treatment on small lesions shows good short-term results given that there are low postoperative demands on the joint. In comparison, although young athletes (24 ± 6.5 years) initially showed that over half (52%) returned to their sporting activities after 3 years [21, 22], that in the long term only 37% maintained the same physical activity level[23] and the failure rate between 3 and 10 years post op rose by 7%[23].

It can be concluded from comparing such studies on microfracture that this procedure does have the potential to have positive effects for a patient and is both inexpensive and simple to perform, however what must be taken into account is the expectations of the patient, their activity level and the size on the defect.

Improvements of this technique have been attempted by the inclusion of a thin layered, blood absorbing matrix of either 1) collagen types 1 and 3[24, 25], 2) ‘manipulated’ collagen[26] or 3) chitosan glycerol phosphate[27]. These improvements have shown not
only reproducible clinical results[28], but also possible improvements on long term outcomes[29]

OSTEOTOMY

Osteotomy is the surgical intervention to correct bone and joint misalignment through cutting the bone, with the aim to relieve pain and slow down the arthritic progression. It is mainly considered in patients younger than 55 years of age[30]. It was initially thought up as a solution for the osteoarthritic hip in 1936 [31]. The first initial published reports of osteotomy being performed to correct the alignment of the knee joint is from Jackson et al [32] in 1961 showing the procedure has been being performed for over 50 years. Since this time there has been development into different osteotomy techniques, including; closing wedge, opening wedge, dome and en chevron osteotomies [30], with opening and closing wedge techniques becoming most commonly used[33]. Although having been used for such a long period of time there is still a large amount of debated issues over the use of osteotomies including

• Use of opening or closing wedge
• Graft selection for opening wedge
• Type of fixation for wedge graft
• Comparison with uni-compartmental knee arthroplasty.
• Effects on subsequent joint replacement.

As with nearly all surgical procedure, one of the crucial elements in gaining the best results from an osteotomy procedure is the selection of the ideal patient. Patients likely to have poor outcomes are those with:

• Advanced age [34-36]
• Severe articular destruction [34, 37, 38]
• Patellafemoralarthrosis [39]
• Previous arthroscopic debridement [36]
• Joint stability[39]
• Large decrease in motion range[36]
• Lateral tibial thrust [36]

As for the effects of a patient’s body mass index, studies have shown mixed results some showing higher failure rates for lighter patients[36, 40] and others concluding the
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opposite[41, 42]. However, since UKR and TKR are often deemed less successful in heavier patients, such patients often receive an osteotomy.

**AUTOLOGOUS CHONDROCYTE IMPLANTATION (ACI) AND MATRIC-INDUCED AUTOLOGOUS CHONDROCYTE IMPLANTATION (MACI)**

Used in the treatment of large (1.5-12cm²) full thickness chondral defects of the knee[43], this technique involves the transplantation of cultured chondrocytes into the damaged knee, the process is outlined in Figure 2.2. In comparison to the aforementioned techniques it is relatively new having only been introduced onto the clinical scene about 20 years ago [44].

![Figure 2.2 Processes of ACI/MACI procedure to fix areas of cartilage damage](image)

Although a highly popular procedure, ACI has distinct disadvantages over the more simple interventions mentioned previously such as microfracture. Firstly the ACI procedure is carried out in two separate surgical interventions. This makes it both costly and increases risk to the patient that are associated with surgeries. Other issues are the small risk of developing osteoarthritis at the donor site[45, 46]. One attempt to overcome the risk of creating new sites of OA is to test the potential of taking chondrocytes from other osteoarthritic areas or even other tissue sources, though this is still in early investigative stages[47, 48]. This type of procedure, like microfracturing, has only been shown to be
clinically effective in people under the age of 50 years, presumambly due to age related losses in stem cells and chondocytes[49]

**MOSAICPLASTY**

Mosaicplasty is used in the correction of large, full thickness lesions. It works by taking multiple ‘plugs’ of bone and cartilage from healthy non weight-bearing regions of the joint to treat the damaged areas.

This technique’s main advantage over ACI is that it can be performed in a single surgical procedure; however, it has recently been losing popularity for a number of reasons. Mainly, due to the destiny of the donor sites from which the plugs of bone are taken. These are technically artificially created lesions in an already diseased joint. An effort to correct the damage at these sites is to introduce metrical material in the hope that it will promote spontaneous natural healing [50]. However it is not just the donor site that is of concern. The ‘plugs’ themselves may be damaged when extracted due to high heat produced by drilling when removed from donor site, or the hammering they endure when press-fitted into the damaged area[51].

![Figure 2.3 Photographs showing the use of mosaicplasty for the repair of an osteochondral defect of the medial femoral condyle[43].](image)

**2.1.5 DISCUSSION**

This section has focused on the alternatives to total knee replacements. These alternatives are important as they can bridge between the patient having a painful arthritic knee and the time when a total knee replacement is required. The alternative solutions for treating cartilage repair conserve bone; allowing for them to be an initial solution to cartilage damage and meaning that enough bone can be conserved if the need for a TKA arises later in the patient’s lifetime. These also indirectly influence TKA design; an understanding of these alternatives allows implant designers insight into the state of a knee prior to a TKA.
2.1.6 TKA Statistics

Primary TKAs

Knee replacements have been being performed since the early 1970s. In 2002 the National Joint Registry was set up to collect information on knee, hip, elbow, ankle and shoulder replacement operations with the intention to monitor the joint replacements performance. Figures from the registry show that currently there are approximately 80,000 total knee replacements performed in England and wales each year[1]. This number is increasing by 5-17% a year [52]. In the United Kingdom, as with many developed countries, the population is aging, people are living longer and as a result there is higher demand on the health care system and, relevant to this study, an increase in the need for artificial joints, This predicted increase is shown in figure 2.4 taken from[53]. The overall increase in TKAs being required also means an increase in the number of younger patients (<65 years) having primary TKAs performed.

![Graph showing the projected number of primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures in the United States from 2005 to 2030.](image)

Figure 2.4 The projected number of primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures in the United States from 2005 to 2030[53].

Revision TKAs

The National Joint Registry’s 2013 report on knee revision surgeries reports a total of 5,783 revision surgeries taking place[1]. The majority of these (78%) were single stage revision procedures. 22% were one of the two phases of two stage revisions and less than one percent required conversion to arthrodesis or amputation of the knee[1]. As for reasons behind failure and hence revision, loosening was the most common indication for single-stage revision (38%). Other reasons for failure included, but not limited to: instability, pain,
and wear of polyethylene component. Rate of revision surgery is inversely related to the patient’s age. Patients under the age of 50 years are almost 5 times as likely to require revision 3.5 or more years after surgery as those over the age of 75 years [54].

### 2.2 TKA FAILURE

There are multiple reasons as to why a TKA would need revision surgery. The top three reasons for revisions are: loosening (32%), infection (23%) and instability (15%) [1]. This section looks at these three causes of revision and specifically focuses on loosening as this is the main concern of this study.

![Figure 2.5 Cause of failure of knee replacements in the UK in 2013 (Data taken from NJR[1])](image)

#### 2.2.1 INSTABILITY

Instability is the second highest cause of single stage knee revision (NJR 2013). However, even with the high rate of failure that is put down to instability (10-22%) [55, 56], there is actually still a great deal of debate within modern literature about all aspects of knee instability, including risk factors, prevention, definition, treatment and outcomes [57, 58]. Instability can be split into two categories of early and late stage instability, though as a whole, its definition is the abnormal and excessive displacement of the articular elements.
leading to failure of a TKA[56]. The reasons behind early instability are numerous and can be one of, or a mixture of the following:

- Malalignment of components
- Failure to restore mechanical axis of the limb
- Improper balancing of flexion-extension space
- Rupture of posterior cruciate ligament (PCL)
- Rupture of medial collateral ligament (MCL)
- Patellar tendon rupture
- Patella fracture

As with early stage instability, there can also be multiple reasons behind late instability. However, the most common by far is polyethylene wear (with or without ligamentous instability). The wear is often caused by initial malalignment of the implant which has led to uneven loading on the polyethylene and hence created asymmetric wear patterns.

On top of splitting the definition of instability into early and late instability it can be broken down once again into extension instability and flexion instability[59]. The stability of a knee replacement majorly depends on the degree of constraint put on the replacement in the first case. Extension instability is due to excessive bone resection usually of the distal femur. This extensive loss of bone cannot be rectified by the inclusion of a thicker polyethylene liner as this could lead to joint line elevation and excessive tightness in flexion[59]. Conversely, flexion instability is defined as a flexion gap larger than an extension gap due to undersized femoral components or steep tibial slopes[59]. Both these pathologies indicate the importance of properly defined and measureable surgical techniques.

2.2.2 INFECTION

Infection is the highest reason behind two stage knee revisions[1]and has been reported to have occurred in 1-4% of patients with primary total knee arthroplasty [60]. It is difficult for surgeons to detect between when an implant is septic or aseptically loose (this is further explored in section 4 where diagnosis techniques are discussed). Part of this difficulty stems from the fact that infection is usually caused by coagulase-negative staphyloccus (CNS) which is not only present in low numbers, but is also a skin commensal, meaning it can be difficult to differentiate between skin contaminant and a pathogenic organism.
The causes of infection of a joint replacement are similar to those of any other infection to the body, it occurs when bacteria gain access to the body. Infections develop when bacteria enters the body through breaks and cuts in the skin, either from trauma or surgery. Certain patients can be at greater risk of developing joint replacement infections including those with immune deficiencies (HIV, lymphoma), diabetes mellitus, Peripheral vascular disease (poor extremity circulation) and obesity [61].

There are a few strategies that can be tried in order to retain the original implant and avoid the need for revision these include: arthroscopic debridement [62], open debridement with removal of polyethylene spacer [63], surgical debridement and antibiotics [64]. (More information on debridement can be found in section 2.2.1), however revision surgery still tends to have better success [65]. The aim of this thesis is to investigate ways in which the failure of an implant can be detected earlier. Should this be achievable, there is the potential for the aforementioned techniques aimed at retaining the original implant to be able to be performed at an earlier stage, allowing for more effective use.

2.2.3 CLINICAL LOOSENING

A TKA is made up of three parts (see previous section) and loosening of any one of these parts can be catastrophic to the functioning of the implant and therefore to the patients wellbeing; potentially causing significant pain. In conventional replacements it is more common for the tibial component to loosen than the femoral component, however, this is reversed in the case off high flexion TKAs [66]. Loosening can start with micromotion in the range of 0.1mm-1mm [67, 68]. The reasons behind why implants loosen are varied; inaccurate bony cuts, poor cementation technique and/or deficient bone [69], as such there are numerous in vitro investigations as to why loosening occurs and how it can be reduced [69-84]. This project is not directly aimed at investigating the reasons behind loosening. However, it is hoped that by being able to detect loosening in vivo, patterns of occurrence may become apparent and help in the task of determining why implants loosen, and therefore help reduce its occurrence. The main causes of loosening, osteolysis and osteonecrosis are described below.

OSTEOLYSIS

One major cause of loosening is the pathological breakdown of the bone around the implant, known as osteolysis [85], the breakdown of bone due to the release of wear particles. Location of osteolysis surrounding an implant differs between cemented and uncemented implants. In cemented implants osteolysis is concentrated at the bone cement
interface where there have been defects in the cement mantle allowing polyethylene debris to channel through to the bone [86-88]. Cementless implants tend to have a higher rate of osteolysis [86], polyethylene debris is able to channel through to the bone-prosthesis interface at any incomplete area of press fit of the implant, such as incomplete porous coating, screw holes and incomplete bone growth [86].

OSTEONECROSIS

Breakdown of surrounding bone can also be initiated by poor intraoperative techniques that can lead to unbalanced knees or inaccurate bony cuts. Both these situations can lead to stress being placed on inappropriate parts of the bone surrounding the joint causing stress shielding[89], leading to osteopenia. More specifically these poor intraoperative techniques can result in implant cementation into a sclerotic bone bed, osteonecrosis of the patella and patellar fracture, all leading to increase risks of loosening [90].

2.2.4 PRE-CLINICAL INVESTIGATIONS OF TKA LOOSENING

Creating a protocol capable of testing an implant’s fixation at the design stage could provide valuable information to implant manufacturers and surgeons alike. This section addresses the different techniques that have been used in literature to measure the strength of fixation within pre-clinical settings. It explores the possible bone models that can be used, ranging from cadaveric to computational models. It looks at what loads are imparted on knee fixtures during experiments, including how and why such loads are chosen, and finally it investigates the different ways in which fixation and micromotion can be measured and quantified.

MATERIAL VARIATIONS

Multiple materials/models can be used in preclinical investigations of implant loosening, each with their own set of benefits and disadvantages[91]. Such models include cadaveric, animal, synthetic and computational models. The radar plot in figure 2.6 shows a comparison of these when considering the six features outlined below:

- **Clinical relevance**: Will the findings be relevant to clinical setting?
- **Ethics**: Is it a requirement that ethics permits are obtained in order to carry out experiments?
- **Reproducibility**: Can the same procedures be done on multiple specimens and produce the same results?
• **Cost effectiveness**: How expensive is the study?
• **Time efficiency**: How long will a study take to complete?
• **Skill barrier**: Are personal with specific training and skills required in order to carry out the study?

The further spread, or the larger the area, of each material’s radar plot the more positive features it exhibits.

![Radar plot showing cost effectiveness, time efficiency, skill barrier, and clinical relevance for different model test materials.](image)

**Figure 2.6 Relative benefits of different experimental model test materials.** The further spread the lines in the Radar plot, the better the material each classified in each feature.

The plot in figure 2.6 shows that each of the four main materials has their own unique advantages. Specifically, this project will use synthetic bone models. Synthetic bone material has been validated against human bones in several studies for numerous biomechanical properties [92-94]. There are several benefits of using a synthetic material over cadaveric, animal or computational models [94]:

- Ethics approval is not required. Unlike cadaver use, there is no ethical, religious or cultural controversy in using synthetic bones.
- The cost for synthetic materials is less than those associated with cadavers.
- They allow better repeatability compared to cadaver and animal models. Some studies show cadaver specimens having biomechanical properties that vary up to 100% of the mean.
• There is no need for computationally trained personal to work a computational model.
• Synthetic bones do not disproportionately represent the elderly, which cadaver specimens often do.
• Logistically, synthetic materials are easier to store, transport and obtain.

The main disadvantage of bone substitutes, is that it can be argued that it is not as clinically applicable when compared with cadaveric models.

Polyurethane foam makes a good substitute bone [95]. It can be made in various geometries and densities, with varying pore sizes. A principle producer of such synthetic bone is SAWBONES (Pacific Research Laboratories). Test blocks with different densities can be used to model specific types of bone, for example, to model healthier, better quality bone, higher density blocks would be chosen and, on the other hand, unhealthy, osteoporotic bone can be modelled with lower density blocks.

LOADING

When designing a study that is aimed at creating clinically relevant loads to a knee model, whether the model is cadaveric, animal, synthetic or computational, it is important that these loads match those that are expected to be experienced by a person following their TKA surgery. The contact loads within the knee can be either measured or calculated. Calculated loads use kinematic and ground reaction force data along with inverse dynamic musculoskeletal models. Although this is a common way to gain data on contact forces, a lot of variation is shown between studies. Older studies (>25 years old) report very high loads in the knee joint during normal gait for example: 450% body weight [96] and even older studies report even higher loads of around 650% of body weight [97]. However, modern studies that calculate knee reaction forces commonly agree that the contact forces within the knee during normal gait are somewhere in the range of 200-400% of body weight [98-102]. These studies rely on using models for muscle forces rather than direct measurements from subjects, therefore their results will be dependent on the reliability and validity of these models.

An alternative way of gaining local contact forces in the knee is to have them measured directly, through the use of instrumented implants [103-108]. Forces calculated by Bergmann’s implant are often thought of as gold standard[108]. The details of the implant itself will be discussed in section 4 of this chapter.
Bergmann’s most recent study involved 8 subjects with instrumented implants being monitored during seven activities of daily living (ADL). A complete set of results can be found in the paper [108] in the form of appropriate load cycles for each activity for average and high body weights. These cycles of loads can be adapted to create wave form inputs to cyclic loading machines in a laboratory setting, such that fixation of implants in either, synthetic, animal or cadaver bones can be investigated. The load cycles can also be used in computational studies.

MEASURING MICROMOTIONS/LOOSENING

In order to develop sensors that can measure the degree of loosening of an orthopaedic implant there needs to be an already established method of measuring loosening in laboratory conditions that the sensor readings can be compared to. This section looks at how loosening has previously been quantified within experimental studies of loosening between bone/bone substitutes and implants/implant analogous.

LINEAR VARIABLE DIFFERENTIAL TRANSFORMER (LVDT)

Linear variable differential transducers (LVDT’s) have been the most common technique to measure micromotion of orthopaedic implants during the last couple of decades [109-113]. An LVDT consists of a magnetic inner core that is free to move in and out of three coils: a primary coil and two secondary coils. The schematic in figure 2.7 represents this and how the movement of the core leads to different degrees of crossover between the primary and secondary coils. When the coils and core are aligned they behave like a regular transformer and the voltage out is proportional to the number of coils on each side of the magnetic core. Hence, the movement of the core between the two coils creates a change in voltage and if this voltage is measured and is proportional to the core movement the displacement of the core can be measured.
To set up a LVDT to measure the micromotion between an implant and bone, the outer shell of the LVDT needs to be fixed to either bone or implant and the inner core needs to be attached to the other, then, when movement occurs between the bone and implant the core slides in and out of the shell and creates a change in voltage. There are several ways this set up has been implemented in studies. Figure 2.8 shows the experimental set up from [115]. The LVDT outer shells are fixed to the polyurethane foam which is being used as a substitute for the tibia. Attached to the tibial base plate are small spheres on the end of pins embedded within the base plate. The tips of the inner part of the LVDT are set to rest on these spheres. When the tibial base plate is loaded cyclically in the vertical direction, movement between the base plate and bone analogue are determined through changes in the LVDTs voltages.
Figure 2.8 Experimental set up of tibial sawbone implant construct fixated beneath an impactor with LVDTs outer shells attached to the sawbone and their tips attached to ball bearings fixated to the tibial base plate[115].

Figure 2.9 shows another experimental set up using LVDTs, this time the experiment is looking specifically at shear movements at the stem cement interface of the femoral part of a hip replacement [116]. The main body of the LVDT is fixed to the cement layer through a custom made LVDT holder, while the movable core tip of the LVDT is placed within a small 1mm diameter, 1mm deep hole that has been drilled within the implant stem. As with the previous study, the use of LVDTs means that micromotion is measured only at specific points.

Figure 2.9 Another experimental set up of LVDT measuring micromotion. The main body of the LVDT is fixed to the cement layer through a custom made LVDT holder, while the movable core tip of the LVDT is placed within a small 1mm diameter, 1mm deep hole that has been drilled within the implant stem [116].

LVDTs have the advantage of being affordable, simple and intuitive to use and give good accuracy, however their disadvantages include the fact the they will also include in
their measurement, not only micromotion but also deformation of the bone. LVDT are also limited to measuring specific points on the bone [117].

CUSTOM MICROMOTION SENSORS

An optoelectronic three dimensional movement sensor was developed in 1997 [110] and used in a couple of cadaveric studies aimed at measuring cemented femoral stem stability [118, 119]. The structure of the optoelectric sensor is similar to an LVDT as it has an inner moveable core which is placed on the femoral stem and an outer shell which is fixed to the bone or bone substitute. The difference is that whereas the LVDT used the movement of wire coils to create changes in voltage, the optoelectronic sensor uses a light-emitting diode (LED) and silicon position-sensitive detector (PSD). The LED is attached to the upper side of the inner core, such that when the stem moves, it will cause the core and hence the LED to also move. Attached then to the top of the outer shell, directly above the LED, is the PSD which is able to receive photons sent by the LED. What distinguishes this method from the use of LVDTs is that a single optoelectronic sensor is able to detect movement in all three dimensions, whereas each LVDT is only able to measure movement in one direction and hence three separate LVDTs would be required to get a three dimensional picture of what is happening in regards to micromotion. The position sensitive photodiode detects the movement of the LED in the x-y direction and detects the intensity of the light in order to give a reading in the z direction.

![Diagram](image)

Figure 2.10 Diagram representing experimental set up of the custom micromotion sensor that appears in [119]

OPTICAL TRACKING SYSTEM

Optical tracking systems are regularly used in the measurements of bio-kinematics, especially in the area of gait analysis[120]. However, they have also been used to measure the relative motions between femoral TKA components and bone substitutes in an experimental environment [121]. The study used infrared cameras and reflective markers to
track movement. Attaching a total of seven reflective markers to the experimental set up four infrared cameras were used to acquisition the markers’ kinematics. Mounting reflective markers can be simpler than attaching LVDTs as markers on the implant do not need to be in physical contact with those on the bone, unlike LVDTs which need their inner core to be attached to either bone or implant and their outer shell attached to the other. However, certain disadvantages have meant that this technique is not used in this thesis. The equipment is expensive, requires a large area to perform measurements in, few systems allow real time viewing of data and hence, errors may only become apparent during data processing post experiment, meaning that the experiment would have to be repeated from the start. The system must also be calibrated and the global coordinate system defined at the start of each testing session in order to achieve the same accuracy and reference coordinate system over time[121].

**DISCUSSION**

Literature discussed in this section demonstrates that there is a large amount of in vitro research into orthopaedic implant loosening. From reviewing this data, it has been possible to gain a better understanding of the pros and cons of the possible different testing materials, loading profiles and micromotion measuring techniques. Section 3.4.1 outlined the reasons why synthetic bone substitutes are the material of choice for this project. As for loading profile, the main goal of loading the implant models in further experimental tests in this PhD is to illicit loosening, whether this follows more precise replications of loading profiles experienced by the knee during activities of daily living is less important than the fact that loosening does occur. Simplified loading profiles can be implemented to provide quicker and easier experimental set ups. Since the priority of the loading of the implant is to produce loosening, it is important that this loosening is able to be measured so that readings from any potential sensors are able to be compared to some other measure of loosening. This PhD will use LVDTs to measure the micromotion between implant and bone substitute. LVDTs are readily available for use and, as shown in section 3.4.3 are both simple to implement and can give good results. The disadvantages of LVDT, such as the restriction they present on the area of loosening they can monitor is over shadowed by the advantage of their availability and can be rectified to some extent by using multiple LVDTs to measure movement at various locations.

**2.2.5 FIXATION TECHNIQUES**

There are two main ways of fixation can be employed; the vast majority performed both within the NHS and private sector use bone cement (polymethylmethacrylate (PMMA))
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(89% and 83%) respectively[1]. 2-3% of those performed do not use cement for fixation, but instead rely on press fitting. Since Cementless implants cover such a small percentage of total TKRs being performed, this section will focus on the use of cement in implant fixation.

BONE CEMENT

Bone cement is simply polymethylmethacrylate (PMMA), a type of polymer that has been shown to have biocompatibility and been used within the body since the 1940s [122]. For total joint replacement surgeries the cement is provided in two parts: a powder (pre-polymerized PMMA and initiator) and a liquid (MMA monomer stabilizer, inhibitor). When the two are mixed together a free radical polymerization occurs and the cement changes from an initially low viscosity fluid to a thicker more dough like viscosity this allows the surgeon to apply the cement to desired locations before it fully hardens.

AREA OF CEMENT COVERING

It is vital when using bone cement in the fixation of any joint replacement is to ensure thorough initial even coverage of the cement over the desired implant locations. A failure to achieve this can lead to incorrect alignment of the joint to its normal mechanical axis (the aim is to get to with $0^\circ \pm 3^\circ$ of natural mechanical axis) [123]. Mostly, it is the bone resection and soft tissue release that has the greatest effect on achieving this goal[124], however, application of cement, it thickness and penetration into the bone below both the tibia and femoral prosthetics can contribute to this misalignment. The optimum amount of penetration into the bone can be considered to be between 3-5mm as this is said to reduce the infiltration of wear particles and hence provide more consistent long term mechanical fixation of the implants [125, 126].

There are two different ways in which cement is used to fix an implant, either through the cementing of both the underside of the tibial base plate and the stem (full cement covering) or cementing solely under the tibial base plate (surface cement covering). There is a split in literature regarding which of the two methods is more beneficial with some studies claiming the use of extra cement aids in better fixation and hence less micro-movement thereby increasing long term stability [127, 128], however it also means that if revision surgery is required more cement is present in the proximal tibia potentially creating problems due to further bone loss. Those studies that are in support of cementing only the underside of the tibial tray not only claim sufficient stability but also argue that the underlying bone is loaded more and hence its density and architecture are maintained [129, 130].
EXPERIMENTAL STUDIES

Both cadaveric and synthetic tibiae have been used to investigate the biomechanics of these different degrees of cementing the tibial base plate. Synthetic bone models were used in a study by Bert and McShane [131] to compare the two cement coverings using an Advantim knee system (Wright Medical Technology, Arlington, Tennessee). They compared both cement covers with overlays of 1 and 3mm. Results showed no difference between the different in lift off between the different cement area coverings when the mantle was 3mm but showed a higher degree of lift off on the surface only cemented implants when looking at 1mm cement mantles. Peters et al [132] carried out a similar study using 12 matched cadaveric pairs of tibia. This study used Complete Knee System (Biomet, Warsaw, Indiana) and found that there was a positive correlation between depth of cement penetration and micro movement when the implants were loaded at three times body weight for 6000 cycles (the deeper the cement the more micro motion was observed). Although both these studies clearly show that cement penetration is a key factor in initial implant stability they are unable to make clear conclusions on the long term effects on the implant stability.

COMPUTATIONAL STUDIES

Providing computational studies are validated experimentally, they can provide some benefits that purely experimental studies cannot, such as repeatability, ability to adjust material properties and investigate multiple cycles of loading over shorter periods of time[133]. Cawley et al [134] used three-dimensional finite element analysis to investigate the stresses found below both surface and full cemented tibial baseplates. The results showed that those plates with full cementing would show greater bone resorption in the proximal tibia than surface only cement. This model was validated using synthetic tibia, which also resulted in statistically significant differences between full and surface cementing. These results were mirrored by another finite element model that predicted 29% resorption in proximal bone in fully cemented tibia at 60 months [135].

CEMENT APPLICATION TECHNIQUES

There are two distinct ways in which cement is applied during arthroplasty surgery, either through the use of a spatula and finger packing or alternatively through the use of a cement gun. These two techniques main difference is the amount of cement penetration into the bone they each create. Vanlommel et al investigated five different application techniques on 25 open pore sawbone models to represent proximal tibial cancellous bone [136]. The study used classic polymethylmethacrylate (PMMA) bone cement which was manually mixed
in a controlled environment. Each base plate was impacted into the sawbone in reproducible manner described in a previous study by the same author [137]. The five different application processes are defined as follows:

1. 10 g of cement was applied in a thin layer on the lower surface of the tibial component. The component was then placed and impacted onto the tibia using the specific component impactor supplied by the manufacturer.
2. 20 g of cement was applied in a thick layer on the lower surface of the tibial component.
3. 20 g of cement was applied in equal parts, on both the tibial component and the tibial bone using a spatula.
4. 20 g of cement was applied in equal parts on both the tibial component and the tibial bone, but it was finger-packed into the bone.
5. 20 g of cement was applied to the tibial bone with the use of a cement gun

(adapted from [136])

![Figure 2.11 Representation of the 5 different cement application states used in [136].](image)

The cement was left to fully polymerize (approx. 20mins) and its penetration depth was quantified. Statistical analysis performed showed that method 3 or 4 was most effective at gaining optimal penetration of between 3 and 5mm.

The other methods of only applying cement to the tibial baseplate and not the tray showed insufficient penetration and the method of using the bone gun showed excessive penetration of cement, since penetration greater than 5mm has been shown in separate studies to increase the risk of thermal damage to the bone[138].

Another factor affecting penetration of bone cement is the viscosity of the cement when it is applied. A more viscous PMMA will penetrate less compared to one with lower viscosity. The viscosity of the cement can be affected for multiple reasons, the temperature
at which the cement is stored and mixed [139, 140] can have an effect as can mixing the cement within a vacuum [141].

**DISCUSSION**

Section 3.5 details the process of using bone cement in relation to TKA fixation. In further chapters of this thesis bone cement will be used as a fixation device between tibial base trays and tibial base tray analogous. The section here demonstrates that the quality of the bone cement and the process under which it is applied is vital for successful fixation of the implant and since, in the UK, cemented implants are used nearly 90% of the time [1], this thesis will be investigating not only the loosening of a TKA but also look at the curing of cement. It should be evident from this review that any new method to help evaluate the process of cementing implants would be beneficial; hence, part of the aim of the work presented in this thesis will work towards the development such a method.

### 2.2.6 **Effects of Loosening on Patient**

**Pain and Functionality**

As many as one in five patients are unsatisfied with the post-operative results of their TKAs [142, 143] and in terms of loosening the most obvious symptom is pain. This pain is often debilitating and can severely restrict a patient’s daily activities. The pain is felt across the whole of the knee and can cause particular difficulty for the patient when placing weight onto the joint, for example in daily living tasks such as walking and stair climbing [144]. As well as pain, the patient may experience increased stiffness of the knee leading to diminished motion of the joint; in turn this can lead to serious problems with the patient’s gait, possibly leading to other problems connected with poor gait such as lower limb and back pain [144].

Traditionally, the outcome of a TKA has been defined only by survival rate [145-148]. However more recently there has been a trend to assess the functionality and pain as a measure of success of an implant. Many of these assessments are subjective based questionnaires such as ‘patient-reported outcome measures’ (PROMs) [149] and have many advantages. Due to the fact that they can be self-administered they are often both very cost effective and simple to collect. On top of this, they are reported to be reliable, consistent, responsive to change and reproducible [150, 151]. There are however, various disadvantages of using such measures. As with all questionnaire based assessments, questions can be misinterpreted and are often limited in worldwide use due to cultural differences. The subjective nature of PROMs means that patients measure their perception
of their abilities rather than true performance[149]. Attempts to overcome the subjective based limitations of PROMs include the use of accelerometers and pedometers to quantify physical activity. In addition, through observing patients carrying out performance-based measures such as ‘sit to stand tests’ or ‘stair negotiation tests’, clinicians are more likely to fully characterise change in function after a TKA[152-154].

PSYCHOLOGICAL DISTRESS

The effects of a loosened implant are not just physical, often, if the promise of increased mobility and decreased pain is not met this can impose serious psychological burdens on the patient[155-160]. A study from 2003 reported that as much as one in eight patients one year post-operative with well-functioning and fitting implants still complain of substantial pain [161]. Although it is pre-operative function and pain that indicate most strongly the post-operative function and pain[158, 159], there is still a great deal of variability in TKA outcomes and it is for this reason that the psychosocial factors are increasingly being investigated[159, 160, 162, 163].

In the same way that the physical functionality of a knee replacement is assessed using the Oxford Knee Score, the patient’s psychological distress can be assessed using a variety of questionnaires and scales including; Revised Illness Perception Questionnaire (IPQ-r), Hospital Anxiety and Depression Scale (HADS) and Recovery Locus of Control Scale (RLOC) [155, 164].

REVISED ILLNESS PERCEPTION QUESTIONNAIRE

Developed by Weinman et al in 2002, IPQ-r is a quantitative way of assessing a patients understanding of their condition and has been used for numerous medical conditions. Consisting of 12 subscales the IPQ-r is able to investigate a wide range of patient’s perceptions of illness.

HOSPITAL ANXIETY AND DEPRESSION SCALE

This is a questionnaire that consists of 14 statements, 7 aimed at assessing a patient’s level of anxiety and 7 to their level of depression. Increased agreement with each statements leads to the patient getting a higher score, with a score greater than 11 indicating clinical distress.
**RECOVERY LOCUS OF CONTROL SCALE**

The recovery locus of control scale focuses on how much control the patient feels they have over their recovery. It reflects on internal and external factors, allowing the patient to rate their agreement with a set of statements, such that high scores indicate strong belief in internal factors and low a strong belief in external factors.

### 2.2.7 ALTERNATIVES TO REVISION TOTAL KNEE ARTHROPLASTY

One of the main hopes of the research presented in this project is the earlier detection of failing implants due to loosening. This is particularly important as the more hard and soft tissue that is lost around a failed implant means the methods to correct the situation are more extreme. When it is not possible to correct a failed knee arthroplasty with a rotating hinge joint; which can handle most hard/soft tissue defects if combined with modular metaphyseal sleeves, metallic augment and cones [165-167], then the alternative solutions become: Arthrodesis, resection arthroplasty and amputation.

**ARTHRODESIS**

Arthrodesis is the process of fusing the joint and removing all its mobility. It will have major functional limitations for patients but can help immensely with pain. When the knee is fused it is often fixed at 15° flexion in order to allow clearance of the foot during gait and provide relative comfort to the patient when in a seated position[168]. It is set 5-7% valgus with natural rotation[168]. However, if there has been greater than 3cm loss of bone the knee is set in full extension to avoid leg length discrepancies[169]. The success of knee arthrodesis depends on the extent of infection within the joint. Given no preoperative infection the success rate is as much as 62%, however, if infection present in the joint at the time of surgery the success rate drops to 19%[170].

**RESECTION ARTHROPLASTY/REVISON**

Resection arthroplasty is the removal of the joint surfaces, implant components and residual cement; it is rarely optimal for the patient and its main complication is knee instability. However it has three key benefits for the patient: 1) the patient is able to sit more comfortably 2) no residual hardware is required and 3) only a single surgical procedure is often required [169]. Due to effects of knee instability but also its benefits, this type of surgery is mainly recommended for sedentary patients or those that already showed signs of pre-operative disability.
AMPUTATION

Amputation can be considered the most extreme option to deal with an infected knee replacement, although sometimes it is the only option. It is usually only considered after recurrent/ life threatening infections or after several failed attempts of revision TKAs or arthrodesis. Amputation is additionally problematic for failed TKAs as often they are performed on older or obese patients for which walking with a prosthetic can be particularly difficult due to high energy demand of walking with an above knee prosthetic.[171, 172].

2.2.8 RELEVANCE TO THIS THESIS

Work discussed here demonstrates that alternatives to TKA revisions can have major and severe effects on a patient’s quality of life and ideally it would be best for the patient if these could be avoided. Earlier detection of implant failure due to loosening has the potential to allow earlier intervention on a failing implant. This may allow surgeons to salvage failing implants so that more extreme solutions like those mentioned above do not need to be performed or can be delayed.

2.3 DIAGONOSING LOOSENING

As mentioned previously, loosened implants can have devastating effects on a patient. As such there is extensive research into how to best diagnose such loosening. Along with technology aided diagnosis techniques, diagnosis of a loosened implant is also determinate on the taking a full history of a thorough physical examination of the patient. However, this study is focused on the technical aids that can support a clinician’s diagnosis. Loosening is monitored primarily through imaging techniques; Radiographs and CT/MRI imaging data are often used to investigate if an implant is loose through the presence of radiolucency, migration or subsidence[173]. However, more recently, research has been carried out into instrumented implants [174-186]. Figure 2.15 summarises the main loosening detection techniques being used and investigated at the moment. This section looks at each of these techniques and at both their clinical use and possible future clinical use. It also attempts to analyse these techniques looking at their pros and cons and how they may be improved.
2.3.1 IMAGING ANALYSIS OF IMPLANTS

PLAIN RADIOGRAPHY

X-ray is widely available and quick and simple to carry out. Fundamentally, loosening is defined when there is the appearance of radiolucent lines (lighter lines within x-ray film which demonstrate permeability of the x-rays) surrounding (partially, or fully) the prosthesis [187]. The radiolucent bands are indicative of osteolysis; lack of bone in these areas mean x-rays are able to travel through hence producing the radiolucent bands. Osteolysis is a major indication of implant loosening as explained in section 3. In order to collect consistently accurate results regarding loosening, the implant image should be able to be compared to a post-operative radiograph taken immediately after surgery [188].

The Knee Society published a standardisation criterion for the evaluation of roentgenographic knee images, allowing relative comparisons to be made between different surgeons and centres[189]. Figure 2.13 shows different parts of a generic tibial base plate numbered from 1 to 7, the standardisation criterion used for loosening uses these numbered zones to describe where loosening has occurred[190].
Other factors affecting the reliability of the results are the expertise of the clinicians interpreting radiographs and the criteria they base loosening on, one study investigating the interobserver and intraobserver agreement between evaluations of cemented hip radiographs found that intraobserver agreement was moderate and interobserver agreement was poor [191]. These conclusions demonstrate that even with attempts to standardise the evaluation of radiographs the decision on how to treat the same patient may vary greatly depending on the doctor assessing their knee, this can lead to inconsistencies in the treatment for loosened implants.

Another difficulty that arises from the use of radiographs alone to distinguish loosening is the difficulty presented in distinguishing between aseptic and septic loosening; it is for this reason that other imaging techniques such as scintigraphy are sometimes used[192].

**Radiostereometric Analysis (RSA)**

RSA is a technique used to define the mobility between two structures through the use of small metallic beads of known size and density which are placed within the structures. These beads are made from tantalum, a highly radiopaque metal that has no tissue reaction and has been shown to have no side effects in large studies (>1000s patients)[193] Two radiographs are then taken simultaneously with two angled x-ray tubes in stereoscopic convergent-ray mode. Analysis is performed on the two images in order to determine how one structure has moved relative to the second structure [194].
A major limiting factor when trying to assess and review RSA studies is the lack of standardization between the studies. Variations occur at all points in the RSA process, sizes and numbers of marker beads vary, radiation doses and follow up intervals are not consistent and there are differing image acquisition techniques[195]. Some studies measure translations and rotations around the implants centre of gravity and others the migration of specific beads. In an effort to allow direct comparison between studies Valstar et al has attempted to create guidelines for the standardization of RSA [196]. However there is still a lack of standardisations between most studies and therefore it is hard to compare studies of RSA. Despite this drawback though there are some definite positive conclusions that can be made about the use of RSA in implant stability investigations. Firstly, the radiation that a patient is exposed to with RSA is less than that of traditional radiographs due to the high voltage and low amplitude used [196]. RSA is able to show three dimensional migration[197] of the implant with high accuracy (translation accuracy: 0.05mm->0.5mm, rotational accuracy: 0.15° ->1.15°) [193]. This accuracy is even present in early (2 years) post-operative images taken with RSA [198, 199] and from these early images it is possible to predict failure of an implant in the long run [200, 201] potentially allowing the development of novel orthopaedic implant components that will prevent further loosening.

A further advantage to having such good accuracy is that a smaller sample size of patients [196] potentially allows smaller groups of patients to be monitored for short period of time after implant (2years) in order to determine effectiveness of new joint replacements[202]. The main disadvantages of RSA are the expensive software, the requirement of a second roentgen tube as well as the time of a specially trained person to operate the system [203].

Recently there have been further developments into new RSA techniques. The model based approach requires no tantalum markers and no special implants. Given these advantages there is little trade off with the quality of data gathered [204], hence making this potentially a very beneficial technique. A further step is to create a markerless method of RSA; this would allow larger groups of patients to be investigated [205]. However there are still large disadvantages associated with the markerless approach, results yield lower accuracy and precision and there is the added radiation exposure to the patient due to the need of prior surgery and post-surgery CT scans[206].
**ARTHROGRAPHY**

Arthrography is not a separate technique in itself; it is used alongside radiography [207, 208]. It increases the accuracy of plain radiographs by the injection of contrast agents into the joint in order to increase visualization of the periprosthetic membrane. This increase in accuracy leads to both higher specificity and sensitivity. However it is difficult to draw solid conclusions of its benefits due to the small amount of literature available on the procedure and those papers that report on its use in a clinical setting are often smaller scaled studies [209, 210].

An advancement of arthrography is digital subtraction arthrography (DSA); the densities of the implant and contrast medium can be similar, leading to difficulty in visualisation of the periprosthetic membrane. DSA uses subtracted images during injection to give sharper differentiation between implant and contrast medium [211, 212], leading to increases of 27% in accuracy in hip implant analysis [212].

**SCINTIGRAPHY**

Scintigraphy uses radionuclides chemicals which are consumed by cells creating and repairing bone in the body. It is not often used clinically as plain x-rays are often easier for hospitals to obtain, however, Scintigraphy is able to detect septic loosening so can be used when a distinction between the two types of loosening are required. A gamma-camera is used to detect the release of radiation created by radioisotopes [213]. The technique that is agreed to improve specificity of the scans is the use of gallium scans [214]. As the scans show areas where there is a vast amount of bone activity they are often used in detecting cancer but their secondary use to measure infection and damage of a bone, which can often be in regards to joint replacements.

Loosening criteria is defined by Harris et al[215]. In regards to mechanical loosening Harris states that, a significant pathological uptake of the radioisotopes at the distal tip of the THR of the femoral component indicates loosening. Similarly, such uptake of radioisotopes at the cup-bone interface is a sign of acetabula loosening.

An advantage of Scintigraphy over other imaging techniques is that it can detect infection and septic loosening through looking at the pathological uptake around the implant in blood pool images [192]. Blood pools are areas where inflammation has caused capillaries to dilate and stagnant blood flow and the radioisotope ‘pools’. Therefore, such pools indicate intense or acute inflammation.
FDG-PET

Unlike previously mentioned imaging techniques, this technique does not use an image to look directly at the bone implant interface to determine loosening. Instead FDG-PET (fluorodeoxyglucose-positron emission tomography) uses radionuclides to visualise the transport and metabolic rate of glucose by emitting positrons. Because this technique visualizes metabolic rate, it has the advantage over the aforementioned techniques as it detects septic loosening. Leukocytes and macrophages have a high energy demand leading them to have a high uptake of FDG[216], this is then shown as a positive PET scan[217] indicating septic loosening of the implant.

Aseptic loosening can also be detected through high FDG uptake due to wear debris[218]. Wear debris lead to the development of granulomatous tissue in the periprosthetic membrane [219, 220]. The exact criterion for diagnosing a loose implant varies between studies [218] however, both the specificity and sensitivity are repeatedly high across different studies. Although the most precise diagnosis of infection [221], it is one of the most expensive image techniques and hence is rarely used.

IMAGE ANALYSIS DISCUSSION

Table 2.1 is a summary of the advantages and disadvantages of each of the different imagining techniques that have been discussed in this section.
## Table 2.1 Advantages and disadvantages of different imaging techniques used to diagnose orthopaedic implant loosening.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Plain Radiography      | -Available  
                          -Quick  
                          -Simple  
                          -Standardised criterion | -Radiation  
                          -Can be subjective to different clinicians interpretations  
                          -Cannot distinguish between septic and aseptic loosening |
| Radiostereometric analysis | -3D migration of implant  
                          -High degree of accuracy | -Lack of standardization  
                          -Radiation (not as high as plain radiography)  
                          -Expensive software  
                          -Requirement of two roentgen tubes  
                          -Specially trained personal |
| Arthrography           | -Higher specificity and sensitivity than plain radiography                 | -Lack of large scale data  
                          -Radiation (though if MRI used expense is the negative rather than radiation)  
                          -Movement of joint can cause blur of images |
| Scintigraphy           | -Can detect aseptic and septic loosening                                   | -Not readily used clinically  
                          -Conflict in literature as to its efficiency in diagnoses |
| FDG-PET                | -Can detect aseptic and septic loosening  
                          -One of most precise diagnosis tools for infection  
                          -High sensitivity and specificity | -Variation in literature regarding diagnosis criterion  
                          -Expensive |

On a whole, image analysis in the determination of implant loosening tends to show good specificity and sensitivity with each technique giving values at over 70% [216, 222]. Although clearly effective; image analysis does have its negatives. Firstly, scanning a patient is often expensive and there can be long waiting times for the patient, in which time the patient is often in increasing amounts of pain. With concern to patient pain, another problem with using purely imagining techniques for the diagnosis of loosening is that patients must present with pain or functionality problems before investigations are carried out. Imaging requires the patients to present with pain symptoms rather than proactively detecting failure, creating a delay in the diagnosis of loosening leading not only to increased discomfort for the
patient but also often some considerable amount of loosening has taken place before it is detected. This later detection may limit the corrective procedures that can be carried out on the damaged TKA. An instrumented implant has the potential to monitor the implants condition either continuously or at regular intervals, hence allowing earlier detection of loosening; leading to reduced amount of time the patient is in pain before corrective procedures, such as TKA revision is carried out. It may also mean different procedures could be designed to intervene earlier and potentially prolonging the need for a full TKA replacement.

On top of problems relating to cost and availability of imaging machines, imagining can result in patients being exposed to radiation, however, the level of radiation from plain radiology implemented on the limbs and joints (excluding hip) of a patient is low, the health protection agency (HPA) equates an x-ray of the lower limbs to that of a few days of background radiation and has less than 1 in 1million chance of causing cancer. For the hip it increases to the equivalent of 7 weeks of background radiation with a 1 in 67000 life time additional risk of fatal cancer [223]. These values are low, but often multiple x-rays can be needed and those techniques that include the addition of radioactive nuclides increases radiation exposure and hence the risk of cancer. It would be beneficial if a technique could be developed to measure loosening that does not expose patients to any radiation. An instrumented implant has the potential to address this requirement. The work presented in this thesis will investigate such implants and the outcome of investigations carried out will be a non-radiating sensor capable of monitoring loosening.

Diagnosis from data gathered from image analysis techniques is more often than not reported to be variable between different literatures, mostly due to the subjective nature of the clinician’s opinion when analysing a radiographic image of the TKA[224]. This is problematic as it leads to differences in the treatment received from patients under the care of different clinicians even if their cases are actually very similar [224]. This variation in treatment for what may essentially be the same the same issue can create problems for reviewing which treatments have benefited which patients the best. Creating an implant that is able to provide an objective value of the amount of loosening would overcome this problem of subjectiveness.

2.3.2 SENSOR ANALYSIS OF LOOSE IMPLANTS

Sensor embedded implants are variable in both the parameters they measure and the sensors and techniques used to measure them. However, intelligent implants currently
require four main components: an energy source, sensing unit, processor and transmitter, see Figure 2.14 [174]. The challenge when designing an intelligent implant comes from specific requirements that they must meet: they need to be small, be able to undergo sterilization, be both stable within the implant with stable electronics and lastly must be functional for at least the predictive life time of the implant in question[175]. It is for such reasons why there is on-going work aimed at simplifying the use of the components that make up intelligent implants [175, 176].

Figure 2.14 Common components of instrumented orthopaedic implants

It is possible to use various different parameters to investigate the implant bone interface; these are outlined in Figure 2.15. The most often used parameters are those which look at mechanical and acoustical properties of the implant interface, with resonance frequency and damping being the most common. Biological parameters are only used for the determination of infection within the implant.

This section will take a look at current instrumented implants, most of which use a technique called vibrometry. The section will cover implants and loosening techniques that are still very much lab based as well as those which are being modelled using finite element analysis and even a few that are currently in use clinically.
ACOUSTIC INVESTIGATIONS

VIBROMETRY: EXPERIMENTAL WORK

The principle behind the use of vibration in the analysis of loosened implants, is that the vibration of a disturbed structure will depend on; the structure mass, assembly, material properties and geometry.

The use of vibration analysis in the determination of loosening within implants is not new; the technique has been used for over 25 years[225], with much of the research having been in the field of dentistry [177, 178]. The first attempts to use vibrometry in regards to orthopaedic implants involved the determination of initial stability of an implant intraoperatively [226]. Initial stability of implants has been shown to correlate greatly with long term outcomes of joint replacement surgeries [227, 228]

The majority of past and present research revolves around the use of external vibration excitation, and is both experimentally [179-182, 229, 230] and finite element [183, 229, 231] based. In order to experimentally investigate the vibration of an implant certain components are required; a sensor to measure the vibration (often an accelerometer), an actuator to initiate a vibration in the implant and a way to quantify the varying levels of fixation of the implant within the bone.

Figure 2.15 Representation of the possible different parameters than can be measured in an effort to detect implant loosening

<table>
<thead>
<tr>
<th>Electrical</th>
<th>• Conductivity</th>
</tr>
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<tbody>
<tr>
<td>Mechanical</td>
<td>• Stiffness</td>
</tr>
<tr>
<td></td>
<td>• Micromotion</td>
</tr>
<tr>
<td></td>
<td>• Vibration <em>(Vibrometry)</em></td>
</tr>
<tr>
<td>Acoustical</td>
<td>• Resonance frequency</td>
</tr>
<tr>
<td></td>
<td>• Damping</td>
</tr>
<tr>
<td></td>
<td>• phase shifting</td>
</tr>
<tr>
<td>Biological</td>
<td>• Temperature</td>
</tr>
<tr>
<td></td>
<td>• PH value</td>
</tr>
</tbody>
</table>
Intra-operative evaluation of cement less hip implant stability has been investigated experimentally [179]. The method involved attaching a piezoelectric excitator on a conventional hip implant stem and an accelerometer on a composite femur. The frequency response of the accelerometer was measured for different degrees of fixation that were correlated to the amount of micromotion at the bone implant interface. Repeats on four composite bones found that the most sensitive parameter to stability was the shift in resonance frequency of the stem-bone system, which was highly correlated with residual micromotion on all four specimens. Figure 2.16 shows the frequency response found for stable and unstable implants.

![Figure 2.16](image.png)

Figure 2.16 Typical frequency response function for a stable (a) and unstable implant (b) [179]

A further paper used the same methods to take readings from cadaveric femur bones while simultaneously measuring micromotions with a displacement transducer [180]. The study found a quantitative threshold capable of consistently distinguishing between stable and quasi stable implants, and as such the study was able to conclude that a resonance frequency shift of less than 5Hz during the application of torque would lead to micromotion of less than 150um once the torque is removed.

Nearly all studies looking at vibration arthrometry are focused on total hip replacements. However, a study by Jaing et al uses the premise that the health of a ‘normal knee’, that is to say a knee without an implant, can be assessed through vibration analysis[232]. Numerous studies look at the technique of assessing the health of a knee using vibration measuring techniques[233-235] and it has been determined that through the placement of an accelerometer on the external patella and moving the knee through flexion and extension it was possible to differentiate between knees with different degrees of meniscal and cartilage damage. Jaing et al takes this idea further and applies it to knees that have had total knee replacements. Jaing’s investigations however are focused on looking at
the wear that occurs in the artificial knee joint (specifically at the patella femoral joint), which, as described in section 3.3 of this chapter can be a precursor for implant loosening but it means that in contrast to the sensor aimed to be developed in this PhD Jaing’s technique is not directly measuring the fixation of the implant in the bone.

**Vibrometry: Clinical Work**

Georgiou et al carried out clinical investigations as early as 2001, which concluded that vibration analysis is capable of delivering more accurate information on stability of a total hip replacement then radiographs [184]. In numerical terms, Georgiou found that vibration testing was 20% more sensitive than radiographs from the same patients. This was a clinical study and one of the first of its kind. The patient was required to lie on their side with the testing leg resting on the ‘healthy’ leg such that muscular tension was removed from leg under investigation and it was able to vibrate freely. Figure 2.17 shows the setup with the patient laid on their side with the vibrator attached to a 19mm spherical tip held against their lateral epicondyle. The output vibrations were detected with an accelerometer attached on the greater trochanter of the femur. Limitations in the method of data collection include; the soft tissues filtering out high frequencies and the potential of distortion due to intermittent contact with the bone. Procedures are put in place to limit these effects, such as ensuring both the vibrator and the accelerometer are placed within good bony contact at each site. A major advantage that the sensor developed in this PhD aims to have over this traditional vibration analysis is to be able to directly interact with the implant by being embedded within it and therefore minimising the potential errors outlined above that come with interrogating the implant from outside the body.
Georgiou et al used two parameters to analyse the data produced from the accelerometer. First, through using the Fast Fourier Transform to assess the ‘purity of the output wave’ in terms of number of harmonics, the authors set a loosening criterion that stated an absence of harmonics implies a secure implant. The second criteria looked at the number of resonant peaks, with a singular resonance peak representing a secure prosthesis and two or more peaks indicating loosened prosthesis. These parameters were chosen by looking at the TKR as an analogy of laminated structure. For many years vibration analysis has been used to detect damage in laminated structures such as boat hulls \cite{184} and through modelling the prosthesis, cement and bone as layers of material the same delamination indicators used in vibration analysis of boat hulls is used in this application too. The analogy of the prosthesis, cement, bone structure as a laminated structure will be of value to this PhD when further investigating techniques used to detect damage in structures as there is more knowledge on laminated structures and their reactions to non-destructive testing methods than orthopaedic materials and through utilising the analogy between the two predictions of loosening prosthetic behaviour can be better predicted.

**VIBROMETRY: FINITE ELEMENT ANALYSIS**

Several finite element analysis studies have been carried out to model these experimental situations; their results are in agreement with the experimental studies \cite{183, 229, 231, 236}. Pastrav et al carried out one such finite element study aimed to confirm and quantify the hypothesis that increased implant stability results in a rise in resonance frequency \cite{229}. Pastrav created various contact situations by using the contact tolerance
options in the finite element software (Magics® and Mimics®). The study proceeded to perform a modal analysis for each of these contact situations, varying the percentage of implant in contact with bone and positioning of this contact. The models confirmed, what had been previously been found in experimental studies; that a positive shift in resonance frequency is caused by increased contact between the bone and implant. The study also concluded that this dynamic behaviour is most influenced in proximal zone of the implant. Perhaps this is because the proximal zone contains the thicker part of the implant stem, meaning that a larger proportion of the stems surface area in contact with the bone is within the proximal range. The effect of contact percentage on frequency shift is shown in Figure 2.18.

![Figure 2.18 Frequency shift for different contact levels and modes](image)

**Figure 2.18 Frequency shift for different contact levels and modes [229].**

**VIBROMETRY WITH INTERNAL ACCELEROMETERS**

Early attempts to create implants capable of monitoring loosening were limited in their performance due to the low signal noise ratio of the MEMS accelerometers that existed at the time [237]. However, in 2000 Puers et al published the first paper that described the development of a telemetric hip implant containing an accelerometer [238]. A system diagram demonstrating the operation of the implant is shown in Figure 2.19. The implant contains a capacitive accelerometer and is powered inductively. It is not designed to take continual measurements but instead works similarly to the vibrometry techniques described in the previous section: a ‘shaker’ is placed externally on the patient’s knee and creates vibrations along the bone which, unlike the vibrometry is sensed on the *internally* implanted accelerometer.
The results from this study agreed with those found in Georgiou et al paper [184] (outlined above) in that a secure implant simply shows the harmonic output matching that of the input, but the a loosened implant will show signs of multiple harmonics. This can be seen in figure 2.20, which is a results graph taken from Puers et al.’s study showing the difference in non-distorted sine waves produced by secure implants and distorted ones from loosened implants.

Figure 2.19 Systematic diagram of the workings of the Implant described by Puers [238]

Figure 2.20 Results of cadaver experiment [238]) measured response of a remur-prosthesis system with a fixed prosthesis b) measured response of a femur-prosthesis system with a loose prosthesis, resulting in a distorted sine wave. The excitation frequency is 150Hz.
Embedding the accelerometer within the implant, as opposed to on the surface of the skin at the hip, eliminates the error that could otherwise be created by the damping effects of the subcutis. However, excitation of the internal accelerometer is still performed through the use of an external 'shaker' and as such there will still be error associated with the soft tissue interfering with the vibrations as they pass up the leg towards the implant. Removing the need for an external shaker/vibrator would be the logical next step in the development of an instrumented knee replacement and is what this PhD aims to investigate further.

In 2009 a research group based in Germany further developed this implant design [185]. This group included on-board processing of the data through the use of a lock in amplifier\(^1\) whose amplification was used to provide the oscillation amplitude, reducing the need for the full set of measurements to be transmitted and hence reducing transmission time and energy consumption. The implant was tested first on a bare femur (stripped of all soft tissue) and then an artificial thigh. In order to gain vibration information from the femur an external 'shaker' is applied to the knee at the inner femur condyle. This excites the implant creating vibrations which are read by the internal accelerometer and transmitted to a receiver also situated with the shaker on the knee. The paper also includes detailed information on a mechanical model of the femur bone interface. The study found that additional peak resonances were observed in the proximally loose implants and are slightly better distinguishable in the y (anterior-posterior) direction than the x (lateral-medial) direction.

\[ B(t) = B_x \cdot \sin(\omega t + \varphi) \]

Figure 2.21 System concept for prosthesis excitation and wireless vibration measurement [185].

\(^{1}\) A lock in amplifier is capable of extracting a single signal from an extremely noisy environment.
OTHER VIBRATION TECHNIQUES

A slightly different approach to vibrometry is presented in [186]. This paper describes a method of placing a small oscillator within the stem of a hip implant. The oscillator consists of a spherical permanent magnetic body mounted on a flat spring as shown in Figure 2.22 (taken from the paper). The theory is that an external magnetic field is opposed upon the oscillator, causing it to oscillate and collide with the stem membrane. This collision will be governed by conservation of momentum laws and the velocity at which it oscillates after collision will depend on the membrane tissue interface. Providing these changes in velocity can be detected externally then the state of the implant can be determined. Preliminary tests have been carried out on an over dimensioned experiment rig and initial results have led the group to conclude that the method should be able to 'provide distinct information about the implant loosening at various stages'. However, the methods used to replicate different fixation types by the over dimensioned rig can be argued to be over simplified. Loosening layers made from different thicknesses of gelatine were added between the artificial bone and membrane in order to represent early loosening (3mm) and extensive osteolysis (10mm). In an effort to replicate more closely the boundary layer between bone and implant a water filled pad was included to investigate the influence of higher fluid proportion. The study has produced evidence that the small oscillator within the stem of a hip implant is capable of distinguishing between different thicknesses of gelatine membranes. In order to specify with more confidence that this is feasible way of monitoring loosening within an orthopaedic implant the authors will investigate further more clinically relevant loosening replications.

Figure 2.22 Location of internal oscillator in hip implant stem [186]
INSTRUMENTED IMPLANT DISCUSSION

The literature discussed here shows that initial steps into the development of a self-diagnosing hip implant are well underway, however these early designs still have their problems associated with them. The main concern of these implants is the need for an external shaker. This creates issues relating to soft tissue interference and although some implant designs have moved on to integrate accelerometers into the implant itself, this creates the additional problem of a need for power to be supplied within the implant. The external shaker also adds complexity to taking readings from the implant and determining loosening. A trained personal is likely to be required to apply vibrations in the correct manner that reduces soft tissue interference and provides the best readings. A truly passive sensor on the other hand would simply require data to be read out from the implant without the need for an external input.

It is the aim of this project to learn from these early designs and create a system to allow the loosening of a TKA to be detected firstly without the use of an external shaker and inbuilt power supply and secondly have a way to methodically test for loosening, in a safe and non-invasive way and that does not expose the patient to radiation.

It seems apparent that in order to overcome these problems a ‘self-diagnosing’ implant is required. That is, an implant that is able to monitor its own state and alert doctors of when loosening occurs before it becomes a problem for the patient. There is little evidence in literature of these types of implants existing and those which do monitor the forces exerted upon the implants as opposed to the detecting loosening [176, 185, 237-239]. The next two sections will focus on how these implants are powered and how they transmit data in the order to understand the different techniques that may be applicable to this project.

2.3.3 SUPPLYING POWER TO IMPLANTS

The majority of instrumented joint implants are powered using magnetic coil induction [238, 240-246], and there are also a few examples where energy is harvested from the deformation of the piezoelectric materials that are being used as force sensors [175, 247]. However, despite this small variation in power supplies for implants research is currently being undertaken into how energy can be harvested from the human body that could be used to power implants or skin mounted body systems [175, 247-257]. This section will look at the power techniques currently being used in instrumented implants as well as other possible sources of energy.
MAGNETIC COIL INDUCTION

Many medical implants [240-242, 246], including smart knee designs [243, 244] use magnetic coil induction. As with all the possible power sources addressed in this section, magnetic coil induction has two major advantages: firstly it requires no wires to pass through the patient’s body hence decreasing the risk of infection. Secondly it does not require the implantation of batteries that may need to be replaced with further surgery increasing risk and discomfort to the patient. Another advantage of such a system for power supply is that the receiving coil can double as an antenna and therefore ensure a more compact design [243].

The main disadvantage of this type of power induction is the impracticality it causes by its need for an external coil which must be worn, if not all the time, at least periodically, in order to charge the implant. The efficiency of this system is also low and the coils can only transmit charge over very small distances.

PIEZOELECTRIC ENERGY HARVESTING

The use of piezoelectric materials as a possible power source for implants, is another popular power supply choice, particularly within orthopaedic implants where there is likely to be compression of at least one part of the implant.

A lot of the current smart knees are designed to measure forces [175, 240-245, 258, 259] and as such, many already contain materials such as peizoceramics in order to sense the external forces being placed on the knee. The idea is that the small voltage these materials produce can not only be measured in order to determine the forces within the knee but could also be used to provide power to the telemetry device. This is what has been done in the smart knee design by Almouahed et al who published a paper on self-powered instrumented knee implants[175]. Almouahed and his team used OrCAD/PSpice to create a model that could quantify, during an entire gait cycle, the electrical energy produced by the four piezoceramic sensor within the implanted tibial plate. The results from this model were compared with experimental results. The paper concluded that the 4 sensors were able to produce a mean power output of 1.81mW for a load resistance of 35kohms during a single gate cycle, which is approximately 100th of the power required for an LED TV in sleep mode. Increased amounts of power could be harvested with larger peizoceramics; however, the size of such ceramics is limited in the application of orthopaedic implants.
Another approach when using piezoelectric materials to power implants is, instead of using the compression created within in joints, is to use the tension produced by muscles within the body. In 2009 a paper by Lewandowski et al was published which demonstrated this theory in vivo in rabbit quadriceps [251]. The theory is to surgically place piezoelectric material between the tendon and where it attaches to the bone. Then as the muscle is stimulated and contracts it stretches the piezoelectric material. In this case maximum muscle force, and therefore maximum power production, is dependent on the size of the muscle and the frequency of stimulation. However there is of course a trade of between these parameters and muscle fatigue. In Lawandowski’s study a mechanical muscle analogue test bed was used to test the possible power outcome of using such a method. The results showed power generation in the magnitude of a couple of µW, with increased muscle force (up to 50N) producing the largest power output of approximately 2.5uW. When Lawandowski tested the generator in vivo in rabbits quadriceps comparable results were produced [251]. The conclusion of the Lawandowski study was that mechanical power from muscle contractions is able to be converted to electrical power in excess of that needed to stimulate the motor nerve of the muscle. It is therefore possible that an implantable stimulated-muscle-powered generator system would have the potential to be a power source for implanted electronic medical devices.

In the case of using a method like Lawandowski for a total knee implant aimed at detecting implant loosening there are indications that this would be feasible, with the knees proximity to one of the largest muscles in the human body (the quadriceps) there is a good chance of high power production, however, transferring the harvested energy from the muscle, which is external to the implant, into the implant may create extra complications and, in addition to this, the surgical procedure of inserting the piezoelectric material between bone and tendon would cause extra complications for the patient.

THERMAL

The method of harvesting energy from the heat produced by the body has been used in commercial devices such as the ‘Thermic’ wrist watch developed by Seiko. This watch demonstrates the viability of such energy harvesting. Research into electronics powered by human body heat mainly focuses on wearable devices as opposed to implantable devices[250]. In 2006 Torfs et al demonstrated the practicality of this theory by creating a working pulse oximeter powered solely through harvesting, via a compact wrist band, the thermal energy produced by the human wearer[260]. The harvesting device had a minimal power production of approximately 100uW during the night and in the day the power ranged
from 100μW-600μW. However, standard battery powered pulse oximeters generally consume above 10mW of power[260] and hence the electronic components had to be modified in order to decrease the power consumption.

Other wearable devices powered by body heat include: a body powered ECG head band and EEG wireless system. There is also evidence of this technology being used to power devices embedded within clothing, such as a Wireless ECG shirt[260].

These applications of human body heat energy harvesting show that the technology is capable of producing power of a suitable level for powering small devices. However, if these devices are to be implanted within the body their size will have to be greatly reduced, but this is not the main problem preventing this type of power harvesting from moving from outside the body to inside. The main problem is that in order to harvest energy from heat a thermal gradient must be present. Devices worn on the body surface use the thermal gradient between the heat produced by the body and the ambient temperature in the surrounding environment. Inside the body there is not this thermal gradient and therefore, this type of harvesting is probably not appropriate for the application of this project.

**BODY MOTION**

There are many situations in energy production where energy is harvested from kinematic motion. This type of harvesting is present in large scale energy production, for example, hydraulic power and wind power, and on a smaller scale, in dynamo bicycle lights. It makes sense then, that since the limbs of the body are able to move in dynamic ways, and often in rhythmic cycles such as during walking, that this movement could be harvested into electrical energy.

Early examples of harvesting energy from human movement include a backpack containing an amplified piezoelectric stack which generated energy from the dipping and rising motion that naturally occurs when someone is[261]. Further to this a leg brace is in development which harvests energy from the flexion and extension of the knee during walking (Maxwell ref). The brace is specifically designed to harvest energy when the muscles of the leg are ‘braking’ the leg during its swing forward motion in walking hence not requiring any extra effort from the user.

There is a clear concern with the application of the above methods in regards to implantable devices. The methods mentioned above are relatively large in size and must be fixed externally to the body. This would still require the energy they produced to be
transferred into the body to the implanted device, most likely therefore requiring wire to pass through the subject’s skin increasing risk of infection. It is for these reasons that this type of energy harvesting would not be appropriate for this project, however, a similar form of harvesting that also uses movement, but this time in the form of vibration may be able to be embedded within the human body and is therefore discussed in the next sub heading.

**VIBRATION AND INERTIAL ENERGY**

Vibration energy harvesting is already being used in many industrial situations. Large mechanical machines naturally produce a large amount of vibration. Originally seen as wasted energy and decreasing the efficiency of such machines, these vibrations are now being harvested back into electrical energy that can once again be used to help power the machine itself or other power rich devices [262]. The vibrations in these situations are usually of high frequency and low amplitude and able to harvest tens of mV.

There are several issues that make harvesting energy from body vibration much more difficult than harvesting from machine vibrations. The main one being size constraint, in order to create a viable energy harvester for use with implants the harvesting device needs to be small, ideally no more than 1cm³. Other issues are that human motions occur at much lower frequencies and are much more irregular [263].

A double permanent magnet vibration power generator is being specifically developed for the field of smart orthopaedic devices [239]. It consists simply of two power generators that can be connected either in series or parallel to produce maximum voltage or current respectively. A 2 dimensional representation of the generator is shown in figure 2.23. The theory is that as the patient walks, the magnet will move in a vertical direction passing through each of the two coils, creating a voltage through electromagnetic induction. The difficulty in this technique arises in the processing and conditioning of the voltage and requires extra circuitry to produce a steady output of power. The authors of this double magnet generator study have managed to refine the circuitry and produce 1912.5uJ of useable energy.
ULTRASOUND

Power by ultrasound is an extension of strain power; it harvests energy from piezoelectric materials. However, instead of these materials being deformed though compression of the joint, as described in the section on piezoelectric harvesting; they are deformed by externally applied ultrasonic waves, which travel harmlessly through human tissue. Power through ultrasound was proposed as early as 1958 by Rosen[264] and has been applied both in and outside the field of medical devices. It is used to power device embedded sensors within metals[265], fuel tanks and satellites[266].

Many papers have published on the validity of using ultrasound as a power source for in vivo medical devices. Ozeri et al developed a device that was capable of transferring power at an efficiency of 27% at 70mW output power to an implant imbedded up to 40mm subcutaneously [267]. Arra et al found similar levels of efficiency [268], performing tests in degassed water with efficiencies of 21-35% at distances between 5mm and 105mm.

The efficiency of acoustic power is comparable with electromagnetic coupling. Denisov et al found that at small separation distances (10mm) induction power had a higher efficiency (efficiency 81% vs 39%) [269]. However, at 100mm separation the ultrasonic
systems were found to be more efficient (0.2% vs 0.013%). These efficiencies were calculated through modelling with a receiver of 10mm diameter.

Although the efficiencies of the two techniques may be said to be comparable there are certain advantages of using ultrasound over electromagnetic induction. Firstly electromagnetic induction in medical applications often has a very low coupling value (approximately 0.1) [269]. This means, not only may the coupling coils interfere with nearby devices, e.g. pacemakers, the coil may also pick up external electromagnetic radiation from MRIs or large ferromagnetic structures such as steel doors. Other disadvantages of electromagnetic induction which are not found in ultrasonic power are the possible overheating of the primary coil due to the high currents that must travel through it and the need for the induction coils to be orientated correctly[269].

POWER SUMMARY/DISCUSSION

Table 2.2 represents the advantages and disadvantages of the different techniques that could be used to power implants. Power is a one of the major restrictive parameters involved in designing instrumented implants, as is shown by the large range of literature and studies that have focused on the design of power harvesters for use with in the body. Table 2.3 summarises the power harvesting work carried out on knees alone. Ideally, if power consumption can be reduced as much as possible, the constraint of power is simplified and the whole process of imbedding sensors becomes that much easier. This PhD aims to remove the need for power completely by focusing on the use of passive sensors. The next chapter discusses possible sensor types and explains why impedance analysis from piezoelectric sensors was chosen for this project.
### Table 2.2 Comparison of different techniques with the potential to supply power to implanted medical devices.

<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery</td>
<td>• Been implemented in implants before</td>
<td>• Would need replacing/charging</td>
</tr>
<tr>
<td></td>
<td>• Very simple</td>
<td>• external coil is cumbersome</td>
</tr>
<tr>
<td>Magnetic Coil</td>
<td>• Been implemented in implants before</td>
<td>• Interference with nearby devices</td>
</tr>
<tr>
<td>Induction</td>
<td></td>
<td>• potential over heating (due to large currents)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• need for correct coil orientation</td>
</tr>
<tr>
<td>Piezoelectric</td>
<td>• Been implemented in implants before</td>
<td>• complicated</td>
</tr>
<tr>
<td></td>
<td>• Energy harvesting</td>
<td>• low power</td>
</tr>
<tr>
<td>Thermal</td>
<td>• Energy harvesting</td>
<td>• Lack of thermal gradient within body</td>
</tr>
<tr>
<td>Body motion</td>
<td>• Energy harvesting</td>
<td>• Too large to be implantable</td>
</tr>
<tr>
<td>Vibration &amp; inertial</td>
<td>• Energy harvesting</td>
<td>• complicated</td>
</tr>
<tr>
<td>energy</td>
<td>• There will be vibration &amp; inertial energy in the knee</td>
<td>• low power production</td>
</tr>
<tr>
<td></td>
<td>• Been implemented in implants</td>
<td></td>
</tr>
<tr>
<td>Ultrasound</td>
<td>• greater efficiency over larger distances</td>
<td>• lower near field efficiency than magnetic coil induction</td>
</tr>
</tbody>
</table>

Chapter 2: Review of Current Diagnosis Tools for Implant Loosening
<table>
<thead>
<tr>
<th>Type of harvester</th>
<th>Article</th>
<th>Article Type</th>
<th>Material characteristics for biocompatibility</th>
<th>Test Condition</th>
<th>Harvester Volume</th>
<th>Output energy power</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Platt</td>
<td>2005[247]</td>
<td>PZT ceramic</td>
<td>Laboratory International Standard (ISO 14243-3)</td>
<td>1.2cm³ (1 piezo)</td>
<td>4.8mW (3 piezos)</td>
<td>Unpackaged</td>
</tr>
<tr>
<td></td>
<td>Chen</td>
<td>2010[270]</td>
<td>PZT ceramic</td>
<td>Laboratory International Standard (ISO 14243-3)</td>
<td>0.45cm³</td>
<td>1.2mW</td>
<td>Unpackaged</td>
</tr>
<tr>
<td></td>
<td>Almouahed</td>
<td>2011[271]</td>
<td>PZT ceramic</td>
<td>Laboratory International Standard (ISO 14243-3)</td>
<td>0.4cm³ (1 piezo)</td>
<td>7.2mW (4 piezos)</td>
<td>Unpackaged</td>
</tr>
<tr>
<td>Electromagnetic harvesters</td>
<td>Luciano</td>
<td>2014[272]</td>
<td>NdFeB-copper-ferrite</td>
<td>Laboratory robotic gait device</td>
<td>3.9cm³</td>
<td>70uJ &amp; 56uW (each step)</td>
<td>Non resonant kinetic generator; gait frequency of 1.0Hz</td>
</tr>
<tr>
<td></td>
<td>Romero</td>
<td>2009[273]</td>
<td>NdFeB-copper</td>
<td>Laboratory normal human gait</td>
<td>1.5cm³</td>
<td>3uW</td>
<td>Mechanical resonant frequencies at 2.8Hz and sub-harmonics at 1.5 and 1Hz</td>
</tr>
</tbody>
</table>

Table 2.3 Summary of literature on power harvesters used in knee replacements.  
(Adapted from[274])
2.4 IMPEDANCE BASED HEALTH MONITORING

Introduced and described in this section are the main principles behind non-destructive testing (NDT) of materials. There is a huge field of research into the non-destructive testing of engineering structures such as bridges, railroads and aeroplanes. The principle behind NDT is to detect damage in a structure without causing further damage to said structure. It is exactly this principle that is required to achieve the aims of this PhD in monitoring loosening within a knee implant; the implant needs to be monitored without being destroyed and without the knee being damaged. The type of NDT specifically used in this thesis is impedance analysis. This section introduces the theory behind this technique; it begins with simple explanation of the piezoelectric effect and goes on to look at its application in non-destructive testing, drawing examples of its use from various scientific journals. Throughout this section reference will be made to how impedance analysis will be applied to the problem of TKA loosening.

2.4.1 NON-DESTRUCTIVE TESTING

Table 2.4 summarizes common NDT techniques, with a brief description of how they work and their advantages and disadvantages. Information from the table is used here to discuss the feasibility of each techniques use in the issue of TKA loosening.

Acoustic emission analysis is inappropriate for the application of TKA implant monitoring since it is a dynamic process. This means that the sensor must be active at the exact time a defect between bone and implant occurs and hence, must always be active if it is too detect faults. This would cause high energy requirements in order to ensure the sensor was continuously turned on. A further disadvantage of this technique in the application of implants is that it requires loading to be high enough to cause an acoustic event.

Although eddy current inspection has certain advantages that would lend it to monitoring implant health, such as its ability to monitor parts without the need of the probe to be in contact with said part and its ability to detect small defects in complex structure shapes and sizes. However, it requires the material it is monitoring to be conductive and although the probe does not need to be in direct contact with the material, the penetration range of the probe is limited and in the case of monitoring a knee replacement it would be required to penetrate through varying thicknesses of soft tissue. Most importantly, eddy current analysis is unable to detect flaws parallel to the coil and since flaws between an implant and bone can occur in any direction this would limit a sensor's detection ability.
Magnetic particle testing is clearly unsuitable for the application of smart implants as it requires the material under interrogation to be made from a ferromagnetic material and it can only detect surface cracks.

Ultrasonic and vibration testing has been used previously in smart implants and have been discussed in section 4.2 of this chapter. Impedance analysis has not yet been fully investigated in its application to implant loosening detection and, since it has advantages relating to the requirements of an orthopaedic implant sensor system, this is the technique that will be investigated in this PhD. Features of impedance analysis that lends the technique to orthopaedic implant applications are outlined in section 5.6 of this chapter.
<table>
<thead>
<tr>
<th>Technique</th>
<th>Description</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| Acoustic emission       | When a material fails due to a mechanical or thermal stress and flaws or cracks are created, these produce sonic or ultrasonic wave emissions. Acoustic sensors convert these mechanical waves to electrical signals. | - Versatile (applications are numerous)  
- Highly sensitive (can pick up motions in order of picometers)  
- Passive (‘listens’ for energy being released from defects, energy does not need to be added to the system) | - Dynamic process- only detects faults as they occur  
- Loading must be high enough to cause an acoustic event  
- Only provides qualitative data  
- Noise-signal discrimination and reduction are crucial |
| Eddy Current Inspection | Uses the principle of electromagnetic induction. An expanding and collapsing magnetic field is created by passing an alternating current through a wire coil. Placing this coil close to an electrical inductor induces eddy currents. Changes in the electrical inductor material, such as a defect. Alters the eddy currents which in turn alter the alternating current in the coil. | - Immediate results  
- Very portable equipment  
- Test probe does not need to be in contact with the part.  
- Can inspect complex shapes and sizes  
- Sensitive to small defects | - Material must be conductive  
- High skill and training required  
- Penetration depth is limited  
- Delamination and similar flaws that are parallel to the coil are undetectable. |
| Impedance Analysis      | Surface mounted piezoelectric sensors excite, at a high frequency, the material under interrogation. Simultaneously the sensors detect changes in the mechanical impedance of the structure. | - Small sensors enable monitoring of inaccessible locations  
- Very high sensitivity to minor changes in host material  
- Data can be easily interpreted  
- On-line monitoring is possible  
- Very low power requirements  
- Independent of material type. | - Difficulty in modelling complex geometry behaviour  
- Experimental investigations often need to be performed to find optimal parameters. |
| Magnetic Particle Testing| A crack in a magnetised material, creates a flux leakage. If magnetic particles are placed onto the material they will be attracted to the flux leakage field. This cluster can then be visually seen as an indication of damage. | - Fast and relatively easy to apply | - Material must be made from ferromagnetic material  
- Surface cracks only  
- Requires access to the surface of the material |
| Ultrasonic testing      | A surface pulser emits high frequency ultrasonic energy into the material sound waves travel through the material and are reflected back to a receiver when they collide with a discontinuity / | - Accurate quantitative measurements (information on size, location, material characterization)  
- Instantaneous results  
- Creation of detailed images  
- Only requires access to one side of structure under investigation | - Difficult to apply to rough, irregular shaped, very small or not homogenous materials  
- Reference standards are required for calibration and flaw characterization.  
- High level of skill and training  
- Requires accessible surface |
| Vibration Analysis      | Monitors the vibration signature of a structure using either, displacement sensors, velocity sensors or accelerometers. | - Can be cooperated into portable systems that can be permanently mounted to machines | - Data recording must be compared over time |

Table 2.4 Summary of non-destructive testing techniques (adapted from [275])
2.4.2 PIEZOELECTRIC MATERIALS

THE PIEZOELECTRIC EFFECT

Piezoelectric materials are defined as those materials that become either electrically polarized when subjected to a mechanical strain, or become deformed when exposed to an electric field. These effects are known as the piezoelectric and inverse piezoelectric effect respectively. Figure 2.24 shows the piezoelectric effect in diagrammatic form.

![Diagram of piezoelectric effect](image)

Figure 2.24 Representation of piezoelectric and inverse piezoelectric effect. a) Piezoelectric material in neutral position. b) Direct piezoelectric effect; applied force induces polarization of the sensor. c) Inverse piezoelectric effect; applied electric field results in deformation of the material.

PIEZOELECTRIC MATERIAL STRUCTURE

Many naturally occurring crystals exhibit the piezoelectric effect such as, quartz, tourmaline and sodium potassium tartrate [276], however, it is piezoelectric ceramic that will be used throughout this study, and as such these will be the focus of this section. The most commonly used piezoceramic in impedance based health monitoring are lead zirconate titanate (PZT), due to their high actuation ability [277]. The molecular structure, and hence the properties of PZT, are dependent on temperature. With all PZTs a threshold temperature, known as the Curie point, exists. Above this temperature the PZT takes on a symmetric form with no dipoles but, below the curie point, the structure of the PZT becomes
tetragonal symmetric and it is this that allows the materials electric dipoles to be manipulated by an electric field leading to the piezoelectric effect[278].

**Piezoelectric Constants**

By definition, piezoelectric materials are anisotropic, meaning their physical constants are related to the direction of applied force and the related perpendicular force. The standard naming configuration for the forces are shown in figure 2.25

![Piezoelectric Constants Diagram](image)

Figure 2.25 Standard naming configurations for forces[279]
### Table 2.5 Summary of piezoelectric constants

<table>
<thead>
<tr>
<th>Constant</th>
<th>Definition</th>
<th>Symbol</th>
<th>Subscript 1 (Direction of...)</th>
<th>Subscript 2 (Direction of...)</th>
<th>Superscript (Constant...)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permittivity</strong></td>
<td>dielectric displacement per unit electric field</td>
<td>$\varepsilon_{11}^T$</td>
<td>Dielectric displacement</td>
<td>Electric field</td>
<td>Stress</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$\varepsilon_{33}^S$</td>
<td>Dielectric displacement</td>
<td>Electric field</td>
<td>Stain</td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
<td>Strain produced per unit stress</td>
<td>$S_{11}^F$</td>
<td>Strain</td>
<td>Stress</td>
<td>Electric Field</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$S_{36}^D$</td>
<td>Strain</td>
<td>Stress</td>
<td>Electric Displacement</td>
</tr>
<tr>
<td><strong>Piezoelectric charge constant</strong></td>
<td>Electric polarization generated per unit mechanical stress applied.</td>
<td>$d_{33}$</td>
<td>Induced polarization</td>
<td>Applied stress</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$d_{31}$</td>
<td>Induced polarization</td>
<td>Applied stress</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Piezoelectric Voltage Constant</strong></td>
<td>Electric field generated per unit mechanical stress applied.</td>
<td>$g_{31}$</td>
<td>Induced electric field</td>
<td>Applied unit stress</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$g_{15}$</td>
<td>Induced electric field</td>
<td>Applied unit stress</td>
<td>N/A</td>
</tr>
</tbody>
</table>

#### 2.4.3 Impedance Analysis

Impedance analysis has been used in the area of structural health monitoring for over 20 years, with its first proposed by Liang et al. [280]. The technique utilises both the inverse and direct piezoelectric effect to investigate the otherwise difficult to obtain structural mechanical impedance changes in healthy and damaged structures. The generalised method for impedance analysis is to surface mount a small piezoelectric sensor to a host structure, that is, the structure under interrogation. The sensor excites the host structure at a
high frequency and, in turn, is able to simultaneously detect changes in impedance signature [281]. There are two approaches that are used to achieve piezoelectric self-sensing actuation. Traditionally a bridge circuit [282] is used to compare the output of the sensor signal to the input signal. In this situation the PZT is assumed to be equivalent to and as such is modelled as pure capacitor. The bridge circuit then works by cancelling out the original input signal from the PZT signal which will have been changed due to its induced vibration of the structure adding voltage to the sensor. The limitation of this traditional method is that the high voltage required means that temperature changes can affect the capacitance of the PZT and that the input and output signal can be easily mixed[283]. A simplified method has since been developed where the current of the sensor is measured. The current across the PZT is modulated by the vibrational response of the host structure. Through monitoring this current the electric impedance of the sensor is obtained. This approach simplifies the analysis and does not require a bridge circuit[284].

High frequency excitation means small wavelengths leading to greater sensitivity of the sensors and also a very low voltage requirement [285]. Small wavelengths result in high sensitivity as scientific consensus is that in any wave related defect detection techniques, such as ultrasound or in this case, piezoelectric impedance analysis, a discontinuity must be larger than one half the wavelength in order to be detected[286]. Figure 2.26 and 2.27 represent this in quantitative terms, where figure 2.26 represents the theory of impedance analysis as a whole and figure 2.27 represents an electromechanical model of the process.
Chapter 2: Review of Current Diagnosis Tools for Implant Loosening

Figure 2.26 diagrammatic representation of impedance based structural health monitoring

Figure 2.27 Electrical equivalent circuit of piezoelectric sensor adapted from[287]

**IMPEDANCE ANALYSIS PARAMETERS**

**FREQUENCY RANGE**

The frequency range under which a piezoelectric sensor is interrogated is closely related to its sensitivity. In order to sense the initial stages of damage, the wavelength of excitation must be smaller than the characteristic length of damage [288] and hence frequencies are often in range 30KHz-250KHz [285]. Traditionally a trial and error method is used to determine the most sensitive frequency range and little analytical work has been done to investigate vibration modes of complex structures at such frequencies[289]. A preferable feature of the chosen frequency range is one that has multiple peaks in the
impedance trace. Multiple peaks indicate more modes of vibration between the sensor and host material [281]. Within a frequency range there will be two types of peaks, one related to the structures resonance and the other to the PZT sensors. The PZT resonance peak in lightweight structures is much greater than the structures resonance peak and hence frequency ranges including the PZT resonance frequency should be avoided in lightweight structures [281].

**SENSING REGION**

The high frequency ranges used in impedance analysis limit the PZT sensing range to a localised area [281]. This can be advantageous as it means the sensor is less sensitive to boundary condition variations or operational vibrations. Wave propagation theory has been used to numerically model a piezoelectric sensor’s sensing range [290]. Sensing range is related to the host structures material properties, geometry and the excitation frequency and properties of the piezoelectric sensor and are best found through experimental investigation [281].

**ADVANTAGES OF IMPEDANCE ANALYSIS IN STRUCTURAL HEALTH MONITORING**

Impedance analysis using piezoelectric sensors has multiple advantages over other non-destructive evaluation techniques such as ultrasonic, acoustic emission, impact echo. These advantages include:

- Not based on any model therefore application to complex structures is performed with more ease.
- Small non-intrusive actuators enable monitoring of inaccessible locations.
- The sensor itself has:
  - A large range of linearity
  - Fast response,
  - High conversion efficiency
  - Long term stability.
- Very high sensitive to local minor changes. (due to high frequencies)
- Measured data can be easily interpreted.
- On-line health monitoring is possible.
- Very low power requirements (microwatts)
APPLICATION OF IMPEDANCE ANALYSIS

Impedance analysis has been used to monitor a large range of structures, from simple truss structures [291], to airplane tail sections [284], to gears [292]. The results of these studies all demonstrate a piezoelectric sensors ability to detect damage. Studies show results as frequency vs impedance (or admittance) graphs, from which damage can be qualitatively demonstrated [292]. In order to translate these descriptive measurements of damage into quantitative results several different signal analysis methods are used, these are described and explained in chapter 3.

One application area where impedance analysis is highly utilised is in the monitoring of pipelines. These often convey essential necessities for economic and community recovery after natural disasters, and at the same time are highly likely to be damaged in such disasters, particularly earthquakes, which can cause shaking and landslides [293]. Impedance analysis is suited to this task as it is able to immediately detect and locate damage. Park et al carried out a study on a model section of pipeline with junctions bolted together[294]. Damage was induced through the loosening of bolts. Figure 2.28 shows the results of the total impedance frequency trances taken from piezoelectric sensors surface mounted onto the pipe model. The figure demonstrates the qualitative changes that occur as more bolts are progressively loosened. The graphs show the undamaged impedance trance in black and damaged traces in pink. Larger peaks appear in traces c) and d) when 6 and 8 bolts are loosened respectively. This progressive change in the impedance-frequency trace indicates that peak impedance is a potential feature that could be used when applying impedance analysis to the monitoring of implant loosening. In Park et al.’s study the frequency impedance traces are converted to a single qualitative damage measurement value through the use of root mean square deviation, RMSD (see section 3.2 of chapter 3).
Figure 2.28 The electrical impedance measurements of PZTs. The variation in impedance is increased as the level of damage is increased. A) 2 bolts loosened b) 4 bolts loosened c) 6 bolts loosened d) 8 bolts loosened[294].

An obvious possible obstacle in implementing piezoelectric impedance analysis into a TKA is the ever changing boundary conditions the implant will be under. Loading on the implant will change and vary as the patient performs tasks of daily living such as walking, and stair climbing. However, a study by Park et al [295] investigated the effects of external loading on the frequency-impedance outcome from sensors on a ¼ scale bridge model. In this study Park showed that the impedance method was able to detect between this external changes in boundary conditions and incipient damage to the bridge model[295]. Damage was inflicted on the structure through the loosening of three specific bolts. Boundary conditions were varied through creating vibrations throughout the structure by manually hammering the structure and through adding a 15kg load to the structure. Readings were first taken as these boundary conditions were varied and then bolts were loosened. Results showed that the damage matrix for the two piezoelectric sensors showed all but two vibration and loading changes created damage matrices of less than ten. Whereas the damage matrices of the sensors close to the relevant loosened bolt had value over 65. This substantial difference is indicative that damage can be distinguished from external factors.

The ambient temperature should stay relatively consistent at body temperature and so will not affect the impedance of the piezoelectric sensor; however, infection would increase
the ambient temperature and may have an effect on impedance trace[296]. Instead of this being an obstacle it could be beneficial if the sensors can not only pick up on loosening but also be able to show when a temperature increase has occurred; hence alerting clinician to possible infection.

Many studies have assessed the behaviour of piezoelectric sensors under varying temperatures and what effect this may have on the sensors frequency-impedance trace [296-298]. The graph in figure 2.29 is taken from [298] and is a good representation of what happens to a piezoelectric sensor’s resonance frequencies when temperature is in increased. As temperature is increased the resonance decreases. This is shown by the left shift of the impedance trace in figure 2.29.

Providing this shift can be isolated from other changes in the impedance frequency trace, it could potentially be possible to not only diagnose loosening but also whether the loosening is aseptic or septic.

![Figure 2.29 Variations in the amplitude and frequency shifts in real part of the electrical impedance resulting from temperature changes [298]](image)

### 2.5 SUMMARY AND MOTIVATION FOR TKA MONITORING IMPROVEMENTS

During the last couple of decades there has been an increasing amount of research into the development of instrumented orthopaedic joint implants. Predominantly this research has focused on the development of implants that are capable of measuring the forces within the knee[175, 243-245, 259] and the hip [246, 258]. However, literature shows that a large majority of total knee replacement failures that call for revision are due to the loosening of
the implant; the National Joint Registry reports 32% of values are due to aseptic loosening [1].

There are also an increasing number of joint replacement surgeries being carried in younger patients [299]. These patients typically have greater levels of activity, increasing the likelihood of implant loosening [82]. Although a lot of research is ongoing into how this type of failure can be reduced, there are currently no known implants that are able to measure when, and by how much, an in vivo implant is loosening. This knowledge would be of great benefit to both patients and health care professionals in allowing doctors to intervene before a loosened implant begins to cause pain to the patient. Proposed in this thesis is a sensor that could be embedded within an implant that is able to passively detect loosening. This could potentially provide valuable information on when loosening occurs, the patients in which it occurs, and the risk factors involved, therefore aiding in the design of more successful implants in the future.
3 PIEZOELECTRIC MODELLING AND CLASSIFICATION METHODS

The previous chapter reviewed literature on TKAs, their failures, current diagnostic techniques in detecting loosening of TKAs and finally proposed the application of impedance based health monitoring to the creation of instrumented TKAs capable of detecting loosening between bone and implant. This chapter investigates different modelling techniques used in impedance health monitoring and how data taken from such sensors can be analysed to determine the difference between healthy and unhealthy structures.

3.1 MODELLING PIEZOELECTRIC BEHAVIOUR

The large number of parameters involved in the analysis of a piezoelectric elements response has lead to simplified models with the benefit of being efficient and easy to implement however, their simplicity can produce less accurate results [300]. On the other hand, unintuitive complicated models produce better predictions of behaviour but require deep understanding of the piezoelectric material and large amounts of computer power.

Attempts have been made to model the use of piezoelectric materials in impedance analysis in multiple ways. These range from more simple one dimensional numerical models[301] to more complex finite element models[302]. Sensors and their interaction with host materials are most commonly modelled as electrical equivalent circuits[277]. Electrical equivalent circuits are possible by converting the mechanical components into equivalent electrical components, see table 3.1. The advantages of these equivalent circuits are that it is possible to develop them solely from measured impedance values of the PZT, that is to say no information about the host material is required.

The following two sections introduce some of the available models of piezoelectric ceramics which are based on electrical equivalent circuits. These are grouped into models that consider unloaded and loaded ceramics.
### Table 3.1 Mechanical analogous of electrical components

<table>
<thead>
<tr>
<th>Electrical Quality</th>
<th>Mechanical Analogue I (Force-Current)</th>
<th>Mechanical analogue II (Force Voltage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>Voltage</td>
<td>Force</td>
</tr>
<tr>
<td>Current</td>
<td>Force</td>
<td>Velocity</td>
</tr>
<tr>
<td>Resistance</td>
<td>Lubricity (inverse friction)</td>
<td>Friction</td>
</tr>
<tr>
<td>Capacitance</td>
<td>Mass</td>
<td>Compliance (inverse spring constant)</td>
</tr>
<tr>
<td>Inductance</td>
<td>Compliance (inverse spring constant)</td>
<td>Mass</td>
</tr>
<tr>
<td>Transformer</td>
<td>Lever</td>
<td>Lever</td>
</tr>
</tbody>
</table>

### 3.1.1 Unloaded Piezoelectric Ceramics

**The Van Dyke Model**

This is the most basic circuit model used to characterize piezoelectric ceramics near their resonance frequencies[303]. As shown in Figure 3.1, the van Dyke model is a resistor (R), capacitor (C) and inductor (L) in parallel with a second capacitor. The mechanical analogue of these electrical elements are as specified in Table 3.1, allowing the model to represent the electromechanical behaviour of PZT. A limitation of the van Dyke model is that losses are not included in the model, making it unsuitable for materials with significant losses.

![Figure 3.1 The Van Dyke Model](300)

### The Guan Model

The Guan Model is an adaptation of the Van Dyke and possesses two distinct differences. To the electrostatic capacitor two resistors are added. One in series and another is parallel [277]; this is shown in figure 3.2. The values for the electrical components in this model are found by both visual inspection of the impedance magnitude and phase and the additional resistances are found though the amount of energy dissipation[277]. Although this inclusion of the two extra resistors means the model can encompass into it energy
dissipation, it can introduce inaccuracies since energy loss is dependent on the excitation signals amplitude and frequency [277].

\[
\begin{align*}
R_0 & \\
C_0 & \\
R_s & \\
R_1 & C_1 L_1
\end{align*}
\]

Figure 3.2 The Guan Model-Unloaded Piezoelectric Ceramics [300]

**THE EASY MODEL**

This model includes an RLC tank circuit built in series with a resistor and capacitor. The series resistor allows the unloaded PZT to demonstrate the characteristic of almost constant resistance in frequency ranges far from its resonance. The easy model is fundamentally an adaptation on the Van Dyke Model, with the advantage of easier evaluation of the electrical components of the model, allowing for model automation [300].

\[
\begin{align*}
R_0 & \\
C_0 & \\
C_1 & \\
L_1 & R_1
\end{align*}
\]

Figure 3.3 The Easy Model-Unloaded PZT [300]

**3.1.2 LOADED PIEZOELECTRIC CERAMICS**

**VAN DYKE EXTENDED MODEL**

Changes to the mechanical boundary conditions of a sensor when it is attached to a mechanical host structure means new circuit models must be derived in order to accurately access the loaded piezoelectric ceramic [277]. A piezoelectric sensor mounted to a host material will experience more than a single resonance; hence, a circuit that aims to replicate its behaviour must have multiple resonant frequencies, in the case of the Van Dyke Model this is achieved by the parallel addiction of RCL branches to the original branch [303].
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![Extended Van Dyke Model](image1)

**Figure 3.4 The extended Van Dyke Model-Loaded Piezoelectric Ceramics [300]**

**The Guan Extended Model**

Much like the Van Dyke extended model, the Guan Model is also able to be simply adapted through the addition of extra RLC branches which each stand for a mechanical resonant mode. However, this method of modelling the multiple resonant frequencies has difficulty in determining the values for \( R_i \), \( C_i \) and \( L_i \) when the frequencies are close or overlapping.

![Complete Guan Model](image2)

**Figure 3.5 The complete Guan Model-Loaded piezoelectric ceramics[300]**

**The Easy Model**

The Easy model was developed to overcome the limitations with close/overlapping resonant frequencies described above. It comprises of additional tank circuits to model the multiple resonance frequencies (Figure 37). Previous work has shown this model to be better able to model PZTs in the unloaded and loaded (bonded to structure) cases, with an accuracy of 99% for the unloaded case and 93% for the loaded case. The Easy model has also been demonstrated to be more computationally efficient than other models, and for these reasons this model was employed in the current research [300].
Figure 3.6 Easy Model-Loaded PZT [300]

### 3.1.3 **Project Specific Model**

For this research The Easy Model [300] will be used due to its simplicity and accuracy. In order to use the Easy Model for predictions of impedance responses of PZT the values of the electrical components must be found. This can be done experimentally.

**Unloaded Case**

Reactance, resistance, phase and magnitude vs frequency graphs need to be collected from a sensor under free-free boundary conditions. This was achieved using a Via Bravo Impedance Analyser (AEA technology, Inc.). The sensor was set up such that it was suspended by its connective wires in free space and was not in contact with any solid surfaces. The impedance of the sensor was measured from 100 KHz to 900 KHz with a frequency resolution of 20 KHz. The four graphs created from this frequency sweep are shown in figure 3.7.
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Figure 3.7 Graphs from free free piezoelectric sensor analysis. Top left: Impedance Magnitude. Top right: Impedance Phase. Bottom left: Sensor Resistance. Bottom right: Sensor Reactance

From these 4 graphs it is possible to derive all the electrical component values required to calculate the impedance of the sensor as given by equation 3.1 from paper [300] Figure 3.8 shows the frequency impedance graph created by this model.

\[
Z_{pm,unloaded}(\omega) = R_0 + \frac{1}{j\omega C_0} + \frac{1}{\frac{1}{R_1} + \frac{1}{j\omega L_1} + j\omega C_1}
\]

(3.1)

Each component can be derived as follows:

- **Base Resistance** \( R_0 \): The value to which the resistance graph tends as frequency moves away from its resonance.
  - \( =100\Omega \)
- **Base Capacitance** \( C_0 \): Negative inverse of the reactance at DC.
  - \( 1/1000=1\text{mF} \)
- **Parallel Resonant Frequency** \( \omega_p \): Trough in reactance graph
  - \( 220\text{KHz} \)
- **Frequency** \( \omega \): Independent variable frequency
- **Resistance** \( R_1 \):
  - \( R_1 = R_{p,unloaded}(\omega_p) - R_0 \)
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- **Quality Factor Q (from data sheet):**
  - \[ Q = 100 \]

- **Induction \( L_1 \):**
  - \[ L_1 = \frac{R_1}{w_p Q} \]
  - \[ = 62 \mu H \]

- **Capacitance \( C_1 \):**
  - \[ C_1 = \frac{1}{L_1 w_p^2} \]
  - \[ = 0.33 \mu F \]

Figure 3.8 Frequency impedance graph from easy model analysis of the piezoelectric sensors to be used in this study.

The graph in figure 3.8 shows the piezoelectric sensors resonance frequency to be at 223 KHz, This value was confirmed through experimental investigations. Five sensors were tested and all their resonance frequencies were found to be around the 223 KHz value predicted by the model, see figure 3.9.
Figure 3.9. Frequency impedance plot for five separate piezoelectric sensors with the same characteristics and dimensions. Plot highlights the radial and through thickness vibration frequencies which match those calculated from equation 2.

3.2 PROCESSING IMPEDANCE DATA

The use of impedance analysis in the damage assessment of structures produces qualitative indication of damage. In order to quantify the level of damage three main analysis techniques are commonly undertaken, namely, creating a damage matrix through the use of root mean square deviation, cross correlation coefficients and the use of artificial neural networks. The first half of this section will explore the previous work done on these three techniques, as applied to the field of impedance analysis, and include comparisons of their potential benefits and pitfalls. The second half of the section will look at applying support vector machines.

3.2.1 DAMAGE DETECTION CRITERIA

ROOT MEAN SQUARE DEVIATION (RMSD)

Traditionally RMSD is used to determine how well experimental, or observed, data supports the predication of a model. It is a scale dependent technique that amalgamates multiple error magnitudes at different time/sample points into a single value. It is a widely
used tool with applications ranging from economics [304] to protein structure analysis [305]. In the case of impedance analysis, impedance signals from a damaged structure are compared with those taken from the structure in its original state [306], [307-310]. The value produced by the RMSD evaluation is then compared to a threshold value and damage is indicated in a ‘green/red light form’ [295].

In its mathematical sense the damage matrix can be defined as the squared differences of the real impedance changes at each frequency step, see equation 3.2.

\[
M = \sqrt{\sum_{i=1}^{n} \left[ \frac{\text{Re}(Z_{i,1}) - \text{Re}(Z_{i,2})}{\text{Re}(Z_{i,1})} \right]^2} = \text{Damage Matrix} \quad (3.2)
\]

- \( Z_{i,1} \) = impedance in healthy condition
- \( Z_{i,2} \) = impedance in damaged condition
- \( i \) = frequency interval

It is clear from equation 3.3 that the larger the value of M, the greater the difference between healthy and damaged traces and therefore the higher the indication of damage is.

The main advantage of using RMSD is in its simplicity of application however, because it is a scale dependent, it is unable to compare between different variables and only quantify the accuracy of models for a particular variable [311].

In relation to TKA loosening RMSD would be a suitable damage measure. It would rely on good initial fixation of the implant, such that future impedance readings could be compared to the initial reading in order to determine extent of damage. As time progresses the damage matrix will likely increase due to progressive loosening. This increase could be monitored and, through pre-clinical research a threshold value of when the implant is deemed loose could be calculated.

**CROSS CORRELATION COEFFICIENT (CC)**

Also referred to as the Pearson’s product-moment correlation coefficient, this coefficient is a way of measuring the correlation between two variables, or signals. Developed in the 1880s by Karl Pearson the technique works by calculating the covariance between the two signals and dividing this by the product of the two signals’ standard deviations, it is shown mathematically in equation 3.3. The CC value ranges from -1 to +1 with -1 representing anti-correlation and +1, perfect positive correlation.
As with RMSDs, applications of cross correlation are vast: having been used in anything from electron tomography[312] to single particle analysis[313]. In respect to structural health monitoring impedance analysis, cross correlation is used almost as regularly as RMSD [314, 315]. As with RMSD, a cross correlation coefficient is a feasible method for application in TKA loosening detection through impedance analysis. As the implant begins to loosen, the cc value comparing initial stability of the implant and current stability will begin to tend to -1, i.e. the impedance trace signal of the embedded sensor will diverge away from the original trace, indicating loosening has occurred. Once again, like RMSD the use of CC analysis would rely on the implants initial stability at time zero to be classed as good stability.

**MEAN DIFFERENTIAL**

This feature of a signal is calculated by differentiating the signal and finding the mean value. It is mathematically shown in equation 3.4. It is not currently being used in structural health monitoring impedance analysis but, due to the nature of differentiation it is a good measure of how noisy a signal is. The noisier a signal the more peaks and troughs it contains and the more peaks and troughs within a signal the higher the absolute mean differential value will be. Obtaining a way to quantify the noise of a system is relevant in impedance analysis as the more peaks that are apparent in a frequency impedance trace are due to more modes of vibration which in turn are caused by non-homogenous or damaged nature of a host bond or structure.

\[
\text{Mean Differential} = \frac{\left| \frac{\partial I}{\partial f} \right|}{\text{number samples}} \quad (3.4)
\]
3.2.2 CLASSIFICATION METHODS

ARTIFICIAL NEURAL NETWORKS (ANN)

The basic building block to the majority of neural networks is the ‘Perceptron’ which was first characterised by Frank Rosenblatt in his 1962 book ‘principles of neurodynamics’ [316]. The Perceptron consists of multiple inputs, each with an assigned weight, a ‘nucleus’, and an output. It is the weights that are adjusted during the training of the network. The neuron’s output depends on an activation threshold. As inputs enter the neuron they are multiplied by their associated weight and summed together to create an activation value, see equation 3.5. The output of the neuron therefore depends on how this activation value compares with the neuron's threshold value.

\[ a = \sum_{i=0}^{i=n} w_i x_i \]  \hspace{1cm} (3.5)

- \( a \) = activation value
- \( w \) = weight value
- \( x \) = input value
- \( n \) = total number of inputs

Figure 3.10 Left-Single interactions from \( n \) neurons. Right-Analogy to signal summing in an artificial neuron comprising of a single layer perceptron [317].
SUPPORT VECTOR MACHINE

A Support Vector Machine (SVM) is a classifying algorithm that requires supervised learning to create an optimal hyperplane to separate data into new categories[318]. A training set is used to define how two variables can be split; this can be through using a linear modal, see figure 3.11 or other types of kernels such as Gaussian. Support vectors are then used to optimise this separation hyper plane. Support vectors are the data points closest to the hyperplane, optimisation is performed by minimising the distance of these support vectors from the hyperplane, or, in other words, referring to the image in figure 3.12, maximising the margin between support vectors of each data type [319].

![Figure 3.11 Representation of simple linear Support Vector Machine (SVM) and the creation of an optimal hyperplane [319]](image)

Although SVM has been applied to multiple non-destructive structural health monitoring situations, from detecting defects in line welds[320] to characterising defects in pipelines[318]. It has only been used in two studies relating to impedance based analysis[321] [322]. Both these studies use SVM to classify between two classes; damaged and undamaged structures. Park et al.’s [321] used a two-step SVM classifier to detect and characterise damage to a railroad track. The first step of the SVM detects damage and the second classifies the damage. The two steps use separate kernel functions that have been proven to be optimised for each step. The appropriate kernel function for each step was found by minimising the number of support vectors using the technique described in a
previous paper using SVM in impedance based damage detection [322]. The damage detection estimation rate for Park et al.’s study was 96.67%.

Multiclass support vector machines can be implemented through application of several techniques, predominantly, these involve combining several binary classifiers[323]. The most commonly used technique to adapt SVMs from binary classifiers to multiclass classifiers is through the one-vs-all (OVA) technique[324]. The OVA classifies one class from all the remaining classes and continues to do so for all classes in the system. Although more complicated methods for multiclass classification have been developed recently [325-327], the OVA classifier is said to produce results that are often at least as accurate as these other methods[328]. Due to the simplicity of the implementation of SVM and OVA classification SVMs it is these methods that will be used in the experimental work discussed later in this thesis (Chapter 6). Further advantages and disadvantages of SVM are summarized in table 3.2.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Works with very high dimensional data</td>
<td>Extensive memory requirements</td>
</tr>
<tr>
<td>Use of kernels allows for learning of elaborate concepts</td>
<td>Effectiveness relies on the correct choice of kernel function</td>
</tr>
<tr>
<td></td>
<td>Potentially long computation time</td>
</tr>
<tr>
<td></td>
<td>Traditionally only used in the definition of two data classes</td>
</tr>
</tbody>
</table>

Table 3.2 Advantage and disadvantages of SVM adapted from [329]

3.3 CONCLUSION

Within this chapter the Easy Model has been utilised in order to model the unloaded piezoelectric sensors that will be used in this PhD. From the results of this model a frequency range has been identified into which the natural resonance frequency of the sensors fall. This frequency range can therefore be used in future experiments to analysis bone cement bonds.

Explored here have been different techniques to analyse frequency impedances traces. Mean differential is both easy to calculate and has strong reasoning as to how it
relates to what is physically occurring within the process of the impedance analysis of a structure and will therefore be used in the future experiments in this PhD.

This chapter has summarised two commonly used categorising techniques, SVM and NN. SVMs have been shown to have certain benefits, summarised in table 3.2 that lend it to the application of impedance analysis and it is this technique that will be taken forward in this study to categories different cement bonding situations.
4 CEMENT CURING EXPERIMENTS

Following on from the reviewed literature in chapter 2 which has looked at investigating loosening in vitro, it has been concluded that to create clinically relevant loosening within a laboratory setting would take time to set up. For this reason an intermediate step was created to see if and how piezoelectric sensors interacted with the processes of bone cement curing.

The work in this chapter uses the premise that changing the stiffness of a material will be reflected in the frequency impedance graph from an attached piezoelectric sensor. In order to test this, a metallic plate is used as a tibial base plate analogue, while a block of sawbone is used to represent the tibia. Through taking snap shots of the frequency impedance graph at set intervals in time as the cement between the two materials cure, a correlation between impedance peaks and time allowed to cure is uncovered; indicating strongly the sensors ability to distinguish the curing process of bone cement. This experimental protocol and data analysis is described at the start of this chapter and the results and their implications for the remainder of the PhD are discussed towards the end of the chapter.

4.1.1 CURRENT INVESTIGATIONS INTO CEMENT CURING TIMES

The bone cement industry quantifies curing times by monitoring the temperature during the polymerization reaction between the liquid and powdered parts of the cement. Although temperature monitoring does indicate the changes in the chameical bonds and thermal motion of the cement it is not a direct measure of the material properties of the cement. A generalised temperature time graph for the polymerisation of bone cement is shown in figure 4.1.
A further issue with the industry using temperature to measure curing time is that the curing time measured in a controlled environment within a lab will differ to those cure times created in an intra operative environment. Therefore, although companies will be able to provide surgeons with an estimated cure time, it may differ largely within the operating theatre due to differences in mixing techniques, ambient temperatures and differing air flows. In addition to these factors He et al. has also observed that different surgical gloves can create variations of up to 250% in the measurement of the dough/working period of cement curing as it is calculated by a surgeon. A further problem is that a large amount of cement (ie 40g) is required in order to gain accurate cure times through temperature monitoring and this technique does not produce real time data. Due to these limitations, there has recently been an increase in research into alternative ways to quantify curing intra operatively.

Traditionally, pressure tests are used during surgery to test when cement is cured. This is usually performed in one of two ways, the surgeon either uses a technique involving Gillmore needles or simply uses their thumb nail to press into the side of a block of excess bone cement taken from the same batch being used in the surgery. Using this thumb technique the surgeon determines the cure point to be when the thumb nail no longer creates an indent within the block of cement. Gillmore needle use is very similar, with the
surgeons thumb nail being replaced with the needle tip. The advantages of using Gillmore needles is that the pressure they apply to the cement can be quantified using Gillmore Standards[332]. As mentioned however, the curing behaviour of bone cement is dependent on environmental factors and therefore curing within the bone cavity and curing of the cement in the surgeons hands will differ from each other. For this reason, new techniques have begun to be developed to investigate direct interigation of the cement within the bone cavity. The majority of this work has investigated the use of ultrasound. The speed of sound is sensitive to the viscoelatic properties of a material and hence ultrasound is able to provide information on the actual material properties of the cement [333, 334].

Carlson et al. uses an ultrasonic pulse-echo technique to monitor the curing time of CaSO₄ based bone cement. Figure 4.2 shows the experimental setup, the transducer emits an ultrasonic pulse and detects two reflection pulses, one from the PMMA-cement interface and the other from the cement-steel interface. The time difference between these reflected pulses will be dependent on the speed of the wave propagating through the cement sample. The theory is that as the cement cures, the speed of the propagating wave will change and this can be detected by measuring the change in difference between the two pulses.

![Figure 4.2 Device for ultrasonic pulse-echo measurements of a cement sample as it cures](image)

Carlson et al compared the findings from the ultrasonic pulse-echo measurements to Gillmore needle setting times and concluded that ultrasonic manipulation of the cement provides a more accurate reading of when the cement is cured since the acoustic and manual properties are strongly correlated. It is also advantageous to use acoustic methods since the standards for Gillmore needle tests calls for large amounts of cement (41cm³) to be used in the cure tests and in reality this is reported to often not be met due to the significant cost of bone cement[334].
Another technique aimed at quantifying cement curing intraoperatively is Raman Spectroscopy [335]. The peak at a Raman shift of $1,640\text{cm}^{-1}$ in the peak intensity graph from a Raman spectroscopy of bone cement (PMMA) corresponds to the double carbon bond found in methyl methacrylate which breaks down during the free radical polymerisation that creates the polymethyl methacrylate. As the bone cement cures, and the free radical polymerisation of the methyl methacrylate takes place, these bonds are broken down and the representative peak on the spectroscopy graph reduces in size. Hagan et al's experimental investigations demonstrate that the results of this peak reduction correspond closely with determining cement curing by monitoring temperature (see figure 4.3).

![Figure 4.3 Typical variation in Raman peak intensity and temperature trace of polymerising acrylic bone cement (Palacos® R bone cement stored at 4°C) [335]](image)

There has been one previous research study that has investigated using impedance analysis to detect cement curing [336]. This study used a self-made dielectric cell shown here in figure 4.4. The two electrodes in the figure were connected to a Hewlett-Packard impedance analyser which was set to take impedance readings of the system over a frequency range of 0.4-100 MHz. Readings from the impedance analyser were compared with those taken from Gillmore needle tests performed on the same batch of bone cement.
Despas et al.’s concludes that the curing times determined through looking at parameters taken from impedance readings differ markedly from those obtained by the Gillmore normalized method regardless of the chemical make-up of the cement. Impedance readings show that the cement continues to evolve beyond the point at which the Gillmore test determines the cement has set. The experiments in this chapter will be used to validate the conclusion made by Despas that impedance based tests pre-empt the curing of bone cement. The main difference between the experiments undertaken in this PhD and those performed by Despas is that rather than directly measuring the impedance of the cement, this study will use piezoelectric sensors mechanically coupled to the implant (or implant analogue).

### 4.1.2 Hypothesis

From reviewing the literature of past experiments on the curing of PMMA bone cement as outlined above and the knowledge that the frequency-impedance plots of a piezoelectric sensor is affected by the mechanical impedance of the structure it is adhered to the following hypothesis has been constructed as the bone cement (PMMA) between a sawbone block and aluminium plate cures, the peak impedance of the piezoelectric sensor attached to the top side of the aluminium plate decreases in amplitude.

### 4.2 Preliminary Experiments

A preliminary test was carried out to determine the impedance frequency range most indicative of bond integrity. This allowed investigations to focus solely on this range, hence reducing the amount of unrequired data collected.
4.2.1 METHODS

SPECIMEN PREPARATION

In order to minimize inter specimen variation and complexity, the test materials were simplified versions of the clinical setting. Sawbone polyurethane blocks of density 30pcf and dimensions 40 mm by 40 mm by 60 mm were used as a substitute for the proximal tibia. A 5 mm thick aluminium plate was used to simulate a tibial tray. The plates cross sectional area matched that of the sawbone block (60 x 40 mm). Adhered, using ethyl cyanoacrylate, to the centre of the topside of the aluminium plate was a small piezoelectric sensor (12 mm diameter 0.6 mm thickness, (Steminc-Piezo)). Soldered to these sensors were two 65 mm length multicore wires, one black insulated wire was attached to the electrode in contact with the plate, and a red wire was attached to the upper side electrode (see figure 4.5). The piezoelectric sensor was connected to an impedance analyser (Agilent Impedance Analyser 42494A) in order to measure the sensor’s impedance during the test.

Figure 4.5 ‘Cement Curing Experiment’. On the left is the tibial tray substitute cemented to sawbone. Adhered to the top of the tray is piezoelectric sensor wire to an impedance analyser.

EXPERIMENTAL PROTOCOL

Bone cement (polymethyl methacrylate or PMMA) was manually mixed with a 2:1 ratio of powder to liquid. The tibia tray analogue was thumb pressed onto the bone substitute and through the use of the impedance analyser; the sensor was interrogated over two frequency ranges, the radial (100-400 KHz) and through thickness (1-3 MHz) range. Impedance traces from the sensor were recorded at 10-second intervals for 3 minutes and 20 seconds.

DATA ANALYSIS

For each impedance trace taken at the 10 second intervals, the peak impedance was recorded as the wealth of literature had indicated this feature is key in determining changes
in mechanical impedance in structures. The peak impedance values were then normalised between 0 and 1.

4.2.2 RESULTS

Results show that the radial frequency gave a more distinct indication of curing than the through thickness, where the x axes represents time and the y axes peak impedance, see figure 4.6. In the through thickness frequency range, there is a large spread of normalised impedance peak values throughout each sample from the test as shown by the elongated box plots on each of the sample readings. This spread of data indicates that there is a large range of peak values in which no curing and fully cured cement readings may fall. In the first sample taken in this frequency range the normalised impedance peak value ranges from 0 to 1. In comparison, the graph for radial frequency peak values show much lower variations in normalised impedance peaks (usually in the range of 0.02 for samples taken at the start and end of the cement curing experiments). This means that given a normalised impedance peak value in the radial frequency range it would be possible to conclude the cure state of the cement. The radial range also shows a clear negative sigmoid curve giving information about the mechanical integrity of the cement bond strengthening with time. It is for these reasons that the frequency range used in subsequent experiments was 180 KHz and 360 KHz.
Figure 4.6 Results from preliminary experiments to determine which frequency band will give clearer results for cement curing experiments. The graphs show normalised impedance peaks with timed sample number (each sample number represents a reading taken at 10 second periods) of through thickness frequency range and radial range (top and bottom respectively).

4.3 Main Experiments

4.3.1 Methods

Specimen Preparation

A further 16 samples were investigated. Each sample was identical to those used in the preliminary experiment as well as being identical to each other.

Experimental Protocol

All 16 samples followed the same methodology. Bone cement was manually mixed with a 2:1 ratio of powder to liquid. The tibia tray analogue was pressed onto the bone substitute. The sensor was interrogated over the radial frequency range, 100-400 KHz, following on from preliminary experiment results. Impedance readings at this frequency range were taken every 10 seconds for 10 minutes. Concurrently, an experienced surgeon took bone cement from the same mix and manipulated it until it was considered the cement
had cured in the same way it is determined curing during surgery (when the edge of a small cube of bone cement no longer deforms when an implement is pressed into its side). This time was noted.

**DATA POST PROCESSING**

Data was processed in MATLAB (Mathworks, R2014b). Three-dimensional plots, showing the frequency-impedance trace changing with time were produced for each individual sample. Figure 4.7 shows an example of one such plot. The frequency with the largest initial peak was chosen as the frequency that would be used in further investigations. For clarity, the 3D graph is redrawn in 2D form in figure 4.8. It is annotated such that it is clear how the peak impedance at 273Hz is decreasing over time as the cement cures. The value of the impedance at this frequency was recorded over time and used to create figure 4.9, which shows the mean peak impedance values of all 16 samples against time.

From the graph in figure 4.9, the cured time of the cement, as defined by the sensors, was taken to be when the graph plateaued. This plateau in peak impedance is representative of the cement reaching a steady state of being i.e., the cement can be said to be fully cured. This plateau was calculated using a custom MATLAB script. The script determined the time point at which the differentiated impedance value stayed within ±15% of the maximum differential value for three consecutive time points.

**4.3.2 RESULTS**

From figures 4.7 and 4.8, showing impedance change over time as a function of frequency, it is visually observable that the peak impedance decreases with time. For the sample demonstrated in figure 4.7 (sample 4), over the entirety of the test, the initial impedance peak (466Ω) had approximately halved (264 Ω). A mean curve was constructed from all 16 samples and is shown with one standard deviation error bars in figure 4.9. The image shows the impedance peaks decrease from 550± 50 ohms and proceeds to reach a steady state between 325±50ohms. Figure 4.9 also shows the mean and standard deviations for each cure time. The surgeon determined times are shown in green, while the sensor determined times are shown in red. The thick coloured lines represent the mean cure time while the shaded areas show data that falls within one standard deviation of the mean.

The Pearson’s linear correlation coefficient between sensor and surgeon cure times was calculated to be 0.5 indicating the time of curing determined by the two methods can be considered moderately correlated. This is shown visually in figure 4.10 where each point on
the graph represents a sample and the x and y axes represent the sensor and manual curing times respectively. The average difference in time between sensor and surgeon cure time is 52.5 seconds; with the sensors consistently detecting longer curing time than the surgeon. Referring back to figure 4.9, it is apparent that the surgeon appears to be determining the cure point at the inflection of the impedance peak graph. This theory was tested by calculating the inflection point of the graph (by finding the second derivative of the data) and comparing that to the surgeons determined cure time. This new sensor cure time is shown in figure 4.11 where it is clear that the surgeon cure time is reflected in the inflection point of the graph. On average, the surgeon is only 1.75 seconds away from detecting the exact inflection point of the curve.

![Three dimensional graph showing relationship between frequency and impedance over time: as time increases the peaks in impedance decrease.](image)

Figure 4.7 Three dimensional graph showing relationship between frequency and impedance over time: as time increases the peaks in impedance decrease.
Figure 4.8 Graph showing relationship between frequency and impedance over time: as time increases the peaks in impedance decrease. Initially it is at a peak of 466Ω and almost halves to a value of 264Ω
Chapter 4: Cement Curing Experiment

Figure 4.9 Graph showing change in mean peak impedance values of samples with respect to time. Initially there is a steep drop in impedance peak followed by a plateau, indicating the cement has cured. The green and red patch shows surgeon and sensor curing time data respectively, with the thick middle line representing the mean time and the shaded areas showing one standard deviation of the mean on each side.

Figure 4.10 Correlation between sensor determined cure time and manually determined cure time
Figure 4.11 Graph showing change in mean peak impedance values of samples with respect to time. Initially there is a steep drop in impedance peak followed by a plateau, indicating the cement has cured. The green and red patch shows surgeon and new sensor curing time data respectively, with the thick middle line representing the mean time and the shaded areas showing one standard deviation of the mean on each side.

4.4 DISCUSSION

4.4.1 MOST IMPORTANT FINDINGS

The main finding from this experiment is that small (mm) piezoelectric sensors are able to show when the mechanical interlock between implant and bone (substitute) is formed. There is a clear decrease in peak impedance as the cement cures, as is shown in figures 4.9 and 4.11, which then plateaus indicating further physical changes are no longer effecting the impedance of the sensors. From calculating the time this plateau occurs, it is apparent that the surgeon detects curing at an average of 52.5 seconds prior to the plateau of impedance; and, from further calculations (looking at the second derivative of the impedance) it is apparent that the surgeon’s curing time is detecting at which point the impedance curve undergoes inflection, not where it plateaus. If the surgeon is detecting earlier curing time, as is indicated by this study, there is a risk that, intra operatively, the surgeon is proceeding with the operation before the bone cement has reached its final cured state. Moving the joint before the implant is fully secured may dislodge the implant and cause future problems for the patient [337]. Detecting the complete cure time through the use of a piezoelectric sensor could prevent this premature movement of the joint during surgery and hence lead to a lower incidence of initially unstable implants.
4.4.2 LIMITATIONS

The main limitation of this experiment is the lack of control over environmental factors surrounding apparatus involved. Cement curing time can be affected by several external factors including temperature and surrounding air flow which were not controlled within the lab. However, the main aim of this experiment was to compare the surgeon and sensor determine cure times on the same sample of cement at the same time. This means that enviromental factors within the lab should theoretically effect both these times in the same way; making the relative difference between the two independent of the environment conditions. However, this lack of control in environmental factors may explain the large standard deviation error bars on the plot of average impedance values in figure 4.6. Although enviromental factors do not effect the relative times between each sample they cause differences between samples.

4.4.3 COMPARISONS WITH PUBLISHED RESEARCH

Although there is specific research studies in the field of non destructive testing which investigate how Impedance Analysis can be used to monitor the curing of concrete the research presented here is one of two known works looking into using this technology in the biomechanical field of authopeadics and specifically implant loosening.

The results from Calsons experiment [334] corroborate the findings of the experiments in this chapter, they both show that, although pressure tests (in the case of this experiment the surgeon manipulatging the bone cement and in the Carlson experiment the use of Gillmore needles) detect a change in the material consistancy of the cement, they do not detect a point when the material begins to reach a stable state. This is shown in Carlsons results in figure 4.12. As with the impedance graphs shown in figures 4.9 and 4.11, figure 4.12 shows that the cure time detected from pressure tests (shown by point f on the graph) is roughly the inflection point of the graph. Whereas in contrast, both the impedance graphs (figure 4.10 and 4.11) and Carlsons graph (figure 4.12) show that the mechanical measurement on the y axis of each graph does not plateau until after this pressure test point. Similar results can be seen in Despas et als study [336] where again Gillmore needle tests preemt the point at which curves relating to the mechanical stability of the cement plateous. The main difference between the study presented in this chapter and that presented in Despas's work is that here a piezoelectric sensor is used whereas Despas directly monitors the impedance of the cement. The main reason behind this difference is that Despas's is looking purely at the curing of the cement and therefore monitoring directly the chemical change in the cement as it cures and how this effects the dielectric response of
the material. Through using a piezosensor, this study is monitoring instead the structural integrity of the cement since the electrical impedance of the sensor is coupled to the mechanical impedance of the cement. The advantage of this becomes apparent in the next couple of chapters of this thesis; when work shifts from focusing on cement curing onto the structural break down of the cement bond.

![Figure 4.12 Acoustic impedance of PMMA recorded in Carlson et al. experiment as a function of time](image)

**Figure 4.12 Acoustic impedance of PMMA recorded in Carlson et al. experiment as a function of time** [334].

### 4.4.4 Clinical Relevance and Conclusion

This research has great potential in terms of clinical relevance. As forementioned, the results presented here indicate the surgeon is predicting the cement to have cured before it has reached a steady state of being. Preemting the cure time may lead to progression of surgery before the implant is completely secured which in turn can lead to complications, for example: mall alignment or initial instability of the replacement [338]. If simple PZT sensors like those described in this thesis can be used to more accurately determine when cement has fully cured, there is potential that they can be developed into intraoperative sensors to aid othopedic surgeons in the determination of when it is ‘safe’ to continue with a joint replacement surgery after the cement has been applied.

These sensors are small and will be able to be easily embedded within an implant, one of the great advantages of them is that they are passive sensors and hence no other electrical components, excluding a coil of wire, will need to be embedded within the implant along with the sensor.
5  STATIC LOOSENING IDENTIFICATION

The previous chapter has established that small circular piezoelectric sensors are able to quantify the curing process of bone cement. This chapter looks to investigate if these sensors are able to statically determine the percentage of surface area between a block of sawbone and aluminium plate that is covered and cured with bone cement. This would allow discrete values taken from cemented structures to be used as indication of cement coverage as opposed to a comparative evaluation as presented in the next chapter.

The work presented in this chapter uses a similar experimental format to that used in chapter 4. Aluminium plates, with sensors attached to their topside, are attached to sawbone blocks using varying amounts of cement between the two. Frequency-impedance readings are taken from each sample and results are compared using pattern recognition software.

5.1.1  HYPOTHESIS

Building on knowledge from literature and the results of experiments performed in chapter 4, the hypothesis for the progressive loosening experiments is that increasing the surface area covered by PMMA cement between sawbone and aluminium plates will decrease the differentiated impedance magnitude of piezoelectric sensors attached to the top side of the aluminium plate.

The scientific rational behind this hypothesis is that the blocks with less coverage are going to produce more modes of vibration due to non-homogenous nature of the bond and these vibration modes are represented by peaks in the impedance traces. If the hypothesis is correct, it will have demonstrated that the sensor can identify progressive loosening of the implant, i.e. differentiate between a fully, partially and non-bonded interface.

5.2  EXPERIMENTAL STUDY

5.2.1  METHOD

SPECIMEN PREPARATION

Seventy five blocks of 30pcf sawbones polyurethane bone substitute were cut to dimensions 60mm by 40mm by 20mm. Five pieces of 5mm thick aluminium plate were cut to 60mm by 40mm such that they rested in line upon the saw bone blocks. On the top side of each aluminium plate, a small piezoelectric sensor of dimensions 12mm diameter by 0.6mm thickness was attached in the centre using ethyl cyanoacrylate. These sensors had soldered
to them two 65 mm multicore wires; one black insulated wire was attached to the electrode in contact with the plate, and a red wire was attached to the upper side electrode. These wires were then attached to a Viva Bravo Impedance Analyser (AEA Technologies). See figure 5.1 below.

![Impedance analyser diagram](image)

**Figure 5.1** Diagrammatic representation of the experiment used to test the effect of surface area coverage of bone cement between bone substitute and tibial tray substitute on

**EXPERIMENTAL PROTOCOL**

In total 75 test blocks of saw bone were used, however, only five sensors and five aluminium trays were used as they were rotated in order to save on cost and reduce inter-specimen variation between sensor sensitivity. Experiments were performed in batches. Table 5.1 shows how these batches relate to the amount of cement covering the top face of the sawbone block. Structuring the batches in such a way meant that separate sensor data could be compared to determine if the individual sensors had an effect on the readings in terms of either slight differences in their structure or in their attachment to the aluminium.
<table>
<thead>
<tr>
<th>Batch Number and cement covering ↓</th>
<th>Repeats</th>
<th></th>
<th></th>
<th></th>
<th>Total number ↓</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch 1 (full cement cover)</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Batch 2 (3/4 cement cover)</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Batch 3 (1/2 cement cover)</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Batch 4 (1/4 cement cover)</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Batch 5 (No cement covering)</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td>All 5 Plates</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

Table 5.1: Description of different batch experiments for differing percentage of bone cement coverage.

In each batch that required bone cement to be mixed, the bone cement was hand mixed in the ratio 2:1, powder to liquid. Using a piping bag it was then funnelled onto the sawbone and the aluminium plate, with sensor attached, was pressed into place on the sawbone. In order to achieve the various percentage coverings of bone cement on the sawbone, polytetrafluoroethylene (PTFE) tape was used to cover the appropriate proportion of the sawbone top face before the cement was applied. When preparing batches of full cement covering, no PTFE tape was used and when preparing ¼ covering of cement, three quarters of the top face of the sawbone was layered with PTFE tape, see figure 5.2

Figure 5.2 Photos showing sawbone block samples covered with various amounts of PTFE tape.
Once the aluminium plates had been pressed into place on the Sawbone they were left for 30 minutes in order to ensure the cement was fully cured. Three consecutive readings were then taken from the sensors. These readings were taken using Via Bravo Impedance Analyser (AEA Technologies) over a frequency range of 180 KHz to 360 KHz. The reason for using this frequency range is explained in Chapter 4 section 3.1.4.

**DATA PROCESSING**

The same custom MATLAB script used in the previous two chapters was used to extract frequency-impedance data from the serial input of the Via Bravo. The mean from three consecutive readings from each sample was taken in order to produce one frequency vs impedance reading.

The features of the frequency-impedance graphs that were used to compare the different amounts of cement coverage were: peak impedance value between 250 KHz and 350KHz and the mean differential of the complete signal. The peak impedance value was used as a feature since it was shown, in chapter 4, to be a good indicator of when bone cement is cured. The mean differential was used as on visual inspection of the impedance signals, blocks with less cement coverage showed impedance signals with more peaks and troughs than those with more coverage. This can be explained through the physical properties of the cement blocks. Those with less coverage are going to produce more modes of vibration due to non-homogenous nature of the bond and these vibration modes are represented by peaks in the impedance traces. Mean differential is defined in equation 5.1.

\[
\text{Mean Differential} = \frac{\text{Signal differential}}{\text{number samples}} \quad (5.1)
\]

**COMPUTATIONAL CLASSIFICATION**

A Support Vector Machine (SVM) was used to classify the amount of surface area covered by cement given the impedance trace. Support Vector Machines are described in chapter 3. The SVM standardised the input by centring and scaling it using mean and standard deviation respectively.

Initially data was split into 3 classes: Full cement coverage, partial cement coverage and no cement coverage. After, all 5 classes of cement coverage were assessed. A range of different order polynomial kernel functions were used in the SVM and compared by assessing the SVM’s accuracy as to which gave the best predictive outcome.
5.3 RESULTS

5.3.1 RAW RESULTS

Figure 6.3 shows the results from all tests performed in the experiments explained in section 2 of this chapter. Along the horizontal axes is the percentage covering of cement on the sawbone blocks, while the vertical axes is a measure of mean differential impedance magnitude. The boxplot features are shown in figure 6.4. Figure 6.3 shows that higher mean differentials are associated with lower amounts of cement covering. As cement coverage levels increase the mean differential values reduce at a gradually decreasing rate. There are two anomalies shown in figure 5.3 at 50\% and 75\% coverage. Overall the data shows a clear trend for reducing peak impedance as a function of cement coverage.

\[\text{\% of cement covering}\]

Figure 5.3 Results from experiments comparing mean differential of impedance magnitude across a frequency range of 180 KHz to 360 KHz for aluminium blocks with a full covering of cement to those with varying amounts of cement covering between block and sawbone.
Figure 5.4 Representation of each of the features on the boxplot shown in figure 5.3

Figure 5.5 separates the results which shows the data from each of the five sensors, such that the results can be interpreted depending on the slight difference that may occur between the sensors due to manufacturing differences or small differences in their adhesion to the metal plates. The x axes is a representation of the percentage of the sawbone block covered with cement, the y axes shows the mean differential as calculated in equation 5.1. Error bars represent the maximum and minimum mean differentials from each of the repeats undertaken for each sensor.

The graph shows a decreasing trend in mean differential values for each of the 5 sensors as the amount of cement covering the sawbone increases. For all but one sensor (the sensor represented by the green line) the largest drop in mean differential value occurs between zero covering of cement and quarter covering (with the mean drop of those 4 sensors being 70.7). Between quarter covering and full cement the mean rate of decrease of the mean differential of the sensors impedance magnitude’s is 24.5, showing a reduction in rate of mean differential drop of 92%.

Although the sensor readings differ slightly from each other, not only do they show the same decreasing trend, their absolute drop in mean differential value shows little variation between the sensors. The difference in the mean differential value of the sensors is 60 with a standard deviation of 20.
Figure 5.5 Mean differential of impedance magnitude with respect to percentage covering of cement for 5 different sensors. Each line represents a different sensor and the error bars show maximum and minimum values for each sensor at each percent coverage.

5.3.2 CLASSIFICATION RESULTS

THREE CLASS CLASSIFICATIONS

DETERMINING MOST ACCURATE KERNEL FUNCTION FOR SVM

The SVM was trained using 20 different order polynomial kernel functions. The overall accuracy of each SVM was defined as the number of correctly classified points as a percentage of total number of blocks (75)). Figure 5.6 shows a bar chart showing the relationship between the polynomial order and the overall accuracy. The Graph shows that a polynomial of order 10 kernel function gives the greatest over all accuracy of 92%. Kernel functions with a higher order polynomial than 10 show less accurate outcomes. This is due to the problem of overfitting. Overfitting is when a model, in this case the SVM describes random error or noise in input data rather than an underlying relationship. In the case of increasing the polynomial order, this overfitting occurs as the model becomes excessively complex. Using higher order polynomials increases the computation time. However, the increase in time to train an SVM of polynomial order 2 (which gives an accuracy of 81%) compared with one of order 10 (which gives an accuracy of 92%) is minimal, just 1.5 seconds.
Chapter 5: Static Loosening Identification

Figure 5.6 Bar chart representing the effect of different order polynomial kernel functions on the overall accuracy of an SVM trained to classify samples into three classes: full covered, partially covered and no cement coverage.

**Visual Representation of SVM**

Figure 5.7 shows visual representation of the SVM classifying 3 classes of cement coverage. The x and y axes represent the parameters used in the SVM model. Mean differential and peak impedance and are on the x and y axes respectively. The coloured regions on the graph are the regions for each of the 3 classes as defined by the SVM classifier. The green region represents areas in which if data fell they would be classed as full cement coverage. The blue and red regions represent areas classified as partial and no cement coverage respectively.

The darker coloured data points on the graph in figure 5.7 correspond to experimental data from the tests outlined in section 2 of this chapter. The graph allows visualisation of the effectiveness of the classifier. The majority of data points lie with in the same coloured region as the point itself. This indicates that they are classified by the SVM into the correct class. For example, blue data points within the blue region represent that these partial cement covered samples would be correctly classified as having only partial cement coverage. Figure 5.8 shows the results of an SVM created with order 12 polynomials-it represents that issue of over fitting as shown by the islands of colour found in the graph.
Another way to view this data with clearer numerical values that show percentages of each correct and incorrect classification is through the use of confusion matrices. These are described below.

Figure 5.7 Visual representation of SVM classifier for 3 class cement coverage case with kernel of $4^{th}$ order polynomial. Green, blue and red regions indicate areas where data is classified as full, partial and no cement coverage respectively. The darker coloured green blue and red dots represent experimental data points for full, partial and no cement coverage respectively. Dots in the correct corresponding coloured regions (ie blue dots in the blue region) demonstrate experimental samples classified correctly into the appropriate class.
Figure 5.8 Visual representation of SVM classifier for 3 class cement coverage case with kernel of 12\textsuperscript{th} order polynomial. Green, blue and red regions indicate areas where data is classified as full, partial and no cement coverage respectively. The darker coloured green blue and red dots represent experimental data points for full, partial and no cement coverage respectively. Dots in the correct corresponding coloured regions (ie blue dots in the blue region) demonstrate experimental samples classified correctly into the appropriate class.

**CONFUSION MATRIX**

Table 5.2 shows a generalised confusion matrix. A confusion matrix is used to visually represent data from machine learning algorithms. The columns show each instance of a predicted class and the rows represent instances of actual classes. Confusion matrices have been used here to represent the results from the SVMs used to distinguish between different amounts of cement coverage. Table 5.3 shows the confusion matrix for the SVM that used a polynomial order 10 kernel function. Within the field of diagnostic health care, it is preferable for diagnostic tests to produce more false negative results than false positives. Diagnosing a patient falsely with a condition will lead to further investigations whereas diagnosing a patient as ‘healthy’ when they are suffering from a condition can mean they will not get the treatment that they need. The confusion matrix in table 5.3 shows a thick border separating the data into two parts. The data to the left of this divide shows false negative results while the data to the right shows either correctly classified data or false positives. Looking at the values on each side of the divide, it can be seen that only one sample is classified as falsely
positive and 5 are classified as falsely negative. The other 69 samples are classified into their correct classes, giving the overall accuracy of the SVM as 92%.

<table>
<thead>
<tr>
<th>Predicted</th>
<th>Total Population</th>
<th>Condition positive</th>
<th>Condition negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test outcome positive</td>
<td>True positive</td>
<td>False positive</td>
<td></td>
</tr>
<tr>
<td>Test outcome negative</td>
<td>False negative</td>
<td>True negative</td>
<td></td>
</tr>
</tbody>
</table>

Precision (true positive/test outcome positive)  
Negative predictive value (false negative/test outcome negative)  
Sensitivity (false negative/condition positive)  
Specificity (true negative/condition negative)  
Accuracy (true positive +true negative/ total population)

Table 5.2 General confusion matrix. The different rows represent the different test outcomes and the columns represent the predicted classes. The diagonal of the table shows the number of points correctly classified. At the end of each row and column is a percentage showing the percent of correctly classified test points in each row/column.

<table>
<thead>
<tr>
<th>Predicted</th>
<th>Total Population (75)</th>
<th>Full (15)</th>
<th>Partial (45)</th>
<th>None (15)</th>
</tr>
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<tr>
<td></td>
<td></td>
<td>10</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5</td>
<td>44</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
<td>15</td>
</tr>
</tbody>
</table>

86%  78%  92%  Accuracy 92%

Table 5.3 Confusion matrix for 3 class SVM classifier
FIVE CLASS CLASSIFICATION

DETERMINING MOST ACCURATE KERNEL FUNCTION FOR SVM

As with the three class classification SVM, the five class SVM was trained using 20 different order polynomial kernel functions. Again, overall accuracy of each SVM was defined as the number of correctly classified points as a percentage of total number of blocks (75)). Figure 5.9 shows a bar chart showing the relationship between the polynomial order and the overall accuracy. The Graph shows that a polynomial of order 9 kernel function gives the greatest over all accuracy of 83%. This is 9% lower than the overall accuracy found for the three class system. The reduction in accuracy is expected; by defining 5 classes instead of 3, the system demands a higher degree of categorisation. For the same reason of over fitting found in the 3-class sample, higher order polynomials than 9 in the 5 class case show decreases in accuracy.

Figure 5.9 Bar chart representing the effect of different order polynomial kernel functions on the overall accuracy of an SVM trained to classify samples into five classes: full covered, ¾ coverage, half coverage, ¼ coverage and no cement coverage.
**VISUAL REPRESENTATION OF SVM**

Figure 5.10 shows visual representation of the SVM classifying 5 classes of cement coverage. The x and y axes represent the parameters used in the SVM model. Mean differential and peak impedance and are on the x and y axes respectively. The coloured regions on the graph are the regions for each of the 5 classes as defined by the SVM classifier. The blue region represents areas in which if data fell they would be classed as full cement coverage. The red, yellow, grey and pink regions represent areas classified as ¼ coverage, ½ coverage, ¾ coverage and full coverage respectively.

The darker coloured data points on the graph in figure 5.10 correspond to experimental data from the tests outlined in section 2 of this chapter. The graph allows visualisation of the effectiveness of the classifier. The majority of data points (83%) lie within the same coloured region as the point itself. This indicates that they are classified by the SVM into the correct class. For example, blue data points within the blue region represent that these full cement covered samples would be correctly classified as having full cement coverage.

![Cement Covering Classification Regions](image)

Figure 5.10 Visual representation of SVM classifier for 5 class cement coverage case with kernel of polynomial order 3. Blue, red, yellow, grey and pink regions indicate areas where data is classified as full, ¾, ½, ¼ and no cement coverage respectively. The darker coloured dots of blue, red, yellow, black and pink represent experimental data points for full, ¾, ½, ¼ and no cement coverage respectively. Dots in the correct corresponding coloured regions (ie blue dots in the blue region) demonstrate experimental samples classified
correctly into the appropriate class regions (ie blue dots in the blue region) demonstrate experimental samples classified correctly into the appropriate class.

Figure 5.11 Visual representation of SVM classifier for 5 class cement coverage case with kernel of polynomial order 12. Blue, red, yellow, grey and pink regions indicate areas where data is classified as full, ¾, ½, ¼ and no cement coverage respectively. The darker coloured dots of blue, red, yellow, black and pink represent experimental data points for full, ¾, ½, ¼ and no cement coverage respectively. Dots in the correct corresponding coloured regions (ie blue dots in the blue region) demonstrate experimental samples classified correctly into the appropriate class regions (ie blue dots in the blue region) demonstrate experimental samples classified correctly into the appropriate class. The complex pattern of colours in this graph are indicative of overfitting.

**CONFUSION MATRIX**

Table 5.4 shows the confusion matrix for the SVM that used a polynomial order 9 kernel function. As explained in the case of the 3 class system, within the field of diagnostic health care, it is preferable for diagnostic tests to produce more false negative results than false positives. The confusion matrix in table 5.4 shows a thick border separating the data into two parts. The data to the left of this divide shows false negative results while the data to the right shows either correctly classified data or false positives. Looking at the values on each side of the divide, only 6 samples are classified as falsely positive and 8 are classified
as falsely negative. The other 61 samples are classified into their correct classes, giving the overall accuracy of the SVM as 83%.

<table>
<thead>
<tr>
<th>Test outcome</th>
<th>Total Population (75)</th>
<th>Predicted</th>
<th>Full</th>
<th>3/4</th>
<th>1/2</th>
<th>1/4</th>
<th>0</th>
<th>Accuracy 83%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full (15)</td>
<td></td>
<td></td>
<td>10</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>73</td>
</tr>
<tr>
<td>3/4 (15)</td>
<td></td>
<td></td>
<td>2</td>
<td>10</td>
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<td>15</td>
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</table>

Table 5.4 Confusion Matrix for 5 class SVM classifier

5.4 Discussion

5.4.1 Most Important Findings

The most important finding of the experiments outlined in this chapter is the capability of a single piezoelectric sensor to detect differing levels of cement coverage between bone and implant analogues. The results have shown that, through the use of SVM classifiers, the sensors can determine between 3 classes of cement covering with an accuracy of 92% and between 5 classes with accuracy of 83%.

5.4.2 Limitations

One limitation of this study is the same as that seen in chapter 4; there is no control of the external environment while tests are being carried out. External factors such as temperature can affect the curing of cement. However, the experiments presented here were looking at the final cured state of cement. So although ambient temperature may have
affected the speed the cement cured, as long as measurements were taken once curing was complete, changes in temperature should have little effect on the end state of the cement. For these reasons the cement was left to cure for up to an hour to ensure complete curing had occurred.

Another limitation in these experiments is ensuring that the thickness of cement in each sample is consistent between samples. For each experiment, the cement was mixed with the same ratio of 2:1 liquid, producing cement with the same viscosity for each test. Applying the same amount of cement under the same pressure with the same viscosity helps to create layers of cement between the bone and implant analogue of similar thicknesses. Measurements were taken using an electronic Vernier of the thickness of the sawbone and aluminium plate substrate before and after bone cement was cured between them. The mean thickness of the cement was 1.32mm with a standard deviation of 0.15mm. This small standard deviation is evident that differences in cement thickness were minimal and hence would have minimal effect on the results.

5.4.3 CLINICAL RELEVANCE

For successful implantation it is vital that there is an even and secure covering of bone cement between bone and implant. Failure to achieve this can lead to incorrect alignment of the joint to its normal mechanical axis (the aim is to get to with 0°± 3° of natural mechanical axis) [123]. Poor application of cement, both its thickness and penetration into the bone below the tibia and femoral prosthesis, along with poor bone resection and soft tissue release [124] can contribute to misalignment. There are two different ways in which cement is used to fix an implant, either through the cementing of both the underside of the tibial base plate and the stem (full cement covering) [127, 128], or cementing solely under the tibial base plate (surface cement covering) [129, 130]. In either case, it is impossible for the surgeon to visually see the covering of cement that occurs between the bone and implant as the surgery is carried out. Therefore, a piezoelectric sensor capable of distinguishing the level of cement coverage could provide immediate evidence of successful bonds intraoperative, thus providing surgeons with the ‘green light’ to continue surgery but also allowing further studies investigating the benefits and cons of different cement covering techniques.
This chapter builds on the results from the experiments in the previous chapter. Having found that the small piezoelectric disc sensors in the previous chapter are able to distinguish a pattern of cement curing and different levels of fixation, this set of experiments are used to determine if the same small sensors are able to detect the breakdown of the cement bond between a tibial tray and sawbone tibia analogue. The chapter will discuss the experimental set up of these investigations, how they are related to clinical situations, the results gathered and what these results show in regards to a piezoelectric sensors ability to detect changes in the breakdown of the bond between implant and sawbone.

6.1.1 HYPOTHESIS

Building on knowledge from literature and the results of experiments performed in chapter 4 and 5, the hypothesis for the progressive loosening experiments is that as the bond between the implant and bone substitute is progressively loosened, and is detected by LVDTs measuring the micro-motion between the two, the peak impedance and mean differential of frequency impedance signals taken from a sensor placed on the top face of an implant would increase.

6.2 EXPERIMENTAL STUDY

SPECIMEN PREPERATION

In order to minimize inter specimen variation and complexity, the test materials were simplified versions of the clinical setting. Sawbone tibia analogues were used rather than human or animal cadavers. These analogues were the same as those used in [78]. The blocks are made of two different densities of sawbone in order to represent cancellous (12.5 pcf) and cortical bone (400pcf). The sawbone is cut to simulate the shape matching a 9mm depth resection plane of a medium sized tibial specimen. The cortical sawbone makes a 2.5mm ring around the cancellous bone. The tibial base plates have been provided by Corin.

EXPERIMENTAL SETUP

The underside of the tibial base plate (but not the stem, as per the surgical technique) was thinly layered with 2:1 bone cement and press fitted to the sawbone. A custom made aluminium ring was fitted to the tibial tray using screws to secure it in place. The ring has three small clamps attached to it into which 3 LVDTs (+/-1.5mm) were placed. The tip of these LVDTs rested on aluminium shelves attached to the side of the sawbones through the
use of ethyl cyanoacrylate. This whole structure was clamped to the base of an Instron (Illinois Tool Works Inc.). On top of the tibial base plate, a 12mm diameter, 0.6mm thick piezoelectric sensor was attached using a thin layer of ethyl cyanoacrylate, see figure 6.1. Wires soldered to this sensor were attached to a Via Bravo Impedance Analyser (AEA Technology).

Figure 6.1 Experimental set up of progressive loosening experiment.

Figure 6.2 Location of LVDTs from a top-down view of the tibial base plate.
EXPERIMENTAL PROTOCOL

Initial frequency impedance readings were taken from the piezoelectric sensor via the via bravo impedance analyser. The frequency range was set to sweep between 180 KHz and 360 KHz, the reasoning behind this choice of frequency is explained in chapter 4.

The tibial base plate was then cyclically loaded between 300N and 3000N at a rate of 1Hz and a sine loading profile. These loads are slightly higher than those experienced in normal walking [339] however; they were used in order to accelerate the loosening process. The load was located on the lateral side of the tibial base plate and applied via a flat faced 5mm diameter actuator. As the sample was loaded readings were taken from the three LVDTs. The LVDTs were attached to a data acquisition device (Fylde) and MADAQ software was used to record the micromotion of the tips of the LVDT which, due to their fixed attachment to the tibia base plate represents the relative motion between the base plate and the sawbone. Ten cycles at this load were performed while the LVDTs output was recorded. The mean amplitude of the LVDT sinusoidal traces was taken as a representative of the relevant movement between tibial base plate and sawbone.

After several tens of thousand loading cycles, it became clear that the implant was not going to loosen within a realistic timescale. Loosening was therefore induced by making a cut at the interface of the implant/bone construct using a fine toothed saw. The location of which is represented in figure 6.3. The sample was then loaded for 10,000 cycles at a rate of 5Hz and load between 300N and 3000N, again, these loads and load rates are greater than experienced in normal gait [339] but were required to accelerate the rate of loosening. Once this loading was completed, a frequency sweep between 180 KHz and 360 KHz of the sensor was made and the frequency impedance graph recorded. The system was then loaded once more in order to gain LVDT readings. To acquire these readings the system was loaded at a rate of 1Hz and loads of 300N-3000N for 10 cycles. In order to find the average micromotion the mean amplitude of the LVDT readings was calculated. This process of cutting, loading and taking readings was repeated until the entire circumference of the bond had been cut and is outlined in figure 6.4. The progressive cutting pattern is shown in figure 6.3
Figure 6.3 Diagrammatic representation of cut locations made between the base plate and sawbone. Progressive cuts were made with measurements of LVDT movement and sensor impedance made between each successive cut. Successive cuts are numbered left to right, top to bottom.

Figure 6.4 Representation of experimental cutting, loading and data acquisition for progressive loosening experiment.
POST PROCESSING

Data is processed in the same way as the previous experiments. The impedance traces were differentiated and a mean value given to each differentiated trace.

6.3 RESULTS

Results from four of the five samples are shown in figure 6.5. Sample five has been excluded from the results due to an experimental error causing the implant to break completely away from the sawbone during one of the cuts. The blue, green and red lines on each of the four graphs show the micromotion measured from the three LVDTs whose positions around the implant are indicated in figure 6.2.

The LVDT readings from all four samples show similar trends. Between no cuts and cut number 6, the results of all three LVDTs in all four samples show very little increase in micromotion. The mean change in micromotion between no cuts and 6 cuts is 0.02mm, 0.01mm, 0.05mm and 0.04mm for each of the four samples respectively. A larger change in micromotion is seen after cut 6; sample one, two and four show a mean increase in micromotion of 0.44mm, 0.42mm and 0.48mm respectively. Sample three also shows an increase in micromotion between cut 6 and the final cut 9; however, the two LVDTs at position 1 and 2 show a decrease between cut 8 and 9 of 0.38 and 0.35 respectively. This is unexpected and likely an experimental anomaly.

The piezoelectric sensor data varies between the 4 samples. The mean differential impedance values are shown the graphs in figure 6.5 and will be considered first. In sample one the mean differential of the frequency-impedance of the piezoelectric sensor over the complete test covers a range of only 0.80. Similarly, sample four covers a range of 0.78. However, the data from the piezoelectric sensor in sample four shows an overall increase trend of 0.54 whereas the sensor in sample one shows a decrease of 0.37. The changes in mean impedance differential of the two sensors is minimal, only 2.87% increase for sample four and 1.66% decrease in sample one. Sample three is the only other sample that shows an increase in its piezoelectric sensor data (+16.39%). The data collected from sample two piezoelectric data differs from the other samples; the majority of the piezoelectric sensor readings in sample two are much greater than the others. The mean value of differential impedance as the sample is progressively cut, is approximately twice (43.30) that as the values found in sample 1 (21.96), sample 3 (26.12) and sample 4 (18.85).
Figure 6.5 LVDT and Piezoelectric sensor results from 4 samples from progressive loosening experiments. The loosening cut is represented on the x axis where each of the numbers corresponds to cuts between the sawbone and implant as shown in figure 5.2. The left hand y axes shows the micromotion measurements from the LVDTs and the right hand y axes scale shows the mean differential impedance of the frequency impedance traces taken from the piezoelectric sensor.

The peak impedance of the sensors is plotted alongside the LVDT micromotion measurements in figure 6.6. The peak impedance values of each sensor do not follow a consistent pattern between the four different samples. Samples 2-4 show very little variation in impedance peaks as the tibia plate is loosened from the bone with a maximum percentage variation from max peak of 0.33%, 0.54% and 0.57% respectively. Sample one shows the greatest variation, but this is still only 2.78%. With such small variations in peak impedance as the implant is cut away from the sawbone assessing the trend of the changes is not useful as variation is small enough to be due to experimental error.
Figure 6.6 LVDT and Piezoelectric sensor results from 4 samples from progressive loosening experiments. The loosening cut is represented on the x axis where each of the numbers corresponds to cuts between the sawbone and implant as shown in figure 5. 2. The left hand y axes shows the micromotion measurements from the LVDTs and the right hand y axes scale shows the peak impedance of the frequency impedance traces taken from the piezoelectric sensor.
6.4 DISCUSSION

6.4.1 MOST IMPORTANT FINDINGS

The findings from this study are inconclusive. It was hypothesised that as the bond between the implant and bone substitute was progressively loosened the peak impedance and mean differential of frequency impedance signals taken from a sensor placed on the top face of an implant would increase. The results from the four experimental samples, shown in figure 6.5 and 6.6 indicate that this is not the case for these specific experiments. The small variation in peak impedance across all loosened situations in each of the four samples (max variation of 2.78%, sample one) and the fact that none of the four samples follow similar trends in peak impedance as the sample loosens, indicates that this variation is likely not related to the loosening that is taking place between the implant and sawbone (as indicated by the increase in micromotion that is measured from the three LVDTs). Instead, this variation must be explained by other factors. As it is such a small percentage of variation it can be considered to be due to experimental error.

The mean differential impedance values were also predicted to increase as the samples were loosened. This however was only the case for samples 3 and 4. The increase of sample 4 mean differential impedance is only 2.87% and can be discarded as insignificant. Sample 3 on the other hand increased by 16.39% between readings taken from the fully attached implant to the loosened implant. The decrease in sample on mean differential of 1.66% can again be discarded as experimental error. Sample 2 is an anomaly in terms of mean differentials impedance peaks. It shows values of approximately twice those shown in the other three samples. High values in mean peak differential relates to increased number of modes of vibration. Which are predicted to appear in more unstable structures (i.e. in structures with a loose bond present) as explained in chapter 2. It is therefore possible that the high values present in sample 2 are due to a weaker bond between sensor and implant which is picked up by the sensor.

Above has explained the causes of possible minor variations in data. There are several possible explanations as to why the data trends for both mean differential and peak impedance did not increase as hypothesised, and why these experiments did not show the sensor capturing data indicative of the induced implant loosening.

- The sensing region of the piezoelectric sensor was not of optimal size-the dimensions of a piezoelectric sensor dictates the range over which it is
sensitive to changes in the mechanical properties of host structures (see chapter 2 section 2.4.3).

A sensing region that is too small would mean that the sensor would not detect changes in the bond between implant and bone and instead would only detect the mechanical properties of the material in the immediate surrounding area of the sensor, such as that of the bond between sensor and implant or the those of the implant but not reach the implant sawbone bond. A sensing region that is too large would result in the sensor detecting changes in boundary condition and structural changes beyond the implant sawbone bond. If these changes were substantial the deviations they would cause in the frequency impedance graphs could mask those created by the breakdown of the implant sawbone bond. This is perhaps less likely than the ‘too small’ sensing region.

The previous experiment on cement curing (described in chapter 4) used piezoelectric sensors with the same dimensions of those used in this experiment. The results from chapter 4 indicated that the sensors were detecting changes in the bonding between the implant analogue and sawbone block. This indicated that the sensors range of detection was of appropriate size to detect the bond located 5mm below its position. The thickness of the implant used in the progressive loosening experiments was approximately 2mm; comparable to the aluminium plate used in chapter 4. As such, the same dimension sensors were used in this experiment and should theoretically have an appropriate sensing range. In addition to this Park et al [281] states that higher frequency ranges (>200KHz) provide ‘local’ damage detection and the ranges used in this experiment are high, between 180 KHz and 360 KHz.

• **Sensor sensitivity was not fine enough to identify the induced loosening**

The sensitivity of a piezoelectric sensor is dependent on the excitation frequency[281]. High frequencies create smaller wavelengths, which are able to detect more minor changes in host structures[281]. The frequencies used within this study are considered high suggesting that the sensors should have adequate sensitivity to detect minor changes in bond integrity.

### 6.4.2 Limitations

There are several limitations in this experiment. General limitations, that span other experiments in this PhD, such as specimen material, will be addressed in section 7.4 of
chapter seven. A specific limitation to this chapter surrounds the artificial loosening of the implant from the sawbone. Although LVDTs have been used to establish that loosening is occurring, the exact nature of the loosening depends on precision of the cuts made to the cement bond. These cuts were made with a hacksaw. The aim was to progressively deteriorate the bond between the sawbone and cement, as opposed to the implant and sawbone, however, although all care was taken to achieve this, the process of manually cutting the bond, on occasion may have resulted in breaks developing into the sawbone or into the cement rather than directly between the two. This impact on impedance of this manner of inducing faults may be trivial or inconsistent. This process should, however, be similar to the failure pattern of the implant-bone interface in vivo. A further limitation is the low number of samples used. This was due to time and material constraints and the availability of tibial trays from the manufacturer (Corin). Further tests on more samples are needed, as is a consistent way of creating a loosened boundary between the cement and saw bone. A potential improvement would be to induce loosening solely through the use of a loading profile. This however would be very time consuming.

6.4.3 Comparison with Published Research

There has been no previous research that implements the use of piezoelectric sensors in the detection of interface breakdown between an implant and sawbone. However, there has been previous work to investigate the effect of the loosening of bolts within structures [295, 340, 341]. Mascarenas et al [341] carried out such investigations and his set up is shown in figure 6.7. He found that readings from the two PZTs (locations indicated in figure 6.7 were able to detect a loosened bolt but unable to distinguish between which of the two bolts had been loosened, indicating a universal problem with pinpointing the sensing range of sensors and in locating damage in this manner and consistency in results with our experiments. One solutions to the problem was to place piezoelectric sensors on the nuts and washers[341], as seen in figure 5.8. This is clearly not possible in the orthopaedic implant application.
6.4.4 CONCLUSION

Although the results from the experiments described in this chapter are inconclusive, evidence from the previous chapter and from literature indicate that, with appropriate modifications, further experimental work may be able to establish the changes required in implementing impedance analysis to the problem of implant loosening. Such modifications are explored in section 7.5 of chapter 7.
7 DISCUSSION AND CONCLUSION

The work described in this thesis has been concerned with the investigations into the ability of piezoelectric sensors to monitor the integrity of the cemented bond between bone and implant. The integrity of this bond has been shown in chapter 2 to be vital to the success of an orthopaedic implant and the development of sensing unit that could be integrated within an implants design and is capable of detecting the break down of such a bone would be a valuable addition to the process of creating more advanced implants.

This chapter incorporates the findings from all three experimental chapters (chapters 4, 5 and 6) and the information gathered from the literature review presented in chapter 2 in order to establish the effectiveness of this thesis in addressing the research question as to the feasibility of piezoelectric sensors in the application of implant loosening detection.

The chapter will begin with addressing the empirical findings and their clinical implications. The limitations of the study as a whole will be discussed and potential future improvements on and new experiments will be described. Finally, a conclusion about piezoelectric sensors and loosening detection will be stated.

7.1 EMPIRICAL FINDINGS

The main empirical findings are chapter specific and were summarized within the respective chapters: Chapter 4: Cement Curing, Chapter 5: Static Loosening and Chapter 6: Dynamic Loosening. This section will synthesize the empirical findings to answer the study’s research question.

- Are piezoelectric sensors a feasible solution in the creation of an instrumented implant capable of monitor the Integrity of the cemented bond between bone and implant?

a. Piezoelectric sensors can determine at what point the PMMA bone cement between sawbone and an aluminium plate has cured: Experimental results show a clear decrease in peak impedance as the cement between a block of sawbone and aluminium plate cures. Following this decrease a distinct plateau is evident indicating that further physical changes are no longer effecting the impedance of the sensors. Calculating the time at which this plateau occurs it is possible to determine the time at which the cement no longer indures physical changes and hence can be said to be the time at which the cement is cured.
b. Through the use of piezoelectric sensors it is possible to distinguish between different levels of cement coverage between sawbone and aluminium plate with an accuracy of up to 92%: Experimental results have shown that, through the use of SVM classifiers, the sensors can determine between 3 classes of cement covering with an accuracy of 92% and between 5 classes with accuracy of 83%.

c. Further investigations must be carried out in order to establish the ability of piezoelectric sensors in the detection of progressive loosening between bone and implant: The results from the experiments described in chapter 6 were shown to be inconclusive in proving piezoelectric sensors can detect progressive loosening between an implant and a sawbone tibia. However, due to the promising results from the other two experimental chapters, and the previous work on the use of piezoelectric sensors in bolt loosening investigations, this application of the sensors should not be discarded. Further investigations could provide additional information on how the sensors could be adapted for application in orthopaedic. Additional investigations are described in section 7.5 of this chapter.

7.2 RELEVANCE TO PUBLISHED RESEARCH

This thesis describes the first attempt of translating the use of piezoelectric sensors and impedance analysis to the field of orthopaedics. Multiple studies have used piezoelectric sensors to detect changes in the structural integrity of materials (see chapter 2 section 2.4) and multiple studies have looked into implementing smart implants to detect orthopaedic implant loosening (see chapter 2 section 2.3). There is only one study that takes impedance analysis technology and implements it in the field of orthopaedics [336]. Despas et al.’s work differs from the work presented in this thesis in two key aspects. Firstly the focus of Despas is work is solely on the measurement of cement curing, and although it investigates in depth techniques that could be developed into a self-sensing implant it is not made clear that this is the authors intentions. The second difference is that Despas is directly measuring the electrical properties of the cement without the use of piezoelectric sensors. Although still monitoring the impedance, Despas is interested in the chemical reaction taking place in the cement and how this affects its electrical properties. In contrast this PhD monitors the physical material properties of the cement through mechanically coupling it with piezoelectric sensors. This difference is mostly due to the ultimate aim of each separate study. Despas is fundamentally concerned with the curing of the cement whereas this study is interested not only in how the cement cures but also how its bond between implant and bone breaks down
with the prospect of developing a ‘smart’ knee replacement that can self-monitor for loosening.

7.3 **CLINICAL IMPLICATIONS**

The research presented in this thesis has great potential in the application of diagnosing loose implants, as well as the potential to aid surgeons as they monitor cement curing intraoperatively.

Chapter four details the effect that the cement curing process has on the frequency-impedance trace of a piezoelectric sensor attached to the topside of an aluminium tray which is being cured to a sawbone block with PMMA cement. The results indicate that the PZT sensor can determine a distinct time point at which the physical properties of the cement cease to change, indicating the cement has cured. Further development of these sensors could lead to the creation of a system to quantify this cement cure time and mean orthopaedic operations that utilise bone cement would only progress with procedures once cement had fully cured. This would insure the complete fixation of implanted devices before further manipulation of the limb in the operation leading to reduced risks of creating problems with the initial fixation of devices which in turn can lead to future risks to the patient [338].

The support vector machine performed in chapter 5 strengthens the theory that piezoelectric sensors are capable of providing information on the cement bond between an implant and bone. With appropriate further work, the application of piezoelectric sensor to smart implants could prove invaluable in the quest to earlier, less intrusive diagnosis of implant loosening. The clinical benefits of using smart implants to detect loosening include:

- Earlier detection:
  - Reducing time period patient is in pain.
  - Reducing time of potential bone break down
  - Potential for earlier interventions
- Reduce demand for x-ray diagnosis
- Reduce unnecessary exposure of patient to radiation

7.4 **LIMITATION OF THE STUDY**

As with all experimental work, there are inevitable limitations. Specific limitations have been discussed in the relevant chapters along with explanations as to how the effect of
these limitations have been minimised. General limitations that span the entirety of the experimental work in this thesis are discussed here.

**SPECIMENS**

Polyurethane foam was used for all the experiments carried out in this thesis. The polyurethane foam blocks not only differ from biological bones in terms of material properties but also in terms of geometry and surrounding boundary conditions. However, they do allow for repeatability across the tests. More discussion on the reasons behind choosing sawbone as the test subject can be found in chapter 2 section 2.2.3.

**TEST RIG AND LOADING**

Within this thesis loads were applied to samples to create loosening between the implant and sawbone. The loads used were slightly higher than those experienced in normal walking [339] however; they were used in order to accelerate the loosening process. Another deviation of these loads to physiological loads is they were purely compressive loads. In reality loads to the knee are more complex. The justification of using simplified loading profile is that this study was concerned with measuring loosening, how this loosening occurred was not of prime concern, what mattered was that loosening occurred and this was verified by the increase micromotion measured by the LVDTs.

**ENVIRONMENTAL VARIATIONS**

Environmental conditions of the experiments were not controlled to in vivo specifications. This would be a potential point to take forward with further study as although external conditions were not prominently important when comparing curing times, since these tests were paired comparison tests where the same sample of cement under the same conditions were being compared to each other, one sample being assessed by a surgeon and the other by sensors for the time at which they cured. However, reproducing these experiments in water baths to represent more physiological conditions would be a step closer to firmly concluding the possibility of using these sensors within the body.

**HUMAN ERROR**

There are several points within these experiments where human error may have played a role in the results gained. To reduce the impact of these errors as many samples were tested as possible. Human error was likely to have occurred at the following times:
• Hand mixing the bone cement—although every effort was made to ensure the mixture was fully mixed times to achieve this may have varied slightly across tests and there is always the potential that parts of the cement was not fully formed.

• Inducing loosening between cement and sawbone during the progressive loosening tests.

SIMPLICITY OF EXPERIMENTS

The experiments performed in each of the three experimental chapters (chapter 4, 5 and 6) were all performed on simplified versions of what would be the situation in vivo. Firstly, the experiments were performed using Sawbone which in its self differs slightly in its mechanical properties to bone. However, more importantly to this mechanical properties difference is the that in an in vivo set up there would be the addition of more complex bone geometries as well as the additional complexity of soft tissue such as muscle, fat and ligaments. In addition to this, the artificial boundaries between Sawbone and implant were very, regimented in their structure, in a clinical situation it is much more likely that the break down in the interface would be more sporadic and follow less of a structure. All these factors could play a part in the resonance response of the piezoelectric material. These sawbone experiments allowed excellent repeatability and provided initial evidence of piezoelectric sensors ability to distinguish between difference in fixtures of simple geometries. However, additional further work into more complex geometries and even cadaveric experiments would be recommended to gain evidence that the sensors could work in vivo.

7.5 FUTURE WORK

Following the promising results from the three main experiments carried out in this thesis and outlined in section 7.2 of this chapter, this work could be further developed in a number of ways. Future work can minimize the current limitations and progress investigations to the point of clinical application.

7.5.1 IMPROVEMENTS TO THE RESEARCH PROTOCOLS

There are several improvements that could be made to the current experimental protocols:
• Increase the number of repeats in each of the three experiments, particularly in the progressive loosening experiment.

• Have multiple surgeons provide predicted curing times of the bone cement.

• Carry out cement curing experiments in controlled temperature environment representative of body temperature.

• Use more clinically relevant samples in the cement curing experiment: Initially use real implants on sawbone tibias (like those used in the progressive loosening chapters described in chapter 5) then progress to the use of cadaver knees to test the sensors performance in a situation which more closely represent the conditions, particularly the boundary conditions around the implant.

• Investigate different locations of sensor placement.

• Investigate the use of different sensors with different dimensions.

7.5.2 Future research directions

Creating an intra-operative sensing device to detect when bone cement has cured

The results of chapter four concluded that the surgeon predicts bone cement to have cured before it has reached a steady state of being. This is potentially problematic for the patient since preemting the cure time may lead to progression of surgery before the implant is completely secured which in turn can lead to complications, for example: mall alignment or initial instability of the replacement [338]. By further developing a system of simple PZT sensors it may be possible to more accurately determine intra-operatively when cement has fully cured, there is potential that they can be developed into intraoperative sensors to aid orthopedic surgeons in the determination of when it is ‘safe’ to continue with a joint replacement surgery after the cement has been applied. In order to achieve this goal further investigation into incorporating sensors into an implant would need to be undertaken as would optimisation of the size and placement of sensors. In addition to these practical advancements, work would need to be undertaken to educate and encourage medical staff to use such sensors.

Creating an instrumented sensing device to detect when bone cement has cured

The sensors used in this PhD are small and will be able to be easily embedded within an implant. One of the great advantages of them is that they are passive sensors and hence no other electrical components, excluding a coil of wire, will need to be embedded within the implant along side the sensor. In order to to transmit information from the passive sensors a coil would be in bedded within the implant along side the sensor. This internal coil
will be electrically coupled with an external coil, outside the body, which, when a current is passed through it will induce one in the internal coil and hence the sensor. This concept is shown in figure 7.1 and a complete conceptual design of the potential self sensing implant system is shown in figure 7.2.

Figure 7.1 Concept of using an external and internal coil to interrogate an embedded sensor.
This study is unique in its approach to instrumenting a knee replacement and its results show evidence that, with further work into utilising the structural health monitoring technique of impedance analysis through the use of PZTs within this application, piezoelectric sensors are a very viable choice for self-diagnosing implants.


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