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**THE USE OF 3D SURFACE ANALYSIS TECHNIQUES TO
INVESTIGATE THE WEAR OF MATT SURFACE FINISH
FEMORAL STEMS IN TOTAL HIP REPLACEMENT**

LEIGH TONI BROWN

A thesis submitted to The University of Huddersfield in partial fulfilment of the
requirements for the degree of Doctor of Philosophy

April 2006

ABSTRACT

Total hip replacement is one of the most common surgical procedures carried out both in the UK and Worldwide. With an increasing number of younger patients undergoing the procedure, there is an emphasis on increasing the longevity of prostheses. The following reports on a number of component studies which, when combined give an insight into the mechanism of wear behind the loosening and failure of matt surface finish femoral stems. By examining stems which have been explanted from patients, a method of wear classification has been developed, and also 3D surface measurement techniques have been employed to quantify wear through parametric characterisation and also volume analysis. Initial findings suggested that the wear of matt finish femoral stems differs to that of smoother polished femoral stems.

Studies also provide information regarding the nature of bone cement, its behaviour and the interaction between stem and cement following insertion of the stem. It was found that geometric change in bone cement occurred during polymerisation, and following curing. This geometric change presented itself in the form of differential shrinkage. This shrinkage of cement was observed initially through 3D surface topography analysis and later confirmed with geometric measurement techniques.

The presence of voids between stem and cement give rise to the possibility of debris creation and transportation, adding to the evidence for a difference in wear mechanism between polished and matt surface finish femoral stems.

Some progress was made towards replication of wear in vitro which has future possibilities for wear screening of materials and designs of future prostheses.

The overall conclusion of the study suggests that the dominant wear mechanism which occurred between the stem and bone cement was abrasive in nature and this is likely to explain the accelerated wear of matt stems which has been reported by clinicians and researchers.

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CHAPTER 1. INTRODUCTION

For patients with painful and debilitating diseases such as osteoarthritis, and rheumatoid arthritis, total joint replacement is an effective way of restoring mobility, reducing pain and improving patient's quality of life, often considerably.

Most joints in the body can be and have been successfully replaced, knees, ankles, shoulders, fingers. Total hip replacement is the focus of this study, it being the most common and well established procedure in joint replacement.

Although the procedure is one that has been successfully performed since the 1960's, up to 10% of the 50,000 operations carried out in the UK each year are revision operations to replace prostheses which have failed prematurely (National Joint Registry, 2002) Any joint which fails before the natural end of a person's life is deemed to have failed prematurely, however joints which perform for upwards of 15 years are deemed to be fairly successful. With the increase in life expectancy, and an increase in the number of younger patients requiring joint replacement, there is an emphasis on increasing the longevity of total hip replacement systems.

The most prolific cause of premature failure of total hip replacement is aseptic loosening, accounting for up to 75% of required revision operations. The premise behind all total hip replacements is fundamentally the same; the affected joint is removed and replaced with a prosthesis. The prosthesis is generally comprised of three components: the acetabular cup traditionally manufactured from Ultra High Molecular Weight High Density Polyethylene (UHMWPE); a femoral head (or ball) typically manufactured from metal or ceramic; this is secured into position by inserting a femoral stem down the femoral canal. The stem is fixated in one of two ways, either by relying on bony ingrowth into a porous coating incorporated into the design of the femoral stem or the second and more common method of fixation, and the one which this study concentrates on is by use of a PMMA bone cement, this is introduced into the femoral canal prior to insertion of the stem. The PMMA bone cement cures to a solid medium which serves to stabilise the stem and allow for load distribution. Aseptic loosening is effectively a mechanical failure of the replacement joint system, fractures and breakages of replacement joints are rare

following the implementation of testing standards and improvements in materials. The current primary reason for aseptic loosening is bone resorption due to particulate debris being released during wear of the replacement components. This debris is circulated throughout the system by the hydraulic effects of the pumping action of the implant, induced during the gait cycle. This wear can potentially occur at any interface in the replacement system: abrasive sliding wear between the articulating head and cup is well documented, with new advances this source is being reduced by employing novel materials which reduce the production of wear particles such as ceramics and CoCr alloys with excellent bearing properties. Another interface where wear has long since been observed is the stem/cement interface (Howell et al 2004). Debris at the stem cement interface is attributed to fretting wear due to micromovements of the stem in vivo. The wear at the stem/cement interface is less well documented than the production of debris from the bearing surface, and differences between different designs of femoral stems (of which there are many) have largely been overlooked in terms of the possible contribution of debris (D W Murray et al 1994).

This study focuses on the wear of femoral stems with a matt, bead blasted surface finish, with the aim of defining the wear mechanism involved in the premature failure of femoral stems of this design.

The study is comprised of a number of component studies in order to fulfil the above aim, these studies comprise:

- i) An investigation of wear on explanted stems was carried out where wear was mapped and categorised prior to analysis with 3D surface metrology techniques. Characterisation was achieved through parametric analysis and also mathematical modelling of the wear.
- ii) A method of semi-quantitative volume analysis was developed in order to give a less subjective method of wear assessment
- iii) The nature and behaviour of PMMA bone cement was investigated, to determine the effects of the polymerisation and curing process on the nature of contact at the stem cement interface
- iv) The nature of contact was further investigated utilising different 3D surface

metrology techniques, the original studies concentrated on determining the relevance of surface contact and was further expanded to investigate differences between different types of bone cement

- v) An attempt was made to replicate wear seen on explanted stems in laboratory conditions, initial attempts were conducted with limited success, however further work has produced a reliable and repeatable method of fretting simulation on femoral stems

The culmination of results from all of the component studies gave an insight into the wear mechanism involved in the failure of matt finish femoral stems, and highlighted the differences in mechanisms and severity of wear between stems of differing surface finish. The studies on PMMA bone cement behaviour aimed to confirm hypotheses drawn and also provided some insight into the contact mechanics at the stem/cement interface

The ability to report the wear mechanism, highlight differences in designs and provide new tools for the assessment of wear of femoral stems provided more knowledge, and a less subjective measure of pre clinical success, and has enabled better assessment of future designs through the use of simulation.

CHAPTER 2. TOTAL HIP REPLACEMENT

2.0 Chapter Summary

Total hip replacement is a life changing procedure restoring quality of life to thousands of patients each year world-wide.

Of the 50,000 total hip replacements carried out annually in the UK up to 10% are performed to revise joints that have failed prematurely. (National Joint Registry, 2002) With the increase in patient demands and greater numbers of younger patients requiring surgery there is an emphasis on extending the life of prostheses and decreasing the need for revision surgery.

Developments in materials and manufacturing techniques coupled with advances in operative technique have brought about improvements over the last two decades. The boundaries are now being pushed to investigate further why joints fail; this study concentrates on investigating the influence of the stem/cement interface on debris production and subsequent failure of THR.

It has been reported that bone cement has been referred to as the “weak link” (Dr A J C Lee 1999, S P James et al 1992, G Lewis 1997) in THR. The mechanical properties of bone cement appear to have been thoroughly investigated and tested, though there is limited literature available on the mechanism of wear between the stem and cement and more information could be gathered as to the behaviour of cement and its interaction with the metallic stem it fixes.

2.1 The Need for Total Hip Replacement (THR)

Total hip replacement is one of the most common orthopaedic surgical procedures performed both in the UK and Worldwide. It is well documented as the most effective solution to improving quality of life for individuals with debilitating and painful disorders such as osteo-arthritis, rheumatoid arthritis and necrosis of the hip along with deformities and complicated fractures. In the UK alone there are in excess of 50,000 procedures performed each year. The annual figure for the US is in excess of 200,000 with estimates Worldwide reaching over 0.5million. (National Joint Registry [UK] 2004)

2.2 Expectations

The ultimate aim of performing joint replacement is to improve the quality of life for patients for the duration of their lifetime. To quantify this in years of useful service required from a joint is an onerous task. Presently a joint, which provides function for in excess of 15 years, is hailed a relative success. With the increases in life expectancy, general activity levels and patient demands, there is pressure on the orthopaedic industry and health care authorities alike to ensure the functional lifetime of prosthetic components is increased to account for these factors.

An increase in the longevity of replacement joints would also result in economic benefits for healthcare authorities, where prosthetic joints fail, a revision operation is required. Revision operations are more costly than primary procedures, they are also less successful, often resulting in further revision surgery and also add to the political nightmare of hospital waiting lists.

The benefits in improving total joint replacement technology are great; this is reflected by the huge amount of effort invested by the orthopaedic industry on new product development each year.

2.3 Patient profile

Traditionally THR for the main part has been a procedure received by patients in the later stages of life. This is due to the nature of conditions for which THR is necessary to provide improvement in quality of life. The most common cause of THR is arthritis, a disease, which is generally suffered by the elderly population. There is an increase in people utilising leisure time for sports and pastimes that put strain on the body, in particular the joints. It is predicted that there will be an increase in younger patients requiring the procedure earlier in life due to this increase in activity dictated by the change in lifestyle. The increase in obesity amongst the world's population is also a factor, which will ultimately result in an increase in the need for joint replacement. The skeleton which is a load bearing structure is not designed or built to cope with the strain which excess weight places upon it, causing wear and tear on the joints prematurely.

The above factors coupled with the increase in life expectancy due to the advancement of modern medicine dictates a need for replacement prostheses to be more durable and give a longer life in service, and greater functional performance.

Current guidelines for THR patients suggest that activities outside of walking should be kept to a minimum, so as to prolong the life of the joint; this would not satisfy the patient's increasing demands for the ability to play sports and indulge in strenuous activities. In an increasingly consumer driven society there is a deal of pressure on orthopaedic manufacturers to satisfy their customers demands, whether that be the patient's or the surgeon's.

2.4 Common Causes

The ultimate cause requiring the replacement of a joint is its failure, this failure can occur in a number of ways, all of which are painful and often debilitating. Drug therapy can go some way to alleviate pain, however it is widely accepted that to restore joint function and eliminate pain, replacement of the affected joint is often the most effective treatment.

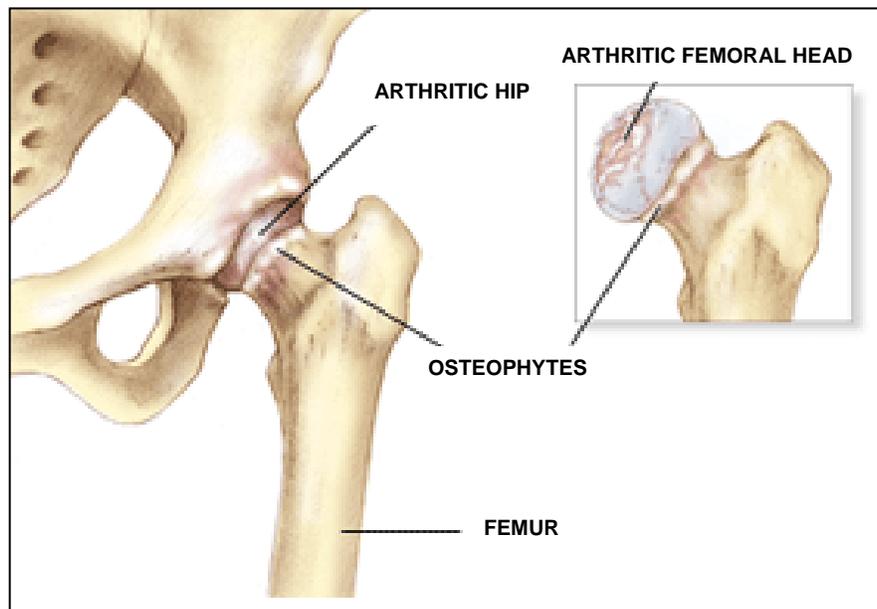


Figure 2.1 – A schematic showing an arthritic hip joint. (www.steadman-hawkins.com)

2.4.1 Osteoarthritis

“A degenerative disease of joints resulting from wear of the articular cartilage, which may lead to changes in the underlying bone” Oxford medical dictionary (1998)

The articular cartilage makes up the bearing surfaces between the ball of the femur and the socket which makes up the hip joint (figure 2.1). Once this bearing surface has worn away through use, the bones are left to grind against each other causing pain and reduction in mobility. In severe cases the patient is unable to walk due to lack of movement in the joint. Due to the degenerative nature of the process being effectively through over use of the joints, this is a condition which is seen almost exclusively in the older patient. A secondary cause of this condition is due to abnormal loading of the joint through deformity, or through damage to the joint following trauma. Osteoarthritis is the most common reason for THR.

2.4.2 Rheumatoid arthritis

This condition occurs independently of age. It affects the synovial lining of joints; problems are usually incurred initially with fingers, wrists, and ankles with later involvement of hips and knees (Oxford medical dictionary 1998). Progression of the disease results in damage to supporting ligaments and erosion of the bone. Severity varies with some patients experiencing spontaneous improvement. Drug therapy can ease symptoms though in extreme cases where bony changes or joint deformity are experienced it is accepted that the most effective treatment is joint replacement.

2.4.3 Necrosis

Necrosis of the hip is often the result of disease, or physical injury and can be attributed to an interference of the blood supply to the hip. The outcome is generally the death of cells in the affected area causing the load bearing ability of the hip joint to be severely reduced leading to loss of movement and instability.

2.4.4 Other Causes

Severe trauma of the hip is also another common condition leading to the need for joint replacement. Where the bone structure is irreparable with modern fixation devices, joint replacement is often the only option. Traditionally in younger patients THR has been viewed a last resort. In these incidences it is imperative that bone stock is retained for the maximum time possible to allow for revision surgery should the joint fail prematurely. This need also highlights the requirement for prostheses with greater durability and longevity.

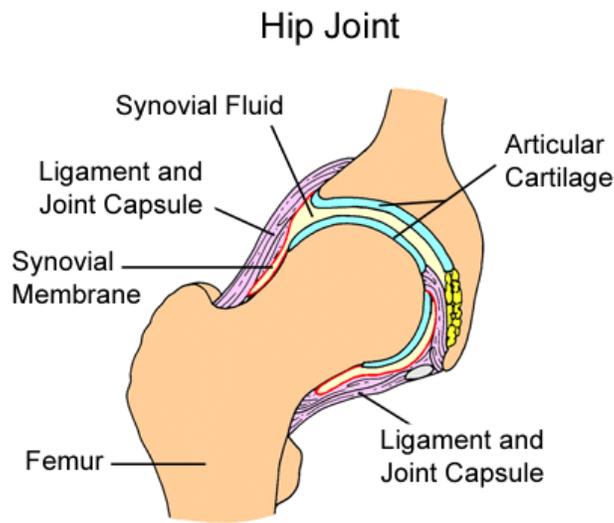


Figure 2.2 – Schematic of the Hip joint (www.childrenshospital.org)

2.5 Procedure

During total hip replacement, the head of the femur is removed and replaced by a prosthetic ball, this is typically secured in place by the insertion of a femoral stem into a cavity in the femur (medullary canal). The ball or femoral head articulates with a replacement acetabular cup, which is inserted into the affected acetabulum in the pelvis. A representation of the positioning of these components can be seen in figure 2.3

There are two main types of total hip replacement and these are categorised by the way in

which the stem is fixed into the femur. Cementless prostheses rely on a surface coating or surface structure to allow for ingrowth of bone into the femoral stem for implant stability. The more traditional method of stem fixation and that which was pioneered by Sir John Charnley, is the introduction of a mantle between bone and femoral stem in the canal. This mantle is created using bone cement, most often PMMA (poly-methyl-methacrylate). The PMMA bone cement is pressurised into the cavity created by the removal of the femoral head and the reaming out of the medullary canal prior to insertion of the stem, giving a method of fixation and also providing enhanced load distribution from the stem to bone.

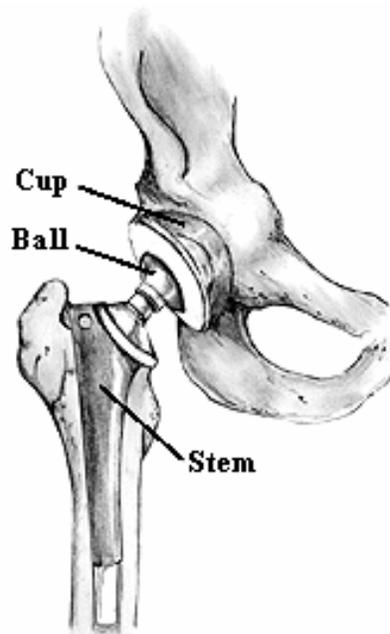


Figure 2.3 Schematic of the replacement hip joint in situ (www.hipsandknees.com)

2.6 History of Total Hip Replacement

Total hip replacement was the pioneering surgical technique in the modern prosthetic replacement family. In the 1950's prototype procedures were being performed to replace affected joints, though with little success and very poor outcomes for the patients. Generally the result was a reduction in quality of life due to additional trauma sustained during procedure. The general idea was to resurface the affected bearing interfaces with a variety of materials ranging from glass, to biological materials such as pigs bladders.

It wasn't until the 1960's that total hip replacement prostheses, as we know them today,

were introduced. These were designed and developed by Sir John Charnley (1911-1982). The main feature of this pioneering technique was the replacement of the whole joint, thus providing a new head and socket at the articulating surface. Since the development of THR in the 1960's the basic concept of replacing the articulating surfaces with femoral components and an acetabular cup has remained constant, though there has been much development in terms of geometrical size, materials used and surgical technique.

Figure 2.4 shows the "Charnley" Hip replacement system, the Charnley design still accounts for a large proportion of market share even today with in around 60% (D W Murray et al 1994) cemented type prostheses available for use.

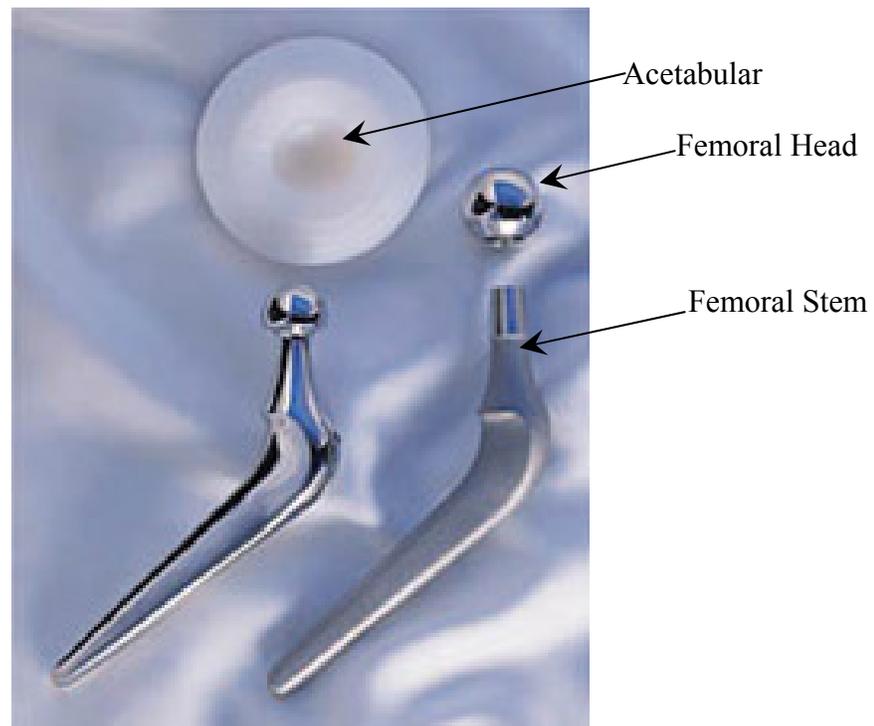


Figure 2.4 – Charnley hip replacement system

(http://www.monica.be/images/fotosknieheup/heup_gecementeerd.jpg)

The other industry gold standard replacement hip prostheses the Exeter hip system pioneered by Prof R S M Ling, A J C Lee et al. The basic rationale of a cemented system is the same as the Charnley hip though the geometrical design differs; figure 2.5 shows the current Exeter stem design.



Figure 2.5 the Exeter hip replacement system (Stryker)

Together these two pioneering designs proved highly successful and still dominate the market world-wide. A positive advance in design saw the introduction of a modular stem. This allows for independent selection of heads, thus facilitating surgeons to more accurately size the components and also allowing for the head to be manufactured from alternative materials to that of the stem, therefore giving the ability to optimise bearing surfaces (D Dowson 1995).

Very recent developments have seen a move back towards research in the resurfacing techniques, investigating new materials with excellent bearing properties to provide new bearing surfaces with minimal disruption to surrounding tissue. Long term results for this technique are not yet available making it impossible to evaluate the prosthetic components or technique in terms of patient success (D McMinn et al 1996, J Daniel et al 2004)

2.7 Design of Prostheses

This study concentrates on the more widely used cemented type of prostheses, even within this one category of implant there are several substantial differences between the vast array of components available on the market.



Figure 2.6. Differing designs of implants

Figure 2.6 indicates a range of implants where design differences can be clearly seen.

Substantial research and testing is carried out prior to the introduction of an implant onto the market, however it is generally accepted that the single best indicator of implant success is its long-term in vivo survival.

D W Murray et al (1994) carried out an extensive investigation into data pertaining to 60 of the implants available for surgeon use on the market in 1995. Of these implants there were very few with long term results to indicate success or otherwise. It has in the past been a general failing to not have a fully inclusive database of survival results for the prostheses available. Sweden made a move to correct this in 1979 being the first nation to

compile a national register of all hip replacements performed in each facility in Sweden. Since its success, a number of other nations have followed suit including Finland (1980), Norway (1987), Denmark (1994), New Zealand (1997), Hungary (1998), Australia (2000), and Canada (2001). The UK now has a national joint registry which has been reporting data since September 2004.

These registers monitor and detail differences in implant usage, surgical technique and conditions, and also monitor design changes and advances in procedure. An insight is given into relative success of different design of prostheses, however further research is still on going to determine the reason for design variations to perform differently in service.

2.7.1 Modes of Fixation

As mentioned there are two ways in which the femoral stem is secured into the femoral canal, through biological fixation of the stem and through the introduction of a cement mantle. Biological fixation is achieved by coating the stem in a porous material to allow for ingrowth of bone into pores, this is often aided by a secondary coating of Hydroxyapatite in order to stimulate the growth of bone further. Cemented stems rely on the introduction of PMMA bone cement into the femoral canal to provide fixation and stability of the implant; it is this type of stem that is the concern of this study. Figure 2.7a and figure 2.7b show the differences between cemented and cementless femoral stem systems.

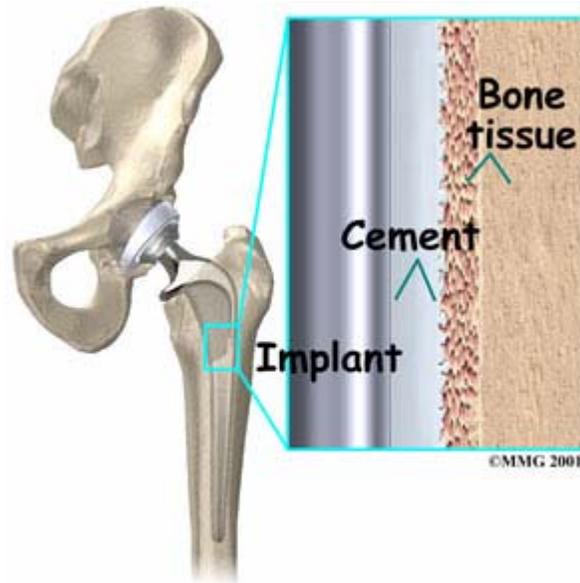


Figure-2.7a – Schematic of cemented hip arthroplasty (www.jointreplacement.com)

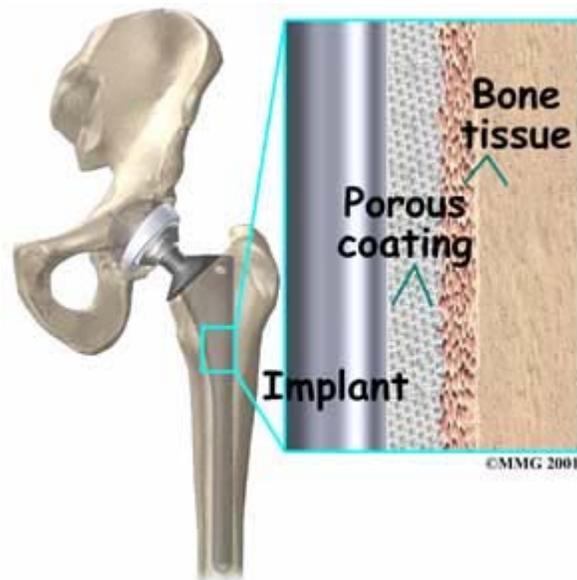


Figure 2.7b- Schematic of an un-cemented hip arthroplasty (www.jointreplacement.com)

Reports show initial prognosis of cementless hip replacements to be good, however long term data is limited, and there are some concerns about their use in older patients due to bone stock and regeneration in the elderly being poor. H Pieringer et al (2003) reported good results with cementless total hip replacement in patient's older than 80 years of age, at a follow up period of 78 months.

2.7.2 Geometry

The basic components of any total hip replacement prosthesis are common to all implants, a femoral head, a femoral stem and an acetabular cup (figure 2.4). Subtle design differences with each of these components can have a great effect on implant stability, longevity and ultimate success.

As has been discussed earlier there are in excess of 60 implants commercially available (D W Murray et al 1994), and the primary area where geometrical differences are most apparent is the femoral stem component. Although size differences occur with head and cup and also ratios of size, the basic geometry is similar. The stem on the other hand displays far more variation, as can be seen in figure 2.6.

2.7.3 Geometry of Femoral Stems

Design differences are required for specific cases such as the need for proximal fixation in patients who have little or poor bone stock distally in the femur. Specific modifications may be required for severe fractures where the inclusion of additional screws and fixators may be required to rebuild the joint. For the majority of patients requiring THR a simple design of stem will suffice. Amongst the stems available there are certain inherent differences in the design of the stem's geometry and form. These differences are reported to have an effect on their success (P Chang et al 1998, G Gie et al 1990)

2.7.4 Double Taper Design

The double taper design is a common type with good clinical history spanning twenty plus years. (J L Fowler et al 1988) The rationale of the design is to allow self locking of the taper in the bone cement through permitting the stem to subside in the mantle creating a mechanical lock between stem and cement. The Exeter Stem is one of the most successful applications of this double taper designs and one of the industry's "gold standards". (Williams et al 2002, Ling 2004)

2.7.5 Collared Stems

The inclusion of a collar on stems is an area for debate (W H Harris 1992). The rationale behind the design is for even distribution of load into the bone. Concerns have been expressed which cite that uneven loading through the collar due to imprecise insertion can lead to bone resorption and premature loosening of stems. The most prominent difference in geometry is the inclusion/absence of a collar at the proximal end of the stem. Implants such as the Charnley and the Stanmore include this collar, and literature suggests that its inclusion facilitates load distribution properties through cortical bone at the proximal end of the femur (J L Lewis et al 1984, I Oh & W Harris 1978). There is debate as to whether or not the inclusion of the collar helps or hinders in this area. Theoretically the load distribution will be improved thus reducing bone resorption due to abnormal loading of the femur. In a study by K Kwong (1990) debates were offered for and against the biomechanical role of the collar: It is clearly necessary to further research the factors contributing to failure of femoral stems in total hip replacement before a definite summary may be offered. The general consensus appears to be that if inserted 100% correctly the collar provides benefit, however even the slightest misalignment leads the collar to have a detrimental effect on prostheses longevity. Other stems also include a flanged area which is deemed to promote greater torsional stability of the stem. (J Loudon & J Charnley 1980)

2.7.6 Modularity

Originally the stem and head were manufactured as a single component, the advent of modularity, using two separate components, gives surgeons the ability to select a combination of head and stem to give more flexibility in sizing and positioning. The ability to introduce more wear resistant materials was also a benefit of the introduction of modularity for example, whilst stainless steel alloys provide excellent mechanical properties for the stem, the head benefits from the wear resistant properties of Cobalt Chrome alloys. The head is fixed to the stem using a push fit double taper. The only drawback of this design feature is the introduction of another interface at which wear can

possibly occur. S D Cook et al (1994) reported the interface between the head and the stem to be a possible source of ion release and wear debris, however noted that development of manufacturing techniques could help to minimise this. The possible wear between the head and stem seems to be far outweighed by the benefits of improved material selection in terms of wear volumes. In addition to Cobalt Chrome Alloys, the introduction of ceramics for use as femoral heads is also permissible with this modular design. Ceramics such as Alumina and Zirconium have the benefit of being machined to a very high accuracy with super smooth surface finish. This had obvious benefits for use at the bearing interface for both the femoral head and the acetabular cup. There is some scepticism about the use of ceramics for orthopaedic implant despite the proven reduction in wear debris during use of the coupling (J A Simon et al 1998), this is in part due to the high profile case of failures with one material (M R Norton et al 2004).

2.7.7 Materials

Material selection for the femoral head and the acetabular cup is based on the need for good bearing properties between the two components, and biocompatibility. The most desirable combination would give a low friction coupling where wear of the components is negligible (R M Hall et al 2001). The materials used also have to be biocompatible to eliminate rejection of the implants following surgery and also to prevent effects of toxicity. Typically the acetabular cup is manufactured from Ultra high molecular weight polyethylene (UHMWPE), it is chosen for its low wear rate, toughness, good impact resistance and low friction which are the qualities necessary for good bearing performance. UHMWPE also displays good biocompatibility and possesses the ability to be sterilised. Recent advances in materials research have brought about the option for ceramics to be used as a replacement for UHMWPE in the manufacture of the acetabular cup and for the manufacture femoral head. (R M Hall et al 2001) The utilisation of ceramics in implant design and manufacture is a relatively new concept, the material properties are excellent for the application of prostheses, and studies have shown the application of their use to be good in reducing wear and associated debris. (S C Scholes et al 2000, V Saikko and H Pfaff 1998, D Dowson 1995, S Santavirta 2003), long term monitoring of their performance in vivo is ongoing. Another advance in material selection has seen a move back towards the use of metal on metal bearings for total hip

replacement with excellent reduction in friction and wear (F Liu et al 2005, J Fisher et al 2002, S L Smith 2001).

With these reductions in wear from what has previously been assumed to be the biggest contributor to wear debris in a THR system, the focus on studying wear at the other interfaces must be examined.

The challenge surrounding material selection for the femoral stem involves a number of factors. Desirable material properties include: flexural, compressive, torsional and tensile strength due to the complicated loading regime in vivo; in addition durability and stiffness are major issues. Optimisation of material properties for the stem is a complicated task, though the materials need the strength and durability to prevent fracture of the joint, high stiffness causes stress shielding and results in further complications for the load transference to the bone. Originally femoral stems were manufactured solely from surgical grade stainless steel, which displays the relative properties and also boasts good biocompatibility.

Although surgical grade stainless steel is still widely used for stems of cemented type prostheses there has been much development into the optimisation of properties and improvement of alloys to improve the material characteristics. Further research into alternative materials has brought about the addition of titanium alloys for the manufacture of femoral stems and cobalt chrome alloys in the manufacture of replacements both for the stem and the femoral head, although the change in material for the femoral head has been proven as a positive step in reducing wear debris. There is little information on how the change in material for the femoral stem has affected this.

The modularity of today's designs facilitates the use of a combination of different materials for the head and the stem if desired. This flexibility in choice allows optimum choice of properties for both components, and as with the acetabular cup the advent of ceramics utilisation in femoral head manufacture has become a major area of research. The advantages of ceramics when used for the femoral head include a decrease in friction, which results in diminished wear, reducing the volume of debris generation (S C Scholes et al 2000, V Saikko and H Pfaff 1998, D Dowson 1995).

2.7.8 Surface Finish

Guidelines are given as to appropriate surface roughness values to give good function in terms of the articulating surfaces (head and cup), in BS ISO 7206 part 2 (1987). The standard reports that the surface finish should be no greater than 70 μ m average roughness (Ra) for metal components and no greater than 30 μ m average roughness (Ra) for ceramic components. In reality, surface finishes of far smoother than this are achieved due to advances in manufacturing techniques and material developments. The need for a highly polished surface finish on these components is due to the necessity for excellent bearing properties between the two through minimisation of contact and friction, hence reducing wear between the components (S L Smith 2001).

EN58J stainless steel was historically the primary material of manufacture for femoral stems. The withdrawn standard BS 3531-2 (1952) EN58J for use in orthopaedic implants stated that the surface finish must be polished. Since its withdrawal from use there are currently no standards relating to the surface finish of femoral stems and consequently with advances in alloys they vary depending upon the brand and design of implant. The effect that the surface finish has on the reliability and longevity of cemented prostheses is an area of debate. In some cases it is assumed that the introduction of a rougher surface finish gives greater mechanical locking between the stem and cement, hence improving stability. (K L Ohashi et al 1998, Harris 1998) Clinical studies have however shown that this is not necessarily the case. The Exeter THR system when developed in 1969 was manufactured from EN58J stainless steel and consequently had a polished surface finish, relatively good success was reported. In 1974 the material of manufacture was changed to 316L stainless steel, and a move was made towards a rougher “matt” surface finish, the rationale being greater mechanical locking between stem and cement and a more stable interface. Following clinical and retrieval studies this proved to be a detrimental move as a higher incidence of aseptic loosening of the femoral stem was encountered. (J L Fowler et al 1988). Other implants report good success with rougher surface finish. However a study by D K Collis and C G Mohler (1998) studies the difference in loosening rates with rough finished and polished stems and concluded that there was higher incidence of

loosening with the rougher surfaced stem. The design of the Exeter stem relies on subsidence into the cement mantle for the self locking taper to be effective, the change in surface finish to a rougher matt appearance is thought to have inhibited the subsidence and this is one school of thought behind its decrease in success. (Middleton et al 1998, J Alfaro-Adrian et al 2001, J L Fowler et al 1988) The geometry of the Charnley prevents subsidence and therefore the surface finish is less of an issue for function.

The surface finish is also thought to affect the way in which wear occurs at the stem cement interface (H Schmotzer et al 2000, C Mohler et al 1995, T McGovern et al 1999) and there are also questions surrounding the transportation of debris to critical areas inducing bone resorption and subsequent failure. (R W Crawford 1999, J Howell et al 2004).

2.8 PMMA Bone cement

PMMA bone cement is the standard medium used for fixation of cemented type prosthesis. During THR the cavity created in the medullary canal is filled with PMMA bone cement prior to insertion of the stem. The introduction of this substance is to fix the stem into position and provide stability of the implant. Lewis (1997) states the main functions of the introduction of cement are to transfer the body weight and service loads from the prosthesis to the bone and increase the load bearing properties between the stem and bone and the cement and bone in the system.

The substance is typically supplied in two component parts; a fine powder containing a radio-opacifying agent and a vial of liquid monomer, upon mixing a liquid substance is formed ready for introduction during the procedure. There are many brands of PMMA bone cement commercially available, all of which vary slightly in their composition. Bone cements commercially available, are differentiated in the main by the viscosity at which they are introduced and the nature of procedure and surgeon preference determines the selection of cement type. There is also a move towards the introduction of antibiotic additives to cement in order to help prevent the onset of infection during and shortly following surgery. In a study by M Baleani et al (2003), it was found that the introduction of antibiotics to the mixture of bone cement did have slight effects on the mechanical properties of the cement but that these were deemed to be insignificant.

There is a large range of PMMA bone cements commercially available, most orthopaedic implant manufacturers also typically produce a range of bone cements. High viscosity cements upon preparation form dough like substances which are similar to putty in texture, these cements are the preferred type for applications such as insertion of the acetabular cup and also are useful in the fixation of components during total knee replacement. Low viscosity cements however mix to form a runny substance with initial consistency of paste. It is during this “paste” phase before the curing process begins and dough like substance is formed, that the cement is generally pressurised into the femoral canal by means of a “cement gun”.



Figure 2.8 Cement pressurisation using a “cement gun”

The cement gun, figure 2.8 allows the surgeon to ensure that the cement has penetrated the cancellous bone in order to achieve integrity at all interfaces and minimise the occurrence of voids in the cement mantle.

The physical and mechanical properties of PMMA bone cement have been well researched and documented (A J C Lee et al 1977, A J C Lee et al 1999, G Lewis 1997, C Liu et al 2001, B Pascual et al 1996, C D Jefferiss et al 1975) there are also a number of studies which investigate optimisation of cementing techniques (R Juliusson et al 1994, G Lewis 1997)

The mixing of components and application of the resulting substance has been the subject of considerable study in order to optimise conditions and function of bone cement during and following THR. There are several variables, which have been investigated in relation to improvements in cementing technique and resulting effects on THR (N Dunne & J Orr 1998). Viscosity of cement on application is a consideration with respect to the resulting shear strength at the Bone/cement and stem/cement interfaces (B Mjoberg et al 1987). In a study by D J Bean et al (1988) low- and moderate- viscosity bone cements were compared at varying pressurisation levels to determine the optimum shear strength. Although the low viscosity bone cement did not penetrate cancellous bone as freely as the moderate viscosity brand with both cements there was little difference in interfacial shear properties between the two brands. It was also determined that pressurisation of greater than 4.14bar did not improve the interfacial shear properties concluding that the optimum pressurisation of the two bone cements in question was between 4.14 and 5.52bar (60 – 80PSI).

Several Studies have concentrated on cement pressurisation as a determining factor in the

success of total hip replacement (A McCaskie et al 1997, W Krause et al 1982). It is generally accepted that for an acceptable level of stability and interfacial shear strength a minimum penetration depth into cancellous bone must be achieved. In a study by R Juliusson et al 1994 viscosity and pressurisation were studied as a variable in relation to penetration of cement into cancellous bone. The finding of that report was an indication of consistency with the theory, that pressurisation is more important than the viscosity of PMMA bone cement.

2.9 Functionality of Total Hip Replacement

2.9.1 Comparative studies.

The vast array of available prostheses has already been highlighted in earlier sections. The differences in design, mode of fixation, material and method of manufacture all highlight possible differences in function and success. There is no one definitive study to compare all of the designs on the market, and there are more variable factors than purely design when assessing the success of the procedure. Several studies have been completed to compare like for like designs and also to compare method of fixation, fixation medium, and operative technique. (P P Anthony et al 1990, S Zimmerman et al 2002, D W Murray et al 1994, D Collis et al 1998)

The most comprehensive comparative study is the Swedish Hip registry. The Swedish Hip Registry was set up in 1979 and was the first register to detail all procedures performed nationally.

2.9.2 Joint Failure

As was outlined earlier, of all the procedures that are carried out around 10% fail prematurely and revision operations are necessary to replace the failed implant. Premature failure of prosthesis is counted as a procedure which has to be revised in the lifetime of the patient. Prosthetic hips are expected to last for upward of 15 years. Though many do there are a significant number however, which do not fulfil this requirement and also with an increase in younger patients undergoing the procedure there is an emphasis on increasing the life of replacement joints in vivo.

There are two key reasons for failure and subsequent need for revision: Firstly septic

loosening of the joint brought on by the onset of infection in the tissue surrounding the joint either at the time of surgery or shortly after; secondly and by far the biggest cause of failure is aseptic loosening which is effectively mechanical failure of one or more components of the replacement joint, this category accounts for around 75% of revision operations (Swedish Hip Registry 2000). Aseptic loosening is a significant area of research and the key factors which contribute are the generation of debris caused by wear of the components; and lesser so with modern design, actual fractures or breakage of one or more of the components.

At each interface within the replacement joint itself, opportunity arises for wear. One of the more prevalently documented areas is the wear of the polymer acetabular cup as it articulates with the harder metallic or ceramic material of the femoral head. (S Lerouge et al 1997, B Derbyshire et al 1994, F C Wang et al 2003, E Ingham & J Fisher 2000). The interface between the femoral stem and the acrylic bone cement is also known to wear although less is known about the nature of the wear at this interface and also about how the debris is transported from this interface to critical areas of cortical bone and tissue (P Revell 1997)

Though the wear of the acetabular cup and femoral head has dominated research, the stem cement interface up until now however has only been the subject of relatively limited study (S Massoud et al 1997). With the advent of novel materials and size optimisation (D Dowson 2001) minimising wear between the bearing surfaces, it is important to understand further how the other interfaces in THR (head/taper, stem/cement and cement/bone) effect the functional success.

Revision operations are less successful than their primary counterparts, due to the more complex nature of the procedure, and the reduction in quality of bone following bone resorption. They are also more costly and create increased pain and discomfort for the patients. Consequently an understanding of all the critical wear interfaces in the THR system is needed if the proportion of revision procedures is to be reduced.

There are three main interfaces at which wear occurs:

- The interface where the femoral head articulates against the acetabular cup
- The interface where the head/stem interface on modular prostheses
- At the stem/cement interface

This project is concerned primarily with studying wear phenomenon at the stem cement/interface.

2.9.3 Aseptic loosening of the stem

Aseptic loosening of the stem typically occurs when there is loss of bone stock (bone resorption) around the stem/cement interface, or when there is a break down in the interface itself.

The process of bone resorption is initiated by the migration of debris into surrounding biological tissue. The auto immune system recognises certain debris as foreign material, the body's defence system is activated to isolate this material, during this phenomenon the osteoclast cells destroy bone stock in the process of surrounding the foreign bodies, ie the particulate debris generated during wear at the interfaces.

A lot of work has been completed to determine the size and type of debris which activates this reaction, the main focus of study has been polyethylene particles generated at the articulating surfaces (A Galvin et al 2005, Fisher et al 2000). More work is being undertaken to determine the effects of metallic debris and ions produced during wear of hard on hard bearings. (P Campbell et al 2004). The debris generated at the stem cement interface has traditionally been thought to be negligible compared to that generated at the articulating bearing surface. Though this may have been the case when investigating wear of polyethylene, the introduction of low wearing ceramics and metallic components may now shift the focus of investigation.

The consequence of bone resorption is generally revision of the affected stem. As previously discussed, revision operations incur a higher cost with decreased success and increased chance of premature failure.

2.9.4 The Stem/Cement Interface

A greater understanding of the nature of wear, which causes premature failure, is needed in order to gain an understanding of how debris is generated, and also how it transports to critical surrounding areas. In a study by M Jasty et al (1991) a series of explanted stems and cement mantles were examined, the comment was made that the specific details of failure of the interface were unclear.

2.9.5 Production of Debris

It has been well documented that during revision operations, upon extraction of the failed stem, debris has been present in surrounding tissue (A Kusaba & Y Kuroli 1997, S D Cook et al 1994). Analysis of the debris present has shown there to be particles of UHMWPE, from the acetabular cup being worn by the articulation of the femoral head (H Minakawa et al 1998). Also observed is the presence of metallic debris from the head and the stem (B F Shahgaldi 1995). The presence of this debris is deemed to be a significant factor in the onset of bone resorption surrounding the implant, leading to subsequent loosening of one or more of the components, resulting in the need for revision.

Observation of explanted components shows there to be a significant amount of damage, often visible to the naked eye. The wear of the head and cup are generally accepted to be due to the interaction between those two components (S K Young et al 1998). The wear of the stem however, is an area where little is known concerning the mechanism of wear which generates the particulate debris that is a fundamental part of premature prosthesis failure.

Initial suggestions attribute the wear of the femoral stem to fretting wear (J Cook 1998). Fretting wear involves oscillatory micro movements between two contacting surfaces, in this case the stem and the cement. The micro movements, which by some are considered to be less than 25 μ m and no greater than 130 μ m (R B Waterhouse 1972), caused the protective oxide layer on the surface of the metal stem to break down, leaving it susceptible to further oxidation and wear. Upon explantation of certain types of stems, characteristic metal oxides, and surface damage have been found (J R Howell et al 2000)

In the 1970's a move by one company (Howmedica, UK) saw the change of surface finish of the stem from a highly polished stem to a rough stem with matt appearance, the rationale behind this being greater fixation of the stem in the cement. After a period of time, it became evident that the matt finish stem possessed a lower success rate than that of the polished stem (J L Fowler et al 1988)

The basic mechanics of fretting wear states "The higher the degree of surface finish, the more severe the effects of fretting wear" (R B Waterhouse 1972), the explanation goes on to describe a study where surfaces with a higher RMS roughness value incur significantly less damage than those with a more polished surface finish. This is due to the ability for plastic deformation of asperities protecting the passive oxide layer. This does not correlate with the higher rate of failure in the matt stems. Evidence suggests that the mechanism behind the wear of matt finish and polished stems may differ but a mechanism of matt stem wear has yet to be defined (J Howell et al 2004).

2.9.6 Transportation of Debris

Although debris generated at the stem cement interface has been observed in areas of bone resorption (D Hale et al 1991) it is unclear how the debris is transported to these areas. With full integrity at the bone cement interface it is assumed that the transportation of metallic debris would not be possible. However, this is not the case as studies have shown, that even when the cement mantle appears to be fully intact, some bone resorption due to the accumulation of metallic debris has been observed (P P Anthony et al 1990)

Investigations into the fluid flow around the prostheses have been carried out. Anthony et al (1990) used a technique during a revision operation to try to determine the depth of the interface, which could be penetrated by the solution; it was found that some of the solution did disperse throughout the interface suggesting that there was loss of integrity at the stem/cement interface.

Other studies have simplified the model investigating the flow between PMMA and stainless steel blocks (R W Crawford et al 1999). Evidence suggests that the contact at the stem/cement interface is more complicated than originally envisaged and may not be continuous, and further investigation is required.

2.10 Overview of Implant Failure

It is established that:

- A number of implants fail due to the production of debris through wear of components
- The exact nature of wear, especially at the stem cement interface is not fully understood
- The contact mechanics at the stem cement interface is an area of contention

To enable the full picture to be established as to the nature and mechanism of wear, and the function of the stem/cement interface, a number of variables require investigation.

- The effect of stem surface roughness on the stem wear
- The mechanism of wear at the stem cement interface
- The behaviour of the PMMA bone cement upon polymerisation
- The nature of the contact at the interface during and following curing
- The effects of cement pressurisation on the contact mechanics
- The effects of chemical composition and viscosity on the performance of the bone cement

2.11 Fretting wear

The term fretting denotes a small oscillatory movement between two solid contacting surfaces (Hutchings I M. 1992). The factors which differentiate fretting from other forms of sliding wear are the magnitude of movement and the nature of damage caused. Fretting is concerned with amplitudes of less than 25 μ m and certainly not greater than 130 μ m (Waterhouse R B. 1972), the movement which is more commonly known as slip is usually tangential to the surface. Fretting wear can take a number of forms but the damage caused by fretting is distinctive.

2.11.1 Fretting Corrosion

The term Fretting corrosion is predominantly concerned with the chemical reaction, which frequently occurs during fretting. Fretting commonly leads to the production of metal oxides on the contacting surfaces, and is identified by the presence of oxide debris and fretting scars on the surface of the material. This debris often has no escape route and accumulates between the surfaces often appearing for steels as a deep red oxide scale.

2.11.2 Fretting Fatigue

The damage that occurs due to the fretting action, in addition to the stresses at the surface caused by the micromovements often leads to the formation of fatigue cracks resulting in a significant reduction in fatigue strength. These cracks can propagate further, possibly leading to catastrophic failure (Vincent L. et al 1992).

2.11.3 Mechanics of fretting

Where two surfaces are in contact permanently and subjected to vibrations or varying stresses fretting may occur. Rabinowicz (1965) sums up fretting as: A case where adhesive, corrosive, and abrasive forms of wear are all present. The adhesive wear is the first stage in fretting, the relative movement between the two contacting surfaces causes adhesive wear between the peaks causing particles to form and further adhere to the opposing surfaces. These particles oxidise causing corrosive wear, the relatively hard oxide debris which can detach from the surface causes abrasive wear to the surfaces as the debris is trapped between the contacting surfaces, causing third body abrasive wear. This is however only one theory, there are several other theories and the mechanism behind fretting and the resulting wear does not appear to be one hundred percent clear. Engel and Klingele (1981) have a slightly different outlook on the process, they report the same mechanisms, but not necessarily in the same order. Another theory is that the protective oxide layer which forms on the surface of a metal is disrupted by the oscillatory micromovements which are present in fretting, when this oxide layer is destroyed, further oxidation and wear of the surface is possible. There are many situations in which fretting is known to occur between contacting surfaces, the first recorded account of it was in a paper on the fatigue of metals published in 1911 by Eden, Rose and Cunningham (Waterhouse R B. 1972).

It is recognised today that fretting is one of the most significant problems with orthopaedic materials. (Cook J E. 1998) Fretting and the damage caused by it has been linked to the premature failure of many types of prostheses including the components used in Total Hip Replacement. Corrosion within the human body raises problems that are not met with elsewhere. Not only is the reduction in strength caused by corrosion important, but even more serious is the effect of the corrosion products on surrounding tissue (Waterhouse R B. 1972). When considering fretting, the consequences of the formation and release of oxide debris could be considered to be of greater concern, when dealing with surgical implants, than with most other applications. This is due to the detrimental effect that the debris could have on tissue within the body, where there is no escape route for the particles and they are left to accumulate. Tissue reaction to wear particles from metal implants may play a major role in the aseptic loosening of implants. (B F Shahgaldi et al 1995).

2.11.4 Surgical Implants

Most implant procedures are performed on limbs that can undergo a large number of stress reversals in one day; the conditions are therefore those in which fretting corrosion can be expected. (Waterhouse R B. 1972)

Femoral Components are more commonly made from one of three types of metal: Titanium alloys typically Ti-6Al-4V; CoCr alloys; and Orthinox® a high grade stainless steel. The standard material for the acetabular cup is UHMWPE (Ultra High molecular weight Polyethylene), with recent exploration into the use of ceramics, such as Alumina or Zirconia as well as metals, typically CoCr alloys. Possible combinations for materials used in modular designs can be seen in figure 2.9.

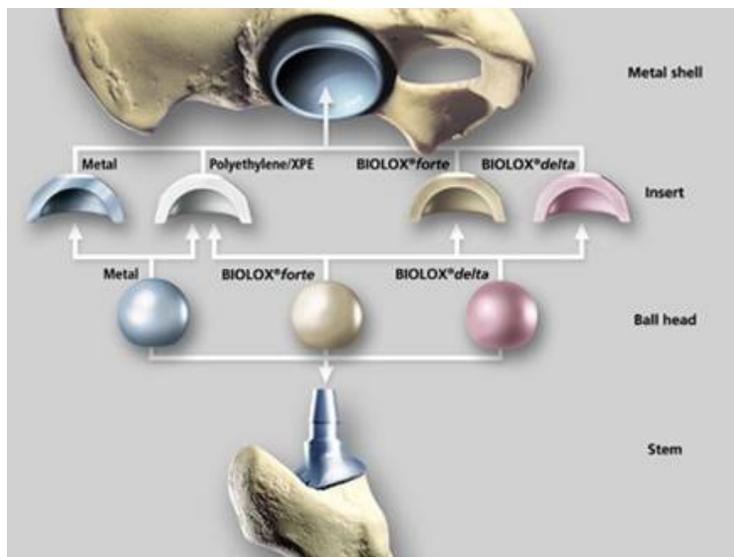


Figure 2.9 - Modular Designs and Material Combinations(www ceramtec.com)

2.11.5 Incidence of Fretting between the Modular Stem and Head

Modular joints offer a greater flexibility in surgical procedures in terms of component interchangeability for head size, neck length, and head material and the benefit of a reduced inventory accompanied with a reduced cost of arthroplasty. (S K.Bhambri & L N Gilbertson 1994) With modular implants the head is a separate component to the femoral stem, The stem and head are mated together using a conical tapered junction, which is susceptible to micromovements and the penetration of fluids (Cook J E. 1998).

S K Bhambri and L N Gilbertson (1994) state “The modular joint has some inherent disadvantages in creating a crevice and causing fretting due to micromovement of two components under cyclic loading.” This is reinforced by the findings of S D Cook et al (1994) where it was stated, “Our findings show that the head -neck interface of modular uncemented femoral stems may sometimes be a source of ion release and wear debris.”

One advantage of the modular system is the variety of materials, including ceramics, that can be used and combined. This is useful as the metals have different advantages and disadvantages when used in THR. Titanium alloys have a modulus of elasticity closer to that of bone than the moduli CoCr alloys or Stainless steel, (U W Bischoff et al 1994), making them ideal for the femoral stem, while cobalt chrome is favoured for the head because of its superior wear properties (S D Cook et al 1994). It was predicted Co-Cr and titanium alloy could be combined in a modular configuration without significantly enhancing the potential for corrosion (Mears 1975). However subsequent studies have shown that corrosion and wear are significantly greater in mixed alloy-systems, (S D Cook et al 1994). It is apparent from the evidence that fretting may occur between the head and the stem of modular prostheses, thus permitting the production of debris at the interface. Mathisen et al (1991) reported the observation that black debris at the modular head, stem taper interface in 4 out of 9 retrieved prostheses. This could conceivably be a factor in the instigation of third body wear, bone lysis and loosening of the prostheses, resulting in premature failure of THR. The advantages of modular prostheses are also apparent enough to warrant investigations into the possible causes of wear and debris production at modular interfaces, with a view to studying ways of minimising the

damage. Importantly, current designs and manufacturing practices have evolved and resolution of this issue should not depend upon debris generation due to fretting-corrosion, since this is understood and can be minimized. Issues related to modularity or not, hopefully, will be resolved before the year 2020. (Jack Lemons 1996)

2.11.6 Incidence of fretting between the stem - bone cement interface in cemented THR

In cemented total hip replacement the femoral stem is fixed into the medullary canal of the femur using bone cement, the bone cement is typically PMMA (Poly-methyl methacrylate). A great proportion of THRs performed today are of the cemented type. Within the cemented variety of THR there are many slight variations on design, material and surface finish of the head and stem.

In a study by Walczac J. et al (1998) 11 stainless steel implants (7 were Muller straight stem and 4 Charnley design), all cemented, were removed from patients, 10 of the implants failed due to aseptic loosening, it was found that in 9 of the 11 implants, corrosion in the form of black discoloration was found on the femoral stem. The formation of black debris is a characteristic sign of fretting corrosion. Examination of the cement mantle also showed the presence of the characteristic black debris.

In a study by J E Cook (1998) wear damage was observed on 4 out of 6 explanted Exeter type femoral stems, it was stated that “The wear damage on each stem was characteristic of that caused by fretting wear.” J E Cook (1998) went on to simulate fretting of the femoral stem in vitro with a test rig, specially designed to mimic in vivo conditions. The tests aimed to exhibit wear equivalent to five years in vivo service. Both polished and matt finished Exeter type stems were examined, on examination of the polished type stems which underwent simulated fretting in the form of Axial and torsional loading it was stated: “The location of the wear damage was consistent with that observed on the explanted femoral stems.”

Many more studies have shown evidence of wear and of fretting damage on both explanted and in vitro tested femoral stems due to micromovements between the stem and cement interface, failure of prostheses does not depend wholly upon the damage caused by fretting, but it has been shown to play a significant part in many revision cases.

2.11.7 Characteristics of Fretting Damage

The phenomenon which occurs when two contacting surfaces experience oscillatory micromovements is called fretting, the movement is usually, but not always tangential to the surface. The result of this action is known as fretting wear and manifests itself in several characteristic ways.

As previously discussed one aspect which differentiates fretting from other forms of reciprocal sliding wear, is the distinct characteristics of fretting damage, and fretting corrosion these characteristics are summarised in the following sections.

2.11.8 Production of Debris

One of the characteristics of fretting wear and in particular fretting corrosion is the production of oxide debris. Where fretting occurs with steel a deep red oxide debris is formed, commonly known as “cocoa” which differs in colour to that of rust. While aluminium oxide generally presents itself in the form of a white powder the oxide debris produced by fretting on aluminium is black.

This debris is often greater in volume than the metal that it is produced from. This gives rise to pitting on the surface of the material.

Godfrey (1951) states “fretting does occur on inert metals and although the debris produced isn’t an oxide there is still debris present.” The debris on unreactive metals such as gold and platinum consists of pure metal powder (Waterhouse RB 1972)

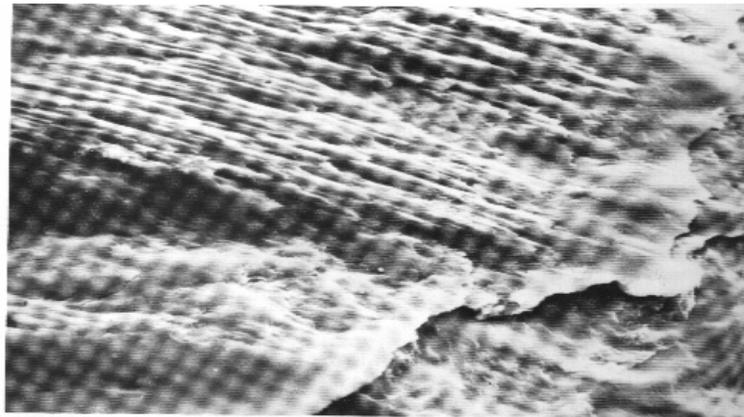
Due to the nature of fretting it is very difficult for the oxide debris to escape from between the contacting surfaces; this may suggest the possibility of third body damage and an increase in wear rate, however I M Hutchings (1992) states during a laboratory test there is often an initial period of rapid wear followed by either a steady or decreasing rate of wear. When considering the incidence of fretting in relation to surgical implants it is this debris production which causes great concern.

2.11.9 Characteristics of Debris

Studies have been carried out to determine the size, shape and composition of the debris produced as a result of fretting. For Steel particle sizes have been reported to be as small as $0.01\mu\text{m}$ to $0.1\mu\text{m}$ in one study (Fenner, Wright and Mann 1956). In a study by Feng and Rightmire (1956) Iron particles were shown to be present as well as the oxide debris, the particles of oxide debris were reported to be of the order $0.25\mu\text{m}$. The iron particles were found to be much larger than the oxide debris some as large as $20\mu\text{m}$. Examination of particles containing alumina viewed under an electron microscope showed a range of particles between $1\mu\text{m}$ to less than $0.05\mu\text{m}$ (Cornelius 1941).

R B. Waterhouse (1972) states “There is some indication that larger amplitudes result in coarser particles, and that the harder the underlying material the smaller the particles”, yet points out that there had been no direct study into the effect of variables on particle size and shape.

The composition of the debris appears to be dependant wholly on the materials and the environment in which fretting occurs, for example, the chemical composition can be very different when studies are conducted in nitrogen as opposed to oxygen, the temperature and humidity also play a part in determining the composition of the debris produced.



*Figure 2.10-A Surface displaying the change in topography due to fretting wear
(Engel & Klingele 1981)*

2.11.10 Surface appearance

In addition to the debris which is produced there are other characteristic signs of fretting wear. These are summarised as

- 1. Grey Staining** - formation of matt surfaces due to micropitting
- 2. Undulations** -in parts metallically smooth
- 3. Pitting formation** -due to the localised piling up of debris.
- 4. Compaction zones** - plastic indentations of the agglomerate into the material.
- 5. Roughening** - in the form of uniform corrugations. Plastic deformation, sometimes with the amassing of loose powdered debris
- 6. Tower like growth** - of a few highly strengthened contact points built up from pasty debris.

(Lothar Engel and Hermann Klingele 1981)

The characteristics listed above are collectively known as fretting scars which often appear on the surface of the material, from these fretting scars it is possible for fatigue cracks to form and propagate from the area of damage. These fatigue cracks can result in a reduction in fatigue strength and can lead to failure of the material.

A further possible result of fretting, in addition to the formation of debris, is localised pitting on the surface (R B Waterhouse 1972). According to Waterhouse this visible sign of fretting appears as approximately two types: shallow dish like depressions and small deep holes, depending on whether or not the debris can escape from the contact area, it is the small deep holes which are likely to occur when the debris becomes entrapped. This is due to the volume of debris being larger than the volume of metal from which it was formed, putting the contents of the hole under a large pressure.

Another characteristic sign of fretting is changes in surface hardness. There is often an increase in surface hardness during fretting due to work hardening and particles of oxide debris becoming embedded in the surface. (R B Waterhouse 1972).

2.12 Simulation of wear

Simulation of wear at the bearing surface has long been used to quantify performance of articulating surfaces, thus evaluating joint performance prior to market release. This is not only a useful tool, but also a requirement of the leading regulatory bodies such as the FDA, ISO and British standards. In simulating wear with optimum loading conditions replicating the gait cycle of walking and other routine activities, functional performance of prostheses can be assessed and refined. It is also a requirement to assess the performance of the strength of a joint with ISO BS 7206 part 4, 6 & 8 stating a requirement for fatigue testing of the stem, neck and taper. With the nature of replacement joints as a product, the design and manufacture is stringently regulated. There is little evidence to suggest that work has been successfully achieved in simulating the wear at the stem/cement interface of femoral components to assess functional aspects of design such as geometry and surface finish. J Cook (1998) did develop a successful model for replicating fretting wear on the Exeter stem, the assessment of the wear was primarily qualitative, however a useful insight into the mechanisms of stem wear was established.

The replication of fretting wear is a useful tool in assessing the design of stems to determine the functionality of stems already available and also to validate new products.

2.13 Developments and Requirements

Current developments in the orthopaedic industry sees a move towards minimally invasive surgery (MIS), computer guided procedures and the introduction of a wealth of new materials and manufacturing techniques.

The overall aim is to produce implants which will last the life of the patient, with minimal disruption to the patient's life and with minimal input of resource from the health authorities in the way of finance and aftercare requirements.

Increasingly younger patients require treatment, and the population in general is living longer. This has obvious implications on the need for improved longevity of replacement joints, with increasingly more complicated designs to fulfil the requirements of minimally invasive surgery and computer guided procedures.

Recent developments have seen the introduction of resurfacing products, hard on hard bearings utilising materials such as cobalt chrome alloys and ceramics, and coated prostheses for uncemented arthroplasty. Though the introduction of these products is set to revolutionise the way in which hip replacement is carried out, there will always ultimately be a need for cemented total hip replacement.

2.13.1 Joint resurfacing

The principles of joint resurfacing hark back to the initial concepts of hip replacement, which were highly unsuccessful and in some cases detrimental (J T Scales 1966). Since then a great deal of research has brought about an understanding of joint loading, improved operative technique and also improved low wearing materials with excellent biocompatibility and mechanical properties. During resurfacing surgery, bone stock is preserved as it is only the head of the femur which is shaped in order to secure the replacement femoral head, which articulates with a large diameter metallic cup. Figure 2.13 shows an example of this.



Figure 2.11 Hip resurfacing procedures

Though the cup generally relies on porous material for bony ingrowth, the head is typically secured using PMMA bone cement in a similar manner to the femoral stem in cemented THR. This head/cement interface is an area which could possibly generate wear through micromotion at the interface, bearing this in mind, investigations into wear of the cement stem interface in THR may prove to be beneficial in predicting/ designing optimal functionality of these implants. This could be of particular interest as the modern resurfacing technique, despite its current popularity, has yet to be proven as a successful alternative to the traditional replacement systems.

2.13.2 Material advances

One of the key areas of development in the orthopaedic industry has been the reduction in wear at the articulating bearing surfaces of implants. This has been achieved through optimisation of geometry and size, improvements in manufacturing and quality controls and the introduction of low wearing materials.

The introduction of the modular stem system has opened up manufacture of femoral heads into new areas, and has allowed the development of hard on hard bearings such as ceramic on ceramic, and metal on metal, or a combination of the two (D Dowson 1995). This has significantly reduced the amount of debris generated at the bearing surface when coupled with precision manufacture to optimise clearances between the two components.

Material advances and modularity have also seen the introduction of Titanium and cobalt chrome for use in manufacture of the femoral stem giving more favourable mechanical properties. There appears to be little evidence of investigation of this into wear of the femoral stem however.

2.14 Rationale

There are gaps in knowledge surrounding fixation and wear of femoral stems in total hip replacement. These gaps are primarily concerned with the nature of contact between the stem and cement, the wear mechanism involved in the generation of metallic debris from the stem cement interface and the means of debris transportation to the critical sites of surrounding tissue. There appears to be more information regarding the wear and failure of polished stems, J Cook (1998) completed a comprehensive study on fretting wear of polished Exeter femoral stems. This study concentrates on gathering information regarding the wear and failure of matt finish femoral stems.

2.15 Aim

The aim of this study is to give an insight into the wear mechanism of the femoral stem which ultimately results in premature failure.

The following objectives will be met in order to achieve this goal.

- Gain a better understanding of the contact mechanics at the stem cement interface.
- Investigate the progression of wear on femoral stems in vivo
- To replicate the wear through practical and mathematical simulation
- To quantify the wear and determine any relationships present
- To investigate the means of debris transportation to critical sites in the body.

CHAPTER 3. METROLOGY

3.0 Introduction

There are two essential areas of metrology which are paramount in the design, function and evaluation of orthopaedic implants. These are geometrical measurement and surface finish assessment. Both methods are utilised in the manufacturing process and are useful tools in the assessment of function following use of implants.

Geometrical metrology encompasses a vast range of techniques from crude assessment of length, to assessment of form such as sphericity or cylindricity with accuracy of sub micron resolution. Surface finish assessment on the other hand is focussed on nanometre measurement of the texture of surfaces following precision manufacturing and finishing techniques.

3.1 The Challenge for metrology in the Orthopaedic Industry

The required successful function of total hip replacement prostheses implies a high degree of precision must be achieved during manufacture in order to ensure that the bearing surfaces perform to an optimum (D Dowson 2001). As displayed in the “Stribeck curve” Figure 3.1, the nature of bearing surfaces as a whole requires minimisation of friction and maximisation of lubrication conditions. Maintenance of clearance requires very precise geometry and this, combined with the surface finish demands, define the required metrological properties of THR.

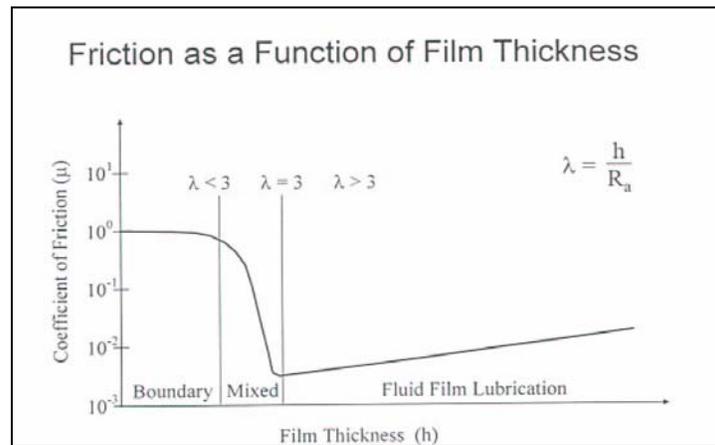


Figure 3.1 – The Stribeck Curve demonstrates the relationship of clearance and surface finish to friction of replacement joints(R M Hall 2003)

The advances in manufacturing technology and also material selection provide a further challenge for metrology in maintaining the momentum with these emerging and developing technologies.

All aspects of implant design and manufacture are subject to rigorous scrutiny by regulatory bodies. The quality of such products is defined by a number of standards, which need to be met in order to satisfy the regulatory requirements. The manufacture of components is often governed by more stringent rules set by orthopaedic manufacturers themselves. This is both in order to be at the forefront of technology and also because the regulatory standards themselves are outdated in terms of what can easily be achieved in manufacture. The primary reason for the standards being outdated is the fast moving developments in manufacturing precision and also the increased selection of materials. The slow process of reviewing and publishing standards to ensure comprehension and accuracy means that it is difficult to update them in line with the fast moving developments in the industry. The standards that do exist (BS EN ISO7206) often refer to the measurement techniques required for quality assurance; these also fall behind as the metrology industry strives to develop technology for measurement in line with the momentum at which manufacturing and precision engineering moves. In addition to quality, modern metrology methodology can be utilised as a tool to identify modes of failure in prosthetic implants, and also as a comparative tool to identify function and success of bearing surfaces aiding the iterative design process.

The primary concern with the bearing surfaces is the generation of particulate debris through wear at the interface, advances in material selection has reduced this wear considerably, and what could once be detected easily by gravimetric assessment is now outside the scope of detection with feasibly affordable instrumentation. The restrictions with assessment by gravimetric means are amplified by the nature of simulated testing, for example, testing is typically conducted in a liquid medium, and components are often secured through use of either bone cement or press fitting. Both of these methods give rise to gravimetric change often greater than that induced through wear at the bearing surface. In the case of ceramics, fluid uptake during testing can be accounted for in some part through use of control specimens; however it is not feasible to determine the difference between material lost from the bearing surface and damage incurred during

fixation of the components. This was negligible when concerned with higher wearing metal on poly components, however with low wearing hard on hard components, it is essential to isolate the bearing surface to examine material loss to gain an accurate picture of the wear characteristics. Therefore to make a distinction between wear of ceramic components it is essential that alternative means of assessing function and wear of components be sought, this is an area where geometrical and surface metrology is starting to be explored and initial studies show clear benefits to this technique. (P Bills et al 2005)

3.2 Geometric Product Specification

The importance of geometric measurement can be traced back to early times where parts of the body were utilised to quantify distance or size, though this gave approximate measurements, each person has different dimension and therefore the results would vary dependent upon the measurer themselves (K Stout 1998). Moves were made to standardise measurement systems, and through many changes historically we have arrived at the system of SI units, as they are known today. All length measurements are dependent upon the international standard of the metre. Similarly all other geometric measurements are determined by international standards ensuring traceability of measurements world-wide.

The increase in accuracy brought about by standardisation has also brought about the need for measurement instrumentation that can ensure both accuracy and repeatability of measurement. With the ease of global collaboration, and the increase in multinational companies operating from several countries this standardisation is paramount, to ensure quality and cost of manufacture are optimum it is also of high importance that the measurement instrumentation gives consistent and traceable results the world over.

3.3 Instrumentation

3.3.1 Coordinate Measuring Machine Technology

The most versatile piece of measurement equipment readily available at feasible cost is the co-ordinate measurement machine (CMM). The CMM is used to measure the overall geometry of a work piece and is normally used to assess dimensions and feature position on a given subject. In the orthopaedic industry the CMM is considered as a standard tool for dimensional checking of manufactured parts. The basic concept of CMM technology has changed little since its first introduction by Ferranti (England 1959), however recent additions to systems and analysis software have enabled measurements to become faster and more accurate.

The configuration of a CMM is invariably a solid granite bed with a probe able to move in 3 axes (x,y,z). The probe is generally made from ruby, due to its favourable thermal expansion, hardness, and form properties. Figure 3.2 shows a schematic of a touch trigger sensor. It is in the probe head where information is gathered and relayed for software analysis.

The probe is driven in order to gently touch a sample and this gives position and measurement relative to a reference plane. Measurement programmes are created in CNC code or are produced through manual operation of the probe position, the CMM will then “learn” these positions in order to enable automated measurement once reference planes and programs are defined.

The industry standard probe technique is touch trigger probe sensors.

3.3.2 Touch Trigger Probe Operation – resistive probe operation

The probe is mounted on a spring mechanism as shown in figure 3.2, the mechanical contacts effectively make up a circuit around a pivot point. When the probe is driven into a sample for measurement, the mechanism moves around the pivot and the circuit is broken. It is this break in the circuit that identifies a measurement point through an infinite increase in the circuit resistance. The position of this point is then recorded. It is

imperative that prior to measurement of a sample, reference planes are determined to identify the position of the object in space, and also to determine the positive direction of each axis.

Calibration is achieved through measurement of a known sphere located to a known point on the bed of the CMM.

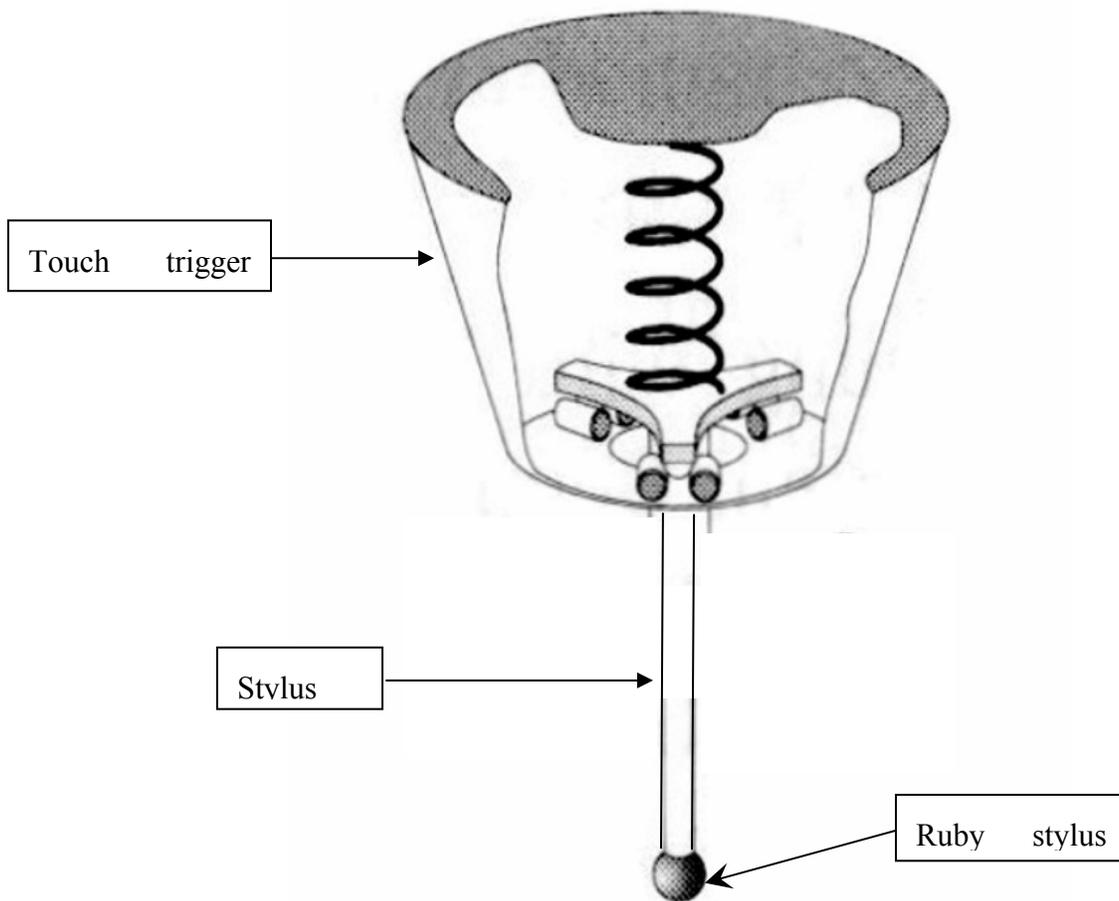


Figure 3.2 Schematic of a touch trigger probe system (www.renishaw.com)

3.4 Geometric Product Specification in the Orthopaedic Industry

In the orthopaedic industry the primary use of CMM's is for quality check purposes. Because of the precision clearances required for minimisation of wear in bearing surfaces, the form and size of components has to be monitored rigidly. Industry standards

have been developed to regulate measurement methods, these standards (BS EN ISO 7206 part 2) all reference CMM's as the standard tool for measurement of form and size.

Attempts were made to define volumetric wear rates of polyethylene bearing surfaces using touch trigger CMM's (S Smith & A Unsworth 1999), however these methods were crude and did not define the optimum measurement conditions, they did give a good indication of change in geometry following simulator testing. One problem with the measurement system was the issue of repeatability between parts due to the difficulties in creating a robust reference datum for measurement comparison. With the advent of hard on hard bearing surfaces such as ceramics and cobalt chrome alloys there is new scope to revisit CMM technology as a tool for quantitative wear determination. This is a method investigated for use in the evaluation of knee prosthesis (P Bills et al 2004). The technique has primarily been utilised to investigate the wear of polyethylene tibial trays. In this case however, a constant contact scanning probe methodology is utilised ensuring a better representation of the subtle changes in the surface associated with wear.

3.5 Surface Finish

The main challenge surrounding the analysis of surface finish is the required accuracy and scale of measurement. Improved material selection and manufacturing techniques have led to the situation where, for bearing surfaces on THR, surface finish is below the measurable resolution that some commercially available instrumentation can detect. Standards state that the surface finish (Ra) of a ceramic femoral head must be below 30 nm and up to 50nm for metal heads. New ceramic and cobalt chrome alloy bearing components are routinely manufactured with surface roughness values of less than Ra = 10nm. In effect the surfaces are smoother than the traditional 2 dimensional contact profilometer techniques can resolve.

3.6 Instrument Classification

There are several types of surface measurement instrumentation, the range and resolution of which can be seen in figure 3.3. The instruments themselves can be split into two broad categories, dependent on the way in which they measure the surface topography: contacting and non contacting.

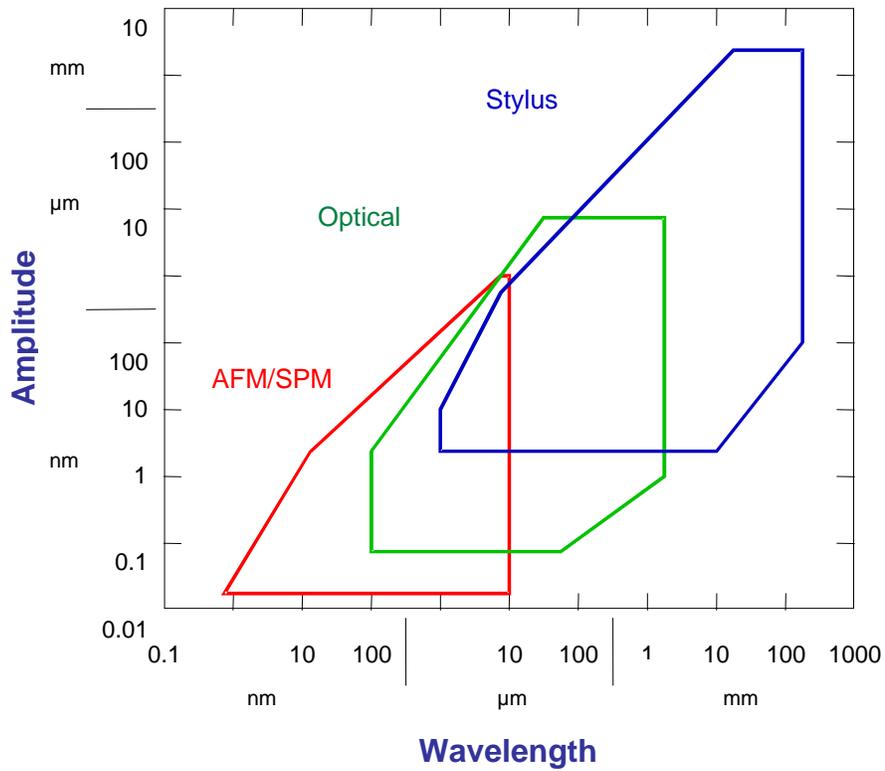


Figure 3.3 - Steadman Diagram showing the range and resolution of available measurement techniques (L Blunt 2004)

3.7 Contacting stylus measurement

Contacting measurement techniques such as the stylus method is the traditional way of measuring surface finish. 2D measurements are routinely performed in such a way to assess the quality of a surface finish. Stylus measurement, being a contacting method, gives a physical measurement of surface roughness. 3D profiles can also be obtained by repeating a number of scans across the surface in the y direction.



Figure 3.4 – Stylus tip of a profilometer performing a measurement

The stylus profilometer works on a similar principle to the stylus pick up of a gramophone in that the movement of a stylus on a gramophone relates to the musical tone and is relayed to an amplifier to emit the sound through a speaker. The stylus of a profilometer translates physical movement of the stylus to measurement of the surface topography. The stylus movement is normally relayed to a PC through means of a transducer and analogue to digital converter. There are several types of transducer used:

Historically the inductive transducer has been the preferred method of data collection. In this method two coaxial coils, one of which is mounted on the arm carrying the stylus, is energised by an AC voltage. The output of the movable coil modulates the AC carrier. A widely used configuration is the linear variable differential transformer (LVDT). In many cases the commercially available stylus profilometers continue to use this technology.

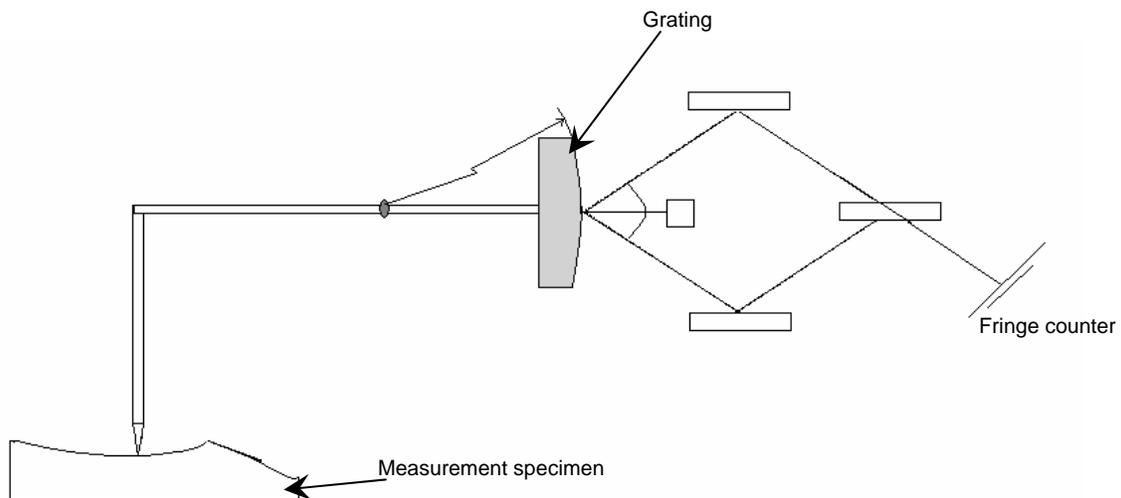


Figure 3.5 Schematic of the Taylor Hobson PGI stylus using the laser interferometer method pickup

A far superior method is the laser interferometer method (figure 3.5). Light from a laser diode passes through a beam splitter. Part of the light is reflected from a fixed mirror and part from a mirror mounted on the stylus arm. The fringes produced by the recombined beams are counted; the shift in the fringe pattern is proportional to the displacement of the moving mirror and hence of the stylus. This emerging technique is pushing through to the market place giving greater resolution and accuracy to the current generation of stylus profilometers.

As with all systems there are advantages and disadvantages of stylus profilometry as a surface measurement technique: the two primary concerns for use with orthopaedic implants are measurement resolution limitations and potential damage to the measurement specimen.

The stylus tip radius generally governs the limitations of a stylus instrument.

Figure 3.6 displays how the stylus tip radius determines the quality of measurement output. The stylus, due to its nature has physical limitations as to the size and depth of scratches and peaks that can be penetrated and fully resolved.

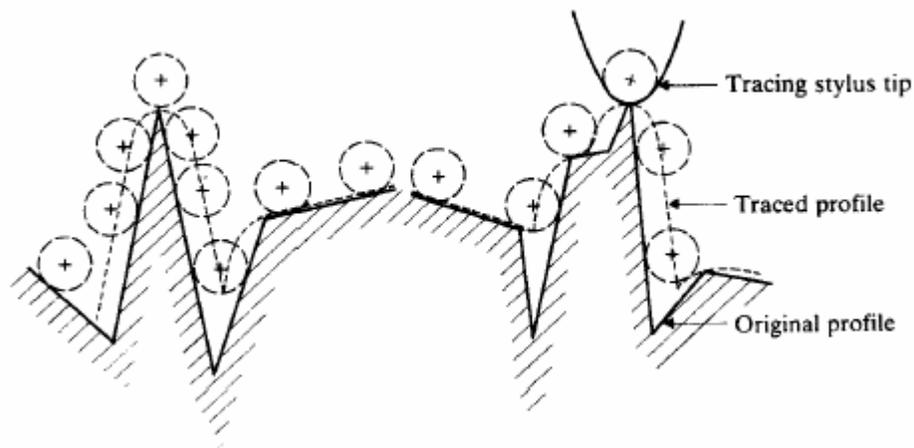


Figure 3.6 - Schematic showing the limitations of the stylus due to the tip size (K J Stout et al 1993)

Another limitation of the stylus type instrument is the damage it may cause to surfaces during the measurement process. With a load of 75mg transmitted through the 2 μ m stylus tip, a high pressure is borne by the surface. This damage is usually restricted to softer materials but can be a factor in selection of measurement technique where non-destructive testing is essential.

With the limitations of range and resolution, and also the possibility of surface damage caused by the use of such physical measurement techniques it is necessary to look to non contacting measurement instrumentation to find a solution.

The system is calibrated through performing a measurement on a hemisphere of known form and texture. The calibration article is obtained from an accredited source to ensure effective correction of the instrument.

3.8 Non Contacting Measurement Instrumentation

From the Steadman diagram figure 3.3, it is clear that for the range and resolution of the contacting stylus group of instruments, there is a non-contacting measurement method that will achieve the desired measurement range and resolution. The most common types of non-contacting instrumentation are optical focus detection, optical interferometry and SEM (scanning electron microscopy).

AFM's (atomic force microscopy) and STM's (scanning tunnelling microscopy) fall into a category of their own as they can not be completely described by the terms contacting and non contacting.

3.8.1 Optical Interferometry

Covering the target range and resolution is the optical interferometer. Many commercially available optical interferometers incorporate two functions, PSI (phase shift interferometry) and VSI (vertical scanning interferometry).

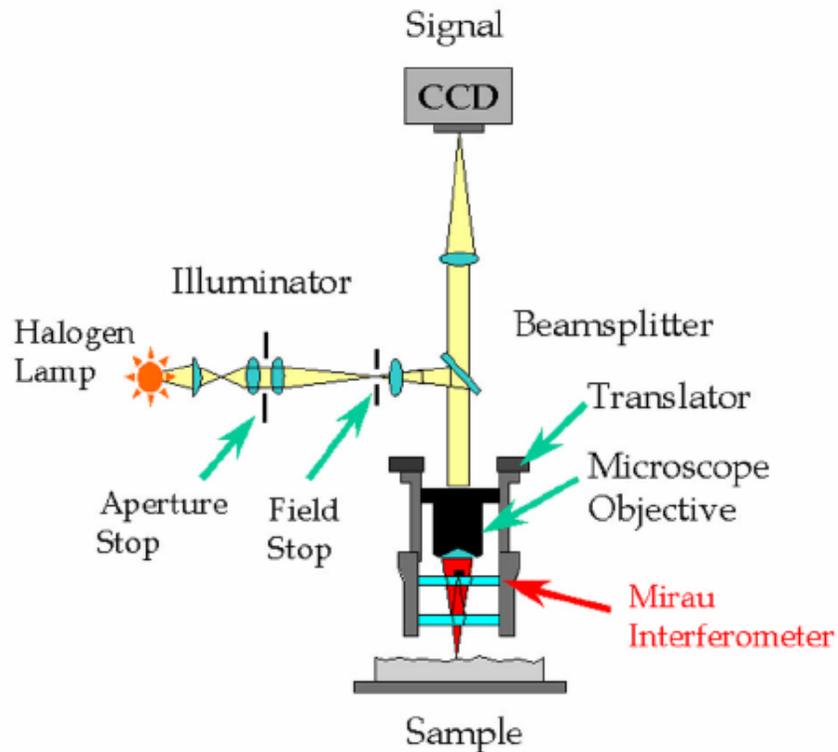


Figure 3.7 shows a schematic of PSI optical interferometry. (Veeco Instruments)

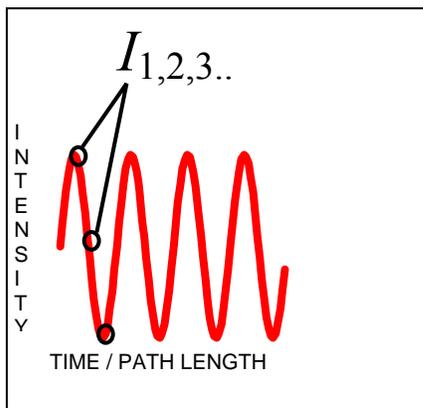
Optical interference techniques work on a principle of interference of two beams of light, at least one of these beams is reflected off the surface of the specimen. The two types of interferometry, which are commercially available, are phase shifting interferometry (PSI) and vertical scanning interferometry (VSI).

Brunning (1974) first developed phase shifting interferometry. Within a microscope a reference surface is built in. During the measurement process a 3D-image detector array records the interference of the light reflected from the specimen surface with the light reflected from a reference mirror. Deviations in the fringe pattern relate to deviations in

height on the specimen surface. The quantitative measurement of the specimen surface is made by detecting the relative phases of a number of different interference patterns. These patterns which are produced by the two wavefronts reflected from the specimen surface and the reference mirror are subjected to appropriate algorithms in order to compute quantitative values of the surface topography.

For the system shown, the phase shifting is achieved through driving the reference surface using a piezo-electric transducer (PZT), the driving PC controls this. The software then uses algorithms to process the data, this allows for accurate reconstruction of the surface.

The system collects data on interference intensity for a sequence of shifted phases, where “I” is the data with respect to time/path length.



$$I(x, y) = A + B \cos[\Phi(x, y) + \alpha_i]$$

The phase shifting algorithm then determines the starting phase

$$\Phi(x, y) = \tan^{-1} \frac{I_4(x, y) - I_2(x, y)}{I_1(x, y) - I_3(x, y)}$$

The height data can then be determined from this starting phase

$$h(x, y) = \frac{\lambda}{4\pi} \Phi(x, y)$$

Where A = average intensity, B = constant and i = axial shift position, α = controlled phase angle

Advantages of this system include the high degree of resolution and also the speed at which measurements can be taken; following set up of the system measurements can

usually be complete within seconds. The restriction is generally the vertical range of the system which is restricted to around 650nm.

For measuring rougher surfaces vertical scanning systems (VSI) can be used. Visible white light has a shorter coherence length and interference occurs only over a narrow height band of the specimen surface. The system measures the degree of fringe modulation, or coherence instead of the phases of interference fringes. A piezo-electric transducer is in this instance utilised to scan the reference mirror vertically above the surface. The z position of the maximum modulation is detected. The fringe contrast increases as the sample comes into focus and then falls as it passes focus. Algorithms are used to filter the information, firstly low frequency components are removed from the signal, it is then rectified by square law detection, following further filtering the peak of the low pass filter is located and the vertical position which corresponds to the peak is recorded. The optical path differences across a surface can be detected and the 3D surface roughness is determined from these differences.

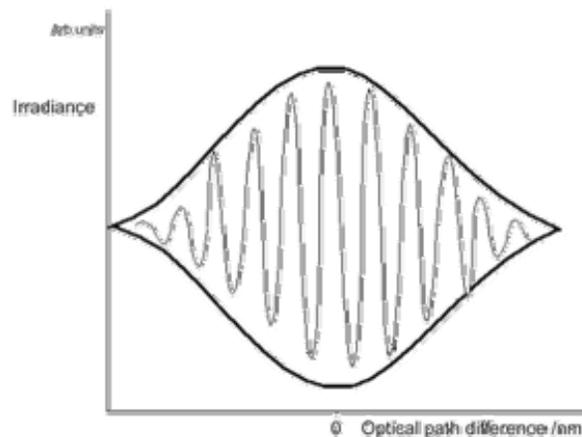


Figure 3.8 Interference data envelope for VSI mode optical interferometry

Figure 3.8 shows the interferogram produced during operation of the VSI mode, the peak of the envelope gives the height data for the topography measured.

The resolution of the VSI system is not as high as the PSI system. However, the vertical range of the system allows for surfaces of greater roughness to be measured, the range extends to 600 μ m or more.

For interferometric measurements with both systems one limiting factor is rapid slope changes, this is due to insufficient returned light. These limits of the system are dependent upon magnification and field of view, however slopes greater than 15° cause problems with measurements, in the case of measuring the unworn matt finish stems, problems may arise as the steepness of slope is greater than this. In this case where data is not complete, software can be used to reliably interpolate data to provide a picture providing the amount of missing data is not too great. Another factor when considering these systems is their conditions and environment of use. The optical interference technique is susceptible to environmental noise and vibration and therefore must be isolated during operation. The limitation of measurement related to the slope of feature is dependant upon the magnification and field of view however is in the region of 15°, this limitation on measurement of slope angle has implications on the ability of the system to accurately measure wear scars due to the potential nature of topography, wear scars often are steep sided features.

Calibration for PSI and VSI differ slightly, both use a reference article obtained from an accredited source to check the accuracy of the system. For PSI the article is an optically flat mirror. For VSI a step height gauge is used.

3.8.2 Atomic force microscopy (AFM)

As mentioned, AFM's fall into a category of thier own when it comes to classifying the way in which they measure surface topography. The AFM is a derivative of scanning tunnelling microscopy (STM). With STM a current is generated between two conducting surfaces, preventing the measurement of non-conducting surfaces such as biological specimens. The AFM however relies on the repulsive, inter atomic, *van der Waals* forces present on any surface and therefore conducting properties are not necessary for measurement. There are two modes in which the AFM can be used, non-contacting and "tapping" mode. In both cases the diamond stylus is traversed across the specimen surface in x and y, and the height data (z) is translated using a piezo-electric transducer. The vertical and lateral resolution of AFM's can be as high as 0.01 and 1 angstroms respectively. The lateral and vertical range however can be restrictive.

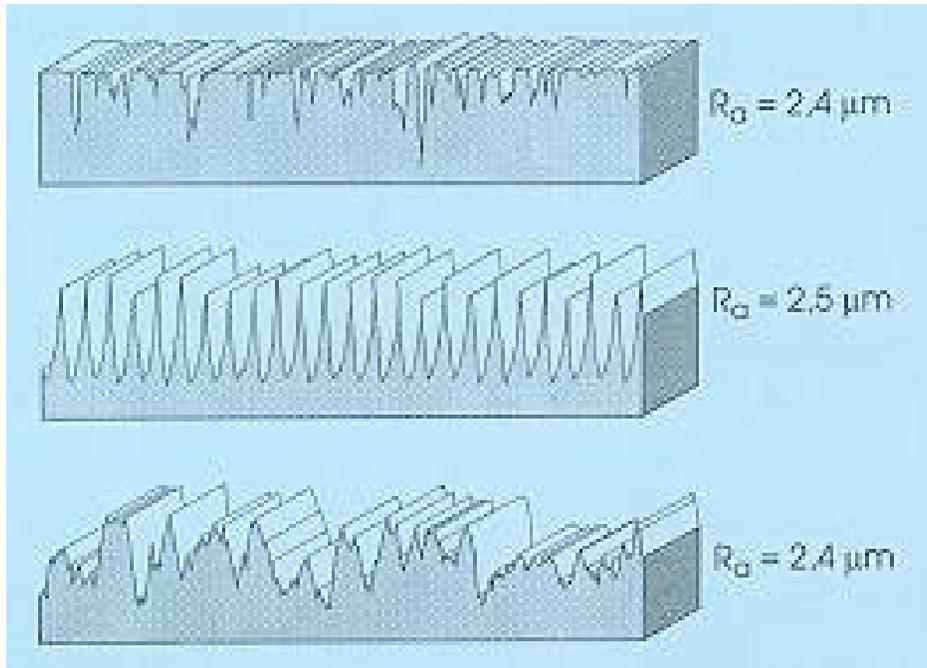
3.9 Characterisation

Following measurement of a surface it is necessary to quantitatively characterise the surface to be able to make direct comparison. This is a method, which has been used since the 1940's and in its most common form is used to specify the required surface finish of a component on a drawing to allow for accurate manufacture. The standard for specifying surface finish is Ra (BS EN ISO 7206 part 2) which is a 2D parameter that simply indicates the average surface roughness in its most primitive form and has been used since its development in the 1940's

3.9.1 2D surface roughness parameters

Following the development and use of Ra, and with the innovation of the PC a large number of parameters were developed each defining a particular aspect of a 2D surface measurement. Development was to the point that there are so many (over 150) it has become confusing with overlap in definition and characterisation. This explosion in parameters has been termed the "Parameter Rash" (Whitehouse 1982).

There are inherent problems with 2D surface measurement and characterisation, a fundamental problem is that a 2D profile does not necessarily indicate functional aspects of the surface. If Ra is taken as an example then, figure 3.8 shows the profiles of three surfaces, all return the same Ra value when filtered under the same conditions. It can be seen that the three surfaces have very different features and consequently very different functional properties.



*Figure 3.9 Profiles showing the same Ra with differing height distributions
(Surface Texture Analysis – The Handbook, L Mummery 1992)*

With 2D measurement and parametric assessment it is also often difficult to determine the exact nature of a topographic feature. Figure 3.9 shows a 2D profile and a 3D surface map of the same component covering the same measurement area. From the 2D profile it is apparent that there is a peak, with the 2D profile alone it would be acceptable to determine that there is a discrete peak on the surface. However when the 3D surface map is examined, it can be seen that the assumed peak is actually a ridge and may have far more bearing on the function of the surface than a discrete peak.

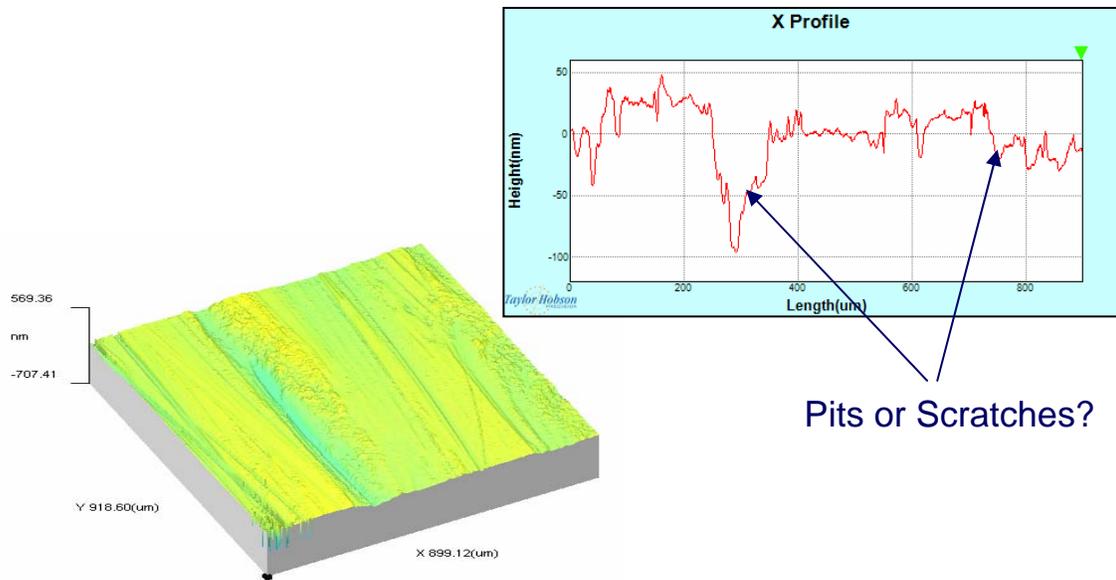


Figure 3.10- A 2D trace taken from a 3D (Areal) measurement shows the ambiguity of 2D measurement and characterisation

The limitations of 2D surface measurement and characterisation have brought about the development of 3D surface measurement and characterisation. 3D techniques give a better understanding of the surface in its functional state.

3.9.2 3D surface characterisation

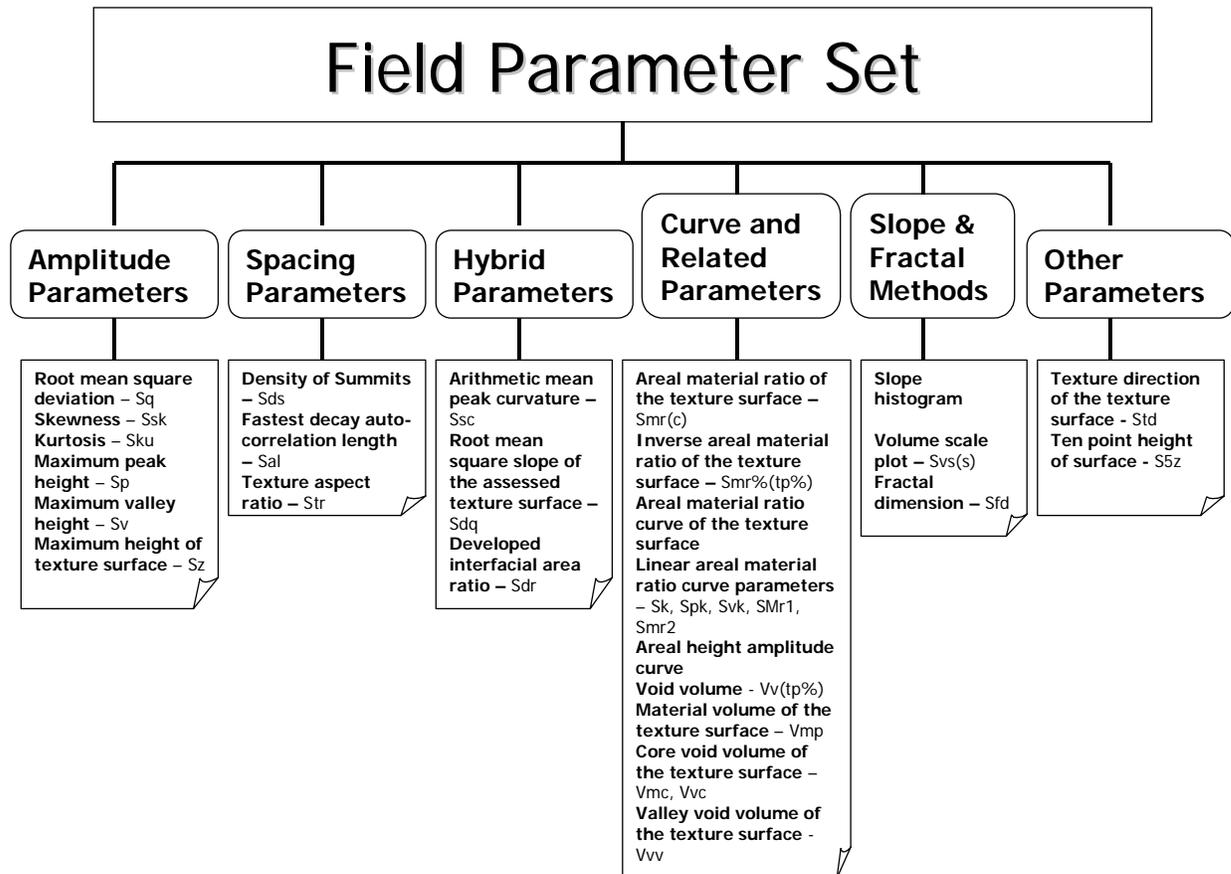


Figure 3.11 – 3D surface texture parameters shown in their family groups

Following the advances in 3D surface measurement instrumentation a need was realised for developments in characterising surfaces in 3D. An EU funded project based at the University of Huddersfield “Surfstand” sought to develop a suite of parameters that effectively characterised the surface without falling into the trap of the “Parameter Rash” (Whitehouse 1982). By standardising filtering and developing characterisation techniques, the group, along with a team of international partners achieved this and the 3D-field parameter set was devised. The 3D surface roughness parameters developed cover the majority of functional aspects of surfaces allowing an holistic picture of the surface to be determined numerically for comparison. The grouping of the parameters into their associated families can be seen in figure 3.10 .

3.9.3 Amplitude Parameters

The amplitude parameters give information regarding the height deviation of topography, there are six parameters in the amplitude family:

Root-Mean-Square Deviation of the Surface S_q is a parameter defined as the root mean square value of the surface departures within the sampling area.

$$S_q = \sqrt{\frac{1}{MN} \sum_{j=1}^N \sum_{i=1}^M \eta^2(x_i, y_j)}$$

where, M is the number of points of per profile, and N is the number of profiles. $\eta(x, y)$ is the data set of the rough surface or the wavy surface or the primary surface texture, depending on a requirement of the surface analysis. S_q describes the “roughness” of a surface and is sometimes referred to as RMS roughness when dealing with the 2D parameter counterparts.

Skewness of Topography Height Distribution S_{sk} is the measurement of asymmetry of surface deviations about the mean /reference plane.

$$S_{sk} = \frac{1}{MNS_q^3} \sum_{j=1}^N \sum_{i=1}^M \eta^3(x_i, y_j)$$

This parameter describes the shape of the topography height distribution. For a Gaussian surface, which has symmetrical topography, the skewness is zero. For a surface which is dominated by positively skewed features such as peaks or ridges, the value of S_{sk} would be positive, similarly should a surface be dominated by valleys or pits, the S_{sk} value would tend to be negative, the greater the value would indicate the extent of asymmetry of the surface.

Kurtosis of Topography Height Distribution S_{ku} is a measure of the peakedness or sharpness of the surface height distribution.

$$S_{ku} = \frac{1}{MNS_q^4} \sum_{j=1}^N \sum_{i=1}^M \eta^4(x_i, y_j)$$

This parameter characterises the spread of the height distribution. A Gaussian surface has a kurtosis value of 3. A centrally distributed surface has a kurtosis value larger than 3

whereas the kurtosis of a well spread distribution is smaller than 3. By a combination of the skewness and the kurtosis, it may be possible to identify surfaces that have a relatively flat top and deep valleys such as honing. In a physical sense the kurtosis indicates the peakedness or sharpness of a surface.

The Maximum Surface Peak Height S_p defined as the largest peak height value from the mean/reference surface within the sampling area.

$$S_p = MAX(\eta_p) \quad \text{with} \quad \eta_p > 0$$

where η_p is the highest surface summit on the surface.

The Lowest Valley of the Surface S_v defined as the largest valley depth value from the mean/reference surface within the sampling area.

$$S_v = MIN(\eta_v) \quad \text{with} \quad \eta_v > 0$$

where η_v is the lowest surface valley on the surface.

Maximum Height of the Topographic Surface S_z defines the sum of the largest peak height value and largest valley depth value within the sampling area.

$$S_z = (|S_p| + |S_v|)$$

S_p , S_v , and S_z give absolute values for features on the surface, they can be useful independently, but also can be used in conjunction with other parameters to describe topography more comprehensively, for instance, by examining both the S_q value and the S_z value, it may be possible to indicate whether the apparent roughness is due to isolated features or overall surface roughness.

3.9.4 Spacing Parameters

The spacing parameters describe the spatial properties of surfaces. These parameters are designed to assess the peak density, and texture strength. These parameters are particularly useful in distinguishing between highly textured and random surface structures. Three parameters are used to characterise spatial properties, density of summits, fastest decay autocorrelation length and texture aspect ratio.

Density of Summits of the Surface S_{ds} is the number of summits of a unit sampling area. Giving an indication of the density of features for the given sampling area

$$S_{ds} = \frac{\text{Number of summits}}{(M-1)(N-1) \cdot \Delta x \cdot \Delta y}$$

The Fastest Decay Auto-correlation Length Sal is a parameter with dimension of length used to describe the autocorrelation character of the surfaces' AACF. It is defined as the horizontal distance of the AACF that has the fastest decay to 0.2.

$$S_{al} = \min_{(\tau_x, \tau_y \in R)} (\sqrt{\tau_x^2 + \tau_y^2}), \quad R = \{(\tau_x, \tau_y) : ACF(\tau_x, \tau_y) \leq 0.2\}$$

where

$$ACF(\tau_x, \tau_y) = \frac{1}{(M-1)(N-1)} \sum \sum \eta(x_k, y_l) \eta(x_{k+i}, y_{l+j})$$

$$i = 0, 1, \dots, m < M, \quad j = 0, 1, \dots, n < N, \quad \tau_i = i \cdot \Delta x, \quad \tau_j = j \cdot \Delta y$$

$ACF(\tau_x, \tau_y)$ is the areal auto-correlation function (ACF) of a surface. For an anisotropic surface Sal is in a direction perpendicular to the surface lay. A large value of Sal denotes that the surface is dominated by long wavelength components, while a small value of the Sal denotes the opposite case.

Texture Aspect Ratio of the Surface Str is a parameter used to identify texture strength. Str can be defined as the ratio of the fastest to slowest decay to correlation length, 0.2, of the surface areal ACF function.

$$S_{tr} = \frac{\min (\sqrt{\tau_x^2 + \tau_y^2})}{\max (\sqrt{\tau_x^2 + \tau_y^2})} \Bigg|_{\tilde{R}(\tau_x, \tau_y) \leq 0.2}, \quad 0 < S_{tr} \leq 1$$

In principle, the texture aspect ratio has a value between 0 and 1. Larger values, say $Str > 0.5$, of the ratio indicates uniform texture in all directions i.e. no defined lay. Smaller values, say $Str < 0.3$, indicates an increasingly strong directional structure or lay.

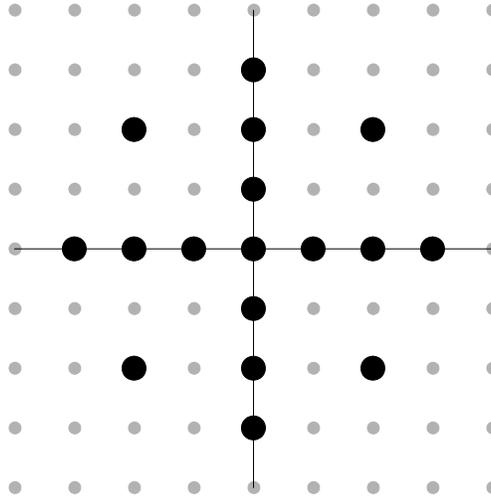
3.9.5 Hybrid Parameters

The hybrid parameters are parameters based upon both amplitude and spatial information. They define numerically hybrid topography properties such as the slope of the surface, the curvature of outliers, and the interfacial area. Any changes that occur in either amplitude or spacing may have an effect on the hybrid property. The parameters have particular relevance to the contact mechanics.

Arithmetic Mean Summit Curvature of the Surface S_{sc} is defined as the arithmetic mean of the principal curvatures of the summits within the sampling area.

$$f(x, y) = a_{00} + a_{10}x + a_{01}y + a_{20}x^2 + a_{11}xy + a_{02}y^2$$

$$S_{sc} = -\frac{1}{2} \frac{1}{n} \sum_{k=1}^n \left(\frac{\partial f_k^2(x, y)}{\partial x^2} + \frac{\partial f_k^2(x, y)}{\partial y^2} \right) = -\frac{1}{n} \sum_{k=1}^n (a_{k,20} + a_{k,02})$$



The least squares polynomial surface $f(x, y)$

Root-Mean-Square Slope of the Assessed Topographic Surface S_{dq} is the root-mean-square value of the surface slope within the sampling area. S_{dq} is calculated by using the Lagrangian polynomial with seven points at orthogonal directions.

$$S_{dq} = \sqrt{\frac{1}{(M-6)(N-6)} \sum_{j=4}^{N-3} \sum_{i=4}^{M-3} \rho_{i,j}^2}$$

Where

$$\rho_{i,j} = \left(\left\{ \frac{1}{60\Delta x} \left[-\eta(x_{i-3}, y_j) + 9\eta(x_{i-2}, y_j) - 45\eta(x_{i-1}, y_j) + 45\eta(x_{i+1}, y_j) - 9\eta(x_{i+2}, y_j) + \eta(x_{i+3}, y_j) \right] \right\}^2 + \left\{ \frac{1}{60\Delta x} \left[-\eta(x_i, y_{j-3}) + 9\eta(x_i, y_{j-2}) - 45\eta(x_i, y_{j-1}) + 45\eta(x_i, y_{j+1}) - 9\eta(x_i, y_{j+2}) + \eta(x_i, y_{j+3}) \right] \right\}^2 \right)^{1/2}$$

Developed Interfacial Area Ratio S_{dr} is the ratio of the increment of the interfacial area of a surface over the sampling area.

$$S_{dr} = \frac{\sum_{j=1}^{N-1} \sum_{i=1}^{M-1} A_{i,j} - (M-1)(N-1)\Delta x \cdot \Delta y}{(M-1)(N-1)\Delta x \cdot \Delta y} \cdot 100\%$$

The developed interfacial area ratio reflects the hybrid property of surfaces. A large value of the parameter indicates the significance of either the amplitude or the spacing or both.

3.9.6 Other Parameters

Texture Direction of the Surface S_{td} is the parameter used to determine the most pronounced direction of the surface texture with respect to the y-axis within the frequency domain, it gives the lay direction of the surface. The texture direction of a surface is given by an angle. By this definition, when the measurement trace direction is perpendicular to the lay the texture direction is 0° .

$$S_{td} = \begin{cases} -\beta, & \beta \leq \frac{\pi}{2} \\ \pi - \beta, & \frac{\pi}{2} < \beta \leq \pi \end{cases}$$

where, β is the position of the maximum value of the angular spectrum.

$$\beta = \operatorname{tg}^{-1} \frac{\operatorname{Re}[F(f_p, f_q)]}{\operatorname{Im}[F(f_p, f_q)]} \left| \frac{1}{\max(\sqrt{\operatorname{Re}[F(f_p, f_q)]^2 + \operatorname{Im}[F(f_p, f_q)]^2})} \right.$$

$$F(f_p, f_q) = \Delta x \cdot \Delta y \sum_{l=0}^{N-1} \sum_{k=0}^{M-1} \eta(x_k, y_l) e^{-j2\pi[(p/M)k + (q/N)l]},$$

$$p = 0, 1, \dots, M-1; \quad q = 0, 1, \dots, N-1; \quad f_p = \frac{p}{\Delta x \cdot M}; \quad f_q = \frac{q}{\Delta y \cdot N}$$

3.9.7 Volume Parameters

The material/void parameter sets are derived from the volume information of areal material ratio curves of the Topographic Surface. The default assumptions for this set of parameters are that the peak material embraces 0~10% of the material ratio whilst the core material/void ranges cover 10~80% and void valley ranges 80~100% of the material ratio. These functional parameters can characterise not only the common functional properties of surfaces, for instance, area and volume geometrical properties, but also interpret wear and tribological properties in a running-in procedure. The Volume parameters in the case of this work show the relative change in material during the progression of wear.

Peak Material Volume of the Topographic Surface V_{mp} is defined as the material volume enclosed in the 10% material ratio and normalised to unity.

$$V_{mp} = \frac{V_m(h_{0.10})}{(M-1)(N-1)\Delta x\Delta y}$$

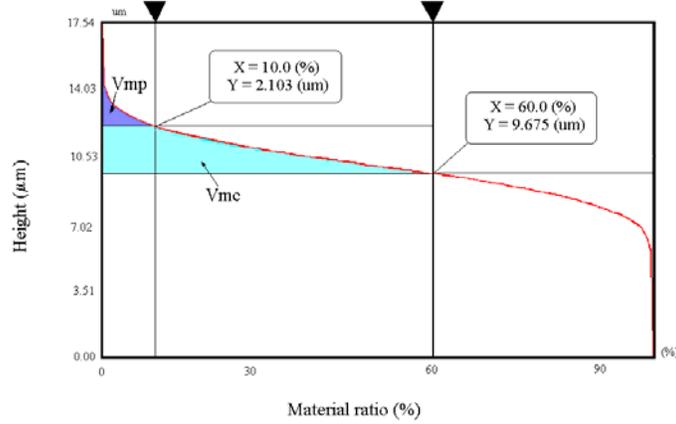
where

$$V_m(h_{0.10}) = \frac{\Delta x \cdot \Delta y}{9} \left\{ 16 \sum_{j=1}^{\frac{N-1}{2}} \sum_{i=1}^{\frac{M-1}{2}} \eta(x_{2i}, y_{2j}) + 8 \left[\sum_{j=1}^{\frac{N-1}{2}} \sum_{i=2}^{\frac{M-1}{2}} \eta(x_{2i-1}, y_{2j}) + \sum_{j=2}^{\frac{N-1}{2}} \sum_{i=1}^{\frac{M-1}{2}} \eta(x_{2i}, y_{2j-1}) \right] \right. \\ + 4 \left[\sum_{j=2}^{\frac{N-1}{2}} \sum_{i=2}^{\frac{M-1}{2}} \eta(x_{2i-1}, y_{2j-1}) + \sum_{i=1}^{\frac{M-1}{2}} [\eta(x_{2i}, y_1) + \eta(x_{2i}, y_{n-1})] + \sum_{j=1}^{\frac{N-1}{2}} [\eta(x_1, y_{2j}) + \eta(x_{m-1}, y_{2j})] \right] \\ + 2 \left[\sum_{i=2}^{\frac{M-1}{2}} [\eta(x_{2i-1}, y_1) + \eta(x_{2i-1}, y_{n-1})] + \sum_{j=2}^{\frac{N-1}{2}} [\eta(x_1, y_{2j-1}) + \eta(x_{m-1}, y_{2j-1})] \right] \\ \left. + [\eta(x_1, y_1) + \eta(x_1, y_{n-1}) + \eta(x_{m-1}, y_1) + \eta(x_{m-1}, y_{n-1})] \right\}, \quad \eta(x, y) \geq h_{0.10}$$

Core Material Volume of the Topographic Surface V_{mc} is the material volume enclosed from 10% to 80% of surface material ratio and normalised to the unit sampling area.

$$V_{mc} = \frac{V_m(h_{0.80}) - V_m(h_{0.10})}{(M-1)(N-1) \cdot \Delta x \Delta y}$$

The material volume is not only a geometrical descriptor of the surface, but can also have significant functional implications. The material volume may reflect wear and the running-in properties.



The material ratio curve and material volume parameters

Core Void Volume of the Surface V_{vc} is the void volume enclosed from 10% to 80% of surface material ratio and normalised to the unit sampling area.

$$V_{vc} = \frac{V_v(h_{0.10}) - V_v(h_{0.8})}{(M-1)(N-1) \cdot \Delta x \Delta y}$$

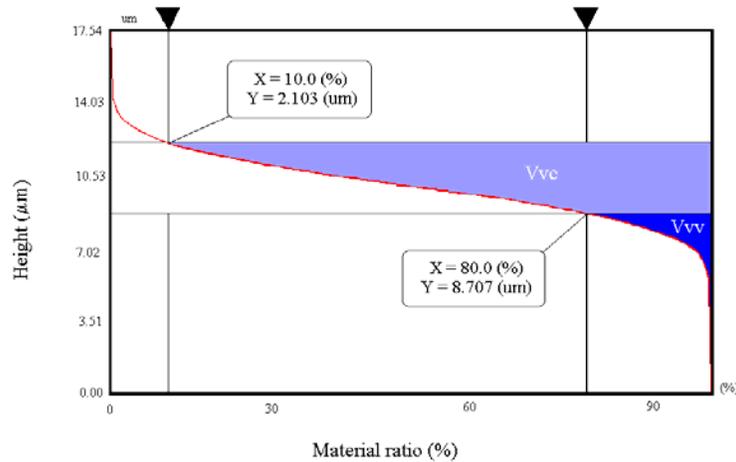
where $V_v(h) = V_v(h_{\max}) - (M-1)(N-1)\Delta x \Delta y (h_{\max} - h) + V_m(h)$

$$V_v(h) = \frac{\Delta x \cdot \Delta y}{9} \left\{ 16 \sum_{j=1}^{\frac{N-1}{2}} \sum_{i=1}^{\frac{M-1}{2}} (h - \eta(x_{2i}, y_{2j})) + 8 \left[\sum_{j=1}^{\frac{N-1}{2}} \sum_{i=2}^{\frac{M-1}{2}} (h - \eta(x_{2i-1}, y_{2j})) + \sum_{j=2}^{\frac{N-1}{2}} \sum_{i=1}^{\frac{M-1}{2}} (h - \eta(x_{2i}, y_{2j-1})) \right] \right. \\ + 4 \left[\sum_{j=2}^{\frac{N-1}{2}} \sum_{i=2}^{\frac{M-1}{2}} (h - \eta(x_{2i-1}, y_{2j-1})) + \sum_{i=1}^{\frac{M-1}{2}} [h - (\eta(x_{2i}, y_1) + \eta(x_{2i}, y_{n-1}))] + \sum_{j=1}^{\frac{N-1}{2}} [h - (\eta(x_{1-1}, y_{2j}) + \eta(x_{m-1}, y_{2j}))] \right] \\ + 2 \left[\sum_{i=2}^{\frac{M-1}{2}} [h - (\eta(x_{2i-1}, y_1) + \eta(x_{2i-1}, y_{n-1}))] + \sum_{j=2}^{\frac{N-1}{2}} [h - (\eta(x_1, y_{2j-1}) + \eta(x_{m-1}, y_{2j-1}))] \right] \\ \left. + [h - (\eta(x_1, y_1) + \eta(x_1, y_{n-1}) + \eta(x_{m-1}, y_1) + \eta(x_{m-1}, y_{n-1}))] \right\}, \quad \eta(x, y) \leq h$$

Valley Void Volume of the Surface V_{vv} of the unit sampling area is defined as a void volume in the valley zone from 80% to 100% surface material ratio.

$$V_{vv} = \frac{V_v(h_{0.8})}{(M-1)(N-1) \cdot \Delta x \Delta y}$$

It represents the fluid retention ability of a contacting surface. A plateaued surface will give a high valley volume whereas a spiked surface will give a large core volume.



The material ratio curve and void volume parameters

3.10 Current use of Surface finish assessment in Orthopaedics

“Surface topographies of orthopaedic joint prostheses have attracted a considerable amount of research interest” (Blunt *et al* 2000). Much of this research is focused on the assessment of the bearing surfaces of components. Blunt *et al* 2000 states that the current standards (ISO 7251, ISO 7206-2) assume that traditional 2D measurement techniques are used and furthermore that the 2D profiles and parameters obtained can only give incomplete descriptions of a surface, even where properly controlled. Manufacturers have established the need for the smoothest possible finish on the articulating surfaces and routinely enforce higher quality finishes than the standards require. Surface topography assessment has also been used to determine the effects of simulated wear on change in surface topography of the bearing surfaces. In a study by A Wang *et al* (1999) a range of Co-Cr-Mo alloy femoral heads and cups were subjected to simulator testing. Both AFM and SEM analysis was completed on 3 unworn heads and also on the remainder of the heads following simulator testing, the wear mechanism was proposed and it was determined that the carbides which were found to sit proud of the surface wore more quickly than the material matrix. In this particular study it may have been useful to use parametric analysis to give insight into the change in surface topography of the material matrix during wear of the prostheses.

In a study by A Elfick *et al* (2002) atomic force microscopy was used to investigate wear

features of acetabular sockets. Six of the sockets were worn under simulator conditions, the remaining four were explanted cemented joints. In this instance the information given from AFM measurement confirmed height information provided through SEM analysis. Again, this study may have benefited from the use of parametric analysis, though the surface topography measurement in itself gave a good indication as to the orientation and mechanism of wear.

Atomic force microscopy and scanning electron microscopy appear to be utilised in orthopaedic research of surface topography more frequently than is documented for alternative measurement methods (P A Campbell et al 1998, I Gwynn & C Wilson 2001, R P S Chaplin et al 2004), The limitations of the methods include the very localised nature of the measurement due to the comparatively small measurement areas achievable.

The studies indicated in Chapter 2 section 2.7.6 also show restrictions in information; this is believed to be due to the dated nature of the current standards in focussing on 2D measurement and analysis.

The scope for surface measurement and analysis as a tool for the orthopaedic industry is vast, studies have shown its benefit in maintaining quality of product, minimising wear of bearing surfaces, and also in “engineering” surfaces for femoral components to ensure stability and ease of fixation.

From the information gained in Chapter 2, it is clear that surface finish is a key part of prosthetic implant design, function, and success. To enable surfaces to be developed for optimum performance, measurement and quantification, the importance of measurement and analysis, as a tool, must be addressed.

Metrology has traditionally been used in the automotive industry to detect and assess wear of cylinder bore liners (D Butler 1999); there are obvious advantages to investigating the wear of hard on hard bearing combinations using similar methods. As discussed, gravimetric assessment of these cobalt alloys and ceramics does not give enough resolution to give statistically significant results. Although surface texture

measurement is often performed during simulator testing and following explant of failed prosthesis, a method has not yet been established for quantitative comparison of the nature and magnitude of wear on the THR bearing system.

CHAPTER 4. RETRIEVAL STUDY OF FEMORAL STEMS WITH A MATT SURFACE FINISH

4.0 Chapter Summary

An investigation of a series of matt finish femoral stems explanted for reasons of aseptic loosening of the femoral stem was carried out. A study on location of wear was completed. This work relates to a study performed by J Cook (1998), both investigations found the location and nature of wear on the explants to follow a pattern. This pattern of location can be related back to the loading regime *in vivo* with wear occurring in specific areas of the femoral stem due to torsional and flexural movement of the implant.

A visual system for grading the severity of wear, originally developed by J Howell (1998) was modified and enhanced to give a qualitative assessment method for classification of wear. The progression of severity grades reflects the progression of wear on femoral stems. In completing the visual grading exercise, it was noted that the progression of wear, originally thought to be a result of fretting, indicated the surface texture became smoother with increase in wear. Subsequently each visually graded area was measured using 3D surface topography measurement instrumentation. An optical method (Optical interferometry) was selected for its ideal range and resolution and because of the non-destructive nature of measurement technique leaving the topography free from damage for future analysis. The 3D surface topography measurement showed distinct changes in the topography and gave an insight into the wear mechanism causing damage.

4.1 Background and Aims

The primary study in this section of the project involved a comprehensive appraisal of wear on a series of explanted stems. The stems examined were all of differing design; however, the general surface finish classification of the stems was common to each explant. The primary focus of study was on stems with a rough “matt” surface finish. The surface finish of such prostheses is achieved by blasting the surface of the stem with a

material of greater hardness than that of the stem itself. This material is in the form of grit or tiny beads which produce a surface with a random pattern of peaks and pits (figure 4.1). The medium used for the grit blasting is typically alumina, this is a material with far greater hardness than the stainless steel, or bone cement. In a paper by Howell et al (2004) alumina residue was found by means of SEM to be still embedded in the surface of the stem. This process gives a matt appearance to the surface. The rationale for the rougher surface is a function of fixation. It is deemed that a rougher surface will provide a mechanical interlock with the cement upon implantation.

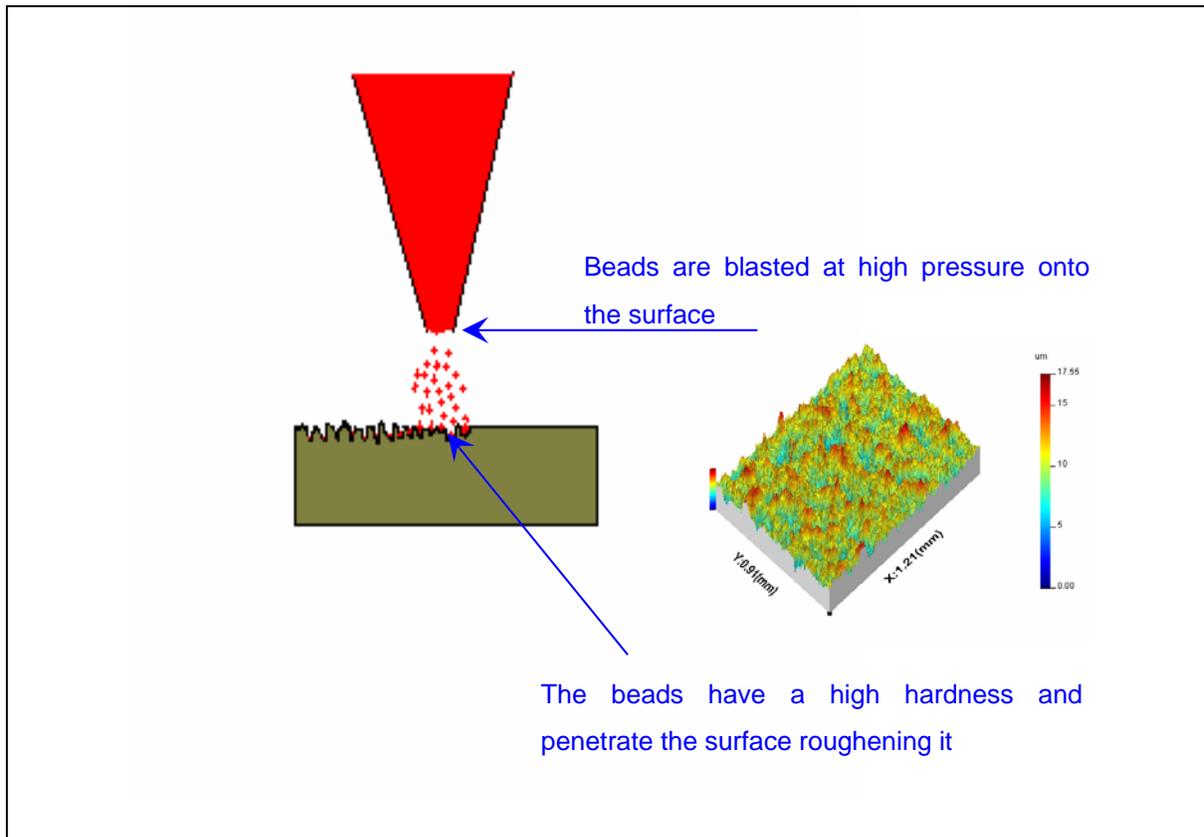


Figure 4.1 – The Bead Blasting Process and Resultant Surface Texture

The optimum surface finish of the femoral stem component of prostheses is an area of controversy, with one school of thought being that the mechanical interlock provides greater mechanical stability and another being that it has a detrimental effect. (K L Ohashi et al 1998, Harris 1998) In a study by J L Fowler et al (1988) it was noted that there was in fact a higher incidence of aseptic loosening with one type of stem (The

Exeter System, Howmedica) where the surface had been roughened compared to stems of the same design, which had a highly polished surface. It is apparent from the literature survey (Chapter 2) that the wear of polished stems is widely accepted to be due to classic fretting wear, where micro motion at the stem/cement interface produced fretting damage and generation of wear debris. Where the aforementioned study showed a greater incidence of aseptic loosening with the Exeter system with grit blasted matt finish femoral stems; it would be one possible assumption that the greater incidence of loosening is due to a higher volume of debris being generated at the stem cement interface due to an increase in wear.

This is a particularly useful study in showing the effect of surface finish as the geometric design of the stem and fixation method changed little. The theoretical view of R B Waterhouse (1972) on the mechanics of fretting wear would suggest the opposite is true. It is suggested that the smoother the surface (the more polished it is) the greater the surface damage through fretting motion and wear. This is due to the fact that the asperities caused by the surface blasting will plastically deform when subjected to micromotion and the passive oxide layer is not removed as it is during fretting of highly polished surfaces. The fact that there is a higher incidence of loosening with the Exeter system with a rougher surface finish suggests if fretting is the cause of wear there is disparity in this theory. Clearly these opposing views make it difficult to resolve the issue of understanding wear mechanisms in matt stems. Consequently the present chapter seeks to address the above issue with two specific aims:

- i) Establish whether a greater volume of material is removed during wear of matt finish femoral stems
- ii) If there are differences in wear mechanisms which result in the failure of matt and polished stems

J Cook (1998) completed a comprehensive study of the location and nature of wear of explanted stems, this study was primarily focussed on stems with a polished surface finish, the study concluded that fretting played a major part in the wear of femoral stems and their subsequent failure.

J Howell (1998) also completed a study on the classification of wear on explanted stems,

devising a visual grading system in order to classify wear on stems, this method is user subjective, and qualitative, however it goes some way towards differentiating severity of wear over the surface of a stem and also between various stems.

Both of the above studies investigated a range of stem designs, though the reported results did not detail their origins.

In this section there are 2 component studies which address the continuation of the work completed by J Howell and J Cook.

It is proposed that the location of wear of matt finish femoral stems will be studied and collated in the method developed by J Cook where polished stems were under investigation, and that this will be subjected to the visual grading system that has been devised. Furthermore, 3D surface texture analysis will be utilised to quantify the visual grades numerically, thus removing most of the subjective nature of the analysis and providing a method for quantification of the severity of wear.

4.2 Location of wear

Previous studies have indicated that explanted stems tend to display signs of wear in similar areas, as reported; J E Cook 1998 confirmed this. Figure 4.2 shows the loading regime that the stem undergoes in vivo. It is this torsional loading and bending of the stem which is believed to induce micro motion between the stem and cement, causing the pattern of wear that has been observed.

For the present study 11 stems were selected from a series of explanted femoral prostheses held at the University of Exeter. Stems were selected that met the following criteria: Exeter type; matt finish, revised or explanted for aseptic loosening. The location and extent of wear was mapped visually.

The location of the wear was noted, using a notation system developed by J Cook (1998). This notation system uses modified Gruen Zones (T A Gruen et al 1978) to segregate the femoral stem into specific areas. The magnitude of wear in each of these areas was then determined and noted. This is a subjective method of wear classification, but it did give a good indication of the location of wear and in what pattern the wear may develop.

Representative forces at 50% of Gait cycle

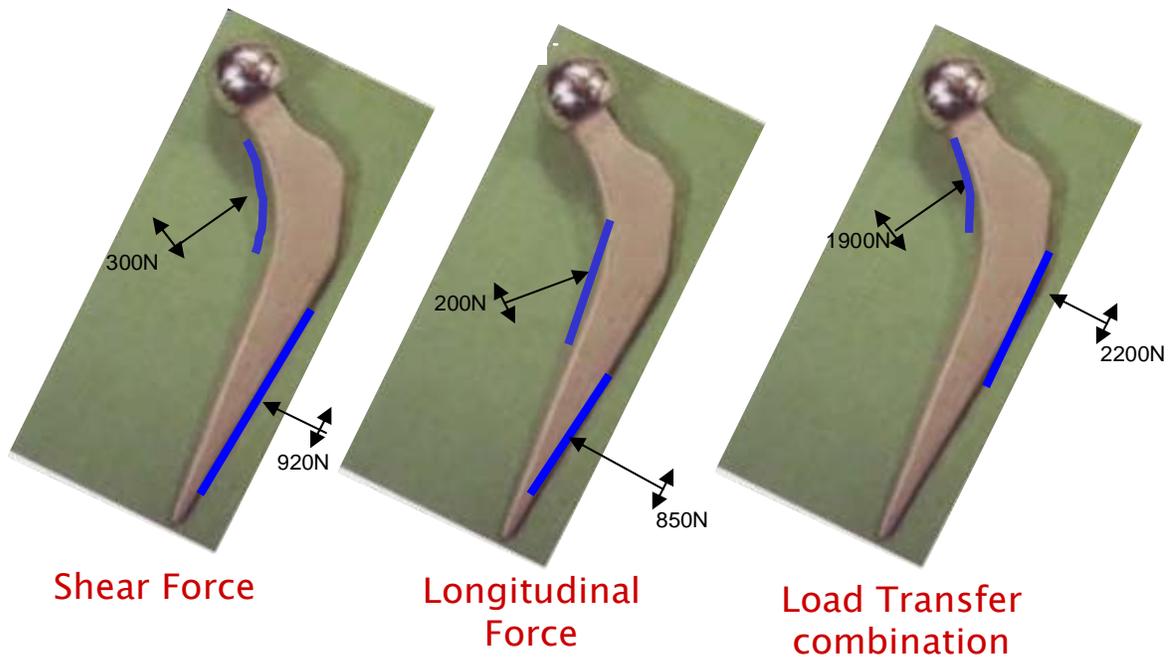


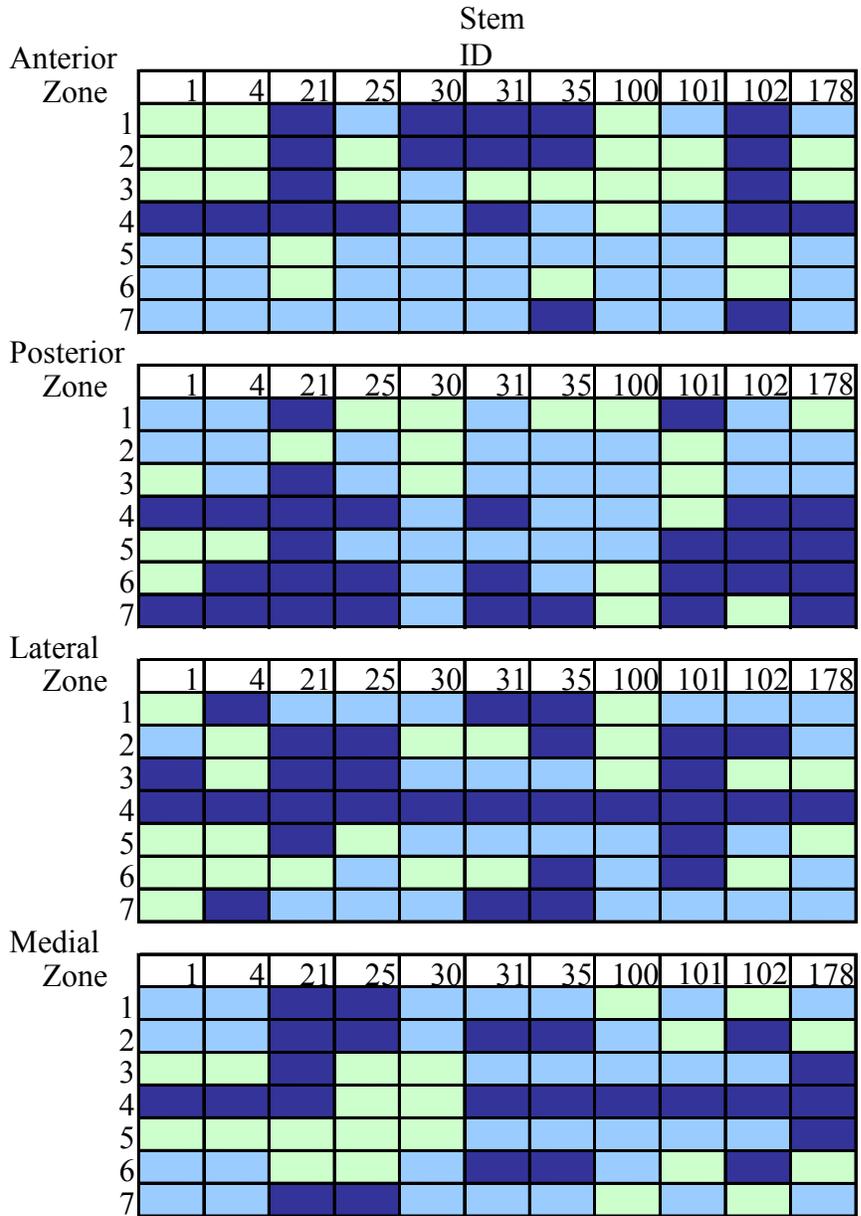
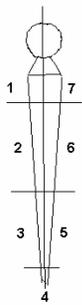
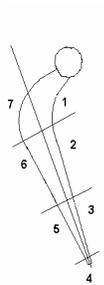
Figure 4.2. Typical loading regime of a stem at 50% of Gait cycle

Table 1 shows the classification of wear. The wear on the stems that show greater visual damage is concentrated to the anterior side to zones 1 and 2, and on the posterior side to zones 6 and 7. There was severe polishing distally, around the area of the centraliser apparent on each of the stems in the series. These findings are in agreement with those reported by J E Cook (1998) where a number of stems polished and matt finish were found to show wear in the same areas as those found in this study. From the study of the series of explants it does not appear that the extent of wear or the location is dependent on the time in vivo. J E Cook (1998) reported the presence of a transfer film on many of the stems thought to have originated from the PMMA bone cement. No transfer film was found in this study; however the stems in this series have been cleaned and stored at Exeter University for several years.

4.2.1 Results – Location of wear

Table 4.1: Representation of the location and severity of wear on the series of explanted stems

Severity	Coverage	Key
None to very light wear	0-25% surface area	
Light to moderate wear	25-50% surface area	
Moderate to severe wear	50% + surface area	



4.2.2 Conclusions - Location of wear

Comparing the results of this study to the study carried out by J Cook (1998) a correlation in results is evident. The study completed confirms the notion that there is a pattern of wear which occurs to stems in vivo, it also confirms that the series of stems under examination show typical wear patterns and it could be assumed that the wear in general is typical of that seen on explanted stems retrieved at revision operations. The areas of wear seen on the explanted stems are consistent with what would be expected due to the loading regimes in vivo. The torsional and flexural loading of the stem could generate micromotion at these points, increasing the wear in these areas.

4.3 Visual Appearance of Wear

The wear of the retrieved stems was different to that observed on polished stems previously studied (J Cook 1998, J Howell et al 1998). Instead of the characteristic scarring and pitting seen on polished stems, smoothing of the surface was apparent. Figure 4.3 shows a picture showing an area of severe wear on one of the explanted stems, the area highlighted indicates where the stem is worn and appears to be polished compared to the rest of the stems topography.

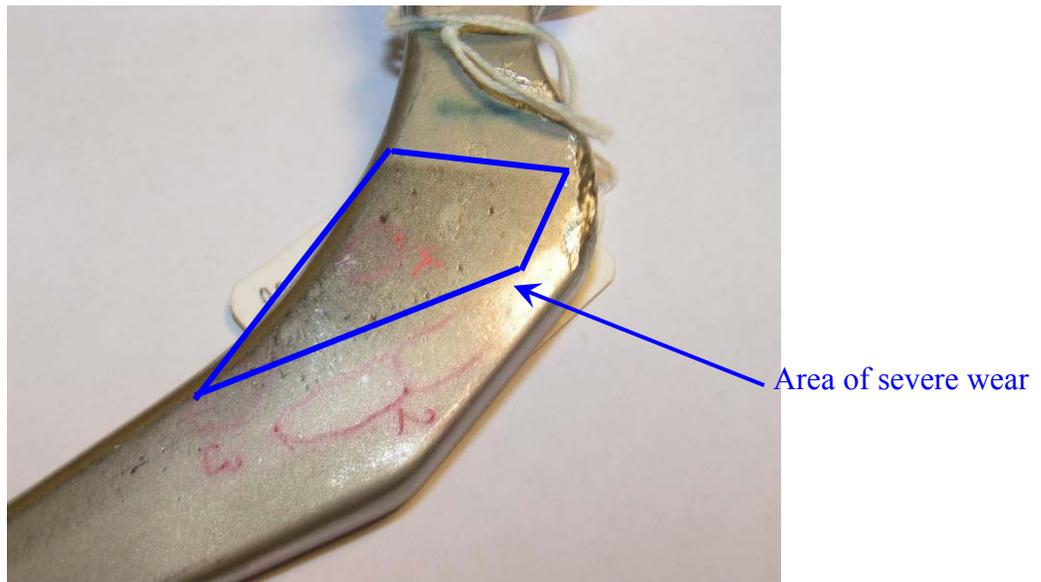


Figure 4.3 – Matt Finish Exeter Femoral Stem showing an area of severe wear

4.4 Visual Grading of wear magnitude

Study of the literature showed that there are studies which qualitatively assess the wear on retrieved femoral stems (M Van Knoch et al 2003), though there is little evidence to suggest that quantitative measurement of wear on stems has been carried out extensively. One such study to quantify wear on femoral stems by J Howell et al (1999) developed a method of visually grading the wear on matt finish femoral stems. In conjunction with the original investigators, this method has been expanded in the present work. Visually grading the wear of femoral stems is a subjective method and is very user sensitive, though it is a good foundation to expand on for a more quantitative assessment. There are certain difficulties in accurate quantitative characterisation of wear of explanted femoral stems; the exact start topography of a stem is unknown and the number of cycles can only be roughly estimated, but without detailed accounts of patients movements throughout the duration of the prostheses life, consequently an accurate picture can not be obtained. From the location study it has been determined that wear on stems occurs at different positions appears to be of varying severity. A visual grading system has been developed by J Howell *et al* (1999) to categorise the severity of wear at different locations on the surface of femoral stems.

This grading system contains 5 categories, shown in table 4.2

Table 4.2: Categorisation of wear – Visual grading system for matt finish stems

Wear category	Severity
Pol0	No Wear
Pol1	
Pol2	
Pol3	
Pol4	Severe wear

In a second study a total of 25 explanted matt finish femoral stems were examined initially, each were of varying design, however all were classified as having a matt (appendix I) surface finish. The degree of wear varied on each one however the position of wear on explanted femoral stems does appear to follow a pattern due to the loading regime in vivo. The stems were examined and the visual grading system was used to categorise the wear in different areas of the stem. Of the 25 explanted stems examined there were 25 stems showing areas of no wear (pol0), 18 of the stems showed areas graded as pol1; 18 of the stems had areas graded as pol2; 9 of the stems had areas graded as pol3 and 5 of the stems showed areas of high wear and were graded as pol4. This grading system in itself gives an indication of the severity of wear on a particular stem, and could be used to compare explanted stems to determine the effects of clinical history, stem design, mode of fixation etc. it is however, subjective and user sensitive and consequently would benefit from quantitative back up.

4.5 Surface Topography Assessment

In an attempt to further quantify wear on femoral stems and to confirm the validity of the visual grading system, 3D surface analysis techniques were employed to measure the surface topography at each visual wear grade. Revisiting the “Steadman Diagram” (figure 3.3) the appropriate instrumentation to satisfy the lateral size of measurement, (0.25mm – 1mm) would be either contacting stylus profilometry or optical interferometry. Optical interferometry was chosen for the following reasons.

- i) Non contact method – no surface damage during measurement
- ii) Fast measurement
- iii) High resolution

The surface topography measurements were carried out using a Wyko NT 2000 optical interferometer in vertical scanning mode (Veeco Instruments USA). Various measurement areas were examined with a vertical magnification of between 25x and 100x. Vertical resolution of this system in the VSI mode is 1nm. Actual measurement of the surface topography such as this reduces the subjectivity of the wear grading process. In order to further quantify the method, 3D surface parameters for each measurement

taken for each visual wear grade of the stems were calculated. These 3D surface texture parameters are known indicators of surface function and can be used to describe features of a surface L Blunt (2003).

4.5.1 3D Surface topography assessment

Figure 4.4 shows the 3D axonometric plots of measurements taken on one stem at each visual wear grade. This is a typical example of the other measurements which can be found in appendix II.

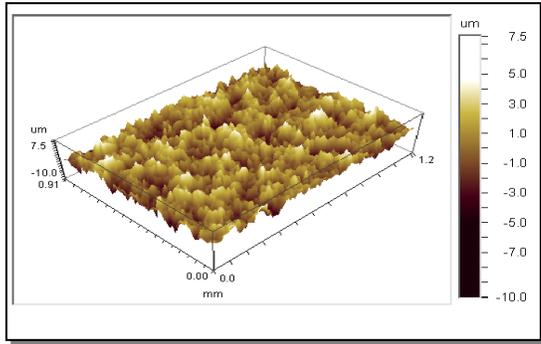


Figure 4.4a.

Pol0 – Measurement of Pol0 is taken from the upper most part of the neck where no contact with cement has been made. This wear grade denotes no wear. The plot shows there to be prominent asperities present.

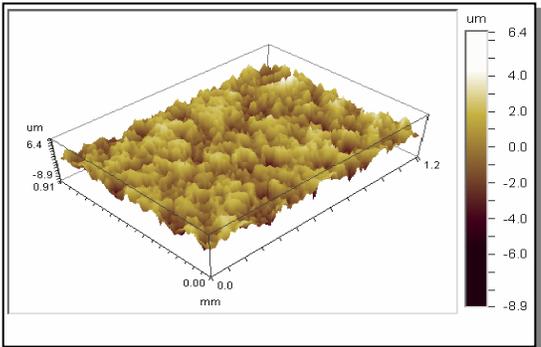


Figure 4.4b.

Pol1 – From visual inspection of the axonometric plot there appears to be little change in the surface topography at Pol1 from Pol0. The height of topography however does appear to be less and the asperities though still present are less sharp.

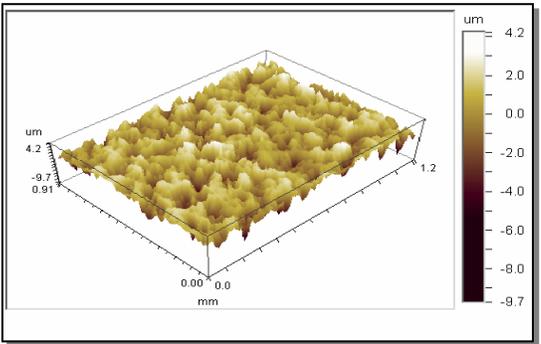


Figure 4.4c.

Pol2 – The asperities are now markedly less sharp and the height of the surface topography has noticeably lessened.

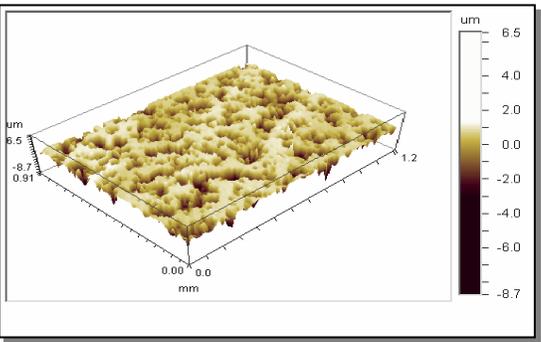


Figure 4.4d..

Pol3 – The asperities are very much flattened compared to Pol0 and Pol1, the surface takes on a more smooth appearance.

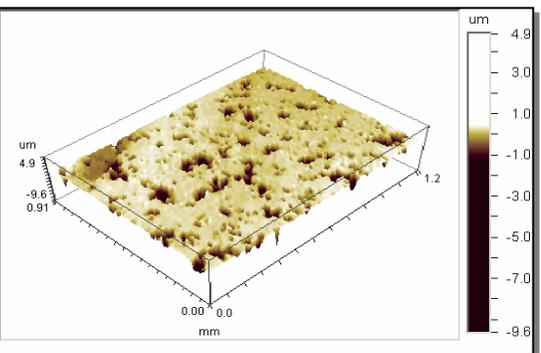


Figure 4.4d.

Pol4 – The plot of Pol4 shows a great reduction in topography height and though valleys are present, the asperities have been almost completely removed. Visually the surface appears polished

INCREASE IN WEAR

It can be seen from the 3D axonometric plots that there is a definite difference in topography between the visual wear grades, the asperities which are prominent at wear grade Pol0 have become less pronounced through the grading system, and have been completely removed at Pol4, the most severe visual wear grade.

4.6 Parametric characterisation

As mentioned in section 3.4, the use of 3D surface roughness parameters can be useful in numerically describing the topography and function of a surface. In this part of the study, each of the field parameter set were calculated for each measurement taken, at each visual wear grade on each of the stems examined. The full analysis can be found in appendix III, a number of parameters were found to be particularly useful in describing the surfaces and the progression of wear, and it is these parameters, the “reduced parameter set” which are detailed in this section.

4.6.1 The reduced parameter set

Amplitude Parameters				Spatial Parameters				Hybrid Parameters			Functional Parameters					
<i>Sq</i>	<i>Sz</i>	<i>Ssk</i>	<i>Sku</i>	<i>Sds</i>	<i>Str</i>	<i>Sal</i>	<i>Std</i>	<i>SΔq</i>	<i>Ssc</i>	<i>Sdr</i>	<i>Sbi</i>	<i>Sci</i>	<i>Svi</i>	<i>Vmp</i>	<i>Vvc</i>	<i>Vvv</i>
●	●	●	●	◐	◑	◐	◑	●	◐	◐	◐	◐	◐	●	●	●

● Very useful – describes the change in surface topography
 ◐ Useful – describes in part the surface topography
 ◑ Not Useful – has no definite use in describing topography

Figure 4.5 – Selecting the reduced parameter set

Figure 4.5 shows the selection of parameters for the reduced parameter set. In total 8 parameters were deemed from the full analysis to be very useful, it is this reduced parameter set which was studied more closely to determine if there was a relationship between the wear grades.

4.6.2 Results – Parametric Characterisation

The parameters above were calculated to describe the progression of wear through the visual wear grades for each of the stems examined, Of the 25 explanted stems examined there were 25 stems showing areas of no wear (pol0), this surface measurement was taken from an area which lies outside of the cement mantle, resulting in no contact hence no possibility of wear. 18 of the stems showed areas graded as pol1; 18 of the stems had areas graded as pol2; 9 of the stems had areas graded as pol3 and 5 of the stems showed areas of high wear and were graded as pol4. The location of wear was consistent with the pattern expected due to loading in vivo, typically pol4 was detected in Gruen zone 7 (T A Gruen 1978)

The results are presented as an average for each wear grade. The aim of showing progression of wear is to confirm the visual grading system as a method of cataloguing wear and also as it may give an insight into the mechanism involved in the wear of matt finish femoral stems.

Sq – Root mean square deviation of the surface

Figure 4.6 shows the results for average change in Sq with increase in wear grade, it can be seen from the results that following an initial increase in Sq there is a definite trend showing a decrease in Sq through wear grades Pol1 to Pol4. This indicates that following an initial very slight increase in roughness at Pol0 there is a definite reduction through wear grades Pol1 to Pol4 or that smoothing of the surface texture has occurred. This phenomenon was visually evident from the 3D axonometric plots. This would reinforce the notion that the asperities are worn away with an increase in wear.

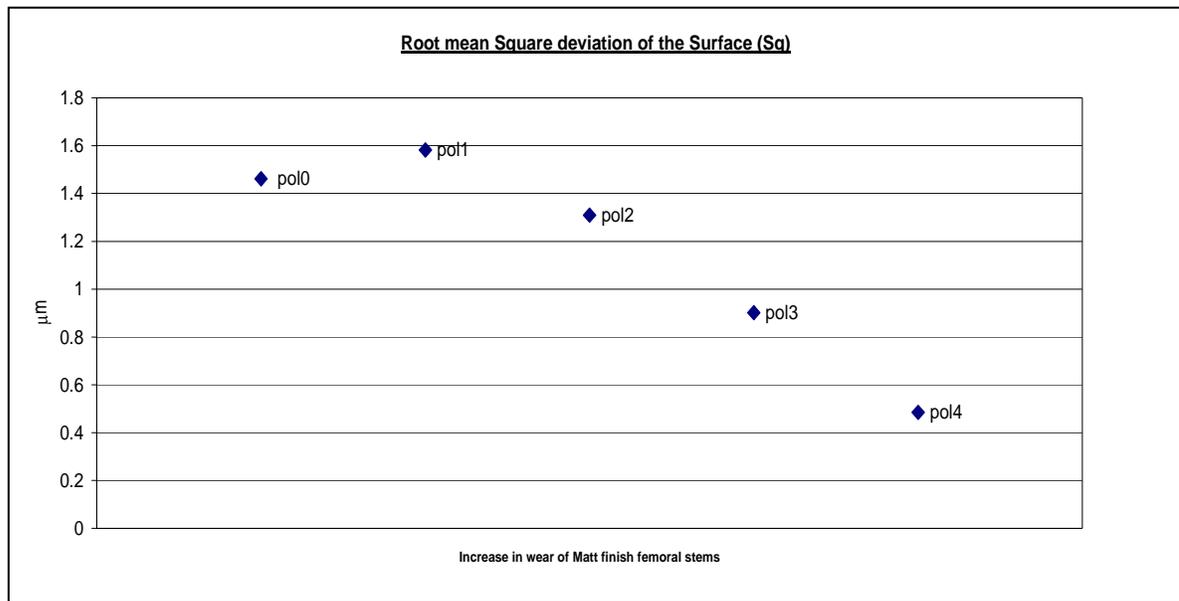


Figure 4.6 – Average change in Sq with increase in visual wear grade for the range of stems measured

Sz – Maximum height of topographic surface

Figure 4.7 shows the average change in Sz with increase in visual wear grade. The trend matches that seen in figure 4.6, the results seen for Sq, there is an initial slight increase in Sz, followed by a steady decrease in the maximum height of the topographic surface. This decrease indicates that the maximum peak to valley height has on average decreased with increase in wear grade, it is not apparent from this parameter whether or not this is due to the valleys becoming shallower or the peaks becoming less pronounced. From analysing at this data along side the 3D axonometric plots, it would be sensible to assume, that this change at least in part is due to the removal of the asperities present at Pol0 and Pol1.

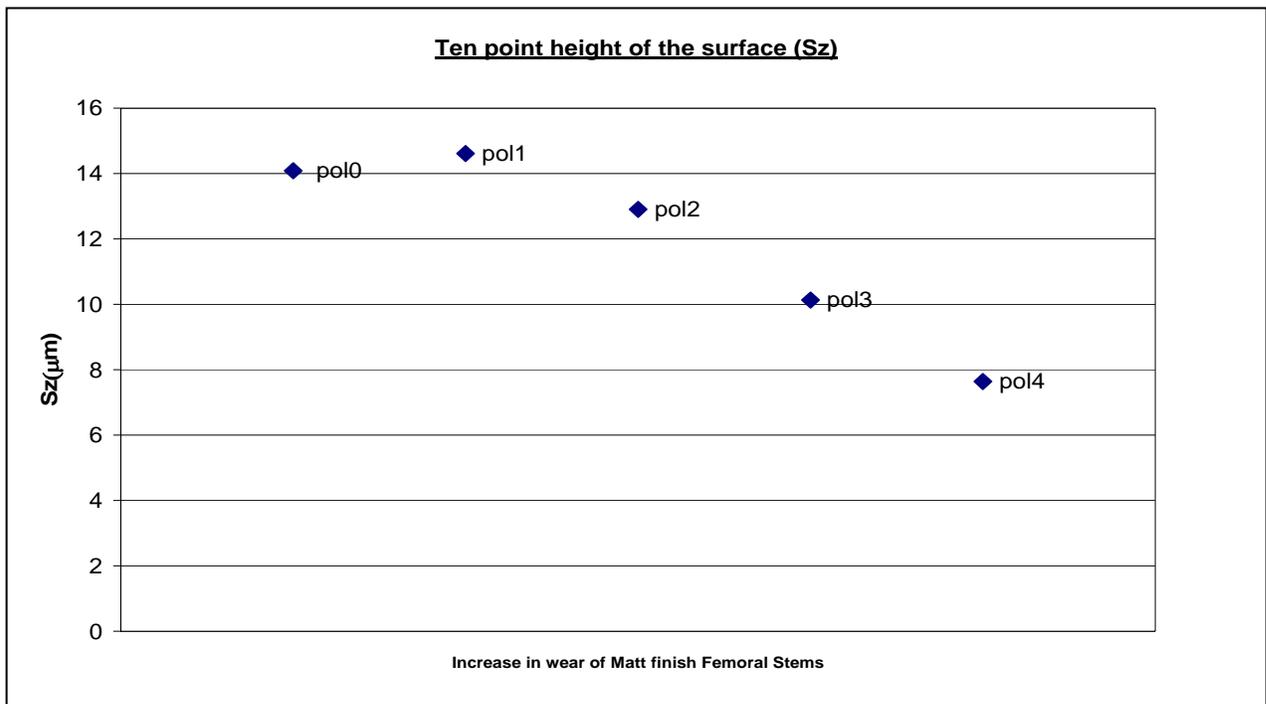


Figure 4.7 – Average change in maximum height of topographic surface with increase in visual wear grade

Ssk – Skewness

Figure 4.8 shows the average change in skewness with increase in visual wear grade, all of the results calculated show negative values, this indicates that the surface is dominated by pits or valleys. Pol0 however has a value close to zero indicating a relatively Gaussian surface as would be expected from a blasted surface. As the wear grade increases the average Ssk value becomes more negative. This indicates that increasing the wear grade also increases the dominance of the valleys compared to an unworn surface. When looking at the parameter in isolation it could be assumed that this is because the valleys are growing in relative magnitude or number. By inspecting the 3D axonometric plots, it is clear that the peaks are becoming smaller, therefore the valleys appear more dominant.

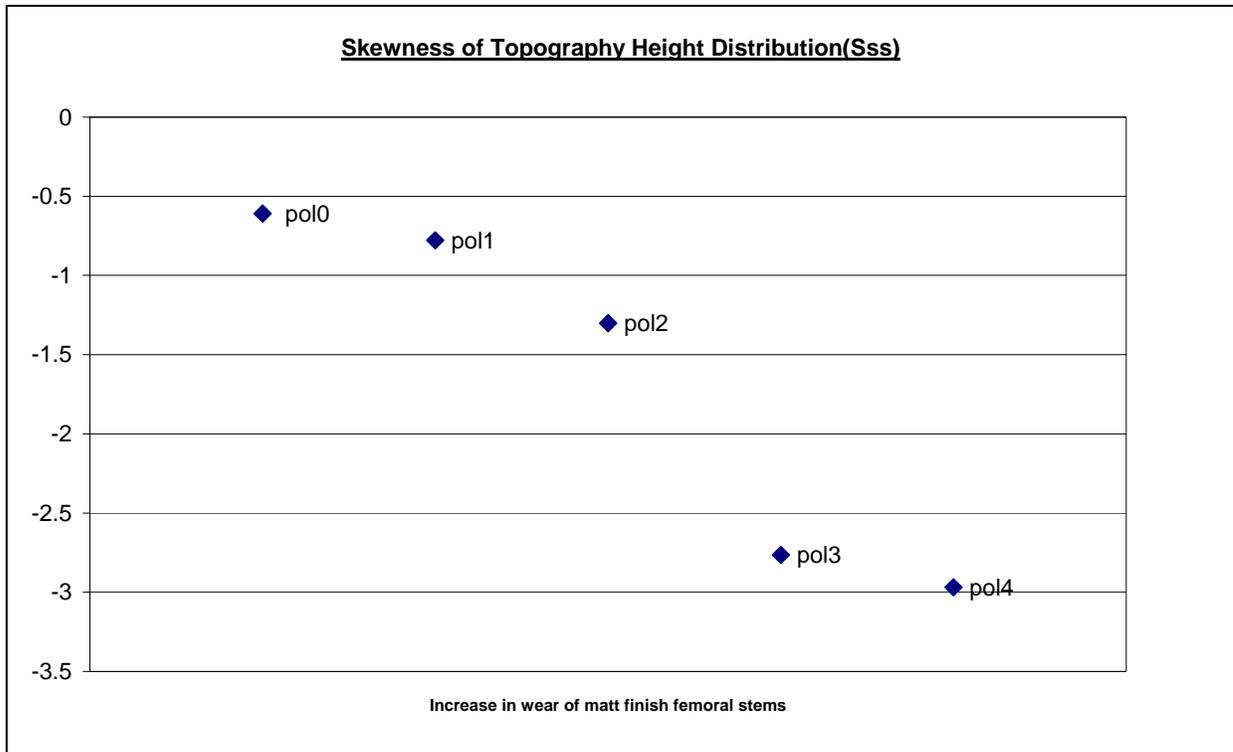


Figure 4.8 – Average change in skewness with increase in wear grade

Sku – Kurtosis

Figure 4.9 shows the average change in Kurtosis with increase in wear grade. From Pol0 through to Pol2 there is a small increase in kurtosis, following this from Pol2 there is a more pronounced increase in Kurtosis. All values for kurtosis are greater than 3 which indicate that the height distribution is becoming narrower, indicating along with the skewness (Ssk) values that the valleys are becoming the dominant feature of the topography.

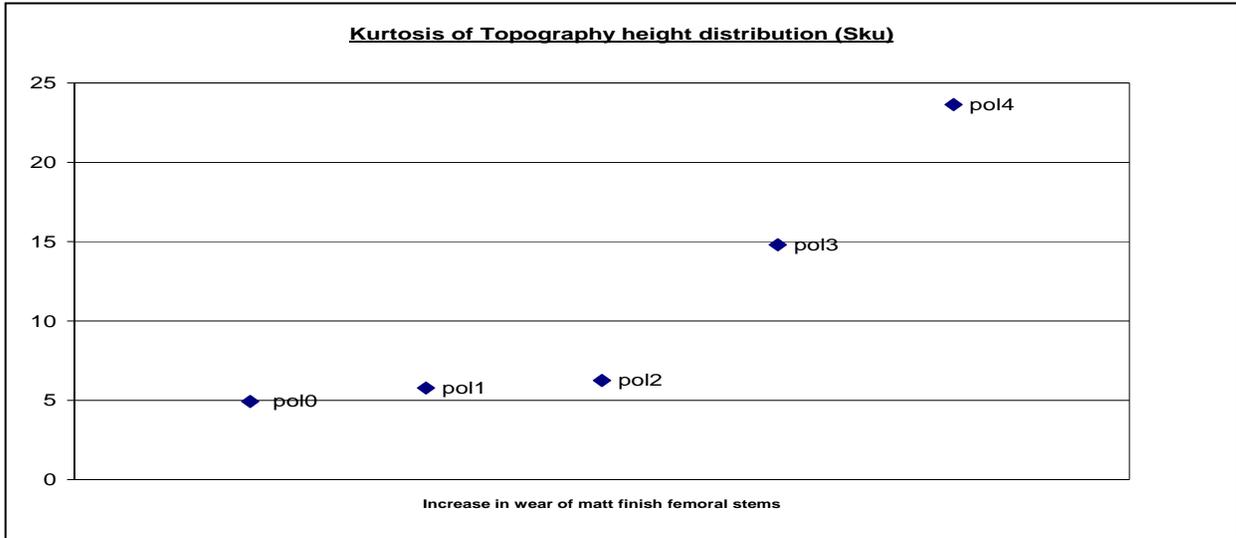


Figure 4.9 Average change in Kurtosis with increase in visual wear grade

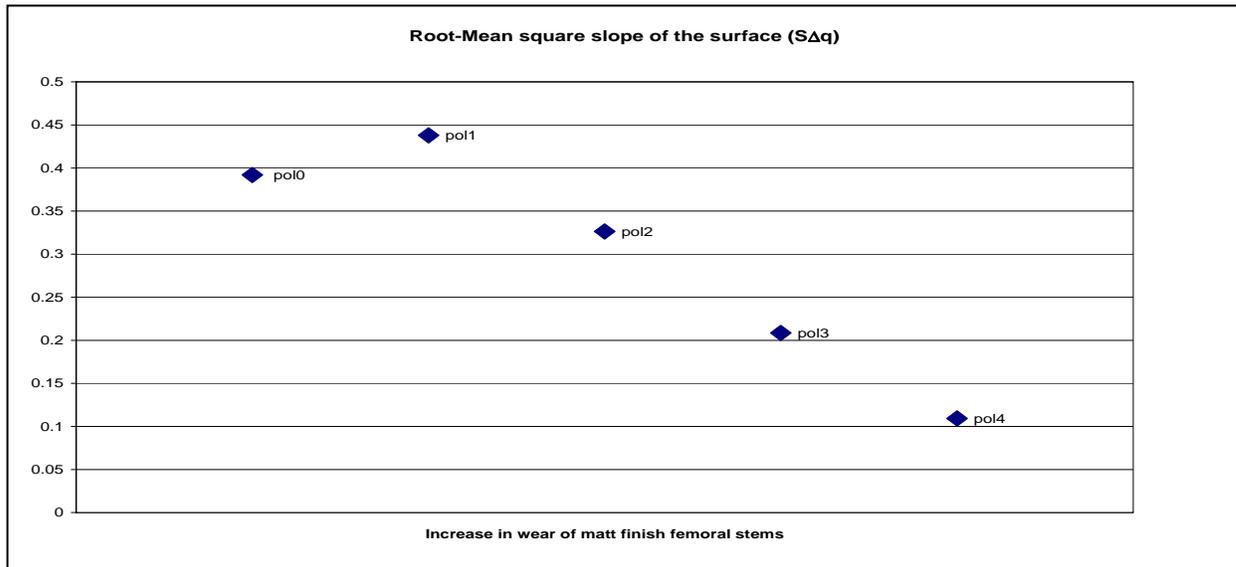


Figure 4.10 The average change in $S\Delta q$ with increase in visual wear grade

$S\Delta q$ – the root mean square slope of the assessed texture surface

Figure 4.10 shows the average change in $S\Delta q$ with increase in visual wear grade. As with Sq and Sz , following an initial increase in value from Pol0 to Pol1, there is a decrease in $S\Delta q$ value with increase in wear grade, indicating that the average slopes of the surface decrease with increase in wear, this correlates with a decrease in roughness shown by the decrease in Sq , and Sz and also correlates with visual inspection of the 3D axonometric plots, where it can be seen the asperities being worn away progressively and there is a general flattening of the surface.

The Volume Family parameters (Vvv Vvc Vmp)

Figure 4.11 shows the average change in each of the volume family parameters with respect to increase in visual wear grade. The results depict the relative change in surface topography rather than absolute change. The trend shows that there is a decrease in Vmp and Vvc, however Vvv remains relatively unchanged, this indicates that the smoothing of the surface is due to removal of asperities rather than the filling of pits. This can be deduced because the stability of Vvv indicates that the valleys remain relatively unchanged compared to the core and the peaks on the surface.

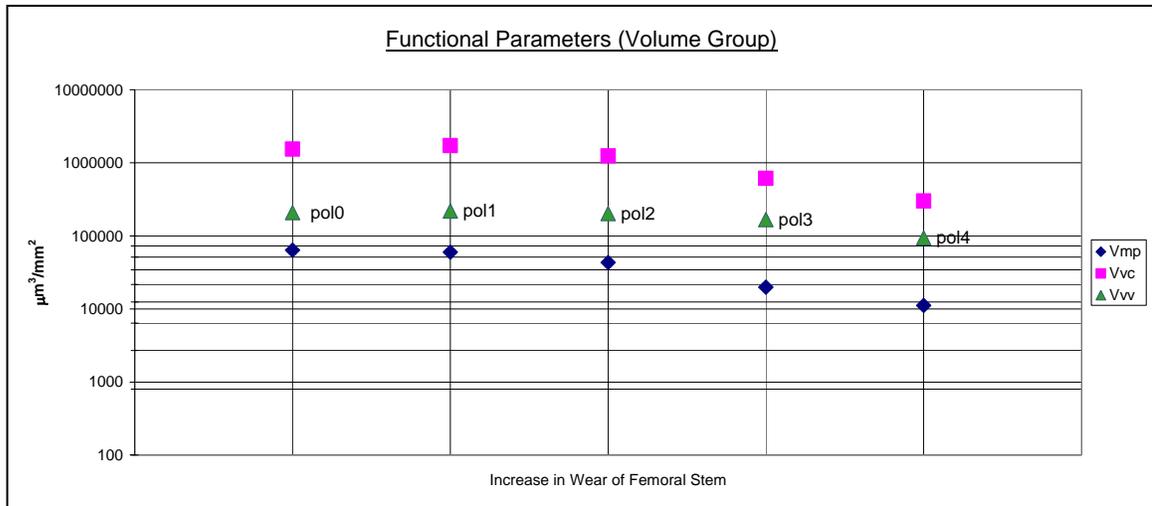


Figure 4.11 The average change volume family parameters with increase in visual wear grade

4.7 Discussion

The study on location of wear on the surface of matt finish femoral stems, shows good correlation with previous works completed (J Cook 1998). This location study serves to confirm that the series of explanted stems are believed to show typical wear characteristics of stems which have been explanted at revision procedures, and consequently produce a sound basis for further study.

Each of the reduced parameter set show there to be a trend with increase in visual wear grade. The parameters show that the surface becomes less rough with increase in wear grade, the asperities are worn away and the valleys remain unchanged.

The anomaly to this is the change between Pol0 and Pol1 for Sq, Sz and SΔq. There are 2 possible explanations for this occurring: One rogue sample skewing the results, though this would seem unlikely looking at the spread of results. More likely, because the unworn topography can not be truly determined, the point of measurement for Pol0, shown in figure 4.11 presents problems. As can be seen from the diagram, that there is a sharp change in geometry where the neck of the stem blends into the head or the taper. This sharp change in geometry will affect the results of bead blasting which is the roughening process these stems undergo. The beads will hit the surface at a slightly different angle at this point to the rest of the stem, thereby generating a different surface topography, one that is smoother. This does show the benefit of parametric characterisation. From visual inspection of the 3D axonometric (figure 4.2) plots alone, this discrepancy can not be determined because the difference in the surfaces is only slight. The presence of the anomaly in the data at this point between Pol0 and Pol1 does indicate that modification to the visual grading system is required. The modification needed is not the way in which the visual grades are categorised, but in the position that measurements for Pol0 are taken.

The wear of this series of explanted stems which have been retrieved at the time of revision operation shows typical wear of femoral stems. The visual grading system requires modification to assess the anomaly between Pol0 and Pol1.

Other than this anomaly the visual grading system could be confirmed as an effective method of classifying wear, it is however a subjective method.

3D surface roughness analysis is potentially an effective method of investigating topography of explanted femoral stems. The 3D axonometric plots show there to be a polishing of the surface during wear of the matt finish femoral stems.

A reduced parameter set, useful for the characterisation of wear on matt finish femoral stems has been selected. The parametric analysis with the 3D field parameter set confirms that the surface is “polishing” as the asperities are removed, yet the valleys remain unchanged. This polishing is not entirely coherent with “fretting wear” from theory presented by R B Waterhouse (1972); the expectation is that rough surfaces will incur less wear due to fretting. This is due to the ability of the asperities to plastically deform. According to Waterhouse, due to the fact that rougher surfaces have a higher plasticity index, some plastic deformation occurs at the tips of asperities, work hardening of the surface is then likely to prevent them from being completely removed and more of the tangential movement is taken up by elastic deformation. Therefore this means that fretting corrosion is less able to take root promoting further wear and third body abrasion. This leads to the belief that though wear of polished femoral stems is widely accepted to be due to fretting wear (J Cook 1998, Middleton et al 1998). The wear of rougher matt finish femoral stems is due to a different mechanism. This wear mechanism requires further investigation and is the subject of future chapters.

4.8 Conclusions

- The location of wear is typical of that previously documented.
- The visual grading system though subjective is effective in the recording of stem wear
- Optical interferometry is potentially effective in the investigation of wear of femoral stems
- Visual inspection of the 3D surface maps indicate “polishing” of the surface
- Parametric characterisation allows numerical description of the functional surface
- During wear the asperities caused by the bead blasting process appear to be worn away to leave a smoother, more polished surface, from which debris could be

generated

- During wear the valleys appear to remain unchanged
- There appear to be differences in the wear mechanism in vivo between polished and matt finish femoral stems.

The initial aims of this chapter sought to:

- i) Establish whether a greater volume of material is removed during wear of matt finish femoral stems
- ii) If there are differences in wear mechanisms which result in the failure of matt and polished stems

The first aim has not been fully investigated in this particular study, and will be discussed further in the next section of work. The second aim to establish if there are differences in wear the mechanisms' which result in the failure of matt and polished stems has been investigated here through analysing the progression of wear of matt finish femoral stems using 3D surface characterisation techniques.

CHAPTER 5. SEMI-QUANTITATIVE VOLUME ANALYSIS AND TRUNCATION

5.0 Chapter Summary

The visual wear grading system has been revised and updated to address the problems shown in chapter 4 with the measurement position for the unworn (Pol0) areas. This revised visual grading system has been tested to validate the revisions.

The study on the explants was expanded to develop a method for quantifying wear on the femoral stems. Evidence that the valleys remained unchanged during the wear process was borne out of the 3D surface texture analyses. It was concluded that the bearing area curve could be used to determine the amount of material removed in each wear area for each visual grade of wear.

This process was successfully completed and the volume of material removal for each wear area was determined. This is a novel method, which gives a good semi-quantitative value for material removal during wear of matt finish stems.

A model for wear on stems was adapted to determine the amount of material removal expected for typical abrasive sliding wear. This mathematical model was compared to the amount of material removal from the semi-quantitative analysis completed on the explanted stems. A definite correlation in results was shown – concluding that the wear of matt finish femoral stems may be due to an abrasive form of wear and not fretting corrosion as in polished stems.

This potentially correlates with theory (R B Waterhouse 1972) that the smoother the surface finish, the greater the fretting damage incurred, it would seem probable therefore that the studies showing a higher rate of failure for matt surface finish femoral stems of certain designs occur due to a potentially different wear mechanism than originally accepted.

5.1 Background and Aims

Through studies completed in the previous chapter, two issues were highlighted: (i) the need to revisit the visual grading system to and modify the position of measurement for

the unworn Pol0 measurement; (ii) the requirement for a quantitative analysis of material removal during wear of matt finish femoral stems. The development of a quantitative measurement method for wear on femoral stems is borne out of the need to determine if greater material removal from matt finish femoral stems is a factor in the higher incidence of their aseptic loosening. From the literature study (chapter 2), no fully quantitative method for the analysis of volumetric materials loss has been developed to date.

Quantitative measurement of wear presents several problems. In the orthopaedic industry, the standard measurement tool for wear in simulated situations is gravimetric assessment. In the case of femoral heads and cups, this has been sufficient for years (B Derbyshire et al 1994, R M Streicher et al 1996). In the case of explanted heads and cups, attempts are made to quantify gross wear through geometric measurement on a CMM; this technique however, does not have a high measurement resolution and can only be accurate to a few μm^3 at best. Gravimetric assessment of wear on femoral stems is not suitable for reasons which include:

The exact weight of the stem prior to implantation would need to be known, as would the instrumentation and calibration used to record it.

One would have to assume that the stem was not damaged by any means other than in vivo wear, for example by insertion or extraction of the stem.

One would also have to assume that there was no weight gain due to material transfer or adhesion, from cement for example.

When performing in vitro simulation of wear on femoral stems it would be very difficult to control these conditions, in the case of explanted stems, where clinical history may not be fully known, it is impossible.

There have been initial investigations into the use of geometric measurement and surface characterisation as a tool for quantifying wear on femoral stems (J Cook 1998, J Howell et al 2004). The AFM (Atomic force microscope) has been utilised to characterise wear scars in some instances, however it is clear that a more comprehensive quantitative method of assessment is required, and that gravimetric assessment is not feasible.

Therefore in this chapter a method has been developed to address this using the data gathered from the series of explants using the 3D surface metrology and surface topography characterisation.

The Aims of the present chapter are:

- i) Develop the visual grading system to be more robust and accurate
- ii) Develop a method for semi-quantitative volumetric measurement of wear
- iii) Establish the wear mechanism involved in wear of matt finish femoral stems

5.2 Revision of the Visual Grading Method

From the previous application of the visual grading study in chapter 4, it was noted that revision of the system was required to make the measurement of Pol0 the unworn areas more robust and accurate.

The measurement area of the unworn surface was modified as shown in figure 5.1, previously measurements were taken under the head, or taper where modular stems were examined. The sharp change in geometry results in inconsistent surface topography from the bead blasting process, and therefore the measurement position for unworn surface was moved further down the neck, but still outside the cement mantle region.

The rest of the classification remained unchanged from the method detailed in chapter 4.

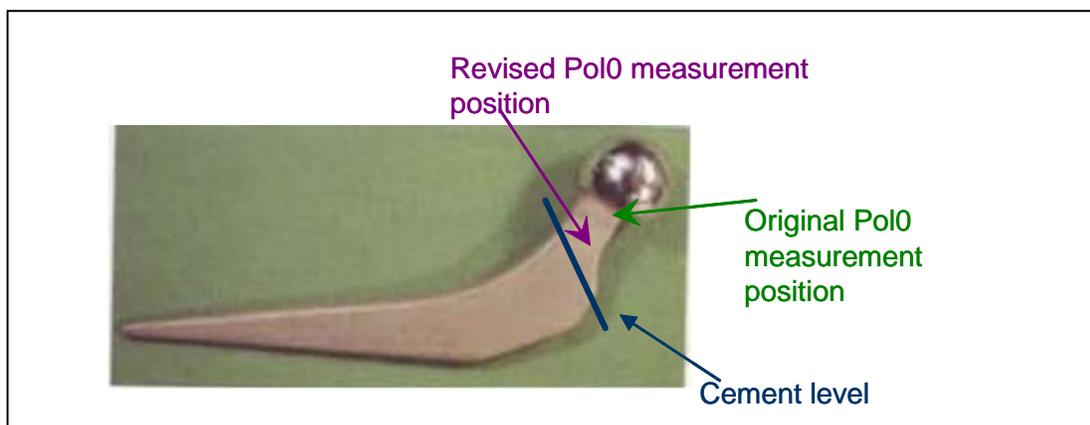


Figure 5.1 Revision of measurement position for visual grade Pol0

5.2.1 Results of the revised system.

3D surface topography measurement and parametric analysis were conducted using the

same protocol as that used for the initial study of the visual grading system. The study was conducted on 4 stems showing the full range of wear within the visual grading system, the design of stems are detailed in appendix IV. Figure 5.2 shows the change in Sq for an average of the 4 stems, with increase in wear grade. It can be seen that by changing the position of measurement for Pol0 the unworn area of stem the trend loses the initial increase in root mean squared deviation of the surface.

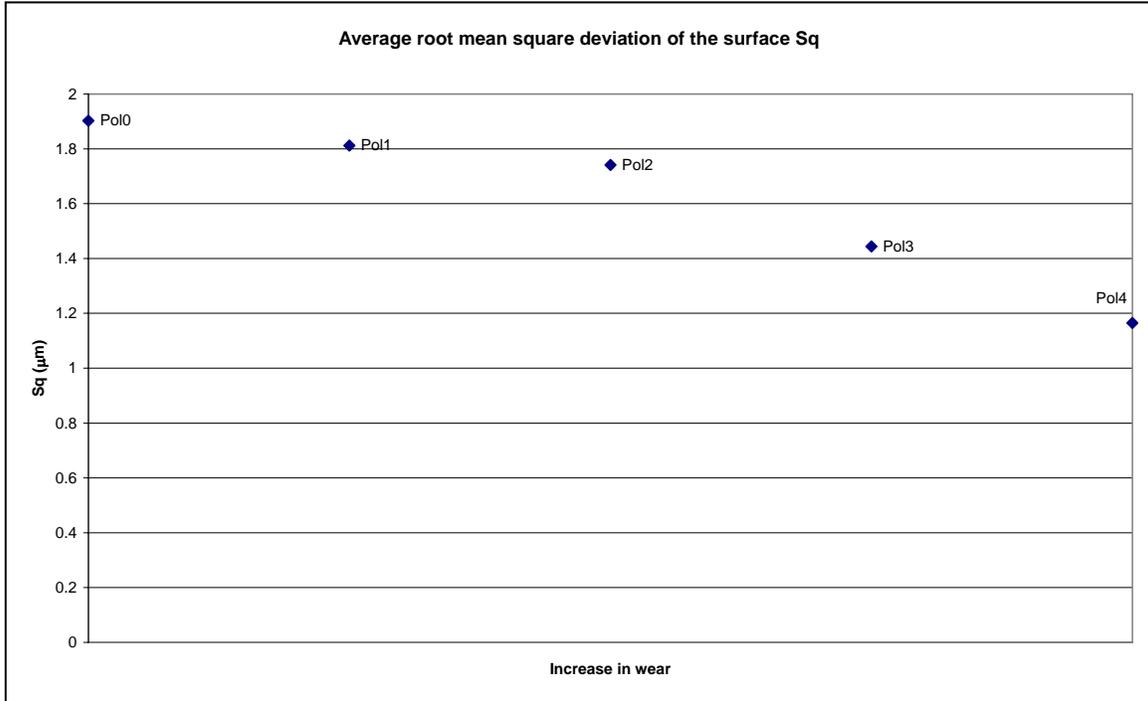


Figure 5.2 – Change in Sq with increase in visual grading system

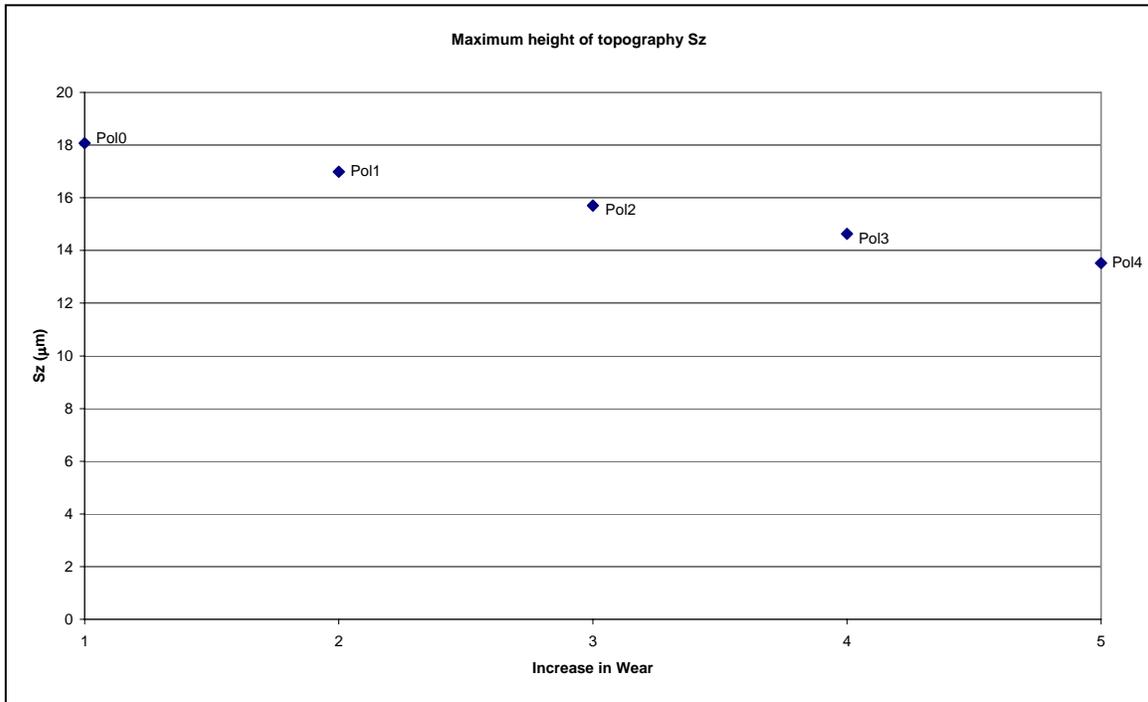


Figure 5.3 Change in Height of the topography of the surface with increase in wear

Figure 5.3 shows the change in maximum peak to valley of the topography. As with Sq where as the initial visual grading showed there to be an initial increase in Sz from Pol0 to Pol1, the trend definitely shows a decrease through the entire grading system from Pol0 to Pol4. There is a slight difference in the values for Sq and Sz, this however is negligible compared to the scale of surface roughness, the inability for exact relocation and the nature of it being an average measurement over a series of stems.

This trend is constant throughout the parameters investigated (appendix III) and it can be concluded that the revisions made to the visual grading system has rectified the initial disparities within the analysis.

5.3 Semi Quantitative volume loss

To provide a fully quantitative analysis of material removal during wear of femoral stems, the exact topography of the stem, prior to implantation would be required. This information is not available, nor is the instrumentation available to provide surface measurement of the entire surfaces at a high enough resolution to gain any sort of

accurate measurement of volume loss of the entire surface of the joint. This is clear from the information presented on the measurement limitations of instrumentation in chapter 3. With this in mind the method which has been developed can only be termed “semi-quantitative” as a good indication can be gained of volumetric wear in localised areas of the stem, and this can be related back to the severity and extent of wear and the surface topography at various locations. The one limitation of this method is that there must be an estimation of the initial surface topography of the stem to act as a datum measurement. It has been determined from the results in chapter 3 that the initial procedure for gaining the unworn topography (pol 0) was flawed due to the geometry surrounding the areas of measurement. This has been addressed and a more robust method now exists for this. The data collected in the previous study was examined and stems were selected that displayed the full range of wear severity in order to make the study more complete.

5.3.1 Assumptions

In order to create the model which the method is based upon, it is necessary to note that from the parametric analysis it has been determined that during wear the deepest valleys remain unchanged and the wear process proceeds by removal of asperities. Assuming that the valleys remain unchanged it is possible to select a mean datum plane for the most worn surface (Pol4). This is achieved through manipulation of the bearing area ratio (figure 5.4); the line shown in red is drawn across the mean plane of the surface, selected from the point of change of the surface from valley domination to asperity domination, and this line then established the datum plane for wear calculations.

5.3.2 Method

Stems were chosen from the series of explants which display topography across the entire range of the visual grading system, i.e. have areas categorised as Pol0, Pol1, Pol2, Pol3, and Pol4.

Assuming that the valleys remain unchanged during wear of the femoral stems, the mean plane height of the topography was determined from the bearing area curve (figure 5.4)

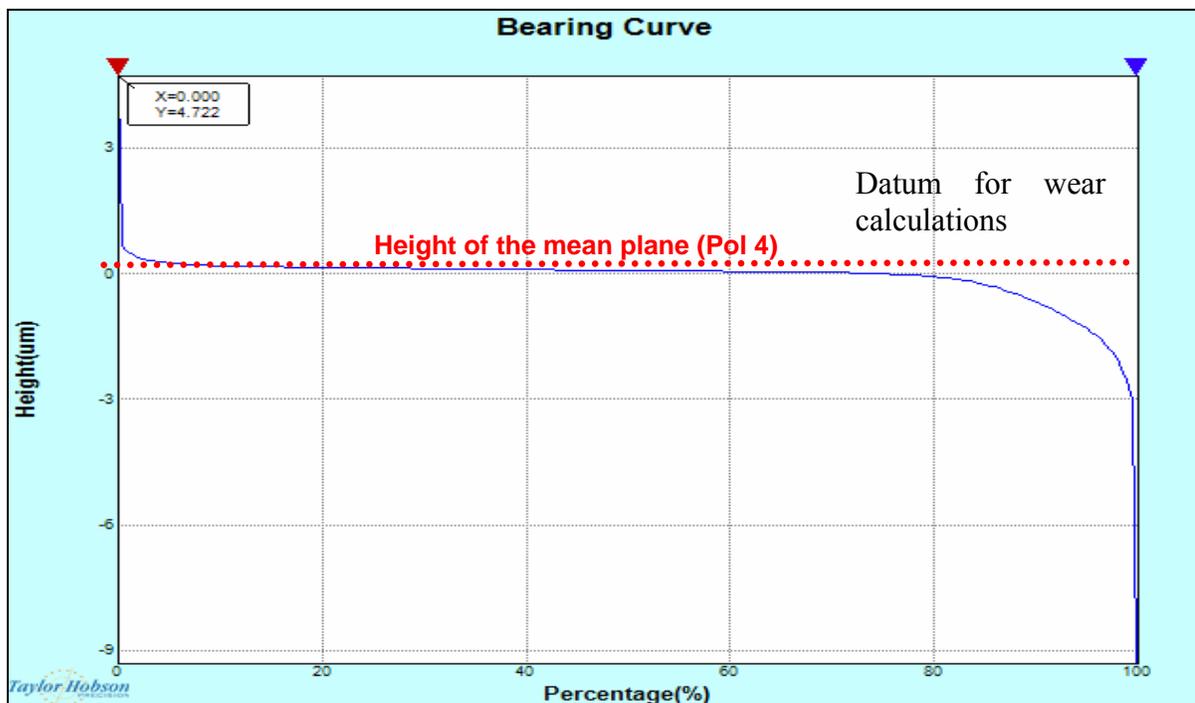


Figure 5.4 Use of the bearing area curve to determine the height of the mean plane

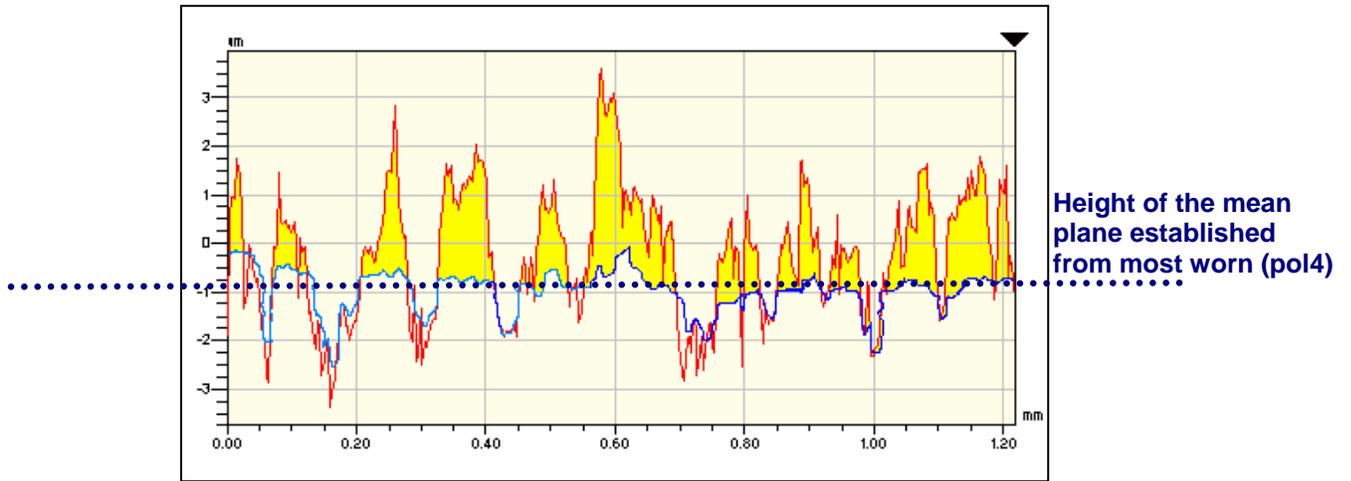
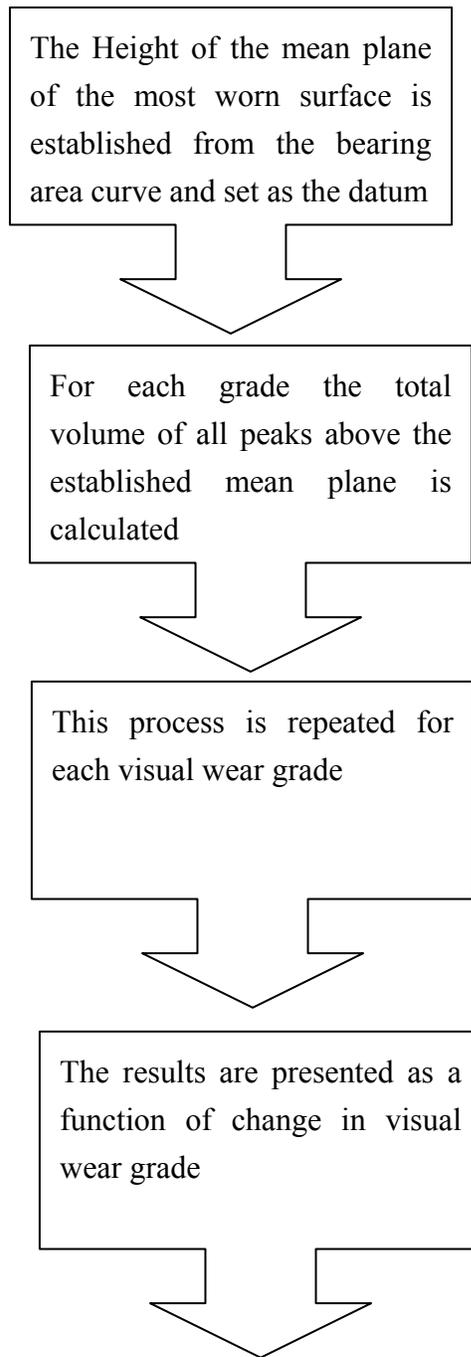


Figure 5.5 Representation of the difference between a pol4 and pol0 surface

Figure 5.5 depicts the way in which the volume is subsequently calculated. The volume of material above the height of the mean plane (shown in yellow) for each of the visual wear grades is calculated. It is this material which has been removed to result in the polished surface of Pol4.

In summary, the following process was used to calculate the volume loss for each region:



Process of semi quantitative volume analysis

5.3.3 Results

If figure 5.6 is reviewed as a function of the visual wear grade, an insight in to the volume of material removal can be gained.

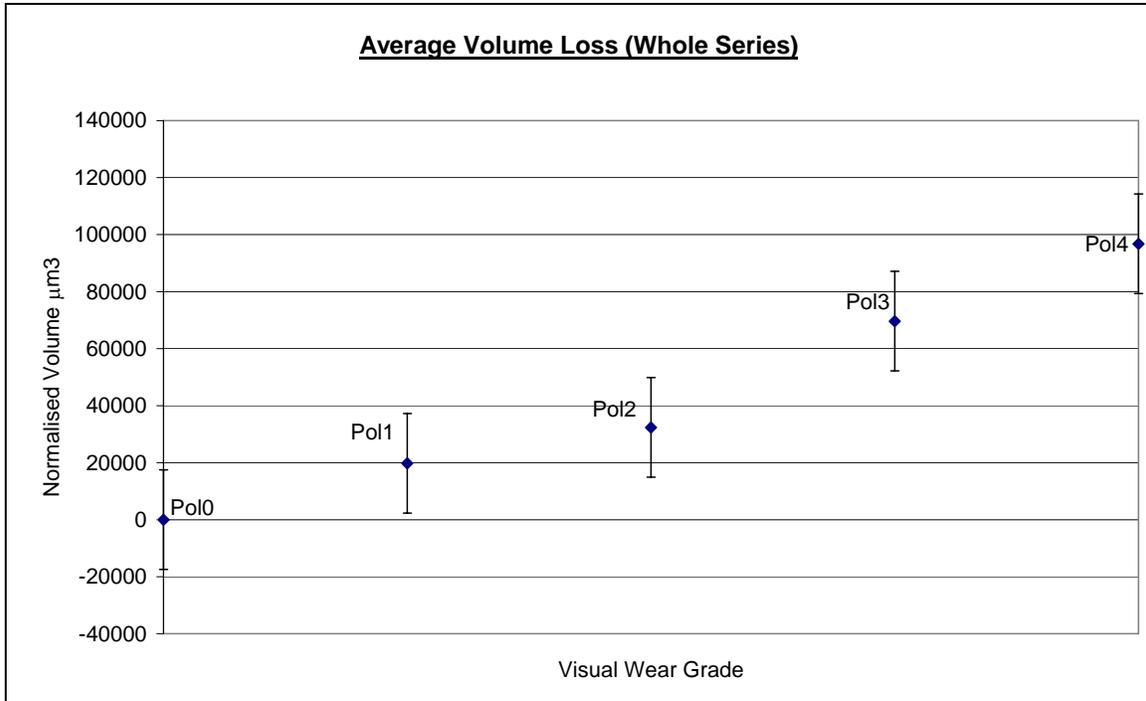


Figure 5.6 – Average volumetric wear loss as a function of visual wear grade

Figure 5.6 shows the volumetric wear loss as a function of visual wear grade, this is the average volumetric loss calculated from all of the 5 stems examined. The trend shows an expected increase in volumetric loss with increase in wear grade.

Figure 5.7 shows the volumetric wear loss of one of the stems in the series. The stem in question is a 316L stainless steel Exeter stem (Howmedica) with a matt surface finish.

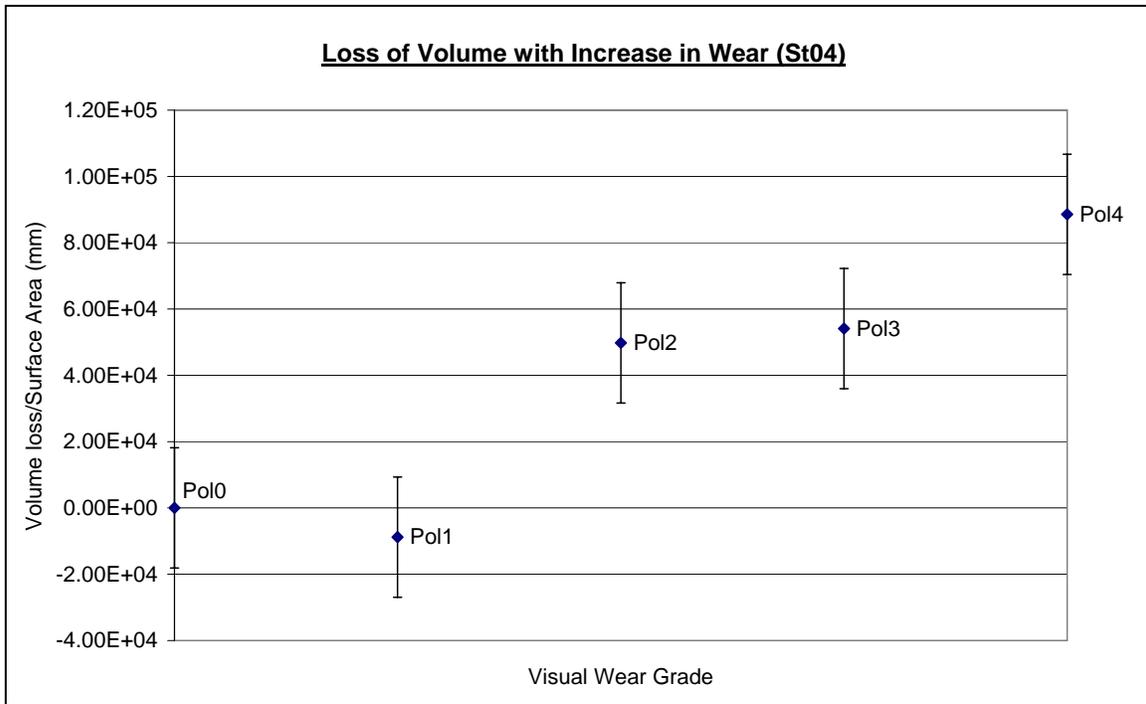


Figure 5.7 –Volumetric wear loss as a function of visual wear grade for a matt finish 316L stainless steel Exeter stem

The graph also shows the increase in volumetric wear with increase in visual wear grade as is expected.

5.4 Truncation model of wear

It is suggested that wear of femoral stems is due to fretting wear, however the theory of fretting wear documented by R B Waterhouse (1981), and I M Hutchings (1992) suggests that the smoother the surface finish the more severe fretting damage. This does not correlate with the findings of long term studies conducted by D W Howie et al (1998) and H D Williams et al (2002), which shows categorically that there was a detrimental effect on the success of the Exeter stem following a move to a rougher matt surface finish. One of the aims of the studies in this chapter is to determine the mechanism of wear incurred by matt finish femoral stems using the information gained from the parametric and volumetric studies of wear on these implants. The hypothesis in this chapter is that the wear shows more typical signs of classic abrasive wear, rather than fretting wear as suggested in the literature.

To confirm the idea that the wear of matt finish femoral stems differs to that of polished stems and that fretting wear is not the primary mechanism of wear associated with the wear of matt finish femoral stems a truncation model has been adapted from a model developed by Spedding et al 1983. This model was successfully developed to model abrasive wear in automobile couples. In the present study it is considered that if the development of the stem topography with wear follows the truncation model when applied to the original unworn (Pol0) topography then an assumption of abrasive wear can reasonably be made.

5.4.1 Method

The baseline measurement of topography was taken as the unworn surface of a stem (Pol0 visual wear grade).

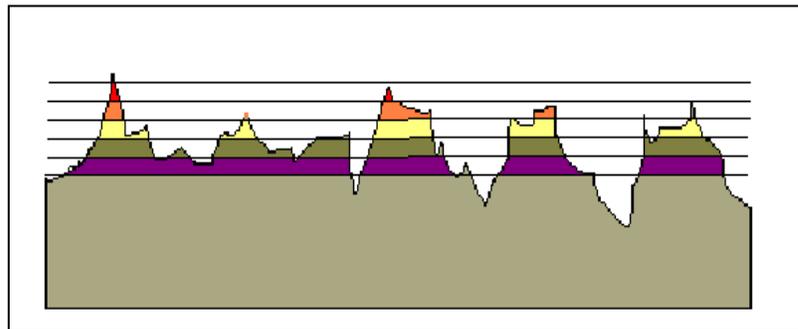


Figure 5.8 – Slices taken through the unworn topography representing “classic abrasive wear”

Slices were taken through the topography digitally as shown schematically in figure 5.8 to represent typical material removal seen in cases of classic abrasive wear. The volume of material removed at each slice was calculated.

Figure 5.9 shows how these slices affected the surface, removing the asperities and leaving the valleys intact, the parametric analysis indicated that this is what occurs during wear of the matt finish femoral stems in chapter 4.

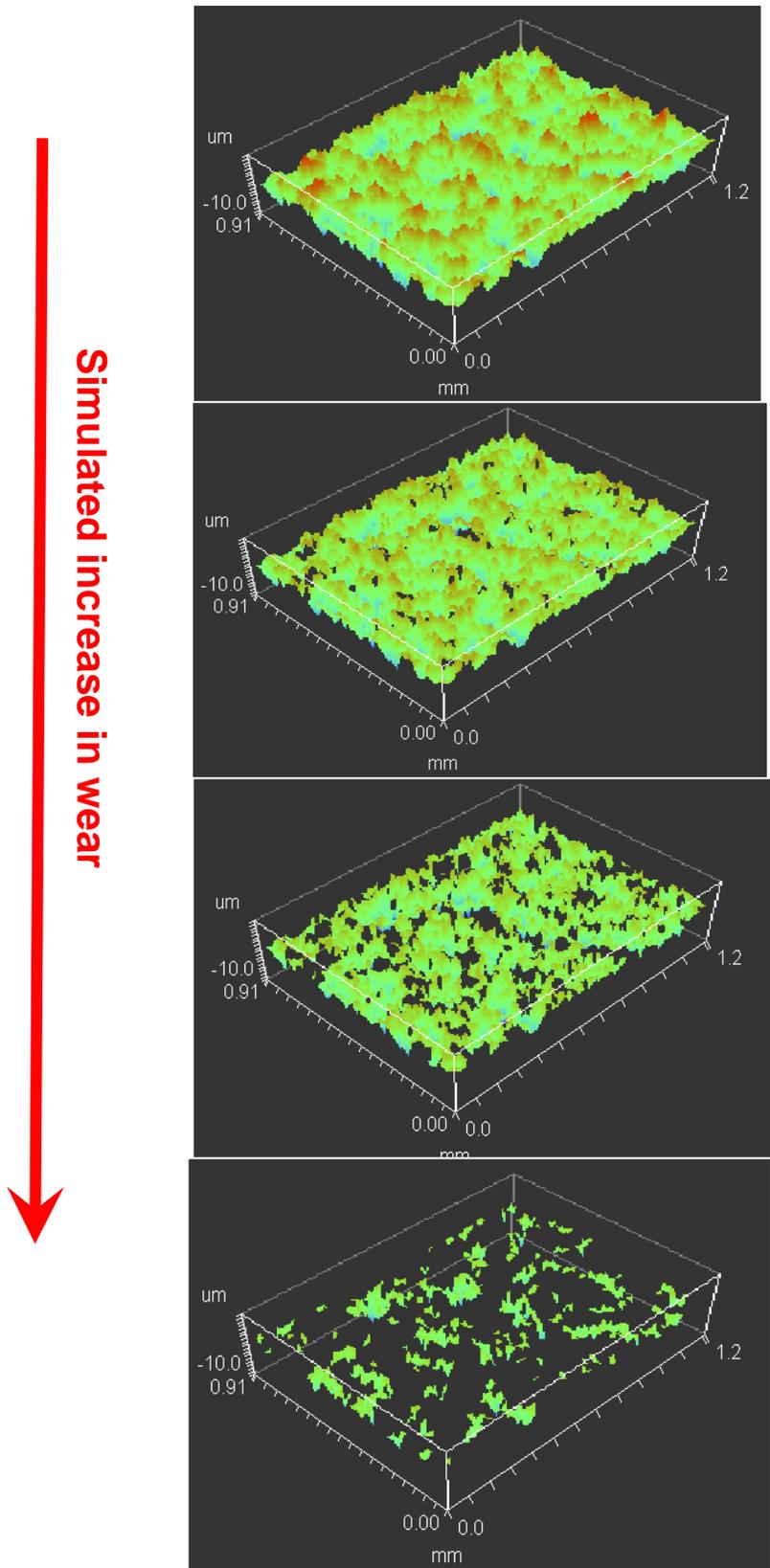


Figure 5.9 – Representation of the development of topography during truncation to simulate “classic abrasive” wear

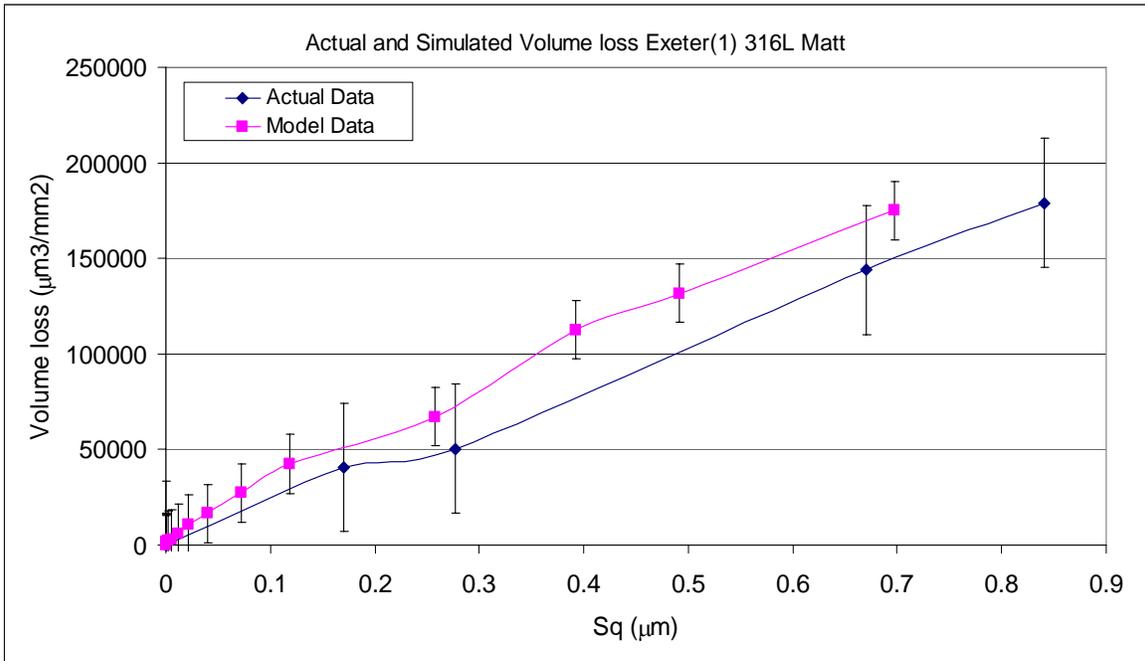


Figure 5.10 – Comparison of actual and simulated wear for St04 Exeter 316L stainless steel matt finish femoral stem

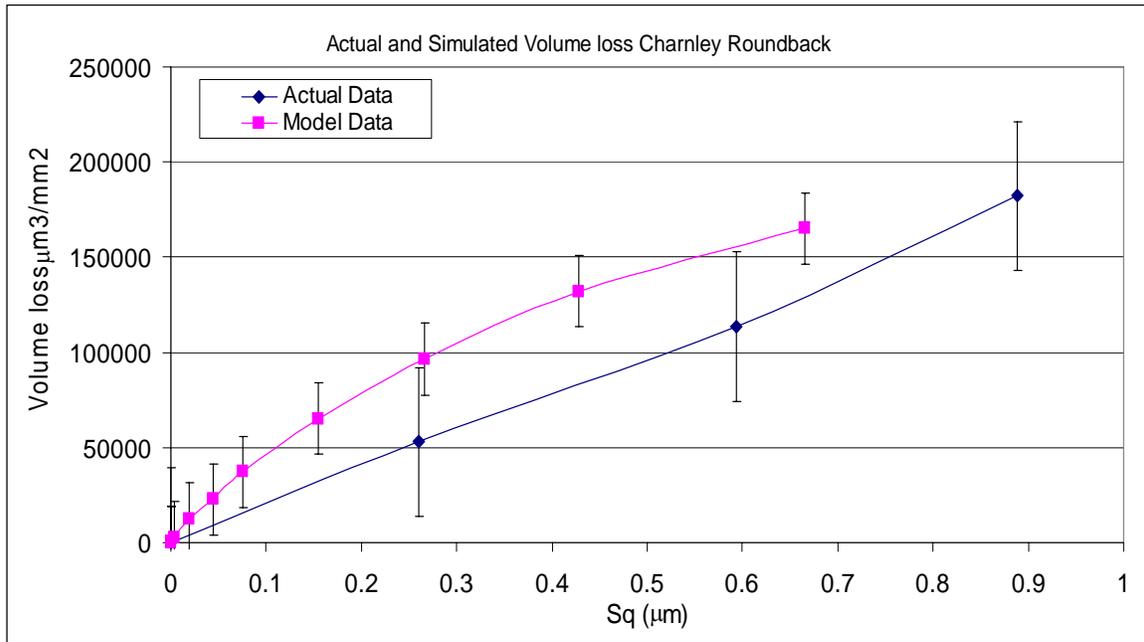


Figure 5.11 – Comparison of actual and simulated wear for a Charnley Roundback stainless steel matt finish femoral stem

It can be seen from figure 5.10, a comparison of actual and simulated wear for an Exeter 316L stainless steel matt finish femoral stem that both the actual and simulated wear volumes, shown as a function of change in RMS roughness S_q , follows a similar trend, this is particularly evident when taking into account the errors in both experimental and theoretical data. This is also the case for the Charnley Roundback stem although the trend is not followed so closely. There are inherent differences in the design of the two stems, the Charnley being a rounder stem with a flanged section for torsional stability and the Exeter being of double taper design. There is no great difference between the actual volume loss between the two stems, though it would indicate that there is the possibility of a slight difference in the wear mechanism of the Charnley to that of the Exeter.

It is evident that the wear trend of the Exeter stem follows the truncated wear model, and this being the case with the other stems studied suggests that the wear mechanism involved in the premature failure of matt finish Exeter stems is more analogous with “classic abrasive wear” than “classic fretting wear”.

5.5 Discussion

The revision of the visual grading system successfully addressed the problems discovered in Chapter 4 whereby the measurement position for the unworn (Pol0) wear grade gave an inaccurate picture of the initial topography of the stems. By moving the measurement position away from the complicated geometry of the neck/head taper to an area where the bead blasting process gives consistent surface finish, the visual grading system was made more accurate and more robust.

Semi-quantitative volume loss of the femoral stems gives a method for localised quantitative analysis, providing a tool for assessing stems performance and function. Literature showed that little work has been carried out on quantification of wear on stems, with the advent of hard on hard bearings reducing the wear during articulation of heads and cups, stem wear is becoming an increasing contributor to the percentage of particulate debris generated in vivo, and therefore for improvement in joint replacement

function, stem wear takes increasing importance in the design of prostheses.

The model presented here enables numerical comparison of the extent of wear of matt finish femoral stem designs. Clearly the numerical analysis presented here, whilst highly significant is only semi-quantitative. What the numbers uniquely give is the extent of material loss of given areas which can only be defined visually. Global figures for stem material loss could only be gained by fully grading the surface area of the stem, e.g 10% Pol0, 30% Pol1, 20% Pol2, 20% Pol3, 10% Pol4. This could have been attempted in the present case but without access to good gravimetric data to compare against it was not considered useful.

The mathematical truncation model contributes to confirmation that the wear of matt finish femoral stems appears to differ to that of polished femoral stems. If fretting wear were the only mechanism involved in the wear of matt finish femoral stems, theory suggests that the asperities should plastically deform and reduce the severity of fretting wear. The mathematical model of classic abrasive wear shows very close trends to that of the wear of matt finish Exeter stems, the trend is also similar to that of the other stems investigated, but this similarity is less pronounced. This finding presents the question as to whether there are differences in wear of matt finish femoral stems depending upon their geometrical design, and possibly the material of manufacture. With information on the fixation medium (brand of PMMA bone cement) unknown in the case of these explants, differences in wear mechanism could also be due to differences in performance of bone cement.

5.6 Conclusions

- The revision of the visual grading system has produced a robust and accurate way of categorizing wear of matt finish femoral stems
- 3D surface topography measurement of the surfaces gives some insight into the progression of topography during wear and also the wear mechanism which causes it
- A method for semi-quantitative volume analysis of abrasive wear on matt finish femoral stems has been developed which provides a tool for the assessment of

prosthesis function

- The truncation model suggests that the wear mechanism involved in the failure of matt finish Exeter femoral stems is not classic fretting wear at least until a fully polished area is attained, then it is believed that classic fretting damage would occur
- It is proposed that the wear mechanism of matt finish femoral stems is abrasive wear in the early stages
- The wear of femoral stems may depend upon their geometrical design
- More information is needed regarding the variation in brands of PMMA bone cement

The initial aims of this chapter were to:

- i) Develop the visual grading system to be more robust and accurate
- ii) Develop a method for semi-quantitative volumetric measurement of wear
- iii) Establish the wear mechanism involved in wear of matt finish femoral stems

The first aim was fully satisfied by moving the measurement position for the pol0 classification to an area away from complicated geometry whilst maintaining a position outside of the cement mantle; this was confirmed to have been successful following parametric analysis.

A method for semi-quantitative volumetric measurement of wear has been developed, thus also partially satisfying an earlier aim of providing a method to compare the volume of debris lost from matt and polished stems.

The wear mechanism involved in the wear of matt finish femoral stems has been suggested to be more of an abrasive mechanism than the fretting wear which was initially suggested; these was primarily hypothesised following the 3D surface characterisation, and then through comparison to a model for abrasive wear.

CHAPTER 6. BEHAVIOUR OF PMMA BONE CEMENT

6.0 Chapter Summary

A strong theme noted in the literature review was the lack of information regarding the behaviour of PMMA bone cement, during and following polymerisation and during curing of the substance. Little work has been found on the comparative properties between the dozen or so brands of PMMA on the market today. Though it should be noted that a comprehensive guide to PMMA bone cement has now been published (D.C Smith 2005)

Due to the exothermic reaction incurred at polymerisation of the polymer substance, a geometrical change is expected. The extent of the geometrical change could have direct bearing on the contact at the stem/cement interface, and could also have an impact on the stress and load bearing properties of the complete cement mantle.

With this in mind an attempt was made to track the change in geometry of semi-constrained PMMA in similar conditions to that which one would find in-vivo.

The conclusive evidence from this investigation was the definite rapid dimensional increase in the bone cement during polymerisation, followed by a decrease in dimension throughout the rest of the curing period to a resultant size smaller than initially noted.

There was significant variation in the rate of expansion and shrinkage between the bone cements, the significance of this indicating that all bone cements do not necessarily possess the same behavioural properties, on polymerisation and curing.

6.1 Background and Aims

From the investigations on explanted femoral stems, it was noted that more information was required about the nature of contact at the stem/cement interface to gain an accurate picture of the wear mechanism involved in the wear of matt finish femoral stems.

It has been noted that bone cement is often referred to as the weak link in cemented type

total hip replacement (Dr A J C Lee 1999, S P James et al 1992, G Lewis 1997) and a large amount of work has been conducted to optimise cementing technique and conditions to maximise the effectiveness and function of the cement mantle in the total hip replacement system (C Liu et al 2001, B Pascual et al 1995, J A Skinner et al 2003)) Although a large amount of work has been carried out to determine the mechanical properties of bone cement and the effect that bone cement variations have on the mechanical properties, little information is available regarding the nature of behaviour during polymerisation and curing of bone cement, and the effect that this might have on the relationship at the stem/cement interface. One study by A Ahmed et al 1982 did conclude that there was an effect of thermal expansion and residual stresses in curing bone cement. To understand the wear of femoral stems fully it is necessary to fully understand the contact at the wear interface. It is believed that gaining a greater understanding of the behaviour of PMMA bone cement during polymerisation and curing a better picture of the resulting interface mechanics may be gained.

The study reported in this chapter has three primary aims:

- i) Study thermal change during polymerisation and curing
- ii) Gain an understanding of geometric change during polymerisation and curing
- iii) Study the geometric change during hydration

6.2 Thermal Change during Polymerisation and Curing

It is reported in the “instructions for use” documentation and elsewhere (A S Carlsson et al 1993) that during polymerisation of PMMA bone cement there is a considerable rise in temperature of the substances. This is true of all poly-methyl-methacrylate compounds that use a powder and a monomer mixture to instigate curing. The chemical reaction which occurs within the resulting mixture is exothermic; temperatures have been reported reaching 80°C. There is literature detailing the effects on surrounding tissue as a result of this exothermic reaction, (R S Majkowski et al 1994) though little information indicates how this thermal change affects the interface between the stem and the cement. Basic engineering theory would suggest that the minimum effect on the stem cement interface

with such a thermal variation would be a geometric change in the material due to thermal expansion.

6.2.1 Method - Thermal change of PMMA Bone Cement

The aims of this study were to establish the nature of thermal change during polymerisation of PMMA bone cement and also to establish if there was a difference in behaviour dependant upon varying cement brand.

In this study 3 brands of bone cement were studied: Simplex P (Stryker Howmedica); Cemfix (Technimed); and Coriplast (Corin Medical), Simplex P with Tobramycin additive was also studied to establish the effect of antibiotic additives on the thermal change.

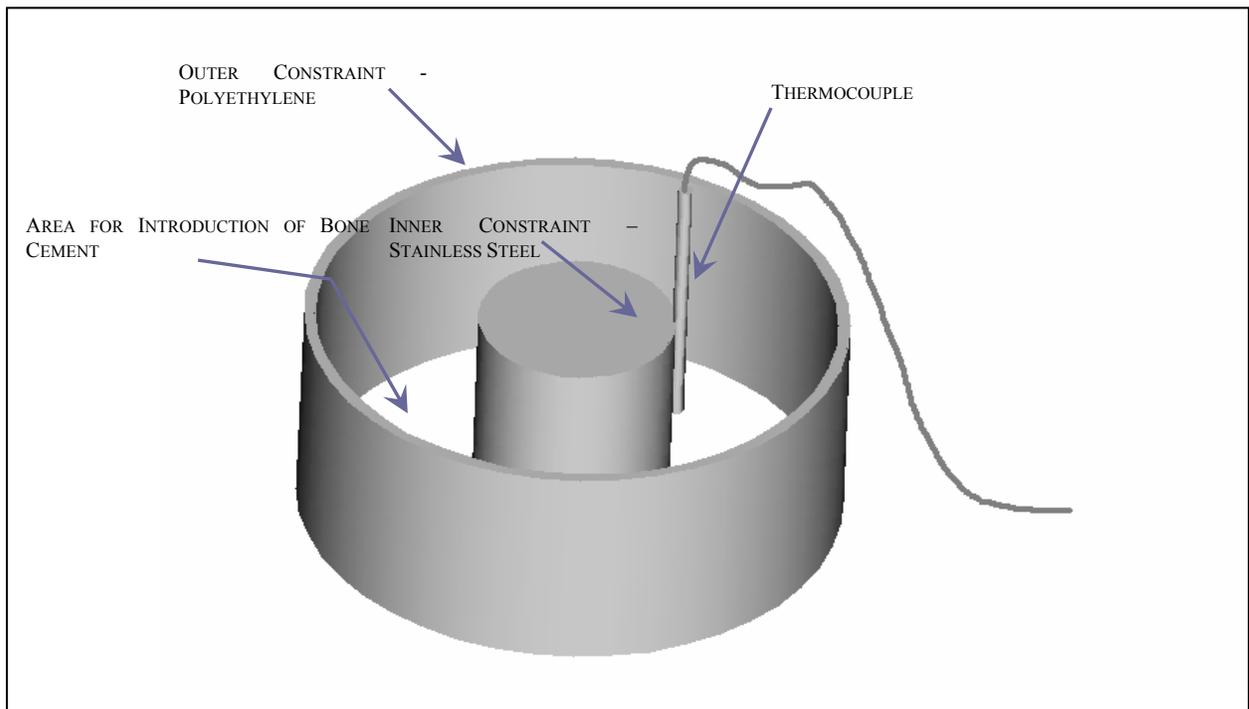


Figure 6.1 Set up of thermal change monitor

The method was developed to mimic the volume and configuration of cement polymerisation in vivo. Figure 6.1 shows the set up. The radial difference between the inner and outer constraints is 4mm, the inner core is manufactured from stainless steel, the outer constraint of polyethylene, giving a material with good conductive properties on the inner core but not on the outer constraint. This represents the situation in vivo where the inner core would be the stem and the outer constraint cortical bone.

The thermocouple used to monitor the thermal change used an analogue data recorder to monitor the output.

Three repeats were conducted for each brand, or variation of bone cement. There is a standardised test for determination of maximum temperature of PMMA bone cement and setting time (BS7253 part 1 :1993), however the standardised model is manufactured from plastic materials and therefore does not account for the effect of the metal stem on polymerisation and thermal changes.

6.2.2 Results – Thermal change during polymerisation

The trend of thermal change which the various bone cements followed was the same, an

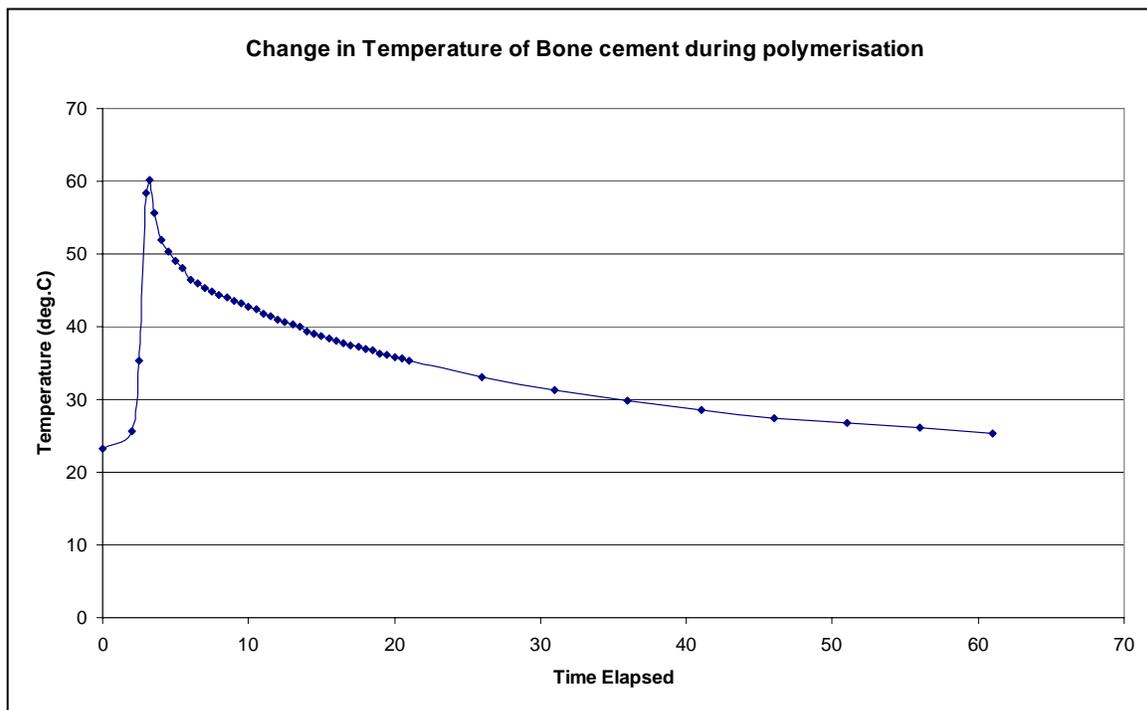


Figure 6.2 – Thermal change of bone cement during polymerisation (Simplex P)

initial sharp increase between 4 and 6 minutes, followed by a steady decrease in temperature over a period of one hour. Figure 6.2 shows this change in temperature graphically for one of the bone cements (Simplex P) The difference in variation of brand which was noted is the maximum temperature reached. Table 6.1 shows the average

maximum temperature reached during polymerisation for the four bone cement variants studied.

Table 6.1 – Maximum Average Temperature for different brands of PMMA bone cement

Cement Brand/Variant	Maximum average temperature
Simplex P	64°C
Simplex P with Tobramycin	64°C
Coriplast	58°C
Cemfix	58°C

Unfortunately no other variants of bone cement were obtainable for thermal analysis during polymerisation. The results showed that the Coriplast and the Cemfix behaved almost identically and also that the addition of antibiotic had no effect on the thermal behaviour of the Simplex P.

These results show that there must be inherent differences between varying brands of bone cement; this presents the question of what other differences there are between brands during polymerisation, and also the difference in their chemical composition. Ultimately it presents the question as to whether the differences in bone cement present differences in function and quality. No evidence of such a study can be found, however it would seem of utmost importance in the study of Cemented Total Hip Replacement success.

The other implication that this thermal change has on the THR system, is the thermal transfer and effects of this on the stem itself. As mentioned previously, various studies have been conducted into the effect of thermal change on surrounding bone and tissue,

however, the effect of the thermal change on the THR components has not been fully considered.

A quick calculation would suggest that the thermal change would have an effect on the geometry of the stem itself:

The physical properties of the exact materials are not known precisely. However, from assumptions made, the coefficient of thermal expansion for materials with similar properties can be used as a guide to the difference in expansion and contraction of the materials.

Taking α_{PMMA} (the thermal coefficient of expansion) to be similar to that of a general grade PMMA polymer, and $\alpha_{316\text{L}}$ to be similar to that of a general grade 316L stainless steel, an idea of the difference in expansion can be gained.

$$\Delta T = 36.9^{\circ}\text{C}$$

$$\alpha_{\text{PMMA}} = 72.9 \times 10^{-5} \text{ }^{\circ}\text{C}^{-1}, \alpha_{316\text{L}} = 16.5 \times 10^{-6} \text{ }^{\circ}\text{C}^{-1}$$

$$L = 1\text{m}$$

$$\Delta L = \alpha \Delta T L$$

This indicates that in the case of the PMMA the expansion for a length of 1m would be approximately 3×10^{-2} m. For 316L stainless steel the expansion for a length of 1m is approximately 7×10^{-4} m.

For the stem this could mean an expansion of up to 21 μm on stainless steel, and 900 μm for the PMMA.

This shows that a greater expansion of the PMMA than the stainless steel, (a typical material for use in prosthetic hip implants) would be expected during polymerisation. With the increase in temperature during the process, it is likely that pressure is distributed throughout the interfaces. During the cooling process of the PMMA following polymerisation, the contraction of the materials may lead to an inconsistency in contact at the bone/cement interface.

During this study, it was also noted visually that the bone cement was contracting away from the constraining surface upon cooling.

Authors' note (R G Middleton et al 1998, J Alfaro Adrian et al 2001) indicates that

polished stems with the collarless double taper design subside into the bone cement after implantation, settling to produce good long-term in vivo results. The nature of the matt surface finish could possibly inhibit this subsidence due to mechanical locking, allowing for more movement within the bone cement than the polished design of femoral stems.

The calculation of thermal expansion, although it shows the difference in geometric change of stainless steel and PMMA in solid state, does not give an accurate picture of the geometric change of the bone cement during polymerisation. It should be noted that the interaction of PMMA upon polymerisation and curing in vivo is far more complex than is represented by the model and calculations. They just suffice to indicate the possibility of expansion/contraction due to thermal change in the PMMA bone cement. The temperature of the PMMA bone cement is generally hottest at the bone interface and shrinks away from the metal stem. The porous and compliant nature of the cortical bone also means that the expansion allows for movement away from the stem. It is also of notes that in an attempt to offset any thermal gradients, many surgeons now prefer to implant stems which are preheated to 37°C. The amount of expansion is also believed to be dependent upon the mixing quality and technique, as vacuum mixing the cement would reduce the amount of air and then in turn reduce the amount of possible expansion.

6.3 Geometric change of PMMA bone cement during polymerisation and curing

Though we have established that there is probably a change in dimension of the stem due to the thermal increase during polymerisation of the PMMA, the geometric change in PMMA bone cement during polymerisation and curing must be established to determine the nature of contact at the stem cement interface. For this study the same 4 variants of bone cement were used, with the aim of noting the geometric change of bone cement and to establish whether or not there is a difference in any change which is brand dependant.

The study aims to give further insight into the nature of contact at the stem cement interface.

The set up was as shown in figure 6.1 with one minor modification, instead of the thermocouple, a digital gauge indicator was used to measure vertical displacement of the constrained body of bone cement thus giving an indication of geometric change during

polymerisation.

The figures below show the change in geometry calculated from the vertical displacement of the DTI.

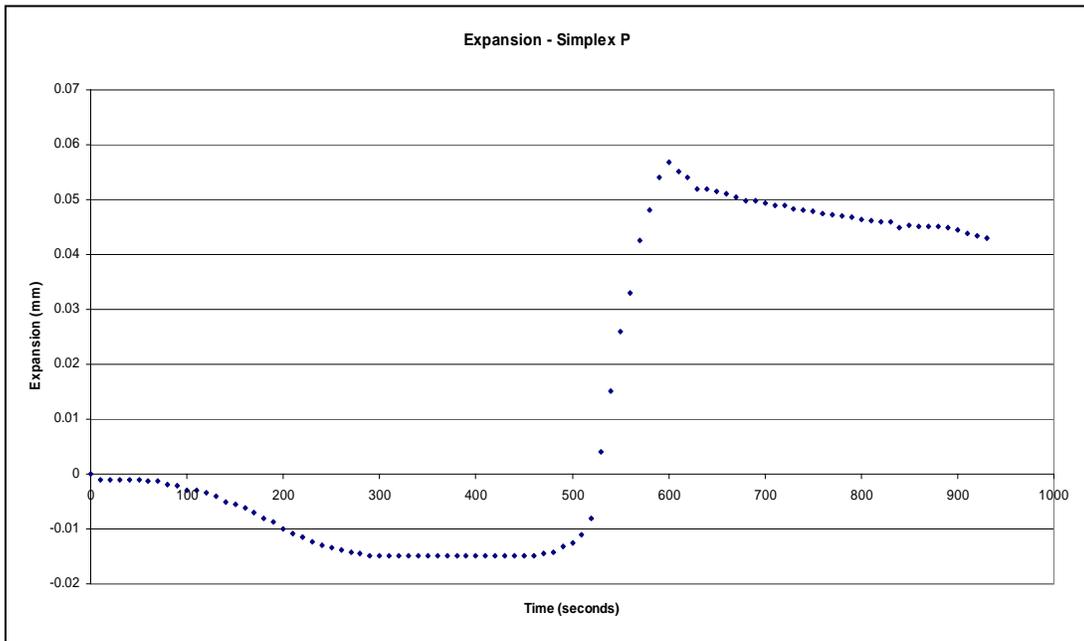


Figure 6.3 – Geometric change of Simplex P during polymerisation

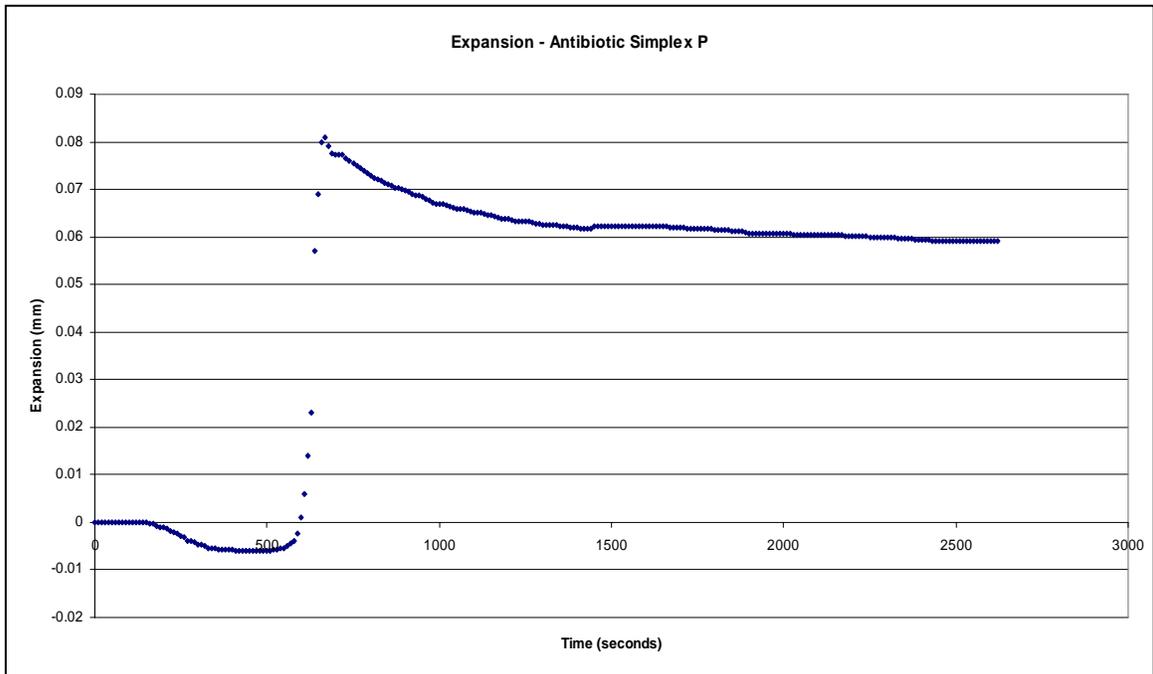


Figure 6.4 – Geometric change of Simplex P with Tobramycin during polymerisation

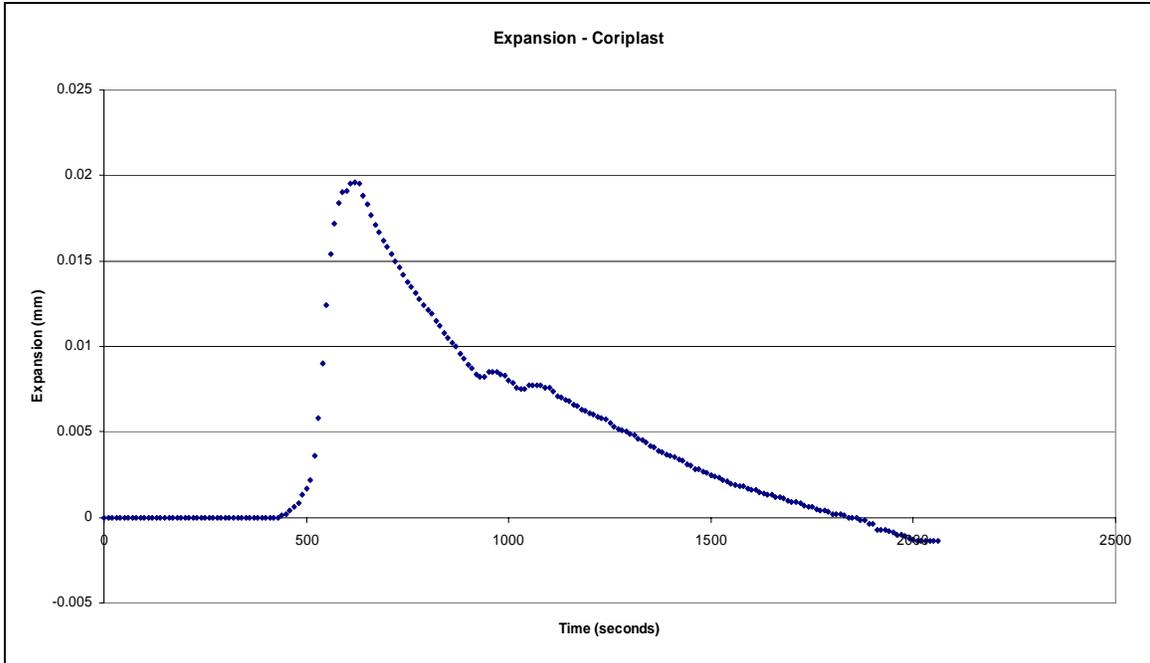


Figure 6.5 – Geometric change of Coriplast during polymerisation

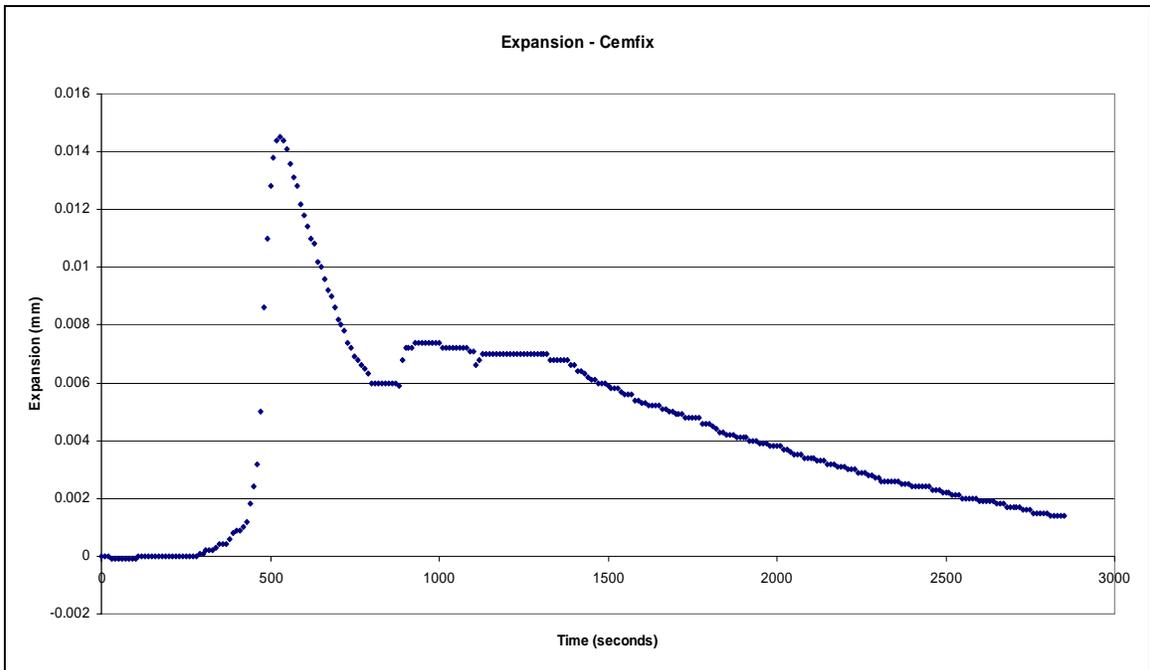


Figure 6.6 – Geometric change of Cemfix during polymerisation

6.4 The effect of cement brand on geometric behaviour

All 4 variants of the bone cement follow a similar trend with an initial sharp increase in dimensions, following the sharp increase there is a distinct difference between the two Simplex cements (figure 6.3 and figure 6.4) and the other two brands of bone cement. The decrease or shrinkage of the Simplex cement is steady and tails off at a magnitude larger than the initial dimension of the cement, the Cemfix and the Coriplast on the other hand show a rapid decrease in dimension. The Coriplast (figure 6.5) and the Cemfix (figure 6.6) show almost identical trends, though the shrinkage of the Cemfix is such that the resulting dimension during the study is less than that at the beginning showing that the resulting density of cement is higher than initially introduced.

The trends of the cements geometrical change is such that the differences in the results between Simplex and the other two brands follow the previous study were found to be highly significant.

The main observations that can be drawn from the studies on thermal and geometric change are:

- There are distinct differences between some brands of bone cement
- The addition of antibiotics showed no effect to the properties studied
- Thermal changes during polymerisation may have an effect on surface interactions
- Geometric change during polymerisation and curing is substantial and may also have a bearing on surface interactions

6.5 Hydration of PMMA bone cement and its effect on geometry

Crawford et al (1999) reports on the possible expansion of cured PMMA bone cement upon hydration due to the introduction of bodily fluids in vivo. The main aim of this final study on the behaviour of PMMA bone cement is to determine if there is any expansion due to hydration of cured cement and to determine the extent of any such change. Having established that shrinkage of cement does occur during curing in the previous study, knowing the effects and extent of change due to hydration is important to establish the exact nature of contact at the stem/cement interface in vivo.

The study was conducted using a Coordinate Measuring Machine (CMM) which enables high accuracy measurement with the ability to detect changes in geometry with a sub micron scale. Five annuluses of each cement variant were cast, four were submerged in ringers solution and one control specimen remained dry, all were stored at a constant temperature of 37.5°C. The internal and external diameters of the annuluses were measured prior to hydration and at intervals of 24 hours for a period of 10 days. Following repeats of the study the results which can be found in appendix VI show no correlation or trend, this is not the expected result, few of the samples showed any significant change, and what change there was did not always indicate an increase in dimension. The study is able to conclude that hydration of bone cement can not be relied upon to counteract any shrinkage incurred by the cement during polymerisation or curing.

6.6 Conclusions

- There appears to be a significant rise in temperature of PMMA bone cement during polymerisation
- The rise in temperature of the bone cement may produce geometrical change of the femoral stem
- There is initial expansion of PMMA bone cement during polymerisation
- During curing of PMMA bone cement shrinkage occurs
- Hydration of bone cement may not be relied upon to counteract any shrinkage in the bone cement
- Varying brands of PMMA bone cement appear to behave in differing ways with respect to polymerisation and curing
- The study on behaviour of PMMA bone cement during polymerisation has given an insight into the possible surface interactions at the stem cement interface.
- Initial thermal and geometric changes during polymerisation may introduce stress at the stem/cement interface
- Subsequent shrinkage of the PMMA bone cement may leave the stem/cement interface incomplete, this may vary for difference types of bone cement

- Different brands of bone cement behave differently and may have an effect on the function and success of the stem cement interface
- The addition of the antibiotic Tobramycin to the cement is shown to have no significant effect on the behaviour the PMMA bone cement in these studies
- The possible void left by cement shrinkage may provide a channel for debris transportation

From these studies it is apparent that there is still not enough known about the stem cement interface to accurately establish the nature of contact, the mechanism of wear and the method of debris transportation.

The initial aims of this study were to:

- i) Study thermal change during polymerisation and curing
- ii) Gain an understanding of geometric change during polymerisation and curing
- iii) Study the geometric change during hydration

The first aim was satisfied through the study on thermal change using the set up outlined in the first section of this chapter. The study could be more comprehensive and study the change in temperature at the stem interface and at the bone interface, and also include a larger number of brands of bone cement for comparison. Also it may prove useful to establish the effects on thermal change of preheating the stem, which is a practice used by some surgeons.

CHAPTER 7. INTERACTIONS AT THE CEMENT STEM INTERFACE

7.0 Chapter Summary

As outlined in the literature survey there are contentious issues surrounding this area of investigation. One of the vacillating concerns is the adhesion, or lack of adhesion at the interface. It has been reported that due to thermal expansion and contraction of metal and bone cement, a gap may appear at the stem cement interface as soon as the cement has finished polymerisation (K L Ohashi et al 1998).

Accurate knowledge of the behaviour of PMMA upon polymerisation and the nature of contact between surfaces is a fundamental issue in the determination of the mechanism of wear involved in the generation of wear, transportation of debris and subsequent failure of the prosthesis.

The aim of this study is to gather information concerning the nature of contact between stem and cement using a simplified model. To facilitate this, the interaction between cement and stainless steel billets of varying surface roughness is investigated, with a view to determining if the selection of surface roughness in the design of femoral stems has an effect on the mechanism of wear at the stem/cement interface.

7.1 Aims and Background

From the previous studies completed, a need was realised for a greater understanding of the contact at the stem cement interface. In this section of the study, a simplified experimental model to determine the interaction of bone cement with stainless steel billets of varying surface roughness was developed. The initial aim was to determine the replication of cement surface onto the billet surface using 3D surface metrology analysis, in order to gain a better understanding of the contact mechanics at the stem cement wear interface.

Further work was completed to determine if any difference in behaviour of cement is brand or time dependent and also if the simplified model was representative of clinical situations.

7.2 Method

Four different surface finishes were selected to represent a range of stem finishes found on prostheses available for surgical use in cemented total hip replacement. The Sq value for each of the selected surface finishes can be seen in Table 7.1. To enable direct comparison between billet and cement, and also to determine the change in surface roughness of the billet and cement following application, a system was devised to allow for relocation of measurement.

Each billet regardless of surface finish was laser etched with a cross as shown in figure 7.1. This gave 6 etched crosses on each billet and thus 24 measurement quadrants.

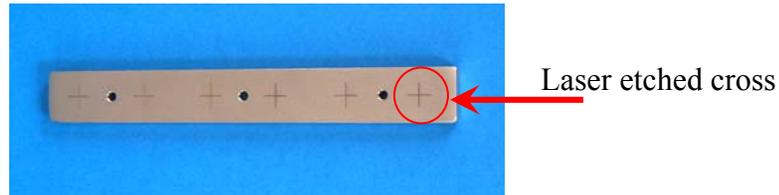


Figure 7.1 – 316L stainless steel billet showing laser etched relocation marks.

The topography of each of the 24 quadrants was measured using the Wyko NT 2000 optical interferometer in vertical scanning mode at a magnification of 5x. A total of 288 initial measurements were taken, 72 for each surface finish.

Following initial surface topography measurements, cement was applied to each quadrant on the billets through a pressurised cement delivery system (figure 7.2). Pressure was upheld on the cement for the duration of curing, this was achieved by the applying a load to the curing cement. There is a change in viscosity of the cement which is time dependant. The cement was applied at time intervals of 1 minute for each quadrant on the billet. This time interval of 1 minute was used to eliminate the effects of viscosity in this particular study. The billets and cement were separated by hand, using a vertical motion, it would in future be more reliable and useful to have used an automated method of separation to eliminate effects of damage occurring at this point and to note the separation loads. This is due to the fact that during hand separation, a number of forces

may be experienced at the interface as shear and torsion are potentially introduced with any non vertical movement during separation. This could affect the resulting surface topography of the cement depending upon the nature of movement at the time of separation.

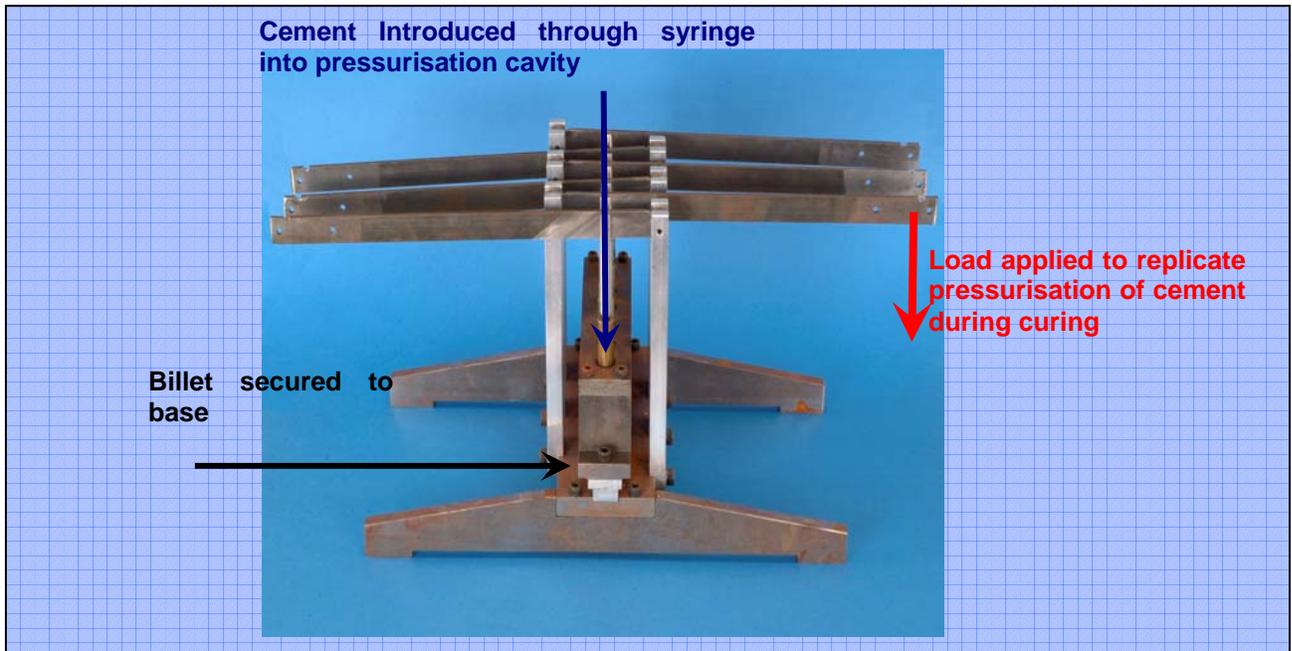


Figure 7.2 – Cement delivery system

The cement and billets were subsequently sputtered with gold the thickness of which was approximately 4nm; this was to allow reflectance of light for measurement with the optical interferometer.

Measurement of the billets post cement and of the post application cement was undertaken with the same measurement conditions as the billets pre application of cement.

Following measurement of the billets, the 3D surface maps were examined visually and the datasets were analysed using Surfstand 2.5 software to calculate the standard 14(+3) 3D surface parameters. Previous studies have determined suitable parameters for use in characterisation of wear of matt femoral stems (Chapter 4). This parameter set has been updated to include additional parameters, which are felt to be beneficial to the characterisation in this study, Table 7.2.

Table 7.1 Average roughness of each billet finish

Surface Finish	Polished	Satin	Matt	Rough
Average Sq Value μm (of all billets)	0.06	0.20	1.03	5.22

Table 7.2 Parameters used in the description of billet and cement surfaces

Family	Nomenclature	Parameter
Amplitude	Sq	Root-mean-square deviation of the surface
	Sz	Ten point height of the surface
	Ssk	Skewness of topography height distribution
	Sku	Kurtosis of topography height distribution
Hybrid	S Δ q	Root-mean-square slope of the surface
	Ssc	Arithmetic mean summit curvature of the surface
Functional Volume	Vmp	Material volume of the surface
	Vmc	Core void volume of the surface
	Vvv	Valley void volume of the surface

7.3 Relocation

As mentioned previously, the billets were marked for relocation; this also resulted in the relocation markings being replicated on the cement. This was used to ensure the same area of billets and cement were measured for direct comparison.

Figure 7.3 shows a contour map of the relocated area, the image on the left shows the data as measured, the image on the right shows the method of data masking for analysis purposes.

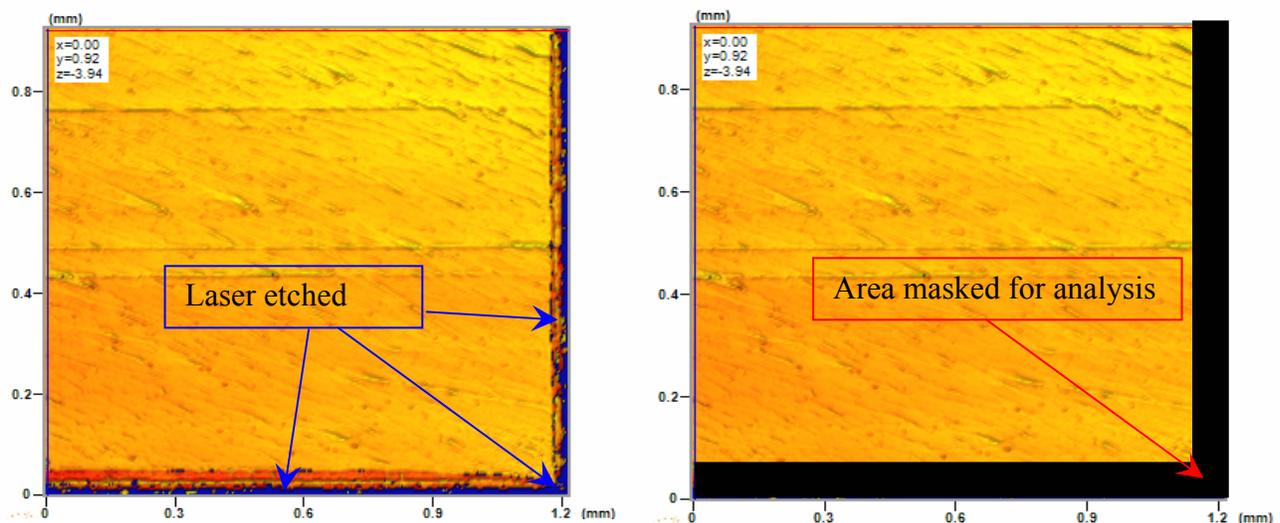


Figure 7.3 – Measurement and relocation of quadrants

From figure 7.3, it can be seen that there is a considerable amount of data loss where the laser etched mark is, the right hand image of figure 7.3 shows the area of measurement “masked” out to enable consistent and direct comparison between billet pre cement, billet post cement, and cement. The areas are masked out using the software to effectively remove the data from calculations, this is required as such a large valley would skew the results, and a clear comparison of interactions could not be made.

7.4 Results

7.4.1 Results - Polished Billets

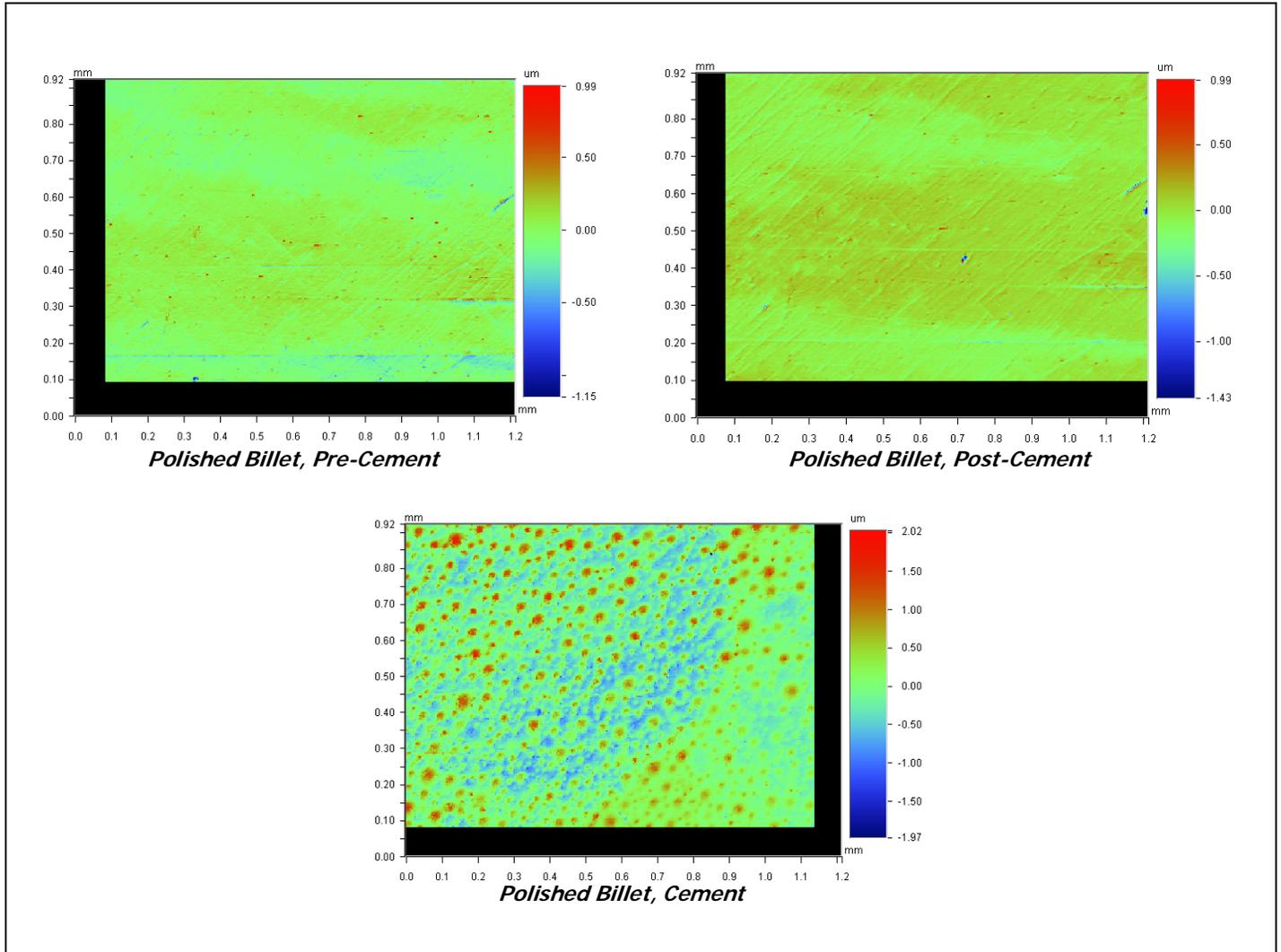


Figure 7.4. Contour Plots comparing topography differences pre and post cement

Figure 7.4 shows a visual comparison of the difference in topography pre and post cementing. The bottom image shows the topography of the cement from the same relocated quadrant on the polished billet. Visually there is a major difference in the topography of the metal billet and the cement quadrant. There are raised areas present of 10 – 15 μm in diameter and up to 1.20 μm in height. On initial inspection it is believed

that these peaks are due to differential micro shrinkage of the PMMA during polymerisation, this phenomenon has been observed before on similar acrylic materials used in surface metrology for replication (R Ruprecht et al 1997). The difference in topography of the stainless steel billet following cementing is negligible. There is an increase in scratches on the surface; it is highly probable that these are due to handling in transportation of the material.

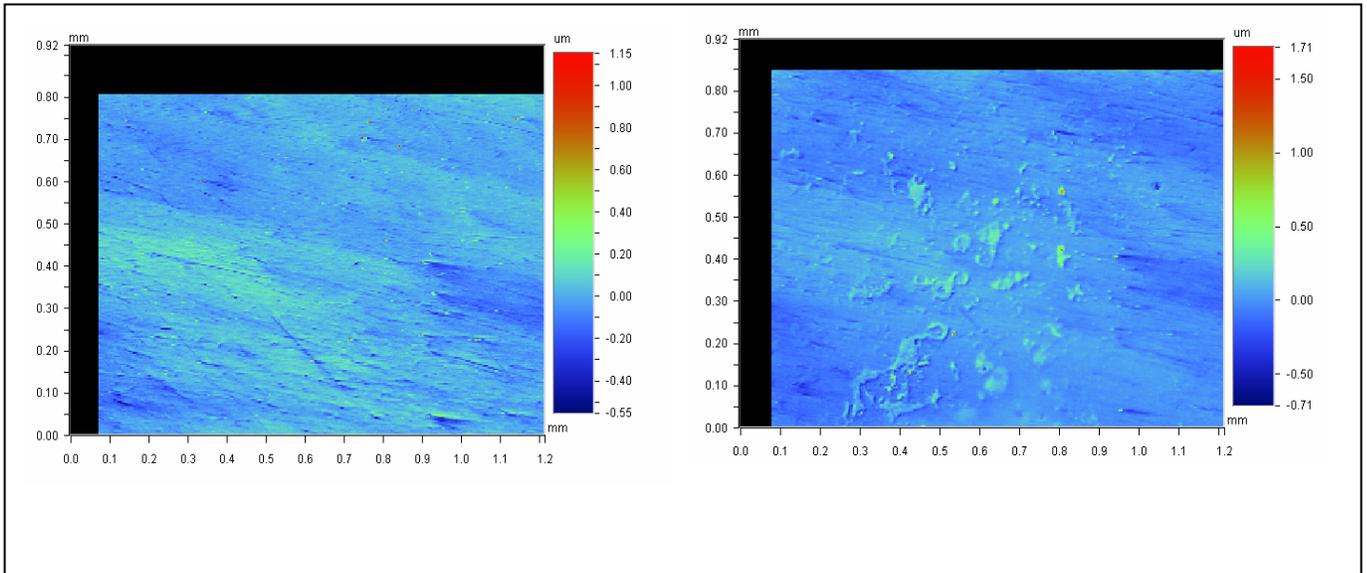


Figure 7.5. Pre and Post Cement Topography of area PB3-P5-5b

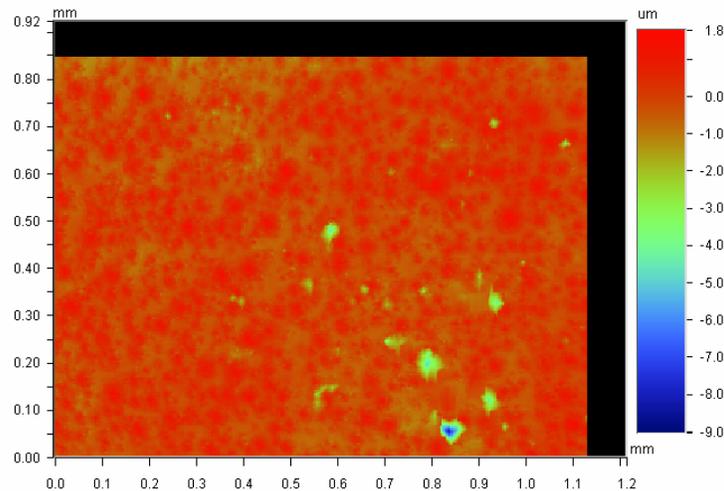


Figure 7.6. Cement Topography from area PB3-P5-5b

As can be seen from the left hand image of figure 7.5, there are select areas of the polished billets which appear to have debris present. On initial inspection, it is feasible that this debris may be caused by adhesion of cement to the surface of the polished billet. Figure 7.6 shows the topography of cement from the same quadrant. There are areas of pitting that coincide with the areas of debris present on the billet surface, this gives a strong case to suggest that there is some transfer of cement to metal in an adhesive process.

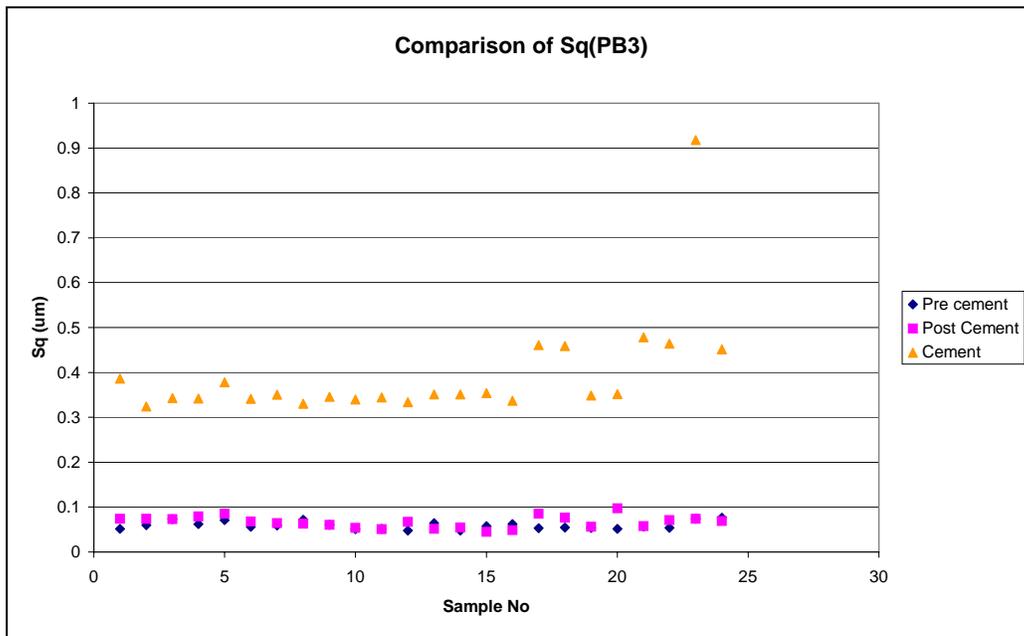


Figure 7.7 Comparison of Sq for polished billet 3

The results from characterisation of the 3D surface parameter analysis show a difference in topography for the polished billets and cement. (figure 7.7) Contained in these results are examples from the set of 11 parameters analysed, which represent the topographical features under discussion. Figure 7.7 shows a comparison of Sq, the root-mean square deviation of the surface for one of the three polished billets. Sq characterises the average rms. roughness of topography. The graph clearly shows there is little change in the roughness of the billet following cementing. The data point marked (sample number 20) shows the data for PB3-P5-5b, which relates to the topography shown in figure 7.6. Compared to the other samples, there is a significant increase in roughness for this billet following cementing. The roughness of the cement is considerably higher than that of the billets before and following cementing. This would tend to confirm the presence of peaks

believed to be caused by shrinkage of the cement upon polymerisation and curing.

7.4.2 Results – Satin Billets

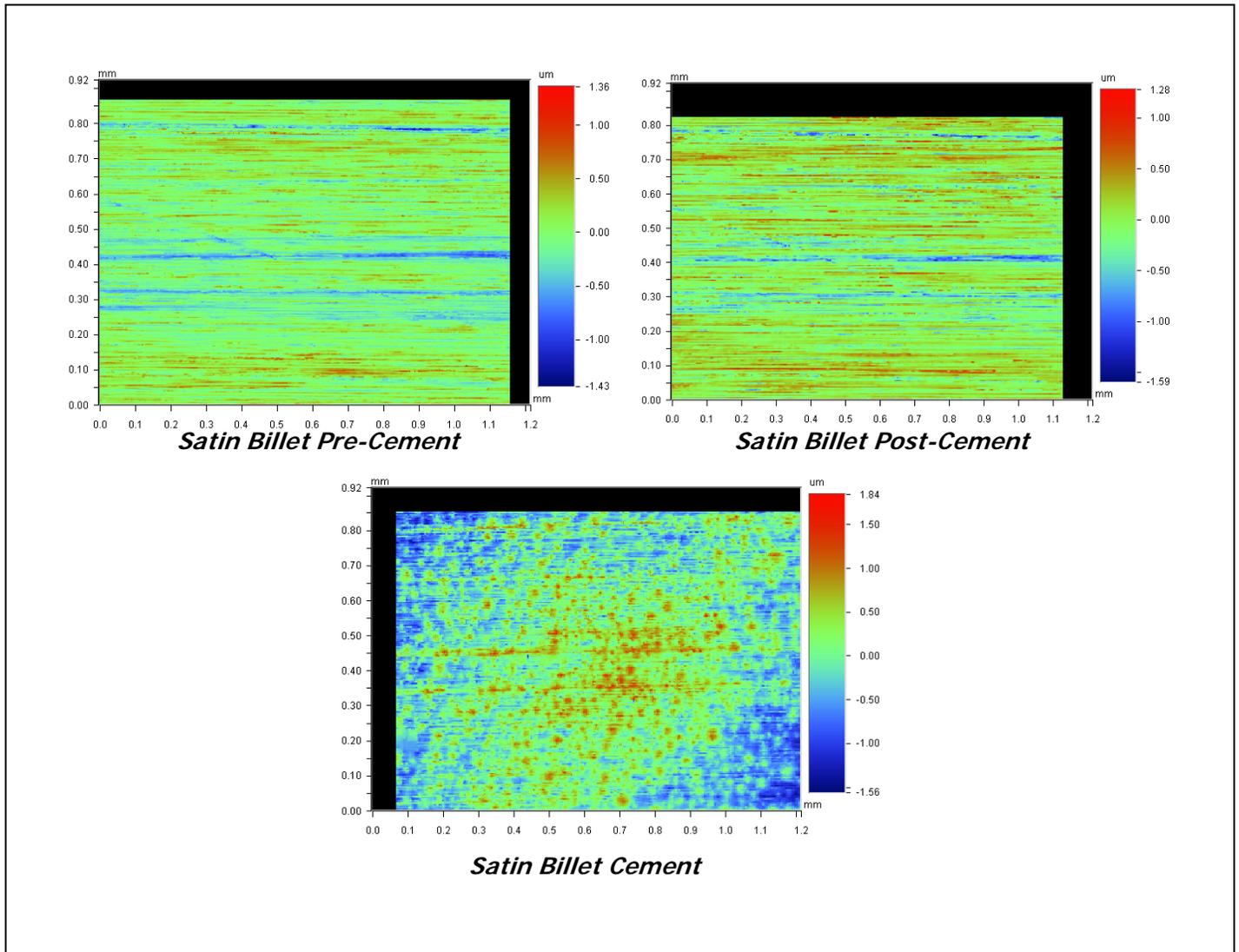


Figure 7.8 Contour Plots comparing topography differences pre and post cement

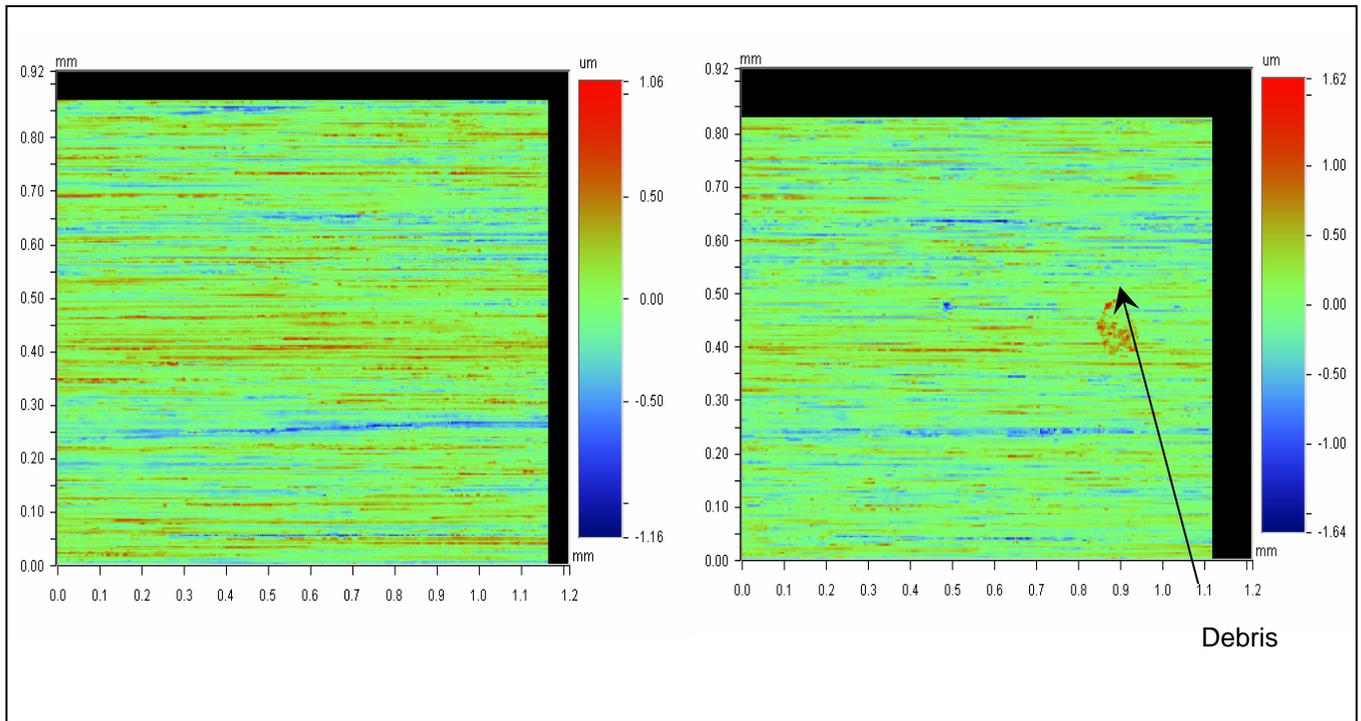


Figure 7.9. Pre and Post Cement Topography of area SB1-P3-3c

Figure 7.8 shows a comparison of the satin billets and the associated cement, as with the polished billets it can be seen that an increase in the scratches on the surface of the billet, caused by handling and transportation. The phenomenon of the “bumps” is also present on the surface of the cement. These have a similar geometry to those noted on the polished billets. This indicates that the shrinkage happens with differing surface finishes and is not restricted to a highly polished surface finish. This would be expected as the shrinkage is due to the cement polymerisation/curing alone.

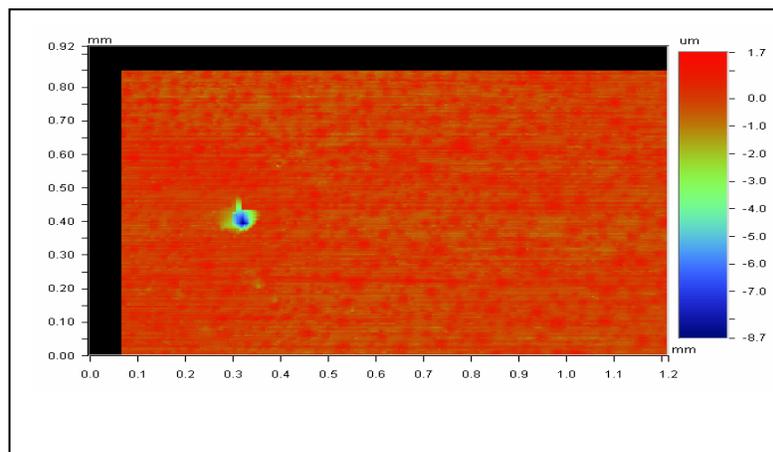


Figure 7.10. Cement Topography from area SB1-P3-3c

Again, there is evidence that there is transfer of cement with the satin billets as with the polished billets indicating the possibility of cement adhesion to the surface.

From figure 7.9 debris can be seen on the surface of the satin billet quadrant. Figure 7.10 shows the cement from the same quadrant, a large pit can be observed, the point at which this occurs corresponds with the area of debris present on the surface of the billet post cementing.

Characterisation of the satin billets with 3D Surface Parameters indicates that as with the polished set, the roughness of the cement is greater than that of the billets, though not to such great an extent. Figure 7.11 shows the comparison of Sq for the three components.

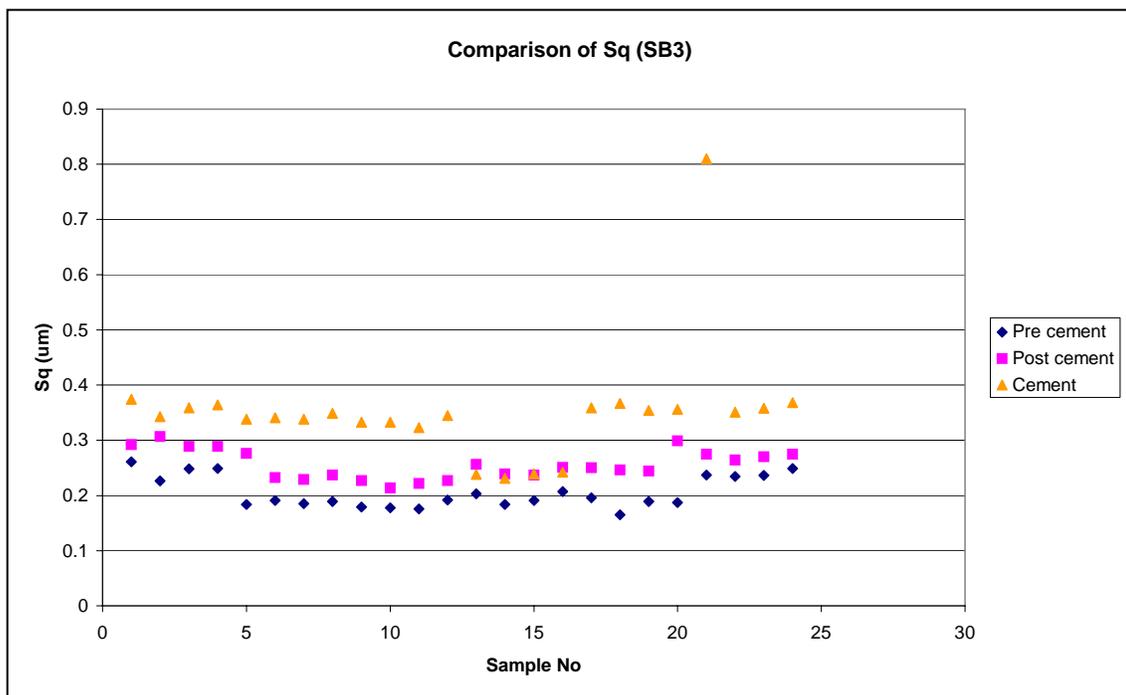


Figure 7.11 Comparison of Sq for satin billet 3

The difference with the satin billets, when looking at the change in roughness as opposed to the polished billets is a significant increase in roughness of the billet post cementing. This could indicate that the incidence of cement adhesion is more prevalent with the satin surface, due to mechanical locking between cement and billet.

There is not as marked an increase in the roughness of cement topography, however if the average roughness values of cement for polished and satin are compared $0.32\mu\text{m}$ and $0.36\mu\text{m}$ respectively. There are indications that there is a lower bound for the roughness of the cement, which is irrespective of the topography of surface to which it is applied, and more dependant on the shrinkage peaks

Figure 7.12 shows a comparison of Ssc (Arithmetic mean summit curvature of the surface)

There is a decrease in Ssc for the billet after cementing. The values of Ssc for the cement lie between those for the billet pre and post cement. This shows that during cementing the curvature of the summits decrease. This needs further consideration however may indicate subtle changes such as transfer of cement filling grooves present through the surface finishing process.

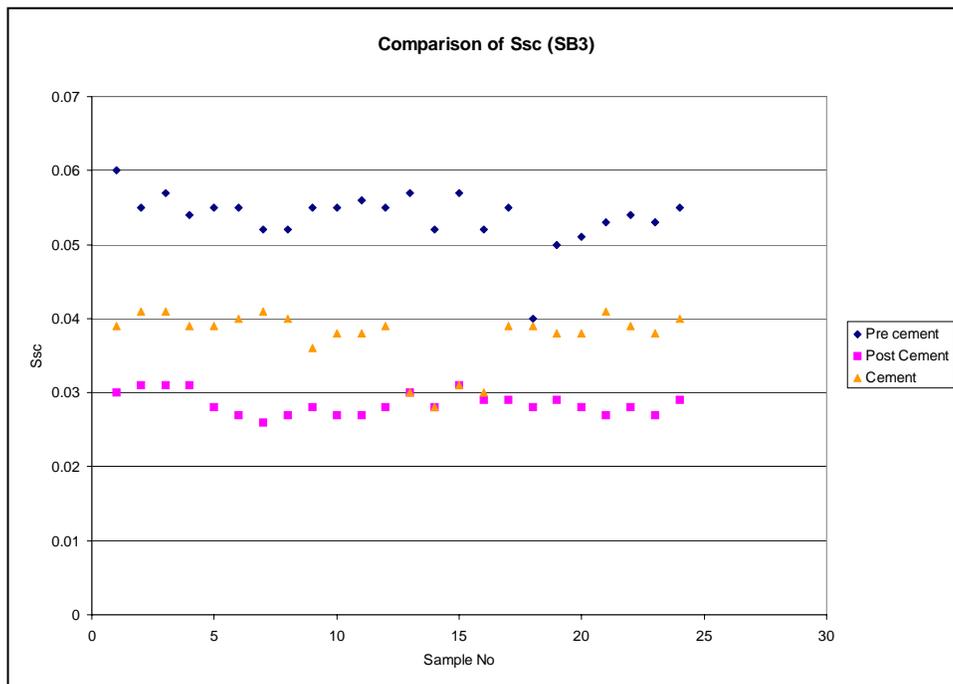


Figure 7.12 Comparison of Ssc for satin billet 3

7.4.3 Results – Matt Billets

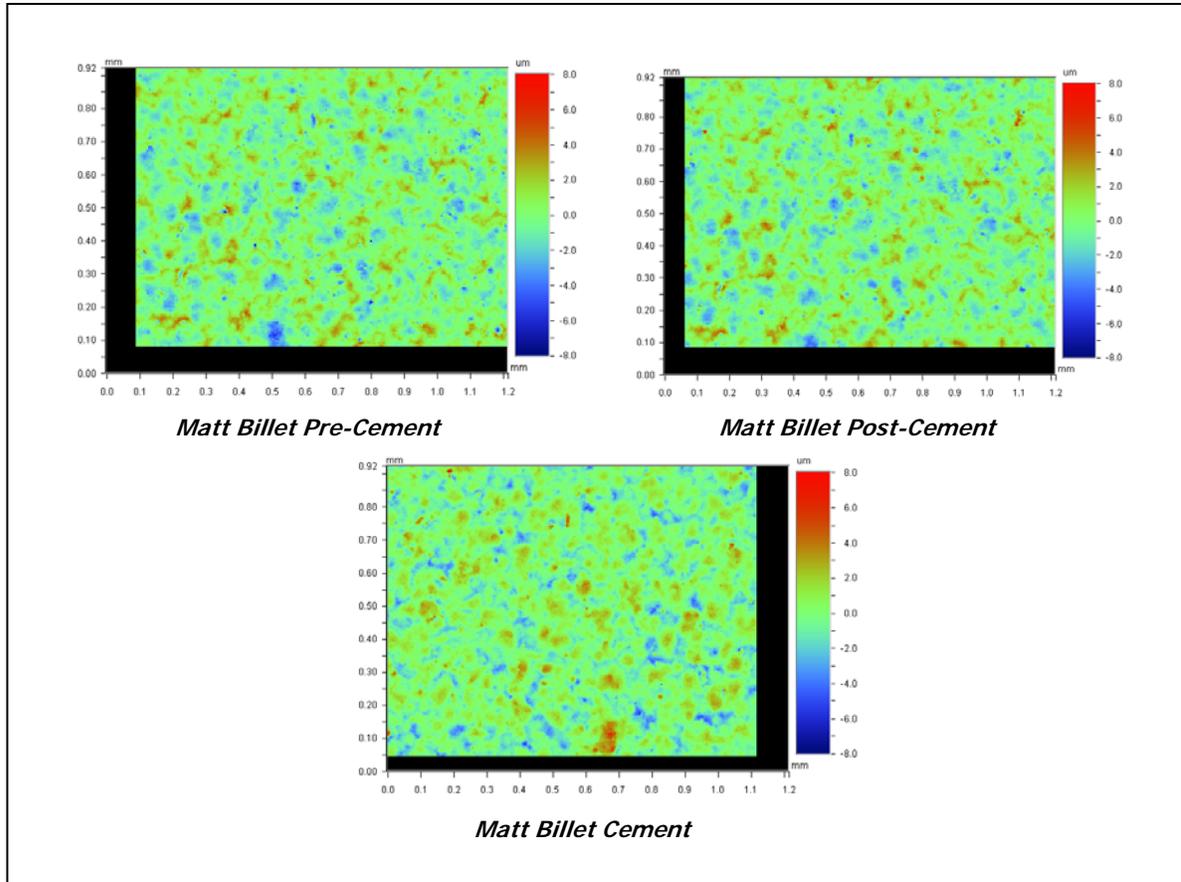


Figure 7.13 Contour Plots comparing topography differences pre and post cement.

As can be seen from the contour plots, typical of the matt billets, there is little difference in the surface topography after cementing. From the 3D surface parameter analysis, we can see little change in Sq (Figure 7.14). The only slight change is the decrease in roughness for certain datasets although this is not typical throughout the results for the matt finish billets.

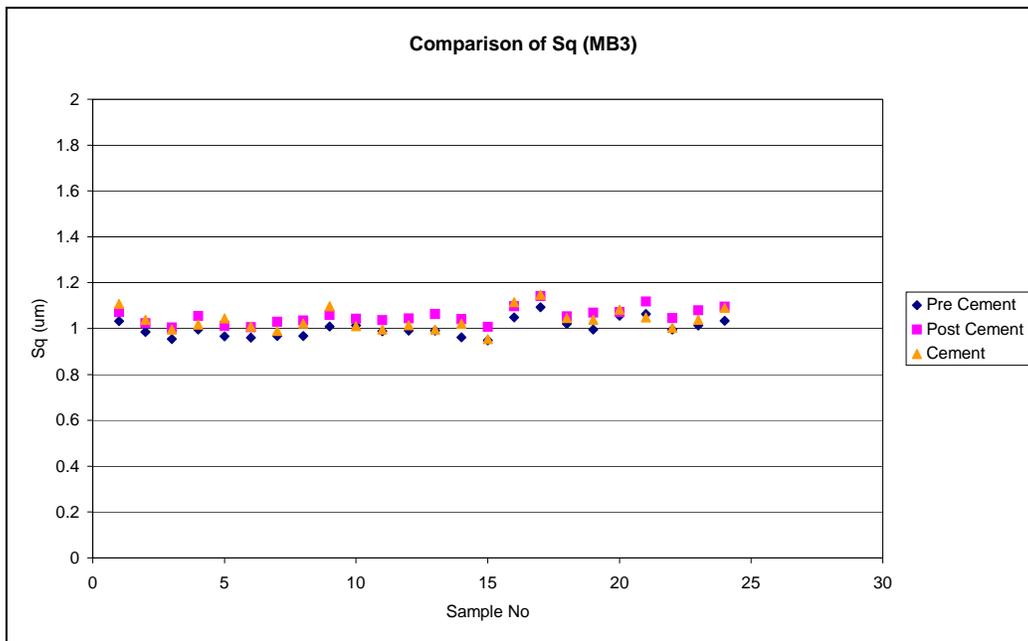


Figure 7.14 Comparison of Sq for matt billet 3

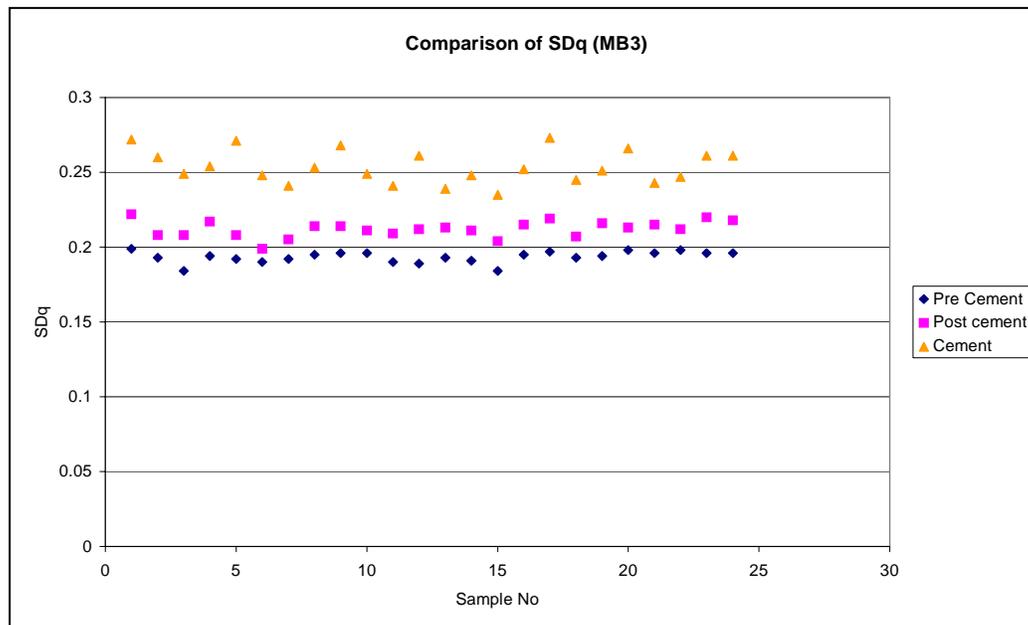


Figure 7.15 Comparison of SDq for matt billet 3

Other 3D surface texture parameters show a definite change in topography figure 7.15 shows a comparison of the parameter $S\Delta q$ (Root mean square slope of the surface).

There is a significant increase in $S\Delta q$ for the billet post-cementing; this indicates that the overall slope of the surface increases after application of cement. This suggests that there is some change in topography with application of cement. It is suggested that this entails cement penetrating the pits caused by bead blasting, when the cement sample is removed from the surface, these peaks of cement shear off and leave debris peaks on the surface thus introducing debris with potentially greater steepness of slope than the original topography.

7.4.4 Results – Rough Billets

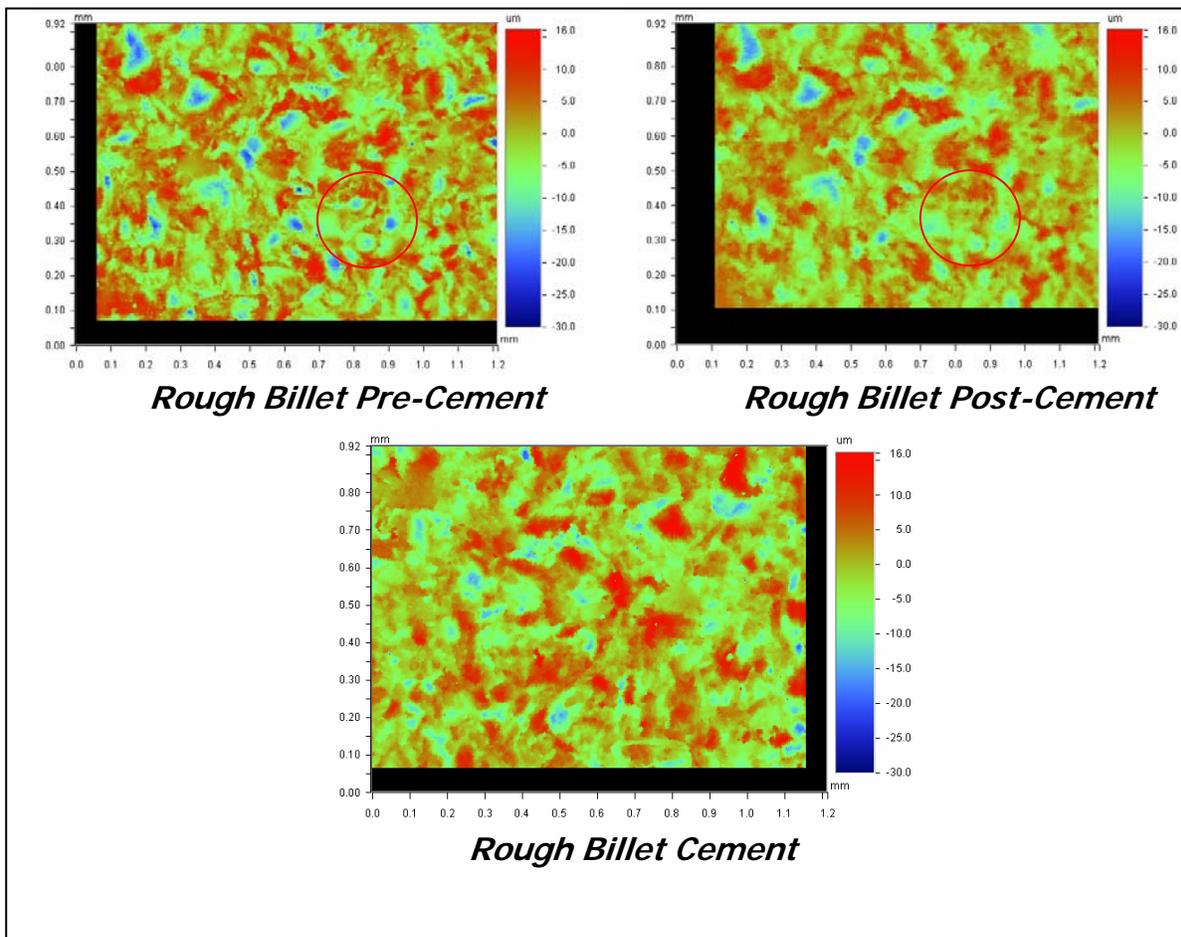


Figure 7.16 Contour Plots comparing topography differences pre and post cement.

The contour plots shown in figure 7.16 show there is little change in the topography, however there appears to be a decrease in the number of pits following cementing. The area marked with a circle on figure 7.16 shows a good example of this.

This phenomenon has also been noted with the matt billets and attributed to bone cement penetrating the pits caused by bead blasting resulting in cement debris remaining in the pits after cement removal.

This can be confirmed with the use of selected 3D surface Parameters.

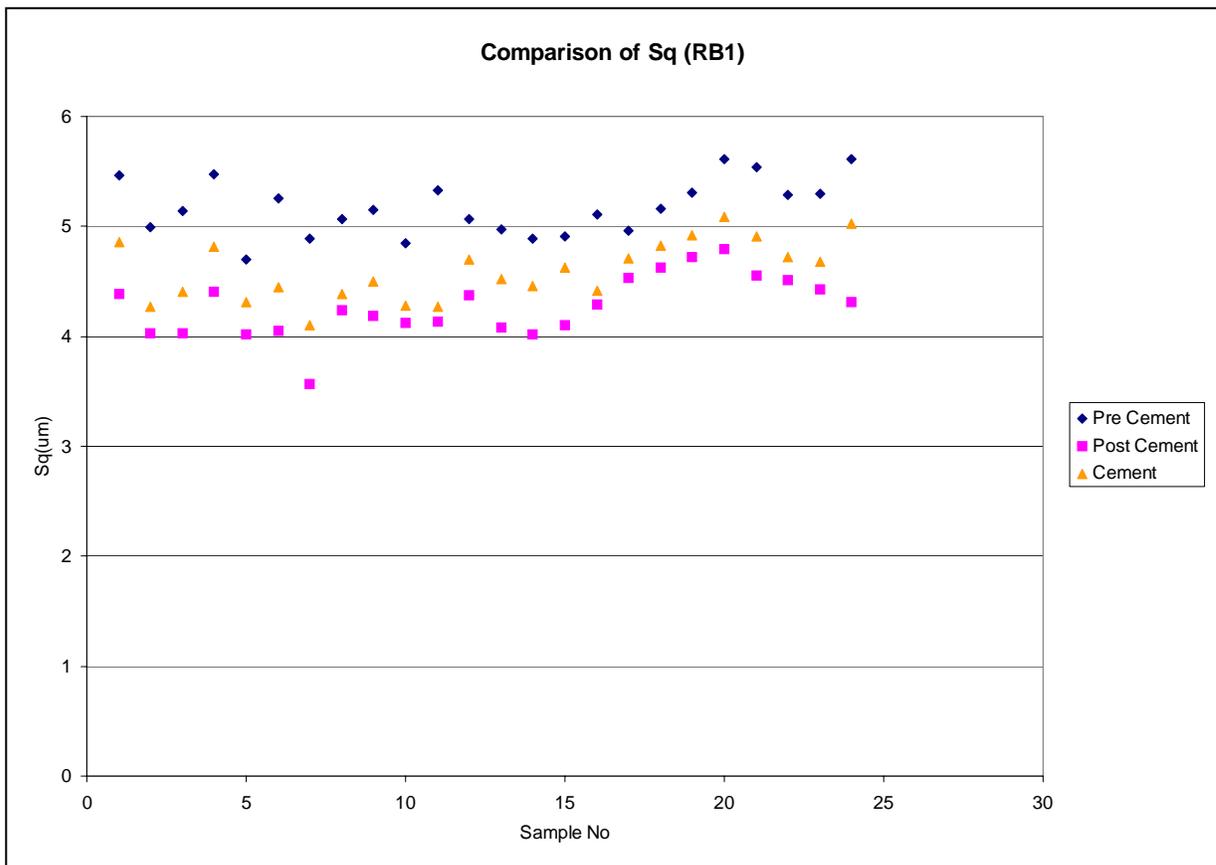


Figure 7.17 Comparison of Sq for rough billet 1

Figure 7.17 shows the value of S_q describing the roughness of the surface is significantly lower for the billet post-cementing. This would be in agreement with the findings from the Wyko NT2000 contour plots. As the pits or holes are filled with the bone cement the roughness of the surface would decrease.

The comparison of $S_{\Delta q}$ (Figure 7.18) for the rough billet confirms the possibility of cement transfer. The values of $S_{\Delta q}$ decrease significantly following cementing, indicating the overall slope of the surface has reduced. It is feasible that the filling of pits with cement causes this.

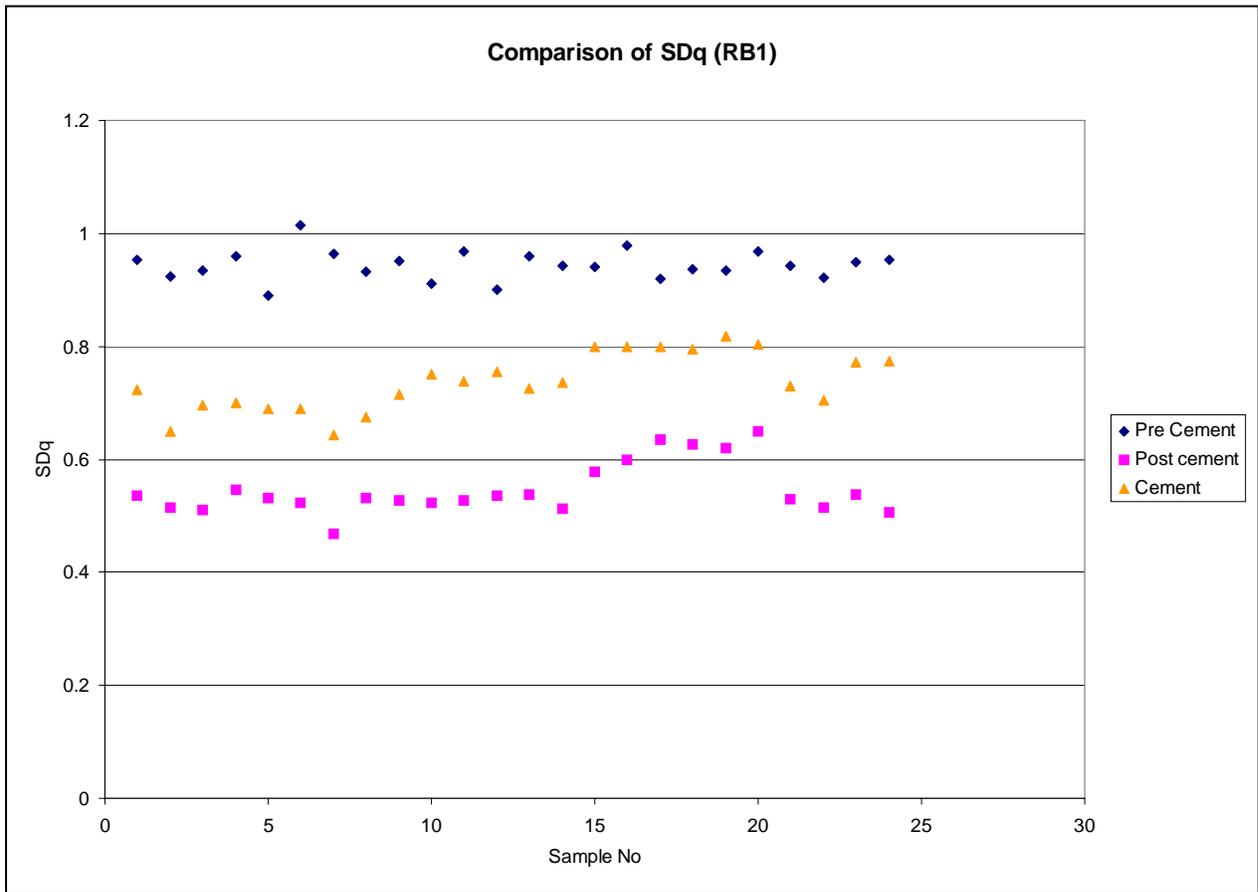


Figure 7.18 Comparison of SDq for rough billet 1

7.5 Further Investigations

Following the results from the initial interface study, there were two possible reasons for the presence of shrinkage “bumps” on the surface of the cement; firstly due purely to shrinkage of the PMMA, and secondly due to the presence of Barium Sulphate in the cement, the second causing serious implications for wear at the interface due to the high hardness of BaSO₄ compared with the cement and the metallic femoral stems, regardless of surface finish.

Another query also arose from the observation of how different brands of cement behave differently upon polymerisation and during curing, which was noted in chapter 6.

The aim of the further investigation completed was to:

- define potential differences in contact mechanics of different types of bone cement
- establish whether barium sulphate could be present in the shrinkage bumps, and the possibility of transfer to the femoral stem
- determine whether the shrinkage bumps phenomenon which occurs with complex stem geometry is the same manner as the simplified billet method

7.6 Variations in cement brand and Barium Sulphate analysis

The procedure for the interface study was repeated for the following bone cements:

Simplex P (standard) (Stryker Howmedica)

Simplex P without BaSO₄ (Stryker Howmedica)

CMW 1 without BaSO₄ (DePuy International)

CMW 3 (standard) (DePuy International)

Pallacos (Biomet)

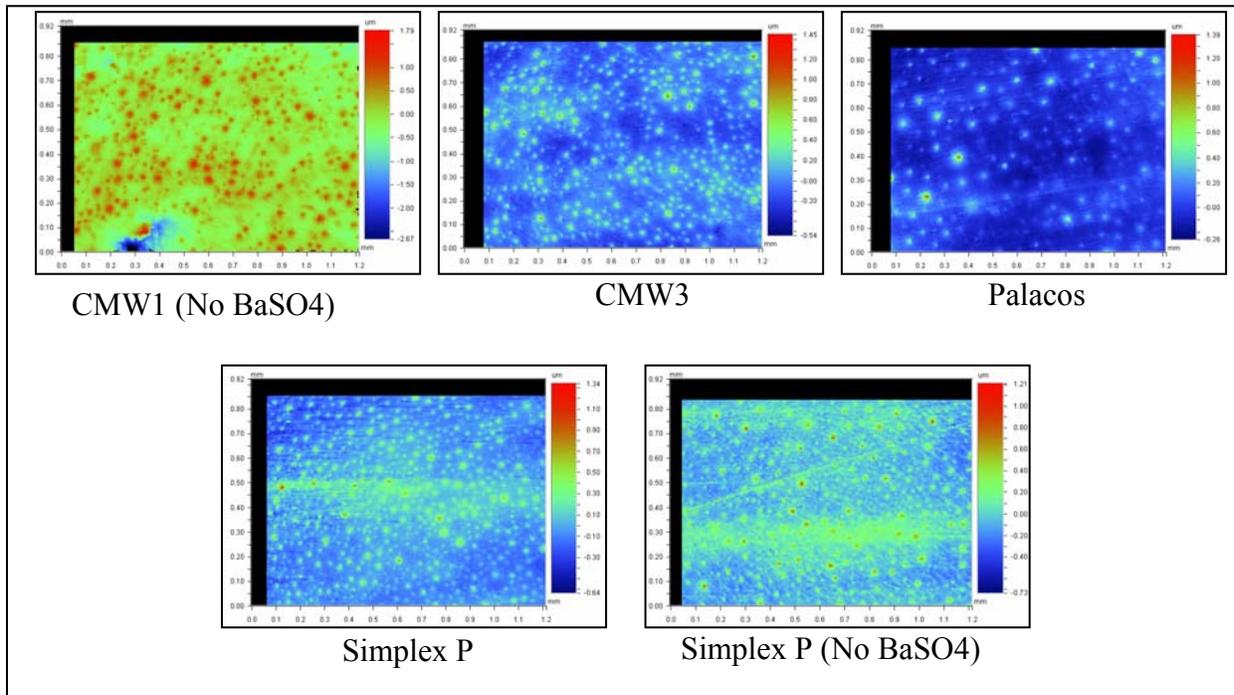


Figure 7.19 – Difference in cement topography with variation in brand

The main observation that can be drawn from figure 7.19, showing the difference in cement topography according to variation in cement brand, is there is not discernable difference in the nature of the topography between the cements with barium sulphate additive and those without. This shows that the presence of the barium sulphate is not the cause of the “bumps” where polished stems were concerned, supporting the theory that the bumps are due purely to differential shrinkage of the PMMA. To support this, tests were carried out to determine the particle size of barium sulphate typically added to commercially available PMMA bone cement.

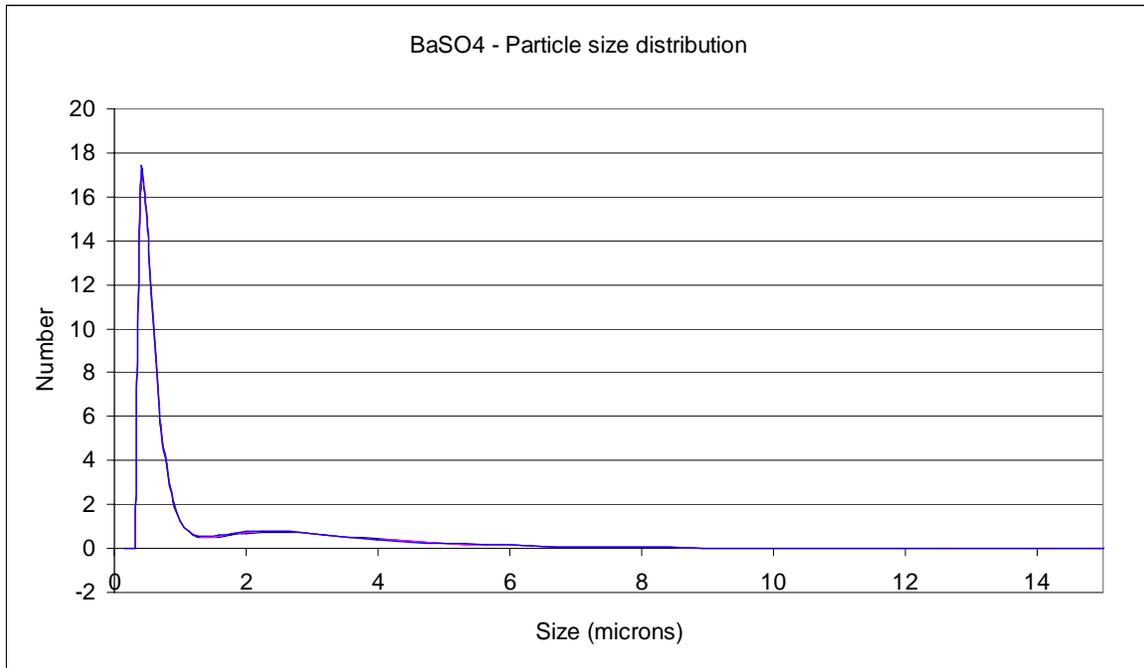
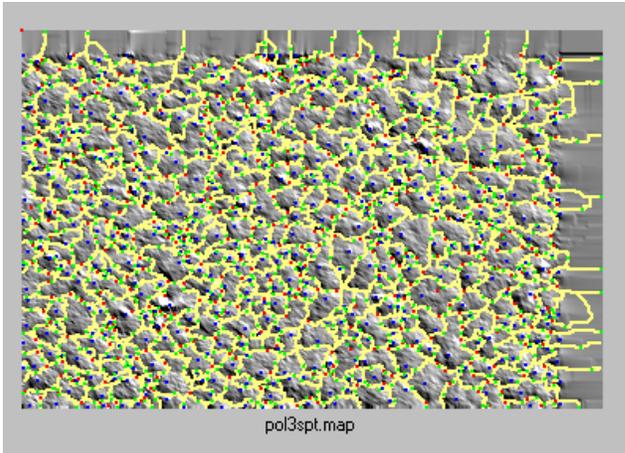


Figure 7.20 – Barium Sulphate Particle size distribution

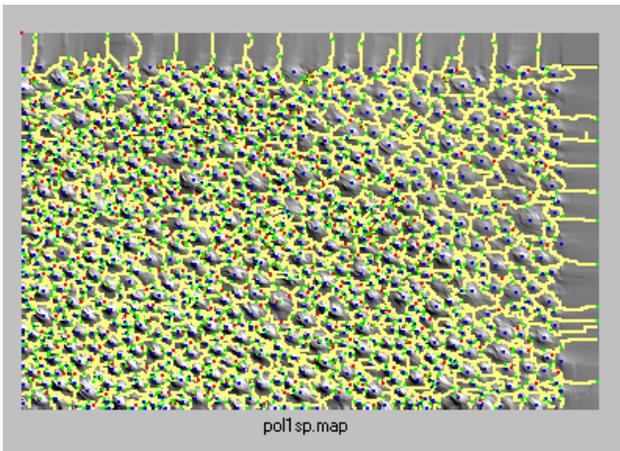
Figure 7.20 shows a particle size distribution for barium sulphate (supplied by Stryker, Ireland) and is representative of material used in the production of Simplex P bone cement. The size of shrinkage bumps are typically in the order of magnitude of 500 – 800nm high and 40-60nm wide, the barium sulphate peaks at around 800nm therefore although this may suggest that barium sulphate particles may be present they are spherical nature and the width of the bumps would suggest that it is therefore improbable that the bumps are comprised wholly of barium sulphate, thus suggesting that from the nature of the bumps, that they are not likely to be barium sulphate.

This work does not however dismiss the presence of barium sulphate at the stem cement interface during shearing of the cement in the shrinkage process, previously seen with the matt surface finished billets.

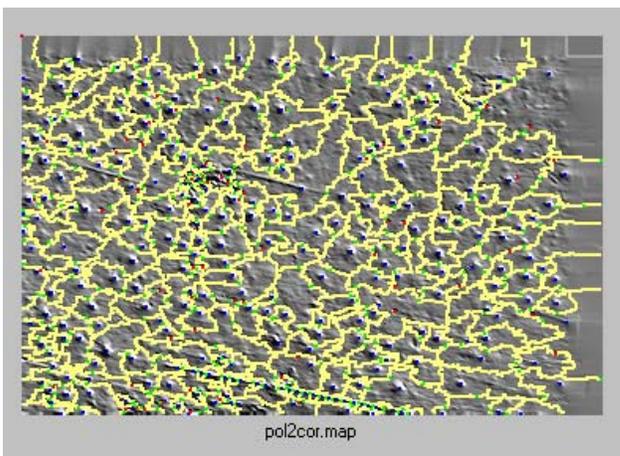
The work did however also indicate that there is some difference in resultant surface topography of cement which is brand dependant. From figure 7.19, far fewer “bumps” can be seen on the Pallacos surface topography than on the Simplex P, even more peaks were seen on the Simplex P with antibiotic additive Tobramycin. Feature recognition software was used to analyse the topography of the cement to enable a “count” of the number of peaks per area.



Simplex P – Peak count = 483



Simplex P with Tobramycin – Peak Count = 862



Pallacos – Peak Count = 275

Figure 7.21 Peak Count of 3 types of bone cement cast against polished billets.

The presence of barium sulphate at the stem cement interface could as mentioned, be of significant interest due to the hardness of the material compared with the cement and the stem. The introduction of a harder material at the interface would give rise to third body wear, and provide some explanation as to the abrasive nature of the wear of matt finish femoral stems.

The difference in the density of peaks on the surface appears to be brand dependant; this could be of significance to the wear mechanism and success of femoral stems. The variation in number and size of peaks would indicate a difference in stresses and loading at the stem cement interface as the actual contact area between stem and cement could alter significantly. It may also have an effect on the stems ability to subside into the cement mantle, which the polished double taper design such as the Exeter relies on.

7.7 The Cement Interface of a Femoral Stem

The simplified billet method enabled analysis on various surface finishes, and also various brands of bone cement. A final study was completed to determine if the results were applicable to the actual geometry of the femoral stem to confirm the validity of the findings.

An Exeter femoral stem (316L stainless steel) was inserted into a sawbone™ under clinical conditions by an experienced surgeon. The cement was left to fully cure before it was sectioned and the topography of the cement was examined. Figure 7.22 shows the resulting topography, where it can be clearly seen that the shrinkage bumps are present, indicating that shrinkage occurs in vivo producing the same phenomenon.

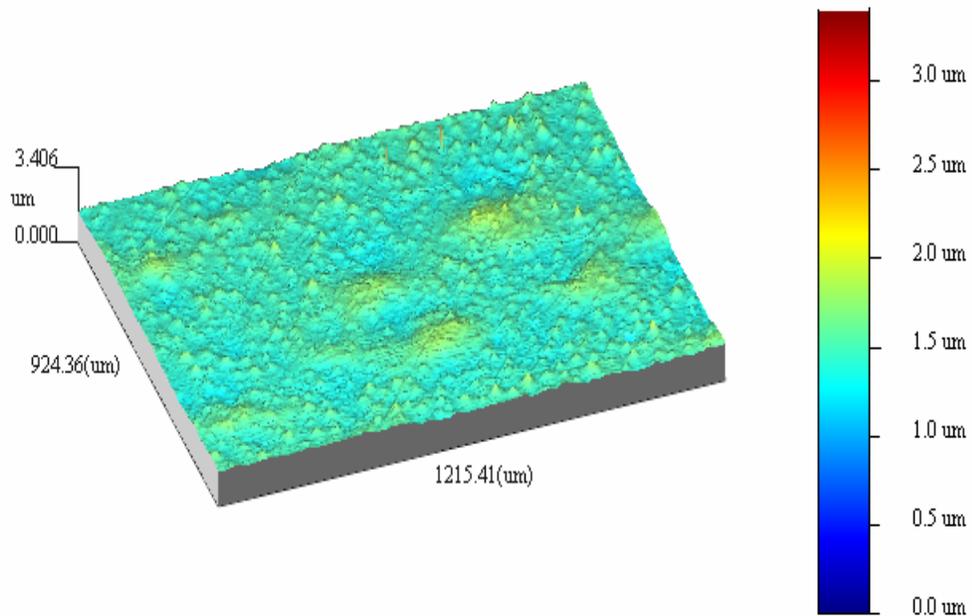


Figure 7.22, Cement topography following clinical insertion of an Exeter polished stem
 Figure 7.23 shows the magnitude of difference between the stem and cement following curing and polymerisation.

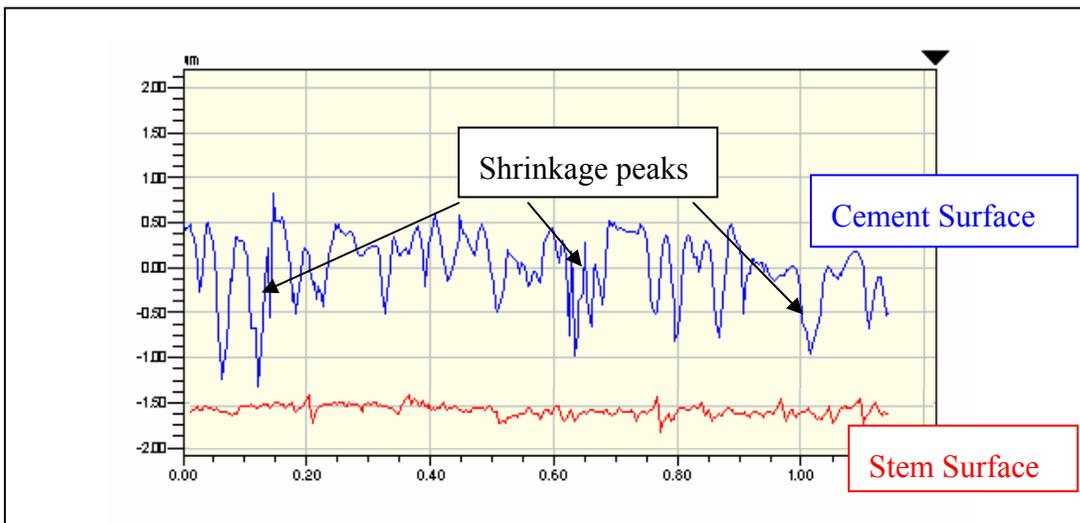


Figure 7.23, 2D plot showing the nature of interaction between stem and cement
 The 2D plot is an extraction from the 3D surface topography measurements of the stainless steel stem and the cement topography following curing and polymerisation, the implications of peak contact can clearly be envisaged in terms of peak supported channels allowing debris transportation, or alternatively should the peaks compress

following continuous loading the implication would be differential contact stresses in the cement giving rise to possible mantle failure.

7.8 Discussion

Preliminary analysis of the results obtained from this study includes a great deal of information about the nature of contact at the cement-stem interface, as well as an indication of behaviour of PMMA upon polymerisation. The peaked areas observed on the cement measurements caused by the shrinkage alter the way in which the contact area of the cement may be considered. If the peaks are still present during contact of stem and cement then the contact area is reduced and therefore the load distribution and the stresses present will follow a different regime i.e high contact pressure at the contact points.

In addition, this may give an explanation as to the path which debris takes through the cement-stem interface. The presence of the peaks could support a system of micro-channels by which transportation of debris may be possible.

Alternatively, plasticity of the PMMA may result in deformation of the peaks to produce full surface contact over the area, even if this is in fact the case there would be a differential stress distribution over the contact surface. More investigations are envisaged to corroborate or contradict these findings.

The preliminary results also give strong suggestions as to why reports indicate matt finished stems incur a lower success rate (R G Middleton et al 1998) than polished stems.

From the topography of the smoother billets and cement surfaces it is proposed that the same phenomenon of shrinkage must occur for matt and rough surfaces. The results indicate the pits caused by bead blasting fill with cement on application. It is suggested that during the shrinkage process, the cement will contract and small masses of cement will be left to fill these holes due to trapping of cement during shrinkage.

The break in cement would result in the production of granular cement debris, which

could, in turn contribute to third body wear of the components. Although the hardness of PMMA is somewhat less than that of 316L surgical grade stainless steel, the majority of commercially available PMMA bone cement contains a radio-opacifier. In the case of Simplex® P, the component to produce radiopaque properties is barium sulphate (BaSO_4). Other brands of bone cement contain Zirconium Oxide. Both of which if contained in the residual debris could feasibly contribute to third body abrasive wear. This phenomenon would also provide an explanation as to the passage by which debris is transported to areas beyond the interface when there is no apparent defect in the cement mantle.

7.9 Conclusions

The following points can be concluded from the various components of this study of the stem-cement interface:

- There is shrinkage upon polymerisation of the PMMA bone cement, the extent of which may depend upon mixing technique.
- The topography of the cement caused by the shrinkage may suggest micro channels are present which allow for the flow of fluid and debris around the interface on all surface finishes
- The subsidence of polished collarless stems may minimise this fluid flow in highly polished prostheses
- Debris generated at the shrinkage process in matt and rough finished stems is likely to contribute to third body abrasive wear
- The stresses and load bearing properties at the interface between stem and cement are highly variable and need further investigation to understand the contact mechanics.

The initial aim in this chapter was to determine the replication of cement surface onto the billet surface using 3D surface metrology analysis, in order to gain a better understanding of the contact mechanics at the stem cement wear interface. This has been achieved, through comparison of 3D surface roughness parameters. In completing this study a number of other contributions have been made to the overall objectives. Further information regarding the contact at the stem cement interface has been presented, and a possible further insight into potential wear mechanisms has been offered.

CHAPTER 8. WEAR SCREENING OF THE STEM CEMENT INTERFACE

8.0 Introduction

The previous studies have highlighted that there are differences in severity and type of wear dependant upon the design and finish of femoral stems. The retrieval study can go some way to highlighting these differences, but to fully quantify the nature and severity of wear whilst isolating varying factors is a task that must be completed in vitro.

The most complete method of in vitro wear screening is to simulate the full system of use, adhering closely to those conditions which would be experienced in vivo. This method of simulated wear is used routinely in the evaluation of femoral heads and cups, and also in the evaluation of the components of total knee replacement systems. (P S Walker et al 1997, I C Burgess et al 1997, L C Mejia & T J Brierley 1994, D Dowson et al 2000) .

The other method of wear screening widely used is to simplify the system, and look at the effect of direct interaction between the surfaces of the wear interfaces. The two most common methods used are pin on disk and pin on plate (A Besong et al 2001, H Schmotzer et al 2000). Pin on plate wear testing generally uses linear reciprocating motion and in the orthopaedic industry is used as a method of screening materials for use in femoral head/cup combinations as well as in studies of materials for use in total knee replacement systems. In a study by Galvin (2005), the pin on plate method was used to determine the differences in wear of UHMWPE pins of varying material grade when coupled with cobalt chrome plates. The method of wear evaluation used was gravimetric analysis; surface metrology was used to supplement this. Pin on disk wear screening is a similar method employing disks rather than plates. Pin on disk instrumentation again tends to be used in the orthopaedic industry for wear screening of femoral heads and cups and tends to be used for polymers against metal components; again the main method of analysis of results is gravimetric.

J Cook 1998, completed an extensive study on fretting simulation of Exeter femoral stems using a hydraulic system to cyclically load stems in order to simulate the fretting wear observed on polished stems in vivo. The study showed the ability to replicate

fretting wear following adaptation of an Instron™ (D Bridson 2002) hydraulic test instrument adapted to produce the loading regime experienced in vivo. The study concentrated on the wear of polished stems and went some way to reproducing the wear location and type seen in vivo. The analysis of the actual wear was qualitative though this was supplemented by the study of the change in properties of the material, these changes were related back to the nature and severity of wear.

8.1 Method and results for fretting simulation

Following the retrieval study presented in chapter 4, J Cooks method was employed to investigate the simulated wear of a matt femoral stem.

In the study by J Cook, both axial, with torsional loading, and pure axial loading apparatus was designed. This present study used the axial test set up, to enable replication of fretting wear on mat finish femoral stems. Relocation was facilitated for measurement purposes through the use of a grid of micro-indentations on the surface of the stem. Measurements were taken at each relocation point using the Wyko NT 2000 optical interferometer prior to simulation to provide a baseline ensuring that the exact change in topography could be determined.

8.1.1 Test Set up

The stem was vertically inserted centrally in the stainless steel specimen holder, following the introduction of Simplex P® (Stryker Howmedica) using a cement pressurization gun. The cement was left to fully cure before the test was initiated under the following conditions: axial cyclic load of 0.2kN to 1.7kN, at a frequency of 4Hz, in the lubrication medium of Ringer's solution at room temperature.

Upon visual inspection, no definite signs of wear were apparent. Surface characterisation using the Wyko NT 2000 optical interferometer did show slight change in the surface topography in localised areas; however the change was less than expected for a cycle count of the 2.5million cycles completed. The results were not conclusive, time and resource only permitted one run and as such the results have no statistical significance for the present study.

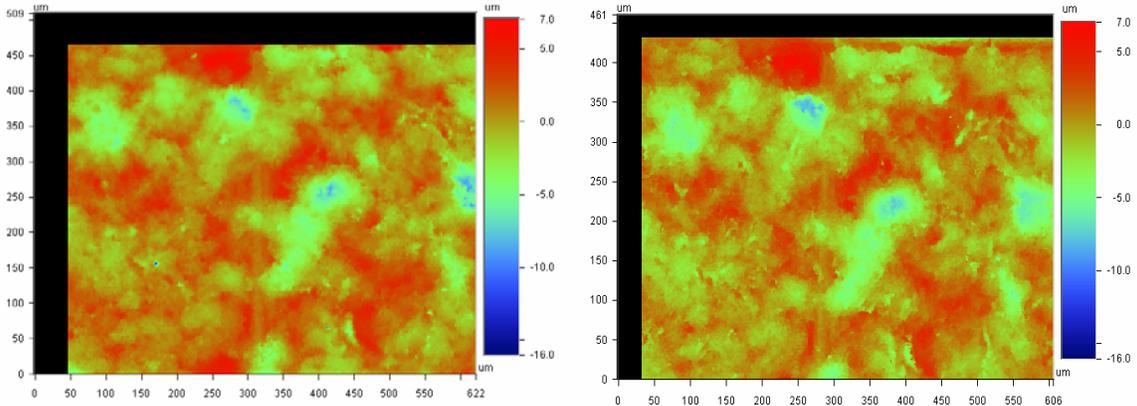


Figure 8.1 – Surface maps of (a) prior to wear and (b) post simulated wear of a matt finish Exeter femoral stem

Figure 8.1 shows a surface map of one area of the stem prior to and following wear, the black outline denotes where the relocation marking was masked off so as not to be included in the analysis. No definite difference can be seen between the areas prior to and following wear and this particular area was potentially the site of most severe wear on the stem. Figure 8.2 shows the change in root mean square deviation (Sq) following simulated wear of the stem. There is no distinguishable change in results. If wear had occurred similar to that seen on explanted stems in the retrieval study detailed in chapter 4, a definite decrease in Sq would be expected as the asperities are worn away.

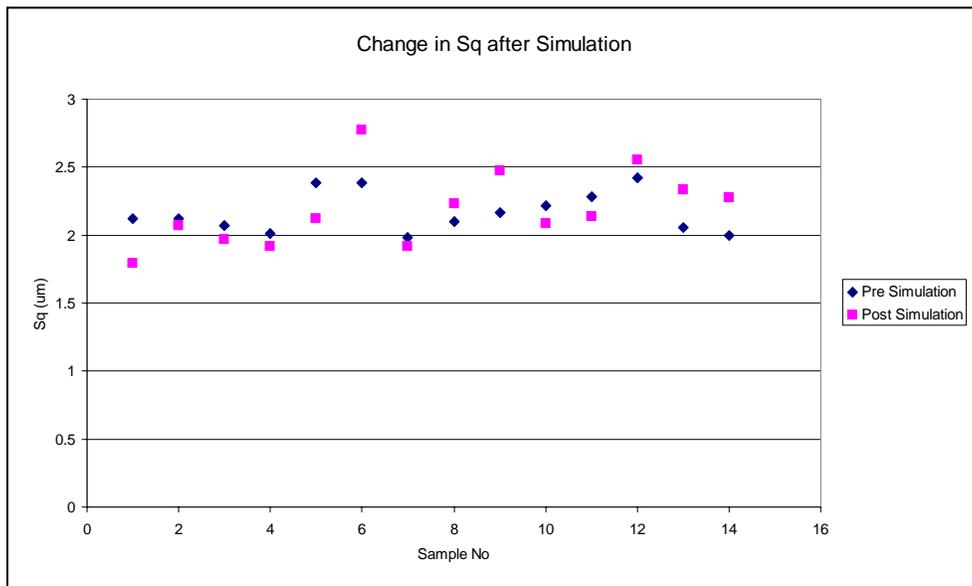


Figure 8.2 – Change in root mean square deviation of topography pre and post wear simulation

8.1.2 Discussion

Though in J Cook's study (1999), the simulation of wear of Exeter femoral stems showed some success at the replication of fretting wear in vivo, the simulation completed and reported here showed limited success. Upon study of the simulation method, it would perhaps be a sensible assumption that this study highlights that there is a difference in the wear mechanisms of matt and polished femoral stems as J Cook noted more success with simulation on polished stems than on matt finish stems of the same design. The polished stems are known to subside in the cement mantle (R S M Ling 2004). This ability to subside would suggest that the stem is free to move up and down within the cement mantle. It is thought that due to the rigid fixation of the stem and cement in the simulator, the flexure and torsion experienced of the stem experienced in vivo due to the mechanical properties of bone is not experienced in simulation and therefore the method may not be suitable without modification for the simulation of wear on matt finish femoral stems. Due to the lack of statistical significance in the results of this study, no hard and fast conclusions can be made, though it would be suggested that the constraining medium of the stem in cement mantle be investigated and a possible source of error, as may be the thickness of the cement mantle.

8.2 Pin on Plate study

The need for greater knowledge about interactions at the stem cement interface was noted following the study in Chapter 7. Another question that studies completed in chapter 7 raises is the determination of how different brands of bone cement behave and how different surface finishes interact with the cement mantle. To make an attempt to investigate this subject further a pin on plate study was devised to isolate the different variables and to investigate the wear between cement pins and plates of varying roughness.

8.2.1 Method

The X-Y stage (Aerotech UNIDEX 11) was programmed to produce a reciprocating motion of 5 microns; the pins were loaded to 50N, this being representative of the force interactions experienced at the stem cement interface. The pins were cast from Simplex P bone cement against the surface of the 4 plates, (Polished, satin, matt and rough). This was to replicate the resulting surface topography of cement that would occur in vivo. Both the pins and plates were marked for alignment to ensure consistency of placement and orientation during test.

Measurements were taken at intervals of 1 million cycles from 0 to 5 million at which point the test ended. A summary of test conditions can be found in table 8.1. All tests were lubricated with Ringers solution (Appendix VII) which was hydrated with distilled water to ensure stability of concentration.

Table 8.1: Fretting Simulation, Test Conditions

Loading – Axial	2050N to -50N
Loading - Torsional	550Nm to -50Nm
Frequency	2.5Hz
Lubrication	Ringers Solution (Appendix VII)
Temperature	37°C

8.2.2 Results

There was no visible change in the surface topography of the plates, the surface topography of the cement did change, and this can be seen in particular for the satin finish plate/cement combination in figure 8.5.

The change in surface topography was not substantial enough to draw a solid conclusion, as exact relocation for measurement was not possible. The creation of relocation marking on the PMMA bone cement would have changed the wear interface substantially due to the scale of the experiment; this may have skewed the results. The lack of exact relocation means that confidence in the results is low because the change in surface topography due to change in measurement position cannot be ruled out.

8.2.3 Discussion

The study did not show any conclusive results, the aim of the study was to confirm the proposed wear mechanism for matt finish femoral stems and show the difference between this and the wear of polished stems, and also to expand the study to determine if a change in brand of bone cement affects the wear at the stem cement interface.

It is thought that a single compressive load coupled with a linear reciprocating motion is too simplified a model to reproduce the wear in vivo. It is also thought that the debris resulting from the wear of the pin and plate would behave differently in this simplified situation with an open system instead of the closed system present in vivo.

The question has been raised as to whether this simplified method of wear screening would be appropriate for this situation. However, with more sophisticated instrumentation a better representation may be made. It may be more appropriate to close the system and induce micro motion between two plates rather than between pin and plate. In following chapter a proposal for this closed loop system is outlined.

8.3 Conclusions

- The fretting simulation was inconclusive, due to the successful nature of J Cooks study of polished stems with the same method, it would suggest that there is further evidence to suggest that there are inherent differences between the wear of matt and polished stems.
- The rigid fixation of the stem and cement, and also the large cement mantle may be contributing factors in the outcome of this study. A proposed method for simulation of wear on stems will be offered in the following chapter.
- The instrumentation used for the pin on plate study was not sophisticated enough to develop the test further, it is believed that a closed system would be more representative of the in vivo situation and also possibly expanding the wear area to mimic the stem cement interface more accurately.
- Though the results of these two studies have shown minimal success against the aims initially set out, more knowledge about the interface and the wear mechanisms has been gained. Steps have also been made towards developing more successful wear screening methods.

8.4 Further Work

Following the Exeter simulation study detailed, development work has been carried out to address the following problems highlighted with the method: the rigidity of the fixture pot in which the stem and cement mantle are fixed; and the magnitude of the cement mantle. A method is proposed which eliminates these factors from the method of simulation and produces a protocol which is more closely matched to the conditions found in vivo. As previously stated, it is believed that the problems were not highlighted with the simulation of polished stems due to the difference in wear mechanism involved in the wear and failure of stems with differing surface finish.

CHAPTER 9. DISCUSSION

The aim of the program of research was primarily to investigate the wear of matt finish femoral stems using 3D analysis techniques. This was borne out of studies which showed there to be a higher incidence of aseptic loosening with some brands of matt finish femoral stem systems than highly polished stems of the same design.

From the present study, the wear of matt and polished femoral stems has been shown to display different characteristics. The study has indicated that the wear of matt stems seems to follow an abrasive mechanism. This finding contrasts with the received theory for polished stems that states wear of polished stems occurs by a classic fretting mechanism. Consequently the assumption that matt stems wear by classic fretting may not be valid.

The preliminary section of research concentrated on examining retrieved stems, to establish a number of factors; (i) the relationship between location and extent of wear; (ii) the progressive change in topography during wear of femoral stems. The location of wear study served to corroborate the validity of the series of explants when compared to previously reported results. Initial examination of topography at different stages of wear indicated progressive reduction in the height of asperities on the surface. The development of this topography was considered to be inconsistent with accepted theory that the damage on matt stems is due to fretting.

Abrasive wear is a more simple process than fretting wear. Fretting damage is caused when oscillatory micro-movement removes the passive oxide layer permitting localised corrosion and specific type damage to the surface of the stem. From the literature surveyed, it became evident that it was widely accepted that wear of femoral stems was attributed to fretting wear, in the case of one type of femoral prosthesis, the Exeter (Stryker Howmedica), there was a noted increase in revision rate following a move to a bead blasted matt finish stem, for this reason, the highly successful polished stem was reintroduced (R M S Ling 2004).

Examining the variables which affect the onset and severity of fretting wear produces the hypothesis that “the higher the degree of surface finish (the smoother), the greater the

magnitude of fretting damage” (R B Waterhouse 1972). This does not concur with a higher incidence of aseptic loosening of femoral stems, when the move to a bead blasted finish was made. The reason for fretting damage to be less severe with rougher surfaces is the ability for peaks, or asperities to plastically deform, and thus the passive oxide layer is not removed by micro motion.

The studies undertaken in this work, all serve to determine whether the mechanisms behind the wear of matt and polished stems are different, with matt finish femoral stems undergoing wear of an abrasive nature, as opposed to the classic fretting damage observed on explanted polished stems (J Howell et al 2000).

From the retrieval study (Chapter 1) where a series of explanted stems were subjected to visual classification, followed by 3D surface topography measurement and characterisation, it was evident that the wear of the matt finish femoral stems was more severe than that found in previous studies on polished stems (J Howell et al 2003). This in itself when considering fretting theory previously mentioned, suggests a difference in the mechanism of wear. This initial study presents two valuable points for discussion, (i) the development of a visual grading structure to classify wear on femoral stems, (ii) a suggested wear mechanism involved in the failure of matt finish femoral stems.

The validity of the series of explants was confirmed through initial wear location studies to ensure the stems were typical of those previously investigated by other parties (J Cook 1998). The visual grading system, developed with assistance from an experienced surgeon was proven, after slight modification, to be useful in the classification and qualitative assessment of wear. The visual grading system also allowed a systematic approach to the investigation of wear using 3D surface topography analysis.

3D surface topography measurement and characterisation showed the change in surface topography at different stages of wear for the matt finish femoral explants. This topography characterisation showed the following: during wear the asperities which are caused by bead blasting are removed, yet the valleys remain unchanged. Pitting and scaring do occur on the surface of matt finish femoral stems, similar to polished stems, however, typically this occurs when abrasive wear of the stem leaves polished areas of topography. This strengthens the hypothesis that the wear mechanism involved in the premature failure of matt and highly polished stems differs in the initial stages of wear.

The characterisation using the 3D surface texture parameters shows that parametric characterisation is a useful tool in the depiction and classification of wear. The parameters of particular use for wear of femoral stems are the amplitude and volume parameters, describing the relative change in surface topography distribution.

From the findings of the retrieval study, it became evident that the damage seen was not restricted to characteristic fretting damage, yet did show attributes of a more abrasive nature. This was primarily noted through the 3D surface topography measurement and characterisation of the increase in severity of wear, and confirmed through comparing the wear to a truncation model of classic abrasive wear.

To investigate this theory further and strengthen the hypothesis, it was deemed that more information regarding the nature of contact at the stem cement interface was needed. There are significant differences in the topography and texture of matt and polished femoral stems, however little is known regarding the difference in behaviour of cement dependant upon the interacting surface, i.e. stems of differing surface texture.

Literature extensively deals with the mechanical properties of bone cement (A J C Lee 1977, G Lewis 1997, C Liu et al 2001, B Pascual et al 1996) and also clinical technique for optimum success (R Juliusson et al 1994, G Lewis 1997); however, not as much information was available regarding the nature of behaviour during polymerisation and how this might affect the overall contact following insertion of the stem.

The section of research concentrating on gathering information regarding the behaviour of bone cement highlighted some key aspects. (i) The exothermic reaction during polymerisation of the PMMA powder and monomer may cause dimensional change of the stem and cement. (ii) There is some geometrical change of PMMA bone cement during the curing process. (iii) The behaviour of PMMA bone cement during hydration is unpredictable.

The exothermic reaction of the PMMA bone cement is well documented, and the reaction of surrounding tissue is also an area where information is available. The effect of this thermal change on the resulting contact mechanics at the stem cement interface is less well recorded. From the study of the thermal change where a simple representation of the femoral stem system was used to determine the temperature change at the interface, two

things were determined: The thermal change is great and sustained enough to cause a slight dimensional change of the stem. The other factor realised during this section of research, is that there are differences in the magnitude and trend of thermal change dependent upon the brand of bone cement used.

This particular section of study did not add to the proposed theory that the wear of polished and matt finish femoral stems may differ, however, it did highlight that the contact mechanics at the stem cement interface are possibly not as clear cut as first thought.

To investigate the nature of contact at the stem cement interface, a simplified model was used to “cast” cement against stainless steel billets of varying roughness (chapter 7). The study aimed to determine the change in topography of the billets and also depict the resultant topography of the cement following curing. This study gave an insight into the interactions between the two surfaces. The following was noted: (i) when cast against polished and satin billets with roughness akin to that of highly polished and ground stems, there was evidence of peaks on the surface of the cement (ii) when cast against billets of matt and rough surface topography akin to that of vaquashine and bead blasted stems the surface topography of the cement showed good replication of billet topography. In the first case, there were in places cement transfer to the billet; however the dominant phenomenon was the presence of these peaks on the surface of the cement (Figure 7.5). The peaks were consistently present for each brand of cement investigated; however their concentration and distribution did differ. PMMA bone cements typically contain a radio opaque substance such as barium sulphate to show presence of cement on x-ray. It was considered possible that these peaks could be caused due to particles of BaSO₄ being present at this critical point of interaction. This was dismissed through particulate size analysis. To confirm that the peaks were present in the absence of BaSO₄ the study was completed with PMMA without the radio opaque additives. The conclusion of this additional work being, that the peaks were present due to differential micro shrinkage of the cement upon polymerisation. In the case of the rough stems, visually, the topography of the cement showed good replication of matt and rough topography, parametric analysis showed the pits present on the surface of these billets to have diminished in some way, the resultant topography of the cement also showed that replication was not as exact as

visual inspection first suggested. The conclusion drawn from parametric analysis was that the pits caused in the manufacturing process of matt and rough billets in many instances were filled with cement; this cement remained following removal of the cement mantle from the billet. This is consistent with the fact that as with the polished billets, the cement shrinks away from the interface, in the case of the matt and rough billets, this shrinkage causes the cement to shear, leaving particles of cement free to move at the stem cement interface giving rise to accelerated third body wear. Figure 9.2 shows a schematic of this, the implication being that full stem cement contact is not maintained. In addition particles of debris are present giving rise to third body wear, a mechanism which typically accelerates wear especially where hard radio opacifier particles are present or Alumina residue from the manufacturing process of the rougher surface finish.

In order to establish the magnitude of shrinkage during curing of bone cement, a study was completed using a simplified model. The magnitude of shrinkage was deemed to be sufficient to allow cement shearing, promoting third body abrasive wear in the case of matt finish femoral stems and also to allow a channel for transportation of debris away from the interface.

Variation between bone cement brands was also noted during the course of the investigations, suggesting that if there are fundamental differences in behaviour, there may be variation of function in vivo.

Although all of the studies on cement behaviour and resultant effects on the stem cement interface have been conducted using simplified models, simulation of surgical procedure in vitro was used to prove the phenomenon in the clinical situation, corroborating the validity of the studies presented. (Chapter 7)

Simulation studies, although gave limited information as to the nature of wear, did allow an effective method of wear simulation to be developed. It is proposed that this method could be used to simulate wear and investigate the effects of these differences in bone cement and also the effects of stem geometry and surface finish.

Taking all of this into consideration, it is proposed that a potential mechanism of wear of matt finish femoral stems progresses by the following route.

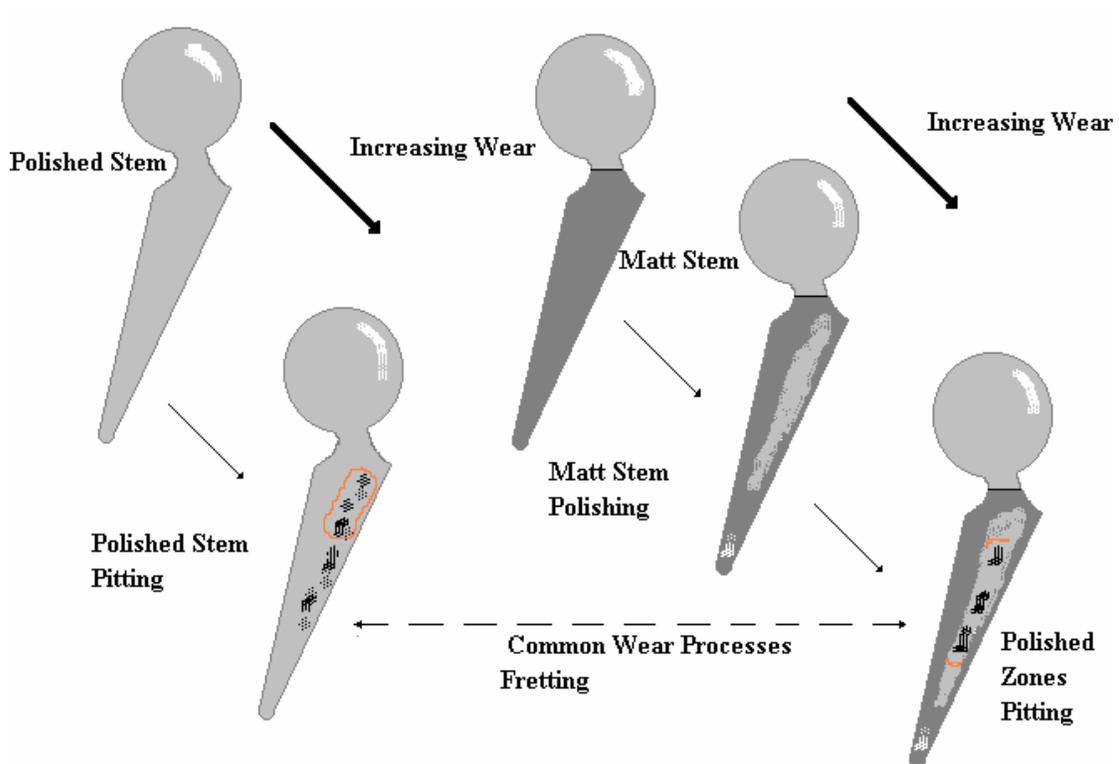


Figure 9.1 The proposed mechanism for wear of matt and polished femoral stems

Figure 9.1 shows the proposed hypothesis for wear of femoral stems, it is deduced that both polished and matt finish femoral stems will be subjected to fretting wear and damage, however prior to this matt finish femoral stems may undergo polishing through an abrasive wear mechanism.

Figure 9.2 shows the proposed process of wear, the abrasion and polishing being confirmed through i) visual observation ii) 3D surface analysis and iii) quantitative analysis, it should be noted, that though a proposed mechanism for wear is offered, the Exeter system does in many cases show in excess of 18 years clinical use with no loosening.

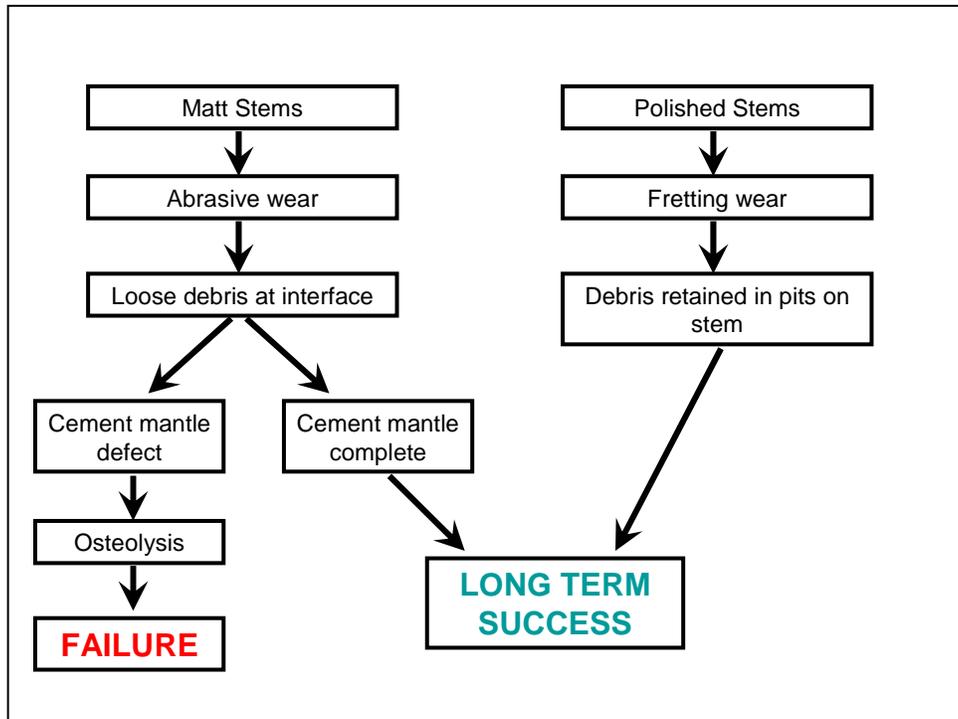


Figure 9.2 The proposed mechanism for wear of matt and polished femoral stems

Figure 9.3 shows the way in which it is believed the mechanism operates on a micro scale, whereby shrinkage of the cement gives rise to abrasive wear and third body particals, and also demonstrates a possible route for debris transportation.



Cement is applied with pressure, penetrating the pits of a bead blasted surface



Cement shrinks during polymerisation leaving cement in the voids at the bottom of pits, particles of cement also shear creating particulate debris



As the stem is loaded, where a polished stem is free to subside, the cement shears under loading and possible defects in the cement mantle form and propagate



Movement of the stem in the cement mantle creates a pumping action allowing for fluid to penetrate defects and the stem cement interface



The integrity of the stem cement interface is compromised and fluid is allowed to flow in the void aided by the pumping action



The fluid creates an abrasive slurry when mixed with the particulate debris, allowing for further wear to take place



Particles of cement contribute to abrasive wear and metallic debris from the asperities is generated during wear



“Polishing” of the asperities occurs as seen in the surface roughness analysis, the void and fluid flow allow for debris transportation to critical areas

This model assumes that the femoral stem is of double tapered collarless design.

Figure 9.3 The influence of cement shrinkage on wear of matt finished femoral stems

CHAPTER 10. CONCLUSIONS

The aim of this study was to give an insight into the wear mechanism of the femoral stem which ultimately results in premature failure.

The following objectives were set out in order to achieve this goal.

- Gain a better understanding of the contact mechanics at the stem cement interface.
- Investigate the progression of wear on femoral stems in vivo
- To replicate the wear through practical and mathematical simulation
- To quantify the wear and determine any relationships present
- To investigate the means of debris transportation to critical sites in the body.

A number of component studies were developed and completed in order to fulfil the aims and objectives, the following conclusions can be drawn from those component studies:

- 3D surface analysis assessment can be a useful tool in the investigation of wear.
- A semi-quantitative analysis of wear can give an insight into the overall material removal during wear of matt finish femoral stems.
- Wear of matt finish femoral stems may be initially due to a form of abrasive sliding wear which then leads on to fretting wear and corrosion.
- Clarification is offered as to the reason why a greater degree of wear is found on matt finish femoral stems despite the fact that fretting wear decreases with increase in surface roughness because of the plastic deformation of surface asperities.
- Significant geometrical changes occur during polymerisation, curing of PMMA bone cement and this leaves the possibility of voids and incomplete contact at the stem/cement interface
- Incomplete contact may promote the possibility of debris transportation
- Barium sulphate as an additive appears to have no effect on the surface topography
- The presence of shrinkage peaks occurs with all brands of bone cement, however different brands do vary in behaviour

- Shearing of cement occurs during shrinkage leaving cement debris in pits of rougher surfaces
- Initial developments on material screening show there is scope to develop the techniques further to aid assessment of fretting wear on materials
- The simulation of fretting wear for comparison of stem design and cements is viable
- With the above methods a comprehensive comparison can be made of the various combinations available on the market, and also to screen new products for wear generation.

The above conclusions have led to the hypothesis that the mechanism responsible for wear of matt finish femoral stems is due to abrasive wear caused by micromotion of the stem in the cement mantle. As a consequence it has been deduced that the wear of matt and polished femoral stems of double tapered collarless design varies, and that this may explain the more severe nature of the wear of matt stems.

CHAPTER 11. FURTHER STUDIES

Areas have been highlighted from the literature review and also the studies completed which warrant further investigation, and these are outlined below

Future projects would aim to provide comprehensive comparisons of commercially available products, through a rigorous testing program, although many countries have a database of information surrounding the in-vivo success of total hip replacements, selection of prostheses is often made because of surgeon or establishment preference. This programme of research aims to provide a more substantial offering for decisions to be based on when selecting components. The study is intended to be wholly independent and all data and findings are to be published for public record, through journal papers and seminars throughout the duration of the project, and ultimately in a complete published document.

The methodology of the project will be based around a systematic program of research, concentrating on critical variables under investigation in turn.

- The initial work will be completed to determine the variation in commercially available bone cements.
- The mechanical properties of the cured compounds will be catalogued utilising mechanical testing equipment, thermal data capture and geometrical metrology instrumentation. In particular the use of co-ordinate metrology machines (CMM) will be useful in determining the geometrical change during various stages of the curing process.
- In tandem with the experimental work, information on the in-vivo use of various bone cements and their relative success will be compiled to give a complete comprehensive comparison of the major clinical bone cements available. (in

collaboration)

- Utilisation of simulation techniques to determine the effect of variation in geometrical and surface design in wear of femoral stems will be investigated. A method for simulation has been devised which produces wear in accordance with that found on explanted prostheses. Although previous simulation techniques have shown limited success, further work has developed a method for fretting simulation of femoral stems. Initial results are promising.
- Another area to be investigated is to assess the impact of accuracy, and geometrical tolerancing in the manufacture of femoral stems in selected designs. Again simulation and also Finite Element analysis are to be utilised in determining the importance of these factors.
- Following component studies of the stem, and the cement, variation in the system as a whole will be assessed, giving an indication as to the importance of cement mantle thickness in the success of THR.

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Appendix I

11.0 History of the series of Explanted Matt Finish Femoral Stems analysed in the retrieval study

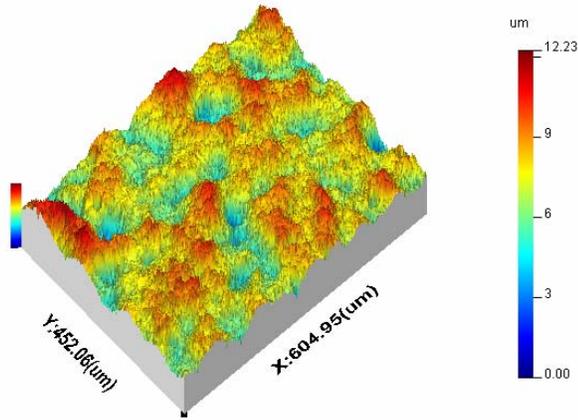
	Stem Type	Surface Finish	Time in vivo
st79	Charnley Flat Back	Matt	Not Known
st76	Charnley Flat Back	Matt	22 years
st75	Stanmore Alvium Straight Stem	Matt	9 years
st74	Stanmore Alvium Standard	Matt	15 years
st73	Stanmore Alvium	Matt	17 years
st4	Exeter 316L	Matt	7 Years
st48	Charnley Round Back	Matt	16 Years
st43	Charnley Cobra	Matt	13 Years
st42	Charnley Cobra	Matt	Not Known
st33	Exeter Orthinox	Matt	13 Years
st29	Exeter 316L	Matt	15 years
st23	Exeter 316L	Matt	14 Years
st19	Exeter Orthinox	Matt	9 Years
st10	Stanmore Tivaloy	Matt/Satin	Not Known
s91	J&J Profile	Matt	8 Years
s264	Charnley Round Back	Matt	18 Years
s262	Titanium Lubinus	Matt	12 Years
s261	Lubinus SP2	Matt	13 Years
s253	Stanmore	Matt	Not Known
s202	Protasol (Muller)	Matt	20+ Years
s170	Protasol (Muller)	Matt	14 Years
s156	Lubinus SP2	Matt	Not Known
s155	PCA Long Stem	Matt	5 Years
s144	Howse (Titanium)	Matt	9 Years
s136	Charnley Cobra	Matt	Not Known

Appendix II

11.1 3D Axonometric Plots displaying wear on a range of Explanted femoral stems

Examples of Surfaces Classified as Pol0

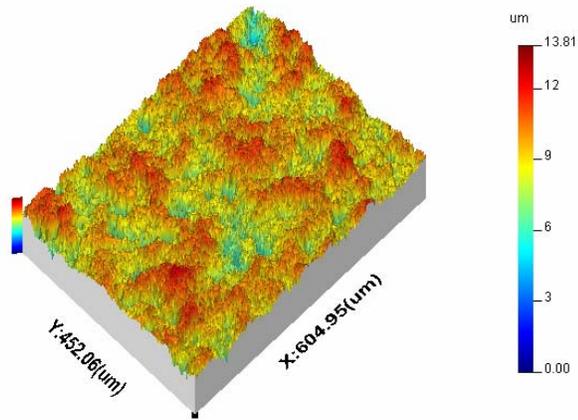
3D Surface



Azimuth: 42.0(deg); Elevation: 66.7(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

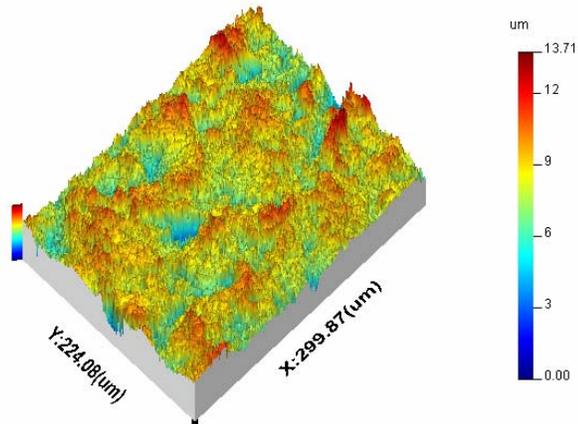
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

3D Surface

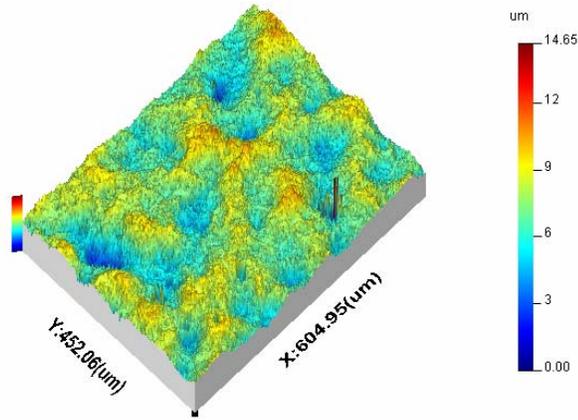


Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

Examples of Surfaces Classified as Pol1

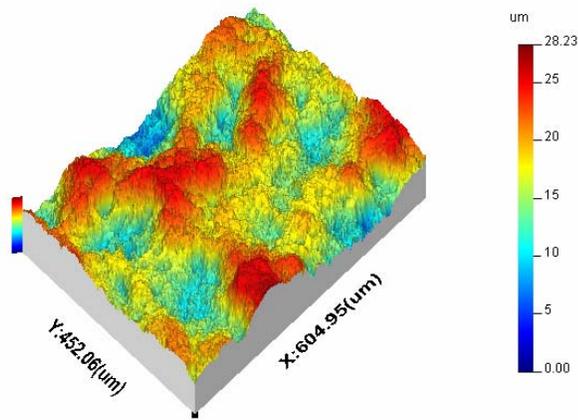
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

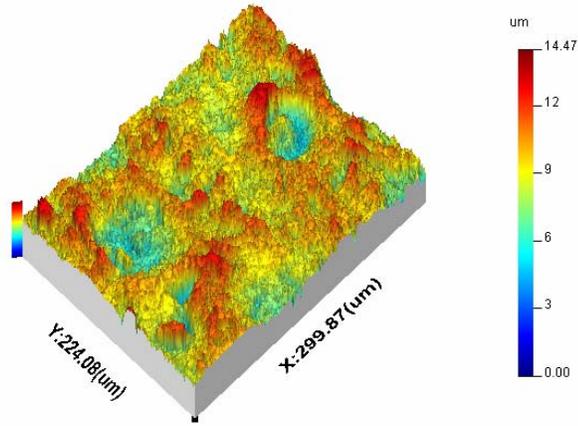
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

3D Surface

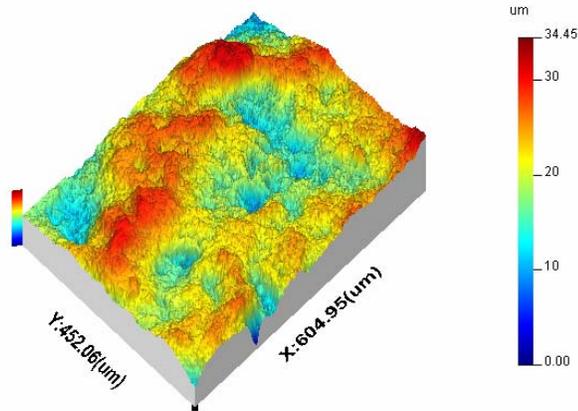


Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

Examples of Surfaces classified as Pol2

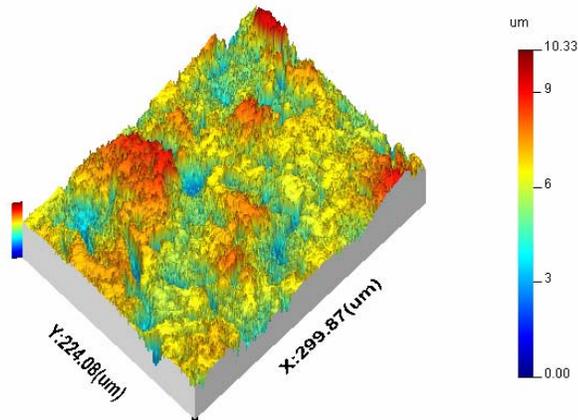
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

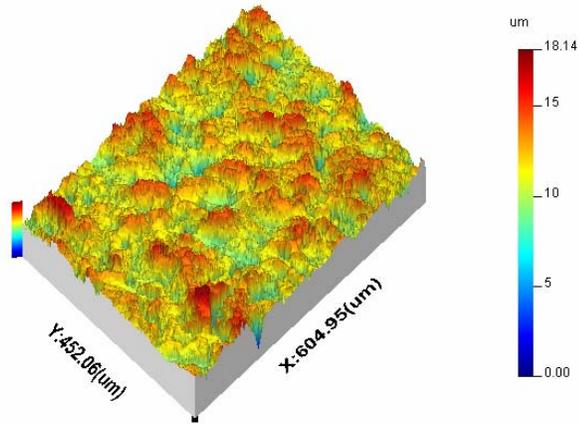
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

3D Surface

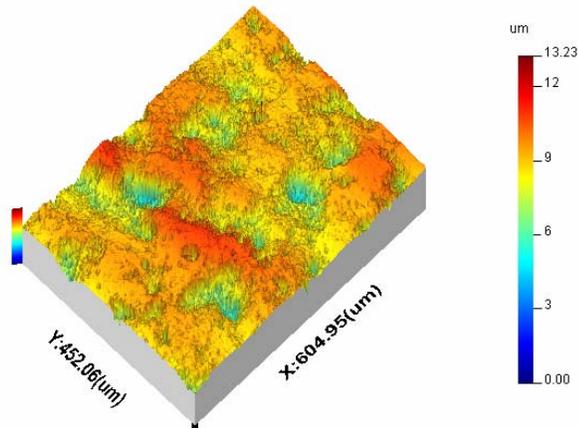


Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

Examples of Surfaces Classified as Pol3

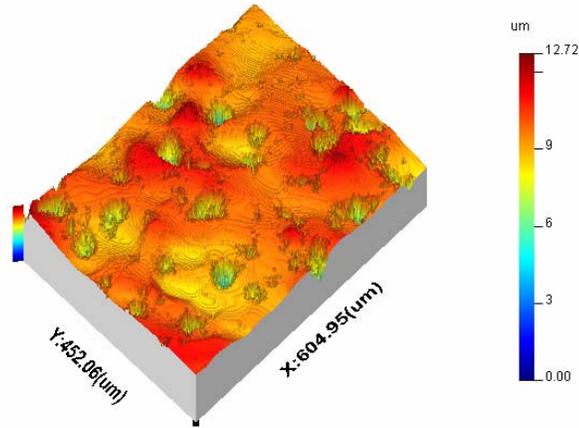
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

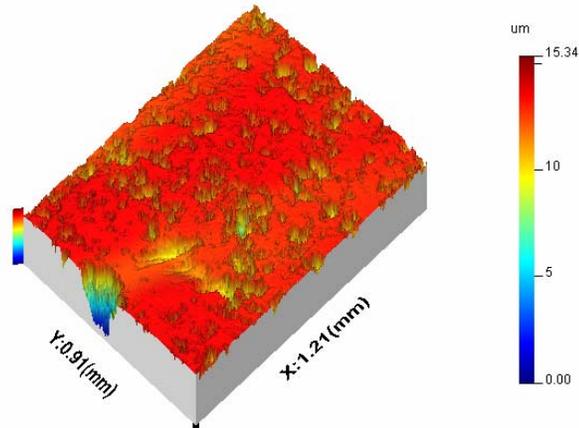
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

3D Surface

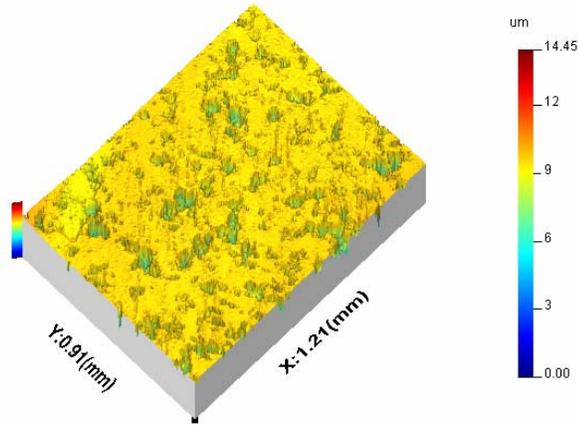


Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

Examples of Surfaces Classified as Pol4

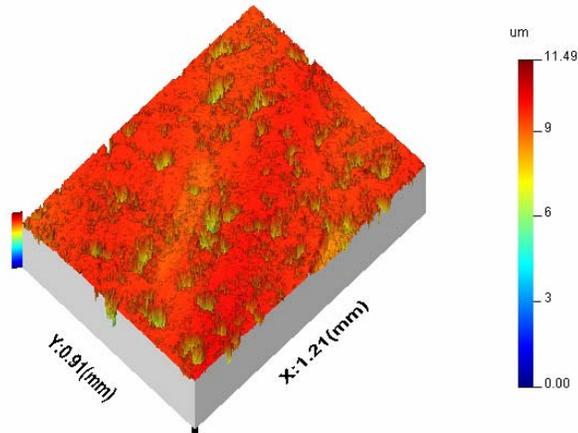
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

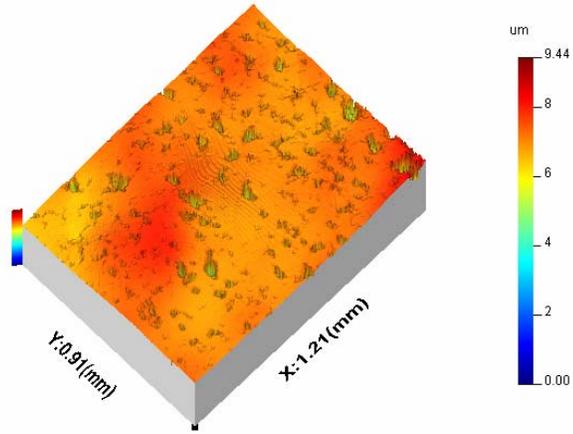
3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

3D Surface



Azimuth: 45.0(deg); Elevation: 70.0(deg)
XScale: 1.00; YScale: 1.00; ZScale: 1.00

Taylor Hobson

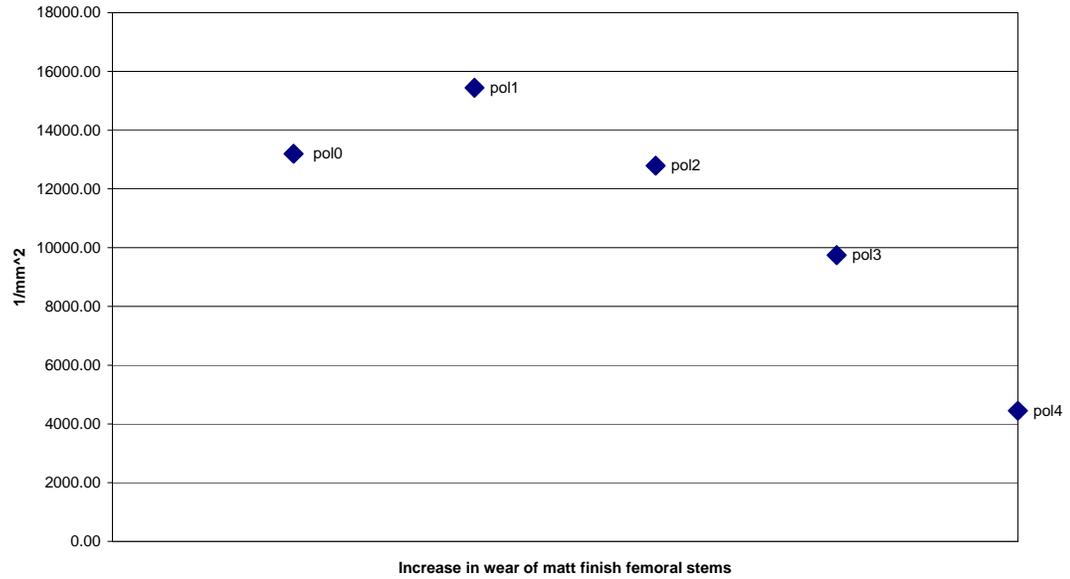
Appendix III

Additional parametric analysis of visual wear grades for the series of matt finish explanted femoral stems

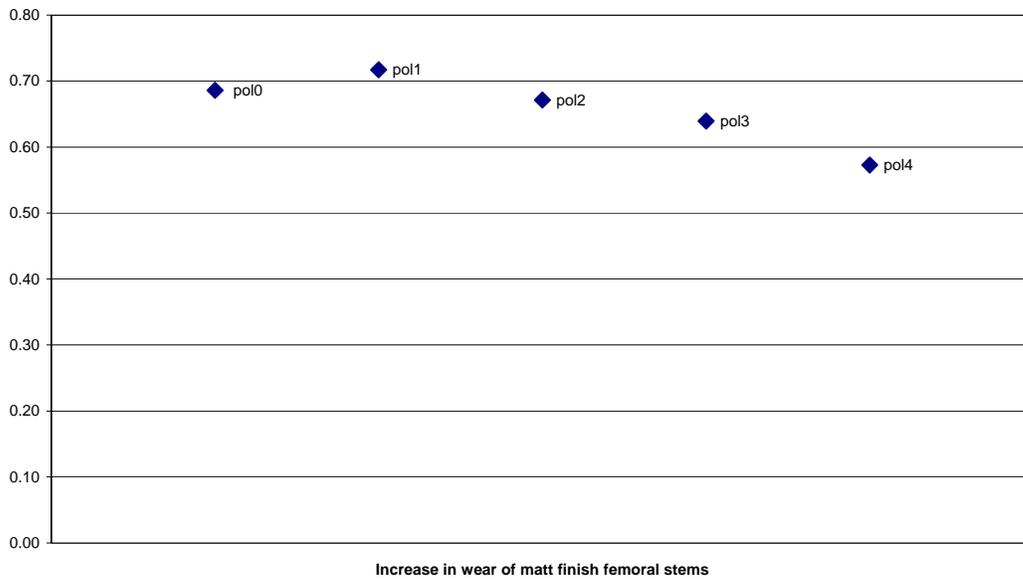
Average Parameters

	Average				
	pol0	pol1	pol2	pol3	pol4
Sq	1.46	1.58	1.31	0.90	0.48
Sz	14.09	14.61	12.91	10.13	7.64
Ssk	-0.61	-0.78	-1.30	-2.76	-2.97
Sku	4.92	5.77	6.25	14.81	23.63
Sds	13200.36	15445.33	12789.67	9745.44	4447.20
Str	0.69	0.72	0.67	0.64	0.57
Sal	0.03	0.03	0.03	0.04	0.05
Std	-16.52	-14.83	-12.50	-19.78	13.60
SDq	0.39	0.44	0.33	0.21	0.11
Ssc	0.30	0.34	0.21	0.11	0.03
Sdr	7.68	8.77	5.19	2.05	0.78
Sbi	0.70	0.73	0.96	1.75	1.84
Sci	1.35	1.33	1.16	0.86	0.94
Svi	0.14	0.14	0.16	0.19	0.19
Vmp	63899.64	60076.11	43237.22	19874.33	11132.00
Vvc	1546509.20	1720488.89	1242661.11	611688.89	301960.00
Vvv	208642.20	219847.22	203073.89	167212.22	94282.00
St	15.82	16.34	14.89	11.61	9.46
Sa	1.12	1.23	0.97	0.56	0.25

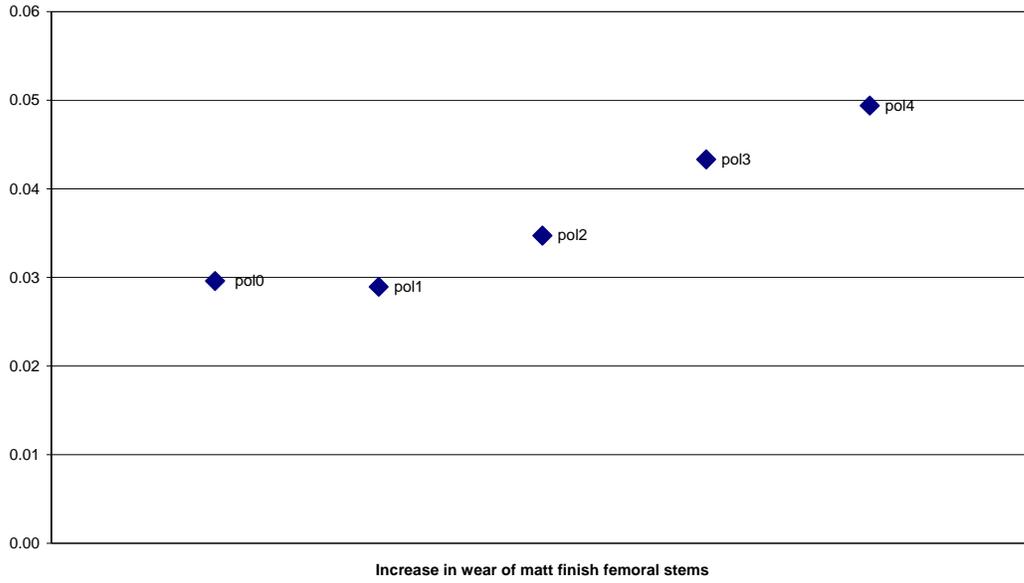
Density of summits of the surface (Sds)



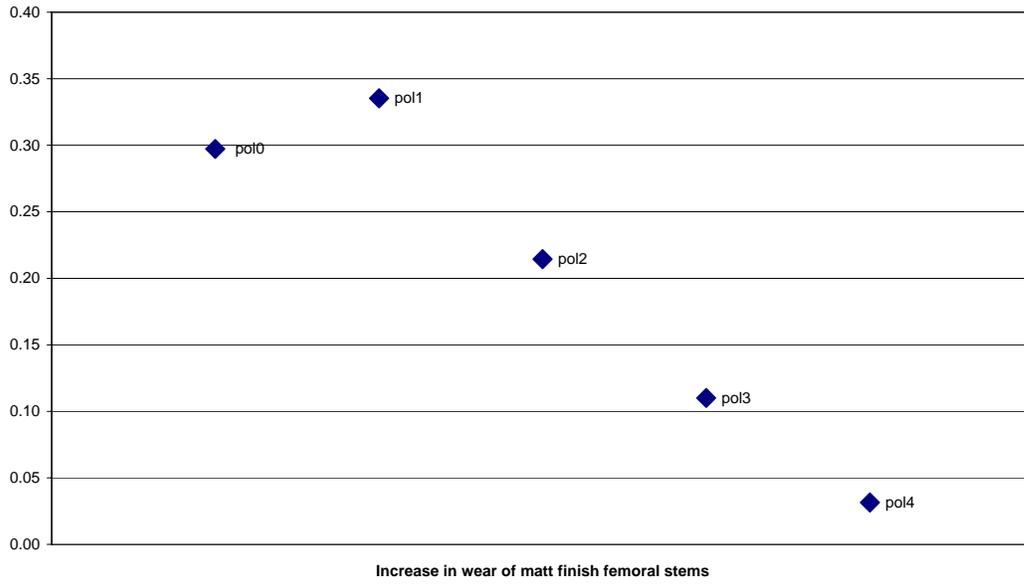
Texture aspect ratio of he surface (Str)



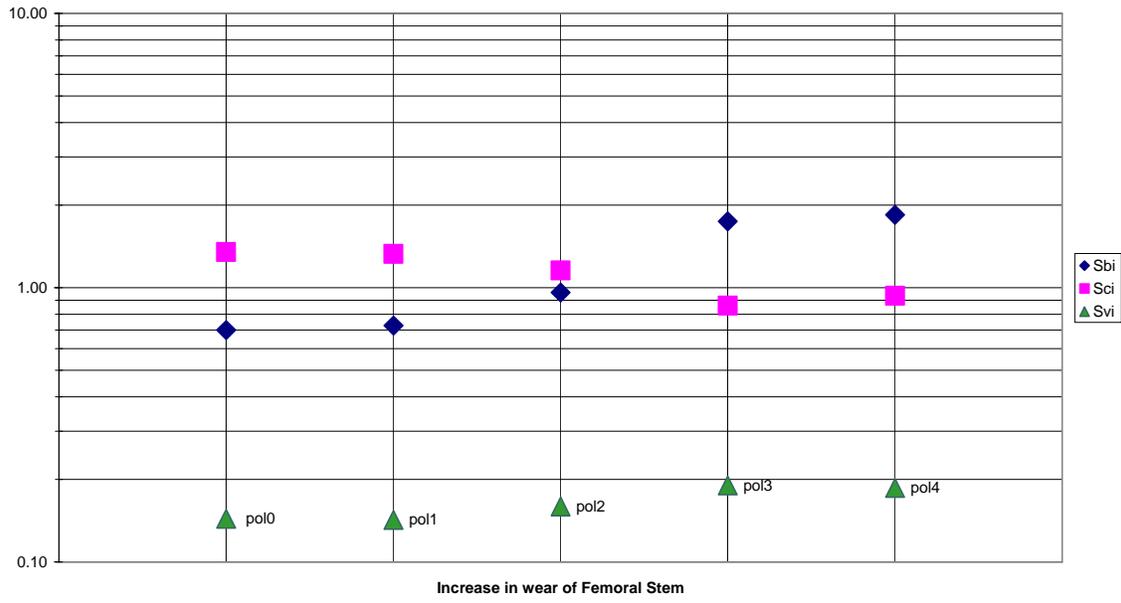
The Fastest decay autocorrelation length (Sal)



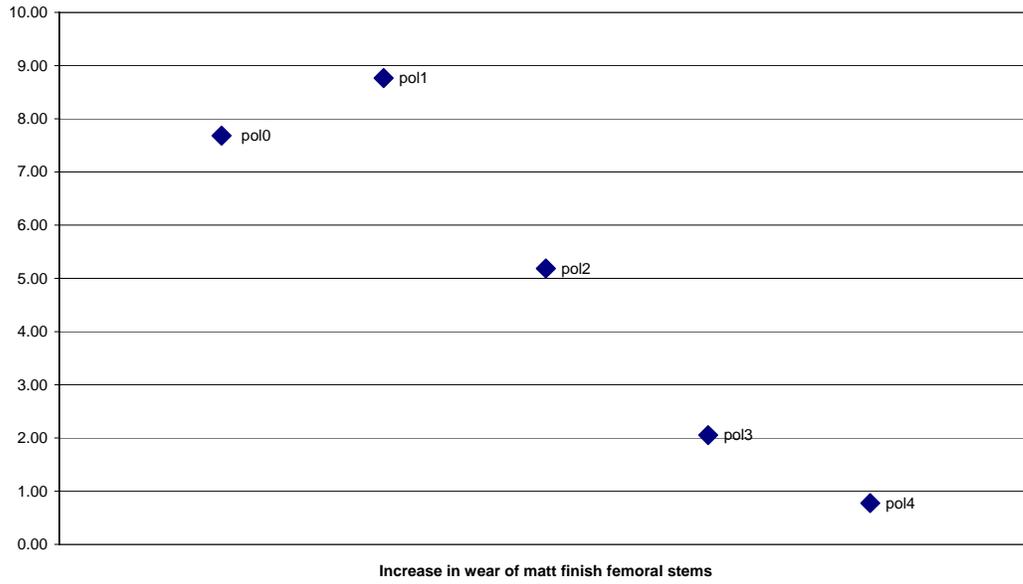
Arithmetic mean summit curvature of the surface (Ssc)



Functional Parameters (Index Group)



Developed interfacial area ratio (Sdr)



Appendix IV

The Femoral Stems examined for volume loss and revision of the visual grading structure.

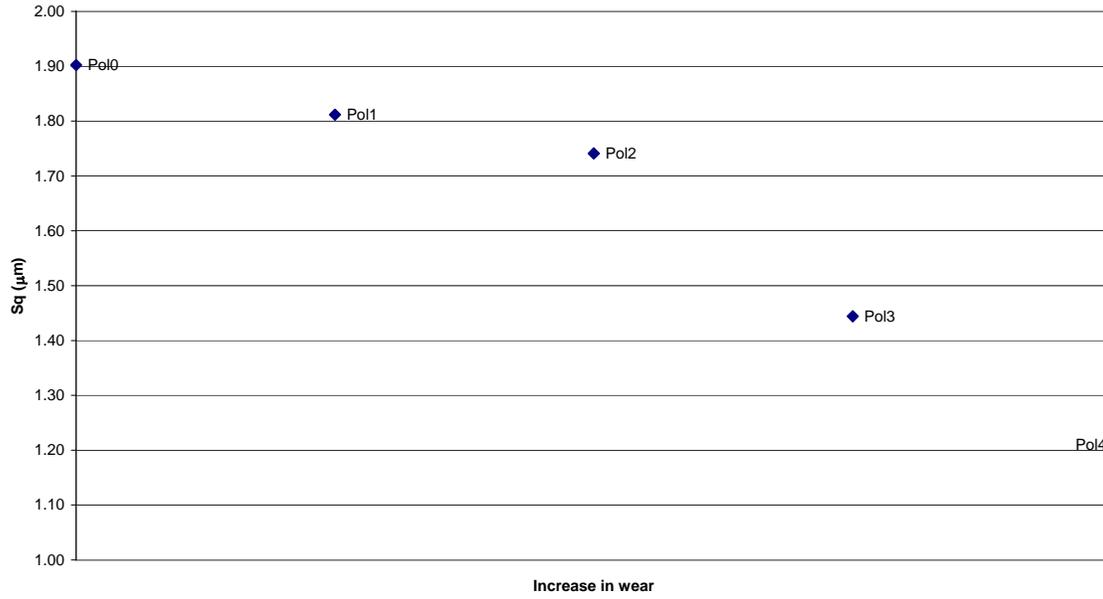
Appendix V

Additional parametric analysis following revision of Pol0 measurement area:

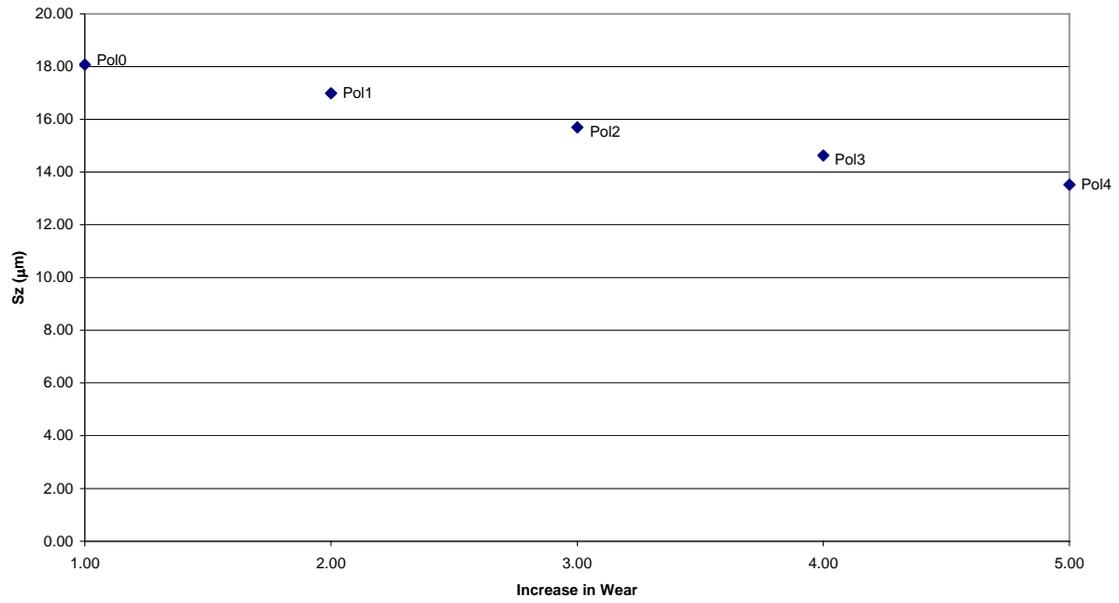
Average Parameters

	Pol0	Pol1	Pol2	Pol3	Pol4
Sq	1.90	1.81	1.74	1.44	1.16
Sz	18.07	16.99	15.70	14.63	13.52
Ssk	-0.35	-0.65	-1.04	-1.36	-1.02
Sku	3.65	4.01	4.66	6.07	6.93
Sds	24453.33	16313.33	17723.33	26946.67	37061.67
Str					
Sal	0.03	0.03	0.03	0.03	0.04
Std					
SDq	0.78	0.67	0.68	0.62	0.52
Sc	0.73	0.46	0.42	0.51	0.53
Sdr	22.50	16.63	16.83	14.25	11.06
Sbi	0.66	0.71	0.84	0.91	0.78
Sci	1.39	1.28	1.06	0.95	1.15
Svi	0.14	0.14	0.17	0.18	0.16
Sm	79620.00	53995.00	36178.33	29188.33	35486.67
Sc	2090500.00	1950666.67	1615833.33	1196683.33	1087450.00
Sv	263366.67	253850.00	282450.00	256116.67	186166.67
St	19.91	20.12	17.61	16.23	15.14
Sa	1.49	1.44	1.38	1.11	0.89

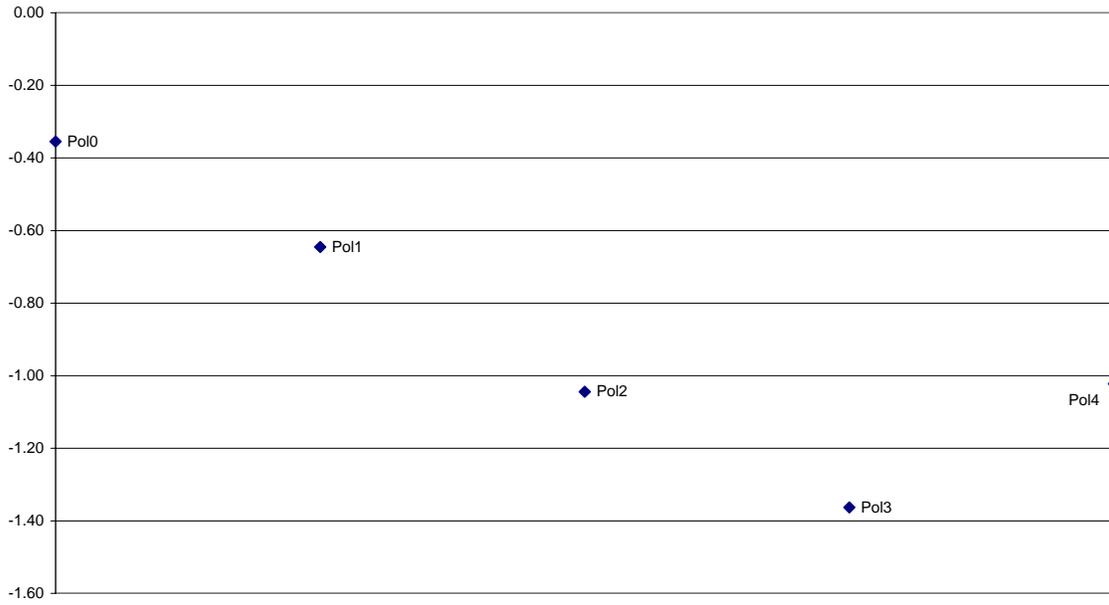
Average root mean square deviation of the surface Sq



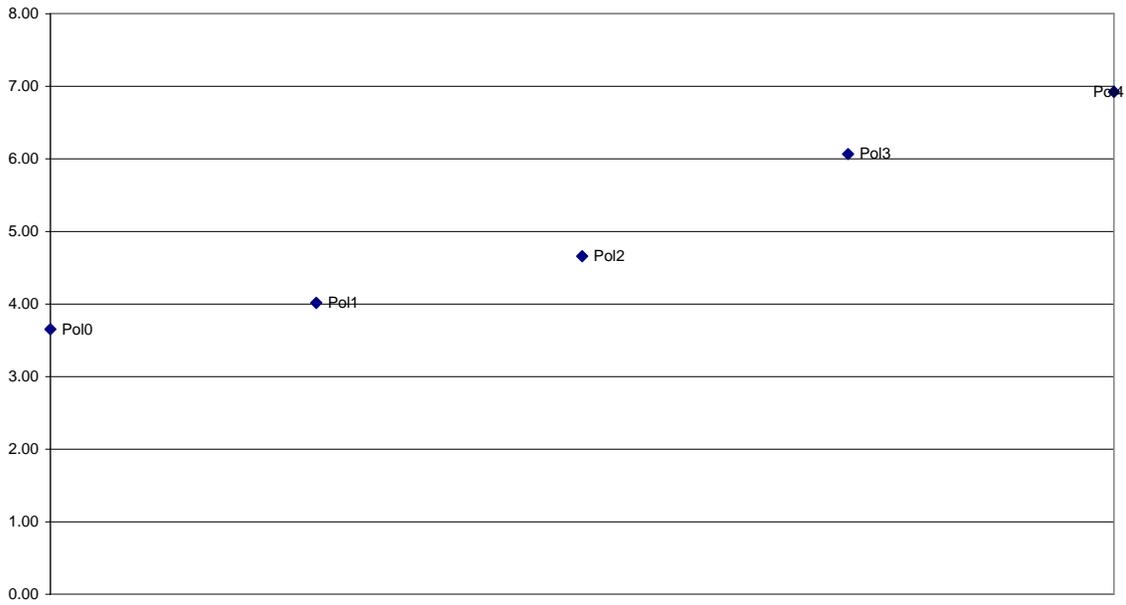
Maximum height of topography Sz



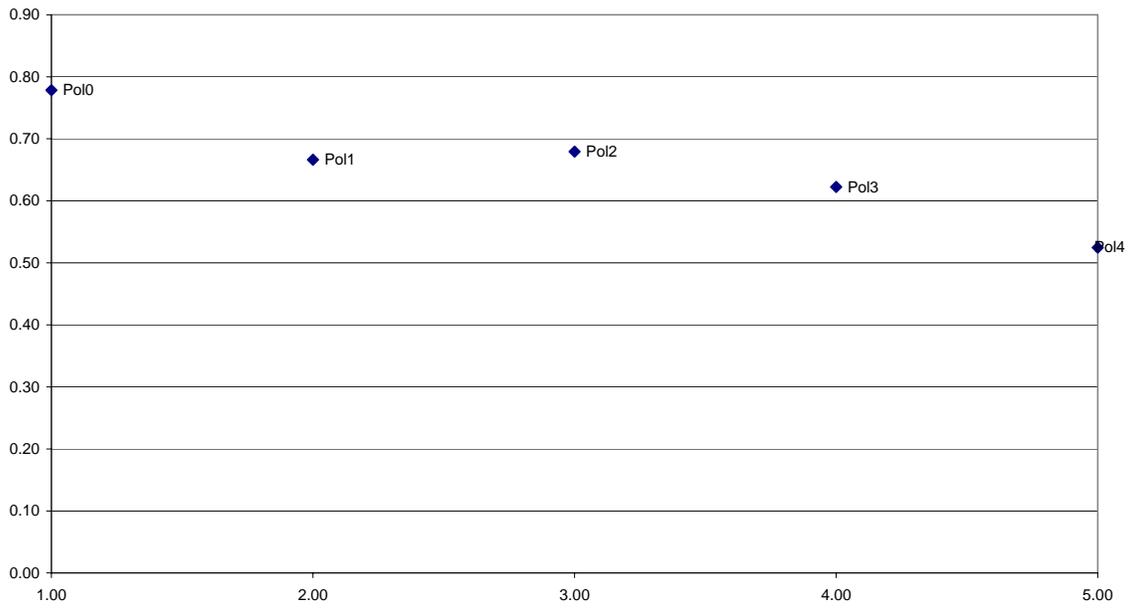
Skewness of Topography height distribution (Ssk)



Kurtosis of topography height distribution (Sku)

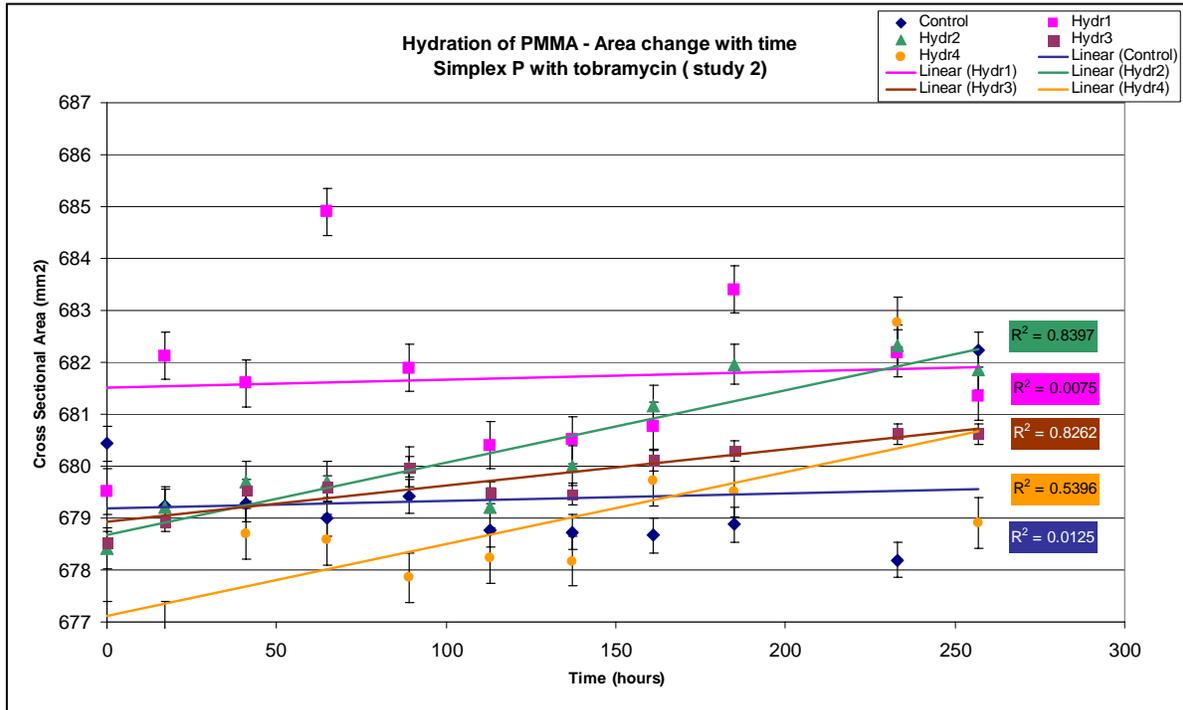
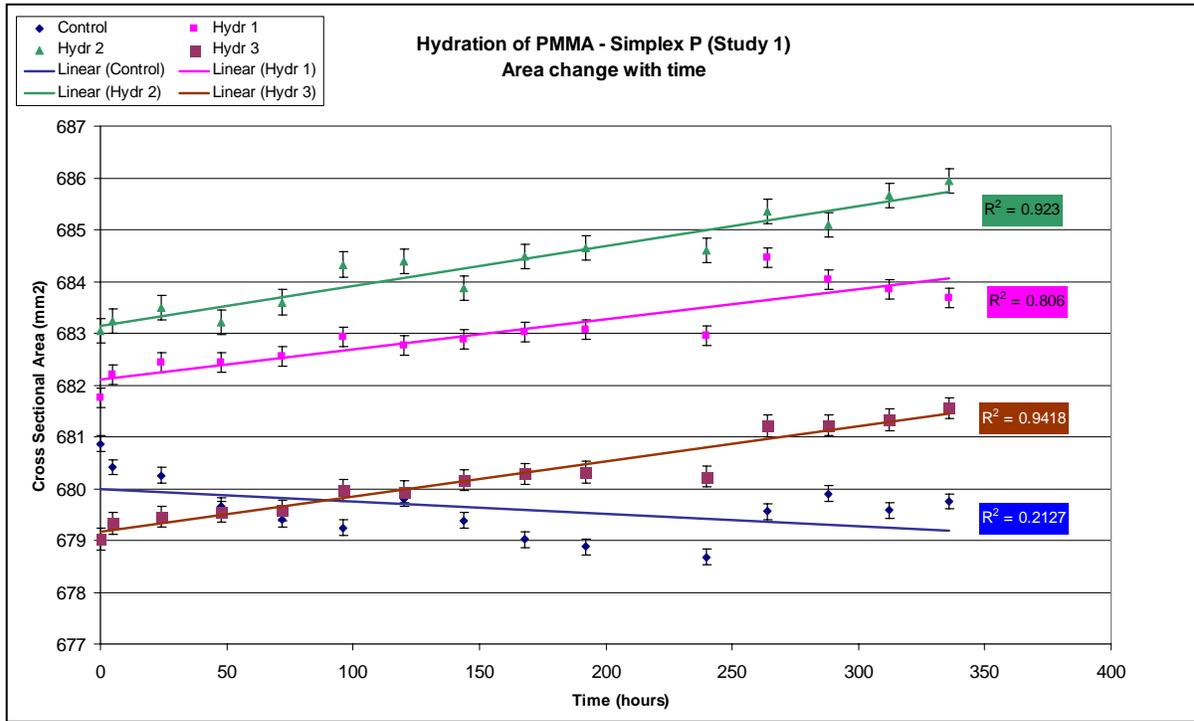


Root mean square slope of the surface (SDq)



Appendix VI

Results of the Hydration of PMMA bone cement study:



Appendix VII

Chemical composition of Ringers Solution as used throughout experimental studies

Ringers solution composition (grams per litre of distilled water) J Cook (1998)			
NaCl 8.5g/l	KCl 0.25g/l	CaCl ₂ 0.22g/l	NaHCO ₃ 0.16g/l

Appendix VIII

A Selection of publications resulting from this project

Brown L., Blunt L., Howell J. (2000) The Development of Surface Topography During Wear of Matt Finish Femoral Stems. Conference Proceedings. Tribology in Environmental Design 2000, 3rd – 6th September 2000, Bournemouth, UK

Brown L., Blunt L., Howell J., Jiang X., Li Z. (2000) Semi-Quantitative Wear Analysis of Matt Finish Femoral stems. Chinese Journal of Biomedical Engineering. Proceedings of The First International Conference on Biomaterials (Beijing, China) July 24th-26th 2001.

Brown L. T. (2001) An Investigation into the Wear of Femoral Stems. Poster Displayed at “Inovative Futures” 2001. Sheffield, UK

Brown L., Blunt L., Howell J. (2001) Use of 3D Analysis to Investigate the Surface Replication of PMMA Bone Cement on Stainless Steel Femoral Stems. NMC2001 (National Measurement Conference November 2001) Harrogate, UK

The Development of Surface Topography During Wear of Matt Finish Femoral Stems

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ABSTRACT

In the UK around 50,000 Total Hip Replacements are performed annually, of these up to 10% are revision operations^[1]. Revision operations are required when a primary prosthesis fails. The premature failure of prostheses has been attributed to the production of debris from the wear of the femoral stem and head. There have been many studies to qualitatively characterise the wear of femoral stems, however few quantitative studies have been performed. In this semi-quantitative study 25 explanted stems were examined and the wear characterised in relation to the extent of damage on the matt surface.

INTRODUCTION

In the UK around 50,000 Total Hip Replacements are performed annually^[1]. Total Hip replacements are performed to give better quality of life to patients with various conditions including osteoarthritis, chronic rheumatoid arthritis, and fractures of the hip. During total hip replacement the head of the femur is removed and replaced with a prosthetic head, normally the head articulates in an ultra high molecular weight polyethylene (UHMPE) acetabular cup. This head is positioned on a femoral stem, which is inserted into the medullary canal of the femur. There are two main types of prostheses, cemented and uncemented, uncemented are made from porous materials which allow for bony ingrowth to occur within the medullary canal. The cemented prosthesis is fixated into the femur using Acrylic bone cement. This study concentrates on the wear of cemented total hip replacement. The expected life of a successful total hip replacement is 10+ years, however of the operations that are performed, up to 10 % can be revision operations to replace prostheses that have failed prematurely. Revision operations are costly and have a lower chance of success compared with Primary Total Hip Replacement. There has been an emphasis in research on determining the reason for premature failure of the implants. A great deal of revisions of femoral

components are due to aseptic loosening of the stem. Premature failure of the femoral stem is often attributed to the production of metallic debris, which damages body tissue causing bone resorption and loosening of the component within the cement mantle.

Initially all cemented femoral stems had a highly polished surface finish, subsequently there was a move towards the use of matt finish femoral stems with a bead blasted surface, which were used in the period 1976 – 1982. The rationale behind matt surfaces was greater fixation of the stem in the cement, however the result was a greater incidence of aseptic loosening in matt finished stems.

In a study by Howie et al (1998), 40 Total Hip replacements were performed, 20 polished and 20 matt finished stems. Apart from the surface finish the stems were identical Exeter type prostheses (Stryker Howmedica). At a nine-year follow up, four of the matt finished stems had been revised for loosening whereas none of the polished stems had shown signs of loosening. The study concluded that: "The matt surface appears to be responsible for increased loosening in the double-tapered stem design."^[6]

Tentative suggestions indicate that the wear of femoral stems in vivo may be due to fretting wear. "Most of these repairs are performed on limbs and these can undergo a large number of stress reversals in one day; the conditions are therefore those in which fretting corrosion can be expected."^[13] Fretting wear is the result of small oscillatory micromovements between two contacting surfaces, the characteristic signs of fretting wear are the production of metal oxide debris and the formation of surface wear scars. Studies have shown these characteristics to be present on explanted stems, both matt and polished and of different materials^[4,10,11]. There does appear to be an additional wear mechanism involved in the wear of matt stems. Before fretting takes place it is suggested that there is polishing of the matt surface where the rough asperities are removed^[2].

Although there have been many studies, in vivo and in vitro, to qualitatively characterise the wear on femoral stems, there has been little work done on quantitative characterisation. The aim of the present study is to examine the development of the surface wear of femoral stems in the hope that understanding the development of the surface topography will lead to better knowledge of the wear mechanisms involved.

THE STUDY

25 Explanted Matt finish femoral stems were examined. The degree of wear varied on each one however the position of wear on explanted femoral stems does appear to follow a pattern due to the loading regime in vivo^[2,4]. The stems were examined and a visual grading system was used to categorise the wear in different areas of the stem^[5]. This grading system contains 5 categories, pol 0 denotes no wear, with an increase in wear denoted by pol 1 through to pol 4, pol 4 being an indicator of high wear. (i.e. a high degree of polishing) Of the 25 explanted stems examined there were 25 stems showing areas of no wear (Pol0), this surface measurement was taken from an area which lies outside of the cement mantle, resulting in no contact hence no possibility of wear. 18 of the stems showed areas graded as pol 1; 18 of the stems had areas graded as pol 2; 9 of the stems had areas graded as pol 3 and 5 of the stems showed areas of high wear and were graded as pol 4.

The surface topography of the visually graded areas was measured using 3D surface measurement.

The specimen surfaces were then measured using a Wyko NT 2000 optical interferometer operating in the vertical scanning mode. Various measurement areas were examined with a vertical magnification of between 25x and 100x. Vertical resolution of this system in the VSI mode is 1nm.

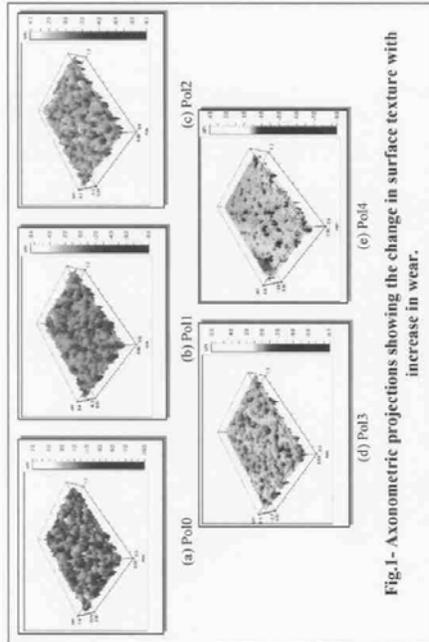


Fig.1- Axonometric projections showing the change in surface texture with increase in wear.

From the axonometric plots (fig.1), it can be seen that the rough asperities caused by the bead blasting process are progressively worn away, and the surface becomes smooth. Debris is generated, through a form of contact wear between the stem and the bone cement, and is a large factor contributing to aseptic loosening of the stem resulting in failure of the prostheses.

Traditionally quantitative surface measurement was carried out using 2D surface parameters. Unfortunately as many as 105 different surface parameters were developed in an attempt at improving functional surface description, the large number of 2D surface parameters has been referred to as a "Parameter rash"^[13]. Most of these parameters were of limited use in describing surface interaction. With developments in 3D surface measurement technology, a need was recognised for the introduction of 3D surface parameters to characterise surface topography more accurately.

In recent years researchers have developed a primary set of 17 surface parameters which seem to describe the 3D surface topography more comprehensively^[11]. The 17 parameters can be found summarised in table 1.

Table.1 3D Parameters

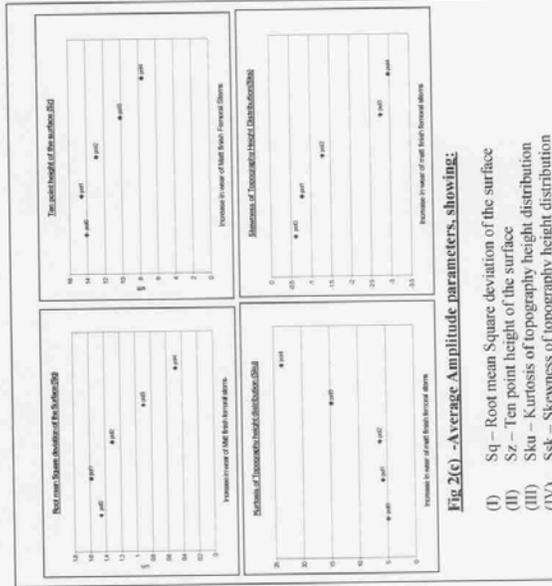
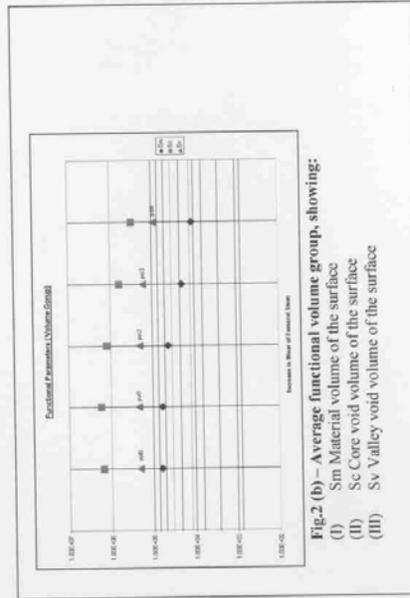
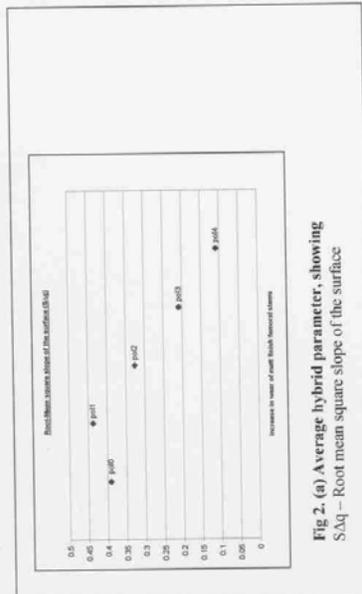
Family	Nomenclature	Parameter
Amplitude	Sq	Root-mean-square deviation of the surface
	Sz	Ten point height of the surface
	Ssk	Skewness of topography height distribution
	Sku	Kurtosis of topography height distribution
	Sds	Density of the summits of the surface
Spatial	Ssr	Texture aspect ratio of the surface
	Ssl	The fastest decay autocorrelation length
	Sld	Texture direction of the surface
Hybrid	Saq	Root-mean-square slope of the surface
	Sec	Arithmetic mean summit curvature of the surface
	Sdr	Developed interfacial area ratio
	Sbu	Surface bearing Index
Functional Index	Sca	Core fluid retention
	Svi	Valley fluid retention
	Ssm	Material volume of the surface
Functional Volume	Sc	Core void volume of the surface
	Sv	Valley void volume of the surface

Many authors have expressed the importance of these 3D parameters in characterising surfaces and manufacturing processes^[3]. With the complicated nature of surface topography a one to one numerical representation is impossible^[11]. Therefore it is necessary to represent surfaces numerically by parameters.

In the present study, each parameter was calculated for each data set taken from the worn stems. To gain an overall picture of the suitability of the parameters for characterisation of the development of surface topography during the wear of femoral stems an average (see previous section *) was taken for each parameter for each grade of wear. The Average parameter values were plotted against visual grade of wear. From these results it was possible to determine which parameters were suitable for characterisation of the development of topography during wear of matt finish femoral stems.

RESULTS

From the results, the most useful parameters for showing fretting wear of explained replacement hip femoral stems were determined, the strong relationship between increase in visual grade of wear and parameter can be seen in fig.2 (a-c)



From these graphs (Fig.2 a-c) the relationship between increase in wear can be clearly seen. The parameters that are believed to be the most suitable for this application are those that show the change in surface amplitude and the change in surface volume with increase in wear: Fig.2a shows the data for the hybrid parameter rms slope of the surface SAQ, although the first data point Po10 does not follow the pattern, the other data points po11 - po14, decrease almost linearly.

SAQ represents the root mean square slope of the surface, the decrease in SAQ shows the steepness of the slopes of the asperities decreases with wear. This is to be expected as the asperities are worn down and the surface becomes smoother.

Fig.2b shows the functional - volume family. Again the data points for po10 show discontinuity with the other results. However the data shows Sm, Material volume of the surface to decrease, this is to be expected as it shows the volume of material to be decreasing as the asperities of the matt surface are worn away with increase in wear grade.

Sc, Core void volume of the surface also decreases with increase in wear grade, though to a lesser degree than the Material volume of the surface.

Sv, Valley void volume of the surface indicates the change in the valleys with increase in wear, from the data shown in fig.2b it can be seen that Sv undergoes only slight change with increase in wear. This shows, with the previous volume family parameters that although the surface is changing with increase in wear the valleys remain relatively unchanged. The pattern

would indicate that the rough asperities of the bead blasted surface are worn away leaving the valleys intact.

The other set of parameters found to be useful are shown in fig 2c, these are the amplitude family of parameters. Sq is the root mean square deviation of the surface, it is a widely used parameter, in statistical terms it is the sample standard deviation of the surface. Again ignoring the data for pol0 there is linear decrease in Sq with increase in wear, showing the overall surface roughness to be decreasing with increase in wear.

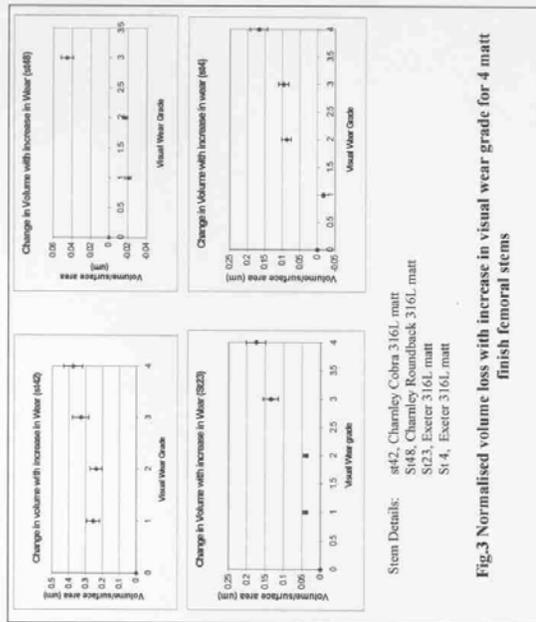
Sz, The ten point height of the gives the average value of the heights of the 5 highest peaks and the depths of the 5 deepest valleys. Sz shows the same relationship with increase in wear, as did the data for Sq. This shows the distance between the highest peak and the deepest valley's is decreasing, this also shows that the asperities are being worn away.

Sku, Kurtosis of topography height distribution is a measure of the peakedness of the surface height distribution, and characterises the spread of the height distribution. The results show that the spread of the height distribution becomes smaller as the value for Sku increases with increase in wear. "A centrally distributed surface has a kurtosis value larger than 3 whereas the kurtosis of a well spread distribution is smaller than 3"¹¹.

Ssk, Skewness of topography height distribution can effectively describe the shape of a topography height distribution. This parameter gives an indication of the structure of a surface. The decrease in Ssk with increase in wear shows the peaks on the surface being removed by the wear process. This correlates with the visual inspection of the axonometric projections where it is apparent that the peaks created by the bead blasting process are worn away to produce a more polished surface.

As the mechanism behind the wear of Matt finish femoral stems is not fully understood, a move towards quantifying the amount of wear of stems in vivo is crucial to determining the wear mechanism. An attempt has been made at a semi quantitative analysis of the wear in addition to the use of 3D parameters to characterise the surface.

From the 25 stems, 4 were chosen which show the full range of visually graded wear, bearing area curve were produced for the most worn plateaus for each stem, the plateau on the bearing area curve gives the average height of the worn areas of the surface. The height of this worn plane was used as a baseline to determine how much material has worn away in terms of volume per mm². By plotting the volume of lost material from pol0 to pol4 a representation of the material loss with increase in wear can be determined.



There seems to be some confusion between Pol1 and Pol2 of the visual grading, as in all 4 cases there is a discontinuity with the results in this area. There does however appear to be a strong pattern suggesting an initial rapid wear rate between pol0 and pol2 becoming a more steady increase in volume lost with pol3 and pol4. This does correlate with the pattern of wear associated with fretting wear however it also follows the regime of most forms of sliding wear. "It must always be borne in mind that the boundary between different types of wear is not always a rigid one."¹⁷

The plots for s148 and s14 show negative values for the volume of material lost, showing there to be some discontinuity with results. This is attributed to the measurement of the values for pol0 being taken under the collar of the femoral head where no wear due to absence of contact has been incurred. It is believed that the initial surface roughness due to bead blasting may differ under the collar, to that of the rest of the stem due to the complex nature of the geometry of the stem resulting in an inconsistent roughness after blasting. This theory is also shown in the work on use of 3D parameters to characterise the surface, where an average of the 25 stems was taken.

DISCUSSION

Fretting wear is the mechanism presently attributed to the wear of femoral stems in vivo. The term Fretting denotes a small oscillatory movement between two solid contacting surfaces [7]. The factors that differentiate fretting from other forms of sliding wear are the magnitude of movement and the nature of the damage caused.

Fretting is concerned with amplitudes of less than 25µm and certainly not greater than 130µm^[15]. From this study of matt finish femoral stems it is apparent that although the wear could be classified as fretting in terms of the magnitude of micromovements between the stem and the bone cement, due to the stress reversals of the limbs. The damage observed on the stem does not exactly mimic that which would be expected of fretting. According to Waterhouse R B (1972) "It is a general observation that the higher the degree of surface finish the more serious is the fretting damage"^[17]. When looking at the semi-quantitative results obtained in this study it is apparent that the Matt stems undergo considerable material loss although the surface finish is of a rough nature." There is possibly another form of wear involved, which initially polishes the surface of the matt stems before classic fretting takes place. The semi-quantitative results indicate that this could be due to a number of types of wear as the data shows a better correlation with ideal abrasive and sliding mechanisms. Referring to ideal abrasive wear Rabinowicz (1993) illustrates, "Blunting of the abrasive surface after wear"^[9].

The wear occurs between the PMMA bone cement and the stainless steel matt finish stem. Third body wear of metallic oxide particles could also play a factor as metallic oxide debris has been found present at revision operations, not only with stainless steel implants but also Titanium and Cobalt Chrome^[14,16].

It is considered that matt finish stems have a higher failure rate than that of polished stems from considerable clinical evidence. From the study of the matt finish femoral stems and from evidence to show the wear of polished stems to be due to fretting, it is apparent that the wear of matt and polished stems is due to two different wear mechanisms. The authors consider that the initial wear of matt stems is of an abrasive form, which, when the matt stems become more polished then changes to a more classical fretting nature.

Further work is needed taking in to account the anomalies with the data for pol0 and using alternative data as a measure of unworn surface. A method of relocation markings on the surface of a stem which undergoes simulation to determine the material loss in relation to number of cycles may be a better way of determining the mechanism behind the wear of both matt and polished femoral stems. The visual grading system also needs to be clarified to establish definite differences between the grades of wear. There appears to be some overlap between the grades of pol1 and pol2, it may be more beneficial to cut the number of grades to 4 showing no wear slight wear heavy wear and severe wear.

There is also scope for performing simulated pin on disk tests, to examine the way PMMA bone cement and stainless steel perform under oscillation.

An additional area of study would be to model the initial wear using a simple truncation wear technique. This would involve digitally wearing a virgin surface using a truncation model. Essentially the surface is sliced away at given depths and at each depth the parameters can be calculated to establish an ideal modelled surface with which the experimental data can be compared.

CONCLUSIONS

- There are 3D parameters, which are useful for characterising the wear of explanted femoral stems.
- The use of semi-quantitative models may go some way to determining the wear mechanism behind the failure of femoral components during total hip replacement.
- The study has provided a good basis for continuing work on quantification, and has provided some insight into the possible wear mechanisms involved.
- The wear mechanisms of matt stems appear to be initially different to that of the more successful polished stems.

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Semi-quantitative wear analysis of matt finish femoral stems

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It is estimated that in excess of 1.5 million total hip replacements are carried out annually, of this figure up to 10% can be revision operations. Revision operations are necessary when the primary implant fails prematurely, and can be more costly and less successful than primary procedures.

Initial suggestions have attributed the damage present on femoral stems at explantation to fretting wear, there is still a certain amount of reservation as to the actual wear mechanism which contributes to the wear and subsequent premature failure of these implants. Various Authors suggest that the matt finish type of cemented prostheses incur a higher failure rate than the polished stems used. There is also uncertainty as to the reason for the increased incidence of loosening in matt finish femoral stems.

The aim of this study is to develop a method for semi-quantitative volume analysis, for characterisation and comparison with truncation models to go some way to clarify the mechanism involved in the wear of these stems.

From previous studies it was determined that there are differences in wear damage between matt and polished stems, from both in-vivo and in-vitro studies. Matt stems are the primary concern in this study as it is felt that the initial wear mechanism differs and that both cases need further independent study. The study includes the 3D topographic analysis of a series of matt finish explanted stems.

The wear on the explants was visually graded according to severity. A grading system previously developed was modified to use in this exercise. In the initial stages of wear of matt finish femoral stems the damage appears as polishing of the stem as the asperities caused by bead blasting are worn away. The visual grades range from Pol0, where no polishing has occurred, through to Pol4, which denotes a high degree of wear. The areas of wear were then each investigated more closely with a Wyko NT 2000 optical interferometer in vertical scanning mode. From these measurements 3D-surface parameters were used to indicate numerically the change in surface topography. The software used, Veeco(tm) determines the volume of material above a baseline and below the surface. This base line was set at the mean height of the most worn area and the volume above this was calculated for each of the other areas. The volume of material remaining above this baseline gives an indication of the material removal. True volume loss for the stem cannot at this time be accurately determined. However this method goes some way as to estimating the amount of material removal during the wear process, and also gives a basis for development of the method to consider image relocation and stitching for true volume loss analysis.

An area of unworn material was analysed and a truncation model was developed to depict classic abrasive wear for comparison with the volume loss results. Upon comparison with the semi-quantitative volume loss measurements, similarities in trends were noted.

Chinese Journal of Biomedical Engineering. Proceedings of The First International Conference on Biomaterials (Beijing, China) July 24th-26th 2001.

An Investigation into the Wear of Femoral Stems

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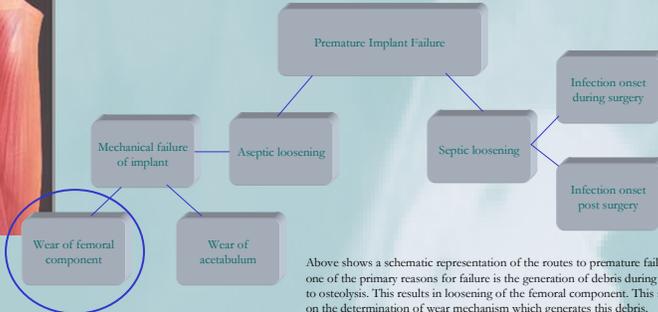
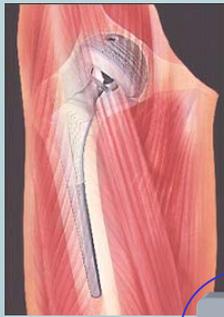


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Total hip replacement is a procedure undertaken to improve the quality of life of patients with painful disorders such as osteo-arthritis, rheumatoid arthritis, necrosis and abnormalities or fractures of the femur. During total hip replacement the head of the femur is removed and replaced with a prosthetic head, normally the head articulates in an ultra high molecular weight polyethylene (UHMPE) acetabular cup. This head is positioned on a femoral stem, which is inserted into the medullary canal of the femur. There are two main types of prostheses, cemented and uncemented, uncemented are made from porous materials which allow for bony ingrowth to occur within the medullary canal. The cemented prosthesis is fixated into the femur using Acrylic bone cement.

Each Year in excess of 32,000 primary total hip replacements are performed annually in the UK alone. The majority of prostheses are successful and can perform well for onwards of 20 years, however over 6,000 operations are performed each year to revise replacements which have failed prematurely.



Above shows a schematic representation of the routes to premature failure of total hip replacement, one of the primary reasons for failure is the generation of debris during wear of components leading to osteolysis. This results in loosening of the femoral component. This research project concentrates on the determination of wear mechanism which generates this debris.

The current research project concentrates the wear of the femoral stem in cemented total hip replacement, its bearing on failure and determination of the wear mechanisms involved. There are over 62 designs of prostheses widely available from a range of 19 manufacturers world-wide. Only a small proportion of these replacement joints have good long term service records, primarily due to the introduction of new designs onto the market in recent years. The majority of prostheses currently available have a highly polished surface finish. The wear of this type is generally accepted to be due to fretting wear. The initial concentration of the project has been the study of wear on matt finish femoral stems, which are less widely used due to reports of a higher incidence of loosening with the rougher surface finish.

- Several methods have been developed and employed to study the wear of matt finish femoral stems, the primary concerns are:
- Investigation of the development of surface topography during wear
 - Quantitative measurement of wear
 - Volume analysis of material wear
 - Investigations into contact mechanics between stem and cement

The surface maps shown are measurements taken from an explanted Exciter (Stryker Howmedica Osteonics) femoral stem at points of increasing severity of wear.

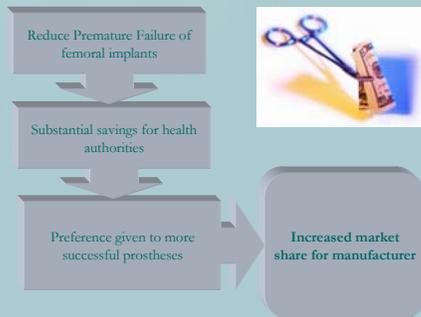


Already differences in the wear mechanism affecting matt and polished stem surfaces have been identified, matt stems undergo an abrasive form of wear causing the polishing phenomenon seen on the axonometric plots, as opposed to the classic fretting wear observed on polished stems. This knowledge of the wear of stems leads us to the future of making attempts to reduce or eradicate the wear, promoting increase longevity of hip replacements

The total cost of total hip replacement procedures in the UK is in excess of £139million per annum, the average cost of a primary procedure is £3,755 where as revision operations can cost up to three times this amount and incur a lower rate of success.

By increasing the longevity of prostheses vast savings will be made for health authorities, waiting lists could be reduced and patients could be assured longer improvements on their quality of life.

A manufacture with the knowledge to make this possible by improving established products, is placed in a prime position to increase their market share in the industry.



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Use of 3D Analysis to Investigate the Surface Replication of PMMA Bone Cement on Stainless Steel Femoral Stems



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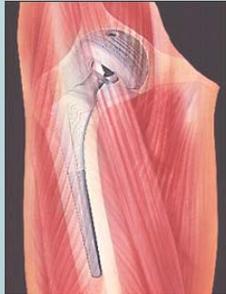


Figure 1. Total Hip Replacement

Introduction

In excess of 32,000 total hip replacements are completed each year, with a further 7,000 operations being carried out to replace those which have failed prematurely. The premature failure of hip replacement is often attributed to debris, generated by wear of the replacement joints, causing bone resorption and subsequent loosening of the joints. The aim of this study is to investigate the contact between the femoral stem and the PMMA bone cement, which is used for fixation. The aim being to establish if: the surface texture of the joint has a bearing on cement contact; and the possible method of debris transportation from the interface. In this study cement was applied to stainless steel billets of varying roughness and the surface topography of each component was studied using an optical interferometer. Analysis was also completed using 3D surface roughness parameters.

The Study

316L surgical grade stainless steel billets were produced with varying surface roughness. Four surface roughnesses were chosen to represent those found on readily available cemented type prostheses. These were categorised for reference as polished, satin, matt, and rough surfaces, as shown in table 1.

Billet Classification	Average Sq(µm)
Polished	0.06
Satin	0.20
Matt	1.02
Rough	5.21

Table 1. Billet classification and corresponding mean roughness Sq (µm)

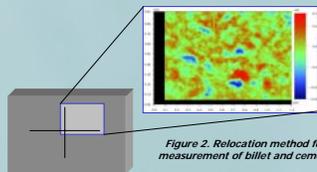


Figure 2. Relocation method for measurement of billet and cement

The billets each had 6 quadrants, laser etched at regular intervals along the billets as shown in figure 2, each quadrant was measured as indicated. The measurements were performed using a Wyko NT 2000 optical interferometer, operating in vertical scanning mode. Magnification of 5.1x gave a measurement area of 1.2mm x 0.92mm. A total of 72 measurements were taken for each of the grades of roughness.

Cement was applied to the billet quadrants using pressures akin to those used in surgery; the cement was left to cure fully before being removed. The billets were then measured again using identical measurement conditions, along with the cement samples.

The field parameter set was employed to analyse the surface topography of the billets to detect and change in topography, which was not visually evident from measurement.

Results

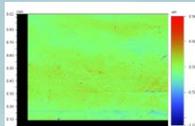


Figure 3a. Polished billet pre-cement

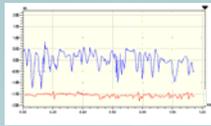


Figure 3d. Profile showing interaction between billet and cement

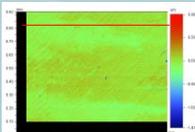


Figure 3b. Polished billet post-cement

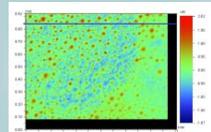


Figure 3c. Polished billet cement

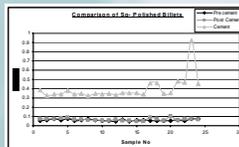


Figure 4. Difference in mean roughness for each sample measurement (Polished Billets)

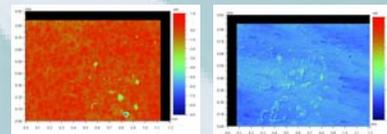


Figure 5. Evidence of cement debris on polished billets

Peaks are present on the surface of the cement for both the polished billets and the satin billets (Fig 3a-c). This indicates the possibility of shrinkage in the cement upon polymerisation, by looking closely at the peaks, it is evident that the surface of the cement has been in contact with the billet and then subsequently shrunk away as the surface topography of the billets has been well replicated by the cement both on the peaks of the cement and in the valleys.

There is evidence of residual bone cement on the surfaces of the polished billets (fig 5) from the contour plot of the surface topography an amount of debris can be seen on the surface of the billet, which corresponds to the voids present on the surface of the cement. It can also be seen that the peaks are present on the surface of the cement. Analysis of the data sets using 3D surface roughness parameters shows, on average little change of the surface of the billet yet a distinct difference in the surface of the billet and the cement. Figure 4 shows the difference in Sq, the root mean square roughness, for the billet pre cement, post cement and for the surface of the cement itself.

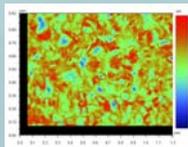


Figure 6a. Rough billet pre-cement

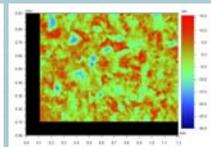


Figure 6b. Rough billet post-cement

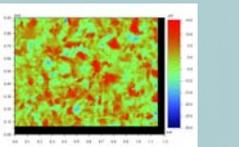


Figure 6c. Rough billet cement

Visually the two roughest surfaces, the matt and the rough (fig 6a-c), showed good surface topography replication. This was reflected in the characterisation with certain 3D surface roughness parameters for the matt surfaces, however the 3D surface parameter Sq, the root mean square deviation of the surface (fig. 7) shows a decrease in value for the billet post cementing, indicating the presence of residual bone cement left in the pits on the rough surface.

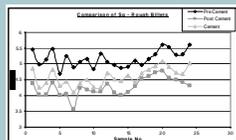


Figure 7. Difference in mean roughness for each sample measurement (Rough Billets)

Conclusions

- The surface roughness has an influence on the success of interface mechanics in total hip replacement,
- Shrinkage of the cement presents a possible explanation as to the passage of debris transportation,
- Debris left by cement in pits of rougher surfaces could contribute to third body wear,
- The presence of "Shrinkage Peaks" on the surface of PMMA bone cement indicates the stress and strain in the bone cement upon loading to be more complicated than initial thoughts,
- Further work is needed to accurately establish the implications of shrinkage on the nature of contact between varying surface roughness.



Poster Presented at NMC 2001, Harrogate, UK.