Understanding Failures of Artificial Joints through Engineering Analysis

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Abstract

The aim of joint arthroplasty is to reduce pain and improve the range of motion and functionality in joints affected by diseases such as osteoarthritis and rheumatoid arthritis. Data recorded in National Joint Registries offers the clinical perspective in relation to prosthesis failures; however, this does not explain why a prosthesis has failed.

Surgeons performing revision surgery for different implants often report similar findings, despite designs of prostheses and the natural joints having numerous differences, including anatomy, loading and range of movement. The underlying factor in the majority of cases of implant failure is complications arising as a result of wear debris.

To understand the failures of artificial joints, a series of studies were performed examining hip prostheses in pre-clinical and post-clinical scenarios and finger prostheses in a post-clinical scenario. The pre-clinical studies focussed on areas including: the effect of acetabular shell deformation; and validating a method to measure volumetric wear from femoral stem trunnions. The deformation studies included an investigation of how bone strength influenced deformation. The post-clinical studies involved analysing retrieved finger and hip prostheses, to quantify the damage surfaces had sustained in vivo. Analysis of the finger prostheses involved the use of a non-contacting surface profilometer, to determine the surface roughness, whilst for the hip prostheses a coordinate measuring machine was used to quantify the volumetric wear.

The deformation studies found that the maximum deformation was 340 µm, which could be sufficient to disrupt the assembly process of modular acetabular components. The strength of the bone was not found to correlate with the size of the deformation. The validation study found that the coordinate measuring machine was able to measure trunnions with a maximum error of 0.13 mm³ compared with gravimetric measurements. The ex vivo cohort of trunnions had a median wear volume of 0.14 mm³ (range 0.04 – 0.28 mm³).

The first finger study analysed coated, metal-on-metal prostheses finding that prostheses had suffered extensive wear on the articulating surfaces. This was hypothesised to be due to the failure of the coating interface, resulting in a hard

"grinding paste" that wore the articulating surfaces. The second finger study examined a cohort of explanted pyrolytic carbon prostheses. Even after use in vivo the roughness average (R_a) for the articulating surfaces was below the 50 nm specified by British Standards as the maximum R_a for orthopaedic implants manufactured from metal or ceramic.

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Figure 1: Photos of the two piece LPM PIP prosthesis taken intra-operatively during implantation

Figure 2: Photo of the PIP joint following revision surgery. Note the blackened staining of the surrounding soft tissue indicative of metallic wear debris

Chapter 1. Introduction

1.1.   Joint Replacement

The aim of joint arthroplasty is to reduce pain and improve mobility in damaged joints, when other less invasive treatments have failed to improve the patients' symptoms. Whilst the vast majority of joint replacement prostheses are well functioning, a small proportion do require revision arthroplasty to replace the prostheses [1]. To document the performance of arthroplasty procedures the National Joint Registry (NJR) was established in 2003. Initially the NJR only documented procedures performed in England and Wales; however from 2013 procedures from Northern Ireland were also included. In 2013 170,935 procedures were documented in the NJR of which 16,145 were revisions[1]. This represented an overall total revision burden of 9.44 % (Table 1), with knee arthroplasty having the lowest revision burden per joint at 6.7 % [1].

Joint	Total number of operations	Number of revisions	Revision burden (%)	Clinical reasons for revision (%)
Hip	80,194	9,751	12.2	Aseptic loosening (38)
				Pain (22)
				Adverse soft tissue reaction (14)
Knee	85,920	5,783	6.7	Aseptic loosening (32)
				Infection (23)
				Instability (15)
Ankle	532	73	13.7	Aseptic loosening (47)
				Undiagnosed pain (41)
				Suspected infection (26)
Elbow	395	113	28.6	Aseptic loosening (56)
				Infection (21)
				Instability (19)
Shoulder	3,894	425	10.9	Conversion from hemi to total arthroplasty (31)
				Cuff insufficiency (26)
				Other (23)
Total	170,935	16,145	9.44	

Table 3: Revision rates and the top three reasons for revision for joint arthroplasties as listed in the 2014 NJR Report

Interestingly hip arthroplasty, regarded by Learmonth et al. as an extremely successful procedure [2], had a higher revision rate than that of knees at 12.2 % for a similar number of primary operations [1]. Both cohorts had comparable mean average ages at primary surgery: 68.78 years (stdev 11.43) for hips and 69.28 years (stdev 9.64) for knees [1], therefore the difference is unlikely to be linked with age. Both cohorts also had a comparable patient physical status grading [1].

The main reason for revision for both hips and knees was aseptic loosening [1], accounting for 38% of revisions in hips and 32% in knees [1]. This equated to 3705 hip revisions and 1851 knee revisions, or a 2:1 ratio [1]. One important difference is that in 2013, 14% (1365 procedures) of hip revisions were performed for adverse soft tissue

reactions [1]. Both aseptic loosening and adverse soft tissue reactions are associated with wear, giving a combined total of 5070 wear related hip revisions. This is close to the number of knee prostheses revised (5783) for any reason in 2013 [1].

It is therefore likely that the difference in performance between hips and knees is linked to the wear performance of the prostheses. For hips there are a number of poorly performing prostheses such as metal-on-metal (MoM) based articulations, which have higher than average revision rates [1]. An example of this is the DePuy Articular Surface Replacement (ASR) (DePuy Synthes, Warsaw, IN, USA), which had a cumulative percentage probability of revision at 10 years of 30.36% [1].

The highest revision rates recorded by the NJR were for elbow and ankle implants [1]. In all revision arthroplasties except shoulders, aseptic loosening was noted to be in the top three reasons for revision arthroplasty (Table 1). For shoulders it was the fourth highest cause, listed in 14% of revisions [1].

The NJR has proved a valuable tool in helping to identify trends in prosthesis performance. By providing relatively "real time" data, surgeons are able to identify particular types of prostheses that are performing below the minimum acceptable threshold, which for hips is a revision rate no greater than 5% at 10 years [3]. For example the Australian National Joint Registry identified issues with the ASR approximately 3 years before it was removed by DePuy from the market [4].

Whilst the NJR is a valuable database there are still improvements that could be made. One of its drawbacks is that no data is collected on prostheses from joints such as the wrist, fingers or toes [1]. This is likely due to the small number of procedures performed in comparison to the other joints listed in the registry. One registry which has recorded data on such joints is the Norwegian Arthroplasty Registry, however it last published an annual report in 2010 [5]. To contextualise the difference in joint numbers, in that year a total of 8224 hip procedures were documented compared to just 102 metacarpophalangeal joint arthroplasty procedures [5]. A useful expansion for the NJR would be to include arthroplasty procedures from all joints.

Failed implants cause not only suffering to the patients, but also have substantial cost implications. This is particularly significant at a time when there is considerable pressure to reduce expenditure. The total cost of revision procedures has

dramatically increased within the last decade. With regards to hip replacements, in 2003 there were 2325 (9.3 % of procedures) hip revision procedures, whilst in 2013 that number had increased to 9751 (12.2 % of procedures). In 2012 Vanhegan et al. noted that for hips, revision costs can vary substantially depending on the reasons for revision [6]. The study reported a mean cost for an aseptic revision of £11,897 and a mean cost for peri-prosthetic fracture of £18,185 [6]. An additional consideration is that these increasing numbers of revision procedures are being performed due to poorly performing prostheses, such as MoM THR and hip resurfacings which are becoming more difficult to treat [1]. MoM prostheses in particular are associated with adverse reactions to metallic debris which can result in substantial tissue destruction [7].

If the number of revisions continues to rise then it could reach a point where it is no longer sustainable given the current economic climate. It is therefore imperative to learn from and prevent failures by examining how prostheses function, as any improvement in their performance could have dramatic and positive implications.

1.2.   The role of engineering analysis

Whilst National Joint Registries offer the clinical perspective in relation to prosthesis failures, this does not explain why a prosthesis has failed. By examining retrieved prostheses using engineering analysis it is possible to understand how and why failure has occurred. Typically, such analysis would include quantifying the volumetric wear, however in situations where this is not possible the surface roughness is examined, as it has previously been associated with wear [8] [9]. In particular the parameter roughness average (R_a) was found to correlate with wear [9]. Such ex vivo analysis has proved effective for a variety of different prostheses including: Charnley [8] [10], ASR [11], MoM hip tapers [12], silicone fingers [13] [14] and ankles [15].

Explant analysis is not a new concept with numerous studies identifying issues surrounding prostheses. For example in the 1990s there were various publications examining explanted metal-on-polyethylene (MoP) prostheses with the aim of determining links between polyethylene wear and variables such as friction, surface roughness and head diameter [8] [10] [16] [17].

In 1998 Elfick et al. investigated the correlation between the femoral head radius and patient parameters [17]. The study measured the volumetric wear rates using a shadowgraph technique and Kabo formula, in addition to calculating the clinical wear factor using a linear regression analysis. The principal finding was the detrimental effect of a larger femoral head, which was reported to increase volumetric wear rate [17]. The advantage of the clinical wear factor was that it enabled a comparison between the wear performance of a prosthesis despite the difference in patient activity levels [17]. A prosthesis should therefore have the same clinical wear factor regardless of being implanted in an active or sedentary patient [17].

Langton et al. examined ex vivo ASR MoM hip prostheses using a coordinate measuring machine (CMM) to determine the wear volume and location of the worn region. The rationale was to determine why this prosthesis had a higher failure rate than other MoM prostheses [1 7 18]. The research identified that the key reason was that the ASR acetabular cup had a relatively small arc of cover (the subtended angle to the articular surface) of between 144° and 160° depending on the diameter of the acetabular cup [19]. This made the ASR particularly prone to "edge loading" where the contact patch of the femoral head extends over the rim of the acetabular cup, resulting in accelerated wear rates [20 21]. Due to this shallow arc of cover the ASR was particularly vulnerable to suboptimal positioning. Optimal positioning was defined by Langton et al. as inclination 40° and 50° and anteversion of 10° to 20° [7].

The studies by Langton et al. examined a large number of variables to determine the failure mode of the ASR. In addition to providing wear volumes, Lord et al. later provided a full engineering validation of the CMM wear volume methodology [22]. However one minor drawback is that the studies by Langton et al. examined ASR prostheses predominantly from one hospital, potentially leading to biased results [18 23 11]. The ASR was available as both a MoM total hip replacement (THR) and a hip resurfacing with both prostheses utilising the same acetabular component.

Whilst joint registries identified higher than expected revision rates with the ASR, engineering analysis showed that the failure mechanism was linked to a specific design feature, namely the shallow arc of cover. In 2010 the ASR was removed from the market after being implanted into an estimated 93,000 patients worldwide [24 25]. The ASR has subsequently been described as "one of the biggest disasters in orthopaedic history" [26].

Following the work on the ASR Langton et al. investigated why MoM THR prostheses had higher revision rates compared with their resurfacing counterparts. In 2012 the results of a study examining two different prostheses, the ASR and the Pinnacle, both manufactured by DePuy, were published [12]. Again a CMM was utilised to quantify the wear volume. The conclusion of the study was that the female taper surface of the femoral head of the THR was responsible for the increased revision rate of THR prostheses [12]. Large femoral head diameters, varus stems and lateral engagement of the trunnion with the taper were noted as potential contributing factors to taper failure [12]. The term trunnion refers to the tapered cone at the top of the femoral stem, which was designed to connect with the taper on the femoral head.

This study had several strengths. Firstly it was the largest cohort of prostheses to undergo taper volumetric wear analysis reported in the literature (n=126). Secondly the CMM directly measured the taper surface, rather than taking a cast and measuring this surface, as is required in optical systems, such as the Redlux [27]. Thirdly it quantified the volumetric wear rather than scoring the surfaces visually using semi-quantitative fretting and corrosion systems, such as that developed by Goldberg et al, as has previously been reported for taper analysis [28] [29] [30] [27] [31] [32] [33] [34] [35]. An added benefit over such scoring systems is that the CMM does not suffer from inter and intra user variability. It is however, important to note that Langton et al. only examined two types of MoM hip replacements [12].

Explant analysis has also been utilised for prostheses from other joints. In 2003 Joyce reported on a cohort of 12 silicone based metacarpophalangeal (MCP) prostheses noting that 10 of these had completely fractured at the junction of the distal stem and the hinge of the prosthesis [36]. The study concluded that the fractures were due to the subluxing forces experienced in rheumatoid MCP joints. To reduce the risk of such fractures occurring the design of the Swanson, another silicone based finger prosthesis, was altered incorporating metal grommets to reduce the risk of fracture at the junction. In 2014 Kanzaki et al. examined the clinical outcome of silicone Swanson metatarsophalangeal joint prostheses with and without grommets [37]. The study noted that the use of titanium grommets appeared to protect the implant and improve the clinical outcome [37].

Engineering analysis can of course be, and is also used in, a preclinical context to examine a range of different parameters. An example of this is using a hip simulator

to simulate the wear performance of a prosthesis across millions of cycles. When using a simulator it is important to understand what exactly is being simulated. In 2010 Kamali et al. offered an explanation as to why hip simulators were reporting lower wear rates than for ex vivo MoM hip prostheses [38]. The authors noted that hip simulators repeatedly perform identical loading patterns to many cycles, however in vivo the loading and movement is more extensive, creating a less favourable lubrication regime than that achieved in a simulator [38]. In an effort to more closely simulate in vivo performance for MoM, the authors proposed a loading and motion cycle to mimic typical daily activities such as climbing stairs [38].

One method of determining the wear performance of a prosthesis is using wear simulators in pre-clinical testing. As wear has been reported to be one of the largest limiting factors in the longevity of implants [39], it is important to fully wear test prostheses prior to clinical use. Such simulator tests should include testing at suboptimal positions to determine worst case scenarios, as this has been shown to be key in the performance of implants such as the ASR hip [40]. This can reduce patient risk by identifying prostheses with high wear rates before they are implanted.

There are however several major limitations associated with simulators. Firstly does the simulator fully recreate the natural biomechanics of the intended joint? This is an important consideration as the wear rate may not be accurate if the simulation is not indicative of the natural biomechanics.

Another limitation is the length of time required to perform a clinically relevant simulation. To run a simulation to 500,000 cycles can take approximately a week depending on the frequency. This includes the time to take measurements. Therefore to run a simulation to 10 million cycles would involve the simulator operating for a period of several months, this time is however much shorter than running a clinical trial. This is therefore a significant advantage over clinical trials. It should be noted that there is debate surrounding how many cycles actually equates to a year in vivo service, as patient activity levels can vary greatly. Generally one million cycles has been accepted to represent one year in vivo [41], however for more active patients three to five million cycles may be a more accurate reflection [42].

In addition to the period required to run the experiments, each of these simulators can only test a limited number of prostheses at any one time. An example of this is the HUT 4 simulator, used by Saikko et al. which is capable of testing 12 prostheses

at any one time [43]. This is however deemed to be large capacity, as most simulators are only capable of testing a maximum of six prostheses simultaneously.

It is also important to mention that there are numerous challenges associated with running a simulator. The first is that an appropriate quantity of lubricant must be used throughout the test. Without this the prosthesis may not be properly lubricated resulting in it running dry, potentially leading to increased wear. The operator should regularly check the lubricant level and refill with deionised water as necessary [44]. In addition the lubricant should be completely replaced every 5×10^5 cycles [44].

Another challenge is that the components must be set up correctly. In addition to obtaining the correct inclination and anteversion, the centres of the axes of rotation for the head and cup of the hip prosthesis must be aligned [44]. This is an important factor for initial tests as it allows comparison between other prostheses tested at the same orientation. Following this, further testing can then be performed to determine how the prostheses perform with different set ups, including suboptimal positioning which has been associated with higher wear rates [45 46 47 48].

In an ideal situation wear would be quantified in vivo, enabling a clinician to determine if a prosthesis is wearing at a higher rate than expected. At present this methodology is suitable only for polyethylene cups where the penetration depth is sufficient that it can be measured on X-ray. An example of this is a programme named PolyWare (Draftware Inc, Ashland Cove Road, IN, USA) which has been utilised extensively in research to calculate wear from a range of different MoP THR prostheses[49 50 51 52 53 54 55]. Alternatively wear can be quantified in vivo by using computer tomography (CT) to calculate the change in thickness of polyethylene cups [56]. The software quantifies the depth of wear, rather than the wear volume, therefore does not offer the same level of precision as the PolyWare system.

1.3.   Other methods of quantifying joint performance

Whilst in vivo volumetric wear analysis is not currently available for MoM prostheses there is another way of determining the in vivo wear performance. When MoM prostheses wear, metal ions are released into the joint and eventually into the blood stream. Studies have noted that analysing blood metal ions is an effective method of identifying how a metal prosthesis is performing in vivo [57 19 58]. This advice is also offered by the NHS [59]; however there is still debate over the specific concentration of

metal ions at which a hip prosthesis is judged to be wearing abnormally. According to a Medical Device Alert issued by the Medicines and Healthcare Products Regulatory Agency (MRHA), if the blood metal ions are higher than 7 µg/L, equating to 119 nmol/L of cobalt or 134.5 nmol/L of chromium, then it is recommended that further investigations be undertaken [60]. However if there are other indicators of poor performance then prostheses could be revised below this value. In contrast, in 2013 the US Food and Drug Administration noted that there is not enough evidence to provide a threshold value of metal ions that would trigger revision surgery [61].

One of the most important factors to consider is patient satisfaction. Since 2009 all providers of NHS funded care have collected Patient Reported Outcome Measures (PROMs), which assess the quality of care from a patient perspective [62]. The aim was to provide some quantification on how satisfied patients were with the outcome of four different procedures including hip and knee replacements [62]. A similar method of performing such an assessment would be the Oxford Hip Score (OHS) or the Oxford Knee Score [63]. Patients are graded on 12 different questions which examine pain and the ability to perform tasks [63]. There are other methods such as the University of California Los Angeles (UCLA) activity scale that can also be used to quantify patient physical activity levels [64].

As described engineering analysis is useful in both a pre and post clinical context. By combining clinical data with engineering analysis a more detailed understanding can be developed with regards to prosthesis performance.

1.4.   Aims and Objectives

The overall aim of the PhD was to examine different problems associated with orthopaedic prostheses using engineering analysis. These problems were separated into four distinctive projects:

Investigation of acetabular shell deformation

Aims:

- Can acetabular cup deformation be accurately measured in cadavers?
- What is the size and nature of the deformation?
- Is there a relationship between bone quality and deformation?

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Objectives:

- Conduct a pilot study to test the suitability of the optical measurement system to measure acetabular cup deformation in cadavers
- Validate the system against a CMM
- Take bone samples from cadavers and quantify the mechanical properties, comparing results to the size of the deformation

Validating a method of calculating volumetric wear from femoral stem trunnions

Aim:

- Validate a method of calculating volumetric wear from the tapered cone atop the femoral stem (known as the trunnion) using a CMM

Objectives:

- Artificially induce wear in increasing amounts, on three different types of trunnions and measure wear volume with both a CMM and gravimetrically
- Examine an ex vivo cohort of trunnions using this methodology to provide a clinical context

Examination of the surface finish of the Exeter Trauma Stem (ETS)

Aim:

- Compare the surfaces of three types of cemented Exeter femoral stems

Objectives:

- Use a ZYGO interferometer to measure the surface roughness of each of the three types of stem
- Compare the results and perform statistical analysis

Examination of the articulating surfaces of retrieved finger prostheses

Aim:

- Determine the failure mode of two cohorts of ex vivo finger prostheses

Objectives:

- Quantify the surface roughness of both cohorts of prostheses using a ZYGO interferometer and compare the results to the British standards for new orthopaedic prostheses
- Measure the Leuwen Poeschmann Metal (LPM) prostheses' surface chemical composition using an environmental scanning electron microscopic (ESEM)

Chapter 2. Analysis of Published Work

The papers listed below examine a variety of orthopaedic problems in both pre-clinical and post clinical settings, using a range of engineering techniques.

Bone MC, Dold P, Flohr M, Preuss R, Joyce TJ, Deehan D and Holland J. A novel method for measuring acetabular cup deformation in cadavers. Proc IMechE Part H 2013;227(12):1341-1344

Dold P, **Bone MC**, Flohr M, Preuss R, Joyce TJ, Deehan D and Holland J. Validation of an optical system to measure acetabular shell deformation in cadavers. Proc IMechE Part H 2014;228(8):781-786

Bone MC, Dold P, Flohr M, Preuss R, Joyce TJ, Aspden RM, Deehan D and Holland J. The influence of the strength of bone on the deformation of acetabular shells. A laboratory experiment in cadavers. Bone Joint J 2015;97(4):473-477

Bone MC, Sidaginamale RP, Lord JK, Scholes SC, Joyce TJ, Nargol AV, Langton DJ. Determining material loss from the femoral stem trunnion in hip arthroplasty using a coordinate measuring machine. Proc IMechE Part H 2015;229(1):69-76

Petheram TG, **Bone M**, Joyce TJ, Serrano-Pedraza I, Reed MR, Partington PF. Surface finish of the Exeter Trauma Stem: A cause for concern? Bone Joint J 2013;95-B(2):173-176

Bone MC, Giddins G and Joyce TJ. An analysis of explanted pyrolytic carbon prostheses. J Hand Surg Eur 2014;39:666-667

Bone MC, Cunningham JL, Lord J, Giddins G, Field J and Joyce TJ. Analysis of failed Van Straten LPM proximal interphalangeal prostheses. J Hand Surg Eur 2013;38(3):313-320

2.1.   A novel method for measuring acetabular cup deformation in cadavers

Deformation has been reported as a potential risk factor for ceramic liner fracture in multi component acetabular systems [65]. Therefore the rationale was to perform a pilot study to investigate whether an optical system is capable of measuring acetabular shell deformation in cadavers.

The objective of the pilot study was to test the suitability of the ATOS optical system and identify key technical challenges. This was done by implanting six custom designed uncemented titanium acetabular shells into cadavers and measuring the deformation. Each shell was measured prior and post implantation using the ATOS optical system [66], with the results compared to determine the total amount of deformation the shells experienced.

There are two methods of achieving fixation for the acetabular component: cemented and uncemented [1]. For cemented acetabular shells the cement provides fixation, however for uncemented acetabular shells the initial stability is provided by under-reaming the acetabulum [67][68]. This provides a press fit fixation to hold the shell in place until bone in-growth has occurred. One of the driving forces behind using uncemented components was to avoid problems arising from the use of cement, which has reportedly resulted in loosening [69][70]. This may have been due to the cementing technique rather than the cement itself [69][70].

Despite any perceived advantage, there are concerns that the forces required to achieve a press fit fixation may inadvertently deform the acetabular shell [67]. This in isolation is not necessarily an issue, however it has been reported that deformation of the shell may result in malpositioning of ceramic liners [65]. This can cause the ceramic to fracture, resulting in the patient requiring revision surgery [71]. These fractures are complex to treat as the debris from the ceramic liner needs to be completely removed. Failure to do so has been reported to result in an "abrasive paste" potentially compromising the newly revised bearing surfaces [65][72]. Ceramic liners are potentially susceptible to fracture, compared with metal or polyethylene, as the ceramic suffers from intrinsic brittleness [65].

There have been numerous studies examining deformation of acetabular components [67][73][74][75][76][77][78]. However, despite the number of studies there still appears to be little agreement between measurement methodologies and study designs, with numerous options reported. For the measurement methodologies the list includes: optical measurement systems [77], telescopic gauges [67], Vernier callipers [67] and CMM [73]. The study designs have included: impaction tests using polyurethane foam [73], finite element analysis [74], two point mechanical loading [67] and cadaveric studies [67][73].

In 2005 Jin et al. published a study consisting of two stages, testing three different types of CoCr alloy acetabular cups, including the DePuy ASR hip resurfacing [73]. The first stage involved removing pelvises from cadavers, implanting acetabular cups and measuring the deformation. Whilst cadavers can recreate the conditions in vivo there are problems with the variability of cadaveric bone. A CMM was then utilised to quantify the deformation of the acetabular cup. The second stage involved implanting acetabular cups into polyurethane foam models of varying design, with the deformation measured via the same CMM method [73].

For the cadaveric measurements the cohort was small, with only seven acetabular cups implanted, however this was due to the limited supply of cadavers. A mean deformation of 64 μm (range 25 to 103 μm) was recorded, while for the cups implanted into the polyurethane foam models, the mean deformation was comparable at 70 μm (range 16 to 123 μm) [73]. Of the three types of polyurethane blocks only the two point loading model provided a suitable representation of the asymmetric deformation noted for the cadaveric measurements [73]. This result is advantageous as it enables researchers to recreate the loading conditions without the need for cadavers. Another consideration is that the blocks are available in different grades each simulating a different values of bone strengths. The term strength refers to compressive, tensile and shear strength.

In 2006 Squire et al reported on a cohort of DePuy Pinnacle acetabular components implanted into eight men and 13 women, with the deformation measured using a customised telescopic gauge and Vernier callipers [67]. All surgical procedures were performed by a single surgeon, thus removing any potential for inter surgeon variability. As the study examined live patients it was necessary to customise the telescopic gauge to fit into the surgical wound and allow it to be washed and sterilised between procedures [67]. Live patients will typically have healthier bone than cadavers; however any testing must fit within the confines of the operation without compromising the patient. As the experimentation focussed on live patients, this also precluded the use of other types of measuring equipment, such as a CMM, again due to issues with access and sterilisation. To the candidates' best knowledge this is the only paper to report in vivo deformation data [67].

Squire et al. reported a mean deformation value of 160 μm (range 0 to 570 μm) [67]. In addition the study also noted a mean force of 414 N (0 to 1539 N) acting on the

acetabular shell as a result of the bone [67]. The mean deformation was in excess of that reported by other cadaveric studies [73] [77]. This is despite Squire et al. noting that as the measurements were taken in the slots of the shells, maximum deformation may not have been measured [67]. The major limitation with the study is that Vernier callipers do not offer the same precision as a CMM or an optical system. Another limitation noted by the authors was that the sample size was small (n=21) [67]. However, the cohort was larger in size than those reported for cadaveric deformation studies such as that by Jin et al (n= 7) and Liu et al. (n=6) [73] [77].

In 2012 Liu et al. reported on a single surgeon study where six Durom monoblock acetabular cups were implanted into the pelvises of three cadavers [77]. A mean deformation value of 42 µm (range 31 to 49 µm) was recorded [77]. This was comparable to the results published by Jin et al., however the mean deformation reported by Squire et al. (160 µm), were substantially higher [73] [67]. This study involved a relatively small cohort; however measurements were carried out at three different time points to determine if the deformation was elastic or plastic. Firstly at implantation, then at 24 hours, after which time the cups were removed from the acetabulum and then finally at seven days post implantation [77]. It would have been beneficial for the acetabular cups to be kept in the pelvises throughout the measurements to determine how this affected the deformation. Another consideration is that it is unclear how the retrieval process affected the results, although this is somewhat addressed by the authors, who reported no statistical difference between the three measurements over the seven days [77].

Liu et al. performed the deformation measurements using an optical system with white and black paint applied to the articulating surface to enable the acetabular cup to be detected [77]. The authors did not quantify the thickness of the paint layer; however as its function was to provide a difference in contrast; it is unlikely to have affected the results. Without this coating it would not have been possible to perform the measurements [77].

The last important limitation was that frozen pelvises were used for the study [77]. Although they were defrosted for 12 hours before use, the authors noted that the freezing process decreased the mechanical properties; however this was not quantified [77]. Therefore the values presented may be an underestimate of the deformation [77].

Liu et al. demonstrated that an optical system can measure deformation in pelvises removed from cadavers [77]. Therefore the methodology proposed by the candidate for the pilot study was to use an optical system. This was a distinct advantage as previous cadaveric studies in this area had been hampered by poor suitability of standard measuring equipment to the cadaveric environment [73] [77]. The second advantage is that the optical system provided a full three dimensional image of the shell illustrating how the entire shell had deformed in vitro.

For the six shells, deformation values of between 30 and 150 μm were recorded with three values over 100 μm recorded. Two measurements were unavailable, one due to an incomplete scan, the other due to corruption as a result of fluid damaging the coating. The deformation values were comparable to those noted in other studies such as Jin et al. (range 25 to 103 μm), Squire et al. (range 0 to 570 μm) and Liu et al. (range 31 to 49 μm) [67] [73] [77]. The deformation was also noted to be asymmetric in nature approximately corresponding with the ischium and ilium bones of the pelvis, again corresponding to the finding of Jin et al. [73].

The pilot study demonstrated the suitability of the optical system to the cadaver lab; however there were some considerations regarding the methodology. The use of cadavers involves several advantages and disadvantages. The main advantage is that it allows the surgeon to recreate the conditions of primary surgery. Other models aiming to recreate the pelvis such as polyurethane blocks, may oversimplify its anatomy. Whilst these blocks are available with various elastic moduli representing different bone strengths, they do not replicate the viscoelastic properties of cortical and cancellous bone [73]. With regards to the blocks the term strength refers to compressive, tensile and shear strength. This is an important consideration for deformation work due to the effect of viscoelastic relaxation, which Jin et al. noted may reduce the size of the deformation and stresses over time [73]. Without some relaxation it is difficult to seat the shell correctly, with multiple attempts required to achieve satisfactory fixation [73].

However there are drawbacks to using cadavers. Firstly they are donated to medical science [79], predominantly by the elderly, leading to an inherently skewed data set. One study examined the distribution of donors noting that the most likely were elderly, educated and married white males [80]. This is not necessarily a significant drawback as the average age of a hip replacement patient is 69 years old [1].

Another consideration is the quality of cadaveric bone. This is the main difference between cadavers and living patients, as the freezing process has been noted to reduce the mechanical properties of the bone [77]. In this regard cadavers may not be fully representative of living patients who may have harder and healthier bone that may result in larger deformation of acetabular components. Ideally the bone quality should have been assessed prior to the procedure; however this could only be done during the operation, in much the same manner as with a living patient.

The study used an optical measurement system similar to that used by Liu et al. [77]. To utilise an optical system a thin layer is needed on the internal surface to provide contrast [77]. In the candidate's study a thin layer (1 μm thick) of titanium oxide was sprayed onto the surface with black and white markers placed around the rim of the shell. The markers used in the candidate's study allowed the pre and post acetabular shell scans to be aligned correctly during the post measurement analysis. Without these markers a comparison would not have been possible and the deformation could not have been calculated. This was slightly different to Liu et al. where white paint was applied to the surface as a base layer with black markers sprayed over the top [77]. The surface coatings were not designed to be functional and due to the thickness, were unlikely to alter the mechanical properties of the shell or influence the deformation results.

One of the technical complications encountered was fluid collecting in the cup. The ATOS is an interferometry based system; any fluid collection could therefore compromise the scan. Surgical swabs and absorbent pads were placed into the incision surrounding the acetabulum to collect as much of the fluid from the soft tissue as possible. Care was taken to ensure that the swabs didn't obstruct the visual access for the ATOS, nor come into contact with the acetabular shell.

The final potential limitation to consider was the sample size. As this was a pilot study the aim was to determine if the methodology was suitable for further testing, rather than producing statistically significant results. A small sample size (n = 6) was therefore not considered to be a substantial drawback.

Following the successful completion of the pilot study, the next stage was to validate the ATOS and quantify its accuracy. A larger cohort could then be implanted and different variables including bone quality examined, to determine the effect upon the size of deformation.

2.2. Validation of an optical system to measure acetabular shell deformation in cadavers

After the pilot study had demonstrated the ATOS' suitability in a cadaveric environment [66], it was necessary to validate the system and determine its accuracy. Whilst Liu et al. offered deformation values for cadaveric measurements using an optical system, to the candidate's best knowledge there has been no reported validation of such a system for this application [77].

The validation compared the ATOS optical system against a CMM to determine the accuracy when measuring acetabular component deformation. The specification set by the candidate stated that in order to be suitable, the accuracy of the optical measurement system should be within 10 µm of the CMM. The objective was therefore to determine if this was the case, by compressing a cohort of acetabular shells and measuring deformation using both systems.

To the author's best knowledge there is only one paper to offer any measurement data using an optical system, however it only included measurements from six Durom metal acetabular cups [77]. The lack of studies using an optical system may be due to the samples requiring preparation, in order to use such a system. As demonstrated by Bone et al. and Liu et al. the surfaces of metal acetabular cups required a thin layer of titanium oxide [66] or paint [77], in order to perform a measurement [66] [77]. Due to the surface finishes and reflectivity it is likely that polyethylene and ceramic would also require such preparation. This is not required for other measurement procedures such as a CMM, therefore reducing the appeal of an optical system.

In 2011 Hothan et al. published the results of a deformation study using a two point loading cell to deform acetabular cups [75]. Ten acetabular cups of varying designs were clamped into the cell between two parallel plane jaws and loaded at three different levels 0, 1000, 2000 N [75]. Despite testing ten different designs, only one shell of each design was tested. The deformation was measured using a CMM at a plane 1.5 mm below the rim, with the maximum diametral deformation ranging between 41 and 730 µm [75]. The maximum deformation value was higher than that reported by other studies such as Jin et al. (123 µm) and Squire et al. (570 µm). The use of a load cell to deform acetabular shells allowed the authors to control the size of the deformation by varying the load; however it is unclear why these particular loads were chosen.

For the candidate's study, the two point loading system, used by Hothan et al [75], was employed to apply predetermined loads to simulate known amounts of deformation. Two shells were compressed and measured using both the ATOS and a CMM.

The system also simulated the asymmetrical nature of the deformation, where the maximum force is expected between the ischia and ilium [73] [77]. Sixty measurements were taken in total for both the ATOS and the CMM with the results compared to determine the maximum difference between them.

At the rim of the shell the maximum difference between the ATOS and the CMM was found to be 5 µm, whilst at the measurement plane closest to the pole the maximum difference was 9 µm. The standard deviation of the ATOS results was 3 µm. The results demonstrated that the deformation measured by the two systems was comparable; with the accuracy decreasing further away from the rim. As maximum deformation was likely to occur at the rim, in the location of maximum load, the accuracy decrease at the pole was not critical to the success of the project [81]. Therefore the ATOS system was judged to have been within the 10 µm limit stated.

The study details the validation of the optical system for measuring acetabular shell deformation. There were several points for discussion. First was the choice of a suitable system against which to compare the ATOS. A CMM was chosen for the comparison as it has previously been utilised. For example, Jin et al. and Hothan et al. have used a CMM to measure the deformation of acetabular cups [73] [75]. In addition CMMs have also been used to quantify the wear of hip prostheses [22] [56] [82] [83] [84] [85] [86] [87]. An alternative system considered was an out of roundness machine, however given that other studies have previously used the CMM to measure deformation, the candidate decided that the CMM was a more appropriate choice.

Another important consideration was the location and number of the measurement planes. As press fit shells are loaded at the rim, this is where the shell will experience the largest force [81] and potentially the maximum deformation, as demonstrated in the pilot study [66]. Consequently the accuracy of the ATOS system in measuring deformation at the rim was of greater importance than at the pole. Therefore the decrease in agreement between the systems away from the pole was not of critical importance.

To the candidate's best knowledge this study is the first validation study for this application. As the accuracy of the ATOS was within the specified 10 μm limit, the system can now be utilised in a full cadaveric study. This should involve investigating the influence of several variables upon the size of the deformation.

2.3. The influence of the strength of bone on the deformation of acetabular shells: A laboratory experiment in cadavers

No study to the author's best knowledge has quantified the influence of bone upon the size of the deformation of acetabular shells. Yet, the quality of the acetabular bone has been noted as one of the variables that potentially influences shell deformation [67].

The aim of the study was therefore to compare the mechanical properties of the bone to the size of deformation. This was done by implanting a cohort of acetabular shells into cadavers and measuring the deformation using the validated ATOS system. Samples of femoral bone were taken from these cadavers and tested using a compression test to quantify the peak modulus and yield stress. These results were then compared to the deformation to determine if there was a statistically significant relationship.

Despite not offering a direct comparison, Squire et al. is the only study in the literature to report any information on both bone quality and deformation [67] [88]. The results indicated that the quality of the bone was marginally related to the size of force acting upon the acetabular shell (p= 0.07) [67].

The study by Squire et al. used the Dorr grading system to grade the bone [67]. One of the benefits of this system is that it can be performed by examining a patient's X-ray, without the need for mechanical testing of bone samples. However this method is very subjective and could suffer from intra-operator variability. Another consideration is that due to the limited number of grading options available many bone samples with different strengths or stiffness's could be placed together within a particular group. Therefore it may not offer enough detail to accurately define the strength or stiffness of the bone. In addition the study did not quantify the strength or stiffness of the bone using mechanical testing.

In 1997 Li and Aspden performed a study examining the mechanical properties of bone cores taken from the femurs of patients undergoing hip replacement [89]. Bone core samples were taken from seven sites on the femoral head as follows: superior, inferior, anterior, posterior, medial, lateral and central [89]. The rationale was that these would represent regions with varying degrees of loading. The superior surface was the most loaded region, the posterior, anterior and medial regions partially loaded and the inferior region the least loaded [89]. In addition cores from the central and lateral regions were obtained, however these regions experienced no direct loading [89]. The axis of all the samples was towards the centre of the femoral head.

Li and Aspden characterised the stiffness of the bone by performing a compression test. Various mechanical properties were quantified including stiffness, yield strength and energy absorbed to yield [89]. Rather than testing the samples to destruction the tests were stopped as soon as the stress-strain curve started to reduce [89]. By performing the study in this manner Li and Aspden left the samples available for further testing.

Another important consideration in the study by Li and Aspden, was that the bone structure in the femur was not constant [89]. The structure of the bone within the femoral head is dependent upon the principal direction of loading [90]. The lateral side of the femoral bone is loaded in tension whilst the medial side is loaded in compression [90]. In the femoral head the bone structure is more complex forming a lattice style structure. Therefore according to Gray's Anatomy there is no single principal direction for trabecular bone within the femoral head [90].

Li and Aspden noted that more heavily loaded regions of the femoral head were stiffer and had a greater density than less heavily loaded regions [89]. An advantage of this study was that samples were taken from multiple locations. This enabled Li and Aspden to demonstrate that the sampling location could have a substantial influence over the mechanical properties of the bone samples.

In addition to quantifying the mechanical properties of the bone and comparing these results to deformation it would be beneficial to compare these values to the surgical intra-operative grading. This would determine if a surgeon is able to accurately grade the properties of the bone based on touch.

In the candidate's study a cohort of 17 custom made titanium acetabular shells were implanted into the acetabulum of eight cadavers. The deformation was then immediately measured using the previously validated ATOS optical system [91]. Prior to implantation the surgeon graded the bone quality of the cadaver using a three point scale by touching the acetabulum with his thumb.

Five bone core samples were taken from each femur from five different locations: superior, inferior, anterior, posterior and central, based upon the locations used by Li and Aspden [89]. The bone samples were then subjected to an unconstrained compression test to calculate the peak modulus and yield stress, again based upon the methodology used by Li and Aspden [89]. Peak modulus was defined as the highest gradient in the stress-strain curve, whilst the yield stress was the stress at yield point. The yield point was defined as the point at which the modulus decreased by 3% from its peak value. The results for the left and right femurs were combined and the highest peak modulus and yield stress for each cadaver was used for comparison against deformation.

The mean deformation was 129 µm (range 3 to 340 µm); however no correlation was identified between either peak modulus or yield stress, and deformation. The surgeon intra operative grading did not match with the peak modulus; however the results indicated a potential correlation between the surgical grading and the yield stress. No statistical analysis was performed for the surgeon grading as the sample size was small.

To the candidate's best knowledge this is the first study to quantify how bone affects the size of deformation. A previous study by Squire et al. noted that the hardness of bone may influence the size of deformation; however this was not quantified [67]. Instead a marginal relationship between the bone quality and the compressive force on the cup was noted [67].

One of the major benefits of the candidate's study was the sample size (n=17), one of the largest cohorts for a deformation study reported in the literature to date. This was accomplished by implanting multiple acetabular shells per cadaver where the surgeon deemed the bone to be of suitable quality. If the bone was not suitable then only one shell was implanted. The surgeon started with the smallest suitable shell and, following completion of the measurement procedure, reamed up to accommodate a larger acetabular shell. Multiple shells were implanted in five out of

11 acetabula used in this study. In each case the fixation of the acetabular shell was such that it would be acceptable in live surgery.

There were two main limitations to the study. The first was the use of femoral bone as a surrogate for acetabular bone. The reason for choosing femoral bone was that the instantaneous modulus of articular cartilage on opposing joint surfaces has previously been shown to be comparable [92]. Therefore the assumption was that other mechanical properties, such as stiffness, may also be comparable.

The second limitation was that although samples were taken from multiple locations these were not properly recorded and so could not be compared. As previously mentioned the structure of the trabecular bone within the femur changes, so the location from which the bone sample is taken will have an influence over its mechanical properties [89]. This was further exacerbated by the loss of 18 out of 75 bone samples, due to technical difficulties including a computer malfunction and samples toppling over during testing.

On the other hand, the aim of the study was not to compare the different mechanical properties of the bone with the sampling location, as Li and Aspden had already published such data [89]. Instead the aim was to determine if there was a correlation between the mechanical properties of the bone and the deformation. To this end the highest peak modulus and yield stress values for the entire cadaver were used for the comparison against the size of deformation. Therefore whilst the sampling location wasn't known, it was still possible to perform the comparison.

There are several avenues that can be pursued with regards to future work. Firstly it is important to establish the relationship between femoral bone and acetabular bone. This will determine if the femoral bone surrogate used to quantify acetabular bone stiffness [93] was appropriate. The density and mineral content of the bone samples could be examined using micro CT, whilst the stiffness could be calculated using the same uniaxial loading method described previously [93]. The results for the femoral and acetabular bone would then be compared to determine any correlation. The reason for the samples toppling over during testing was that the ends were not sufficiently perpendicular. By using a bone saw rather than a surgical knife the number of samples toppling over should be substantially reduced. It is also important to compare the bone samples taken from the same femoral head, as the bone structure and thus properties can change depending on the sampling location [89].

Until now the deformation work has focussed upon developing, validating and using a measurement method for determining shell deformation. However these tests have only involved generic titanium (Ti6Al4v) acetabular shells. A logical extension to this work would be to test currently available acetabular shells using the same methodology. In addition this could be expanded to examine how the shell-liner assembly process is affected by deformation. Such testing would utilise the same surgical and measurement methodology as used by the candidate previously [66][93].

In conclusion the paper documented one of the first studies to quantify how the mechanical properties of the bone related to the size of acetabular shell deformation. No correlation was found between peak modulus or yield stress and deformation or yield stress. In addition it also provided one of the largest cohorts of acetabular shells tested in a cadaveric environment for this application.

2.4. Determining material loss from the femoral stem trunnion in hip arthroplasty using a coordinate measuring machine

Wear analysis for THR prostheses has primarily focussed upon bearing [22][86] and taper surfaces [12][94]. However the taper only forms half of the taper junction with the trunnion forming the other half. Only one study has published volumetric wear data on trunnions and this consisted of a cohort of only two samples [94]. No validation or accuracy data is available for these two measurements.

The study's aim was to validate and determine the accuracy of the CMM for measuring volumetric wear of trunnion surfaces. This was done by simulating trunnion wear and measuring wear volumes with the CMM and gravimetrically. The gravimetric results were then converted into a wear volume. In addition the maximum error for the CMM for each wear stage was also calculated, by determining the difference between the median value and the upper and lower values. This measurement method was then used on a cohort of ex vivo hip prostheses.

Higher numbers of adverse reaction to metal debris (ARMD) revisions for MoM THR compared with hip resurfacing prostheses [1], has resulted in the taper junction being implicated as a potential cause of failure [95][12][96]. The Morse taper was introduced into total hip arthroplasty over 30 years ago and is now the only design used in modular THR femoral heads [97]. A Morse taper is a cone within a cone, where both have similar tapered angles resulting in an interference fit [12]. The female cone is

located in the femoral head and is termed the "taper", whilst the male cone is located atop the femoral stem and is termed the "trunnion". Due to limitations in manufacturing processes, contact along the entire length of the cones is not possible [97]. Therefore the angles of the taper and trunnion are designed in such a way that contact occurs over a reduced length at one end of the taper [97]. The end at which contact occurs is dependent upon the angle of the trunnion relative to the taper.

Whilst extensive research has been conducted into damage of the femoral head taper [12 28 32 34 94 95 96 98], there have been a limited number of studies examining the trunnion [27 94 99]. To the author's best knowledge there has been only one study reporting wear volumes for the trunnion [94]. This paper by Bishop et al. provided results for only two trunnions, reporting wear volumes of 0.035 mm³ and 0.020 mm³ [94]. The wear volume from the corresponding tapers was 8.1 mm³ and 2.6 mm³ respectively [94]. All measurements were performed using a CMM [94]. Whilst two wear volumes have been offered, to date there has been no study published in the literature offering the accuracy of such measurements. This is in contrast to measurement methods for the taper and bearing surfaces, which have been validated and found accurate to 0.2 mm³ [12] and 0.5 mm³ [22] respectively. Both of these studies used a CMM to perform the measurements.

Whilst various systems such as a Redlux (an optical measurement system) have been used to examine the surfaces of trunnions, no volumetric wear data has been reported using this methodology. Therefore based upon the literature the most common method used for measuring volumetric wear of hip replacement prostheses is a CMM. In addition a CMM was used as to validate the ATOS optical system in the study "*Validation of an optical system to measure acetabular shell deformation in cadavers*".

In the study "*Determining material loss from the femoral stem trunnion in hip arthroplasty using a coordinate measuring machine*" three types of trunnion were examined: an Exeter (Stryker), Corail (DePuy Synthes) and an Accolade (Stryker). These represented the most popular stems for cemented (Exeter) and uncemented (Corail and Accolade) THR arthroplasty [100]. Two of these trunnions (Exeter and Accolade) had a smooth surface finish, whilst the Corail had a grooved surface finish. This grooved finish was a design feature specifically introduced for use with ceramic femoral heads, but incorporated into all Corail stems.

To simulate different wear stages sandpaper was used to remove an increasing amount of material. In total, four wear stages were tested including the unworn stage. In all but one of these stages an unworn ring was left at the top of the trunnion. In the final wear test of the Accolade stem the entire trunnion surface was worn to determine if the CMM was able to calculate a wear volume and if this was comparable to the gravimetric results. This represented the worst case scenario likely to be encountered in a retrieved prosthesis. Following the conclusion of the validation study a cohort of 28 ex vivo Corail trunnions were measured using this methodology to add a clinical context.

The maximum difference between the gravimetric and CMM measurements was 0.13 mm³. The maximum error between individual measurements for the worn stages (excluding the unworn stage) was 0.02 mm³ for the Corail and 0.03 mm³ for the other Exeter and Accolade stems. This was determined by calculating the mean values for both the CMM and gravimetric measurements at each stage and subtracting one from the other.

For the unworn stage the Corail trunnion had the largest CMM wear volume recorded in the study (0.13 mm³), whilst for the other two stems the unworn wear volume was 0.05 mm³. This difference was hypothesised to be due to the grooved surface finish of the Corail compared with the smooth finish of the Exeter and the Accolade. In the final wear stage of the Accolade where the entire surface was worn, the CMM was not able to accurately determine the wear volume. This was due to the lack of a reference surface from which to determine the unworn surface. The median volumetric wear for the 28 ex vivo Corail trunnions was 0.14 mm³ (range 0.04 – 0.28 mm³).

The paper presents, to the author's best knowledge, the first validation of a method that quantifies the volumetric wear from the trunnion surface. In addition it also offers results for the largest cohort of ex vivo trunnions (n=28) to undergo volumetric wear analysis reported in the scientific literature. The primary finding for the ex vivo cohort was that the wear volumes were substantially lower than those reported for the bearing and taper surfaces [7][12][22][86]. To contextualise, Langton et al reported median wear volumes in excess of 2 mm³ for a cohort of 111 MoM femoral head tapers [12].

There were several considerations for the study. The first was the choice of measurement system. Previously it was noted that gravimetric measurements were

the most accurate method for quantifying material loss due to wear [84] [87]. However whilst gravimetric may be the most accurate method, it is not practical for ex vivo wear analysis as there is no reference point available from which to calculate wear. An alternative method was therefore necessary. The CMM had previously been utilised in the deformation validation study [91] and has been used for several studies to quantify the material loss of bearing [86] [22] [94] and taper surfaces [12] [94]. Bishop et al. have also measured two trunnion surfaces using a CMM [94]. Based upon this it was decided that the CMM would be a suitable system to use provided that the accuracy was comparable to the taper surfaces (0.2 mm³).

Ideally a greater number of different types of trunnion would have been tested; however the small sample size was due to the limited stock available. Orthopaedic implants cannot be purchased except by medical centres. For this study the three femoral stems used had recently breached the implantation time limit and thus were made available for research purposes. The three trunnions represented the most commonly implanted cemented and uncemented femoral stems according to the NJR [1].

In order to determine the unworn surface the CMM uses the straightness parameter, which is defined as the distance between two parallel lines touching and enclosing the data points at a minimum distance to each other [101]. For new types of trunnion the straightness of the unworn surface will need to be quantified using a profilometer prior to performing the CMM measurements. This measurement needs to be performed on a new, unworn trunnion. Measurements taken for the three trunnions indicated that the maximum straightness was less than 0.0025 mm. This value was used for the CMM measurements, with straightness values greater than 0.0025 mm indicating wear. For a new trunnion, if the straightness values are greater than 0.0025 mm then the CMM threshold needs to be raised to avoid excluding unworn surfaces. Whilst this aspect was not independently validated the entire method of determining volumetric wear was compared to gravimetric measurements for all three trunnions.

One of the major limitations with ex vivo studies is that the dataset is inherently skewed. However it is by examining these cohorts that trends can be identified in order to understand the modes of failure with the aim of preventing them (such as the ASR hip and the LPM finger) in the future. It is also important to note that clinical

data is not always provided for all ex vivo prostheses. Ideally they should come with a full medical history; however the completeness of the notes is usually dependent upon the clinical practitioners supplying the prostheses.

There are numerous avenues that can be pursued as a result of this study. Firstly research should focus upon understanding how tapers and trunnions wear. Trunnions form half of the taper trunnion junction, so it is vital to determine if there are factors that may increase risk of wear at this junction. There are numerous variables that have been identified as potentially influencing the performance of the taper trunnion junction yet current studies have indicated that the problem is not well understood [34] [102].

One of the variables of interest is the surface roughness of both the taper and trunnion surfaces. Munir et al. recently examined eleven trunnions from five different manufacturers noting that there were differences in the topography [102]. Further work should build upon this by measuring trunnions and tapers using the CMM to quantify the volumetric wear and a contact profilometer to quantify the roughness of the worn surface. The results could then be compared to determine if higher roughness is associated with higher wear from either the taper or trunnion surfaces. An expansion of this would be to examine the areas identified by the CMM as worn and unworn to determine if there is a difference in roughness between worn and unworn surfaces. Studies have identified imprinting of the trunnion surface finish on to the taper surface indicating that changes in surface roughness do occur [94] [12].

Another variable that could be examined is the relative angle between the taper and trunnion surfaces. This angle influences the contact location and also the length of the contact region. Such work could involve the use of a CMM to examine new and retrieved prostheses and thus calculate these angles.

To conclude this study presents the first validation of a method to measure volumetric wear from the trunnion surface. The maximum error between the CMM and gravimetric measurements was found to be 0.13 mm³. In addition the study also reports the wear volumes of the largest cohort of ex vivo trunnions reported in the literature.

2.5.   Surface finish of the Exeter Trauma Stem: A cause for concern?

The National Institute for Health and Care Excellence (NICE) recently recommended the use of clinically proven femoral stems in place of designs such as the Austin Moore and Thomson for hemiarthroplasty procedures. One of the stems listed as a suitable design is the Exeter Trauma Stem (ETS), which is based upon the clinically successful Exeter THR stem, despite having a different surface finish. Previous changes in Exeter stem surface finish have resulted in adverse clinical performance [103]. The rationale of the study was to examine the surface finish of the ETS stem and determine if it was equivalent to the Exeter stem as inferred by NICE.

The primary concern of the study was therefore not the clinical performance of the ETS; more the potential misrepresentation as an equivalent to the Exeter stem for the treatment of hip fracture patients. If the surface finishes were different then it cannot be assumed that the performance of the ETS would mirror that of the original Exeter. This is especially pertinent given the high rate of loosening of femoral stems as a result of a change in surface finish [103].

The aim of the candidate's study was therefore to determine if there was a difference in the surface finish between the three types of Exeter stem. This involved measuring the surface roughness of three different Exeter stems: the ETS, original Exeter and the matt finished Exeter. The objective was to determine if the difference between the surface roughness values of the three stems were significant.

Femoral stems utilised for THR are available in cemented and uncemented designs. The Stryker Exeter and the DePuy Corail represent the most commonly implanted cemented and uncemented stem designs according to the data from the 2014 NJR annual report [1].

Cemented stems, such as the Exeter V40 (Stryker, Kalamazoo, MI, USA), have a polished finish, reducing friction between the prosthesis and the cement. This allows the stems to subside distally from the initial position achieved during primary surgery to a final position of stability, taking advantage of a phenomenon known as cement creep [104]. The fixation of the stem has been termed taper lock [105] [106].

During the migration process the stem is continuously in contact with cement, enabling it to subside without damaging or fracturing the cement. The specific geometry, in particular the taper angle [105] of the stem helps reduce shear stress and

promote radial compressive loading. Race et al. also noted that the coefficient of friction between the stem and the cement is another important factor in obtaining a secure taper lock [105]. Taper lock is a fundamentally different fixation concept to that employed by non-polished stems, which rely upon a press fit to provide fixation until bone ingrowth has occurred [107].

The importance of the surface finish to fixation was demonstrated when alterations were made to the Exeter stem, changing the finish from polished to matt. In 1993 Rockborn and Olsson reported on a cohort of 110 hips at a minimum follow up of five years, all utilising the matt stem. They found that 15 (13.6%) had definite radiographic loosening and eight (7.3%) had suspected radiographic loosening [108]. As this was a clinical study, ex vivo analysis was outside the scope of the project.

Another study in 1998 by Howie et al. reported on a cohort of 40 Exeter stems split equally into two groups: 20 polished stems and 20 matt finish stems. At nine years, a total of 15 patients (16 THRs) had died, six in the matt cohort and ten in the polished cohort [103]. This was a significant limitation. Four matt stems required revision, three of these at four years and the final stem at eight years [103]. In contrast only two stems from the polished cohort required revision, one at two years and the other at seven years [103]. For the matt stems it was suggested that the surface finish of the stems prevented the distal motion within the cement, crucial for its performance [103] [108]. It should be noted that no roughness values were reported.

In 2010 Race et al. reported that the R_a for two original matt finished Exeter stems was approximately 1 μm [105]. However it did not state what system was used to measure the roughness. Stems were implanted into cadaveric femurs and subjected to cyclic loading, simulating star climbing for the equivalent of 10^7 cycles [105]. This tested how the surface finish affected the ability of the stem to subside within the cement mantle [105]. The study determined that taper lock did occur for the polished stems but not for the matt finished stems [105]. This led the authors to conclude that their testing would have predicted the higher loosening rate for matt stems compared with polished stems [105].

One limitation of their study was that matt stems were difficult to obtain, so the authors bead blasted contemporary stems to recreate the rough surface of the matt finish Exeter [105]. Therefore the stems were comparable but not identical. However the aim of the study was to present a novel method of testing the cement creep

performance of stems with different surface finishes rather than particular stems themselves.

As R_a had previously been used by Race et al. to quantify the roughness of two Exeter matt stems, it was decided that the candidate's study would use this parameter to enable a comparison [105]. Roughness average is defined as the average deviation from the ideal surface profile [101].

The surfaces of the three different types of stems were examined using a ZYGO interferometer. Two ETS and two Exeter stems were available for testing, whilst one retrieved, matt finish Exeter stem was also obtained. ZYGO images of the surface were taken in addition to roughness values.

The results revealed a tenfold increase in the mean R_a of the ETS (0.200 μm and 0.276 μm) compared with the original Exeter (0.022 μm and 0.027 μm); whilst the surface finish of the matt finish Exeter (0.973 μm) was three times higher than the ETS. The difference between the ETS and the Exeter was found to be statistically significant ($p < 0.001$). ZYGO images clearly identified distinct differences between the surfaces of the ETS and the Exeter.

Following the publication of the study, Dr AJ Clive Lee an honorary university fellow and Mr JR Howell a consultant orthopaedic surgeon penned a response raising several points [119]. The first was that the introduction of the ETS predated the NICE guidelines, therefore it could not have been considered during the design stage [119]. Secondly Lee and Howell noted that, in a study examining abrasive wear in stems, wear only occurred in stems with R_a values greater than 0.3 μm [120]. As the ETS R_a was slightly below this level (mean 0.238 μm) Lee and Howell conjectured that this may be due to luck [119], noting that the five year mortality rate of hemiarthroplasty patients is around 73% [121]. Lee and Howell stated that the long term performance of a trauma stem is of lower importance compared with other hip arthroplasty prostheses utilised in younger patients [119].

In response, the primary concern that arose in the study "*Surface finish of the Exeter Trauma Stem: A cause for concern?*" was not of the long term performance of the stem; more the misrepresentation of the ETS stem as an equivalent to the original Exeter for the treatment of hip fracture patients. Therefore as the ETS and Exeter stems have a different surface finish it cannot be assumed that the performance of

the ETS stem will mirror that of the original Exeter. This is especially poignant given the high rate of loosening reported due to the change from a polished to a matt finish [117].

The small sample size may also be considered as a limitation of the study. This was however offset by the number of readings taken from each stem (n=40), twenty on each side, to ensure that the sample size was large enough. Retrospective power analysis supported the findings, indicating that five readings on each side would have been sufficient to obtain a power of 95 %. Ideally at least one other Exeter matt stem would have been used to ensure two of each type of stem were tested; however as the stem was discontinued numerous years ago this was not possible.

Another point regarding the matt stem analysed in this study was that it was an ex vivo prosthesis. Upon inspection the stem didn't have cement adhering to the surface and did not appear to have any significant damage which could have skewed the results. To ensure that the roughness results were representative of the original surface finish of the matt stem, the R_a results (mean 0.973 μm) were compared to those published by Race et al. for an unused stem (1 μm) and found to be similar [105].

The parameter R_a was chosen for several reasons. Firstly it had been utilised by Race et al. therefore enabling the results of the two studies to be compared. Secondly it is the most widely used roughness parameter [109]. Finally, it was stated as the preferred parameter by the British Standard 7251-4:1997 for defining the surface finish of the bearing surfaces of hip replacements [110]. Whilst this standard does not directly apply to non-bearing surfaces it provides a basis to the study. The use of R_a was not designed to indicate how the stem was likely to subside in clinical use, more to represent the differences between the three stem types. However one of the main drawbacks of using R_a is the inability of the parameter to distinguish between peaks and valleys [17]. To this end it would have been beneficial to utilise other amplitude parameters such as maximum valley depth, maximum peak height and peak to valley.

Future work should focus upon understanding how the difference in surface finish affects the ability of the stem to subside within the cement mantle. As discussed previously Race et al. performed cyclic loading to test the ability of a stem to subside to a position of stability [105]. Such a study could be performed with the ETS and the

performance compared to the Exeter. The results could also be compared with those of Race et al. to further contextualise the performance of the ETS [105].

To conclude, the study demonstrated that the difference in surface roughness between the three types of stems were significant ($p < 0.001$). Therefore the candidate is of the opinion that the ETS should not be advertised by NICE as an equivalent stem to the Exeter for treatment of hip fracture patients.

2.6. Analysis of failed Van Straten LPM proximal interphalangeal prostheses

Reports of high failure rates of the LPM PIP prosthesis (Figure 1) [111], led to an audit by the British Society for Surgery of the Hand, which found that 29% of these had failed, with a further 20% at risk of failure. Massive osteolysis leading to aseptic loosening was recorded as the most common failure mode [112]. At retrieval, blackened staining of the surrounding soft tissue was observed, indicative of wear debris [111] (Figure 2). However, despite the clinical failure of the LPM no explant analysis had been reported in the literature.
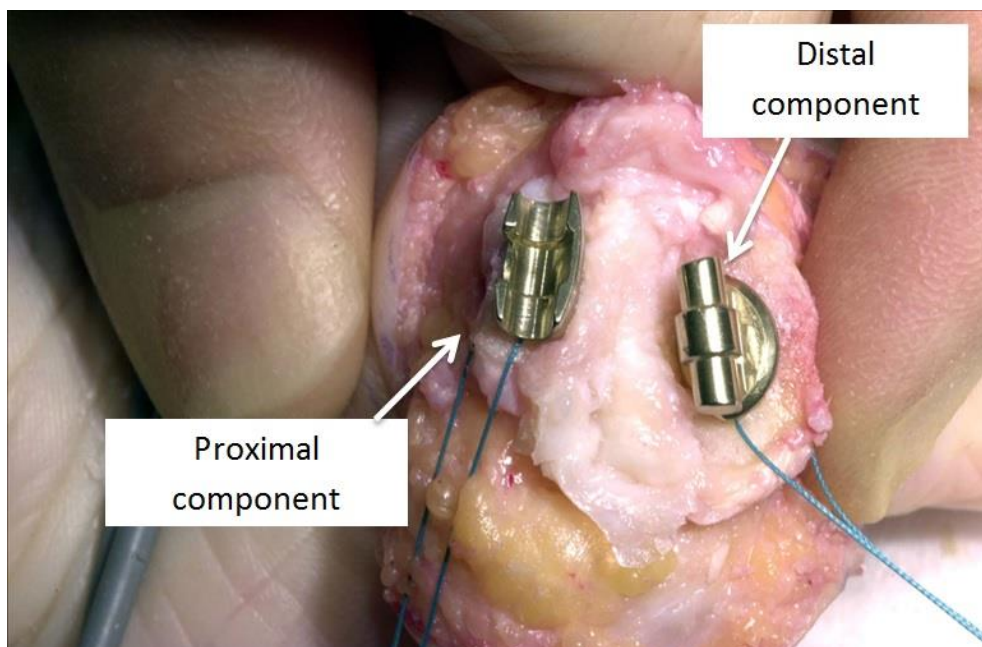

Figure 1: Photos of the two piece LPM PIP prosthesis taken intra-operatively during implantation
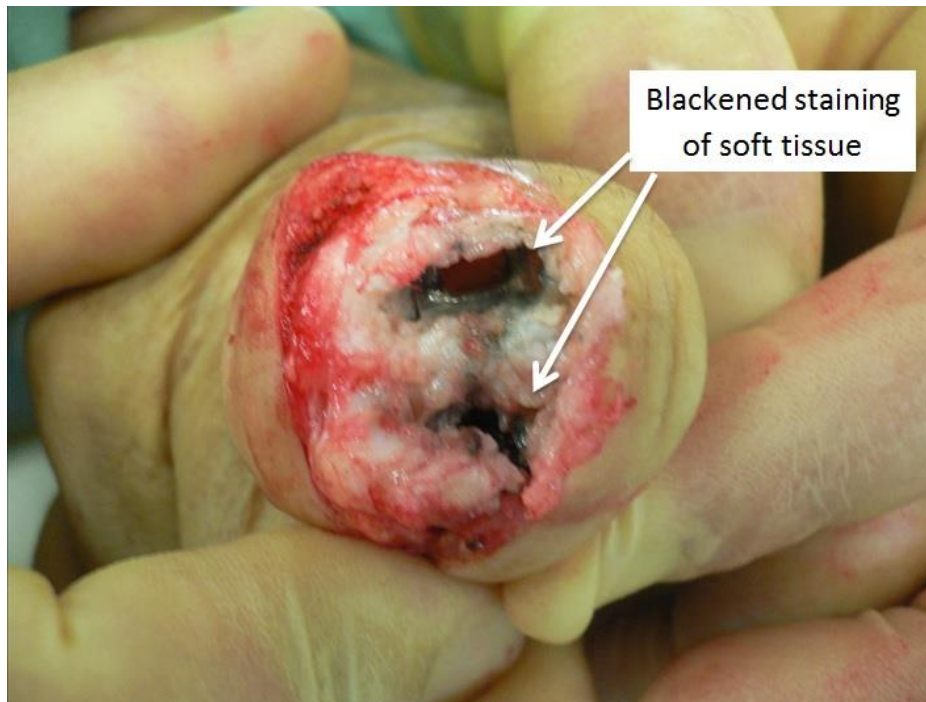
Figure 2: Photo of the PIP joint following revision surgery. Note the blackened staining of the surrounding soft tissue indicative of metallic wear debris

The aim of the study was therefore to determine the failure mode of the LPM by examining a cohort of ex vivo prostheses. To accomplish this, surface roughness and chemical composition of the articulating surfaces were measured using profilometers and an environmental scanning electron microscopy (ESEM).

The LPM was a two piece semi-constrained prosthesis designed for use in the PIP joint. The distal articulating surface was cylindrically shaped, whilst the proximal component was concave (Figure 1). The substrate was manufactured from CoCrMo with a coating of titanium niobium on the articulating surfaces [113]. Such coatings were used to enhance properties such as surface finish or scratch resistance [114].

There are to the candidate's best knowledge only two papers on the LPM prosthesis. The first published the results of a clinical study on a cohort of 20 LPM prostheses [111]. Six prostheses required revision surgery at a mean time of 19 months, with a further two listed for revision. This equated to a failure rate of 40%. While the cohort was small, this was the first study to report on the clinical performance of the LPM prosthesis.

The second paper published the results of an audit into the clinical performance of the LPM [112]. Data was collected on 164 (63.8%) prostheses out of 257 sold in the

UK [112]. At a maximum follow up of six years the study noted that 47 (29 %) had been revised and a further 33 (20%) had radiological and clinical indications of failure. The most common failure mode was reported as aseptic loosening due to "*massive osteolysis*" [112].

One limitation of the audit was incomplete data [112]. Whilst 257 prostheses were sold, the authors of the audit were not able to determine how many prostheses were implanted into patients. Some of the prostheses purchased were likely to have been retained by the hospital as stock and therefore could not be accounted for. In addition numerous prostheses were lost to follow up, however this number could not be quantified. The authors noted that even if all the prostheses that were lost to follow up were fully functioning, the clinical performance of the LPM would still have been below the acceptable standard [112].

Despite the subpar clinical performance of the LPM prosthesis no study has reported any explant analysis to determine the failure mode. In 2009 Joyce published an essay in which he hypothesised that the hard titanium niobium coating failed at the substrate coating interface, resulting in "a *very hard, golden-coloured grinding paste*" [113]. However due to the lack of explant analysis this hypothesis has not yet been proven.

As no ex vivo analysis had been reported for the LPM, it was necessary to investigate other methods of determining the failure mode. In 2010 Joyce reported on a single Digital Joint Operative Arthroplasty (DJOA) prosthesis tested in a finger wear simulator [115]. Wear was determined gravimetrically, however in addition a ZYGO was used to measure the surface roughness, before and after testing [115]. Roughness average was used, although the study does not state why this was the case.

There have been several other studies that have used similar profilometers to examine the surfaces of different types of explanted prostheses. Que et al used it to analyse knees, Vassiliou et al used it for hips, Joyce examined a metatarsophalangeal prosthesis and it has also been used to examine temporomandibular joint prostheses [116] [117] [118] [119]. This demonstrated that such a methodology has been widely used throughout this field to quantify surface finish.

Profilometers have been used for various different studies in the literature. In addition the candidate has previously utilised a profilometer for the study "*Surface finish of the Exeter Trauma Stem: A cause for concern?*"

In the candidate's study a ZYGO interferometer was used to measure the R_a of the bearing surfaces to determine the extent of the damage the prostheses had suffered in vivo. In addition to measuring the R_a, the ZYGO also provided images of the surface that can indicate scratching or other surface damage. Due to the shape of the proximal components (Figure 1) it was not possible to measure them with a ZYGO. Therefore it was necessary to use a contact profilometer (Talysurf) to measure the proximal surfaces. All prostheses were measured using the Talysurf, with the results compared to those obtained by the ZYGO for the three distal prostheses. This was to ensure that the measurements were comparable between the two systems.

As the LPM has a titanium niobium coating upon a CoCrMo substrate the damage to this coating was quantified by examining the chemical content. To determine if the coating was intact, the chemical composition at various locations on the bearing surfaces was analysed using an ESEM. If the coating was intact then the chemical composition would detect only titanium and niobium. However, if the coating was damaged then the substrate elements of CoCrMo would be detected.

All five LPM prostheses showed evidence of substantial damage to the bearing surfaces. In several locations the coating was completely missing, thus exposing the substrate. In addition, the surfaces were found to have high R_a values (range 100 nm to 2200 nm). These values are higher than the 50 nm limit set by British Standards [110]. These findings tie in with the hypothesis proposed by Joyce that the failed coating resulted in a "*very hard, golden-coloured grinding paste*", thus further damaging the surfaces of the prostheses [113]. This wear debris is likely to have resulted in the osteolysis reported clinically [111] [112].

This study was the first to examine the failure mode of the LPM prostheses. Whilst there was an audit into the poor clinical performance [112], it was imperative that the specific issues that led to the failure of the LPM were investigated. Despite having a small sample size (n=5) this is the only study to offer any ex vivo data for the prosthesis and the first to propose a failure mode based upon experimental data.

This study built upon the roughness methodology utilised in the study "*Surface finish of the Exeter Trauma Stem: A cause for concern?*" One of the major limitations for the LPM study was the lack of volumetric wear analysis. Ideally this would have been performed; however the manufacturing tolerances would need to be determined prior to testing. This can be done using the CMM by measuring an undamaged prosthesis and determining the form error, which could equate to the manufacturing tolerances in this situation. Without the tolerances, wear may be over or under calculated. As the LPM was withdrawn from the market and only 257 prostheses were sold it was not possible to obtain a new prosthesis. Therefore volumetric wear analysis was not able to be attempted.

As wear was not measured surface roughness was used to provide an indication of the in vivo wear performance. It has previously been shown that roughness, and in particular R_a, is associated with wear for in vitro studies of hip prostheses [8] [9]. In 1997 Hall et al. reported that two roughness parameters, skewness and R_a, were found to correlate with wear, however the power of the relationship was significantly smaller than that found in in vitro studies [8]. Hall et al. stated that there were numerous factors that may have influenced this, including the variability of the surface roughness on explanted femoral heads [8]. In the absence of wear measurements R_a provided some indication of the in vivo wear performance of the prostheses. The parameter R_a was chosen not only to represent wear, but also to enable a comparison with the British Standards for orthopaedic devices [110].

Whilst the ZYGO would have ideally been used to analyse all LPM components, due to the shape of the proximal component this was not possible. It was therefore necessary to use the Talysurf contact profilometer (Taylor Hobson, Leicester, UK) on all prostheses to quantify the R_a, as the ZYGO could only be used on the distal components. The results from the two profilometers were comparable, however the ZYGO has a higher resolution (1 nm) than those of the Talysurf (10 nm).

The lack of volumetric wear analysis was a limitation, however it was evident from visual inspection that the surfaces had suffered substantial amount of damage. Despite the damage to the surface it was unclear whether the TiNb or the CoCrMo caused the osteolysis reported clinically [111] [112]. The hypothesis is that it was likely to be a combination of the two, where the failed coating resulted in a hard grinding paste that accelerated the wear of the CoCrMo substrate.

For the LPM prostheses there is limited benefit to future work, as the prosthesis was withdrawn from the market by the manufacturer. Therefore the candidate would not recommend any further work on this prosthesis. However other prostheses utilise TiNb coatings, therefore future work should focus on examining and understanding how these coatings function and the effect that wear debris has upon patients.

To conclude the study presented the first ex vivo engineering analysis for the LPM prosthesis. The failure mode of the LPM was related to the failing of the coating, which resulted in wear debris generation. This ties in with the "massive osteolysis" reported clinically [112].

2.7. An analysis of explanted pyrolytic carbon prostheses

Reports of the clinical performance of pyrolytic carbon prostheses in the small joints of the hand have been mixed; however there has been no ex vivo analysis reported for pyrolytic carbon prostheses in the literature to understand why these prostheses may fail [120] [121] [122].

The aim of the candidate's study was therefore to determine whether the failure of a cohort of pyrolytic carbon finger prostheses was linked to wear. Once again, R_a was measured using a ZYGO interferometer, as it has previously been shown to correlate with wear [8] [9].

Early indications for pyrolytic carbon were promising, as the material offered several major benefits over its competitors. Prior to its use in artificial joints, the material was successfully used in millions of artificial heart valves from the 1960s, as it offered excellent wear properties in addition to good bio-compatibility [123]. This was beneficial, as it meant that in theory, minimal wear debris would be produced compared to other materials [124]. Additionally it had a similar elastic modulus to that of cortical bone, reducing the stresses at the implant-bone interface, thus allowing good fixation [125] [126].

The outcomes of pyrolytic carbon arthroplasty in the hand have been mixed and high complication rates have been reported in various studies, in one instance as high as 83% [124]. Table 2 documents the findings of numerous clinical studies on pyrolytic finger prostheses. Common complications included subluxation [121] [126], dislocation [124] [127] [128] [129], contraction of the joint [124] and a squeaking sound experienced by a large

number of patients [124] [125]. Rates of complication and revision do not appear to be related to specific joints of the hand or the primary disease, with results varying across these groups (Table 2).

There are considerations to discuss regarding these clinical studies. Firstly some such as Nunley et al. and Nunez and Citron had small sample sizes so caution should be used when interpreting their results [130] [129]. A second consideration is the short follow up time on some of the studies, with only one study reporting a mean follow up in excess of five years [120]. Despite the mixed clinical performance, no ex vivo analysis has been reported in the literature.

Mean follow-up (months)	No. of implants	No. of patients	Primary reason	Joint	No. of Complications	No. of Revisions	Reference
19	19	10	OA	PIP	6 (31.6%)	0 (0%)	(Branam et al., 2007)
37	50	35	OA/RA/Post-traumatic OA	PIP	18 (36.0%)	4 (8%)	(Bravo et al., 2007)
17	7	5	Post-traumatic OA	PIP	5 (71.4%)	2 (28.6%)	(Nunley et al., 2006)
13	18	8	OA	PIP	15 (83.3%)	0 (0%)	(Tuttle and Stern, 2006)
140	151	53	RA	MCP	18 (11.9%)	18 (11.9%)	(Cook et al., 1999)
39	28	16	RA	MCP	13 (46.4%)	0 (0%)	(Leon-Andrino et al., 2008)
26	10	7	RA	MCP	1 (10.0%)	0 (0%)	(Nunez and Citron, 2005)
17	142	61	RA	MCP	20 (14.1%)	1 (0.7%)	(Parker et al., 2007)
22	54	49	OA	Tapezial-metacarpal (TM)	15 (27.8%)	9 (16.7%)	(de Aragon et al., 2009)

Table 4: Details of studies that have examined the clinical performance of pyrolytic carbon prostheses. Note that OA refers to osteoarthritis and RA refers to rheumatoid arthritis

In the candidate's study a cohort of 12 ex vivo pyrolytic carbon prostheses were examined using a ZYGO profilometer to quantify the surface roughness parameter, R_a. These results were then compared against the British Standards limit of 50 nm for orthopaedic devices, to determine if they could be classified as worn [110].

Results showed that the articulating surfaces had R_a values between 12 nm – 43 nm (Table 2), indicative of relatively unworn surfaces. This range is below the 50nm limit discussed [110].

This study built upon the use of profilometers in the literature as well as two previous studies by the candidate: "*Surface finish of the Exeter Trauma Stem: A cause for*

concern?" and "*Analysis of failed Van Straten LPM proximal interphalangeal prostheses*".   Both these studies and the current study used the ZYGO to quantify roughness with the parameter R_a utilised in order to provide a reference for the in vivo wear performance of the prostheses.

By using R_a the result could be compared to the British Standard for orthopaedic devices [110]. Although this Standard does not specifically cover pyrolytic carbon, similar roughness values are believed to be applicable to this material, as it is can be polished to achieve comparable values of surface roughness [131].   Values above the 50 nm limit would indicate that the surfaces had roughened in vivo, indicating a wear process.

One pyrolytic carbon sample had been implanted only three weeks before revision due to dislocation. In some ways this component could therefore be considered a 'control' sample, providing an indication of the unworn surface roughness of these prostheses. The results indicated that the articulating surfaces were not worn (R_a <50 nm [110]), and thus wear is unlikely to have contributed to the failure of the prostheses in this cohort.

It should be noted that this is a small cohort (n=12), however it is the first to the candidate's knowledge to offer any ex vivo analysis of pyrolytic carbon prostheses. These results indicate that the pyrolytic carbon prostheses may be one of the first types not to be affected by wear debris. However further research supporting this finding is required.

Further work could involve developing a measurement method for quantifying the volumetric wear from the articulating surfaces of ex vivo prostheses. Such work would use the CMM, which has already been used for this purpose for hip prostheses [12 7 18 22 132].   Recently, several new pyrocarbon prostheses were received through collaboration with clinicians from Wrightington hospital. These could be examined using the CMM to determine the manufacturing tolerances, thus providing the foundation for future volumetric wear analysis.

To conclude, the study presented the first ex vivo analysis of a cohort of pyrolytic carbon prostheses. The low R_a values (12 nm – 43 nm) indicated that the prostheses were not heavily worn. It is therefore unlikely that the failure of the prostheses was wear related.

Chapter 3. Discussion

3.1. Introduction

The papers presented in this thesis examined a range of orthopaedic problems using engineering analysis. There are many different factors that can influence how a prosthesis will perform in vivo, however it is not always possible to identify specific issues from clinical data alone. It is therefore important to fully examine prostheses both in a pre and post clinical context in order to understand and improve their in vivo performance.

The aim of this thesis was to examine a range of problems within orthopaedics to determine how engineering analysis can contribute to the body of knowledge currently available. As demonstrated through the seven papers previously detailed many of these issues would not have been fully understood through clinical observations and registry data alone. Clinically the failure of a prosthesis will manifest itself in a particular manner, as will be discussed below; however that does not necessarily identify the failure mode of the prosthesis. Also without extensive pre-clinical testing, patients could potentially receive substandard prostheses.

Factors that could affect performance may include disease progression (i.e. rheumatoid and osteoarthritis have different clinical pathways), prosthesis design and biomechanical factors.

3.2. Reasons for arthroplasty

The most common indicator for joint arthroplasty is arthritis which affects approximately ten million people, or one in five, in the UK [133]. Osteoarthritis (OA) is the most prevalent type of arthritis [134]. It is estimated that by the year 2030 the number of cases of OA in the UK will double to more than 17 million [135].

Osteoarthritis has been defined as "a failure of the repair process of damaged cartilage due to biomechanical and biochemical changes in the joint" (Figure 3) [136]. In a healthy joint the hyaline cartilage matrix is continually broken down and repaired by cells known as chondrocytes [137]. The process is in a state of equilibrium so there is no significant loss or gain of cartilage [137]. Osteoarthritis causes an imbalance of this equilibrium, resulting in the chondrocytes failing to repair the cartilage matrix,

eventually leading to the loss of articular cartilage [137] [138]. As the disease progresses, osteophytes form at the end of the joint margins, whilst the subchondral bone and synovial membrane may also thicken, resulting in deformation of the joint [139] [140]. Bone remodelling may also occur [136]. The pathway of OA however is not well understood and there is growing consensus that OA is not a single disease, but a group of diseases [136] [141].
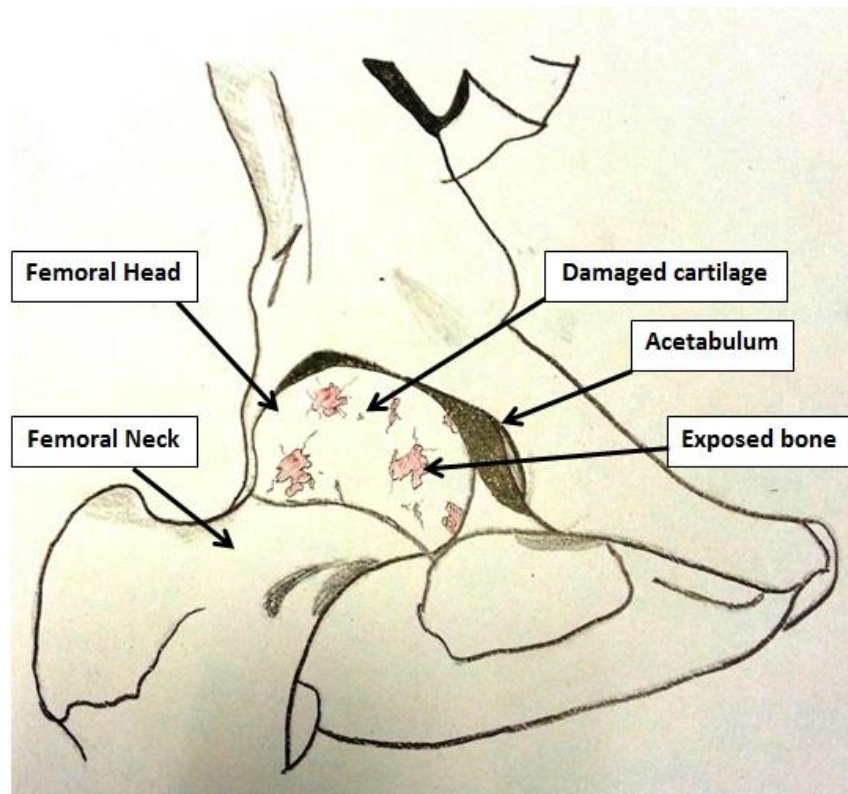

Figure 3: Diagram showing the anatomy of the hip joint and the typical surface damage caused by OA to the articular cartilage

After OA the second most common type of arthritis is rheumatoid arthritis (RA); estimated to affect 580,000 people in the UK [142]. There are fundamental differences in the progression of Rheumatoid arthritis compared with OA. Rheumatoid Arthritis is characterised as an auto-immune disease, causing persistent inflammation of synovial joints, damage to the articular cartilage and bone and the generation of antibodies [143] [144]. The most commonly affected joints are the PIP, MCP, metatarsophalangeal (MTP), wrist and ankle [145] [5].

The majority of joint arthroplasties are performed as a result of OA [1] [133]. A total of 91% of all hip arthroplasties (73,049 procedures) reported in the 2014 NJR Annual Report were for OA, whilst rheumatoid arthritis accounted for 1% (1,040 procedures)

[3]. However for the small minority of rheumatoid arthritis patients undergoing arthroplasty, there have been reports of poorer clinical outcomes compared to OA patients [146] [147] [148]. This included: lower functional outcome [146] [148], higher incidence of pain [146] and dislocation [147]. Other reports have contradicted these findings indicating no difference in performance between OA and rheumatoid arthritis [149] [150] [151]. The higher rates of dislocation in rheumatoid arthritis patients may be due to an increased risk of developing osteoporosis and poorer soft tissue quality [147]. This is in comparison to patients with OA. However the poorer clinical outcome of rheumatoid arthritis patients is not well understood and further research is required.

3.3.   Design of prostheses

As anatomical structures of joints vary, it is to be expected that the prostheses used to replace them will also differ.

Hip prostheses have changed significantly since the original Charnley design, introduced in the early 1960s. The original Charnley THR prosthesis comprised of two components: a stainless steel femoral stem with a hemispherical ball 22.225mm in diameter and a polytetrafluoroethylene (PTFE) acetabular cup [152]. Whilst the prosthesis was clinically successful there were issues associated with high wear rates and osteolysis [153] [154].

The Charnley was not the only type of hip prosthesis in development around the 1960s. The McKee-Farrar was a type of MoM prosthesis with both femoral and acetabular components manufactured from CoCrMo alloy [155]. As well as the material, another significant difference was the diameter of the femoral head, which at 41.275 mm was nearly twice the size of the Charnley prosthesis [155]. Due to concerns with osteolysis in MoP arthroplasty the use of MoM bearing prostheses increased, however whilst MoM had a reduced rate of osteolysis, it was associated with localised effects of metallic debris [156]. This resulted in MoM arthroplasty being shunned by many clinicians around the mid-1970s, with many reverting back to using the Charnley [157].

The 1970s saw the first Exeter stem implanted [158]. The stem had a double tapered geometry with a polished surface finish and was manufactured from stainless steel. The term double taper refers to the specific geometry of the stem where it is tapered in two directions. It is not to be confused with a femoral head taper which is the cone

into which the trunnion is inserted. The Exeter design utilised a larger 30 mm femoral head to reduce the risk of dislocation [158]. Despite promising initial results, the surface finish of the Exeter stem was altered from a polished finish to a matt finish in 1976, as a result of a limited number of fractures at the femoral neck [158]. It was unclear why the manufacturers felt this alteration would improve the performance of the stem.

The manufacturer however, did not anticipate the effect this change would have on the stem's performance, with matt finish stems soon associated with a higher rate of loosening [103] [159] [108]. After a decade the manufacturers reverted back to a polished surface finish [158]. Two years later a taper was incorporated into the femoral head to provide modularity. This provided greater flexibility to a surgeon during a revision procedure, enabling them to keep a well fixed stem, whilst replacing only the damaged femoral head.

Despite their lack of use, work continued on developing improved MoM hip prostheses, in order to overcome the continuing issues with osteolysis. The failure of first generation MoM was hypothesised to be due to the poor design of the implants rather than the material used [157]. Designs, such as the Metasul (Zimmer, Warsaw, IN, US), were introduced into the market in the late 1980s, with these prostheses hypothesised to benefit from improved manufacturing techniques and optimisation of the bearing surfaces [160] [161]. The driving force was to understand and improve upon the poor performance of the first generation of MoM hip prostheses.

Figure 4: Photo of the Zimmer MoM Durom THR prosthesis (top left) and the Durom hip resurfacing prosthesis (bottom right). Note that both prostheses utilise the same design of acetabular component

One of the largest alterations to the fundamental design of a hip prosthesis was the introduction of the hip resurfacing procedure. It was aimed at younger patients suffering from severe arthritis, but with reasonable quality of bone [162]. The procedure consists of "resurfacing" the femoral head and the acetabulum rather than replacing the entire joint with a THA. On the femoral side, both the femoral head and neck are left intact and the prosthesis "resurfaces" the femoral head. The resurfacing femoral head has a small femoral stem protruding from the posterior surface designed to insert into the femoral neck. The acetabular component consists of a single metal monoblock constituent.

The market leading hip resurfacing was, and remains, the Birmingham Hip Resurfacing (BHR) [163], although other manufacturers have offered their own variants including: the DePuy ASR and the Zimmer Durom (figure 4).

Hip resurfacing was hypothesised to offer several benefits compared with a THR, including: lower rate of dislocation [164], preservation of femoral bone stock [165], greater

range of motion [164] [166] and superior lubrication [167]. It was developed predominantly for younger patients to enable them to maintain high levels of activity hypothesised not to be achievable with conventional THR [41]. Preservation of the femoral neck is also important in younger patients who may require more than one hip arthroplasty procedure in their lifetime [165]. Upon failure of the hip resurfacing, a surgeon is able to perform a conversion to a THR by removing the femoral neck and inserting a 'conventional' femoral stem. The acetabular component can also be replaced during the same procedure.

Whilst hip resurfacing consists of a CoCrMo femoral head and monoblock acetabular cup [22], modern THRs typically utilise four components, namely: a femoral head, femoral stem, acetabular shell and acetabular liner. These multicomponent acetabular systems are known as modular cups. An example of this system is the DePuy Pinnacle which consists of a titanium alloy acetabular shell, with the liner manufactured from metal, polyethylene or ceramic. The driving force behind this was to enable modularity so that a surgeon could revise a damaged liner without needing to remove a well fixed acetabular shell. Numerous studies have however noted, that acetabular shells are potentially susceptible to deformation as a result of surgical implantation [67] [168] [77].

Acetabular cups are available for both cemented and uncemented procedures [1]. The introduction of uncemented acetabular components had several benefits. Firstly it removed the need for cement which had been associated with several problems including loosening [69] [70], although these may have been down to the cementing technique rather than the cement [69] [70]. Secondly by removing the cement a larger acetabular cup could be accommodated within the acetabulum.

Another noticeable change in hip prostheses has been the increase in the diameter of femoral heads. The original Charnley prosthesis had a 22.225mm diameter head [152]. However more recently there has been a trend to implant larger femoral heads as they are associated with lower rates of dislocation [169] and a greater range of motion [169]. According to the NJR, in 2003 the most common size of femoral head implanted was 28 mm whilst in 2013 it was 32 mm [1].

Further changes have focussed on the bearing surface materials to reduce wear volumes. There have been two major changes to the polymeric material used in acetabular components. The first was the introduction of ultra high molecular weight

polyethylene (UHMWPE) [170], and more recently cross linked polyethylene (XLPE) [171]. Both of these were designed to increase the wear resistance of the material, thus reducing wear volumes and improving the longevity of the implant.

While many prostheses are designed to be anatomically correct this is not always the case. In PIP arthroplasty there are two predominant designs: single component non-anatomically correct prostheses (Figure 5) and two component anatomically correct prostheses (Figure 6). Since its introduction in the 1960s the Swanson prosthesis (Figure 5A) has been one of the leading prostheses for arthroplasty of the PIP and MCP joints, despite not being anatomically correct [172]. The Swanson is a single piece silicone prosthesis designed to act primarily as a spacer, preventing bone on bone contact [173] [174]. The primary aim of the implant is to relieve pain whilst providing a limited amount of functionality to the affected joint, rather than restoring its natural biomechanics. The prosthesis is not fixed into the bone [175], allowing it to undergo a "piston" action during flexion extension, where the stems of the prosthesis glide within the intramedullary cavities [176]. This was hypothesised to increase the lifespan of the prosthesis by dispersing the forces along a broader area [172].
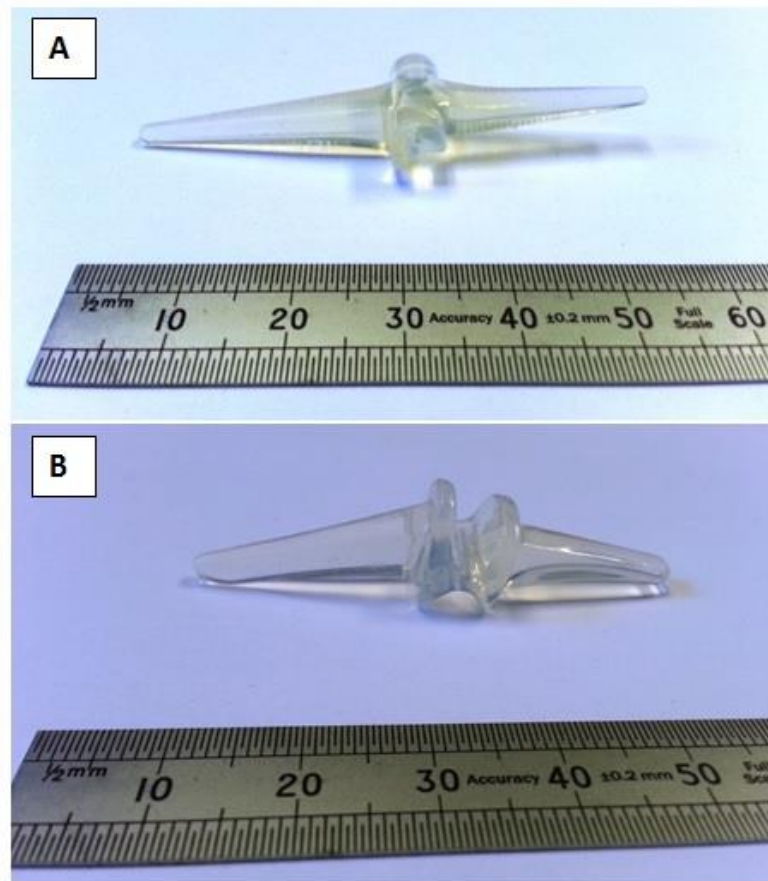
Figure 5: Single piece silicone PIP prostheses: A) Wright Medical Technology Swanson prosthesis B) DePuy NeuFlex prosthesis.
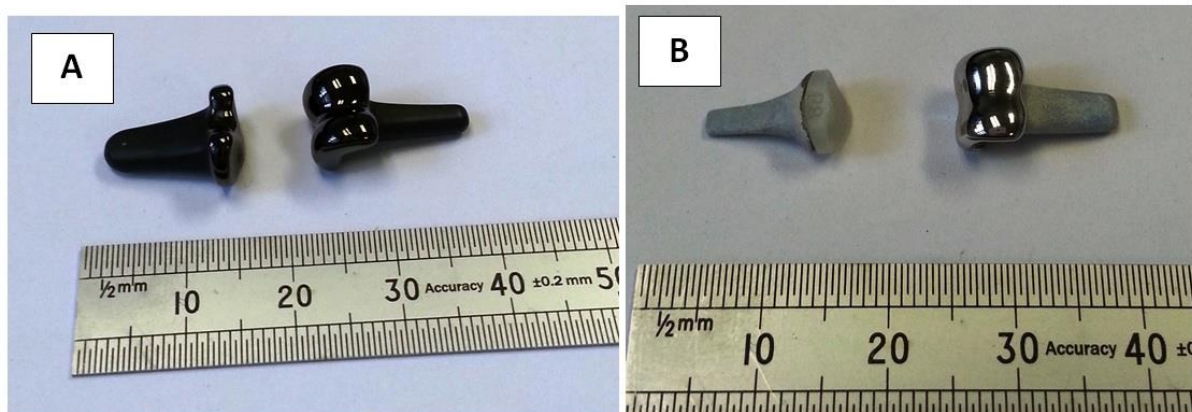
Figure 6: Two piece PIP prostheses: A) Ascension Pyrocarbon prosthesis B) MatOrtho PIP MoP replacement prosthesis

A later version of the Swanson utilises titanium grommets around the stem hinge interface, hypothesised to reduce the incidence of fracture [175]. The success of the Swanson has led other manufacturers to develop their own modified versions of the single piece silicone spacer, such as the NeuFlex (Figure 5B). The NeuFlex has a

hinge design with a 30° flexion angle, mimicking the natural anatomy of the joint [175]. The design rationale was that this would reduce the strain in the material, thus decreasing the risk of fracture [175]. Despite the issues surrounding fracture, silicone prostheses are still considered to be the "gold standard" in PIP arthroplasty [177].

Whilst the Swanson predominantly functions as a spacer for the joint, there is an alternative group of prostheses that utilise articulating bearing surfaces to replicate the natural anatomy and biomechanics of the joint [178]. The two most common designs (Figure 6 A and B) are the Pyrocarbon PIP prosthesis (Ascension / Integralife, Plainsboro, New Jersey, USA) and the surface replacement (SR) PIP prosthesis (Small Bone Innovations Inc., Morrisville, PA, USA).

The SR PIP prosthesis consists of an UHMWPE component and a CoCrMo component, both using a titanium alloy stem [178]. This combination of articulating surfaces forms a MoP bearing couple [179]. PyroCarbon PIP prostheses are manufactured from a high strength graphite substrate [125] which is then coated in pyrolytic carbon using a process known as chemical vapour deposition [128]. The manufacturers claim that pyrolytic carbon is a hard wearing material which virtually eliminates the problem of wear related failures [180].

The main advantages of using a non-anatomically correct implant such as the Swanson is that it provides an increased amount of stability compared with anatomically correct prosthesis [173]. As two piece prostheses mimic the natural biomechanics of the joint, stability can be difficult to achieve with such prostheses, as they rely upon the quality of soft tissue. In rheumatoid arthritis the disease can result in increased soft tissue imbalance as ligaments are elongated and tendons displaced [181]. It has also been shown that in these circumstances two piece unconstrained PIP joint prostheses have poorer clinical outcomes than Swanson silicone arthroplasty [181].

3.4.   Failure modes of joint prostheses

As mentioned previously there are many different ways in which a prosthesis may fail. For anatomically correct prostheses the bearing surfaces articulate against one another allowing movement of the joint. During the articulation process there are several possible modes of failure, which will be discussed in turn.

The first method of failure is wear related. During relative motion between the articulating surfaces of the prostheses, asperity contact may result in wear particle generation [39] [182]. The most commonly observed wear regime is abrasion [182]. The host response is dependent upon the type of wear debris, so it is important to differentiate it into three categories: polymer, metal and ceramic.

The release of polyethylene wear particles cause a host response of periprosthetic bone resorption, known as osteolysis, leading to aseptic loosening [39] [183] [184] [185]. This is defined as mechanical failure of the interface between the prosthesis and the host [186]. Aseptic loosening was noted as one of the top three reasons for revision for the majority of joint arthroplasties listed in the NJR 2014 annual report (hips, knees, ankles and elbows) with shoulder arthroplasties the exception to this (Table 1) [1]. Numerous studies have reported wear debris induced osteolysis in arthroplasties of joints such as hips [39] [183], knees [187] and ankles [188], supporting the findings of the NJR [1].

There have also been reports of PIP joint osteolysis in the literature [189] [112]. In 2008 the results of an audit into the failure of the LPM PIP prosthesis were published, with "massive osteolysis leading to aseptic loosening" noted to be the most common cause of failure [112]. These findings indicate that wear related failures are a limiting factor for the longevity of different types of prostheses.

Metallic wear particles have been reported to result in a number of different clinical problems including pseudotumour formation [190] [191] (Figure 7), aseptic lymphocyte-dominated vasculitis associated lesion (ALVAL) [190], tissue destruction [7] and adverse soft tissue reactions [7]. These problems are categorised under the term ARMD failure, which is an acronym of adverse reaction to metal debris. In 2013 such adverse reactions were responsible for 14 % (1,363 procedures) of all hip revisions according to the NJR [1].
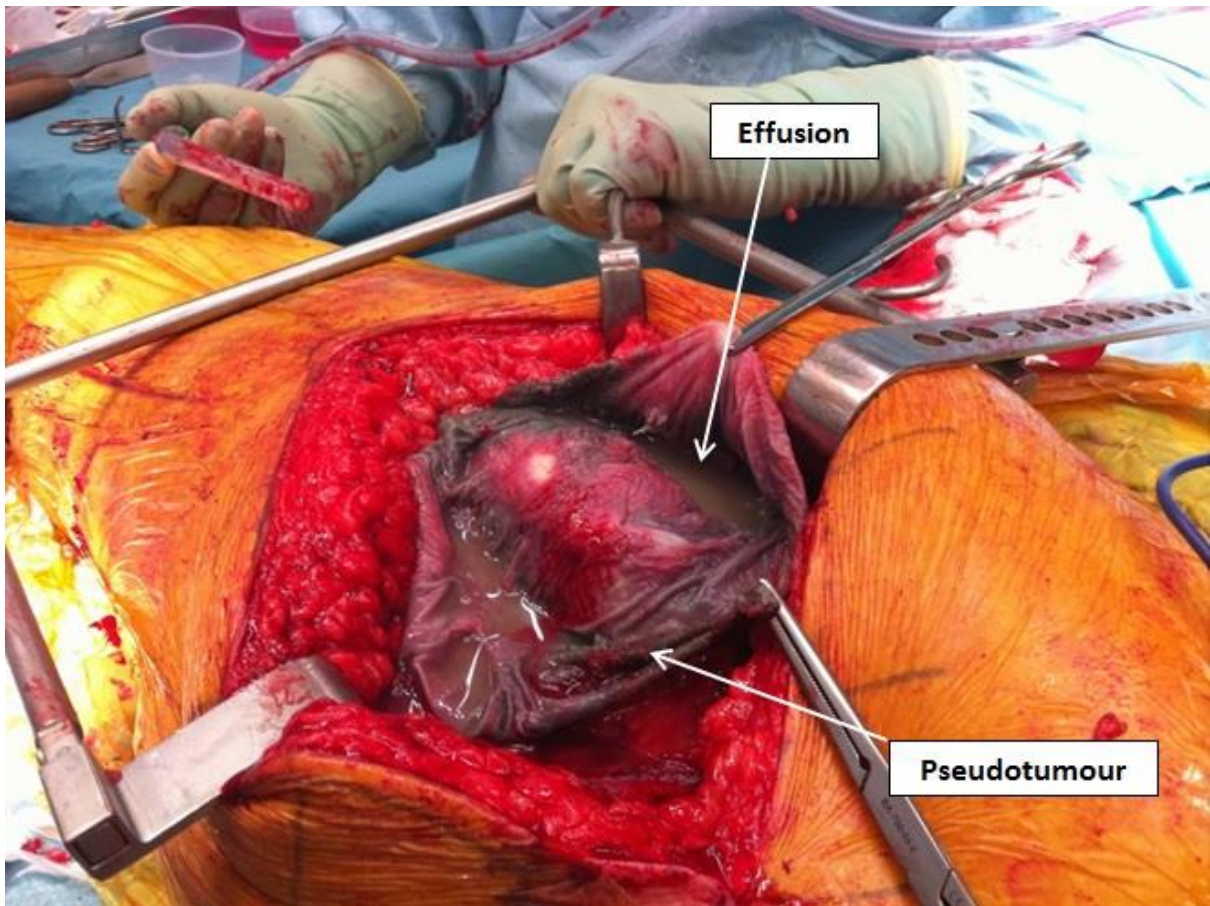
Figure 7: An intraoperative photo of a MoM hip revision procedure showing a pseudotumour and effusion

Ceramic orthopaedic products such as the BIOLOX range (CeramTec GmbH, Lauf Site, Germany) are manufactured from a zirconia toughened alumina ceramic [192]. Numerous studies have reported low wear rates for CoC THAs, in comparison to metal or polyethylene based articulations [193][194][195]. However while ceramic particles are noted to be more biologically inert, if they were to be released in sufficient numbers it could potentially result in osteolysis similar to that of polyethylene particles [196].

Another common reason for revision is dislocation or subluxation (partial dislocation), which in 2013 accounted for 13% (1,303 procedures) of hip revisions [1]. Dislocation usually occurs as a result of trauma, forcing the bones of a joint to undergo abnormal separation. For hip replacements there are several reported causes of dislocation such as patient factors [197] and implant factors including head diameter [197][198][199] and the positioning of the acetabular cup [200][201]. For the PIP joint, dislocation is also an issue [5] due to the unconstrained nature of many of the prostheses utilised and the reduced stability of the surrounding soft tissue due to RA.

Fractures are also a common cause of failure[1]. In the NJR 2014 annual report the term fracture may refer to fracture of the prosthesis, acetabulum or femoral neck [1]. Of these the most common fracture was periprosthetic fractures, a fracture of the bone surrounding the implant, which resulted in 10 % (963 procedures) of hip revisions in 2013 [1]. Femoral neck fracture following hip arthroplasty was commonly associated with intra operative notching of the femoral neck [202 203], varus placement of the femoral component and insufficient cover of the reamed femoral bone by the prosthesis [203 202]. In contrast to hips, broken or defective prostheses accounted for 38 % of all PIP revisions noted in the Norwegian arthroplasty register [5]. Numerous studies have also reported PIP prosthesis fractures [174 176 128 204 205].

Finally, whilst not a failure mode per say, pyrolytic carbon PIP prostheses, CoC and MoM hip prostheses have been reported to squeak in vivo [206 205,207]. However, a squeaky prosthesis is unlikely to be revised in the absence of other clinical symptoms such as pain.

3.5. Thesis contribution to the literature

The overarching aim of the studies presented within this thesis was to apply engineering analysis to identify failure modes of prostheses both in a pre and post clinical context. The studies examined a range of different problems presented in orthopaedics, some of which are not widely publicised.

The deformation studies have provided a detailed account of the testing, validation and implementation of an optical system to measure acetabular shell deformation in cadavers. One of the largest contributions to the literature is the validation of the ATOS system, a validation which has not been reported for any other measurement system used for this application. The third deformation study "*The influence of the strength of bone on the deformation of acetabular shells*" also offers the first quantified comparison between the mechanical properties of bone and size of the deformation. Combined, these studies provide a detailed methodology that can be applied by other researchers to standardise the testing of acetabular shell deformation and allow direct comparison between studies.

The trunnion study was not the first to present volumetric wear results, however it was the first to include a large cohort of ex vivo samples (n=28), the largest cohort reported in the literature. In addition to this it is the first study to validate a

measurement method for quantifying the volumetric wear from the trunnion surface. This methodology can now be applied by other studies examining the trunnion surfaces.

The study "*Surface finish of the Exeter Trauma Stem: A cause for concern?*" was not the first to offer surface roughness data for the Exeter matt finish stem. However it was the first study to offer a comparison between the original Exeter, the ETS and the Exeter matt stems, demonstrating the different surface finishes of all three types. The study found that there was a statistical difference between the surface finish of the ETS and the Exeter stem. Given that NICE have implied that the ETS is equivalent to the Exeter stem, the results indicate that this may be misleading and further research should be conducted to determine if it has a similar clinical performance.

The study entitled "*An analysis of explanted pyrolytic carbon prostheses*" was the first independent ex vivo analysis of such implants reported in the literature. Similarly the study "*Analysis of failed Van Straten LPM proximal interphalangeal prostheses*" offered the first explant analysis of this design of prosthesis. Given the limited ex vivo analysis performed on finger prostheses, an important issue highlighted previously [36]; these two studies represent a significant contribution in this field.

3.6. Links between studies

The major link between all the studies is that they examined orthopaedic prostheses using engineering analysis. Whilst the specific issues being investigated varied from study to study, the underlying theme between them remained the same. The aspect that changed was the measurement methods used.

There is a distinct link between the three deformation studies as these were performed in a linear sequence where the previous paper informed the following one. All three studies used the same optical system to measure deformation; however the second paper "*Validation of an optical system to measure acetabular shell deformation in cadavers*" also used a CMM. The study "*Determining material loss from the femoral stem trunnion in hip arthroplasty using a coordinate measuring machine*" also uses a CMM.

In addition to both using a CMM, the studies were also validations of measurement methods. The study "*Validation of an optical system to measure acetabular shell deformation in cadavers*" used a CMM to validate the optical system, whilst the study "*Determining material loss from the femoral stem trunnion in hip arthroplasty using a coordinate measuring machine*" used gravimetric measurements to validate the CMM.

The studies "*Surface finish of the Exeter Trauma Stem: A cause for concern?*" "*An analysis of explanted pyrolytic carbon prostheses*" and "*Analysis of failed Van Straten LPM proximal interphalangeal prostheses*" characterised the topography by using a profilometer to measure the surface roughness. In addition all of the studies used the same parameter R_a.

The ETS study focussed upon the roughness of the main surface of the stem, whereas the finger explant studies focussed on characterising the bearing surfaces. The method of measuring roughness using a ZYGO was first applied to the ETS hip prostheses, before being used for the finger prostheses. In addition the trunnion validation study also utilised a profilometer although this was used to characterise the straightness of the trunnion samples rather than the roughness.

Chapter 4. Suggestions for future work

Future work could and should examine prostheses from different joints using similar methods to those described in this thesis to understand their performance.

Firstly in vitro wear testing should be standard for new prostheses to avoid implanting potentially dangerous devices into patients. For hips, this should include at high inclination and anteversion angles of the acetabular component.

Whilst pre-clinical evaluation is important, one of the key ways in which prostheses can be improved is by routinely performing ex vivo analysis on failed prostheses to determine the mode of failure. Such analysis should include quantifying the wear, which has been shown to be a major limiting factor in the long term survival of prostheses [208]. Measurements can quickly be performed using machines such as a CMM, which is capable of measuring the bearing surfaces of two hip replacements in a mean time of 45 minutes [87]. Where this is not possible roughness should be measured to provide some quantification of the surface damage.

The main difficulty is not with the measurement methodology, but the lack of a protocol that specifies what should happen with failed joint replacements. The lack of consensus on how ex vivo prostheses should be treated currently results in the majority of prostheses being destroyed. A practical solution would be to establish retrieval centres with an expansion of the NJR to include volumetric wear of different prostheses.

A pilot study running since November 2013, known as the Northern Retrieval Registry (NRR), has already been established between five hospitals in North Tees, Durham, Sunderland and Newcastle [87]. It functions by utilising an online data tagging system. Once a surgeon has retrieved a hip prosthesis they enter the details into the NRR online system which generates a code for that particular prosthesis. This code links the patient details stored in the NHS to the hip prosthesis so that different variables can be investigated. All hip prostheses retrieved from these hospitals during revision surgery are sterilised and then sent to the retrieval centre for volumetric wear analysis. The aim is to identify key design factors that are associated with clinical success or failure in order to identify harmful prostheses early. The use of patient variables allows other parameters, such as gender and BMI to also be compared to wear.

Chapter 5. General candidate statement on published works

It should be noted that there were issues in obtaining correct reflections of the candidate's contribution to each study.

For the Exeter Trauma Stem paper all measurements and analysis were performed by the candidate, with the exception of the statistical analysis. The data was supplied to the surgeons as requested and from this a paper was drafted. The paper was not sent to the authors at Newcastle University prior to submission, with a copy instead supplied after submission for inspection. This was indicative of the way in which the project functioned.

For the trunnion validation study the generic design of the experiments was proposed by David Langton with the specifics defined by the candidate. The research was conducted by the candidate and one other co-author in a 50:50 split between gravimetric and CMM measurements. The candidate was responsible for the CMM measurements and all the data analysis, whilst the second author was responsible for the gravimetric measurements.

Throughout the collaboration with Ceramtec there have been complications and significant disagreement over how the project should be run, and who was responsible for which aspects of each study. An example of this was the validation study, where the draft manuscript provided by Ceramtec was completely inadequate for publication and in several instances plagiarised our previous work. The candidate spent several months completely rewriting the manuscript to ensure it was of suitable quality for publication and ensuring that it did not plagiarise.

In order to get Ceramtec to sign the documents for the three papers they were involved with, lower percentage contributions from the candidate were presented to all co-authors. The surgeons and academic staff involved with the study signed the documents confirming the candidate's contribution; however Ceramtec disputed the already reduced values, lowering them further still. Whilst this was substantially lower than the actual contribution, there was little choice but to accept the revised values, otherwise the signatures would have been retracted and the forms left unsigned.

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