

Focal Femoral Osteolysis in Cemented Total Hip Replacement.

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Abstract

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As implant survival extends into the second and third decades focal osteolysis around cemented femoral components in total hip replacement is emerging as an important failure mechanism. Whilst the problem of focal osteolysis is well recognised, there are many aspects of its development which are poorly understood. The broad aim of this thesis is to try to provide some insights into how, why and where focal osteolysis develops around the cemented femoral component.

There are broadly two sections to this thesis, chapters 2-5 present clinical and geometrical studies and chapters 6-10 a series of experimental studies. The aim of the first section was to establish what is observed in clinical practice, the aim of the second to try to explain these findings.

A mid-term clinical study showed that focal osteolysis is more common with rough than polished stems that differed in no aspect other than their surface finish. Further studies established that focal osteolysis is probably always associated with defects in the cement mantle. These defects occur anteriorly at the mid-stem of the prosthesis and posteriorly at the component tip. The distribution of focal osteolysis and its strong association with cement mantle defects suggests the importance of the stem-cement interface as a pathway for fluid and debris to reach the distal femur. However, at 15-25 years, osteolysis rarely develops with the polished Exeter stem even in the presence of confirmed defects in the cement mantle, suggesting that the stem seals the stem-cement interface against fluid and debris.

In an attempt to explain the clinical findings a series of bench top experiments were undertaken. These studies showed that the behaviour of fluid and dye at the stem-cement interface was significantly influenced by component surface finish. Bonded and debonded stem-cement interfaces of rough stems provided an incomplete barrier to fluid movement along this interface. In contrast, polished stems both bonded and debonded were able to provide a seal at the stem-cement interface. The seal at this interface was improved with component subsidence in the presence of rotational stability.

It is believed that this thesis provides a rationale explanation for why focal osteolysis rarely develops around the Exeter stem in clinical practice. It also explains how, where, and why osteolysis develops around certain designs of cemented femoral components used in total hip replacement.

Dedication

This thesis is dedicated to my family,
and in particular
to my wife, Jenny,
to our children Lucille and Thomas,
and my parents;
and to
Robin Ling
without whom this never would have happened.

Acknowledgments

A number of authors contributed various amounts to different chapters of this thesis. The work contributed will be recognised below. In particular the contribution of Professor Robin Ling must be emphasised. He provided guidance and wisdom throughout the evolution of this project, as well as more practical assistance.

Chapter 2. The clinical material provided in this chapter was based on a series of operations performed by Graham Gie. If he had not taken the time to carefully document his operative cases this thesis never would have happened. Nita Wendover must be recognised for her assistance in the clinical review of the cases.

Chapter 5. The clinical cases on which this chapter is based are from the original series of Exeter hips performed in Exeter and followed over the years by John Timperley and Prof. Ling. Prof. Ling subsequently performed much of the radiographic review of the cases with cement mantle fractures.

Chapter 7, 8, 9. Though the concept of the experimental design in these chapters was the authors the concept would never have come to fruition without the skills of Mervyn Evans the design engineer at the Oxford Orthopaedic Engineering Centre who completed the plans which allowed the equipment to be produced.

Chapter 11. The photographs of the stem surfaces used in this chapter were provided by Jonathan Howell and are greatly appreciated.

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CHAPTER 1.

INTRODUCTION

The concept of relative barriers to polyethylene debris migration is of paramount importance to total hip prosthetic design and use.

J Bobyn et. al., J. Arthroplasty, 1995.

HYPOTHESIS

The principal hypothesis of this thesis is that osteolysis distal to the implant articulation is caused by fluid migrating along the stem-cement interface to reach areas of deficiency in the cement mantle. Where the fluid accesses endosteal bone it may lead to osteolysis as a response to wear debris or cytokines transported in the fluid, or by pressure caused by fluid being pumped along the stem-cement interface (Aspenberg 1998). Furthermore, it is proposed that the surface finish of the implant has an important influence on fluid migration at the stem-cement interface and that smooth surfaced implants, particularly those of a geometry that allows them to subside into the cement mantle, will more effectively seal this interface against fluid and wear debris than rough surfaced implants.

1.1. Overview

Total hip replacement is a successful operation that reliably relieves pain (Wilklunch 1991, Laupacis 1993). However failures do occur, with aseptic loosening recognised as the commonest cause of implant failure (Malchau 1998). Osteolysis may develop prior to and usually progresses to aseptic loosening (Huddleston 1988). This has lead to the widely accepted belief that osteolysis is one of the major problems associated with total hip replacement. In spite of this, many factors regarding how osteolysis is mediated and its distribution within the femur remain poorly understood. These factors include its anatomical distribution, its etiology, and its relationship to femoral component design. Some of these factors have been alluded to in the literature without a clear or coherent picture developing which can explain the process of focal endosteal osteolysis.



Figure 1.1. Aseptic loosening showing proximal and focal distal osteolysis in association with component loosening and subsidence.

Osteolysis adjacent to the implant articulation (Figure 1.1) can be explained as being due to direct access of joint fluid and wear particles to the endosteal bone via the bone-cement interface (Schmalzried 1992). Whether this process may occur along a stable interface or only at interfaces that remain unstable following initial migration (Moberg 1994) is not certain. What is certain is that this mechanism does not explain osteolysis occurring focally, distal to the articulation, in the presence of well-fixed bone-cement interfaces proximal to the zone of lysis (Figure 1.2).



Figure 1.2. Mid stem and distal focal osteolysis.

Focal endosteal osteolysis has been described around the middle and tip of both well fixed (Tallroth 1989, Rockborn 1993, Maloney 1990, Kobayshi 1997, Huddleston 1988) and loose cemented femoral components (Scott 1985, Anthony 1990, Tallroth 1989). Although this process is not widely reported it is not uncommon and has been seen before the onset of component loosening in 8 out of 110 matt Exeter components (Rockborn 1993) that showed no evidence of migration at the stem-cement interface at a minimum 5 year follow-up. In a series of 72 Charnley prosthesis revised for aseptic loosening 24 (34%) of prostheses had developed endosteal cavitation (Pacheco 1988) prior to revision surgery. In its most destructive form, this pattern of

focal endosteal osteolysis has been labeled as “an aggressive granulomatous lesion different from simple loosening or infection” (Tallroth 1989).

1.2. Osteolysis and stem surface finish

In the majority of series in the literature which report on endosteal osteolysis around cemented femoral components the stem has a roughened surface (Tallroth 1989, Rockborn 1993, Collis 1998, Anthony 1990, Berry 1999) (Figure 1.3). In contrast focal endosteal osteolysis appears to be very unusual in the presence of a polished stem (Hamilton 1986, Fowler 1988, Schulte 1993, Williams 1999) even at longer term follow-up.

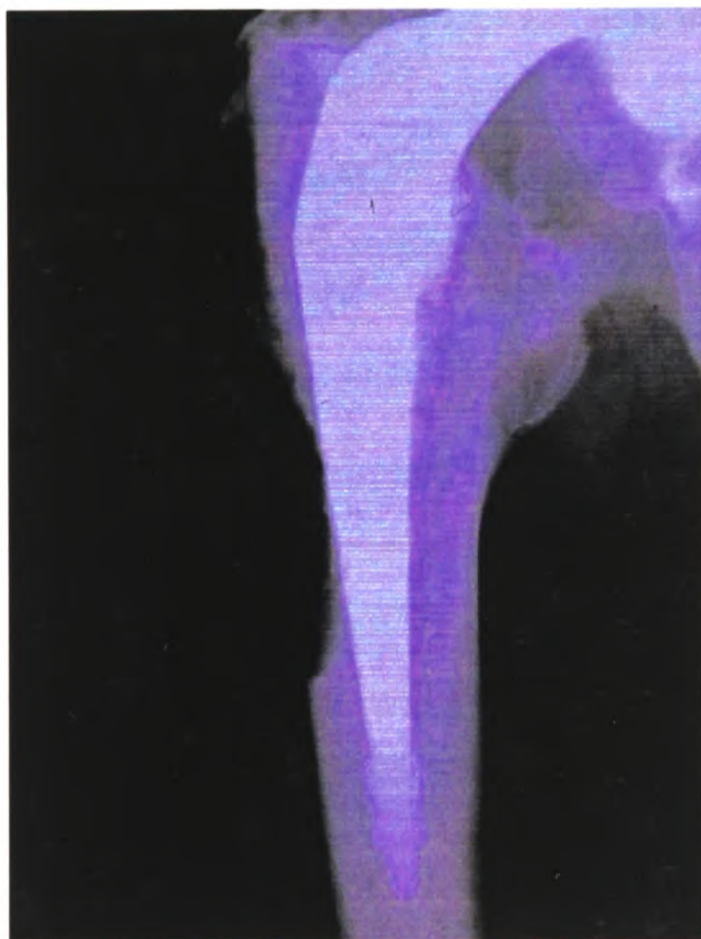


Figure 1.3 Mid-stem osteolysis with a matt surfaced Exeter component.

In the study by Collis and Mohler (Collis 1998) loosening rates and bone lysis associated with stems of different surface finish were reported. None of the polished Charnley stems showed focal osteolysis at an average 12 year follow-up with a 2.4% aseptic loosening rate. Similarly the T28 stem showed a 1.4% aseptic loosening rate and no associated osteolysis. This compared with 228 matt surfaced T28 stems at a

mean 10.5 year follow-up of which 2.2% required revision and a further 6.8% showed focal osteolysis.

Though there have been a number of changes to the Charnley stems over the years one of these changes has been a change in surface finish with the original stems being polished and the later matt. Dall et. al. (Dall 1993) found a worse outcome with the later generation Charnley stems. In the Trent hip registry (Fender 1999) there was a 5.2% gross radiographic failure rate with the matt Charnley stem with gross migration, fracture of cement or extensive lucencies by 5 years post implantation. This finding compares poorly with the series of polished Charnleys such as that reported above (Collis 1998). It must be noted that not all series of polished Charnley stems are as favourable as that reported by Collis (which was a single surgeon series by a very experienced hip surgeon). At a 3-11 year follow-up of another single surgeon series of polished Charnley stems (Hamilton 1986) a 3.5 % incidence of focal osteolysis was reported based on a review of AP radiographs alone. The true incidence of osteolysis could thus be higher than this as at times osteolysis may only be seen on lateral projections.

In a series of 110 matt Exeter stems (Rockborn 1993) reviewed at a minimum 5 years focal osteolysis was observed around 8 stems which were apparently well fixed. A further 16 stems which had subsided showed focal osteolysis. This compares to the recently reported 10 year figures for the polished Exeter stem which showed no osteolysis in over 300 stems at a minimum 10 years (Williams 1999).

Though the evidence from the literature is quite strong that osteolysis is more common around rough than polished stems, changes to the design and surface finish of femoral components are common (Murray 1995) and the consequences of such changes are often not immediately apparent. Changes are often multiple and may be accompanied by changes in operative technique. This makes comparison of results of different designs difficult, particularly when multiple surgeons are involved. Recognising this problem, the first study undertaken in this thesis, presented in chapter 2, was a prospective clinical and radiological review of Exeter total hip

replacements of differing surface finish, at 8-10 years following implantation. Stems were inserted consecutively by a single surgeon using an identical operative technique. Whilst this study assessed the clinical and radiological outcome its principle aim was to determine whether rates of focal osteolysis differed between these 2 types of stem, that were identical apart from their surface finish.

1.3 Debonding at the stem-cement interface and focal osteolysis

Debonding at the stem-cement interface, of both polished and rough surfaced stems under physiological loads, has been predicted on finite element analysis (Crowninshield 1980) and confirmed on cadaveric (Jasty 1991) studies with recent RSA studies providing evidence that migration at this interface is probably universal (Alfaro 1998). Thus all stems, even if asymptomatic, are probably at least partially debonded at the stem-cement interface and thus associated with potential channels for fluid flow along this interface. This belief, that all stems are at least partially debonded, was further reinforced by an acoustic emission and ultrasound study which concluded that "...the cement-metal interface does indeed debond under physiological loading. Furthermore this debonding occurred relatively early in the loading history..."(Davies 1996).

The femoral stem of a cemented hip replacement consists of a rod inside 2 tubes, the inner of which is of cement and the outer of bone (Shen 1998). The Exeter stem, is a polished double taper which on loading subsides into the cement mantle. The function of a taper (the criterion for which is that there should be a linear relationship between the loads needed to push the stem into the cement and the loads needed to pull it out) depends on subsidence in order to maintain a tight fit. Subsidence of the femoral component into the cement mantle transfers compressive forces on the component into radial hoop stresses in the cement. These radial forces are thought to impart more favorable stress patterns at the bone-cement interface than bonded stems (Verdonshot 1997) and explain the lack of stress shielding in the proximal femur seen with the Exeter stem (Patel 1998) and contribute to low rates of osteolysis even with component subsidence (Williams 1999).

Stems which aim to fix a rigid bond to the cement act as composite beams. Compressive stresses to the component are transmitted as shear stresses at the stem-cement and bone cement interfaces. Debonding and subsidence, at the stem-cement interface, of stems of this design, appear to have a completely different implication to that for polished stems, particularly those that are tapered, with subsidence of rough stems being associated with less favourable clinical results (Mulroy 1995). Furthermore with rough stems debonding may be associated with the rapid onset of osteolysis (Mohler 1995). In a series examining the fate of 4 different types of rough stem following debonding it was found that once stems were seen to migrate at the stem-cement interface (which happened a mean 2.6 years following implantation) rapidly progressive osteolysis developed in 93% of cases (Berry 1999).

Debonding and stem design is a complicated issue and appears to be less clinically important for polished stems even those that are not tapered. For example the original polished Charnley stem was associated with a low rate of osteolysis even though it was a single taper and had a small collar. However radiographically apparent subsidence of such stems was observed in a large percentage of Charnleys' original series (Weber 1975) often leading to a fracture in the cement mantle. Berry et. al. (Berry 1998) noted at least a 33% radiographically apparent incidence of subsidence of the polished Charnley, with 5% subsiding more than 2 mm. Though they did not comment on osteolysis they did note that stems which subsided more than 2 mm had a significantly worse outcome.

Cement mantle fractures have been described as a definite sign of component loosening (Harris 1982) and have been associated with a high incidence of focal osteolysis (Huddleston 1988). With the Charnley stem (Pacheco 1988) fractures in the cement mantle are recognised as a risk factor for component failure. A report of failures of the Bechtol stem (a matt surfaced Charnley look alike stem) showed that 28 hips had a total of 42 punch-out fractures of the cement mantle. Of these 42 fractures 27 were associated with osteolysis at the fracture site, an incidence of 64.3% (Huddleston 1988).

In an alternate view to accepted wisdom with regards to the poor prognostic sign represented by fractures of the cement mantle, Charnley, almost 25 years ago, proposed that “With an end bearing stem the distal part of the stem will be in tension and this will lead to fracture (of the cement mantle), with the result that the prosthesis will subside and take up a new, lower position in the tapered cavity, where the load will be transmitted evenly over the whole surface of the cement. Once this situation has been achieved a new situation of stability and symptomless function exists ” (Weber and Charnley 1975). This belief was reconfirmed with the good short term clinical results observed with the Charnley stem (Griffith 1978).

Cement mantle fracture is associated with component subsidence (Pacheco 1988) and osteolysis (Fender 1999) with nearly all stems designs. Even the polished Charnley stem has a worse outcome with excessive component subsidence. However in series of the Exeter stem in which large numbers of cement mantle fractures were observed component survival was good (Fowler 1988). If a polished tapered stem is associated with a low incidence of osteolysis and its subsidence does improve its stability then cement mantle fractures should have a benign outcome. This question will be investigated in chapter 3 in which the long term outcome of the Exeter stem in which fractures of the cement mantle have developed will be investigated.

The issue of component surface finish, stem subsidence, cement mantle fracture and focal osteolysis will be further explored in the discussion section at the end of this thesis.

1.4. Etiology of focal endosteal osteolysis

Since the initial belief that femoral osteolysis was due to cement disease (Jones 1987) there have been many theories postulated as to its etiology. It would be ideal if a single theory could explain focal osteolysis around femoral components, both cemented and uncemented. The access of joint fluid to endosteal bone offers such a possible explanation, and will be elaborated upon here.

Many proposed mechanisms for femoral osteolysis around cemented femoral components have been forwarded. The most widely held include; stem micromotion (Charnley 1975, Carlsson 1983), allergy to metal (Evans 1974), a tissue response to wear particles such as polymethylmethacrylate (Jones 1987, Horowitz 1993), high density polyethylene (Willert 1990, Jiranek 1993, Sabokbar 1996, Howie 1988) or metal debris (Glant 1994, Haynes 1993), a response to cytokines produced in the hip capsule and transported in synovial fluid (Nivbrant 1999) or as a tissue response to fluid under pressure (van der Vis 1998). It is possible that the above described mechanisms may act in isolation or in combination. The ultimate result is the activation of bone resorbing cells (Atkins 1997, Sabokbar 1996, Ohlin 1990), which lead to osteolysis. It is not the authors belief that the clinical and experimental work contained in this thesis is able to establish firmly which of these mechanisms is responsible for producing focal osteolysis. However it is proposed, in the first instance, to discuss how the most widely accepted theories on the development of focal endosteal osteolysis relate to this study.

Component micromotion and the presence of fragmented bone cement produced where the cement mantle is defective, are the only two generally accepted theories on the etiology of focal endosteal osteolysis, that do not imply the need for an external stimulus to gain access to the endosteal surface of the femur. In this section, evidence is considered that opposes these two theories. This will be followed by a short discussion on the evidence that exists, that it is the access of wear particles, and more probably synovial fluid under pressure, to the endosteal surface of the femur, which is responsible for the development of osteolysis around cemented femoral components.

Micromotion

It has been proposed that focal osteolysis around femoral components may be produced by motion of the femoral component against the endosteal surface of the femur (Carlsson 1983). This mechanism may explain osteolysis seen around the tip

of a femoral component which is end bearing on the endosteal surface of the femur. However there are a number of clinical observations which suggest that this mechanism can not explain most cases of focal osteolysis. The following arguments against this theory are proposed:

1. Focal osteolysis can proceed implant failure. Osteolysis may be painless and progress extensively prior to the patient developing symptoms. A stem which is moving enough to produce osteolysis, and which is end bearing, would probably be symptomatic.
2. Once osteolysis commences it can become quite extensive. This often progresses well beyond where the stem is contacting the endosteal surface of the femur. There is no question of this more extensive lysis being due directly to stem-movement.
3. There is a high incidence of focal distal osteolysis in the presence of fractures of the cement mantle and a rough surfaced stem (Huddleston 1988). In these incidences the component is rarely if ever in direct contact with the femoral cortex and thus direct contact of the stem with the femoral cortex can not be the cause of osteolysis.
4. Mid-stem osteolysis can not be explained by component micromotion on endosteal bone. The stem is usually not in direct contact with the endosteal surface around the mid point of the prostheses even with extensive osteolysis. Mid stem osteolysis can develop adjacent to components which are not in contact with the endosteal surface of the femur.
5. Osteolysis can develop around well fixed components.

The author believes that there is sufficient evidence to believe that in the majority of cases focal endosteal osteolysis is not due to the mechanical effect of stem micromotion against the endosteal surface of the femur. However, it is possible that

stem micromotion can contribute to the development of osteolysis in a different way to that previously proposed. If a debonded stem moves within the cement mantle it can act as a paddle and transmit large forces to, and through, any fluid in the stem-cement interface. This movement could pump fluid to defects in the cement mantle and produce waves of pressure which may produce osteolysis (van der Vis 1998). The author believes that it is the gradual increase in motion of rough stems within their cement mantles that leads to an expansion of the stem-cement interface as a result of abrasive wear. The motion of the stem produces the pressures necessary to force metal debris out of the stem-cement interface (as witnessed by metal particles being detected in the serum of loose and well fixed femoral components) and to pump fluid and particles to points where the cement mantle is defective, where focal osteolysis may develop.

Tissue response to bone cement.

Though there are a number of in vitro models which support the belief that there is an association between particulate PMMA and osteolysis (Horowitz 1993) the evidence is far from conclusive. Retrieval of tissue from around loose total hip replacements has shown the presence of macrophages containing PMMA (Horowitz 1993, Jasty 1991). This finding coupled with the fact that in vitro, macrophages which phagocytose small particles of PMMA (Horowitz 1993), produce cytokines which may stimulate bone resorption in mice (Tashjian 1987), has lead some authors to believe that particulate PMMA leads to bone resorption at the bone-cement interface.

In contrast to these studies more recent work has questioned the importance of PMMA in the etiology of osteolysis. In an experimental study in rabbits the response to intra-articular and intramedullary particles of zirconium oxide (which are recognised as the component of PMMA which produces a macrophage response in vitro (Sabokbar 1997)) was universally benign. In fact, in this model, new bone formation was identified around an intramedullary plug of PMMA in the presence of zirconium particles. This amount of new bone formation did not differ from controls in which no particles were present.

In the work of Sabokbar et. al. (Sabokbar 1997), particles of PMMA with and without radio-opaque additives were added to mouse monocytes and cocultured with osteoblast like cells on bone slices. The addition of PMMA alone caused no increase in bone resorption relative to control cocultures. It was only with the addition of radio-opaque markers that increased levels of bone resorption were observed. The development of focal osteolysis in the presence of radiolucent cement suggests that the PMMA cannot be implicated as the cause of osteolysis in these cases.

Further evidence against the primary role of PMMA in producing focal osteolysis is the report of spontaneous healing of a localised lytic area around the distal third of a cemented femoral component (Franzen 1995). If particles of PMMA were the cause of the lysis, their continued presence should have ensured that the osteolysis progressed. In fact, any particles which produced osteolysis would still be present, precluding them as the cause of osteolysis in this case, unless it is postulated that the delivery of particles ceased. The healing of the lesion implies a change in the mechanical environment, which may have occurred due to stem subsidence at the stem-cement interface. The fact that in this case cortical hypertrophy developed over the period that the lytic lesion healed suggests this may have been the case. An altered mechanical environment may have changed the way pressures and particles were transmitted through the effective joint space (this could occur by the stem-cement interface sealing due to a change in the conditions at the interface).

The strongest argument against the role of bone cement in producing osteolysis is the fact that osteolysis has been reported in the absence of cement (Martell 1993). In fact higher rates of osteolysis have been reported in many series of uncemented femoral components, when compared to series of cemented components. This shows without question that it is not fragmented acrylic cement which is uniquely responsible for the development of osteolysis (Harris 1996). For cement to be the particle which initiates osteolysis around cemented components requires that two different explanations, one for cemented components and one for uncemented components, are necessary for the production of focal endosteal osteolysis. Whilst this is possible, it is more reasonable

to assume a similar mechanism for osteolysis in both cemented and uncemented components. What can be stated quite simply, is that bone cement cannot be the sole agent which leads to the development of focal osteolysis around femoral components in total hip arthroplasty.

Osteolysis has been described in the absence of all wear particles except fragmented bone cement (Jasty 1986). This led to the postulate that focal osteolysis may develop as a response to fragmented bone cement. This paper has been widely quoted as evidence that focal osteolysis around apparently well fixed components is due to a response to bone cement. However, in a subsequent study Schmalzried et al. (Schmalzried 1992) re-examined the tissue from the initial study and identified polyethylene in all cases. This means that the polyethylene particles, rather than the cement, may have been responsible for the production of osteolysis. The finding of cement debris at areas of defects in the cement mantle may be incidental, and its presence alone cannot lead to the conclusion that bone cement is able to induce osteolysis. There is still no good evidence in the literature that implicates PMMA as the particle which is responsible for the production of focal osteolysis.

If the cases of Jasty et. al. (Jasty 1986) discussed above were truly stable then the fragmented cement at the zones of osteolysis must have been created at the time of component insertion. It has been postulated that this is due to incomplete polymerisation of the acrylic on the surface of the cement (Willert 1974). This hypothesis cannot explain the difference in the incidence of focal osteolysis based on stem surface finish reported in the literature. It also cannot explain the geographical distribution of osteolysis which is usually located anteriorly at the mid-stem and posteriorly at the stem-tip. If it was purely an effect of unpolymerised polymer producing osteolysis it would be randomly distributed in the femur and an equal incidence with rough and polished stems observed. Both these points will be reinforced with the work contained in this study.

A histological study by Charnley (Charnley 1968) of the bone-cement interface of well fixed components at up to 7 years showed the presence of fragmented cement

surrounded by foreign body giant cells. Whether any of the PMMA was intra-cellular was not reported, but this study did show that fragmented cement can be tolerated for long periods. In a second histological study, which will be discussed in more detail in the following section, Linder and Carlsson found fragments of cement in 5 of 13 membranes from the bone cement interface around well fixed femoral components (Linder 1986). The membranes were taken from areas where the membrane was non-progressive and there was no evidence of instability. In at least one of the cases there were foreign body giant cells in association with the fragments of cement with no evidence of localised bone resorption. This study provides further evidence that particulate cement can be well tolerated in vivo, even in the presence of a foreign body response.

Given the in vitro evidence that PMMA particles may lead to macrophage activation (Tashjian 1987) it is possible that its presence at zones of osteolysis contributes to the development of this osteolysis in vivo. However, it appears that the weight of evidence supports the fact that fragmented PMMA cannot be implicated as the principle, or even important factor, leading to the development of focal osteolysis. Its presence at zones of lysis is more probably related to the associated cement mantle defects, or the fact that it is brought to the osteolytic areas as part of the slurry produced at the stem-cement interface (vide infra), and is incidental.

Synovial fluid access to endosteal bone of the femur

If fragmented PMMA and component micromotion can be excluded as causes of osteolysis, then all current theories, which reasonably explain focal osteolysis, require the initiating stimulus to the osteolysis to be transported from elsewhere in the effective joint space. This section will briefly discuss current theories on osteolysis aside from the two described above and show that they are all consistent with the hypothesis that synovial fluid is able to gain access to endosteal bone. Some speculation as to the etiology of focal osteolysis will be presented. In the following section the more important issue of how the mediators of osteolysis reach points where osteolysis may develop will be discussed.

Wear particles

The presence of wear debris within areas of focal osteolysis is probably universal. This has led to the generally held belief that focal osteolysis is produced as a result of wear debris being phagocytosed by histiocytic cells and this in turn results in the release of factors producing macrophage-associated (Athanasou 1992) or osteoclastic (Murray 1990) bone resorption. It is worth noting that if wear debris, and in particular polyethylene, is not seen in a section from an area of osteolysis it may be due to a defect of the technique used to visualise it as particles may be difficult or impossible to identify on histological studies, even with special stains. For example, extremely small particles of UHMW polyethylene may only be detected using gas-chromatography mass spectrometry or by the measurement of melt and recrystallisation temperatures (Willert 1999). This is important, as the presence of the material used in the bearing surface of an implant confirms, without doubt, that a pathway between the joint articulation and areas of focal osteolysis is established at some time in the service life of an implant.

Metal and polyethylene particles are the most commonly implicated particles activating osteolysis though ceramic particles (Wirganowicz 1997) are also thought to be capable of initiating osteolysis *in vivo*. There has been an enormous amount of research directed at trying to understand the role of particles in the development of osteolysis over the last decade, without a consensus being reached. It is not intended to debate this issue here, but it is worth emphasising that as millions of particles are produced at bearing surfaces with each cycle of a hip implant, particles can be expected to be found at any extension of the effective joint space.

Recently there has been doubt cast on the importance of particulate debris in the production of osteolysis (Moberg 1994, Aspenberg 1996). This is based partially on the findings that micromovement and cyclical pressure may produce osteolysis (*vide infra*), on the healing of osteolytic lesions in the presence of heavy particle loads (Wroblewski 1995), and the fact that particle induced osteolysis cannot explain the

RSA findings that continued early migration equates to component loosening (Ryd 1992). This is argued coherently in a review article to which the reader is referred (Moberg 1994).

Cyclical pressure / micromovement

That pressure can cause bone resorption in vivo is well illustrated by the erosion of vertebral bodies by aortic aneurysms (Carruthers 1986) and the loss of bone caused by slow growing extra-osseous tumours. Recently the role of cyclical pressure in producing focal osteolysis in a rabbit model has been studied. Short periods of cyclical fluid pressure applied to bone produced focal osteolysis around stable titanium implants in the absence of wear particles (Aspenberg 1998). This model showed that 'fluctuating high fluid pressures in pseudo-joints can lead to osteolysis even when only present during short periods of time, provided that the pressures reach bone regions via the effective joint space'. There is also evidence that cyclical pressure, in the absence of particles, can activate macrophages to produce a number of cytokines which are implicated in the production of osteolysis in vivo (McEvoy 1999).

An experimental study in rats investigated the relative importance of micromovement and particles in producing osteolysis (Aspenberg 1996). In this study micromotion, in the absence of particles, lead to the formation of a membrane between the implant and the bone where bone resorption had occurred. The addition of polyethylene particles to this model caused no increase in the thickness of the membrane, meaning that the presence of particles did not increase bone resorption. The presence of particles at the bone-implant interface, in the absence of component motion, did not lead to membrane formation which meant there was no resorption of bone. The only effect of polyethylene particles was to limit new bone formation at the bone-implant interface once micromotion ceased. The limitation of new bone formation, proportional to the particle load, has also been observed in other experimental work (Goodman 1996). The findings of the above model suggest that

mechanical stimuli are of primary importance for prosthetic loosening. It may be that particles are only important in modulating the later stages of the loosening process.

Further evidence that bone resorption can occur in the absence of particles is seen in the growth of osteoarthritic cysts. The membrane from osteoarthritic cysts shows a similar cellular profile to that of revision membranes around failed implants and the cells from the cyst membrane produce a similar cytokine profile to that produced by the cells within the revision membrane (Jiranek 1997). The author in conjunction with others has recently shown that cells isolated from the wall of cysts associated with osteoarthritic hips are capable of producing osteoclast activation and bone resorption in the same way as cells from revision membranes (Sabokbar 1998).

Given the above evidence it is possible that fluid and particles may act synergistically to produce osteolysis. Clinically this was suspected to be the reason that led to the rapid enlargement of an osteoarthritic cyst in the proximal tibio-fibular joint in a patient with a unicompartamental knee replacement (Crawford 1998). The cyst grew to occupy most of the metaphysis of the tibia, and its rapid growth led to it being provisionally diagnosed as a giant cell tumour. Histological examination revealed the presence of polyethylene particles within the cyst. The presence of polyethylene particles within the cyst suggesting that its growth was amplified by these particles. The relative importance of pressure and particles in the growth of the cyst could not be determined. On current evidence the same holds true for the development of osteolysis in vivo around total joint replacements. The presence of particles at areas of osteolysis implies a pathway for fluid, and potentially pressure changes with implant loading, as well as for particles.

The importance of the difference in mechanical environment to osteolysis was speculated upon by Perry et.al.. (Perry 1997) as being the reason for the increased finding of erosive osteolysis around hip as compared to knee replacements. Focal (erosive) osteolysis was not seen in failed knee implants only in hips. Given that wear particles in failed hip and knee replacements are present in similar densities

(Margevicius 1994) it is reasonable to assume that the mechanical environment is important in determining the development of focal osteolysis.

The pattern and distribution of osteolysis can also give some insights into the importance of the mechanical environment. If osteolysis was mediated by particles alone, osteolysis would be expected to radiate peripherally from the joint articulation, as this is where the particle load will be greatest. In the femur progressive lysis spreading distally eroding the femur would be a common pattern of osteolysis. This is not consistent with clinical experience. That osteolysis occurs at areas where the cement mantle is defective (see chapter 4), or fractured (see chapter 3), and when it does radiate from the joint articulation, does so in a narrow band along an unstable bone cement interface, suggests the importance of pressure, as at least a contributing factor in the development of osteolysis. Furthermore the circular shape of expanding osteolytic lesions (Figure 1.4) suggest that pressure is contributing to the osteolytic process as there is no reason why particles acting in isolation should produce such a pattern.

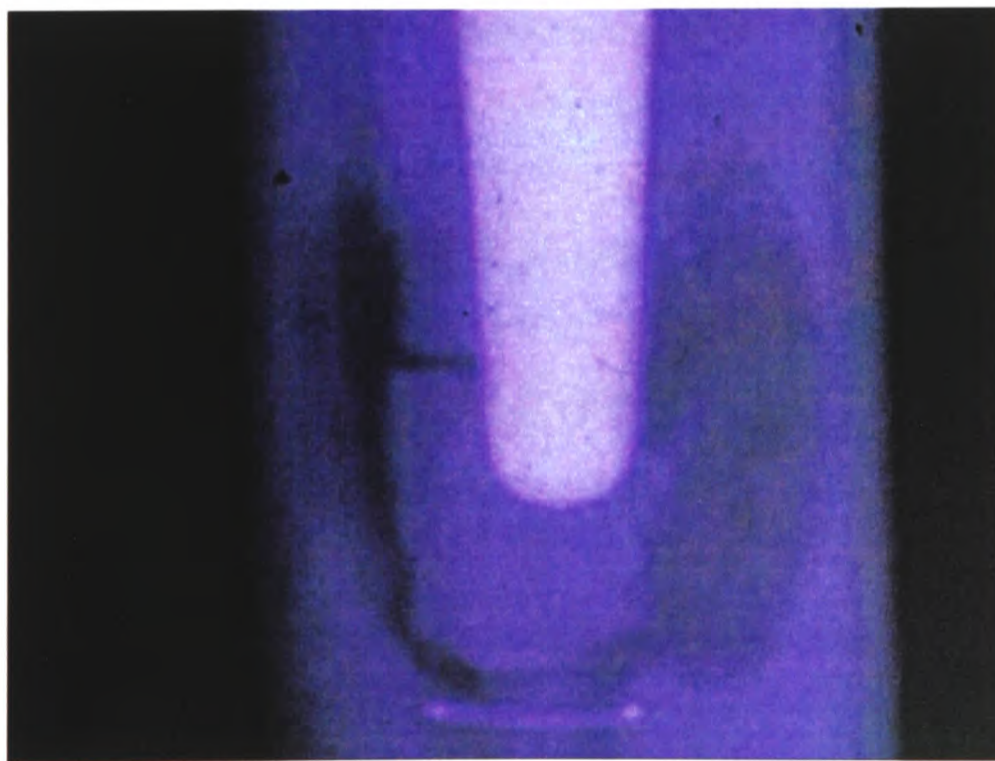


Figure 1.4. Focal osteolysis at the tip of a component showing its circular shape.

Whatever the initial stimulating factor cytokines have been implicated as activators of bone resorption around implants (Murray 1992). These cytokines are produced by activated macrophages identified from membranes around failed joint replacement. (Shanbharg 1995). However, more recently cytokines capable of activating bone resorption have been found in the synovial fluid even around apparently well fixed prosthesis (Nivbrant 1999). It was hypothesised that the cytokines are produced by macrophages in the joint capsule and these may be activated by the local environment. If these cytokines are able to induce osteolysis then they may do so where synovial fluid contacts bone. The fact that cytokines produced elsewhere in the effective joint space may produce osteolysis where they contact endosteal bone indicates the importance of the stem sealing the stem-cement interface to limit the effective joint space. Furthermore it suggests that the local environment is critical in the development of osteolysis or osteolysis could be expected to occur wherever this fluid contacted host bone, and in particular at the joint articulation.

In conclusion, the author believes that there is good evidence that the access of synovial fluid to the endosteal surface of the femur is required to produce osteolysis. The fluid may contribute to osteolysis due to pressure, due to contained particles, due to mediators of osteolysis produced at other areas in the effective joint space and transported by fluid or, most probably, a combination of these factors. Fragmented cement may modify this process, but it is probable that its presence alone is not sufficient to initiate and drive the osteolytic process. A stem which can seal the stem-cement interface against fluid, and therefore particles, will be expected, as observed in this thesis, to protect against osteolysis distal to the joint articulation, no matter what the initiating stimulus.

1.5. How may fluid and particle reach the endosteal surface of the femur?

In the last section it was argued that it is the access of fluid or particles to the endosteal surface of the femur which initiates and drives the process of focal endosteal osteolysis. Whilst the theories on how micromotion and pressure changes

may produce osteolysis are not widely accepted, this body of work adds little new information to the micromotion versus particle debate. However, given the increasing evidence that mechanical factors can produce osteolysis, an explanation of how both wear debris and pressure changes may be transmitted to the endosteal surface of the femur needs to be established, to explain focal osteolysis. It is believed that the studies which will be presented in this thesis provide important insights as to how the stimuli to osteolysis reach the endosteal surface of the femur.

The presence of polyethylene at zones of osteolysis has been well established (Willert 1993, Schmalzried 1992), and it is probably always present when polyethylene is used as the bearing surface (Willert 1999). As the acetabular component is the only implanted polyethylene, this must be the source of polyethylene particles found within areas of osteolysis. This establishes the presence of a pathway of communication between the joint articulation and areas of osteolysis. For cemented components there are three potential channels of fluid and particle transport, pre-existing anatomical channels such as lymphatics, the stem-cement interface and the bone-cement interface. In this section the relative merits of the different pathways for fluid and debris transport to the distal femur will be discussed.

Lymphatic drainage

There is no doubt that particles can be transported in the lymphatics around total joint replacements. This theory was first forwarded by Willert (Willert 1977) who has demonstrated this histologically. The detection of particles in lymph nodes (Case 1994) confirms that the lymphatic system is an important mechanism for clearing particles from the periprosthetic tissue. Further evidence that lymphatic channels can rapidly clear particles from the effective joint space is provided by an arthrographic study of painful total hip replacements (Hendrix 1983), which showed that the lymphatic channels around the hip filled in 25 of 31 patients following the injection of dye and patient mobilisation. There is however no reason, given the anatomical distribution of the lymphatic system and the way in which it functions, that lymphatic drainage should transport particles to regions of focal osteolysis. Particles seen in

lymphatics around zones of osteolysis are more likely to be been en route from their area of concentration, i.e. the lytic lesion, and being transported to regional lymph nodes. Furthermore there is no reason that lymphatics should concentrate the debris produced in an artificial joint at a point where the cement mantle is defective, at well defined points distal to the joint articulation. As a final point, it is clear that pressure changes and other mechanical stimuli to osteolysis, cannot be transmitted via lymphatics.

Bone-cement and stem-cement interface

Willert and Buchhorn (Willert 1999) question the role of the bone-cement interface as a pathway for the migration of wear particles (they in fact favour the peri-articular lymphatics as the most logical pathway of spread) and in particular ask two questions ‘How do the living tissues at the interface provide pathways that are not anatomically pre-formed, but through which wear particles can migrate?’ and ‘What are the driving forces for the particle transport along existing periprosthetic spaces?’

In cemented implants, in which the osteolysis is observed at the proximal end of the femur adjacent to the articulation (Gruen zones 1,7), these questions can be answered. In such cases it is reasonable to believe that the wear particles have gained access to the endosteal bone by passing directly along the bone-cement interface when this is not osteointegrated (Figure 1.5). This pattern of osteolysis does occur clinically and it is not being argued that the bone-cement interface, does not in such cases, provide an extension of the effective joint space which transmits mechanical and biological stimuli to osteolysis. Further evidence for this is the penetration of dye along the bone-cement interface of loose implants seen on arthrography (Hendrix 1983).

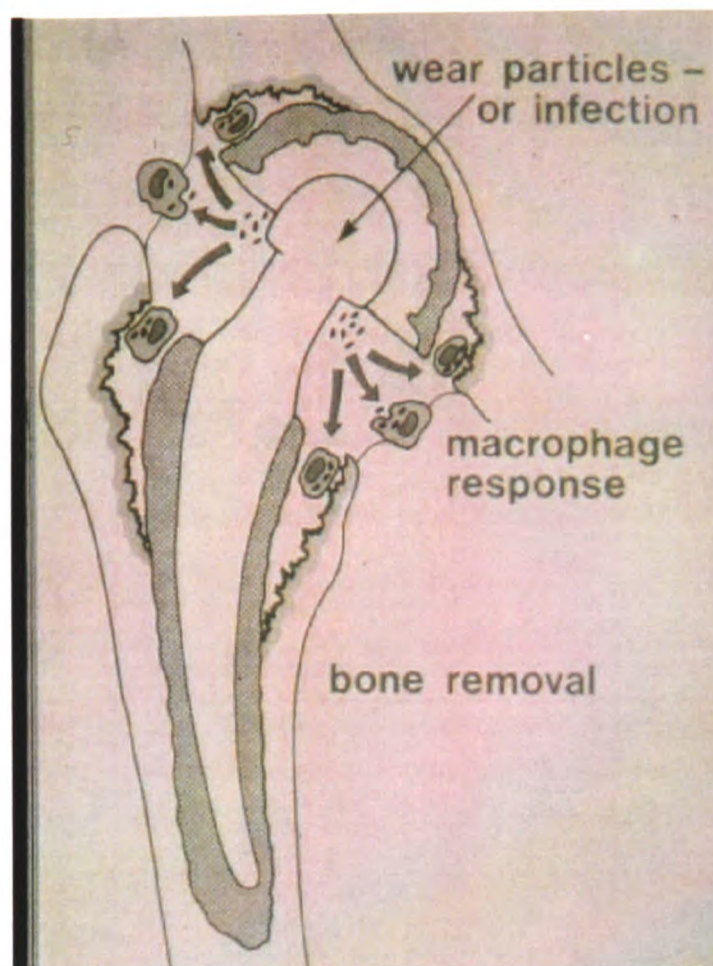


Figure 1.5. Diagrammatic representation of how proximal osteolysis may progress along the bone-cement interface (from Older 1990).

For focal osteolysis, distal to the lesser trochanter, the questions of Willert cannot reasonably be answered for fluid and particle migration, at the bone cement interface. This must bring into doubt how the bone-cement interface can be proposed as a reasonable pathway for dissemination of debris, when this interface is fully healed or osteointegrated or the site of a stable fibrous interface.

For the stem-cement interface Willert's questions are easily answered. The stem-cement interface (around certain designs of femoral component) is a newly formed pathway along which particles can migrate. The driving forces in a well fixed stem for transport at this interface are the surface phenomenon of capillary flow and contact angle flow. For debonded stems the driving force for fluid movement is the motion of the stem within the cement mantle.

The 4 cases of focal osteolysis around matt Exeter stems reported by Anthony et al (Anthony 1990) provide insights into the avenue of communication between the joint

articulation and areas of focal osteolysis distal to the lesser trochanter. These cases all showed areas of focal osteolysis adjacent to cement mantle defects. Histological study of the tissue from within the osteolytic defects revealed polyethylene particles in all 4 cases. This established that there was a communication between the joint and the osteolytic defect. In an attempt to establish what the pathway of communication between the osteolytic lesions and the joint articulation was, methylene blue was injected into the joint capsule of 3 cases prior to disarticulating the prosthesis. In both cases, dye passed rapidly to the defects via the stem-cement interface. This was confirmed by the staining of the stem and the *inside* of the cement mantle with dye. Removal of the proximal cement revealed that it was well fixed and that there was no staining at the interface between the stem and the cement. In these cases a communication between distal osteolysis and the joint via the stem-cement interface was established.

An avenue of communication between the joint capsule and the distal femur via the stem cement interface could explain, the vast majority, if not all cases, of osteolysis reported in the literature. For example Tallroth et al (Tallroth 1987), described 19 cases of aggressive osteolysis around cemented femoral components. This study reinforces a number of points made in this thesis. Firstly they only reported on AP radiographs but concluded that “ the first postoperative radiograph had shown the stem in a technically correct, neutral position. Interestingly osteolysis “appeared to start in the region of the lesser trochanter” in 10 of 12 cases in which there was proximal lysis. They also reported granulomas around the lower stem in 11 cases and around the tip in two. They concluded that the cause of these lesions, particularly around the 5 stable implants studied (i.e. with well fixed bone-cement interfaces), was unclear. However it is still possible that the osteolysis in these cases could be attributed to fluid passing along the stem-cement interface to incomplete cement mantles not apparent on AP radiographs. The importance of incomplete cement mantles seen only on lateral radiographs will be expanded below.

The same is true of cases of unexplained focal and mid stem osteolysis reported by other authors (Carlsson 1983, Jasty 1986, Huddleston 1988, Mohler 1995). In the

last of these studies, which looked at matt coated Iowa stems, focal osteolysis was identified around the tip of the component in 18 of the 20 cases which developed osteolysis. In all cases which came to revision, there was debonding of the stem from the cement and the bone-cement interfaces were 'grossly intact in areas without osteolysis. The authors were unsure as to how the osteolysis developed. The opening of the stem-cement interface to fluid and debris is the best possible explanation.

Distal localised osteolysis was reported around four 'rigidly' fixed rough surfaced implants (Jasty 1986). Three of the 4 implants were revised and were shown at the time of operation to be mechanically stable at the bone-cement and cement-implant interfaces. In at least 2 of the cases it is clearly stated that there was no evidence of a membrane at the bone cement interface proximal to the lytic lesion. Tissue was obtained from all osteolytic lesions and in all case fragmented bone cement was identified with no evidence of polyethylene. However in a subsequent study Schmalzried et al. (Schmalzried 1992) re-examined the tissue from the zones of osteolysis in the above cases, (and other cases which they had reported in the literature in which polyethylene was not identified in focal osteolytic lesions). Re-examination identified polyethylene in all cases. This meant that in the presence of a rough stem and well fixed bone-cement interfaces, polyethylene had migrated to the mid point of the component where it was found within areas of osteolysis. These cases show that in the presence of a rough surfaced implant (Jasty 1986) and mechanically stable bone-cement and cement-implant interfaces polyethylene can be found well distal to the joint articulation.

Histological studies

There is not a lot of histological work which confirms the pathway of debris migration from the joint articulation to the femur distal to the lesser trochanter. What there is usually consists of only small numbers of cases. As previously outlined, in the study of Schmalzried et al. (Schmalzried 1992), autopsy specimens with focal osteolysis were reviewed histologically. In one of these stems, longitudinal sections revealed polyethylene particles within the stem-cement interface along the length of

the prosthesis and in the area of osteolysis. There was no evidence of polyethylene particles at the stem-cement interface. This study established that the stem-cement interface of cement femoral components can be a pathway for debris transport to the distal femur (Personal communication, R. Ling).

In a case report (Draenert 1990) a well cemented component (type unspecified) retrieved 7 years after implantation 'revealed an intact cement sheath integrated to bone over the proximal two-thirds of its length'. Histologically the osteolytic area showed polyethylene particles. In this case, as in those above, the only logical conclusion, is that the particles reached the osteolytic area via the stem-cement interface.

That stable bone-cement interfaces are associated with little or no polyethylene particles was highlighted by Linder and Carlsson (Linder 1986). In this study they took biopsies from the bone cement interface of cemented femoral components with radiologically stable interfaces. They only identified polyethylene or polyacetal in 2 of 13 cases. These were both Christiansen prostheses which have had an unacceptably high failure rate (Ohlin 1990) associated with marked component wear. In the 2 cases which showed polyethylene there were rarely more than 5 particles per high powered field, suggesting that stable bone cement interfaces are not the pathway for large volumes of wear particles. This study would suggest that in the presence of a stable bone-cement interface, large numbers of polyethylene wear particles must reach osteolytic foci via another pathway. This is most logically the stem-cement interface.

Even around loose components, histological study of the soft tissue membrane between bone and cement, shows that there are few wear particles contained within the membrane (Linder 1983). That in most sections wear particles were rare or absent, suggests that even in membranes associated with loosening, the bone-cement interface is not an important pathway for particle migration.

Biopsy specimens from areas of focal osteolysis are shown to be greater than from biopsy specimens from other sites around failed femoral components (Hirakawa 1996). The finding that “the most critical factor in the pathogenesis of osteolysis is the concentration of polyethylene particles accumulated in the tissues” (Kobayashi 1997) is also more supportive of the particles reaching lytic areas via the stem-cement than the bone-cement interface. It is difficult to explain how, if particles pass along the bone-cement interface, that their concentration suddenly increases at a zone of osteolysis. Higher concentrations of particles in the membrane in lytic areas than non-lytic is logically explained by particles passing to the lytic area via another pathway.

Experimental studies

There are two widely quoted studies (Roberts 1997, Liebs 1997) which concluded that the bone-cement interface is the important pathway for particulate dispersal in total joint arthroplasty. In the first study, 12 cemented femoral components were retrieved at autopsy and exposed to fluid under pressure at the stem-cement and bone cement interfaces. In all cases fluid passed along the entire length of the bone-cement interface (it is of interest to note that it also passed along the stem-cement interface in all cases but this was ignored). This study looked at retrieved implants which were completely debonded at the bone-cement interface. When the bone-cement interface is fully debonded this interface may provide a pathway for fluid and particle transport. In appropriately selected cases the bone-cement interface will allow the passage of fluid and particles. This interface is not however a logical pathway for fluid and particle transport when it is stable. The findings on how fluid migrated around implants in this study, does not explain isolated focal osteolysis.

In a cadaveric study (Liebs 1997) a direct communication between the hip joint capsule and the distal femur was demonstrated, along the cement/bone interface in all cases. This was a remarkable study, in which a polished Muller prosthesis was cemented into a cadaveric femur. The stem was cyclically loaded for 1000 cycles and then debonded from its cement mantle. Finally the stem-cement and bone cement

interface were subjected to pressure (up to 250 mm Hg) applied at the joint pseudo-capsule. Pressures recorded adjacent to the stem tip at the bone-cement interface were 23% of that applied proximally with a figure of 11% at the stem tip at the stem-cement interface. The final conclusion was, that debonding of the stem-cement interface and the presence of mantle defects, per se, may play no role in the etiology of distal osteolytic lesions.

For pressures of 60 mm Hg to be transmitted along the bone-cement interface after 1000 load cycles there can have been no bond between the cement and the bone. This finding of complete debonding at this interface is not what occurs clinically, which means the model can offer little, or no, insight into what occurs in vivo. Furthermore, how the stem-cement interface could be dismissed as a pathway for communication between the stem tip and the joint articulation in this study is unclear. In all cases a communication capable of transmitting pressure along the stem-cement interface between the joint and the stem tip was demonstrated.

The balance of evidence from a review of the current literature suggest that the stem-cement interface is a far more important avenue for the transport of fluid and particles than has previously been assumed. It is most probable that in all cases, the pathway by which fluid and wear particles reach these defects, is the stem-cement, not an intact bone-cement, interface.

1.6 Osteolysis and cement mantle defects

Osteolysis is more common with cement mantle defects (Huddleston 1998, Maloney 1990, Jasty 1991) particularly when the stem lies in direct contact with cortical bone (Huddleston 1998, Carlsson 1983). However there are cases reported in the literature (Carlsson 1983, Huddleston 1998) in which osteolysis develops in the presence of apparently intact cement mantles. However, the presence of defects in the cement mantle are underestimated on radiographs (Barden 1995) and there are both inter-

and intra-observer errors when grading these defects (Kelly 1996). Often cement mantle defects are only observed at revision operation (Jasty 1992) or at autopsy review (Jasty 1991). This raises the question as to whether focal osteolysis can develop in the femur in the absence of cement mantle defects or whether on inspection of the cement mantle a defect will always be observed. As far as the author is aware there are no cases reported in the literature in which focal osteolysis has been identified in the confirmed absence of a defect in the cement mantle. This question will be further explored in chapter 4 where 18 cases with focal femoral osteolysis and apparently intact cement mantles on A-P radiographs were explored at the time of surgery for the presence of cement mantle defects.

The importance of an even cement mantle around femoral components, when viewed on AP radiographs, has been appreciated) but its anatomical distribution only briefly discussed and poorly appreciated. In the only identifiable published study on cement mantle defects (Berger 1997) it was concluded that incomplete cement mantles occur posteriorly at the mid-stem of a prosthesis and anteriorly at its tip. However in this model, the fact that the femoral neck arises anterior to the mid axis of the femoral shaft was ignored (Figure 1.6).

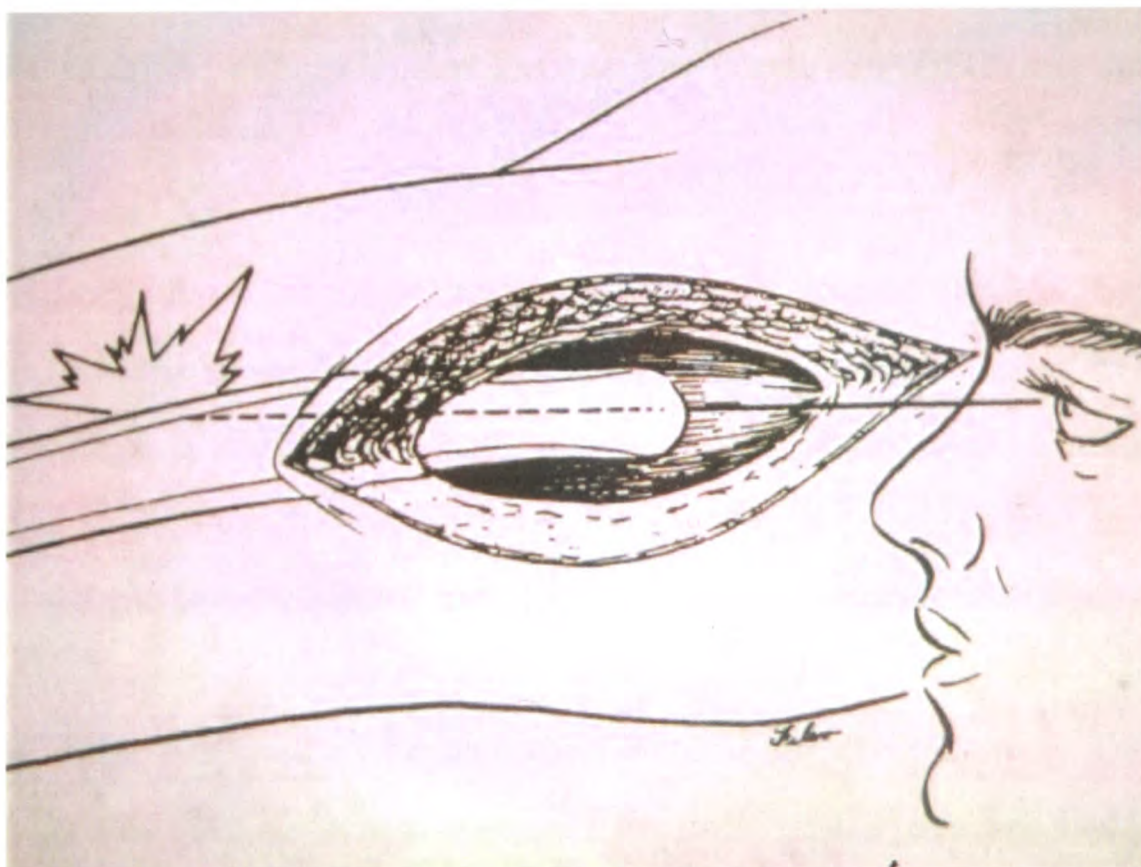


Figure 1.6. Theoretical line of femoral component when the influence of the femoral neck is ignored.

Recommendations on implant sizing and operative technique to reduce the incidence of incomplete cement mantles in the coronal plane are widely discussed (Star et al.1994, Egund et.al.1990). However there has been an almost complete disregard in the literature for the influence of the sagittal anatomy on the completeness of the cement mantle around femoral components. In an attempt to improve understanding of how defects in the cement mantle can occur and their anatomical distribution a model based on the anatomy of the proximal femur in the sagittal plane was developed. The findings of this will be presented in chapter 5.

1.7. Does a potential space exist at the stem-cement interface and how may it form?

In the previous sections it was shown that there is reasonable evidence in the literature that the stem-cement interface may be a possible pathway for communication between the joint articulation and defects in the cement mantle distal to the joint articulation. For this to be true there would need to be a space formed at the stem-cement interface. The scientific basis to this possibility will be explored in this section.

There is evidence that soon after implantation there is a space between implant and cement and that this space fills with blood or fibrous tissue (Fornasier 1976). This space may enlarge or shrink with time, depending on factors such as loading, stem geometry and surface finish. Furthermore this space may have different implications depending on these factors with regards to the long term survival of the implant.

In a study (Wang 1999) in which cemented femoral components were inserted into pig femora before being sectioned, spaces of the order of 100 microns were observed at both the stem-cement and bone-cement interface. These spaces were never

circumferential but were found in all specimens. In this model there was thus always a potential space at the stem-cement interface along which fluid and debris could migrate. These findings are consistent with those of Fornasier described above. It does appear that in vivo a space will exist at the stem-cement interface soon after component implantation and there are a number of reasons why this space may form.

As PMMA polymerises it undergoes changes in volume that are highly variable and vary throughout the polymerisation process (Haas 1975). Early work on the volumetric changes of bone cement showed a small expansion (Charnley 1970) of the cement during polymerisation. In contrast later studies on cements, which are of a similar composition to those used in THR currently, showed the reverse with a 2-5% shrinkage of the cement during polymerisation (Homsy 1972, Haas 1975). Early in the polymerisation the cement variably underwent contraction or expansion (though it never expanded when pressurised) but invariably contracted during the stage of rapid polymerisation with “..shrinkage from the maximum volume expected to produce crevices or voids at the bone-cement or cement-prosthesis interface” (Haas 1975). Differences in thermal expansion and contraction of metal and bone cement could in theory lead to a space forming at the stem-cement interface even if perfect interdigitation of cement into the rough stem occurred. The differences in the thermal properties of cement and metal have been shown, on finite element modelling, to predict a gap at stem-cement interfaces of up to 7 microns when the cement finishes polymerisation (Ahmed 1982).

A second possible mechanism that could explain how a space may develop at this interface is the differences in thermal expansion and contraction of metal and bone cement. The polymerisation of PMMA is an exothermic reaction. This reaction leads to heating of the femoral component and will cause it to expand. As the stem cools following implantation it returns to its original dimensions potentially creating a void between the stem and the cement.

Hydration of the cement mantle that occurs over the first month of it being soaked in saline (Simone 1994, Haas 1975) may lead to the formation or enlargement of the

space at the stem-cement interface. Firstly it is important to note that an increase in weight of the cement does not equal an increase in volume because molecules of water are able to enter between the polymer chains during hydration and increase the weight more than the volume. This means that any experiments which equate an increase in weight with an increase in volume overestimate the expansion with hydration.

The expansion and contraction of metals depends on the type of metal and its shape and has been well characterised in engineering. For example in thin sheets of metal with large inner diameters (such as a garbage bin) the inner and outer diameter will increase as the metal heats. In thicker blocks of metal with smaller inner diameters when heated the inner diameter decreases. The way in which the bone cement expands with hydration is important in predicting if the stem-cement interface will open or seal. If the bone cement expands both towards the stem and the femoral cortex as it hydrates then it will enhance the bond at the stem-cement interface. Alternately as it expands its inner and outer diameters may increase meaning that the cement will pull away from the stem. It may be that because the cement is contained within the tube of the femur and so it cannot expand outwards. However it is possible that if a layer of blood formed between the cement and the femur at the time of component insertion or that the necrotic implant bed is partially resorbed a space may develop into which the cement may expand. Furthermore in the animal model referred to above (Wang 1999) 10% of the bone-cement interface was found to be separated by gaps, the majority of which were less than 100 microns but some of which were up to 500 microns in size.

The way in which PMMA will behave during expansion and shrinkage cannot be predicted and cannot be modelled from first principles as it has such a complex structure. Even in the one patient the properties of PMMA are different depending on its thickness and its polymerisation history. Thin sheets of cement are stronger than thicker sheets (per unit area) and are more ductile than thicker sheets (Brown 1984). As well as thicker samples those formed in the presence of a poor heat sink are also not as strong. This means that even in the same patient the PMMA will be

heterogeneous and its behaviour will be dependant on the distribution of the cement mantle. Thus to try to understand the effects of hydration the experimental evidence becomes of fundamental importance. This is one of the issues to be addressed in the experimental models which are presented in chapters 6-10.

There are further possible reasons why a space may develop at the stem-cement interface of roughened femoral components. Even under controlled experimental conditions cement is a poor adhesive (Raab 1981, Mann 1991) meaning the fixation at the stem-cement interface of roughened stems is due to interdigitation of the cement into the asperities of the femoral component. If perfect interdigitation does not occur then a space could exist between the troughs and asperities of the femoral component and the PMMA.

Talysurf studies on the surface of roughened femoral components and their cement mantles following implantation under ideal conditions shows that the Ra is the same on both surfaces. However Ra, the difference between the peaks and troughs, represents an average roughness and does not give insight into the height of the largest peaks or the depths of the asperities on a surface (Rz). When casts of matt femoral components and their cement mantles, even those produced under ideal conditions, are examined, it is found that the peaks and troughs on the stems are larger than those measured on the surface of the cement (Ling, personal communication). This shows that perfect interdigitation does not occur between a rough femoral component and its cement mantle and that a potential space exists from the moment the stem is implanted. An example of a talysurf reading from a rough surfaced component is shown in figure 1.7. Given the surface profile it is possible to imagine how cement may not reach into the depths of the asperities of the stem.

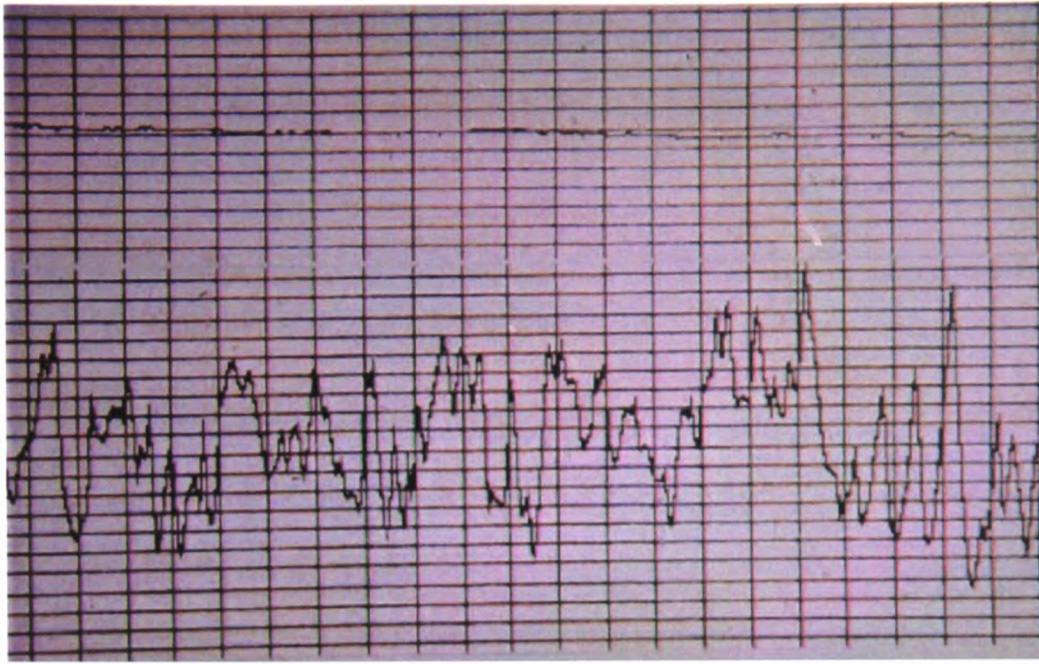


Figure 1.7. Talysurf of matt femoral component showing surface profile.

Inadequate interdigitation of the cement into the asperities of the stem thus provides a further explanation as to how a space may develop at the stem-cement interface of roughened components.

There is thus strong theoretical evidence to support the hypothesis that a space could form at the stem cement interface during the routine insertion of a femoral component. This then raises two further fundamental questions. Firstly how differences in stem design and surface finish may be predicted to affect fluid and debris movement at this interface and secondly if this has any clinical significance.

1.8. Surface finish and fluid movement at the stem-cement interface

The spread of fluids on surfaces is complex and is difficult to characterise (Adamson 1990). Like any physical process, the flow of fluid occurs because a system moves to a lower energy state. Fluid movement is thus a balance between forces resisting and forces driving this movement. The principle force preventing the spread of a liquid is its surface tension which is a result of the attraction of the molecules of the liquid for each other. The forces driving movement are surface wettability and capillary action. An example of this phenomenon in such a system is seen with thin layer chromatography in which the spontaneous flow of a fluid on a thin layer plate is

caused by the surface effects driving the spread of fluid (Geiss 1987). By entering the capillary cavities of the layer the liquid seeks to lower its surface tension and hence its free energy.

The wettability of a surface by a liquid is defined by the contact angle. This is the angle between tangents to the surface and to the drop of fluid at the edge of the drop. If the fluid covers the surface and the contact angle is zero this is defined as wetting. If the contact angle is 90 degrees it is non wetting. For the majority of fluids on a solid the contact angle lies between these values with the lower the contact angle the greater the tendency for the fluid to spread on the surface. The wetting properties of the liquid are dependant on the surface and the characteristics of the fluid including its viscosity and can be considered as a material property of the system. In a liquid which partially wets a surface (such as blood or serum on a stainless steel stem) the spread of the liquid is increased if the surface is roughened (Myers 1991). If we consider the cement and the stem of the rough stems as two approximated roughened surfaces then some of the fluid movement along this interface may have been driven by this phenomenon. The driving force for fluid along the stem-cement interface of rough stems can be predicted to be greater than that for polished stems considering purely contact angle physics.

As well as the wettability of the surface the other phenomenon which leads to the spread of a fluid on a surface is capillary action. The equation for flow by capillary action is known as the Washburn equation which is complex but shows that the rate of entry of a liquid into a capillary is proportional to the diameter of the radius of the channels. The flow rate within the capillary is represented by the Poiseilles equation

$$\text{Flow rate} = \frac{\pi r^4 P}{8 \eta l}$$

r = radius of capillary

η = viscosity

P = pressure

l = length of capillary.

Capillary spaces which presumably exist in the depths of the asperities of the stem will provide capillary channels for flow. Larger diameter channels will be responsible for the majority of the fluid flow in this instance. In the polished stems the closer approximation of the stem to the cement and the properties of the flat surface will combine to limit the spread of fluid.

These surface phenomena of surface wettability and capillary action give important insights as to the behaviour of fluids on rough and polished stems under the conditions observed in this study. In particular we can understand the spread of liquid along the stem-cement interface of the roughened components.

Whilst surface wettability and capillary action are the principle forces driving the movement of fluid along the stem-cement interface of the roughened components it is an almost impossible experiment to model mathematically. This is due to the complexity of the interface and to the fact that fluids move and flow differently at microscopic levels as to fluid flow at macroscopic levels (Knight 1998). Flow at a microscopic level is so poorly characterised and understood that conventional methods cannot be used to explain how it occurs. This shows how important experimental observation is in characterising the movement of fluid at the stem-cement interface. Such observations will be made in chapters 6 -10 in this thesis.

1.9. Uncemented Components

Though this thesis is not concerned with non-cemented implants directly, patterns of osteolysis around uncemented femoral components can provide insights into this study and visa-versa. Firstly, as outlined above, osteolysis is widely reported around

uncemented components (Agins 1988, Nasser 1990, Goetz 1994) meaning unequivocally that osteolysis is able to occur in the absence of cement. If PMMA is to be considered the principle cause of osteolysis around cemented components then a second mechanism must be surmised for non-cemented components.

A comparison of the patterns of osteolysis observed around the PCA (Howmedica) component and the Harris-Galante (Zimmer) stem show that the osteolysis occurs proximally with the PCA and around the distal stem with the Harris-Galante. In one study of 21 loose PCA stems (Learmonth 1996) all the stems showed osteolysis in Gruen zone 7 (proximal-medial portion of the stem) with no osteolytic area being located solely around the middle or distal portion of the stem. This pattern of osteolysis was also observed in all 4 of 84 PCA stems reported by Cooper et al (Cooper 1992).

As distinct to the above pattern, with Harris Galante stems the osteolysis is nearly always observed around the stem tip (Maloney 1990). Tanzer et al (Tanzer 1992) reported that in a series of 26 H-G stems with osteolysis, stable stems showed osteolysis around the distal third of the stem in 60% of AP and 70% of lateral radiographs. For loose components these percentages increased to 88% and 92% respectively.

Why these different patterns of osteolysis are observed is probably related to stem design. The PCA stem is fully porous coated proximally whilst the Harris-Galante stem is not porous coated circumferentially between the pads. This is important in considering the concept of fluid and wear particles accessing endosteal bone. In areas where an uncemented component is smooth, ingrowth will not be achieved and a pathway for fluid and particles from the articulation to the distal femur may be produced. In fact one of the designers of the Harris-Galante component acknowledged that "It is likely that the areas of smooth metal not covered by fibre mesh provide a pathway for the migration of polyethylene distally and this contributed to the location of the lysis distally with this implant" (Smith and Harris 1995).

It is also of note that of the cases of distal osteolysis in the series of H-G stems reported by Maloney et al (Maloney 1990) 14 of the 16 cases (88%) occurred in men who were active. It is not unreasonable to hypothesise that the forces pumping fluid and debris along the bone cement interface would have been greater in this population. Of further note was that in the 2 revised cases in this series polyethylene was found in the osteolytic areas around the stem tip. This is an identical finding to nearly all cases of focal osteolysis reported in the literature around both cemented and cementless prostheses.

In an animal study of non-cemented components which were partially porous coated, polyethylene, and by inference fluid, was found to preferentially migrate along the smooth interface (Boby 1995) to access endosteal bone distally. The concept of fluid migrating to reach the endosteal surface of the femur is a logical explanation for osteolysis around uncemented components, which are not fully coated proximally. In this paper the author discussed the principle of relative barriers to particle debris migration around cementless implants. Given these insights, it is surprising, that fluid and particle migration at the stem-cement interface of cemented femoral components has been almost completely ignored, in the orthopaedic literature.

In fully porous coated stems, the bone cement interface may achieve sufficient ingrowth to limit the movement of fluid and particles along the interface. Pressure and particle loads will be greatest proximally and this may explain the formation of osteolysis in Gruen zone 7 with the PCA stem. It is clearly more complicated than this for both cemented and cementless implants. For example, almost no loss of the calcar and no osteolysis in Gruen zone 7 was observed in the cases reported in chapter 2 in which it is hypothesised that there was an effective seal of the stem-cement interface. The lysis in uncemented cases is not directly related to polyethylene wear (Learmonth 1996) meaning that other factors are involved. These factors could include the mechanical environment and host factors such as hypersensitivity and immunological response.

It is important to note the fundamental difference between uncemented and cemented components with regards to surface roughness. It has been proposed that with bone ingrowth into the surface of an uncemented component the bone implant interface can be sealed. This is the complete opposite to what is seen with cemented components where the only way to seal the stem-cement interface is with a polished tapered stem. No conclusions on the type of interface of cemented stems should be inferred from the behaviour of uncemented stems or visa versa.

1.10. Summary

The ultimate aim of this thesis is to develop a model of periprosthetic osteolysis and to determine the influence of stem design and surface finish on osteolysis. Many models are used to attempt to predict how implants will behave in vivo. This body of work was performed not to predict how components may behave but rather to try to explain and understand what has been observed clinically over many years. A clinical problem, that is focal osteolysis around cemented femoral components, which is usually only seen after an implant has been in situ for a number of years was identified. Through clinical, anatomical, geometric and laboratory models a rational explanation for how, why and where this phenomenon occurred is hoped to be provided. The insights gained from this study should have important implications for the design of cemented femoral components and the behaviour of established femoral components should also be better understood.

CHAPTER 2

AN 8 TO 10 CLINICAL AND RADIOLOGICAL REVIEW COMPARING POLISHED AND MATT EXETER STEMS.

SUMMARY

In a single surgeon series of primary Exeter hip arthroplasties with 100% follow-up at a minimum of 8 years, two types of femoral component were used that were identical except for their surface finish. This differed between the two types by two orders of magnitude. None of those stems with a surface finish between 0.01 & 0.03um Ra (polished stems) were revised for loosening with one stem showing a possible zone of localised osteolysis. By contrast, one of the components with a surface finish (Ra) between 0.7 & 1.42um (matt-surfaced stems) had to be revised for aseptic loosening with associated osteolysis and three others developed localised osteolysis. These differences in the development of focal osteolysis are statistically significant by patient numbers ($p=0.038$) and by Gruen zone ($p<0.01$).

INTRODUCTION

The Exeter femoral component, first released in 1970, was originally designed with a polished surface. In 1976 the surface finish was roughened by the manufacturers. The highly polished stems have a surface roughness of 0.01 μm , the matt of 1.2 μm . This represents a difference in surface roughness of two orders of magnitude.

By 1986 it appeared that the failure rate of the roughened stems was greater than that of the polished stems, which led to the surface finish of the implant being changed back to polished. This higher failure rate of matt Exeter stems has subsequently been reported in the orthopaedic literature (Malchau 1996, Malchau 1998). As well as failing at a higher rate, the rough stems appeared to be associated with more pronounced osteolysis. However, as far as the author is aware no study, in which the only variable was the surface finish of the femoral component, has been previously undertaken to examine this hypothesis.

At the time that the Exeter stem was again polished in 1986, no other changes were made to its design. This meant that two stems were available for implantation which were identical except for their surface finish. The changes in design of the Exeter stem during its production life are presented in Table 2.1.

The purpose of this study was to determine if rates of failure, or rates of periprosthetic osteolysis, were different for matt or polished Exeter femoral components at an 8-10 year review. Stems had the same geometry and were implanted by a single surgeon using a surgical technique which was identical for all patients.

A point of terminology should be emphasised here. The terms 'smooth' and 'polished' are not synonymous. The polished stems reported in this chapter have a surface roughness (R_a), measured with a Surtronic 4 Talysurf (Rank Taylor Hobson, UK), of 0.01 to 0.03 microns. To the palpating finger, these stems feel 'smooth'. The matt stems have a surface roughness that varies from approximately 0.7 to 1.42 microns. These stems feel notably less 'smooth' to the palpating finger. However,

any stem with a surface roughness of approximately 0.6 microns or less feels 'smooth' to the palpating finger. The point to emphasise is that a roughness of 0.6 microns is an order of magnitude greater than that of the polished stems, yet both may feel 'smooth' on palpation.

Dates	Surface finish	Alloy	Sizes	Offset	Head size	Stem section	Centraliser
1970-75	Polished	En58J	2	44 mm	30 mm	Slim in AP section. Tapered up to base of neck in lateral view	Metal
1976-83	Matt	316l	5 3	44 mm 37.5 mm	30 mm	Increased by 1 mm in AP section. Parallel sided ant. & posteriorly above the shoulder	Metal
1984-85	Matt	Rex 734	As for 1976-83	As for 1976-83	30 mm	As for 1976-83	Metal
1986-88	Polished	Rex 734	As for 1976-83	As for 1976-83	30 mm	As for 1976-83	Hollow PMMA
1988 - Present	Polished	Rex 734	2 4 4	50 mm 44 mm 37.5 mm	22,26,28, 30,and 32 mm	Tapered up to base of neck in lateral view, as in the 1970-75 stems. Otherwise as for 1976-83, except for rounding of the shoulder	Hollow PMMA

Table 2.1. Modifications to the Exeter stem from its development to present.

MATERIALS AND METHODS

A consecutive series of 122 cemented Exeter (Howmedica) total hip replacements were performed in 111 patients over a 19 month period by a single surgeon. The study period was from July 1985 to February 1987. There were 72 female and 39 male patients with an average age of 70 years (39 to 87 years). Pre-operative diagnosis is presented in table 2.2.

Diagnosis	No.	Percent
Osteoarthritis	65	82.4%
Rheumatoid	3	3.7%
Protrusio	2	2.5%
Previous osteotomy	2	2.5%
Avascular necrosis	2	2.5%
Other	5	6.4%
Total	79	100%

Table 2.2. Pre-operative diagnosis.

The surface finish of the femoral components was either matt or polished. Matt stems were used exclusively until April 1986 when the polished stem was re-introduced. Both matt and polished stems were used until September 1986. Beyond this time only polished stems were implanted. All femoral components were monoblock and all had 30 mm diameter heads.

All clinical, demographic and operative technical data were recorded prospectively on structured proformata. All operations were performed using the posterior approach by a single surgeon. The surgical technique was the same in all cases. Acetabular preparation involved removal of the curtain osteophyte and decortication (where feasible) of the acetabular walls and roof. Pulsed lavage was employed to clean the cancellous bone and hydrogen peroxide soaked swabs (Hankin 1984) and pressure to control bleeding. Cement was pressurised using a balloon type pressuriser (Lee 1974). Eccentric polyethylene sockets of outside diameter varying between 44 and 56 mm and inside diameter of 30 mm were inserted, 44 being metal backed and 35 all-polyethylene.

Femoral canal preparation was performed using taper-pin reamers and Austin-Moore broaches. Prior to femoral component insertion, the femoral canal was cleaned with pulsed lavage brushed and then plugged distally. Peroxide soaked gauze was used to dry the canal. Approximately 3 minutes after the beginning of mixing, Simplex opaque cement was inserted retrograde with the use of a cement gun. Pressurisation by continued cement injection through a proximal femoral seal was continued until the cement viscosity had risen to the stage at which stem insertion was judged to be appropriate, generally about 6 minutes after the beginning of mixing. No specific measures were taken to reduce cement porosity. All matt-surfaced stems were inserted after a distal, finned, metal centraliser had been fitted, and all polished stems after the fitting of a hollow, plastic, distal centraliser designed to prevent the stem from being 'end-bearing' in the cement. Once the femoral component was inserted, a flexible 'horse collar' type proximal femoral seal was used to prevent the cement-bone interface pressure in the proximal femur falling below the intra-femoral bleeding pressure (Heyse-Moore 1982).

At 8-10 year follow-up patients were reviewed clinically and radiologically. Clinical review included an assessment of Charnley grade and scores for pain, function and range of motion. Radiographic assessment included stem subsidence within the cement using the method of measurement described by Fowler et al (Fowler 1970), the state of the medial femoral neck, and the presence of radiolucent lines at the bone/cement interface using the zones as described by Gruen et al (Gruen 1979). The integrity of the cement mantle was determined by the consensus of 2 reviewers and was based on AP and lateral radiographs. Statistical analysis was performed using the Yates modification of the chi-squared test.

RESULTS

Pre-operative Charnley scores for pain, function and range of motion were 2.2, 2.5 and 2.9 respectively.

The fate of every implant was known. At the time of follow-up 36 patients were deceased (38 hips). None of the deceased patients had had further surgery to their hips. Five patients who were too frail to travel for follow-up were contacted by telephone with none of these patients having any complaints relating to their hips and all having their original implants in situ. This left 79 hips in 75 patients which were reviewed clinically and radiologically at a minimum of 8.5 years. The average follow-up was 111 months with a range from 102 to 130 months. Mean follow-up for the matt stems was 114 months and for the polished stems 108 months. This difference was not significant.

Follow up Charnley scores for pain, function, and range of motion overall were 5.6, 5.4 and 5.8 respectively. The Charnley scores for pain and function for both the matt and polished stems were identical. Patients who had polished stems scored 5.8 for range of motion whilst the matt group scored 5.9.

Five sockets have been revised for aseptic loosening. One asymptomatic socket showed a progressive complete radiolucent line greater than 2 mm without evidence of migration and is graded as radiologically loose. All other sockets are asymptomatic with 32 being line free and the remaining 41 nearly all showing benign radiological interfaces.

Of the 79 stems which had clinical and radiological review 56 were polished and 23 matt finished.

No polished stem has been revised. Fifty-five of the 56 polished stems showed no evidence of radiolucencies at the bone-cement interface (Figure 2.1). One polished stem showed a radiolucency in zone 2 occupying less than 10% of the bone-cement interface. This radiolucency appeared benign with no evidence of cortical thinning.



Figure 2.1. Polished stem at 9 years.

Of the 23 matt stems 1 (4.4%) has been revised for loosening with associated osteolysis (Figure 2.2). The osteolysis in the failed case was focal at the mid-stem (Gruen zone 2) as well as proximally. A further 3 patients showed zones of localised osteolysis with associated cortical thinning. All cases showed zone 2 osteolysis associated with thin or deficient cement mantles seen anteriorly on lateral radiographs. Two patient also showed a focal zone of distal osteolysis associated with an incomplete posterior cement mantle (Figure 2.3). The difference in lysis rates between patients with matt and polished stems is significant ($p=0.038$). Matt stems showed osteolysis in 7 Gruen zones and polished in one. Statistical analysis comparing osteolysis by zone also showed a significant difference ($p< 0.001$).



Figure 2.2. Failed matt stem with proximal and mid -stem osteolysis.

Details on stem subsidence within the cement are presented in table 2.3. The radiographic technique for measuring subsidence is presented in figure 2.4. Ninety-eight percent of polished and 39% of matt stems subsided within the cement. This difference was statistically significant ($p < 0.001$). No case showed clear evidence of subsidence at the cement-bone interface, based purely on the plain X-ray appearances.

Distance (mm)	Polished	Matt
0	2	14
<1	13	6
1-2	41	2
>2	0	1 - (failed)

Table 2.3. Subsidence of femoral component.

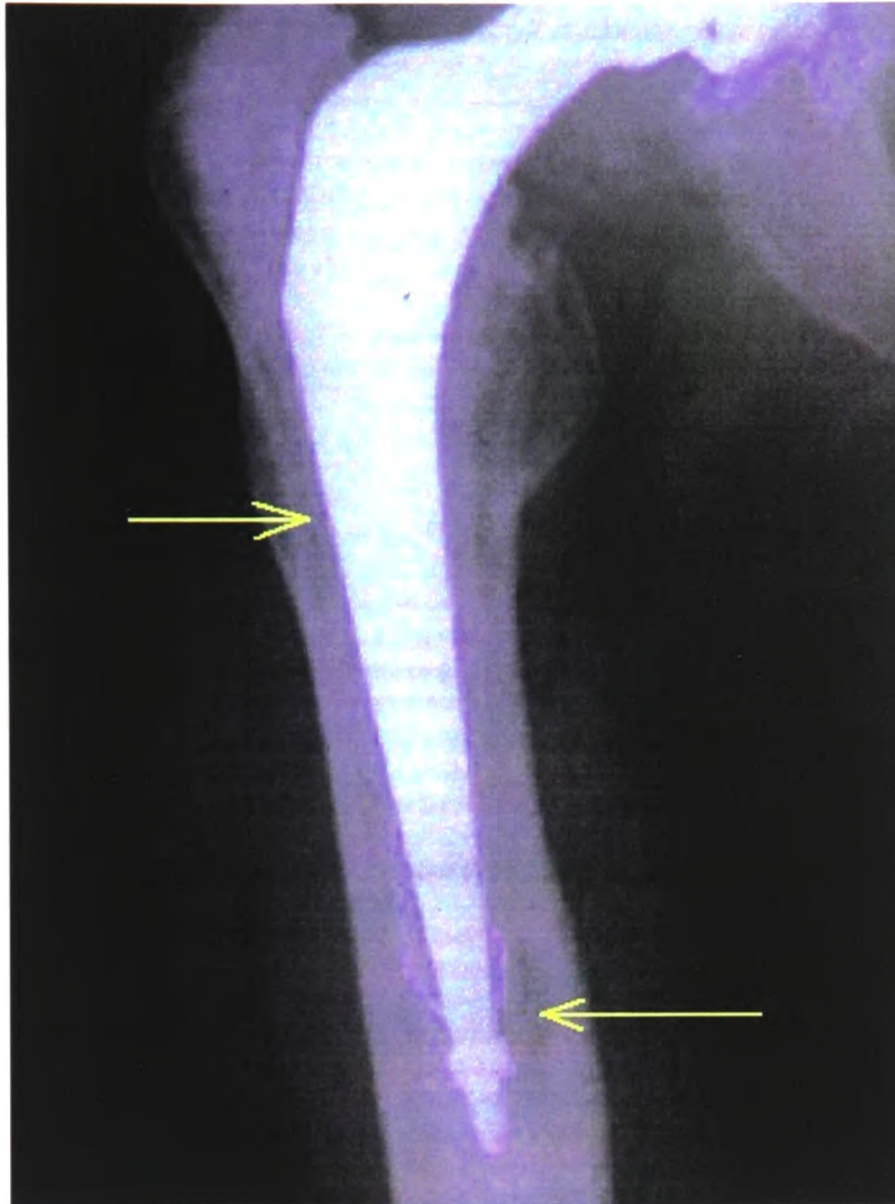


Figure 2.3. Matt stem showing focal mid stem and distal osteolysis.

Table 2.4 presents details on bone loss of the medial femoral neck. Seventy-one percent of patients with polished stems showed no evidence of bone loss at the medial femoral neck whilst this figure was 42% for matt stems.

Bone loss	Polished	Matt
Nil	40	11
Rounded	12	7
<2mm	2	2
2-5 mm	2	2
>5mm	0	1 - (failed)

Table 2.4. State of medial femoral neck.

Details of the integrity of the cement mantles, based on zonal analysis of AP and lateral radiographs are shown in table 2.5.

	Cement mantle intact	Cement mantle defective
Polished stems	86.8%	13.3%
Matt stems	87.1%	13.0%

Table 2.5. Integrity of cement mantle based on AP and lateral radiographs.

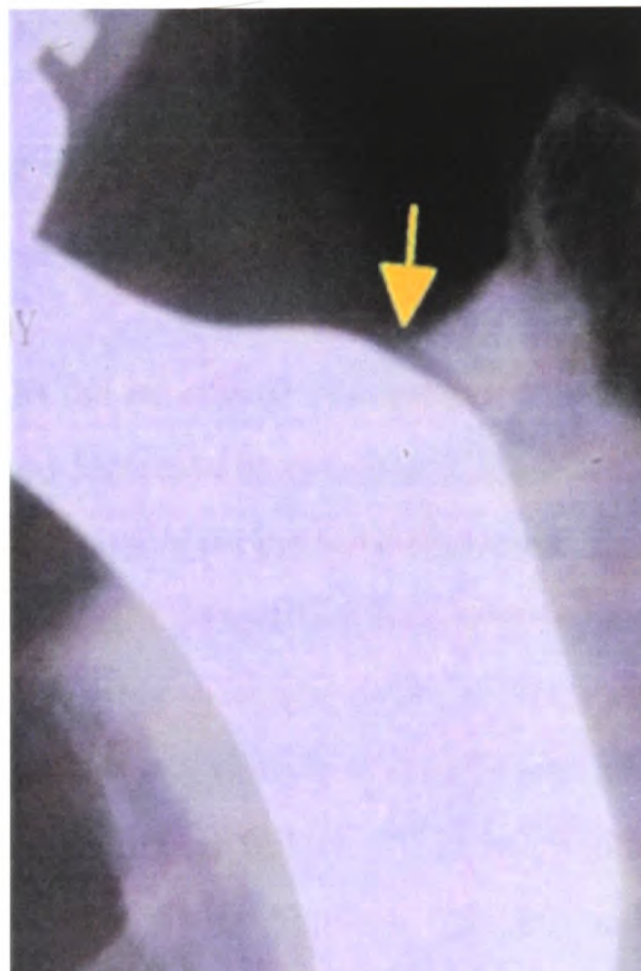


Figure 2.4. Subsidence of component within cement mantle measured at shoulder of component.

DISCUSSION

There is, first of all, an important point to be emphasised concerning the comparative behaviour of the polished and matt surfaced stems in this series, and this relates to the distinction between stem design or shape and surface finish. All the stems in this series were of identical design. The difference between the 2 groups lies purely in their surface finish. It does not necessarily follow that similar differences in surface finish will have such striking effects with other stem designs.

Significance of the difference in the incidence of osteolysis

In this series, due to the relatively small numbers, the clinical failure rate of matt stems was not significantly greater than that of polished stems. In fact, as will be expanded below, the survival of the matt Exeter was over 95% at a mean of 9 years. In spite of the fact that survivorship of the two stem types was not different the differences in the number of patients ($p=0.039$) and number of Gruen zones ($p<0.01$) which showed osteolysis was.

Focal osteolysis distant to the prosthesis articulation has been reported as occurring around matt and precoated femoral components (Callaghan 1997, Jasty 1986). This process of endosteal cavitation is a progressive phenomenon (Pacheco 1988, Carlsson 1983) and in the series reported by Huddleston (1988) all focal osteolysis progressed to component loosening. Further evidence of the importance of focal osteolysis was demonstrated by Kobayashi et. al. (Kobayashi 1997) who showed that its appearance is a predictor of subsequent implant failure. This emphasises the importance in the difference in rates of focal osteolysis between the matt and polished stems in this study. Based on the difference in the incidence of osteolysis between the two stem types observed in this study and the evidence from the literature it is reasonable to predict that the difference between the survival of the stems will widen, with more matt stems failing in the intermediate term.

Survivorship and follow-up

At 9 years follow-up in the Swedish hip registry the survival of the matt Exeter is under 90% whilst that of the polished Exeter is around 96% (the same as the matt stems in this series). Worse clinical outcome for the matt Exeter stem than observed in this series has also been reported in series from single institutions (Rockborn 1993, Howie 1998). The incidence of focal endosteal osteolysis proved to be the most important difference between the two stem types studied in the series. Without the radiographic study a falsely optimistic picture of the matt stem would have been reported. This study shows that single surgeon series can be deceptive when assessing the outcome of an implant. This suggests that a certain amount of caution should be exercised when reviewing clinical series performed by single surgeons. It is unlikely that, in general, implants will perform as well in the hands of surgeons who are not dedicated users of the prosthesis. In support of this is a recent study of the outcome of Charnley Elite prostheses in which the implant showed a significantly better outcome in the hands of the senior author than in that of more junior surgeons (Wroblewski 1998).

Although 3 of the unrevised matt stems showed marked osteolysis the pain scores in the patients with matt stems were identical with that of the patients with polished stems. The clinical findings, like the survivorship, were of no use in differentiating between the matt and polished groups. This phenomenon, of painless osteolysis, was also described by Rockborn (Rockborn 1993) who found that in 6 of 8 patients with bone lysis around matt Exeter stems the patient was pain free.

These findings suggest that clinical scores and survivorship do not necessarily provide enough information, at least at 8-10 years, to differentiate between stem types and emphasise the importance of radiographic follow-up when presenting and following clinical series.

Cement mantle

In this series a radiographic review of both AP and lateral radiographs showed incomplete cement mantles in approximately 13% of both the matt and polished

stems. The author acknowledges that radiographic grading is an inaccurate measure of the true incidence of incomplete cement mantles (Kelly 1996, Barden 1995). However, the finding that the radiographic incidence of incomplete cement mantles is the same between the two groups suggests there is no gross difference in cement mantle integrity. More importantly, as the femoral components in this series were identical in their geometry and were all inserted using the same technique, the same incidence of incomplete cement mantles could be expected in both the matt and polished groups.

The integrity of the cement mantle and its importance on the development of focal osteolysis will be further explored in later chapters. At this point it is worth noting that the four matt stems with osteolysis all showed these changes around the mid-stem (Gruen zones 2 & 6) and or tip of the femoral component and that in all cases the cement mantle appeared to be deficient at these points on lateral radiographs.

The difference in the incidence of osteolysis observed between the matt and polished stems in this study cannot be explained by a difference in the incidence of defects in the cement mantle, by the presence of cement, or by differences in surgical technique or stem geometry. As the only difference between the matt and polished stems was their surface finish it is believed that it is this difference that lead to the increase in osteolysis around matt stems.

Why are we observing a difference in osteolysis between matt and polished stems?

The difference in osteolysis between matt and polished stems relates to differences in load transmission, debris production (Hale 1990, Lee 1993) and probably, though never before investigated, periprosthetic fluid transport, along the stem-cement interface, by these two varieties of stem. This difference in periprosthetic fluid transport along the stem-cement interface of stems of differing surface finish is the fundamental issue being explored in this thesis and is modelled in chapters 6-10. The relationship between surface finish, load transmission, debris production, fluid

movement at the stem-cement interface, and focal osteolysis will be expanded in later chapters

Medial femoral neck and stem subsidence.

Though this study is principally aimed at an understanding of focal endosteal osteolysis the observations on the medial femoral neck made here have relevance to the behaviour of the implants studied. The Exeter stem is a polished double taper which on loading subsides into the cement mantle (Archibald 1991). The function of a taper depends on subsidence in order to maintain a tight fit. Radiographically measurable subsidence of the polished Exeter femoral component into the cement mantle and hollow centraliser occurred in virtually all cases in this series (98%). Subsidence of the femoral component into the cement mantle transfers axial forces on the component into hoop stresses in the cement (Miles 1991). After stress relaxation, that occurs in the cement whilst the axial load is reduced during periods of rest, the hoop tensile stresses become converted to radial compressive stresses. These radial forces are thought to explain the almost universal retention of the cortical bone at the medial femoral neck observed in this series. This finding is further supported by the lack of stress shielding in the proximal femur seen with the Exeter stem on DEXA scanning observed by Patel et al (1998).

Debonding and surface finish

At least 98% of the polished Exeter stems in this study subsided and thus are loose by the definition of stem failure proposed by Harris et al (Harris 1982). It is clear from this study that migration of the polished Exeter stem at the stem-cement interface does not represent the initiation of failure. In fact subsidence into the cement mantle is fundamental to its behaviour and it will be demonstrated in subsequent chapters that it is the subsidence of the polished stem into the cement mantle coupled with its surface finish which is thought to contribute to the low incidence of osteolysis observed around the polished Exeter femoral component in this and other series.

Conclusion

This study is a single surgeon series with 100% follow-up at a minimum of 8 years allowing a comparison to be made between femoral implants which are of the same geometry and only differ in their surface finish. There have been no revisions of the polished Exeter stem at a minimum 8 year follow-up and these stems are showing significantly lower rates of lysis than matt surfaced stems.

CHAPTER 3

CEMENT FRACTURE DOES NOT NECESSARILY PROGRESS TO OSTEOLYSIS OR IMPLANT FAILURE

SUMMARY

The aim of this study was to investigate the incidence of osteolysis in association with cement mantle fractures around polished Exeter stems implanted longer than 15 years. All surviving patients from a series of 433 consecutive polished Exeter stems were reviewed radiographically at 15 to 20 year follow-up and again at 20-25 years. There were 100 patients in the 15 to 20 year review and 49 at the 20-25 year review. Of the 100 stems reviewed at 15-20 years, 25 showed transverse fractures of the cement mantle. 17 of these fractures had been present for more than 10 years. Two patients had focal osteolysis in association with the mantle fractures. Of the 49 stems at 20-25 year follow-up there were eight punch-out fractures with no associated focal osteolysis. This meant that at 15-20 years the incidence of localised lysis adjacent to cement mantle fractures was 8 % and at a minimum of 20 years was 0 %. Osteolysis does not necessarily follow cement mantle fracture in a stem which is tapered, polished and can subside within the cement mantle.

INTRODUCTION

As outlined in chapter 1 fractures of the cement mantle in association with most stem designs have been recognised as a significant risk factor for stem failure (Figure 3.1). In fact it has been stated (Harris 1982) that fracture of the cement mantle is a definite sign of implant loosening. As well as cement mantle fractures being a risk factor for stem failure there is good evidence that fractures in the cement mantle, with certain designs of stem, are associated with high rates of osteolysis (Huddleston 1988).

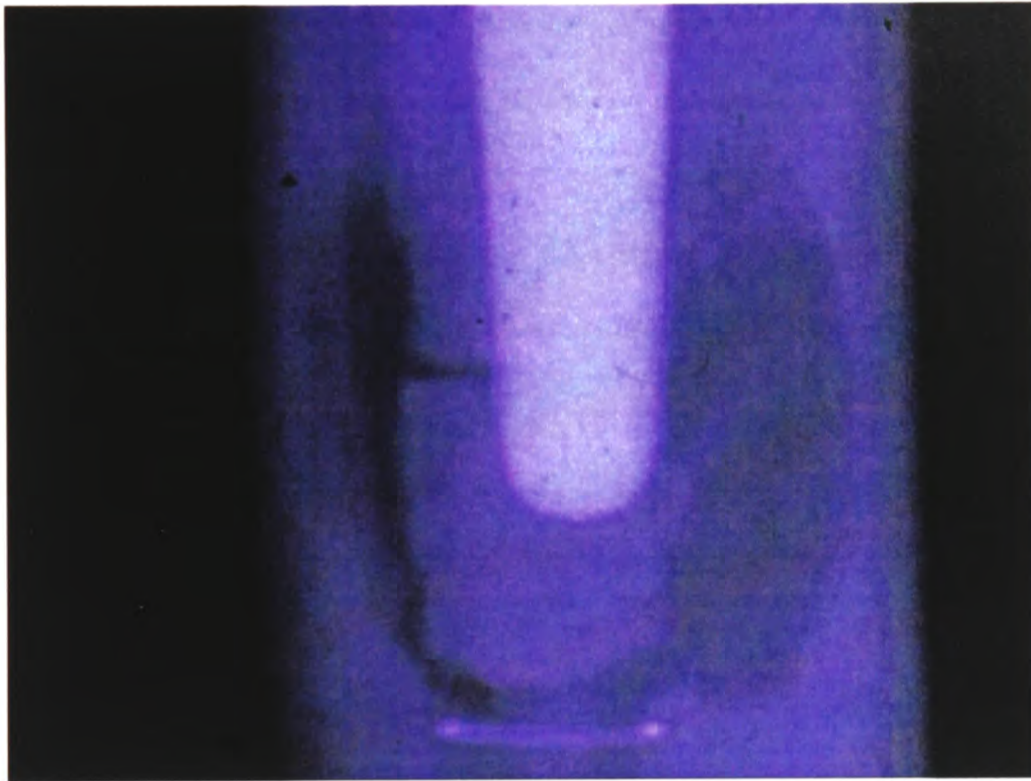


Figure 3.1 Focal osteolysis adjacent to a cement mantle fracture 4 years following implantation of a Charnley Elite prosthesis.

Cement mantle defects appear to have a relatively benign outcome with polished Exeter stems (see chapter 2). However the long term effect of cement mantle fractures around polished stems which can subside in their cement mantle is not known. The aim of this study was to study the long term outcome of cement mantle fractures around polished Exeter stems by a review of these stems that had been implanted for longer than 15 years, and had developed transverse ‘punch out’ fractures of the cement mantle.

MATERIALS AND METHODS

A radiographic and clinical review was performed of the surviving Exeter (Howmedica, Basildon, England) polished stems, from an original series of 433, (Fowler 1988, Timperley 1993). Patients were reviewed at 15 to 20 years and again at 20-25 years.

All operative data had been collected prospectively on structured proformata. All components were implanted through a posterior approach and the femoral cement (Simplex) had been introduced orthograde using finger packing. No measures to reduce cement porosity were employed, and no attempts were made to clean or dry the bone surfaces before cement insertion. No intramedullary plugs were used. All stems were highly polished with a surface roughness (Ra) measured with a Surtronic 4 Talysurf (Rank Taylor Hobson UK) of 0.01 to 0.03 microns. A finned metal centraliser was used around the tip of most of the prostheses. The components were inserted by 16 different surgeons, 13 being in training grades.

In this chapter the author reports specifically on the outcome and radiographic features of all cases with transverse fractures of the cement mantle as seen on a review of AP and lateral radiographs.

RESULTS

One hundred stems were reviewed at 15-20 years. Mean follow-up was 17 years. Twenty-five cases (25 %) in 22 patients showed punch-out fractures seen on either AP or lateral films (Figure 5.2). Seventeen of these fractures had been present for more than 10 years. Two cases showed evidence of osteolysis in relation to the punch-out fractures. These 2 cases are described in more detail below. In all other cases there was no evidence of any cortical erosion adjacent to the fracture in the cement mantle (Figure 3.3). This meant that at a mean of 17 years the incidence of lysis adjacent to a cement mantle fracture was 8 %.

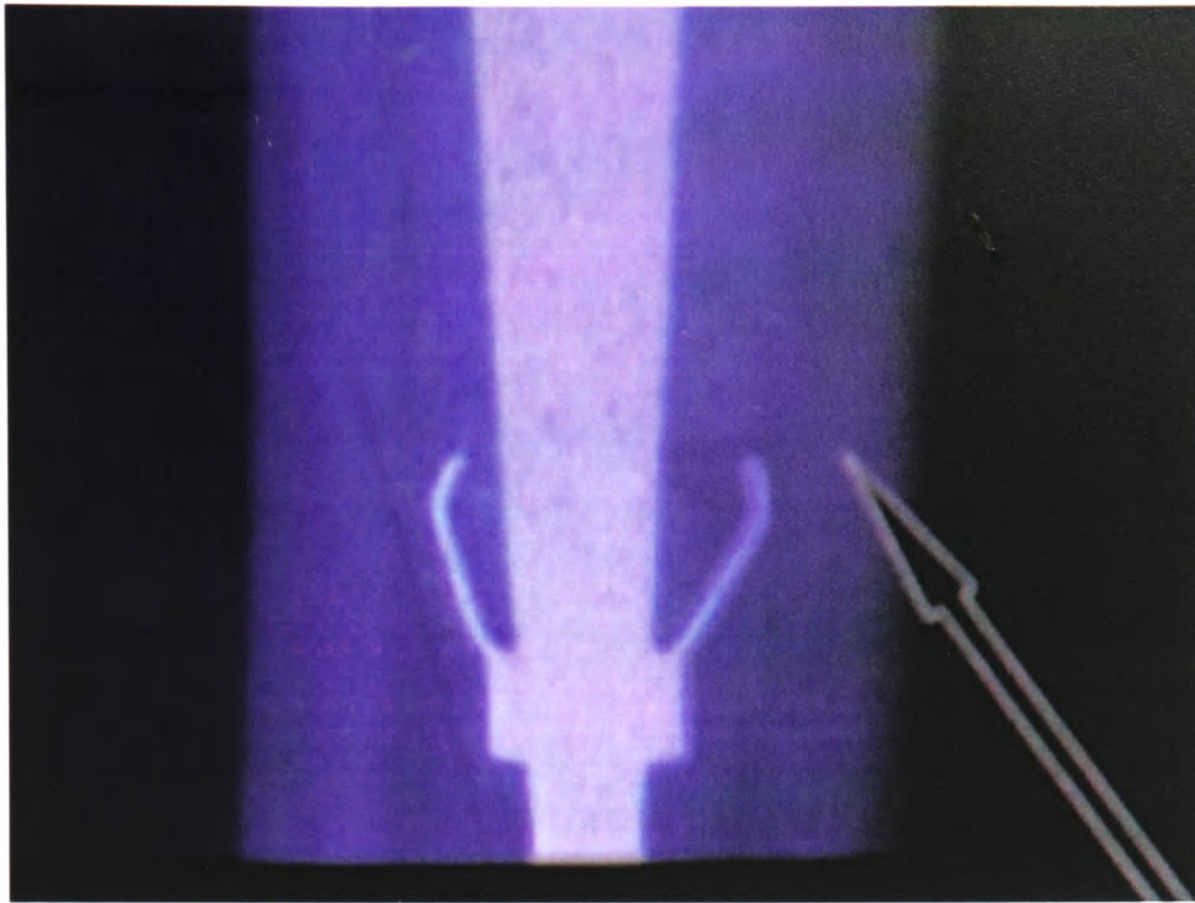


Figure 3.2 'Punch out' fracture of the cement mantle around the lower third of an Exeter stem.

Case 1. WW. Age 57 at primary surgery. Cement mantle fracture first seen at 2 year follow-up in zones 3 and 5. Remained entirely symptom free throughout his life. Radiograph at 18 years showed stem subsidence of 2 mm and a 2 cm by 0.5 cm area of osteolysis in zone 5 adjacent to the cement mantle fracture. The patient died soon after review. At post-mortem the stem was retrieved and found to be plastically deformed (Figure 3.4).

Case 2. DB. Age 62 at primary surgery. A stem-cement interface gap was seen on the immediate post-operative X-ray. At 9 years there was no evidence of a fracture in the cement mantle though the socket was loose and there was an area of osteolysis in Zone 2. At 14 year follow-up a transverse cement mantle fracture was first seen. The stem had subsided > 10 mm and there was marked pelvic and femoral osteolysis throughout all Gruen zones. Acetabular and femoral revision at 19 years.

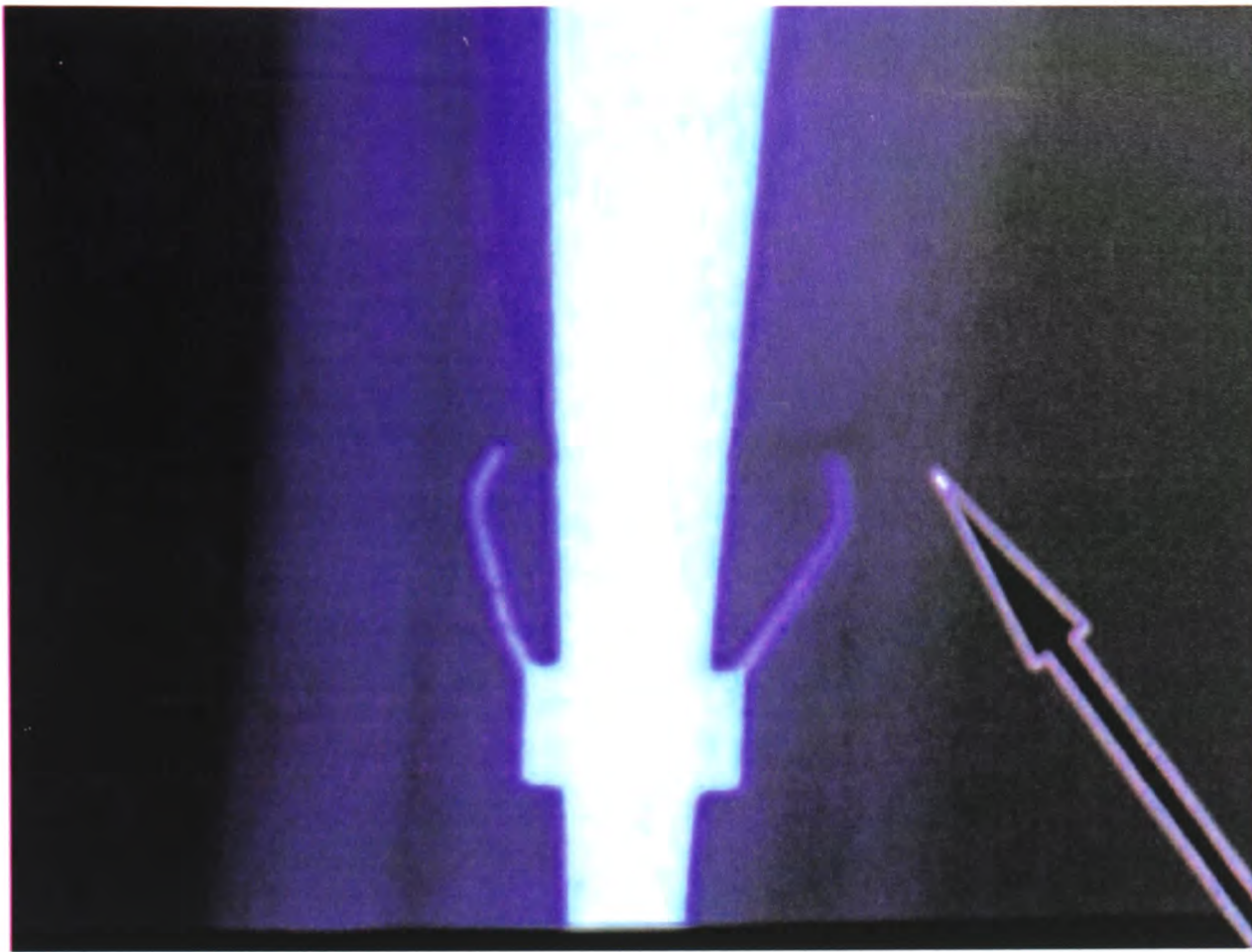


Figure 3.3. Same case as Figure 3.2 showing lack of endosteal reaction 15 years after implantation

At 20- 25 years the 49 surviving patients were again reviewed. This cohort included 8 patients with cement mantle fractures (16%). Aside from case 2 above none of the remaining 21 patients had had a complication relating to their femoral component or had had surgery as a consequence of the deficient cement mantle between the 2 review periods. Of these 8 cases none had any evidence of osteolysis relating to the cement mantle fracture, an incidence of osteolysis at a minimum of 20 years follow-up of 0%.

21 of 25 fractures (84%) at 15-20 years were located around the distal third of the stem (Gruen zones 3-5). Of the 8 fractures at 20-25 years all were around the distal third of the stem.

Of the original 433 stems there have been 12 revisions including case 2 above. Four of these revised cases (33 %) had cement mantle fractures with only 1 of these stems

showing a small zone of osteolysis. No revision in any patient in this series was performed as a result of a fracture of the cement mantle.

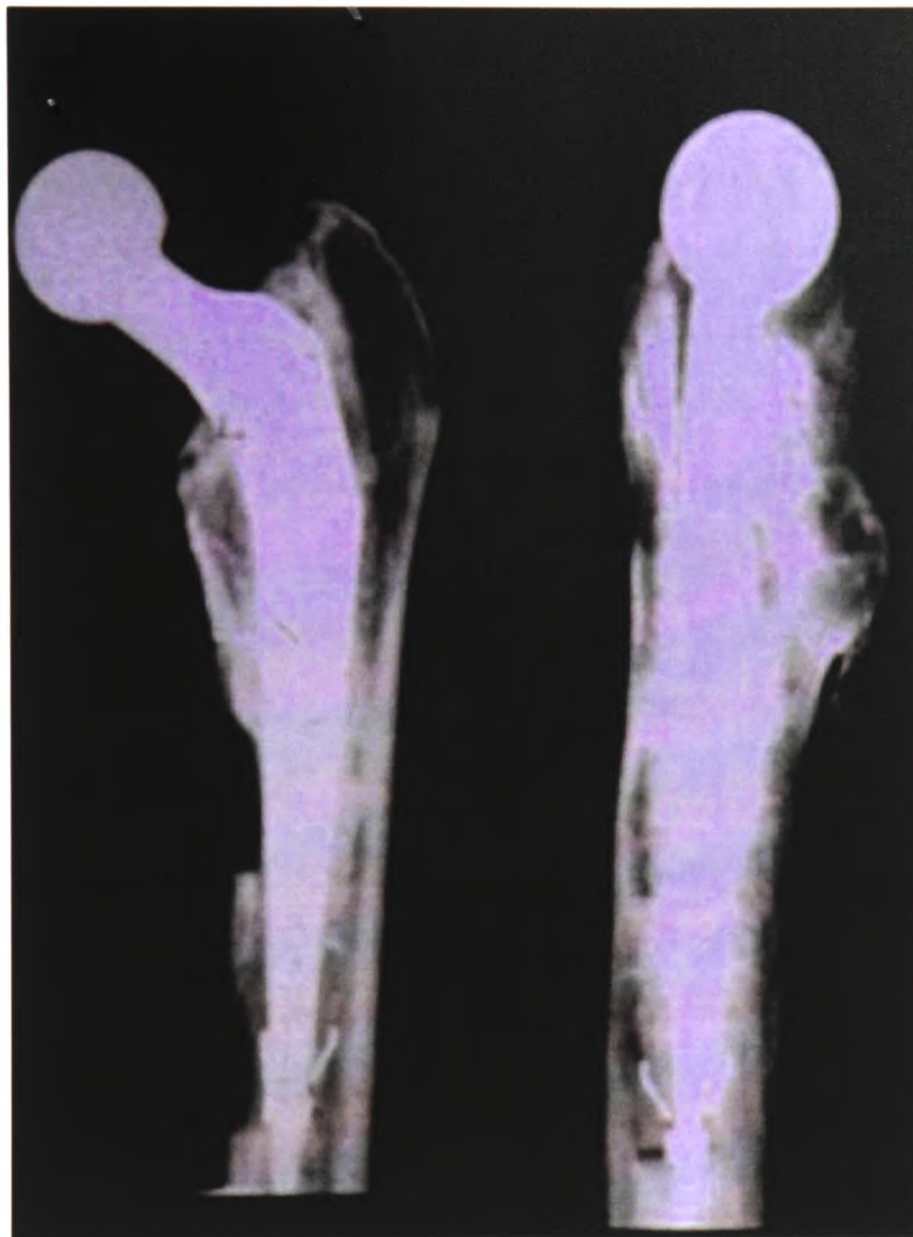


Figure 3.4 Postmortem radiograph of patient WW (case 1) showing cement mantle fracture at component tip with a zone of osteolysis. There is also an area of mid-stem osteolysis in association with a cement mantle defect.

DISCUSSION

As far as the author is aware there are no published long term studies on the outcome of cemented polished femoral components with cement mantle fractures. The findings from this study show that osteolysis and implant failure do not generally follow cement mantle fracture, of the punch-out type, at least not by 15 to 25 years, in

a stem which is double tapered, devoid of a collar, polished and can subside within the cement mantle. In this series, osteolysis was identified in 2 of 25 cases that showed punch-out fractures at 15-20 years, and in none of 8 that showed a punch-out fracture at a minimum of 20 years follow-up. This incidence of 8% osteolysis at a minimum of 15 years compares with the report of failures of the Bechtol stem (a matt surfaced Charnley look alike stem) in which 28 hips had a total of 42 punch-out fractures of the cement mantle. Of these 42 fractures 27 were associated with osteolysis at the fracture site, an incidence of 64.3% (Huddleston 1988).

The Exeter stem is designed to subside into the cement mantle and this subsidence is fundamental to the way that it behaves. The Exeter stems reported here were used with a metal centraliser and were end bearing so it is therefore not surprising that there was such a large percentage of cement mantle fractures in this series (25 % of cases at 15-25 year follow-up). The mantle fractures in this series presumably occurred as the subsiding stem increased the longitudinal tensile stresses in the cement mantle above the tensile fatigue strength of the cement. This leads to longitudinal failure of the cement mantle, and a transverse fracture, followed by variable displacement, at the cement bone interface, of the cement mantle distal to the fracture. This is supported by the fact that the majority of fractures (84%) occurred near the stem tip, where the stems were 'end-bearing'. In the cases reported in chapter 2 and other series in which the stem is used with a hollow centraliser, subsidence is almost never associated with punch-out fractures of the cement mantle. In fact it is probably not unreasonable to hypothesise that the formation of the cement mantle fractures in this series was essential to allow the stems to behave as a taper and may in fact have been important in their long term survival.

That the formation of fractures in the cement mantle is fundamentally linked to stem design was also illustrated in a series by Loudon and Charnley (Loudon 1980). They looked at a series of 100 round back Charnley stems and compared them with 75 Cobra stems (Charnley stems expanded laterally into a collar) looking at subsidence and cement mantle fractures. Subsidence was 4 times greater with the non flanged (roundback) stems and 26% of patients had fractures of the cement mantle with these

stems compared to none of the flanged stems. This showed that the addition of the flange had a profound effect on the way that the stems behaved. By decreasing subsidence it was possible to prevent cement mantle fractures but this meant that the stem was now behaving more as a composite beam than a taper (Shen 1998). It is of interest to note that Charnley felt that cement fractures with the roundback stem were benign (Weber 1975) whereas with later designs of stem the formation of fractures in the cement mantle has been recognised as a risk factor for component failure (Pacheco 1988).

The significance of fractures in the cement mantle appears to be dependent on stem design and function. It is apparent that, with the Exeter type of stem, the endosteal bone is able to tolerate not only the cement fracture, but also the distal displacement at the cement-bone interface of the cement mantle distal to the fracture, for long periods and possibly indefinitely. This raises two points of interest. First, a punch-out fracture, per se, may produce very little or no particulate polymethylmethacrylate, and little is produced by fretting movements of a polished stem against the cement surface, in contradistinction to the situation with a rougher stem (Howell 1999, Lee 1993). Second, the cement-bone interface in the region of the punch-out fracture may not be exposed to fluid flow, pressure changes, and debris from the effective joint space if a combination of stem surface finish and subsidence of the stem in the cement has excluded the effective joint space from this region of the cement-bone interface, assuming the latter is osseointegrated above the mantle fracture. This is probably a reasonable assumption, at least in this series, on the basis that the cases reported here were radiolucent line free at the cement bone interface.

Subsidence of the stem within the cement, without fretting damage to the cement, cannot occur with the Bechtol or non polished flat-back versions of the Charnley stems. With these stems, the geometry and surface finish ensures that the conduit at the stem-cement interface cannot be closed by subsidence within the cement. Furthermore abrasive wear to the inner aspect of the cement mantle occurs from micro movements between the stem and the cement. This gradually increases the internal dimensions of the cement mantle, and thus steadily destabilises the stem,

leading in turn to increased movement and abrasive damage, and probably to the development of higher cyclical fluid pressures in the effective joint space. Thus, a vicious circle is created that may culminate in stem loosening.

Stem fracture was a problem with earlier Exeter stems (Fowler 1988) and was not infrequently associated with plastic deformation of the stem into varus and retroversion. These phenomena were due to the high ductility and inferior fatigue strength of the EN58J alloy used in their manufacture. Wroblewski (1982) reported plastic deformation of a similar type in association with every fractured Charnley 'flat back' that he studied, manufactured from the same alloy. Deformation of the stem may open a conduit between the stem and the cement to allow fluid to pass along the interface and reach the cement fracture, and this conduit cannot, in the presence of a stem that is plastically deformed into varus and retroversion, be closed by stem subsidence within the cement. This probably explains how osteolysis developed in case 1 presented above and is consistent with the hypothesis that osteolysis around polished stems is low because of their ability to seal the stem-cement interface against fluid.

From this study the author concludes that cement mantle defects in the form of punch-out fractures in relation to a highly polished, collarless, stem that can subside into the cement mantle are associated with a low incidence of osteolysis. The reason that cement mantle fractures are so well tolerated is hypothesised to be due to a combination of the highly polished stem surface finish and the double tapered geometry sealing the stem-cement interface against fluid thus limiting the effective joint space. This hypothesis is the same as that proposed for the low incidence of osteolysis around the polished stems presented in chapter 2.

CHAPTER 4.

DISTAL AND MID-STEM PERIPROSTHETIC FEMORAL OSTEOLYSIS -A REPORT OF 18 CASES.

‘We defined aggressive granulomatosis as the radiographic appearance of large, focal and usually ovoid lytic areas around the prosthesis in the definite absence of infection. The lytic areas do not correspond in outline to the general shape of the cement around the prosthesis and sometimes appear to grow rapidly.’

Tallroth et. al. J. Bone Joint Surg. 1989.

SUMMARY

Eighteen cases with mid-stem or distal femoral osteolysis requiring revision total hip replacement for aseptic loosening were identified. Cases were selected in which the post-primary A-P radiographs showed a well positioned femoral component with an apparently intact cement mantle, and the pre-revision A-P radiographs demonstrated mid-stem and/or distal periprosthetic femoral osteolysis in the presence of otherwise intact bone-cement interfaces. Pre-revision lateral radiographs were then obtained for assessment and in all cases showed that the regions of osteolysis in the coronal plane were associated with and presumably caused by incomplete cement mantles in the sagittal plane. These findings were confirmed at operation.

In this series focal osteolysis was always associated with incomplete cement mantles in the sagittal plane. The deficient mantles were caused by component malpositioning in this plane.

Based on the findings of these 18 cases and by using Poisson's confidence limits for rare events (Pearson 1966) the 95% confidence limits for the hypothesis that in aseptic loosening focal endosteal osteolysis only develops in the presence of a defect in the cement mantle are 86-100%.

INTRODUCTION

Localised bony resorption around femoral stems was first described in the presence of infection (Bergstrom 1974). However endosteal cavitation is usually associated with aseptic failure of cemented femoral components (Huddleston 1998, Anthony 1990, Carlsson 1983, Pacheco 1998). Periprosthetic osteolysis can be seen around already loose components or may occur around apparently well fixed prostheses (Maloney 1990, Jasty 1986) where it may lead to implant loosening or periprosthetic fractures (Scott 1985).

As previously outlined osteolysis is more common with cement mantle defects. However there are cases reported in the literature in which osteolysis develops in the presence of apparently intact cement mantles. The fact that mantle defects may be missed on single radiographic reviews was highlighted in the cases presented in chapter 2. In these cases it was observed that the areas of osteolysis corresponded to defects in the cement mantle which were only seen on lateral radiographs. This further reinforces the hypothesis that is looked for, defects in the cement mantle will always be detected when focal osteolysis is observed.

The first aim of this chapter was to study a series of cases with focal femoral osteolysis and apparently intact cement mantles on A-P radiographs to determine the incidence of cement mantle defects in association with osteolysis. Secondly the anatomical distribution of the mantle defects and osteolysis was recorded.

MATERIALS AND METHODS

Eighteen cases requiring revision total hip replacement for aseptic loosening of femoral components were identified. Cases were selected in which the post-primary A-P radiographs showed a well positioned femoral component with an apparently intact cement mantle (Figure 4.1 (a)), and the pre-revision A-P radiographs demonstrated mid-stem and/or distal periprosthetic femoral osteolysis in the presence

of otherwise intact bone-cement interfaces (Figure 4.1(b)). Pre-revision lateral radiographs were then obtained for assessment.

The location of osteolysis on A-P and lateral radiographs was recorded using the femoral zones as described by Gruen (1979) and Johnston (1990).

The intra-operative state and distribution of the cement mantle was recorded and correlated with the radiographic findings. Tissue for histological analysis was obtained from zones of osteolysis in 7 of the 18 cases.



Figure 4.1(a) Well cemented Hinek prosthesis



Figure 4.1(b) Mid stem and distal osteolysis around the Hinek prosthesis shown in figure 4.1 (a).

RESULTS

Of the 18 revised femoral components 5 were matt Exeter (Howmedica, Rutherford, USA), 7 Charnley (DePuy, Leeds, UK), 1 Ultralock (Zimmer, Swindon, UK) and 5 Hi-nek (Corin, Cirencester, UK). The stems reflect those components commonly revised at the two centers involved in this study (Nuffield Orthopaedic Center and Princess Elizabeth Orthopaedic Hospital). Time to revision ranged from 4 to 10 years with an average of 7.3 years. All revisions were for aseptic loosening.

On A-P radiographs 4 components showed osteolysis at the level of the mid stem, 10 showed only distal osteolysis, whilst 4 showed both mid-stem and distal osteolysis. Pre-revision lateral radiographs showed that the zones of osteolysis were associated with thin or incomplete cement mantles, seen only on these radiographic views (Figure 4.2). In the 8 cases with mid stem osteolysis lateral radiographs showed thin

or incomplete cement mantle anteriorly, at or just below the lesser trochanter (Gruen zone 9). All 14 cases of distal osteolysis were associated with thin or incomplete cement mantles posteriorly (Gruen zone 12). The osteolytic area was adjacent to the cement mantle defect in all cases (Figure 4.2).

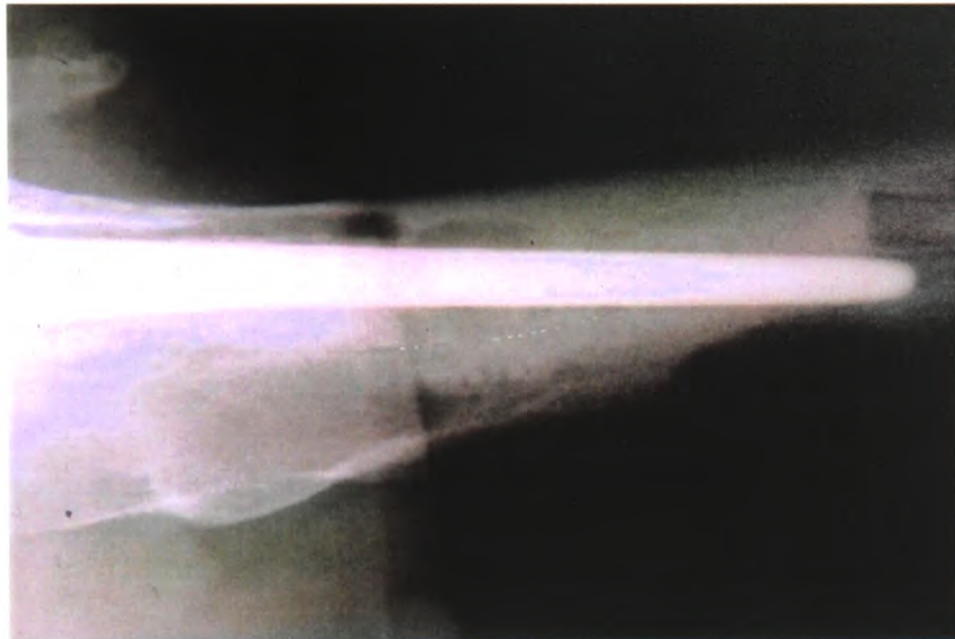


Figure 4.2 Lateral radiograph of the case shown in figure 4.1 showing mid stem and distal osteolysis adjacent to cement mantle defects

At the time of revision surgery direct observation of the cement mantle confirmed the radiographic findings, and showed that at the sites at which radiographs suggested that the mantles were thin but intact, there were, in fact mantle defects. The cement-bone interface away from the areas of osteolysis was well fixed to bone. In all cases with mid-stem osteolysis the cement mantle was deficient anteriorly at or just below the lesser trochanter. The cases with distal osteolysis showed a deficient distal cement mantle which lay posteriorly. The distribution of the cement mantle and the relationship of the femoral component were remarkably consistent. At the level of the lesser trochanter the cement mantle is thin anteriorly and thick posteriorly whilst distally the reverse is true. The femoral components were thus passing from anterior in the femoral canal proximally to lie posteriorly more distally (Figure 4.3).

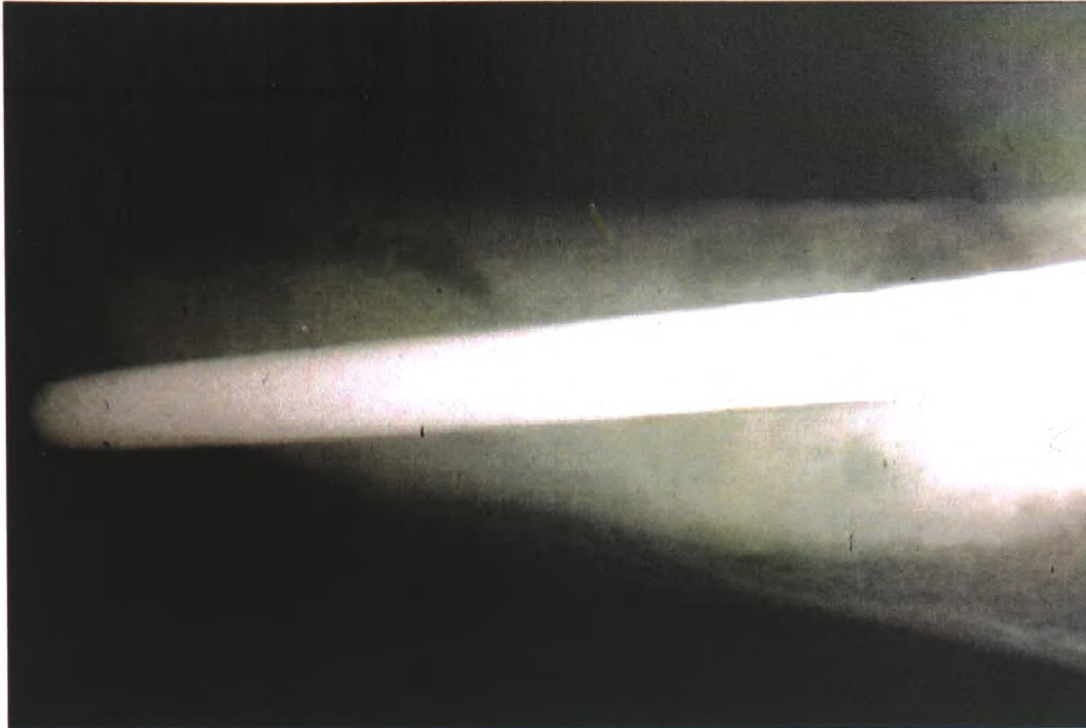


Figure 4.3 Femoral component passing from anteriorly in the femoral canal proximally to the posterior cortex at its tip.

Five of the femoral components associated with distal osteolysis were retrieved. These were all burnished on the posterior hemisphere of their tip where they may have been end bearing either on the distal end of the cement mantle or on the endosteal surface of the femur. In 4 cases tissue was obtained from zones of proximal osteolysis and in 3 from distal zones. In all cases polyethylene debris as well as fragments of acrylic cement were identified within the sectioned tissue.

DISCUSSION

Mid-stem and distal osteolysis around cemented femoral components has been previously described. However in most cases no explanation for its development is forwarded and it is still questioned how it may develop (Tallroth 1989, Carlsson 1983, Huddleston 1998). In series in which only AP radiographs are performed cement mantle defects in the sagittal plane could easily be missed. Even when AP and lateral radiographs are performed approximately 50% of defects are undetected (Barden 1995). This means that by only examining the cement mantle at the time of revision surgery can its integrity be determined. In this study of 18 cases, with a total of 26 zones of osteolysis, all zones of osteolysis were associated with defects in the cement mantle. Furthermore in the 7 lytic areas where tissue was taken for

histological analysis polyethylene was identified in all cases, confirming a communication between the joint articulation and the area of osteolysis.

It is generally accepted that periprosthetic osteolysis is caused by particles gaining access to endosteal bone by passing along the stem-cement interface. In this study the well fixed bone-cement interfaces proximal to the osteolytic lesions makes this an unlikely pathway for particles to be transported to the area of osteolysis. The 100% association of osteolysis with cement mantle defects makes the stem-cement interface the most logical pathway of communication between the joint articulation and the osteolytic area (Figure 4.4). In this study 18 consecutive cases, with a total of 26 zones of focal osteolysis, had focal endosteal osteolysis associated with mantle defects. By using Poisson's' confidence limits for rare events (Pearson 1966) it is possible to calculate that the 95% confidence limits for saying that in aseptic loosening focal endosteal osteolysis only develops in the presence of a defect in the cement mantle are 86-100%.

It is hypothesized, based on this study, that in cases in which mid-stem or distal osteolysis is observed even in the presence of radiologically intact cement mantles on AP radiographs that a cement mantle defect will always be present. If this is true then a potential avenue for communication for fluid and wear debris from the joint articulation to the osteolytic area, via the stem-cement interface always exists.

It is not being proposed that cement mantle defects always lead to osteolysis. It may be that with certain designs of prostheses cement mantle defects are less significant than with other designs. Furthermore, even with stems of the same design, as highlighted in the previous chapter, osteolysis may only occur in a percentage of cases with cement mantle defects. Clearly the relationship between cement mantle defects and osteolysis is multifactorial and complex. It does appear however, based on the cases presented here that a cement mantle defect is a prerequisite for the development of focal osteolysis distal to the joint articulation.

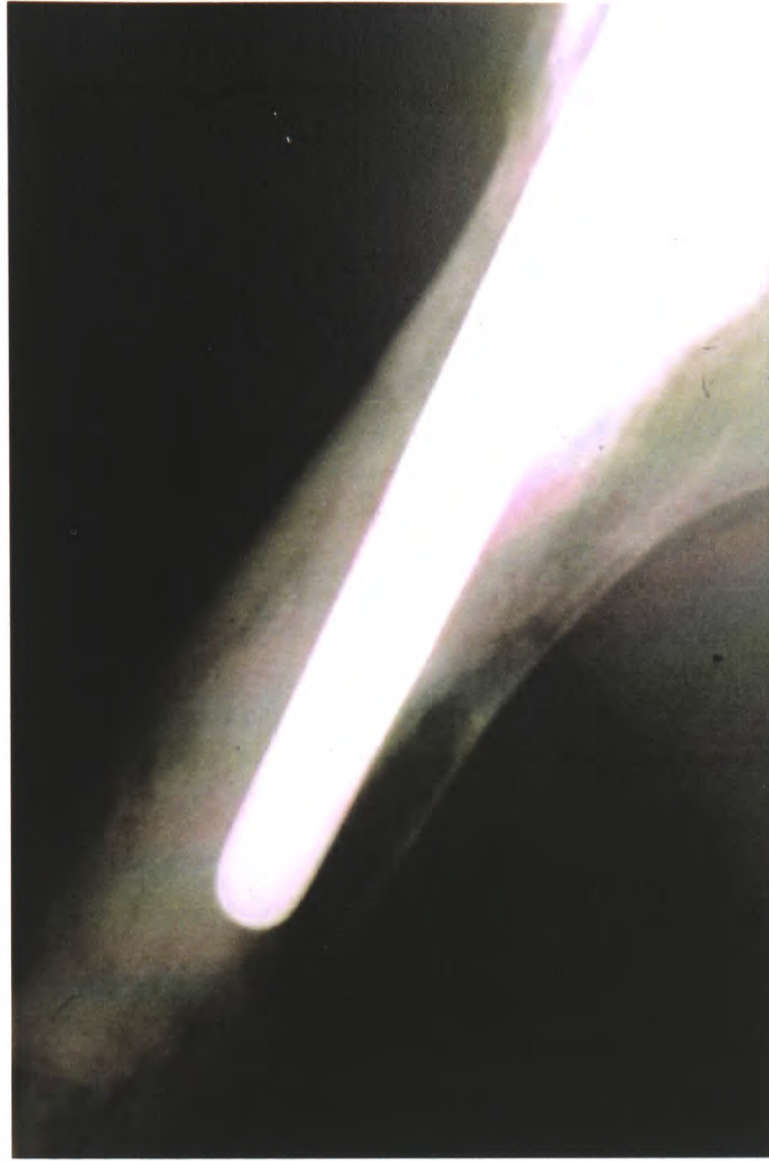


Figure 4.4 Focal osteolysis at the stem tip in the presence of well fixed bone-cement interface proximally.

CHAPTER 5.

PERIPROSTHETIC FEMORAL OSTEOLYSIS: AN ANATOMICAL EXPLANATION.

“In the prostheses without a centraliser, most cement mantle defects were present on the anterior aspect of the distal stem, a consequence of the normal anterior bow of the femur. When a straight-stemmed prosthesis is centered proximally and distally, the middle portion of the stem will be situated posteriorly in the canal because of the normal anterior bow of the femur.”

Berger et. al. J. Arthroplasty, 1997.

SUMMARY

Incomplete cement mantles around femoral components usually occur in the sagittal plane anteriorly at the middle of the stem and posteriorly at its tip. These mantle defects are produced as a consequence of inserting a straight prosthesis into a curved femur. The axis of the femoral neck is anterior to the femoral shaft and this anatomical fact contributes most to the formation of incomplete cement mantles.

Operative and design factors which contribute to incomplete cement mantles are proximal and distal stem centralisers, high neck resection and the use of long stem prostheses.

INTRODUCTION

On A-P radiographs isolated localised endosteal resorption is commonly seen around femoral stems in the region of the lesser trochanter (Gruen zones 2, 6) and at the tip of the implant (Huddleston 1998) even when the cement mantle appears intact (Scott 1985, Carlsson 1983). We saw in the previous chapter that in all cases studied the distribution of this lysis could be explained by incomplete cement mantles and that these mantle defects occurred in Gruen zones 9 and 12 (anteriorly at the mid-stem and posteriorly at the stem tip). Why incomplete cement mantles should occur at these points has been little explored. In fact there has been an almost complete disregard in the literature for the influence of the sagittal anatomy on the completeness of the cement mantle around femoral components. It is believed that it was malpositioning of the components in the sagittal plane which lead to the incomplete cement mantles, and the subsequent development of osteolysis, in the cases presented in the previous chapter.

The aims of this study were two. Firstly to determine why cement mantle defects and focal osteolysis are distributed in the femur as they are and secondly to develop a simple geometrical model of the relationship of a femoral component to the endosteal surface of the femur, based on the sagittal anatomy of the proximal femur. The aim of the model is to study how operative techniques and component design, can contribute to incomplete cement mantles. If the hypothesis proposed in chapter 4 that incomplete cement mantles are essential for the development of focal osteolysis is true, then preventing these mantle defects should decrease the subsequent development of osteolysis.

ANATOMICAL EXPLANATION

To consider how defects in the cement mantle may be produced in the sagittal plane it is necessary to consider the lateral anatomy of the proximal femur, which is complex (Husmann1997) but can be simplified by considering 3 important factors:

The femoral neck is anteverted and has a posterior bow

The femoral shaft has an anterior bow.

The axis of the femoral neck is in front of that of the proximal femur (Figure 5.1).

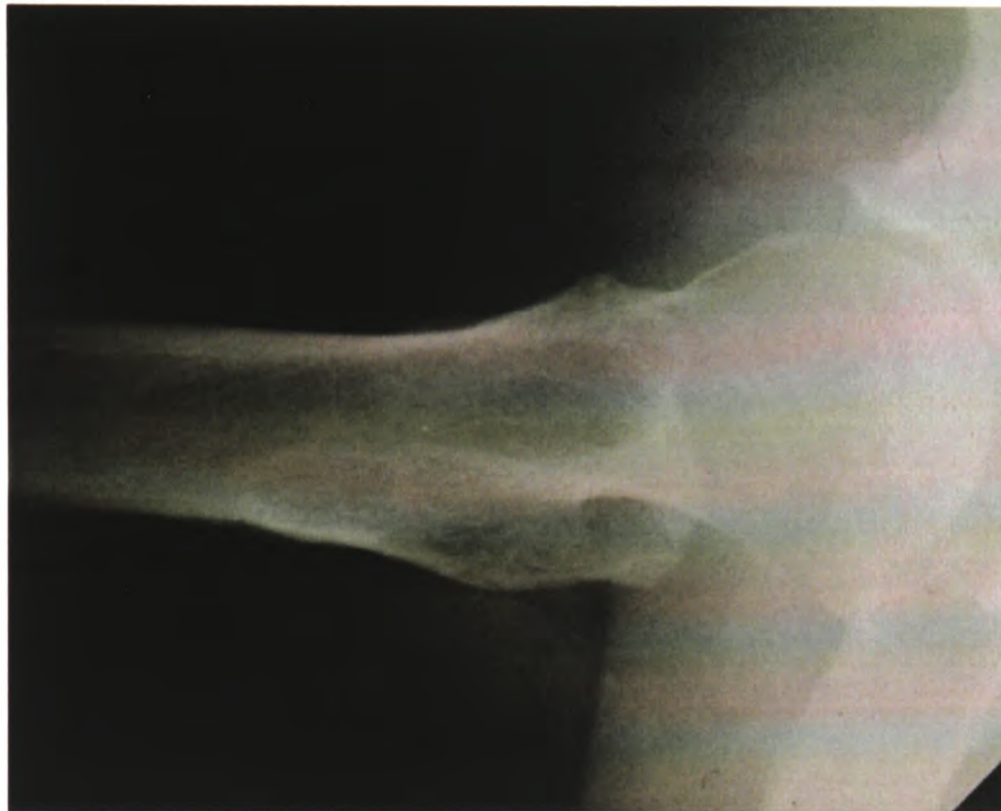


Figure 5.1 Lateral radiograph of proximal femur.

Femoral neck anteversion is reported as ranging from 13 to 20 degrees (Pick 1940, Reikeras 1983, McMinn 1994) and is increased by 6 degrees in patients with osteoarthritis of the hip (Reikeras 1983). As well as being anteverted the femoral neck arises anterior to the axis of the medullary canal. The bow of the femoral shaft averages 8 degrees with its apex anteriorly (Harper 1987). The bow of the femoral neck and shaft are defined by the point of the apex of the bow.

When a component is placed in the femur, at the point of neck osteotomy, its axis lies anterior to the axis of the femoral shaft. It has been determined from a cadaveric study that at the level of neck resection for a total hip replacement the mid-point of the femoral neck lies an average of 8 mm anterior to the projected medullary axis of the femur (Noble et al.,1988). It is this anterior entry point that determines that the

effective cavity of the proximal femur, the area available for intramedullary implants, is smaller than the actual cross-section of the proximal femur and lies well anterior to the mid-point of the femoral canal at the level of the lesser trochanter (Dai 1985). This means that the anterior edge of a component lies close to, or against, the anterior endosteal surface of the femur at or just below the lesser trochanter (Figure 5.2). Further distally the bow of the femoral shaft, and the orientation of the stem imposed by the proximal femur, means the tip of the component approaches, and may abut the posterior endosteal surface of the femur (Figure 5.2).

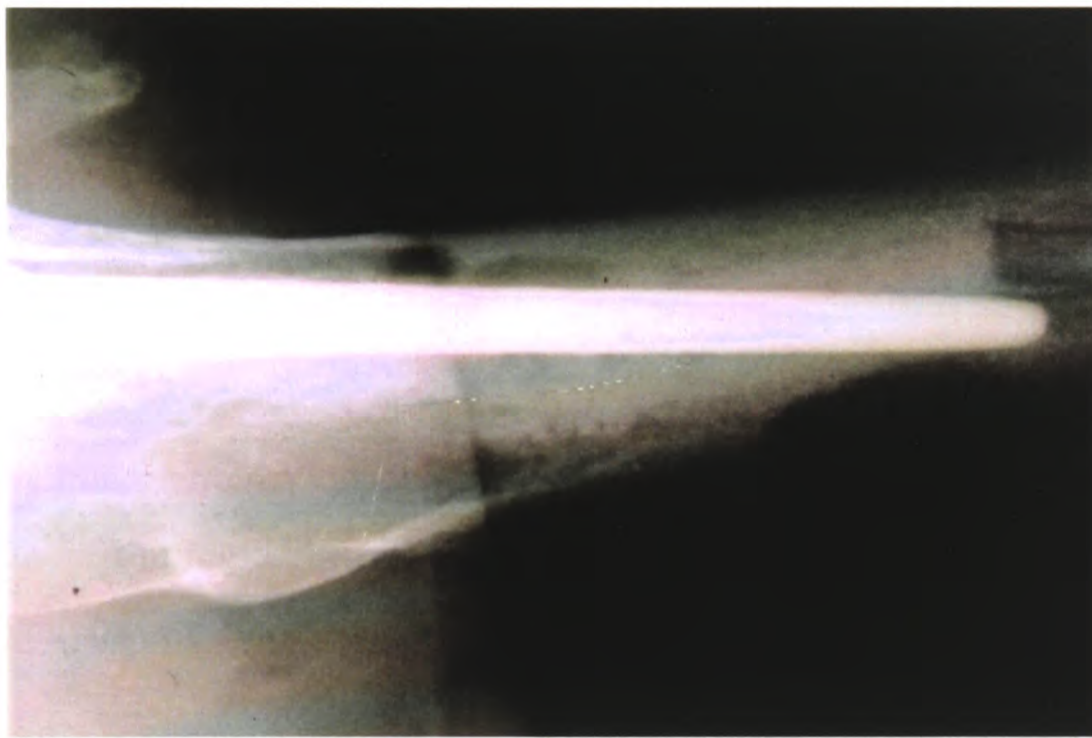


Figure 5.2. Femoral component against the anterior endosteal surface of the femur at the mid stem and the posterior endosteal surface at the tip

GEOMETRICAL MODEL

To try to understand how design features of a component and operative technique influence the formation of cement mantle defects a geometrical model based on the known sagittal anatomy of the proximal femur was constructed. Though the model can be used to produce absolute values its main aim is to illustrate how the likelihood of incomplete cement mantles is modified by implant and operative conditions. As well as using information on the femoral bow and average entry point for a prosthesis

the following published data about the average dimensions of the proximal femur was utilised.

1. The endosteal sagittal width of the femur at the level of the base of the femoral neck is 16.5 mm, at the level of the lesser trochanter it is 26.7 mm, 2cm below the mid point of the lesser trochanter it is 22.2 mm and at the isthmus of the canal it is 16.9 mm (Eckrich 1994).
2. The endosteal diameter of the femur at the level of femoral neck osteotomy is 24 mm in the sagittal plane and 45mm in the coronal plane (Noble 1988).

To complete the geometrical model the approximate point of intersection of the anterior and posterior bows of the femur and the height of the lesser trochanter were established.

The point of intersection of the bows of the femur was identified by tracing the posterior bow of the femoral neck and the anterior bow of the femoral shaft on 20 lateral radiographs of the hip.

The dimensions of the lesser trochanter were measured on 20 post-operative A-P radiographs in which the diameter of the femoral prosthetic head was used to correct for magnification.

Using the above anatomy the relationship of a cemented femoral component to the endosteal surface of the femur was then established. The femoral component was modelled on the Exeter femoral component. The length of the component modelled was 130mms from neck-stem junction, its sagittal width was 10mms at the junction of the proximal and middle thirds, and approximately 5mms at the tip of the stem. The offset of the component was 44 mm.

RESULTS

Radiographic study

The anterior and posterior femoral bows of the femur were always found to intersect at approximately the level of the mid point of the lesser trochanter. This measurement, it is accepted, is not highly precise. The only way of establishing this point exactly would be using perfectly reconstructed sagittal CT scans of the proximal femur. As we can see from Figure 5.1 the relationship of the femoral neck to the proximal femur is not perfectly described by a bow. However for the establishment of this relatively simple geometrical model the point of intersection is sufficiently accurate. The height of the lesser trochanter averaged 25.6 mm with a range from 19 to 31 mm.

The relevance of the above investigations to the model should be explained. As we are concerned with incomplete cement mantles anteriorly around the middle third of the stem it is necessary to establish the point where the anterior endosteal surface of the proximal femur is most likely to contact the femoral component. If we consider the endosteal dimension of the proximal femur as consistent then this point is that at which the bows of the proximal femur intersect.

The height of the lesser trochanter is essential for determining the distance that the level of the femoral neck osteotomy lies above the mid point of the lesser trochanter.

Calculations

A standard femoral neck resection for total hip replacement is completed one fingers breadth (approximately 13 mm) above the top of the lesser trochanter and is angled from medial to lateral at approximately 45 degrees. The mid-point, in the coronal plane, of a routine femoral neck osteotomy cut in a standard fashion, that is beginning 13 mm above the lesser trochanter and sloped at 45 degrees, will lie 28.5

mm above the plane of the top of the lesser trochanter ($13 + 0.5 \times \text{coronal width of canal} \times \sin 45$). This places the cut approximately 40 mm above the mid-point of the lesser trochanter (Figure 5.3).

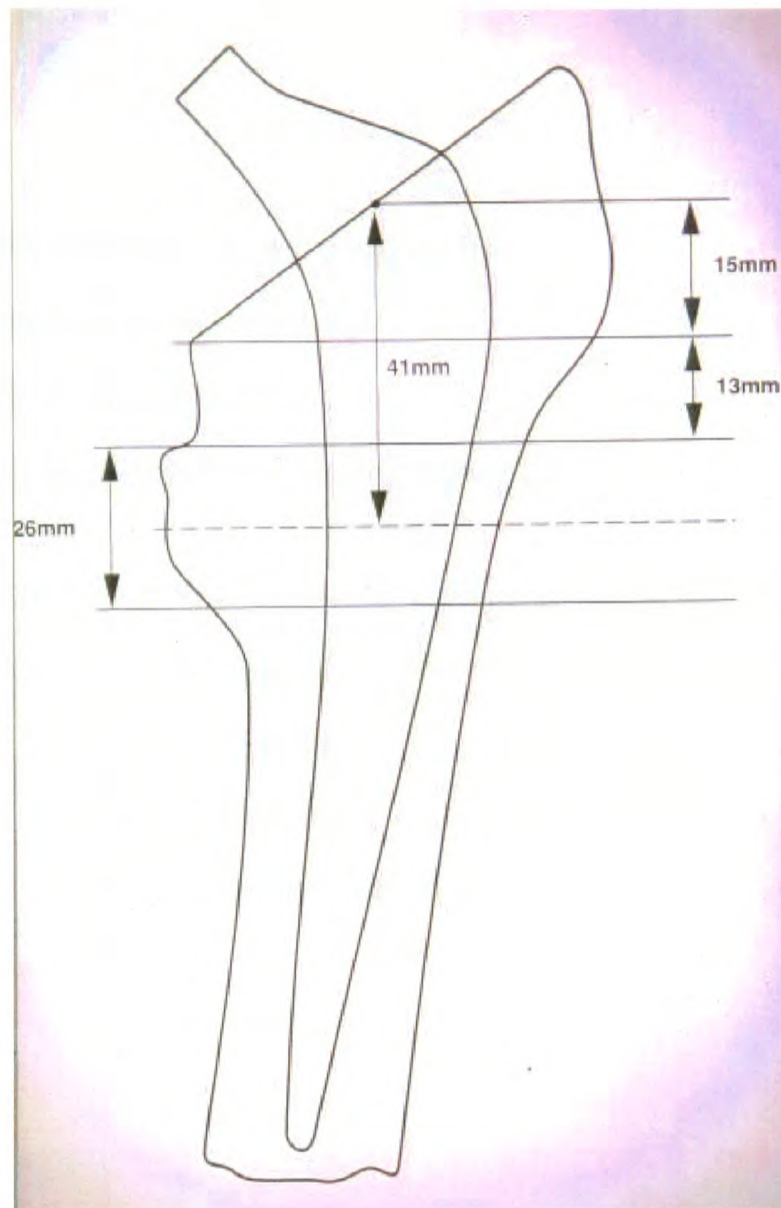


Figure 5.3 Diagrammatic representation of level of femoral neck resection for routine cemented total hip replacement

The mid-axis of a femoral component placed in the center of the medullary canal at the level of neck resection lies 8 mm anterior to the projected medullary axis of the femur (Noble 1988). The tip when centralised, by definition, lies on the medullary axis. By simple geometry it is possible to calculate where any point on a femoral component lies in relationship to the axis of the femur and its endosteal surface. The easiest way to calculate this is to consider the mid-axis of the component. The mid axis at the tip lies on the medullary axis whilst the mid axis at the level of neck

resection lies 8 mm anterior to the projected medullary axis. At the mid point of the stem its mid axis will lie 4 mm anterior to the medullary axis. This is represented as

$$M = \frac{X \times E}{L}$$

where M is the mid axis of the component

X is the distance from the stem tip

L is the length of the stem

E is the entry point (relative to medullary axis)

As the mid point of the lesser trochanter lies 40 mm below the mid point of the level of femoral neck resection so 40 mm of stem lies proximal to this point. This means that for our modelled 130 mm component 90 mm lie distal to the lesser trochanter. The central axis of a 130 mm component, centralised proximally and distally will lie 5.5 mm anterior to the axis of the femoral canal at the level of the mid-point of the lesser trochanter. Thus

$$T = \frac{9 \times E}{13}$$

$$T = \frac{9 \times 8 \text{ mm}}{13} = 5.5 \text{ mm}$$

where T is the mid axis of the component at the level of the lesser trochanter

By using the equation described above the relative position of any point on the mid axis of the stem can be simply calculated.

The Exeter component, on which this model is based, is quite slim in the sagittal plane and is 10 mm wide 90 mm from its tip (the level of the stem corresponding to the mid-point of the lesser trochanter). The anterior edge of the component where it is 10 mm wide will lie 5 mm anterior to its mid axis. This places the anterior edge of our model component 10.5 mm anterior to the projected medullary axis of the femur

at the mid-point of the lesser trochanter. This can be calculated for any component thickness by using the formula

$$A = T + \frac{C}{2}$$

where A is the anterior edge of the component

C is the component thickness (sagittal)

To accommodate the stem and no cement mantle the femoral canal, at the mid-point of the lesser trochanter, must be twice as wide as the distance A. Thus

$$S = 2 \times A$$

where S is the sagittal dimension of the canal necessary to accommodate the stem. For our model stem this dimension is 21 mm.

For there to be a 2 mm cement mantle at this point the canal must be 25 mm wide at this level (2 x (10.5 + mantle thickness)). This is calculated as

$$R = 2 \times (AC + 2)$$

where R is the sagittal dimension of the canal necessary to accommodate the stem and a 2 mm cement mantle

By using the above technique it is possible to calculate that at a point 1cm below the lesser trochanter the canal must have an endosteal diameter of 22.6 mm to accommodate a component and a 2mm cement mantle anteriorly.

An average femur has a sagittal diameter of 26.7 mm at the lesser trochanter and tapers quite quickly to 22.2 mm a point 2 cm below. This means that the endosteal sagittal dimensions of the femoral canal at and just below the level of the lesser

trochanter will often be inadequate to accommodate a femoral component with a 2 mm cement mantle. Femoral canals which are narrower than average may not allow any capacity for an anterior cement mantle at either the level of the mid point of the lesser trochanter or at a point levels. These findings offer a reasonable explanation for the incomplete cement mantles seen in the clinical cases presented in the previous chapter.

Thus the sagittal dimension of the canal (SD) necessary to accommodate a stem, centralised distally, with a Y mm cement mantle at any point in the proximal femur can be calculated from the formula

$$SD = 2 \times \left(\frac{X}{L} \times E + \frac{C}{2} + Y \right)$$

This equation shows that long stems, an anterior proximal entry point and thick components all decrease the thickness of the proximal cement mantle anteriorly for a given femur.

INFLUENCE OF OPERATIVE TECHNIQUE AND IMPLANT DESIGN

By considering the above model it is possible to determine how changes in operative technique influence the distribution of the cement mantle. Centralisation of femoral components has been recommended both proximally (Noble 1991) and distally (Star 1994). The affect of component entry point, centralisation, neck resection, component design and anteversion will be modelled in this section.

Component entry point

Many practicing hip surgeons recognise the fact that the piriform fossa is the ideal entry point to commence reaming and broaching the femoral canal This brings the entry point more in line with the axis of the shaft of the femur and will make complete cement mantles around the femoral component more likely. This can be modeled by the equation below and previously described. This equation shows that if the component is placed in the proximal femur in line with the axis of the femoral

shaft, which may involve removing a large part of the posterior cortex of the neck of the femur, then the anteversion of the femoral neck and its posterior bow can be ignored.

$$SD = 2 \times \left(\frac{X}{L} \times E + \frac{C}{2} + Y \right)$$

where SD is the sagittal dimension of the canal necessary to accommodate a stem

X is the distance from the stem tip

L is the length of the stem

E is the entry point (relative to medullary axis)

C is the component thickness (sagittal) and

Y is the desired thickness of cement

In this instance E is zero as the entry point is in line with the axis of the femoral shaft.

The equation then becomes

$$SD = 2 \times \left(\frac{C}{2} + Y \right)$$

Thus when the component is placed along the axis of the femoral shaft the only factor which determines the thickness of the cement mantle at the level of the lesser trochanter is the component thickness and the sagittal thickness of the femoral shaft of the patient at this level. Such placement will ensure more even cement mantles around femoral components.

Posterior placement of the component at the level of neck resection may be easier through the posterior approach and this may be one reason that aseptic loosening is less common with the posterior as compared to anterior approach (Malchau 1998). This will be outlined in more detail in the final section.

Distal centraliser

Improved stem alignment (Star 1994) and stem tip positioning (Egund 1990) has been observed with distal centralising. If a distal centraliser is not used an incomplete mantle will often be seen posteriorly at the tip of a femoral component. It would thus appear that distal centralisers will produce more even cement mantles around femoral components. However if a stem is centralised distally there is an increased risk of an incomplete cement mantle at the level of the lesser trochanter anteriorly compared to when the femoral component abuts the posterior cortex distally. This is best understood by applying the above model and appreciating that the femoral canal is 17 mm wide at the isthmus (the point at which the tip lies).

The tip of our modelled component is 5 mm wide in the sagittal plane. This means for a component centralised distally the posterior edge of the tip will lie 6mm from the posterior endosteal surface of the femur and thus allow a 6 mm cement mantle. This is determined by the equation

$$\begin{aligned} \text{PCM} &= 0.5 \times I - 0.5 \times \text{ST} \\ &= 0.5 \times 17 - 0.5 \times 5 \\ &= 8.5 - 2.5 \\ &= 6 \end{aligned}$$

where PCM is the thickness of the posterior cement mantle

I is the sagittal endosteal diameter of the femoral canal at the isthmus and

ST is the thickness of the stem at the tip

If a 2 mm cement mantle was considered to be adequate the whole prosthesis, and thus its mid axis, could be allowed to pass 4 mm further posteriorly along the femoral canal. This would mean that the mid-axis of the stem tip lies 4 mm posterior to the

intramedullary axis and each point on the stem, except the entry point which remains fixed, will lie more posteriorly than when the stem is centralised distally. This calculation can be approximated for any stem length, mantle thickness and point on the prosthesis by the formula

$$N = \frac{(L - X)}{L} \times TP$$

where N is the distance the stem is translated posteriorly and TP is the distance the stem tip is moved posterior to the mid point of the femoral shaft

By using the above equation we can calculate that for our modelled stem, with a 2mm distal cement mantle posteriorly, the canal must have an endosteal diameter of 22.6 mm at the lesser trochanter to accommodate a component and a 2mm cement mantle rather than 25 mm if it were centralised at the tip. Thus at the mid point of the lesser trochanter a complete cement mantle becomes more likely if the stem tip is not centralised distally, compared to when it is.

For a non-centralised stem the equation to calculate the necessary sagittal dimension of the femoral canal to accommodate a stem and a cement mantle of a given thickness with the stem tip free to be placed more posteriorly in the femoral canal becomes

$$SD = 2 \times \left\{ \left(\frac{X}{L} \times E + \frac{C}{2} + Y \right) - \frac{(L - X)}{L} \times TP \right\}$$

This model suggests that the best compromise, for ensuring complete cement mantles proximally and distally when using a spacer on the tip of a component, is to ensure that the tip of the femoral component is held off the posterior cortex of the femur about 2 mm using a centraliser 2 mm wider than the stem tip. This situation would allow the component to pass more posteriorly at the level of the lesser trochanter increasing the chance of having a complete cement mantle at this level whilst ensuring a complete mantle distally. The question as to whether 2 mm is an adequate

cement mantle at the tip is still not known but different thickness' of cement at the tip of the component can be modelled using the formula presented above.

This equation can be used to model the thickness of the cement mantle at any point around a given stem in a femur of known dimensions. This is not of great practical use but a knowledge of the effects of stem centralisation may help in surgical planning. More usefully the calculations show centralising the stem tip distally may avoid cement mantle defects at this point but create defects in the cement mantle proximally. It can also be seen that the broader the tip of the stem the more likely mantle defects are to occur both proximally and distally. The finding that components were less well centralised in the proximal femur when a distal centraliser is used was also noted in the study of Berger et al.(1997).

Proximal centraliser

At the level of neck resection the sagittal dimension of the femoral neck is 24 mm (Noble 1988). The Exeter stem is 12 mm from front to back at this level. Though the osteotomy is clearly not a perfect rectangle if we model it as such we can see that if the posterior edge of the component was placed against the posterior endosteal surface at this level the whole component would be translated posteriorly 6 mm. This would mean that the mid-axis of the stem would lie only 2 mm anterior to the projected medullary axis of the femur at the level of neck resection and 1.4 mm anterior to this axis at the level of the mid-point of the lesser trochanter. The anterior edge of our model component will thus pass well posterior to the anterior endosteal surface of the femur throughout its length. Placement of the femoral component posteriorly at the osteotomy site will create a more even cement mantle than if the stem is centralised. However, as the proximal femur is oval and not a rectangle, the total posterior translation achieved by this method is likely to be far less than this theoretical 6 mm.

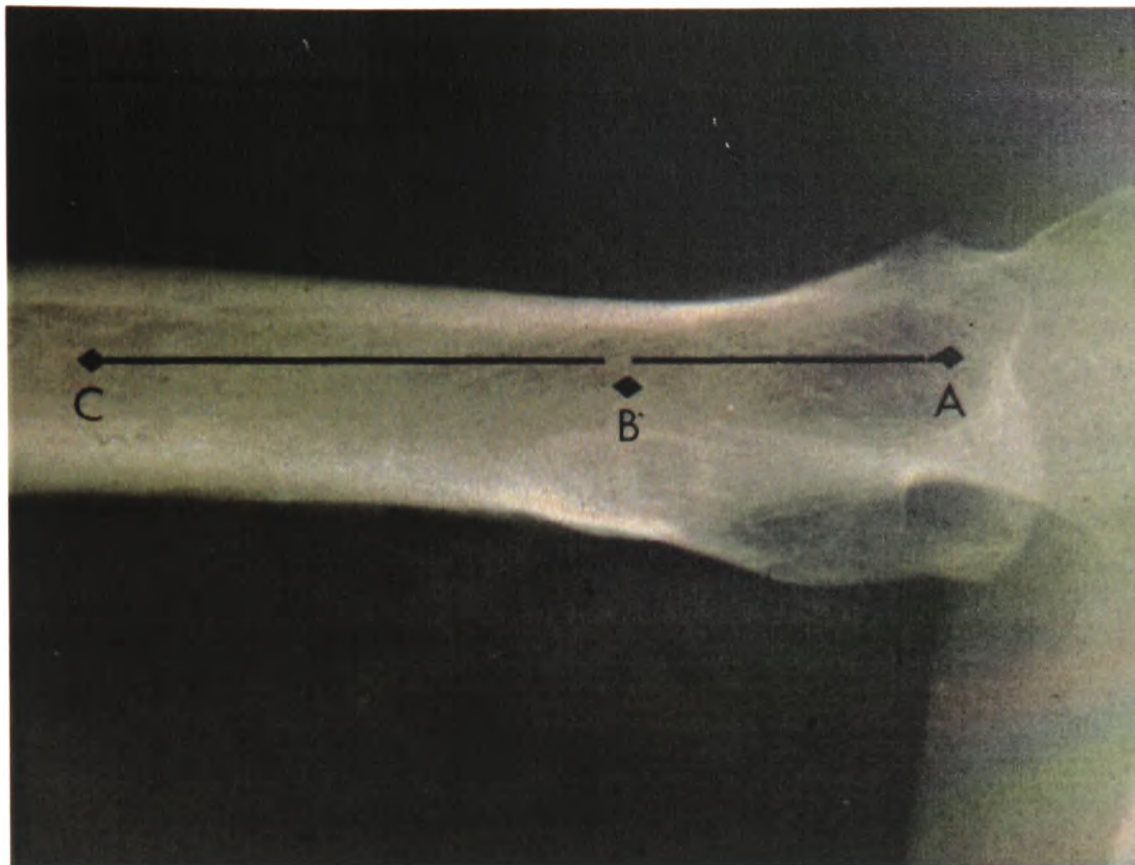


Figure 5.4 Diagrammatic representation showing the axis of a component centralised proximally and distally in the femoral canal.

The model illustrates how posterior placement of the component at the level of insertion will decrease the risk of incomplete cement mantles at the mid-stem. This means that a stem which is placed in the middle of the femur at the level of neck resection (as is achieved by the use of proximal centralisers or prostheses which are expanded proximally) make incomplete cement mantles more likely at the mid-stem of the component (Figure 5.4). This means that although proximal centralisers have been shown to improve coronal positioning of the femoral stem (Noble 1991) the use of proximal centralisers or expansion of prostheses proximally will lead to an increase in incomplete cement mantles in the sagittal plane..

Neck resection

The femoral neck arises anterior to the projected medullary axis of the femur and its anterior inclination determines that the higher the level of neck resection the further anteriorly the entry point of the stem will lie. The more femoral neck is preserved the further anteriorly the entry point for the femoral component will lie in relation to the femoral axis. Anteversion is not exactly equivalent to anterior projection but for the

purpose of our model it can be used to highlight the influence of femoral neck retention on component positioning. If we use 15 degrees as a relatively conservative estimate of anteversion then for every 1 mm of neck retention the mid-axis of the neck osteotomy moves a further 0.26 mm anteriorly.

$$\text{Anterior translation of axis} = \text{neck retention (mm)} \times \sin \alpha$$

where α = angle of neck anteversion

Thus if 1 cm of neck is retained beyond a normal neck osteotomy the entry point for the femoral component will lie a further 2.6 mm anterior to the projected medullary axis. This means for a given patient an extra 1 cm of neck resection will mean that the stem will lie a further 1.8 mm further anteriorly at the level of the mid-point of the lesser trochanter virtually ensuring an incomplete cement mantle at this point.

For any level of neck resection, femoral neck anteversion, stem thickness, or component length calculations can be performed, using equations previously described, to determine how they influence the thickness of the cement mantle. Again though the calculations are more useful in broader terms and show how femoral neck retention is a predictable technique for producing cement mantle defects.

Component dimensions

a. Length

The longer the femoral component the more likely incomplete cement mantles either proximally or distally. If we model a component of 220 mm (with 200 mm being within the femur), centrally placed in the femoral canal proximally and distally the canal would need to be a further 2 mm wide in its sagittal dimensions to accommodate the component and a 2 mm cement mantle at the level of the lesser trochanter. With very long prostheses 3 point endosteal fixation of the implant may occur anteriorly around the mid-stem and distally at the tip of the component. The

influence of stem length on the thickness of the cement is contained in the equation below which was described earlier.

$$SD = 2 \times \left(\frac{X}{L} \times P + \frac{C}{2} + Y \right)$$

b. Breadth

Components which are broader than 1 cm at the junction of the middle and distal 1/3, in the sagittal plane, are more likely to have an incomplete cement mantle than the component modelled in our study. For every 2 mm broader the component is at this point the canal must be 1 mm wider in the sagittal plane. The same is true of the tip of the component. Being broader at either of these points makes maintaining complete mantles around the component more difficult at either point as the less posteriorly the component lies at the tip the more likely incomplete cement mantles are anteriorly around the proximal 1/3 of the component and visa-versa.

Curved implant

The problem of deficient cement mantle, especially with high neck resection, can theoretically be minimised by using implants which are curved in the sagittal plane. However as the anatomy of the femur in the sagittal plane is variable the implant must be precisely positioned and may not always fit the curves of the femur to ensure a complete cement mantle. The femoral bow, the degree of anteversion and even the level of neck resection will vary the relationship of the prosthesis to the endosteal surface of the femur and it may in fact be more difficult to control placement of a curved than a straight component.

Anteversion

The influence of anteverting the component (or more accurately, rotating the component anteriorly) on its position in the femoral canal is difficult, if not impossible to calculate. The final orientation will depend on which axis the

component is rotated and how this rotation is achieved. The best way to model the effect of component rotation is to study several axis around which the component may be rotated and how this rotation affects the relationship of the stem to the endosteal surface of the femur.

The tip of the stem is centralised and is assumed to be a fixed point. Anteversion occurs through this point and a point proximally. If the rotation occurs around an axis along the shaft of the stem this will make incomplete mantles more likely proximally. This is because as the antero-lateral edge of the component moves backwards with rotation the antero-medial edge moves the same distance towards the anterior cortex of the femur.

It is more likely that the axis of rotation occurs through the tip of the component and an axis proximally which lies somewhere between the shoulder and the head of the component (this is the point on the stem that the surgeon uses as a point of reference during component insertion). If this is the case then the axis of rotation passes approximately through the medial edge of the prosthesis at the junction of the proximal and middle thirds. Rotation of the stem through this axis will not affect the probability of a mantle defect being produced because the antero-medial edge of the component will not move with rotation.

As the stem tip lies on the axis of rotation anteversion will not influence distal cement mantle defects. Anteversion is thus not likely to alter, to any appreciable extent, the cement mantle thickness at the points that incomplete cement mantles have been predicted to be produced.

DISCUSSION

The observation of cement mantle defects anteriorly at the level of the lesser trochanter and posteriorly at the stem tip is in direct contradiction to a recent publication (Berger 1997) which suggests that cement mantle defects in the sagittal plane occur posteriorly at the level of the lesser trochanter and anteriorly at the stem

tip. In no case did we see this pattern of cement mantle defects and the author believes that that the model described by Berger et al. is wrong. In their model, the fact that the femoral neck arises anterior to the mid axis of the femoral shaft was ignored (Figure 1.6, see page 29). It has been shown in the present study that the orientation of the femoral neck is an important determinant of component positioning in the sagittal plane and cannot be ignored. To ensure the most even cement mantle around a femoral component it must be placed as posteriorly as possible at the level of the neck resection.

Over-reaming with femoral broaches will prepare a cavity able to accommodate the femoral component and a cement mantle. The thickness of this mantle is determined by the size of the broaches relative to the femoral component. However at times large amounts of bone must be removed from the femur at the level of the lesser trochanter in order to insert a broach. This involves vigorous hammering and it is probable that the femur deforms to accommodate the broach and returns to its original dimensions following extraction of the broach. Furthermore over-reaming with broaches is not always possible and may lead to fractures of the proximal femur. These factors, and the fact that it is not possible to always place the component exactly in the same orientation as the broach means that the use of broaches will not reliably prevent incomplete cement mantles. This holds as true in the sagittal plane as for the coronal plane where it is highlighted by varus and valgus stem positioning.

Stems which are curved in the sagittal plane may conform to the proximal femur better than straight stems and are thus theoretically less likely to be associated with incomplete cement mantles. However a curved stem does not ensure a complete cement mantle unless the curves of the implant exactly match the variable sagittal anatomy of the proximal femur. Component positioning still remains critical.

The cement mantle, when viewed on the sagittal plane, is more likely to be complete if the stem is placed posteriorly in the canal at the level of neck resection. When inserting the femoral component it is easier to place the component posteriorly through a posterior approach than through an antero-lateral approach as with the later

the abductors needs to be retracted posteriorly. The more of the abductors that are retained the more difficult this becomes. Furthermore it is possible that when approaching the femur from anteriorly it is more likely that the femoral neck will be divided perpendicular to its axis. This makes the posterior neck cut disproportionately high in relation to the anterior meaning that even if the stem is placed against the posterior cortex from an anterior approach it still lies further anteriorly compared to a posterior approach. This means that mantles are more likely to be complete around components inserted from a posterior approach than through an antero-lateral approach. This may in part explain why the Swedish hip registry shows that failure of a cemented implant is 50 per cent greater when the surgeon uses an antero-lateral approach when compared to a posterior approach (Malchau and Herberts 1998). However it is almost certain that this is not the whole story and there are a number of other possible explanations for this difference. Firstly it may be that more experienced surgeons favour the posterior over the antero-lateral approach. Secondly the more extensive division of the contracted posterior capsule and external rotators may alter the loading moments on the femoral components. A third possibility is that surgeons place components in slightly different orientation when using the anterior and the posterior approaches. Recent RSA evidence (Alfaro, 1998) suggests that the rotational stability of the Charnley prostheses is critically dependent on the anti version in which it is placed. Greater rotational stability is seen in implants which are placed in more anteversion. If surgeons are placing the components in more anteversion when using a posterior approach then this may lead to increased rotational stability.

Human anatomy is variable and the endosteal dimensions of the femoral canal will differ between patients. Pre-operative lateral radiographs should be studied on all patients undergoing total hip replacement to assess the dimensions of the femoral canal and determine the component size compatible with complete cement mantles. This is at least as important as studying AP radiographs. If adequate cement mantles cannot be predicted on templating then modifications to operative technique, such as cutting the femoral neck lower, can be planned. Templating can not be performed by laying the template over the femoral shaft. The femoral neck must be identified and

the component orientated as it will lie in the canal. Only then can the orientation of the component within the femoral canal and the distribution and thickness of the cement mantle be judged.

Femoral neck retention in total hip arthroplasty has been suggested as a way of increasing the resistance of the femoral component to torsional forces (Freeman 1986) and R.S.A. studies suggest that neck retention may be one of the ways to decrease rotational movement of femoral stems (Kiss 1996). The possible benefits of high neck resection must be considered against the increased likelihood of incomplete cement mantles produced by high neck resection. In fact the model described in this chapter shows that a high neck cut is one of the surest ways to produce an incomplete cement mantle in the sagittal plane. The Hinek prosthesis is designed to be inserted with a high femoral neck resection. This component is used with broaches which are not over sized. The component inserted is the same size as the broach. This means when a component is selected after broaching an incomplete cement mantle, and 3 point fixation, is almost guaranteed. The stem inevitably passes from anteriorly to posteriorly in the femoral canal as is associated with incomplete cement mantles both at the tip and around the mid-stem (Figure 5.2). The association of osteolysis with incomplete cement mantles was described in the previous chapter. From the findings presented here high neck resection cannot be recommended for cemented total hip replacement.

Design modifications to implants may have unexpected influences on outcome. Modifications to the Charnley prosthesis (De Puy) have lead to decreased survival (Dall 1993). The reasons for this are not clear as a number of modifications to shape and surface finish were made. One modification was the expansion of the prosthesis proximally with the use of a flanged collar. The flange effectively increases the sagittal diameter of the prosthesis and acts as a proximal centraliser. As proximal centralisation will increase the risk of periprosthetic osteolysis this design change may be a factor contributing to the decreased survival of the newer prosthesis. The changes to the component also included changes in surface finish, which has been shown with some implants to decrease component survival (Malchau 1998), whilst

the increased cross sectional area increased the component stiffness. The reason for a difference in survival between the implants in the above study (Dall 1993) will remain speculative. It does however illustrate the importance of considering the femur in 3 dimensions when suggesting modifications which may at first appear of benefit.

CONCLUSIONS

The sagittal anatomy of the proximal femur is an important determinant of incomplete cement mantles around cemented femoral components. These defects occur anteriorly at the level of the lesser trochanter and posteriorly at the stem tip. Incomplete cement mantles in the sagittal plane(as highlighted in chapter 3) can be as destructive as those in the coronal plane with regards to the development of focal endosteal osteolysis. Surgeons must be aware of this sagittal anatomy when performing total hip replacement. Only by correct positioning of the femoral component in the sagittal and coronal planes can incomplete cement mantles be avoided which should lead to a decrease in focal osteolysis. To increase the likelihood of complete mantles the surgeon should be aware that

1. If a patient has a narrow femoral canal or a femoral neck which projects further anteriorly than normal a low neck resection may be required as high neck resection makes an incomplete cement mantle more likely.
2. The femoral component should be placed as posteriorly as possible at the level of neck resection. This is particularly difficult using the anterior approach. Attempts to centralise the femoral component in the sagittal plain proximally should be discouraged.
3. A centraliser should be used on the tip of the femoral stem. To decrease the likelihood of an incomplete cement mantle proximally it should not centralise the stem tip but hold it away from the posterior cortex.

4. Long stem prostheses should not be used for routine primary hip replacement .

CHAPTER 6

EXPERIMENTAL DESIGN

“Clinical experiments may be more realistic but provide little control over experimental conditions. With animal and laboratory models as intermediates, computer models are remote from reality but offer virtually complete control over experimental conditions” (Verdonshot and Huiskes 1996).

INTRODUCTION

In previous chapters the low incidence of osteolysis around polished Exeter stems with a significant increase in osteolysis with matt stems has been mentioned. This suggests that the surface finish of a cemented femoral component has an important influence on the development of osteolysis. This finding, along with the finding that focal osteolysis was strongly associated with incomplete cement mantles at the mid-point and tip of femoral components lead to the hypothesis that the stem-cement interface was an important pathway for communication between the arthroplasty articulation and the endosteal surface of the femur for rough, but not polished tapered stems.

To explore this hypothesis bench top experiments were performed to investigate fluid flow at the interface between bone cement (polymethylmethacrylate-PMMA) and stems of differing surface characteristics and geometry, under a variety of conditions. Stems were inserted into PMMA to produce model stem/cement composites. These composites were then studied under both bonded and debonded (at the stem-cement interface) conditions. These experiments are described in more detail in the following chapters. In this chapter an overview of the experimental design and the design of the equipment used in the experiments is presented.

EXPERIMENTAL DESIGN

Femoral components

To model femoral components corrosion resistant stainless steel tapers were manufactured (Figure 6.1a,b). The tapered components, 70 mm in length, had an upper diameter of 9 mm and a lower of 2.5 mm with an even taper throughout. The cylindrical components were of the same length and were 9mm in diameter throughout their length. Components were either highly polished or roughened. Surface roughness was produced by shot blasting. Two different surface roughnesses

were modelled. These were of Ra 1.5 μm and Ra 3 μm . These were selected because they approximate the surface roughness of commonly inserted cemented femoral components. Some values for implanted components are given in Table 6.1.

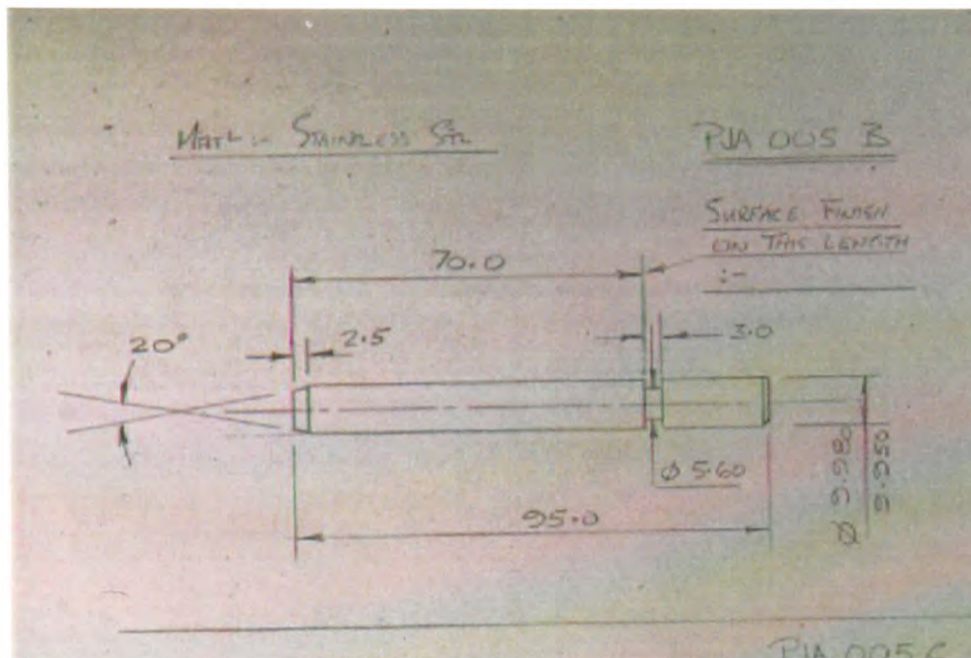


Figure 6.1(a). Line drawing of cylindrical stem.



Figure 6.1(b). Photograph of tapered stems.

Implant	Manufacturer	Ra (μm)
Polished Exeter	Howmedica	0.01
Matt Exeter	Howmedica	1.2
Charnley Elite	DePuy	1.16
TR28	Zimmer	1.5
Lubinus	Waldermar link	1.4
Spectron	Smith-Nephew	1.9
Spectron EF	Smith-Nephew	2.8
VerSys plus	Zimmer	2.4
Ultimate C	DePuy	3.5

Table 6.1. Surface roughness (Ra) of selected cemented femoral components.
(1 μm = 40 microinches).

The surface roughness of the components listed in Table 6.1 were taken from papers by Crowninshield (Crowninshield 1998) and Harris (Harris 1998) and were supplied by the manufacturers. De Puy would not supply the roughness of the matt Charnley Cobra stem. However the surface roughness of this component was measured on retrieved implants (Lee 1993) and found to measure 1.16 μm (almost identical to the matt Exeter). As previously outlined the matt Exeter stem has a surface roughness (Ra) of around 1.2 μm .

Definitions of surface roughness

The surface roughness of a component can be defined from a profilometer tracing of its surface. The most commonly quoted surface roughness parameters are Ra, Rz, and Rsk.

Ra is the average roughness of the surface and is calculated as the average height of the peaks and depth of the troughs from the centre line of the roughness profile

(Figure 6.2) (Crowninshield 1998). This is the most commonly quoted figure on surface roughness.

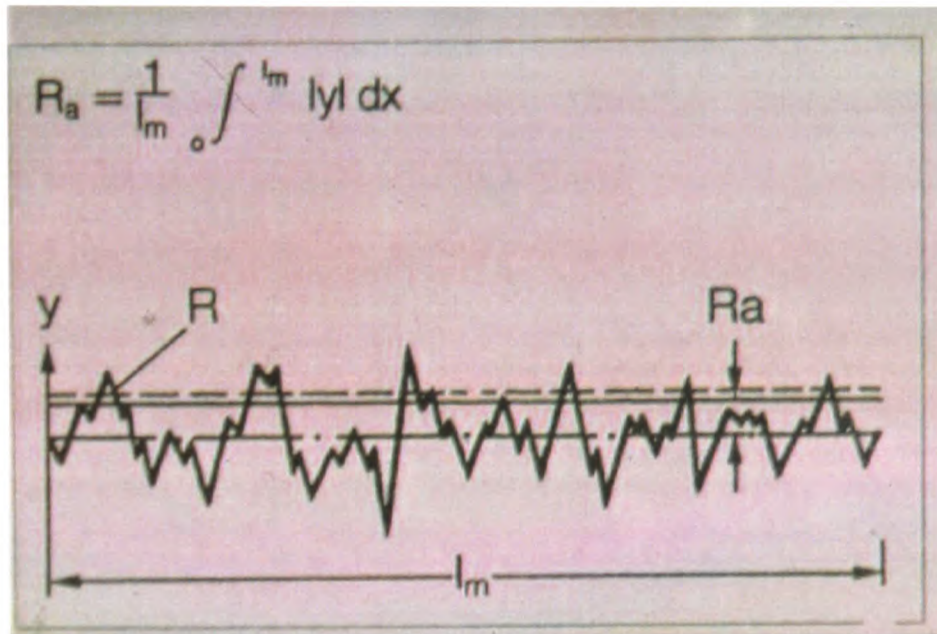


Figure 6.2. Diagrammatic representation of Ra.

Rz (the mean roughness depth) is the mean of the depths (highest peak to lowest valley) of 5 consecutive sample lengths within the roughness profile (Figure 6.3).

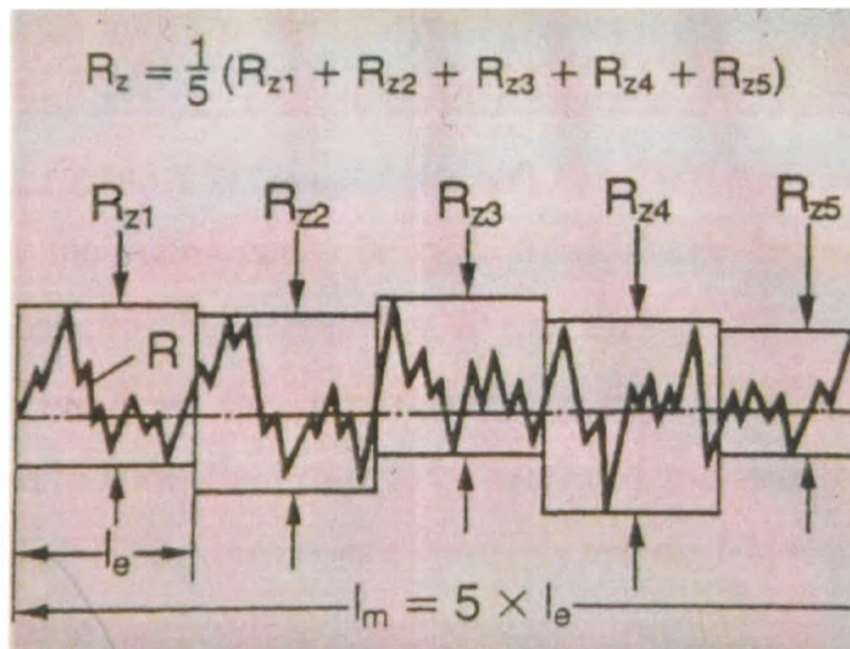


Figure 6.3 Diagrammatic representation of Rz.

Rsk characterises the asymmetry of the surface. A negative skew indicates that the valleys are more prominent than the peaks.

Sectioned Exeter stems

To more realistically recreate the stem-cement interface seen in THR a number of experiments were undertaken using sectioned Exeter femoral components. Complete components would not fit into the casting jig or the pressure chamber (see below) so the stems were sectioned 60 mm from their tips. Modelling sections of these stems should provide an accurate representation of how the stem behaves in vivo as the stems are evenly tapered throughout. The stems were either matt (Ra 1.2 μm) or polished. In both instances a proximal extension, which ensured stem centralisation and sealing of the pressure system, was fitted to the sectioned Exeter stem. The proximal extension was removable which allowed the component to be inserted into the pressure chamber without it being centralised. The significance of this will be elaborated in the sections looking at cementing technique and component subsidence.

Casting rig.

To ensure adequate pressurisation of cement and even reproducible cement mantles (Figure 6.4) a purpose built rig was designed (Figure 6.5). The rig consists of a 3 piece brass casing and a 2 piece polytetrafluoroethylene (PTFE) mould. The upper piece of the casting rig has a proximal extension to ensure centralisation of the rods and to ensure that the stems could be held rigid during cement polymerisation. Distally a central hole allowed the cylinders to pass through the cement mantle whilst still maintaining pressure on the cement throughout polymerisation. This design feature was included to allow fluid flow to be measured and to enable the stems to be controllably debonded. The dimensions of the rods and the PTFE mould meant that a minimum 5 mm mantle was produced.



Figure 6.4 Tapered stem within cement mantle.



Figure 6.5. 'Well used' casting rig

Pressurisation of cement was ensured by producing a closed system except for vent holes which allowed controlled escape of the cement. There were 3 vent holes in each

of the upper and lower mounts. These holes could be sealed to ensure cement pressurisation and uncovered to allow controlled release of cement.

Preparation technique

Simplex (Howmedica, Rutherford, N.J.) cement was used for all cases. The preparation of the polymethylmethacrylate PMMA was performed with the same technique as that used for cementing femoral components during total hip replacement. Whilst still in a low viscous state, at approximately 1 minute, the cement was poured into the PTFE mould. The mould was contained by the casting jig. The lid of the casting jig was then fitted, or not, depending on the experimental design, before the stem was introduced. Pressurisation of cement (again as appropriate) was maintained until it had fully polymerised. The prepared stem-cement composites were then removed from the casing before fluid movement at the stem-cement interface was studied.

Pressure chamber and cycling rig.

In a number of experiments fluid under pressure was applied to the upper interface of the stem/cement composites. In order to effectively and controllably deliver the pressure a pressure chamber was constructed (Figure 6.6). The pressure chamber was connected to an external air source which was controlled by a pressure valve thus allowing the fluid around the composite to be delivered at pre-determined pressures.

The pressure chamber was designed to prevent fluid flow from the delivery point (the upper surface) to the collecting chamber except along the stem/cement interfaces (Figure 6.7). All other interfaces were sealed with O-rings. Fluid which moved along the stem-cement interface was collected in the base of the pressure chamber and measured to determine flow rates along the stem cement interface.



Figure 6.6. Pressure chamber.

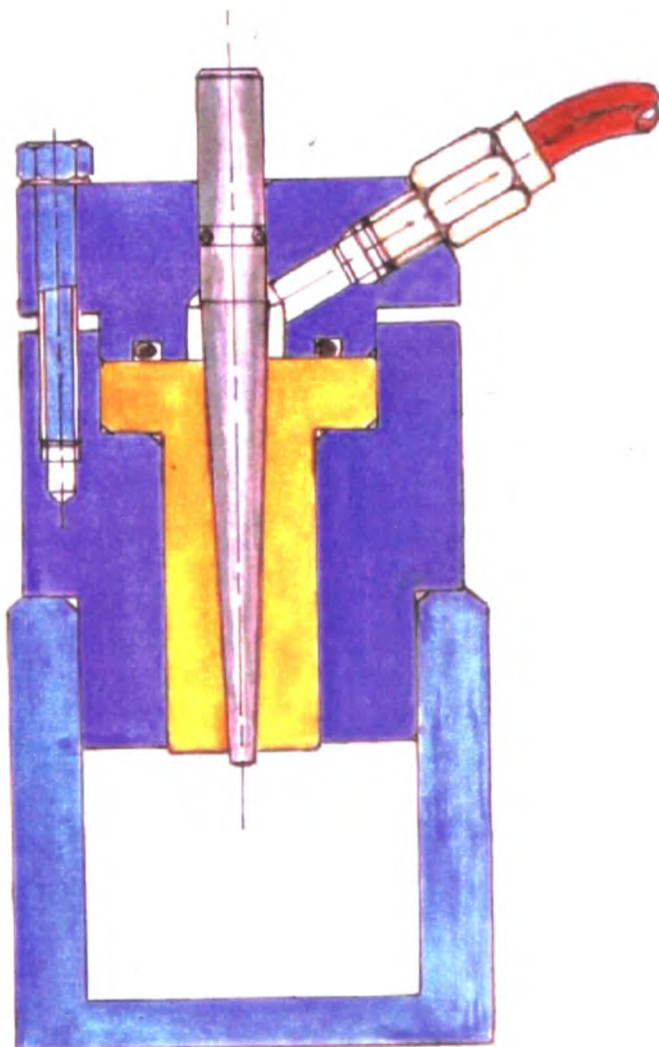


Figure 6.7. Line drawing of pressure chamber.

CHAPTER 7

IN VITRO INVESTIGATION OF FLUID FLOW AROUND WELL FIXED SIMULATED FEMORAL COMPONENTS OF DIFFERING GEOMETRY AND SURFACE FINISH.

“Stem cement debonding accelerates the failure process (of THR) and promotes the formation of a pathway for debris at the stem-cement interface, particularly when the bone support to the cement mantle is reduced. Hence, this study supports the hypothesis that the survival of cemented THA is enhanced by a firm and lasting bond between the stem and the cement mantle (Harris 1992), although this may be difficult to realise clinically.” (Verdonshot and Huiskes 1997)

SUMMARY

If fluid is able to migrate along the stem cement interface of well fixed cemented femoral components it may gain access to endosteal bone via cracks or defects in the cement mantle. It may also contribute to membrane formation and stem debonding by decreasing the strength of the stem-cement interface. In this chapter the hypothesis that the surface finish of a component may influence the ability for fluid to migrate along the stem-cement interface of bonded femoral components was examined. Dye movement along the interface between bone cement and model femoral components which differed in surface finish and in shape was measured. Dye movement along the bone-cement interface of rough stems (3 μm) was significantly greater than that for smooth stems ($p < 0.001$). This was true for both cylindrical and conical tapered stems. For stems of the same surface finish shape did not influence dye movement.

INTRODUCTION

The evidence from a review of the published literature (Verdonshot 1996), ultrasound (Davies 1992), RSA (Alfaro-Adrian 1998), and histological studies (Jasty 1991) is that debonding at the stem cement interface, at least in part occurs, at some time during the service life of even well functioning implants. As previously outlined experimental evidence suggests that due to differences in thermal expansion and contraction of metal and bone cement, when the stem is not modified by sintering or pre-coating, a gap will appear at the stem-cement interface as soon as the thermal effects of polymerisation have finished (Ahmed 1982). This would mean that no stem is truly bonded to its cement mantle and that a space, along which fluid and particles may potentially migrate, is established between the stem and the cement from the moment of implantation. This space, if it coexists with cement mantle defects or radial cracks in the cement, could provide access for joint fluid to the endosteal surface of the femur. This in turn could lead to osteolysis by direct pressure (Aspenberg 1998) or macrophages induced by wear particles (Murray 1990).

The purpose of this study was to model the stem-cement interface of rough (Ra 3 μ m) and highly polished femoral components to observe if the predicted space at the stem-cement interface provided a potential pathway for fluid flow in the first 6 weeks following implantation. This study aimed to look at well cemented, unloaded components, to model the stem-cement interface under ideal conditions.

MATERIALS AND METHODS

Overview

Fluid flow along the interface between bone cement (polymethylmethacrylate-PMMA) and stainless steel rods which differed in surface finish and in shape was measured. Rods were inserted into PMMA to produce a model stem/cement composite as described in the previous chapter. These composites were then soaked

in normal saline stained with methylene blue for 6 weeks before being sectioned and the stem-cement interface inspected for evidence of fluid migration.

Soaking

Five smooth and 5 roughened (Ra 3 μ m) stem-cement composites of both cylinders and tapers were soaked in saline stained with methylene blue for 6 weeks at room temperature. The specimens were kept in a centrally heated room which was maintained at a reasonably constant temperature of around 24 degrees. After 6 weeks the cement mantles were sectioned and the stems and cement mantles inspected. The distance that fluid had penetrated the interfaces was recorded. Statistical comparison on the distance fluid penetrated the interfaces was made using a two tailed Students t-test.

Saline at 37 degrees centigrade.

The behaviour of PMMA is dependent on temperature and so it is at least theoretically possible that the fact that the above experiments were not performed at body temperature might affect the findings of these experiments.

In an attempt to study if temperature had an influence on fluid and dye migration at the stem-cement interface the experiments described above were repeated with 2 rough and 2 smooth stems being soaked in saline stained with methylene blue at 37 degrees centigrade. To ensure a constant temperature the specimens were stored in an incubator for 6 weeks. This experiment was performed in limited numbers for two reasons, firstly that the results obtained were no different to the experiments reported earlier in the chapter (even with such small numbers a significant difference was observed between the 2 stem types), and secondly because of limited access to incubators which had to be tied up for extended periods.

Flow against gravity

To investigate if fluid could move along the rough stem-cement interface against gravity one rough stem-cement composite was inverted and placed so that the saline stained with methylene blue reached only to the junction of the stem and cement.

RESULTS

Rough v Smooth Cylindrical stems.

In all cases fluid containing dye penetrated the implant/stem interface of the matt composites at the proximal and distal ends. The matt stems showed staining on their surfaces corresponding to the region of fluid penetration (Figure 7.1). The mean, range of penetration of methylene blue and the standard deviation are presented in Table 7.1. In 3 specimens the cement was sectioned to examine it for evidence of dye penetration. In no case was there any macroscopic evidence of dye penetration through the cement, thus excluding this as a path of fluid migration.

	Mean penetration (mm)	Range (mm)	SD (mm)
Rough interfaces n=10	8.4	5-14	2.9
Polished interfaces n=10	0.8	0-3	1.1

Table 7.1. Methylene blue penetration at rough and smooth cylindrical interfaces.

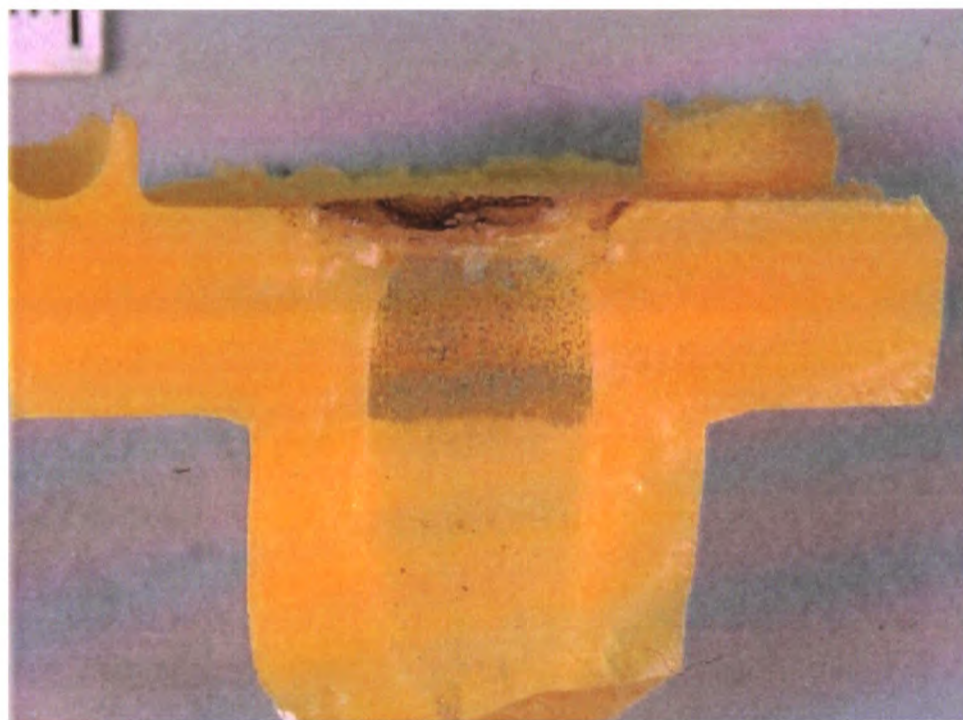
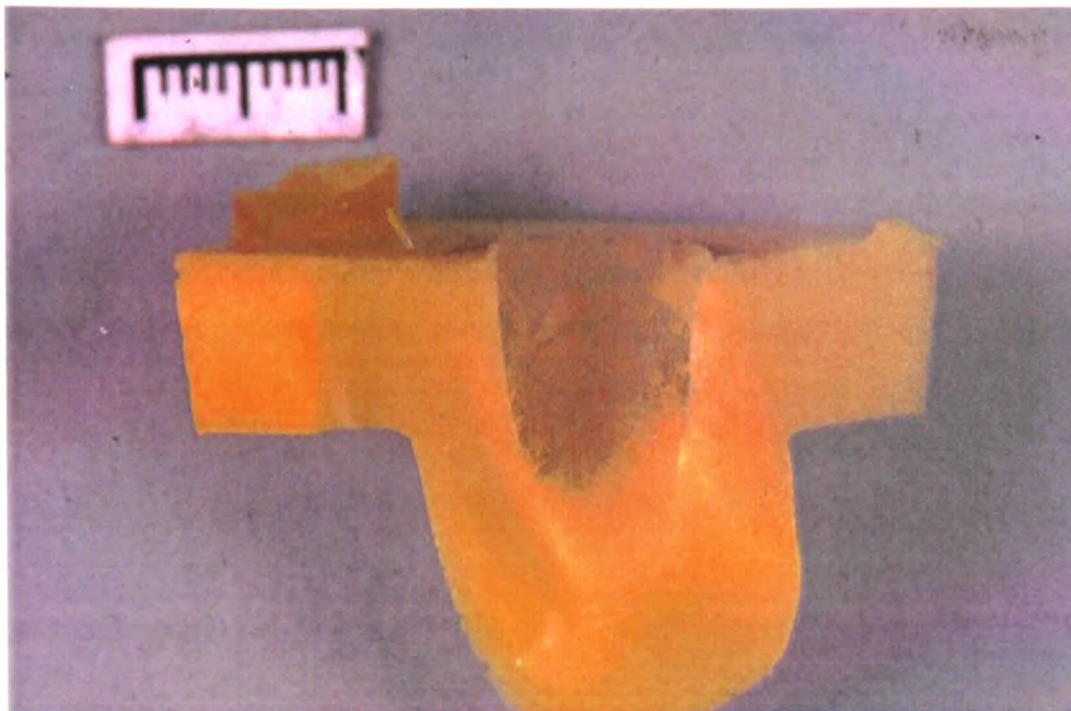


Figure 7.1 Photographs of 2 matt cement mantles showing dye staining the cement where it had passed along the stem-cement interface.

Of the polished stems 6, interfaces showed a tide mark at the border of the cement where it was in contact with the fluid. There was no macroscopic evidence of dye penetration along the stem/cement interface at any of these 6 interfaces (Figure 7.2). At the other 4 interfaces a maximum penetration of 3 mm was measured. The mean, range of penetration of methylene blue and the standard deviation for polished stems are presented in Table 7.1. The difference in fluid penetration along the stem-cement

interface of smooth and rough cylindrical stems was statistically significant ($p < 0.001$).

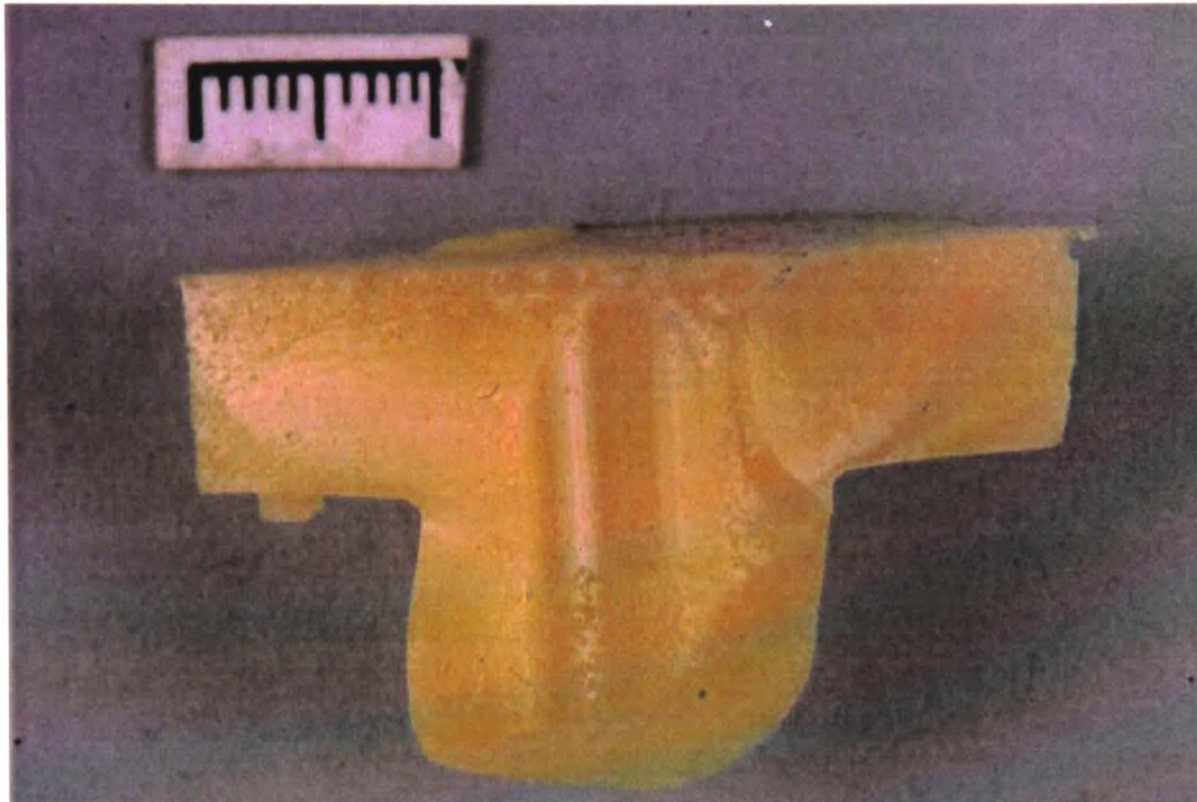


Figure 7.2 Photograph of polished cement mantle showing no evidence of dye penetration.

Rough v Smooth Tapered stems.

The pattern of fluid migration observed with tapered stems was similar to cylindrical stems and is presented in table 2. The difference in fluid penetration along the stem-cement interface of smooth and rough tapered stems was, as for cylindrical stems, statistically significant ($p < 0.001$).

	Mean penetration (mm)	Range (mm)	SD (mm)
Rough interfaces n=10	8.2	4-14	3.2
Polished interfaces n=10	0.9	0-2	0.87

Table 7.2. Methylene blue penetration at rough and smooth tapered interfaces.

Stem shape

There was no statistical difference between the fluid penetration along the stem-cement interface of well cemented cylindrical and tapered stems when the influence of surface finish was excluded. This was true for both rough ($p=0.87$) and smooth stems ($p=0.82$).

Saline at 37 degrees centigrade.

In this series of experiments the 2 polished stems showed a tide mark at the upper and lower borders of the cement where it was in contact with the fluid. There was macroscopic evidence of dye penetration along only 1 of the polished stem/cement interfaces, this was of 2 mm. Fluid penetrated the stem-cement interface of all rough stems. Sections revealed dye had penetrated a mean of 6.5 mm along the stem/cement interface (range 4-9 mm, SD 2.4).

Though there were only a total of 4 interfaces studied in each of the stem types, a significant difference was demonstrated on the distance fluid penetrated the rough and polished stems ($p = 0.035$). There was no difference between the polished ($p = 0.47$) or the matt stems which were studied at room temperature and at 37 degrees in an incubator ($p= 0.35$).

Capillary flow

In the inverted specimen fluid had moved 6mms along the stem-cement interface by 6 weeks.

DISCUSSION

In chapter 1 how a space may develop at the stem-cement interface and why this is different for rough and polished stems and how and why fluid may move along the stem-cement interface of rough stems was discussed. This model appears to confirm that predicted by theory and raises a number of important questions. The most important of these is does the presence of fluid at this interface have any relevance to what may occur in vivo with cemented total hip replacements? This will be addressed at the end of this chapter.

Cementing technique in this study, and thus the quality of the stem-cement interface, was better than could realistically be expected in an operating theatre. High pressures were exerted on the cement following implant insertion, the stem was held rigid by the casting jig during cement curing, and no biological material, which is known to weaken the interface (Stone 1989), contaminated the cement or the stem-cement interface. Furthermore the stem was inserted into the cement whilst the latter was still at a low viscosity making it more likely that it would penetrate fully the depths of any asperities on the rough stems than if it had been inserted later in its polymerisation. This study thus represents ideal conditions and show that even in these circumstances, by 6 weeks, fluid penetrates 10-15% of the stem-cement interface of rough surfaced components. That dye penetrated significantly further along the interface of the rough surfaced composites suggests a fundamental difference in the ability of the 2 studied interfaces to move fluid.

As outlined in chapter 1 the way in which PMMA will behave during expansion and shrinkage cannot be predicted and cannot be modeled from first principles as it has such a complex structure. Thus to try to understand the effects of hydration the experimental evidence becomes of fundamental importance. In the experimental model presented here we can say with confidence that after 6 weeks in saline the hydration of cement did not lead to sufficient change in the diameter of the cement

mantle to permit dye to pass more than a mean of 0.8/0.9 mm along the stem-cement interface of smooth stems.

The failure of fluid to move along the smooth interface either means there is no space at the stem-cement interface or that if a space does exist that the surface characteristics of the interface prevent fluid movement (Figure 7.3). A study of the bonding forces between stems of differing surface finish and PMMA found an unexplained increase in the bonding force as the stem became increasingly smooth (Bundy and Penn, 1987). As surfaces become infinitely smooth it can be predicted that the bonding force will become infinite showing how powerful the bond between surfaces can become even in the absence of any attempt to 'bond' them. The increase bonding force observed between increasingly smooth surfaces and the PMMA was surmised to be due to an atomic (or chemical) interaction. The situation is analogous to "the adhesion between two highly polished optical flat disks placed in contact due to the enhanced proximity of the surfaces. An increased electrostatic interaction between the metal and bone cement due to van der Waals forces could possibly be involved." (Bundy and Penn, 1987).

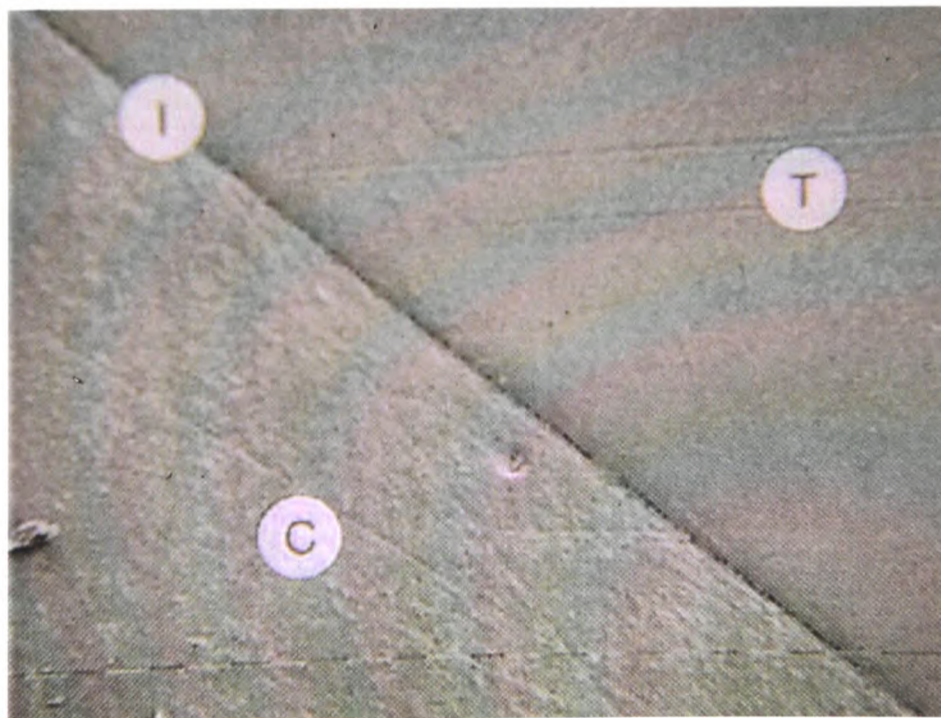


Figure 7.3. Polished stem in contact with its cement mantle (from Verdonshot 1995).

The term van der Waals forces denotes the interactions between closed-shell molecules. The attractive contributions to these forces include the interactions

between the partial electric charge of polar molecules (Atkins 1996). Van der Waals interactions include dipole-dipole, dipole induced dipole and dispersion interactions. The description of these interactions is beyond the scope of this study. What is important is that all 3 interactions vary as the inverse sixth power of the separation so we may write

$$V = \frac{C}{r^6}$$

Where V is the strength of the Van der Waals force

C is a coefficient that depends on the identity of the molecules
and r is the distance of separation

As the strength of the interaction varies to the sixth power this means that the distance of separation between the bone cement and the implant is critical. Polished stems would be expected to be approximated more closely to the cement than roughened stems particularly if the cement does not penetrate to the depths of the asperities of the rough stem.

It is thus most likely that the polished surfaces of the cement and the femoral component are more closely approximated than those of rough stems and their mantles. This in combination with the strong anatomical bond which forms between the 2 surfaces and the decreased drive for fluid to spread on smooth surfaces combine to limit movement of fluid and dye along the stem-cement interface of smooth components.

Possible clinical implications.

In theory the majority of cemented femoral components are intended to function as a composite beam (Shen 1998), for which it is a requirement that the bond at the stem-cement interface and the bond at the cement-bone interface both remain intact. As long as these bonds and the cement remain intact, neither the surface roughness of the stem nor the frictional behaviour of the stem-cement interface would be expected to be of any consequence, since there is no relative movement at that interface under

load. However if the stem-cement interface provides a pathway along which fluid and/or particles may move then even if a reliable bond can be established at this interface osteolysis may develop. It is probable that this is not an important consideration clinically (as at least partial debonding at the stem-cement interface is probably required to produce sufficient pressures and pathways for fluid and particles to pass in large enough quantities to produce osteolysis), but does offer a possible explanation for osteolysis around so called well fixed prostheses. Other possible implications of fluid at the stem-cement interface of apparently well fixed stems, which will be further elaborated in the final chapter, include component corrosion and the development of slurry wear of the PMMA and the femoral component. In the remainder of this section the influence of fluid within the stem-cement interface on component debonding and its relevance to finite element analysis will be discussed.

As the author believes this is the first model to consider the implications of fluid at the stem-cement interface of cemented femoral components there is little in the orthopaedic literature which can give insights into the clinical implications of the findings presented here. There is however some relevant engineering literature that shows the fundamental importance of fluid entering the interface between two bonded surfaces.

It is almost certain that the presence of fluid at the stem-cement interface of femoral components in vivo will change the strength and nature of the bond between stem and cement. In engineering it is well established that the presence of fluid will weaken an adhesive joint (Schonhorn 1973). This is well illustrated by the 'stripping' of a blacktop road surface where water penetrates the interface between the rock aggregates and the asphalt. The important question is how does the presence of fluid at the stem-cement interface affect the quality and the nature of the bond between the stem and the cement. As well as clinical implications this also has implications for theoretical studies using the finite element method which attempt to study debonding of the stem-cement interface.

Part of the bond of a visco elastic material to a hard material (such as that between a stem and PMMA) comes from plastic and elastic deformation which occur with loading (plastic deformation is non-recoverable deformation following load and elastic deformation is recoverable). This is illustrated by the fact that when a block is in contact with a substrate the actual contact area will not be the whole area of the block (area A) but the area of real contact (area ΔA). ΔA is always less than A because even the most highly polished surfaces have asperities at the molecular level. With time and load (as occurs clinically with total hip replacement) thermally induced creep will lead to an increase in the contact area ($\Delta A(t)$) (Persson 1999). The increase in the contact area with time will lead to a steady increase in the static friction force with time (which equates to an increased bond at the interface). This should imply a steady increase in the strength of the bond between stem and cement clinically unless complicated by loss of mechanical interlock as may be seen with loss of asperities of the stem or cement. Importantly the presence of fluid in the interface between a visco elastic material and a hard material will lead to a decrease, by a factor of 10, of the strength of this bond.

The phenomenon of load increasing contact areas and leading to an improved interlock between two surfaces by elastic deformation is seen when a tyre grips a road. The importance of this deformation to grip and how the presence of fluid in the interface limits elastic deformation of the visco-elastic material is illustrated by the inferior grip of a tyre on a wet road (Persson 1999). The decreased strength of the bond between a visco elastic and a hard material due to the presence of fluid may, at least partially, explain how the bond of a rough stem to its cement mantle may weaken with time.

In rough stem surfaces with deep asperities perfect interdigitation of cement into the asperities is not predicted mathematically (Ahmed 1982) or seen experimentally. This would mean that some of the bond strength between the stem and the cement will come from the elastic deformation of the cement into the asperities of the stem. The presence of fluid in the asperities will limit the deformation of the PMMA and weaken the bond. As fluid moves along the stem-cement interface it would be

expected to cause progressive weakening of the interface and contribute to debonding. As debonding increases the interface will be further opened to fluid and debris and fretting at the stem cement interface can occur. Fluid spreading across a rough interface, the normal situation (Myers 1991), can also trap air in the interface further decreasing the actual area of adhesive contact significantly lowering the cohesion strength.

There are thus strong theoretical considerations that predict the progressive weakening of the bond between stem and cement if fluid accesses the stem-cement interface. This means that whilst probably not being the most important factor leading to component debonding the presence of fluid within the stem-cement interface must be considered as a potential contributing factor to breakdown of the stem-cement interface of implanted roughened femoral components.

The presence of a space at the stem-cement interface of rough surfaced components and the behaviour of PMMA during its polymerisation suggests an important implication for cementing technique with roughened stems. Contemporary cementing technique includes early delivery of the cement to the femur followed by cement pressurisation until the cement reaches a high viscosity. Cement pressurisation prevents the volumetric expansion of PMMA (Haas 1975) which is sometimes seen during the early polymerisation period and late introduction of a rough stem into partly polymerised cement makes it less likely that cement will “flow” into the asperities of the stem. This means that the stem is only in contact with the cement whilst it is undergoing a volumetric reduction. All these factors would be expected to decrease the mechanical interlock at the stem-cement interface and increase the likelihood of debonding at this interface. This has been confirmed experimentally (Keller 1980) with weaker interfaces being produced when rough model stems were inserted into PMMA formed late in the dough stage compared to interfaces produced prior to the dough stage. A lesser interlock of the stem and cement would also be expected to produce larger channels for fluid movement at the stem-cement interface. This means that there is strong theoretical evidence against the combined use of cement pressurisation, late stem insertion, and the use of rough

stems. Advantages such as improved mechanical interlock at the bone-cement interface with cement pressurisation (Macdonald 1993) may thus be partially offset by a worsened mechanical interlock at the stem-cement interface for rough stems under these circumstances. The use of pressurisation and more contemporary cementing has led to the short term improvement of cemented femoral components (Malchau 1998). However osteolysis is often not apparent until beyond 5 or even 10 years following component implantation and it will be interesting to see if there is an increase of stem debonding and osteolysis around rough stems at intermediate and long term follow-up.

Relevance of findings to finite element analysis

Finite element modelling is widely used to predict the behaviour of cemented total hip replacements (Verdonschot 1997, Mann 1997, Harrigan 1992, Fagan 1986). Finite element studies are computer simulated models which are most commonly used to predict how strains will produce stress at different points in a studied field. They are the most widely used numerical analysis technique in bioengineering and the results of these studies have been used to predict how design modifications will alter the clinical behaviour of implants.

It has been stressed that great caution must be used in the interpretation of finite element models as the accuracy of the results depends on accurate modelling of boundary conditions (Lee 1992) as well as the material and interface properties. In fact if a finite element analysis study does not state explicitly the boundary and interface conditions, the properties of the materials modelled and assumptions of conditions made in the analysis the results should be viewed with extreme caution. "There is a considerable danger with finite element analysis as used in bioengineering - it is very easy to produce impressive results with beautiful graphics which can be used to convince non-experts that some particular situation will occur" (Lee 1992). However even in the hands of world leaders on finite element analysis these models are considered as less predictive of the true behaviour in vivo of hip replacements than bench top experiments (Verdonschot 1996).

The interface between the implant and the cement will be fundamentally altered by the presence of fluid at the interface. As the potential for fluid to access the stem-cement interface of roughened femoral components studies has been demonstrated, studies which consider bonding strength and behaviour at the stem-cement interface should make consideration for the presence of fluid, and potentially a membrane, even under ideal cementing conditions. As far as the author is aware no finite element studies have considered the presence of fluid in the stem-cement interface. This throws into doubt the true interface conditions which need to be modelled to give an accurate representation of this interface. Finite element analysis has particularly been used to consider the issue of debonding of the stem-cement interface (Mann 1997, Harrigan 1992) with most studies predicting a decreased likelihood of debonding with rough femoral components. Patterns of peak stress and points of initial debonding have been modelled using these techniques and the conclusions used in modifying the design of femoral components. As the conclusions of finite element analysis are totally dependant on the selected boundary and interface conditions the findings of these studies which do not account for fluid at the interface must be interpreted with caution.

Conclusions

The author concludes from this chapter that there is a fundamental difference in the ability of fluid to move along the stem-cement interface of well cemented, unloaded rough and polished stems in vitro. This pattern of fluid migration was not influenced by component geometry. The clinical significance of this study is that it has demonstrated that the stem-cement interface of roughened stems is not a barrier to fluid migration even under ideal conditions. This may explain how focal osteolysis may develop around even well fixed components (Jasty 1991) and may lead to a weakening of the bond between stem and cement.

CHAPTER 8

IN VITRO INVESTIGATION OF FLUID FLOW AROUND DEBONDED SIMULATED FEMORAL COMPONENTS OF DIFFERING SURFACE FINISH.

“In a prosthesis specifically designed to prevent bonding between the metal implant and the cement-mantle, debris can migrate in this space and reach the endosteal surface through defects in the mantle.” (Schmalzried 1992).

SUMMARY

The aim of this chapter was to study how debonding of polished and rough model femoral components influenced fluid flow at the stem-cement interface.

Fluid flow along the stem-cement interface of five highly polished and ten rough finished (5 of Ra ~ 1.5 μ m and 5 of Ra ~ 3 μ m) debonded tapered circular stems was measured. None of the rough stems were able to prevent fluid flow along the stem-cement interface. Polished tapered stems sealed the stem-cement interface and after 48 hr of continuous pressure no fluid flow was observed. This difference in the ability to seal effectively the stem-cement interface between rough and polished stems was highly statistically significantly (Fishers Exact test $p = 0.0003$).

INTRODUCTION

As discussed in more detail in chapter 1 increasing evidence from the published literature suggests that attempts to establish a perfect bond at the stem-cement interface, by increasing the surface roughness of the femoral component, are detrimental to implant survival (Dall 1993, Mohler 1995, Malchau 1998, Sporer 1998). This is believed to be due to increased stresses at the bone-cement interface in implants which have an enhanced bond at the stem-cement interface (Mann 1992), and to the increased production of wear particles generated by debonded roughened components. However focal osteolysis is more common around rough surfaced (Berry 1998, Rockborn 1993, Mohler 1995) than highly polished stems (Fowler 1988, Schulte 1993) even in those that differ in no feature other than surface finish (chapter 2). It is thus reasonable to assume, at least in some cases, that another possible explanation for the difference in survival between rough and polished stems, is that increased rates of osteolysis lead to increased implant failure with rough stems.

Osteolysis rates of 93% within 2 years of debonding of rough surfaced chromium cobalt stems of 4 different designs have been reported (Berry 1998). This compares with 3% focal osteolysis in polished Charnley stems at a minimum 20 years follow up (Schulte 1993) and no convincing evidence of osteolysis around polished Exeter stems at 8-10 years following implantation as reported in chapter 2. Osteolysis may be focal and commonly occurs around the tip of the stem even when the cement mantle proximal to the lesion is intact (Willert 1990, Chapter 3). This difference may be due to the fact that debonded rough stems produce metal and acrylic wear particles. However as osteolysis is reported around apparently well fixed rough stems it appears that the production of metallic and acrylic wear particles at the stem-cement interface is not essential for the development of osteolysis. This has lead to the hypothesis that the differences in rates of osteolysis between rough and polished stems in the presence of cement mantle defects and with fractures of the cement mantle are due to differences in the ability for fluid and/or particles to migrate along the stem-cement interface.

In the previous chapter we saw that under even under ideal conditions fluid moves significantly further along the stem-cement interface of well cemented rough components as compared to highly polished. However as discussed in chapter 1 debonding at the stem-cement interface, of both polished and rough surfaced stems under physiological loads is probably universal. To address this issue, as an extension of the study in the previous chapter and in an attempt to model what are probably more realistic interface conditions in vivo, an in vitro model to investigate the influence of surface finish on fluid flow along the stem-cement interface of debonded cemented femoral components was produced.

MATERIALS AND METHODS

Overview

In this study experiments were performed to investigate fluid flow at the stem/cement interface of debonded components. Stems were debonded at the stem-cement interface, loaded for 48 hours and then fluid under pressure was applied to the upper surface of the stem-cement interface. Fluid flow along the stem-cement interface was measured at the tip of the prosthesis (Figure 8.1).

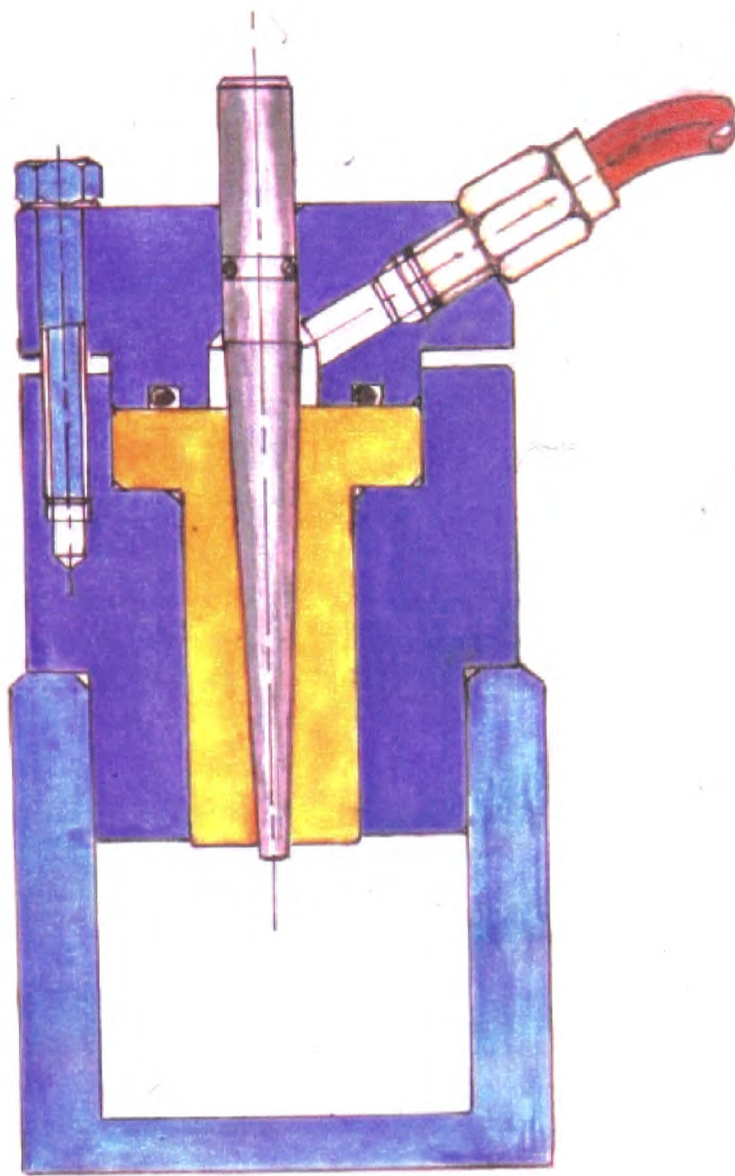


Figure 8.1 Diagrammatic representation of pressure chamber. Fluid passing along the stem-cement interface is collected at the base of the chamber and measured.

Stem cement composites were prepared in the routine fashion as described in chapter 6. In the first series of experiments model tapered stems with a highly polished surface finish and an Ra of $1.5 \mu\text{m}$ and of $3 \mu\text{m}$ were studied. In the second series of experiments sectioned matt and polished Exeter femoral components were studied.

For all component types the experiments were repeated 5 times

Debonding

Stems were debonded from their cement mantles in an Instron 1122 materials testing machine. Debonding was produced by inverting the specimens and gradually increasing a retrograde load on the stem tips, which protruded below the cement mantle. Load was applied at 0.05 mm/min (the lowest possible rate). Following

debonding the stems were returned to their cement mantle and loaded in an antegrade fashion in the Instron machine at 500 Newton for 48 hours. The load was removed prior to the stem-cement interface being subjected to fluid under pressure in the pressure rig.

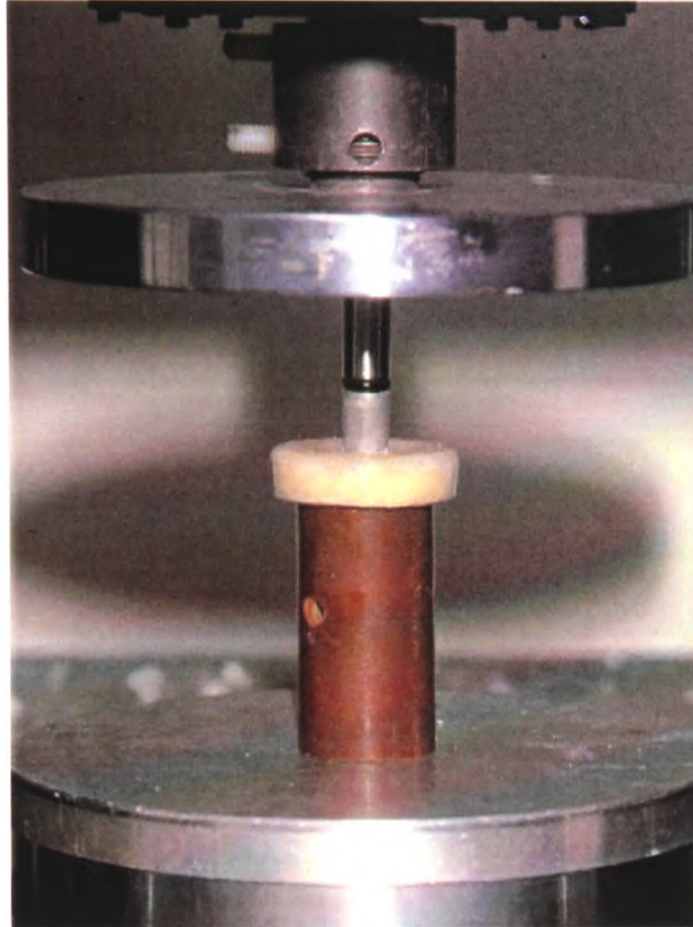


Figure 8.2. Stem-cement construct under load in an Instron testing machine.

Fluid pressure

In vivo pressures of 160 mm Hg have been measured in the pseudo-capsule of loose total hip replacements during hip rotation (Robertsson 1997) whilst pressures transmitted from the hip joint along the stem-cement interface can reach around 200 mm of Hg at zones of focal osteolysis (Anthony 1990). Though others have measured pressures of up to 700 mm Hg in the pseudojoint following the injection of dye (Hendrix 1983) it was elected to deliver pressure at 150 mm Hg to the upper surface of the cement and thus the stem-cement interface as this approximated the more commonly observed pressures. If no flow was observed within the first hour, pressure was applied for a total of 48 hr and any flow measured. If fluid flowed along the stem-cement interface in the first hour it was collected and measured.

Statistics

Statistical comparison of debonding forces was made using a 2 tailed Students t-test. Comparison on the absolute ability to seal the stem-cement interface was made using Fishers exact test. For comparison of flow rates between the tapers with 3 different surface finishes the fact that a statistical difference was present was established using ANOVA ($p < 0.001$). The difference in the means of the different stem types were then studied using a 2 tailed Students t-test.

RESULTS

There was no significant difference in loads to debonding between polished stems and stems with a surface roughness of $1.5 \mu\text{m}$ ($p = 0.41$). The difference in load to debonding between both polished stems and stems with a surface roughness of $1.5 \mu\text{m}$, and stems with a surface roughness of $3 \mu\text{m}$ was statistically significant ($p < 0.001$). The mean forces to initiate debonding are presented in Table 8.1.

	Load to debonding (Newton)	Range (Newton)	SD (Newton)
Polished stems n=5	1220	900-1850	404
Rough stem ($1.5 \mu\text{m}$) n=5	1440	1000-1900	391
Rough stem ($3 \mu\text{m}$) n=5	3790	3200-4600	581

Table 8.1. Loads to debonding at stem-cement interface.

All 5 polished tapered stems sealed the stem-cement interface and after 48 hr of continuous pressure no fluid flow was observed. In each of the 10 rough stems fluid flow along the stem-cement interface was observed as soon as pressure was applied. Mean flow rates, range of flow, and standard deviation are presented in Table 8.2.

	Mean flow (mm/hr)	Range (mm/hr)	SD (mm/hr)
Polished stems n=5	0	0	0
Rough stem (1.5 μm) n=5	1.1	0.8-1.4	0.23
Rough stem (3 μm) n=5	7.5	4-11	2.7

Table 8 2. Fluid flow at the stem-cement interface.

This difference in the ability to seal the stem-cement interface (fluid flow v not) between rough and polished stems was highly statistically significantly (Fishers Exact test $p = 0.0003$). Differences in mean flows between polished and both 1.5 μm and 3 μm surface finish were observed ($p < 0.001$ and $p < 0.001$ respectively) and also between the rough stems of different surface finish ($p < 0.001$).

The results on fluid flow around polished and matt Exeter stems are presented below in table 8.3.

	Mean flow (mm/hr)	Range (mm/hr)	SD (mm/hr)
Polished stems n=5	0	0	0
Matt stems (1.2 μm) n=5	0.4	0.24-0.6	0.16

Table 8.3. Fluid flow at the stem-cement interface of Exeter stems.

The difference in the ability to seal the stem-cement interface (fluid flow v not) between rough and polished stems was statistically significantly (Fishers Exact test p

= 0.002). Differences in mean flows between polished and matt stems were significant ($p = 0.005$).

DISCUSSION

In this model a significant difference in fluid flow around tapered stems of differing surface finish has been demonstrated. Polished tapered stems which have been reintroduced to their cement mantle and loaded for 48 hr were able to completely seal the stem cement interface against fluid under pressures that are likely to be encountered in vivo. The probable explanation for this is that loaded polished tapered stems (which never establish a bond at the stem-cement interface) re-establish the interface conditions described in the previous chapter following reinsertion into the cement mantle. It is also possible that they subside slightly and conform more tightly to their cement mantle following loading (Verdonshot 1995) thus putting the cement under compression (Miles 1990). This will further close any potential space at the stem-cement interface. The creep properties of the PMMA allow it to accommodate stem migration (Perkins 1989) and will contribute to the effective sealing of the stem-cement interface. Theory would also predict that component loading will improve the seal at the stem cement interface for polished stems based on increased contact areas between the stem and the cement as they are loaded due to plastic and elastic deformation of the PMMA.

As distinct to the behaviour of polished stems loaded rough surfaced stems which debonded from their cement mantles allowed fluid movement at the stem-cement interface. Increasing the surface roughness increased the flow rate significantly between stems with an Ra of 1.5 and of 3 microns. This suggests that increased stem roughness increases the size of the channels along which fluid may pass. Flow in a tube is proportional to r^4 ($r = \text{radius}$) and so only a small increase in the size of the channels produced by debonding is required to produce a marked increase in flow.

Debonding of rough stems will produce damage to the inner surface of the cement mantle which becomes entrapped between the taper and the cement providing a

further expanded pathway for fluid migration along the interface (Verdonshot 1995). With loads encountered in vivo debonded rough stems become polished producing metal debris (Mohler 1995) and damage to the cement mantle, this would be predicted to further open the stem-cement interface to fluid and particle flow (Hale 1990, Mohler 1995).

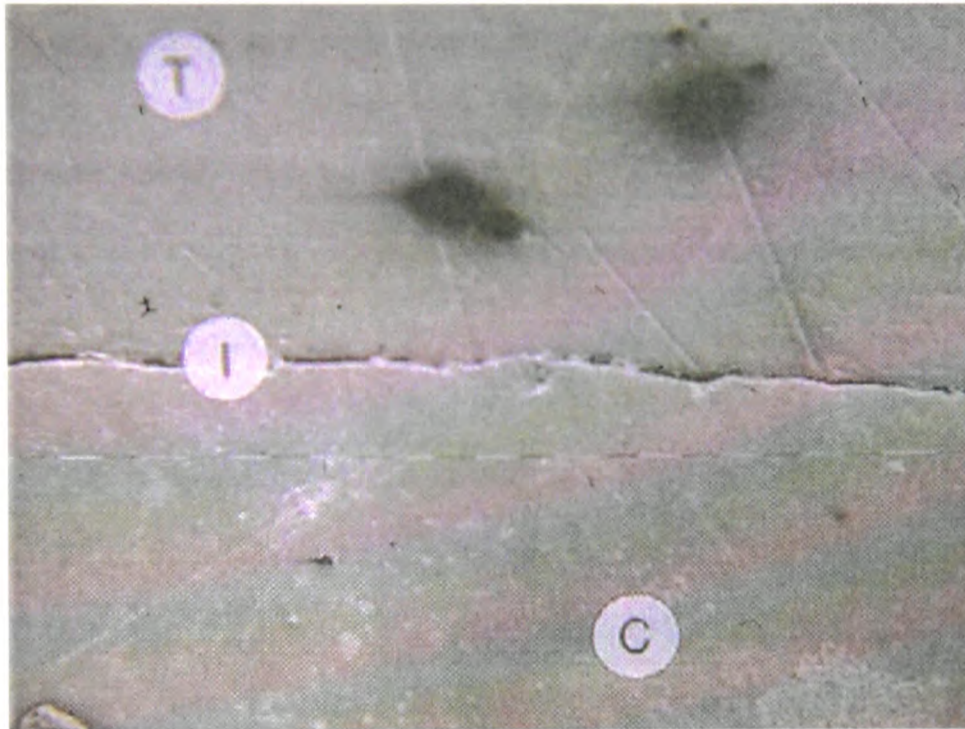


Figure 8.3. Interface of a debonded rough surfaced femoral component (from Verdonshot 1995).

The experimental model which looks at debonded femoral components is clearly only a model and by definition cannot reproduce what is occurring in vivo. The single most obvious criticism is that the stems were debonded with a single retrograde load and loaded in pure axial compression without being subjected to cyclical loads or rotational moments. An appreciation on how surface finish and component geometry affect stem behaviour reveals that it is unlikely that loading a polished stem cyclically or with a rotational moment would have opened the interface of the polished stems to fluid. These aspects of stem design subsidence and the influence of loading will be outlined in chapter 10 which studies the effect of component subsidence and fluid flow at the stem-cement interface of polished stems. Suffice it to say here that the fact that a taper by definition does not back out of its mantle following loading and

unloading, that any damage which occurs to a polished stem in vivo occurs sub-surface and so does not damage the cement mantle, and that clinically the Exeter stem is rotationally stable to physiological loads may mean, in combination with the time dependant properties of PMMA, that had the polished stems in this study been subjected to cyclical and rotational loads the findings would not have been expected to be different.

Further damage to the stem-cement interface of rough stems would have been expected to occur to rough stems under cyclical load. Experimentally (Verdenshot 1995) and clinically (Howell 1999) it has been demonstrated that significantly more debris is produced at the stem cement interface with movement of rough then polished stems. Clinically, fretting damage to rough stems in the form of polishing and sometimes corrosion has been described not only in stems that were obviously loose (Pazzaglia 1988, Shardllow 1997) but also in those that were stable (Lee 1993). Such damage to the stem is inevitably associated with damage to the inside of the cement mantle that may accumulate and lead to an increase in the internal dimensions of the cement mantle and thus further open the stem-cement interface.

From the evidence presented above it could be predicted that had cyclical or rotational loads been applied to the rough stems then higher fluid flows at the stem-cement interface would have occurred as a consequence of the expanded interface. It is therefore apparent that a single retrograde load was the least damaging method of debonding for the stem-cement interface of roughened stems. For this reason this model was chosen as it represents the best case scenario for a debonded rough stem with respect to sealing of the stem cement interface.

In this study there was no attempt to move debris along the interface. This will be discussed in the final chapter which will further expand the clinical consequences of fluid at the stem-cement interface. It should be noted that experimentally, pressures of between 50 and 150 mm Hg have recently been shown to produce osteonecrosis even in the absence of wear particles (Aspenberg 1998). The model presented here has shown low flow rates at low pressures with stems that had not been cycled or

subjected to rotational moments. However even low flow rates can lead to large pressures in confined systems, particularly if the loose stem is acting as a paddle to pump the fluid, and thus high pressures at sites of defects in the cement mantle are compatible with this model. As the stem-cement interface debonds, rough stems accumulate debris and the stem and the cement become further damaged, the interface would be expected to enlarge and even larger volumes of fluid with particles may be transported along this interface.

Based on clinical experience which shows focal osteolysis usually does not develop for a number of years following component implantation it probably takes some time for the stem-cement interface to expand to the point where fluid and particles can pass in sufficient volumes to mediate osteolysis. The low rates of osteolysis around polished Exeter stems probably are due to the fact that the stem-cement interface does not open to fluid (and thus also not debris) even after many years of implantation.

CHAPTER 9

THE INFLUENCE OF CEMENTING TECHNIQUE ON THE ABILITY FOR FLUID TO MIGRATE ALONG THE STEM CEMENT INTERFACE OF SMOOTH SURFACED IMPLANTS

SUMMARY

The aim of this chapter was to examine how cementing technique influenced fluid flow at the stem-cement interface. More specifically it was to observe the influence of component movement during cement polymerisation, and the influence of contamination of the stem-cement interface with blood or scratching of the femoral stem.

In the first series of experiments model polished stems and sectioned polished Exeter stems were oscillated throughout cement polymerisation to produce sub-optimal stem-cement interface conditions.

Firstly polished tapered stems were rotated by hand through approximately 5-10 degrees during cement polymerisation. The stem-cement interface was then subject to fluid under 150 mm of pressure for up to 24 hr. In no case did fluid move along the stem-cement interface. To test a non cylindrical taper the lower third of a polished Exeter stem was hand held during cement curing and moved continuously. The composite was again subject to fluid under pressure as previously. This experiment was repeated 5 times for both stem types and in all cases there was no fluid movement at the stem- cement interface.

In the second study blood contaminating the stem-cement interface did not increase penetration of dye along the interface of polished stems by 6 weeks. In the final study it was noted that scratches on polished stems allowed fluid and dye to pass along the scratches without contaminating the rest of the interface.

These studies show that movement of a polished tapered stem throughout cement polymerisation, blood in the stem cement interface and scratches on the femoral component are still compatible with an effective seal of the stem-cement interface.

INTRODUCTION

When a femoral component is inserted into bone cement *in vivo* it is held by the surgeon as the cement completes polymerisation. Movement of the stem during the final stages of polymerisation may lead to an opening of the space between the stem and the cement. This will be true for both rough and polished stems but may have different significance depending on the surface finish of the stem. In the previous two chapters we observed that under ideal cementing conditions polished stems both bonded and debonded were able to seal the stem-cement interface against fluid whereas rough stems did not. The first aim of this chapter was firstly to attempt to study how movement of a polished stem at the stem-cement interface during cement polymerisation affected fluid movement at this interface.

At times during stem insertion *in vivo* it is not unusual to have a small amount of blood contaminate the stem-cement interface. It is theoretically possible that this blood could weaken the seal that the polished interface has produced and open the stem-cement interface to fluid. It is also possible, that when inserting a femoral component *in vivo*, the stem could become scratched. These scratches may provide a potential conduit for fluid and particles even in the presence of a polished stem. Neither of these factors complicated the studies in chapter 7. These factors are studied in this chapter to examine if their theoretical disadvantages had an effect on the movement of fluid and dye at the stem-cement interface *in vitro*.

Surgeons do not perform a total hip replacement with a clearly defined technique across centres or even surgeons. This leads to differences in survival of implants depending on where the surgery is performed (Herberts 1998) and the seniority of the surgeon within an institution (Wroblewski 1998). This means that an attempt to study experimental conditions in the laboratory are at best an approximation as to what is occurring in the operating theatre. In the studies in this section attempts were made to study defects in operative technique which may occur in the operating theatre to see if this opened the stem-cement interface of polished stems to fluid and debris. To this end a small number of studies were performed with fewer numbers than previous

studies or with less rigidly defined experimental design. It is acknowledged that the findings here are less scientifically valid than those reported in previous sections. However, as the defects in operative technique were deliberately exaggerated beyond what would be expected to occur operatively even in the worst of hands, it is felt that they can offer further insights into the behaviour of the stem-cement interface of polished stems.

MATERIALS AND METHODS

Poor cementing

In the first experiments 5 polished tapered cylindrical stems were centralised and the cement pressurised throughout polymerisation but as distinct from earlier studies the stem was deliberately oscillated throughout cement polymerisation.

Cement was hand mixed and poured into the casting jig at approximately 1 minute. The lid of the jig was fitted and at approximately 4 minutes the stem was inserted into the cement. From the time of stem insertion until the cement had completed polymerisation the stem was oscillated by hand through an arc of no greater than 5-10 degrees.

Following cement polymerisation the stem-cement composite was placed in the pressure chamber and fluid delivered at 150 mm Hg for up to 24 hr. Flow at the stem-cement interface was measured.

In this second study on poor cementing even less ideal cementing conditions than described above were produced using sectioned polished Exeter stems. In this study the top of the casting jig was not fitted (meaning the cement was poorly pressurised), the stem was not centralised and the stem was agitated throughout cement polymerisation. The tapered stems used in the first set of experiments had to be centralised by the proximal extension of the casting rig to ensure that they would fit into the pressure chamber (due to the tight tolerances between the composites and the

pressure chamber). The sectioned Exeter stems have a proximal extension which can be removed prior to fitting the stem-cement composite into the pressure chamber. This meant that preparation of stem-cement composites could be performed without cement pressurisation and without stem centralisation as well as with motion of the component. Otherwise the experimental conditions were identical, as described above.

Blood staining

In this study 2 polished tapered cylindrical stems were coated with the authors blood prior to implantation into the cement mantle. Due to health and safety considerations and the authors desire to avoid repeated venesection this experiment was only performed twice. The cement preparation and cementing technique were routine. Following cementing the stems were soaked in saline stained with methylene blue for 6 weeks.

Scratching

In the final study 3 cylindrical femoral components were scratched along their length with an osteotome to produce 4 longitudinal scratches on each component, prior to being cemented in a routine fashion. These stems were soaked in saline stained with methylene blue for 6 weeks.

RESULTS

Poor cementing

As the cement polymerised it became increasingly difficult to move the stem by hand and the arc through which the stems could be rotated gradually decreased. This is clearly a subjective finding and is hard to quantify. All interfaces provided an effective seal against fluid for up to 24 hr in an identical pattern as previously observed.

In the second experiment, performed with sectioned Exeter stems, as the cement polymerised the stem also became harder to rotate until there was no perceptible movement at the stem-cement interface. Again the 5 specimens when subjected to fluid under pressure at the stem-cement interface showed a complete seal for 24hr

Blood staining

Following sectioning of the composites at the stem-cement interface the surfaces of the stem and the cement were inspected. The blood was found to have been wiped from the lower half of the stem. Presumably this occurred as the stem was inserted into the cement. Proximally the stem and the cement mantle were blood stained with no evidence that there had been any dye penetrating the interface.

Scratching

Following sectioning of the cement mantle an interesting pattern of staining of the cement mantle was observed. Dye had passed along the scratches for much of their length staining the cement mantle. Dye however had not spread peripheral to the scratches to contaminate the rest of the interface. In these 3 cases, with a total of 12 scratches, in all cases the scratch provided a focal pathway for dye and fluid only within the confines of the scratch.

DISCUSSION

Though this is a very subjective study the most striking finding was how difficult it was to produce an ineffective seal at the stem-cement interface of the polished stems. In the two studies described here in which modest amounts of movement at the stem-cement interface were attempted by hand, the polished model tapers and the polished Exeter stems maintained a seal at the stem-cement interface following cement polymerisation. In all instances it became more and more difficult to maintain movement of the stems as the cement hardened until there was no perceptible movement at the stem-cement interface. There was a deliberate attempt to agitate the

stem throughout cement polymerisation in the hope of opening the interface to fluid. This was not achieved and the stem-cement interface continued to provide a seal against fluid even with movements of the stem greater than could be expected to occur clinically. This study reinforces the findings from previous chapters by showing that the seal at the stem-cement interface is maintained in the presence of deliberately poor, as well as ideal cementing conditions.

The presence of blood at the stem-cement interface has been shown experimentally to weaken the bond at the stem-cement interface (Stone 1989). For polished tapered stems which in vivo debond from their cement mantles early (Ornstein 1997) this weakened interface is not an issue with regards to debonding. However the finding of blood or a membrane within the stem-cement interface of retrieved stems shows that this interface may become contaminated very early in the service life of a prosthesis. This may alter the behaviour of the interface but, recognising the deficiencies of the study, and the fact that the experiment was only performed twice, it does appear that the presence of even large amounts of blood at the stem-cement interface does not open the interface of polished stems to fluid, at least in the short term.

That fluid moved into the channels created by scratching the stem is not surprising. The fact that it is retained within the scratches reinforces the study of Howell et al (Howell 1999) who showed that when subsurface damage occurred to a polished stem in the majority of cases the debris produced was retained within the pits produced by the damage. It would thus appear that scratches to the surface of a polished stem during component insertion will allow the passage of fluid along these scratches without causing contamination of more of the interface.

What is surprising is that a tapered, polished, collarless stem would be produced with a groove along its length. The Furlong stem range (Joint Replacement Inst. Ltd) has such a groove and unless it completely fills with cement during stem implantation and remains completely aligned with this protuberant cement during stem subsidence this groove could provide a potential channel for fluid to be transported along the

stem-cement interface to the tip of the stem. This is another illustration of how a small design change may have effects beyond those intended.

These studies suggest as do the clinical results in chapters 2 and 5 that a polished tapered stem is forgiving. We have seen in the earlier clinical studies that the polished stem appears to be forgiving of incomplete and fractured cement mantles. Experimentally it appears to be forgiving, at least with regards to fluid passing along the stem-cement interface, to poor cementing, to blood staining during component insertion and to scratches to its surface.

CHAPTER 10

THE INFLUENCE OF COMPONENT SUBSIDENCE ON THE ABILITY FOR FLUID TO MIGRATE ALONG THE STEM CEMENT INTERFACE OF SMOOTH SURFACED IMPLANTS

SUMMARY

In this chapter, fluid flow at the stem-cement interface of model polished tapered stems and sectioned polished Exeter stems was measured pre- and post- component subsidence.

In the first study 5 polished tapered model stems were rotated through 360 degrees until the cement was fully polymerised. Following cement curing the stem-cement composites were subject to fluid under pressure, as previously described, and in no instance did the stem-cement interface prevent fluid movement at this interface. The composites were then loaded to 1000 N to produce subsidence at the stem-cement interface. Mean subsidence was 5.6 mm. Fluid at 150 mm Hg was applied to the stem-cement interface for 1 hour. In no case was fluid flow observed following loading and subsidence. Component subsidence significantly improved the seal of the stem-cement interface (Fishers Exact test $P = 0.02$).

To test a non cylindrical taper the lower third of a polished Exeter stem was moved throughout cement polymerisation to create a stem-cement interface with 5-10 degrees of rotational instability. This ensured that in all cases, prior to loading, the stem-cement interface provided a pathway for fluid migration with flow rates greater than 100 mm/hr. Subsidence of the stems was produced by an antegrade load which was removed in each instance prior to fluid being applied to the stem-cement interface. Subsidence of the stem into the cement mantle produced a gradually more effective seal of the stem-cement interface and in 5 of the 8 cases the interface was completely sealed by component subsidence of 1.0-1.4 mm. In the remaining three cases the cement mantle fractured following greater than 1.0 mm of subsidence but not before fluid flow was decreased to less than 0.1mm/hr.

These studies show that in the presence of gross instability of a polished tapered stem subsidence of the component within its cement mantle can improve, and in most cases seal, the stem-cement interface against fluid flow.

INTRODUCTION

Though subsidence of the femoral component has been proposed as beneficial to its function (Ling 1992), subsidence of a femoral component has been widely regarded as a sign of loosening (Harris 1982). However it is probable that it is the site of subsidence of the component which is important. RSA studies have shown that the polished Exeter stem subsides at the stem-cement rather than the bone cement interface (Alfaro 1999, Ornstein 1997) This subsidence has been associated with excellent clinical results (Malchau 1998, chapter 2) (Figure 10-1). This is in contrast to subsidence of stems which aim to achieve a bond at the stem-cement interface where subsidence has been associated with less favourable clinical results (Mulroy 1995) and where stem debonding is associated with the rapid onset of osteolysis (Mohler 1995).

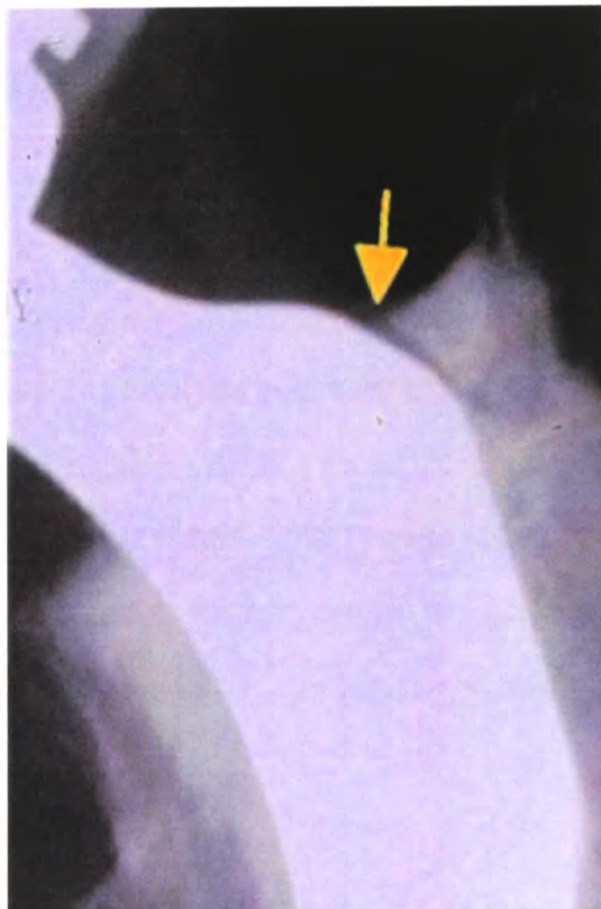


Figure 10.1. Subsidence of polished Exeter stem at the stem-cement interface.

Undoubtedly the best models to show that subsidence of a polished taper does not open the stem-cement interface to fluid are provided by the clinical cases presented in chapters 2 and 5 (the relevance of in vivo loading and the time dependent properties

of PMMA will be introduced in the discussion section of this chapter to explain why these clinical examples can never be accurately reproduced outside the body). In chapter 2 at least 98% of the polished stems subsided into the cement mantle and, even in the presence of at least a 13% incidence of incomplete cement mantle defects, osteolysis was not convincingly observed in any Gruen zone. In chapter 5 all the stems subsided once the mantle fractured and osteolysis was observed in only 2 of the 25 cases. These studies show that the stem-cement interface, even after many years, did not open to fluid and debris even in the presence of component subsidence at the stem-cement interface.

Accepting the limitations of modeling stem subsidence in vitro, the aim of this chapter was to explore how component subsidence influenced fluid migration along the stem cement interface of polished tapered model femoral components.

MATERIALS AND METHODS

Experiment 1

In the first study 5 polished tapered model stems were rotated through 360 degrees during cement polymerisation. The cement was pressurised, the stem centralised and the stem continuously rotated by hand. Following cement curing the stem-cement composites were subject to fluid under pressure as previously described. The composites were then loaded to 1000 N to produce subsidence at the stem-cement interface.

The loading regime was slightly complicated. First the stem was removed from its mantle and, as fluid was in the interface in all instances following initial application of water under pressure, the interfaces dried. The next step involved loading to 500 N at a loading rate of 0.1 mm/min with the stem-cement composite at room temperature. The load was then removed and the composite placed in normal saline at between 35 and 40 degrees centigrade. The load was then reapplied at the same rate up to 1000 N and component subsidence measured. Finally the stem was

removed from the saline and reloaded to 1000 N for 24 hr. Component subsidence at 24 hr was again measured prior to the load being removed.

Initial subsidence with a load of 500 N was used to seal, at least partially, the stem-cement interface prior to placing the component in water. It was elected to load the component in water heated to 35-40 degrees to increase the creep within the cement. The creep properties of PMMA are temperature dependent (Lee 1990) meaning that for a given load greater subsidence will be observed at increased temperatures. To avoid potential cement fractures with the load used to produce component subsidence in this model it was decided to perform loading at approximately body temperature.

Following removal of the composites from the Instron materials testing machine fluid under pressure was applied to the interfaces in a routine fashion for up to 1 hour at 150 mm Hg and fluid flows measured.

Experiment 2

In the second series of experiments sectioned polished Exeter stems were prepared in a grossly defective manner to ensure an incongruity between the stem and the cement mantle. This was repeated 8 times. Stems were rotated throughout cement polymerisation by a pair of pliers applied to the top of the stem. The use of pliers was necessary because as the cement polymerised it became impossible to move the stem through an arc by hand. At the end of cement polymerisation all specimens showed between approximately 5 and 10 degrees of rotational instability and the cement mantle showed an hour-glass deformity.

Following cement polymerisation the position of the stem relative to the cement mantle was recorded on an Instron 1122 materials testing machine. Composites were then placed in the pressure rig and fluid at 150 mm Hg applied to the unloaded stem-cement interface. Volumes of flow were recorded in the routine fashion.

Stepwise subsidence of the femoral component into the cement mantle was produced by loading at 0.1 mm/hr in saline at between 35 and 40 degrees centigrade. Increments of subsidence of 0.1-0.2 mm were produced. Following each increment of subsidence the composites were returned to the pressure chamber and fluid flow over the following hour measured. This process was repeated until the interface was sealed against fluid for 1 hr or until the cement mantle fractured.

RESULTS

Experiment 1

No polished tapered stem effectively sealed the stem-cement interface prior to loading with a mean flow rate of 5.2 ml/hr (range 1.2-8.4 ml/hr).

Mean subsidence following loading was 0.56 mm (range 0.4-0.7 mm) at both 1 and 24 hr.

Following loading the stem-cement interface provided a complete seal against fluid flow in all 5 studied specimens. There was a significant difference in the ability of the stem cement interface to provide an effective seal against fluid for components pre- and post- loading (Fishers Exact test $p = 0.02$).

Experiment 2

In all cases following cement polymerisation the stem could be rotated 5-10 degrees within the cement mantle. This rotation was assessed by fixing a metal wire to the stem and measuring the range of rotation of the stem against a protractor.

When fluid was first applied to the stem-cement interface flow rates of greater than 100 ml/hr were observed in all cases. Flow rates greater than 100 mm/hr were maintained in all specimens with subsidence of up to 0.4 mm. Beyond this point flow rates decreased with incremental loading. In none of the 8 cases studied, with a total of 39 increments of subsidence measured beyond the point that flow rates

decreased to less than 100 mm/hr, did an increase in flow rate occur with subsidence. In 5 cases the stem-cement interface was sealed with subsidence between 1.0 and 1.3 mm (mean 1.14 mm). In 3 cases the cement mantle fractured prior to the stem-cement interface being completely sealed. Mean subsidence to fracture was 1.17 mm (range 1.0-1.3mm). The fractures always occurred at the junction of the expanded proximal portion and the narrow distal segment of the stem where stresses were greatest (Figure 10.2). In all cases prior to fracture the fluid movement at the stem-cement interface had decreased to less than 0.1 mm/hr.

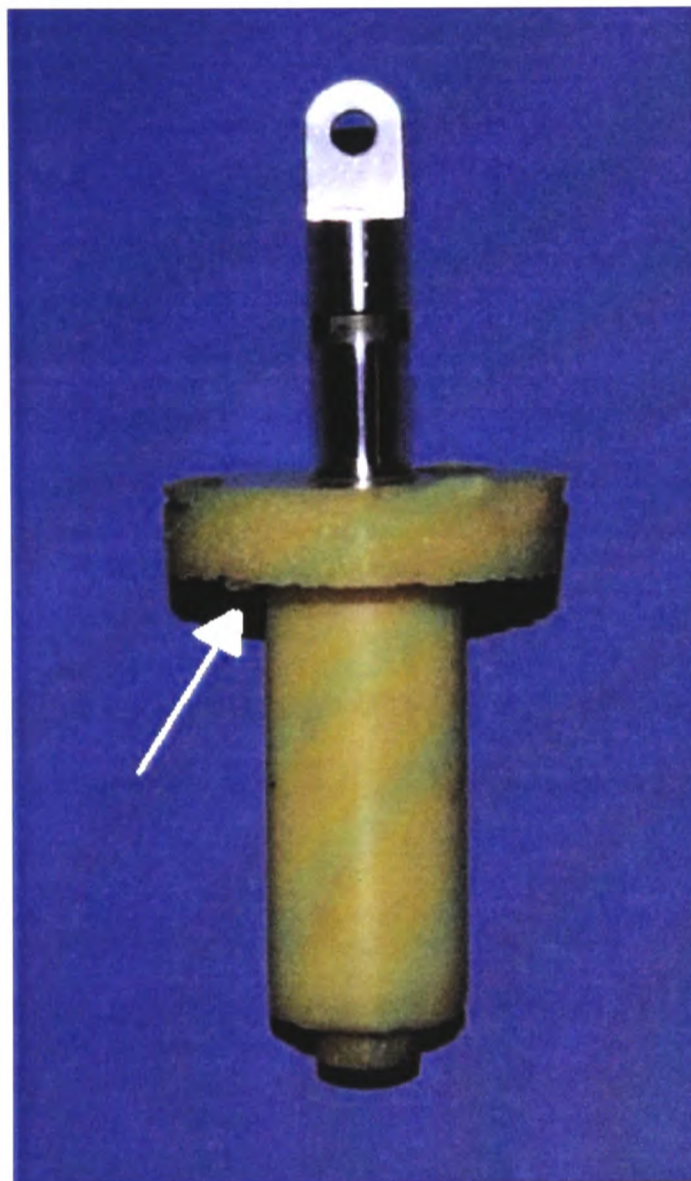


Figure 10.2. Fracture point of loaded cement mantles.

DISCUSSION

It was seen in the previous chapter that even with extremely poor cementing technique the stem cement interface of the polished stem was resistant to fluid flow along the stem-cement interface. In an attempt to model how subsidence of a stem

affected fluid movement at the stem-cement interface of polished stems it was necessary to produce even more extreme deficiencies in cementing technique. Clinically these extremes would not be expected to occur but the author still believes that these experiments give some insights into how subsidence affects the sealing of the stem cement interface. It is important to note that each increment of component subsidence improved the seal at the stem cement interface. Subsidence never made the seal less effective.

Even with 5-10 degrees of rotational instability at the stem cement interface and the unrealistic loading regime, subsidence of the magnitude encountered clinically with polished Exeter stems was able to decrease fluid flow to zero in 5 of 8 cases and to less than 0.01 mm/hr in the other 3 cases prior to mantle fracture. It is more than likely that had the loads been applied over a more extended period and the stress riser in the cement mantle had been avoided further subsidence at the stem-cement interface would have been tolerated and all interfaces completely sealed prior to mantle fracture. In vivo such a stress riser would not be present and so such a failure mechanism would not occur.

In vivo, cyclical loading occurs at the rate of 1-2 million cycles per/year usually with an 8 hour break from loading each day. Loading regimes which load components for example, at 1-2 Hertz continuously, are unrealistic as they ignore the time dependent properties of PMMA. The loading regime used in this study was also different from that encountered in vivo which could explain the fractures of the cement mantle seen in 3 of the 8 cases. The aim of this study was to produce component subsidence to study how this affected fluid movement at the stem-cement interface in the short term. The fractures that occurred in the cement mantle are a reflection of the study design and are in no way intended to reflect the ability of a component to subside inside its cement mantle in vivo.

In order to tie in the findings of this study with those of the previous chapter, the earlier clinical studies, and observations from the literature it is necessary to introduce the concept of taper-slip fixation, to outline some of the time dependent

properties of PMMA and to discuss how component geometry and surface finish will influence fluid movement and the clinical outcome of cemented femoral components. The rest of this chapter will be devoted to such a discussion.

TAPER-SLIP FIXATION

A fundamental characteristic of the taper is the fact that progressive instability is not a sequel to its subsidence or engagement: in fact, the latter increases the stability of the device. This is easily demonstrated in the laboratory (Ling 1980, Lee 1978). With a tapered stem, friction between the stem and the cement, that is related to the surface finish of the stem (Miles 1990, Verdenshot 1996) has a profound effect on load transmission, not only at the stem-cement interface, but indirectly also through the cement and at the cement-bone interface (Ling 1992) in both of which the time-dependent behaviour of cement also plays an important part (Holm 1980, Perkins 1990, Hustosky 1996, Hughes 1997). When friction is low, as with the polished tapered surface, the ratio of radial compression to shear at the stem-cement interface is high. As the friction between stem and cement increases, the ratio of radial compression to shear becomes less, and with a stem that is fully bonded to the cement, there is no compression at all. This high level of radial compression occurring at the stem-cement interface is probably critical in maintaining the seal of the stem cement interface with the Exeter prosthesis in vivo contributing to the low incidence of osteolysis associated with this stem.

As stated previously a taper, when loaded, subsides and does not back out of its mantle when the load is removed (Mann 1991, Manley 1985). If a loaded component was polished but not tapered it would probably back out following loading or if it was unsupported distally would pass through the cement mantle. In the cases presented in this chapter, and chapter 8, fluid under pressure was applied to the stem-cement interfaces whilst the components were unloaded. This provides further evidence that the Exeter stem, or at least its lower third, is acting as a true taper. Components which did not act as tapers would not maintain their subsidence following unloading and the incremental decrease in fluid flow at the stem cement interface as observed in

this chapter would not have been observed. This illustrates how it is component geometry as well as surface finish which is important in maintaining the seal of the interface achieved by component loading.

Stem rotation

In vivo there are posteriorly directed forces on the femoral head which tend to force the femoral component into retroversion. The RSA study of Alfaro et al (Alfaro 1998), showed that as well as subsiding at the stem-cement interface the Exeter stem migrated into slight valgus and the femoral head migrated posteriorly. This rotation of the polished Exeter component was significantly less than the Charnley Elite stem (which has a roughened surface). Furthermore the rotational stability of the Exeter stem was not affected by the orientation in which it was placed in the femoral canal (i.e. initial anteversion). This was in contrast to the Charnley Elite stem in which rotational stability was dependent on initial anteversion. It appears that clinically the subsidence of the Exeter stem within the cement mantle gives it increased rotational stability and in vivo it only rotates posteriorly a few degrees

The subsidence of the Exeter stem reported by Alfaro et. al. averaged around 1 mm over the first year with the maximum posterior head migration being less than 1.5 mm. It can be calculated from the rotation measured in this study that the movement of the corners of the stem, relative to the bone would be a maximum of approximately 0.1 mm. This means that the subsidence of the stem is one order of magnitude greater than its rotation. No information is available on where the rotation of the component occurred in this study though it may have been at the bone-cement interface (unlikely as no subsidence occurred at this interface), within the cement or at the stem-cement interface. This rotation of the Exeter stem observed on RSA means that a space at the stem-cement interface, which may allow the passage of fluid and debris may be created with time. As a stem which is not circular rotates a space will open behind the trailing edges (for an Exeter stem the maximum void created would be 0.1 mm if all movement occurred at the stem-cement interface; unlikely as cement creeps under torque, vide infra). The fact that fractures of, and

defects in the cement mantle, are tolerated so well for extended periods of time suggests that this potential space is not created in vivo or if it does develop it closes with time..

It has been demonstrated in this chapter that subsidence similar to that observed in vivo will virtually eliminate fluid movement at the stem-cement interface even with rotational instability well beyond that encountered clinically. In the short term the stem-cement interface is probably, at least partially, sealed by the subsiding polished stem jamming into the cement mantle. The tapered Exeter stem will, as it subsides into its cement mantle, present a larger cross sectional area to each point on the cement mantle (Figure 10.1). This will at least partially close the stem-cement interface. The subsidence of the stem into the cement mantle is dependent on cement creep and stress relaxation. Cement creep will occur in the direction of load and normal to the load (lateral creep), and it is probable the time dependent properties of PMMA are ideally suited for sealing any voids created at the stem-cement interface not closed by the subsiding stem, even in the presence of stem rotation. How this may occur will be discussed in the following section

Finally, in this section, it is important to note that the rotational stability of the polished tapered Exeter stem observed in vivo, which was so much less than modeled here suggests that applying a rotational moment to the implant following debonding in chapter 8 would not have opened the interface to fluid.

TIME DEPENDENT PROPERTIES OF PMMA

As stated above PMMA creeps under load. Materials which creep do so in response to stresses applied in any direction which means that they will creep in torsion as well as in compression. Torsional creep of methacrylate dental composites has been well characterised (Papadogianis 1984). For concrete it was found that creep under torsional loading is affected by stress, water-cement ratio and ambient temperature in qualitatively the same way as creep in compression and that the creep-time curve is

the same in torsion as compression (Neville 1995). It is not unreasonable to propose that PMMA will creep in vivo under rotational loads for long periods in the same manner as in compression. This means that some, or all, of the rotation observed by Alfaro et al (Alfaro 1999) may have occurred within the cement. Furthermore if the stem was rotating within the cement creep and stress relaxation (Chivirut 1984) of the cement in response to the load would minimise stresses within the construct.

When creep occurs in a substance it does so both in the direction of compression and normal to the line of compression. This is referred to lateral creep and is characterised by the Poisson ratio. For PMMA the Poisson ratio, which is defined by lateral strain/axial strain is poorly characterised though it is usually considered as 0.32 (Kusy 1978) Lateral creep (as a consequence of lateral strain) on a stem loaded in compression will contribute to closing any space which opens around a rotating stem.

An important question is whether the stem-cement interface will eventually open to fluid with time. The very long term creep properties of PMMA (i.e. greater than 20 years) have not been studied in vitro, but it is a statement of fact that any material when loaded will creep (even though it may not be measurable), and that creep will continue indefinitely, or until failure. This is a basic physical characteristic of all materials. Experimentally this has been shown with concrete, (whose creep characteristics are probably better studied than any other material) which continues to creep under compressive load for at least 30 years (Troszell 1958). The creep is not insignificant with time, being 36% at 30 years as compared to at 1 year. Thus, though the creep rate may be seen to decrease with time the stem-cement interface of a polished taper will remain under compression and the cement continue to deform as a consequence of the transmitted load. The seal developed at the stem-cement interface should therefore be expected to be preserved, or even enhanced with time.

In this chapter we have observed the beneficial effect of subsidence of polished tapered stems in sealing the stem-cement interface against fluid flow at the stem-cement interface. It is believed that in vivo it is the combination of the stem surface

finish, the stem geometry and the properties of PMMA that seal the stem-cement interface of the polished Exeter stem against fluid (and debris). This is believed to be one of the principle reasons that these stems are associated with such a low incidence of osteolysis in the presence of incomplete cement mantles and cement mantle fractures.

CHAPTER 11

DISCUSSION-CONCLUSIONS

INTRODUCTION

The principle aim of this thesis was to establish, and to explain, the low incidence of osteolysis around polished tapered Exeter femoral components. The clinical studies have confirmed a low incidence, and it is believed that the experimental studies provide a rational explanation for the clinical findings. The principle conclusion is that polished Exeter stems are rarely associated with focal osteolysis in vivo because they prevent fluid (and therefore particles and cytokines which may activate osteolysis) from passing along the stem-cement interface. This occurs because of a combination of surface finish (which also ensures that they do not generate debris at the stem-cement interface with debonding), component geometry and the time dependent properties of PMMA.

Beyond this principle conclusion, a pathway of communication for fluid along the stem-cement interface of roughened stems raises a number of important implications for the study of cemented femoral components. Some of these were discussed previously, whilst others will be explored in this chapter.

11.1. Fluid and debris access to the endosteal surface of the femur

In chapter 1 a review of the literature with regards to focal osteolysis the issue of pathways of access from the joint articulation to zones of focal osteolysis was introduced. It is believed that the work contained in this thesis adds significant new insights to current knowledge suggesting that it is the stem-cement rather than the bone-cement interface which is the principle pathway along which fluid and particles migrate to produce focal osteolysis around the distal two-thirds of a cemented femoral component.

The most important clinical evidence in this thesis that identifies the stem-cement interface as the principle pathway for fluid and particles to reach foci of osteolysis are

the finding of chapter 4. In particular all cases of focal osteolysis around the middle or distal thirds of the studied femoral components were associated with

1. Incomplete cement mantles
2. Polyethylene in all zones in which it was looked for and
3. Well fixed bone-cement interfaces (as determined at operation) proximal to the zones of lysis.

Some examples of such cases are illustrated below (Figure 11.1,2)

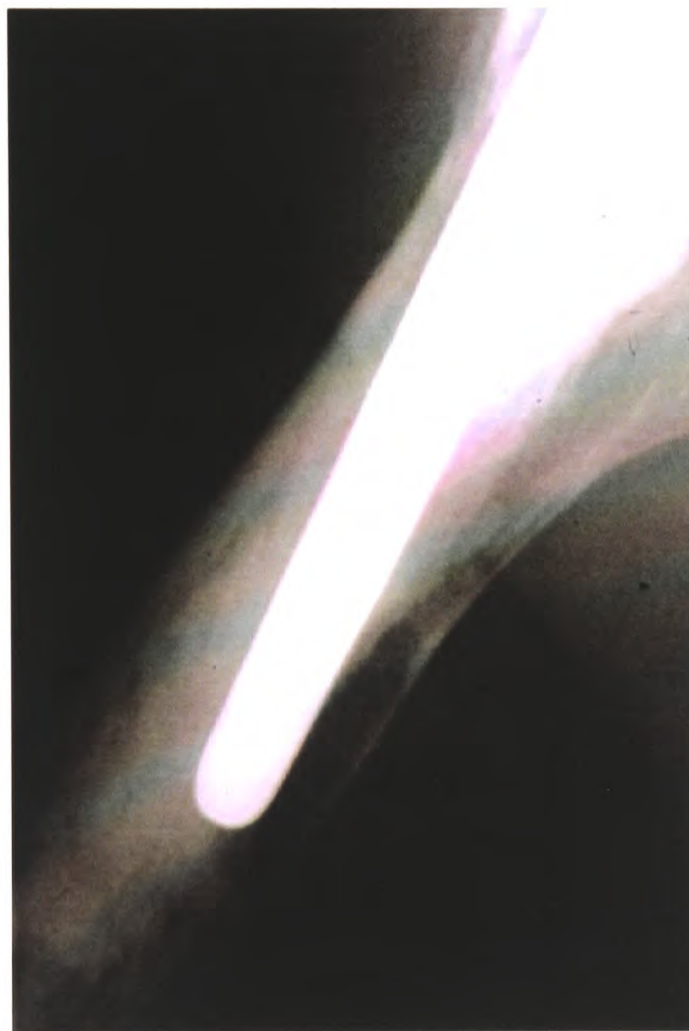


Figure 11.1. Stem tip osteolysis with a rough surfaced Charnley component.

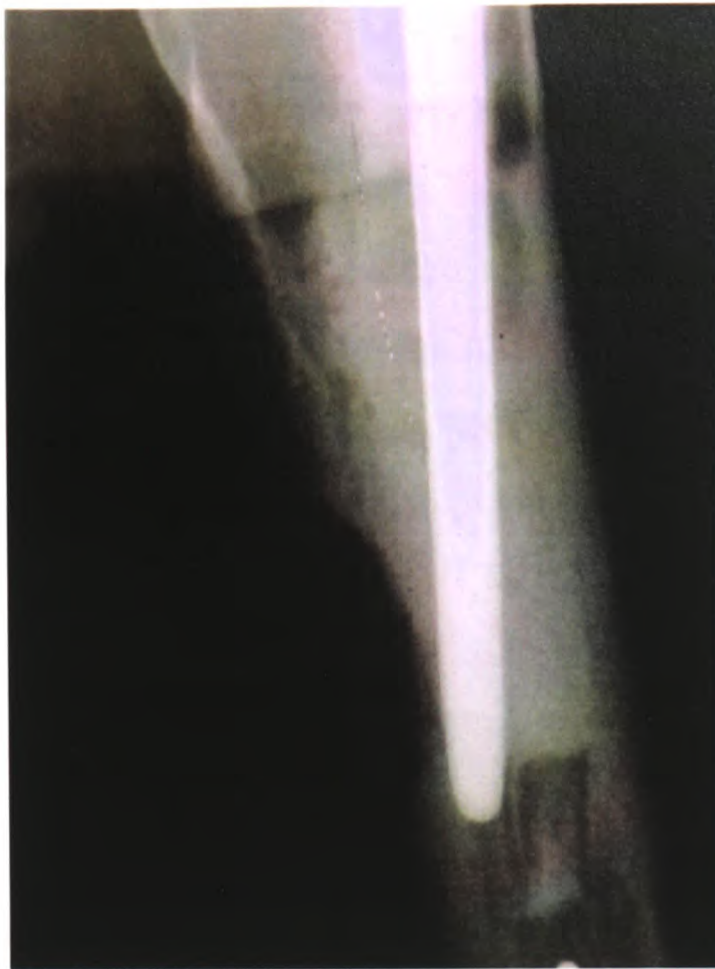


Figure 11.2. Mid-stem and distal osteolysis with a Hinek component

The work from chapter 4 has been integrated into an expanded study (Anthony 1999) which adds further evidence to the above hypothesis. We have now gathered 30 cases of focal endosteal osteolysis in which every lesion has been directly explored either at surgery or at post-mortem and has been found to be in direct continuity with a cement mantle defect. Histology is available in 20 of the 30 cases, all 20 of which show the presence of particulate debris of polyethylene; most also show the presence of fine metal and acrylic debris. In 3 of the cases, histological examination of the cement-bone interface proximal to the site of the lesion showed direct contact between the cement and living bone excluding this as a potential pathway for fluid and particle migration. Radiologically and intra-operatively, in all surgical cases, the cement-bone interfaces proximal to the lytic lesions were intact again making this interface an unlikely explanation for how polyethylene reaches the osteolytic foci. With the number of cases in this study the confidence limits for the association of cement mantle defects and focal osteolysis, using Poisson's variable for rare events, become 88-100%. This means that the chances of a lytic lesion occurring in the distal femur in the absence of a contiguous cement mantle defect is under 12%.

In the cases reported in chapter 4, and the matt Exeter stems with lysis identified in chapter 2, the lysis always occurred anteriorly at the mid-stem of the prosthesis and posteriorly at its tip. This is a constant finding with mid-stem and distal osteolysis and the anatomical explanation for this was outlined in chapter 5. If particles moved along the bone-cement interface to produce zones of focal osteolysis there is no reason that they would be distributed anteriorly at the level of the mid-stem of the prosthesis and posteriorly at the stem tip. It could be argued, though not very convincingly, that proximally the cement mantle is thinner anteriorly (Figure 11.3) and that this somehow produces a weaker stem-cement interface than posteriorly. This may allow particles to move preferentially along the anterior edge of the prosthesis. This argument becomes even weaker when distal osteolysis is considered, as the cement mantle posteriorly is thickest throughout much of the length of the stem (Figure 11.3). If the bone-cement interface transports particles it must do so in a spiral pattern to explain focal osteolysis anteriorly at the mid-stem and posteriorly at the level of the component tip.

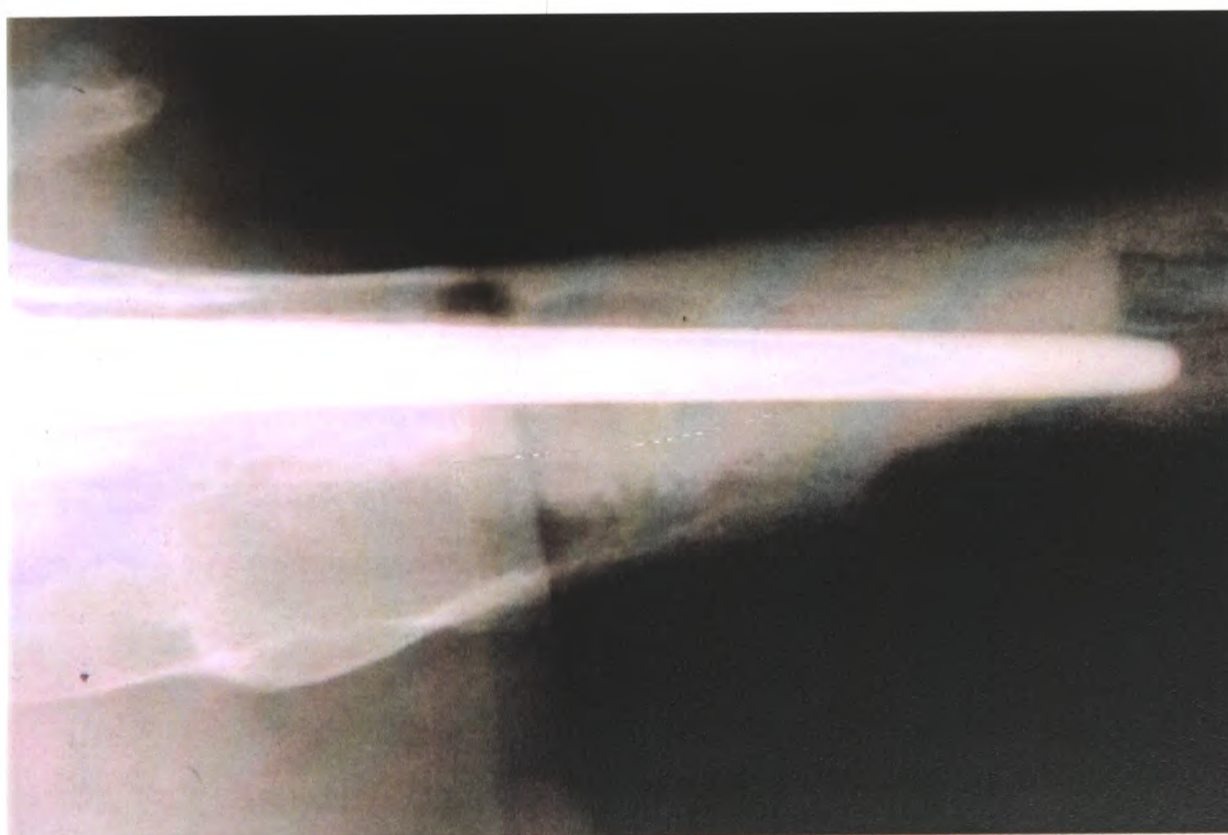


Figure 11.3. Anterior and posterior osteolysis. Do particles or pressure spiral along the bone-cement interface?

The anatomical distribution of cases of focal osteolysis reported in the literature are entirely consistent with the findings reported here. For example Tallroth et al (Tallroth 1987), described 19 cases of aggressive osteolysis around cemented femoral components. osteolysis and in 10 of 12 cases in which there was proximal lysis it “appeared to start in the region of the lesser trochanter”. They also reported granulomas around the lower stem in 11 cases and around the tip in two. The anatomical distribution of osteolysis they describe is entirely consistent with the predicted distribution of cement mantle defects described in chapters 4 and 5 of this thesis. The same is true of cases of unexplained focal and mid stem osteolysis reported by other authors (Carlsson 1983, Jasty 1986, Huddleston 1988, Mohler 1995). In the last of these studies, which looked at matt coated Iowa stems, focal osteolysis was identified around the tip of the component in 18 of the 20 cases which developed osteolysis. In all cases which came to revision, there was debonding of the stem from the cement and the bone-cement interfaces were ‘grossly intact in areas without osteolysis. The authors were unsure as to how the osteolysis developed. The opening of the stem-cement interface to fluid and debris accessing endosteal bone by passing through defects in the cement mantle is the best possible explanation.

In chapter 2 it was observed that focal osteolysis was significantly more common with matt than polished stems in the presence of an identical operative technique. As femoral preparation was the same in all cases there is no reason to expect that the bone-cement interfaces were any different at the time of preparation. At 8-10 year follow-up the clinical scores were the same for both the matt and polished stems and radiographically in neither stem type was osteolysis noted in Gruen zone 1 or 7. This suggests that the bone-cement interfaces were the same for the two different types of stem.

It is possible, though not likely, that there are differences between the bone-cement interfaces of the matt and polished stems in spite of the fact that no clinical or radiological difference was noted. It is postulated that the shear stresses at the bone-cement interface are less with polished than rough stems (Shen 1998) thus protecting

this interface from debonding (Gardiner 1994). This premise was confirmed on two recent RSA studies (Alfaro 1998, Ornstein 1997) which showed that migration of polished Exeter stems occurred solely at the stem-cement interface whilst rough surfaced Charnley stems migrated, at least in part, at the bone-cement interface. In RSA studies implants which are destined to fail continue to migrate (Ryd 1992) indicating that a stable situation is not achieved. The good clinical result of the matt stems suggests that a stable situation was achieved, implying a stable bone-cement interface.

Histological study of stable bone-cement interfaces show either intimate bone-cement contact or a stable membrane between the bone and the cement (Schmalzried 1993, Linder 1986). In Schmalzried's study they showed intimate bone-cement contact was found in the presence of rough surfaced stems which were mostly partly debonded at the stem-cement interface. There is thus no reason to suspect any difference in the bone-cement interface of the two series of matt and polished Exeter stems reported in chapter 2. This means that differences at this interface cannot explain the difference in the incidence of focal osteolysis. What could explain the difference, is the surface finish of the implants, with the stem-cement interface being sealed by the polished stems, preventing osteolysis, even in the presence of at least a 13 % incidence of cement mantle defects.

It is differences at the stem-cement rather than the bone-cement interface that explain the different significance of cement mantle fractures depending on stem surface finish and design. Punch-out cement mantle fractures occur because of increased tensile loads in the mantle generated by an end bearing stem. With fracture the stem and the lower part of the mantle move distally. The proximal cement mantle remains undisturbed implying an intact bone-cement interface. The relative motion between the stem and the proximal mantle means there has been component debonding at the stem-cement interface. For rough stems this opens the stem-cement interface to fluid and debris producing a high incidence of osteolysis (Huddleston 1998). With the polished Exeter stem, subsidence of the stem seals the interface and prevents osteolysis in the majority of cases (Chapter 3).

It is believed that the balance of evidence from the cases presented in this thesis and those reported in the literature suggest that the stem-cement interface is a far more important avenue for the transport of fluid and particles than has previously been assumed. To repeat what was concluded in chapter 3, it is probable that in aseptic loosening, focal distal osteolysis is always associated with defects in the cement mantle. It is most probable that in all cases, the pathway by which fluid and wear particles reach these defects, is the stem-cement, not an intact bone-cement, interface.

11.2 Fluid at the stem-cement interface and corrosion of implants

It has been shown how the passage of fluid into the stem-cement interface may contribute to debonding of components and how the opening of this interface to fluid and, ultimately to debris, may contribute to focal osteolysis. As well as these effects, the presence of fluid at the stem-cement interface may accelerate both implant corrosion and wear at the stem-cement interface. These processes will both increase debris production, further expanding the stem-cement interface for the passage of debris and pressure changes. In this and the next section the implications of fluid at the stem-cement interface with reference to these two points will be discussed.

Degradation of metal-alloy implants produces the release of metal particles. “Degradation may result from electrochemical dissolution phenomena, wear, or a synergistic combination of the two” (Jacobs 1998). Corrosion of orthopaedic implants is a complex multifactorial phenomenon. The free energy for oxidation (corrosion) of the metals commonly used for the femoral component in total hip replacement are negative. What this means is that if these metals are not treated to form a barrier to oxidation then spontaneous corrosion of the metal will occur. The principle method of preventing corrosion of metallic components is by passivation. This process involves the formation of a stable metal-oxide layer on the surface of the component and prevent the migration of ions across this barrier. If the passivation layer is lost then corrosion may develop as exemplified by the micromotion (fretting)

of Morse tapers leading to abrasive loss of the passivating oxide layer with the subsequent development of corrosion (Mc Kellop 1992).

Fretting and micromotion may lead to the loss of the passivation layer from the stem of a femoral component, but it can also be lost due to applied stresses (Jacobs 1998). Even well fixed femoral components are subjected to stresses and it is at areas of peak stress that stem-cement debonding is thought to be initiated. Once the passivation layer is lost, the presence of fluid at the stem-cement interface of stems at the areas of peak stress, may accelerate the corrosion process.

When a metal corrodes it does so by oxidation (that is the loss of electrons). For the oxidation process to continue a reduction reaction must occur. The typical reduction reaction for orthopaedic implants is the reduction of oxygen and water to form hydroxide. If this reaction is eliminated then corrosion will be suppressed (Jacobs 1998). This may occur in the depths of isolated crevices. The presence of a pathway of communication for body fluids at the stem-cement interface will mean that for rough surfaced implants the reduction reaction, and component corrosion can continue.

Metal particles and ions can be produced at the stem-cement interface of well fixed (Black 1988) and loose femoral components (Jacobs 1991). Once loss of metal begins the mode of component damage becomes difficult to determine. It is possible that fretting is the only source of metallic debris production but this is unlikely. It is probable that mechanically increased electrochemical phenomena such as fretting corrosion, stress corrosion and corrosion fatigue contribute to the loss of ions from loose implants (Jacobs 1991). That corrosion is one form of loss of metal from the surface of certain designs of chrome-cobalt prostheses was confirmed by a retrieval study of loose cemented implants (Smethurst 1978). In this study using a combination of scanning electron microscopy and energy dispersive X-ray analysis (a technique which allows qualitative and quantitative analysis of elements with atomic numbers greater than 11 on the surface of implants) they were able to confirm that

corrosion of these implants occurs in vivo. There is thus good evidence that corrosive wear of implants can occur.

Crevice corrosion can occur within Morse tapers at the head neck junction and lead to sufficient metal breakdown to produce fractures of the prosthesis (Collier 1995). Given that 'elimination of fluid from the crevice environment will eliminate the potential for corrosion' (Collier 1995), it is understandable how the corrosion of rough surfaced femoral components will be accelerated by the presence of fluid in the stem-cement interface

11.3 Fluid flow and debris production at the stem-cement interface.

The scale of movement that occurs at the stem-cement interface of partially debonded but otherwise 'well-fixed' stems in vivo is not known. Careful inspection, in appropriate light, of the surfaces of such stems that have been retrieved at re-operation or post-mortem, irrespective of their geometry or the alloy from which they were manufactured, often shows clear evidence of wear damage that implies interfacial movements of small amplitude. These changes are easily missed on superficial inspection of the stem surface. In stems that are loose within the cement, the damage is more marked. The distribution of the wear damage is characteristic (Anthony 1990, Lee 1993, Howells 1999) affecting mainly the medial half of the posterior surface and the lateral half of the anterior surface of the stem (Figure 11.4) thus reflecting the importance of the torsional forces applied to the device during life.



Figure 11.4 Burnishing along the antero-medial aspect of a retrieved matt Exeter stem.

Surface roughness traces and scanning electron photo-micrographs of device surfaces demonstrate the loss of metal that these interfacial movements may produce and suggest that an important part of this process is abrasive wear. In addition to abrasive loss of metal, there is similar sacrifice of cement from the corresponding internal surface of the cement mantle. These appearances imply the production, at the stem-cement interface, of large numbers of fine metal and acrylic wear particles together with particles of the radio-opacifier in the cement. Furthermore particles of alumina, the 4 hardest known substance, which is used to roughen the stem may be exposed (Figure 11.5).



Figure 11.5. EM photograph showing an exposed particle of alumina, on the surface of a roughened femoral component.

Once produced, different particles act as third bodies at the stem-cement interface and produce third body abrasive wear and slurry erosion, that contributes to further damage of the stem surface and wear of the adjacent parts of the inner surface of the cement mantle. A surface that appears completely polished can be produced in this way. It is not generally appreciated that the production of a polished stem during manufacture is through a series of steps that involve wearing down the rough surface of the original stem forging. In fact, the polished stem can be looked on as a 'pre-worn' stem. Thus, the rougher the surface of the stem when the abrasive damage begins, the more debris is produced as the process continues and a comparison of scanning EM traces from undamaged matt-surfaced and polished areas shows the marked loss of metal from polished areas of rough stems (Figure 11.6,7). In addition, the excessive production of debris has been convincingly confirmed clinically (Mohler 1995, Sporer 1998) as well as in loading experiments comparing polished and rough tapered surfaces (Verdonschot 1995). These experiments showed that acrylic debris was copious at the interface between a rough taper and the cement, whereas it was not found at the interface between a polished taper and the cement.



Figure 11.6 EM photograph of undamaged area of a rough surfaced component.

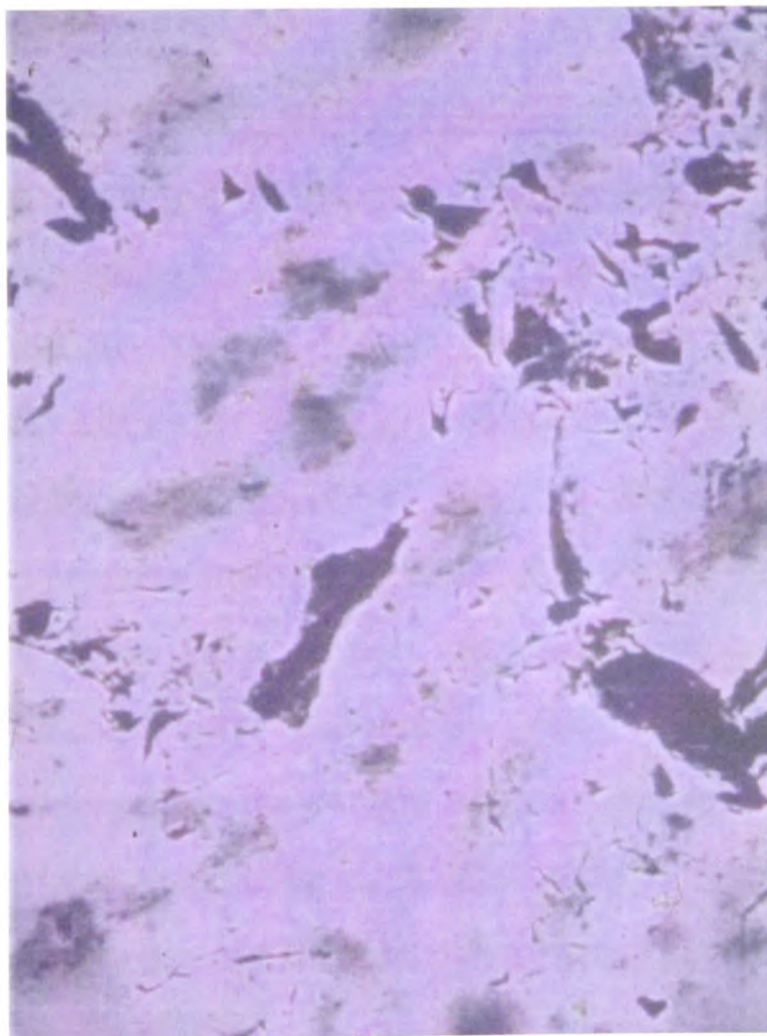


Figure 11.7. EM photograph of 'polished' area of a rough surfaced femoral component.

The progressive attrition of the inner surface of the cement mantle that the abrasive wear creates, leads to a slow increase in the internal dimensions of the cement mantle that, in turn, allows the amplitude of cyclical stem movements under load to become gradually larger, and so further increase the wear damage as the stem becomes steadily more unstable. A vicious circle is thus created that may be aggravated by toggling of the stem on the collar or by end-bearing in the cement mantle, so that the stem, supported by the cement at its tip then begins to behave, under torsional loads, rather like a spinning top that is reciprocating rather than spinning. Under these circumstances, the additional hydrostatic effects produced by the stem moving inside the cement mantle may be profound (Anthony 1990) and contribute to the liberation of debris from the stem-cement interface into the joint space. This was confirmed by the retrieval study of Howell et al (Howell 1999) which showed that there was little retention of debris at the sites at which it was produced with rough surfaced stems. Such debris may act as third bodies in relation to the articulation itself, scratch the femoral head, and increase the wear of the polythene socket.

Although evidence of wear damage to polished stems is sometimes seen in vivo the mechanism in relation to the polished surface is one of fretting rather than abrasion. The importance of this distinction is that with the former, the loss of metal is below the original level of the stem surface (Howell 1999) (Figure 11.8), whereas with the latter there is progressive abrasion of the tips of the asperities above the level of the bases of the valleys between the asperities. Thus the fretting damage to a polished stem is not such as to produce attrition of the inner aspect of the cement mantle and subsequent instability of the stem, so that the small amount of debris formed is retained at the interface and not liberated into the joint (Howell 1999). Subsidence of the polished tapered stem within the cement will tend to close any gap which does form between cement and stem, trapping debris in the stem-cement interface, and generally preventing further damage from secondary slurry erosion.



Figure 11.8. Sub-surface fretting damage to a polished stem.

A recent investigation into the fretting wear seen on explanted hip replacement femoral stems revealed that some of the abrasive damage was due to slurry wear (Howell 1999). Slurry wear is the process where the abrasive-removal process is produced by the mixture of an abrasive substance with water or other fluid. Particles can produce wear on a surface, but the addition of a fluid to the system improves the efficiency of the abrasive process (Kalpakjian 1992). Abrasive wear cannot occur without the presence of particles. The finding of the characteristic pattern of slurry wear on retrieved rough stems confirms the presence of fluid carrying wear particles capable of abrasion at the stem-cement interface (Figure 11.9).

It has been demonstrated previously that the cement mantle and the stem become abraded with movement of loose rough stems which suggests an expanded space for fluid and particle migration at this interface (Lee 1992). However the finding of slurry wear shows that a further consequence of fluid and particles moving along the stem-cement interface is an increase in wear of roughened stems. This increased wear will lead to an increase in the production of metal and polymethylmethacrylate particles further opening the stem-cement interface to fluid and wear particles from the joint articulation. Increased numbers of particles of polymethylmethacrylate,

polyethylene, and metal, are produced leading to an increased potential for fluid to access the endosteal bone via defects in the cement mantle.

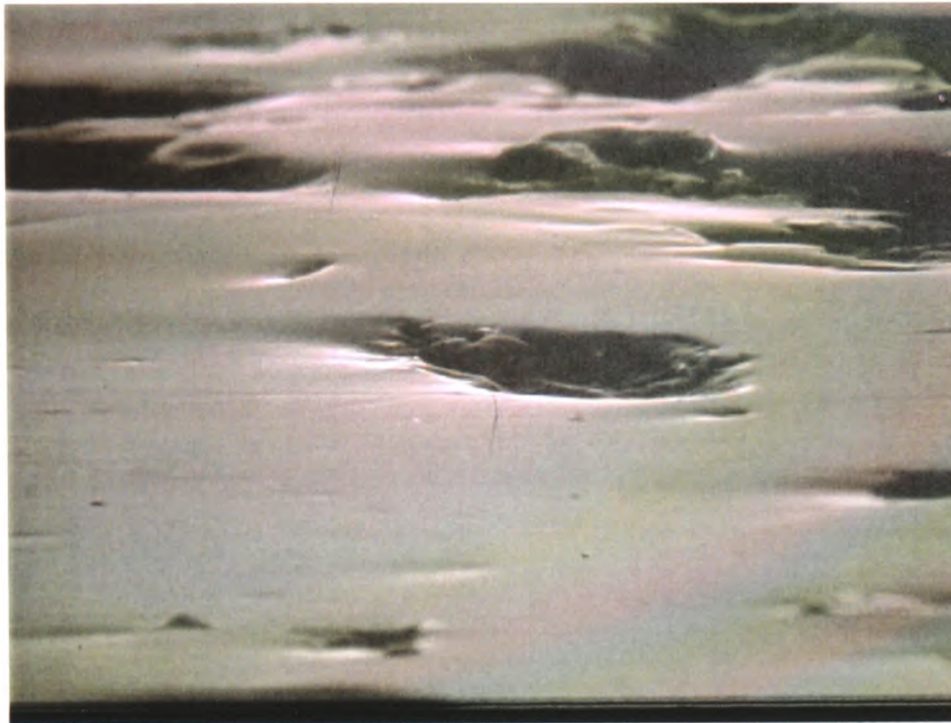


Figure 11.9 Slurry wear on a retrieved rough stems confirming the presence of fluid carrying wear particles within the stem-cement interface.

11.4 Why does osteolysis not occur inevitably with rough stems and incomplete cement mantles?

The development of focal osteolysis is a complicated issue and many factors as to its development remain unresolved. It is proposed here that focal femoral osteolysis, below the level of the lesser trochanter, will not develop in the absence of a cement mantle defect. However cement mantle defects are more common than osteolysis, which raises the question as to why osteolysis does not always develop with rough stems and cement mantle defects. As fluid can pass along the stem-cement interface of rough stems, both debonded and bonded, providing a possible conduit for wear particles and pressure changes from the joint articulation, it could be argued that osteolysis should be inevitable around such components, in the presence of incomplete cement mantles.

It may be that osteolysis will ultimately develop at the points where cement mantles are incomplete if the implant remains in situ long enough. Only long term follow-up of implanted components will reveal the answer to this. However it is probable that other mechanisms are involved. In this section a number of these possibilities will be discussed whilst acknowledging that they remain speculative.

There are two broad reasons why lysis may not develop at points of incomplete cement mantles. Firstly the stem-cement interface may become effectively sealed, or at least sealed sufficiently to limit the osteolytic stimulus at the point where the cement mantle is defective, even with rough stems, under certain conditions. Secondly there are factors relating to the biology of the patient.

The membrane at the bone-cement interface of loose components may be well organised and contain low numbers of wear particles (Linder 1975), meaning it may, in certain instances, provide a barrier to particle migration. Membranes retrieved from the bone-cement interface of loose implants retrieved from dogs (Hori 1982) showed a similarly well organised, fibrous membrane. The membrane was compliant and underwent large strains with load. Fluid was squeezed out of the membrane and when the load was removed it slowly rehydrated. Such a membrane may be organised enough to block the passage of particles and may dampen the fluid fluxes sufficiently to prevent pressures sufficiently high to cause osteolysis being produced.

Studies which have looked for a membrane at the stem-cement interface have always identified one (Fornasier 1976, Anthony 1990). A membrane at the stem-cement interface could act in a similar way to the membranes described at the bone-cement interface, and in certain cases, become stable enough to contribute to the long term survival of the component. The membrane at the stem-cement interface may also limit the passage of fluid and particles along this interface, to such low pressures and numbers respectively, that there is not a sufficiently great stimulus at the area of an incomplete mantle to incite a macrophage response. In cases where osteolysis develops the membrane has presumably not developed sufficiently to form a barrier to the biological stimulus essential to the development of osteolysis.

In chapter 1 it was discussed how particles and pressure may play a synergistic role in the development of osteolysis. It is also possible that different particles act in a similarly synergistic way to initiate the osteolytic process. Components and bearing surfaces consist of many different materials and these different materials may insight a different biological response in different patients. Furthermore stem geometry may play a role in the way pressure is transmitted along the stem-cement interface. Certain stem types may become relatively more stable than others following debonding. Some stem types may be more resistant to debonding in the first instance. Clearly this study does not provide all the answers to these questions but does suggest future directions of study which will be discussed in more detail below.

Modern cellular biology suggests that the tissue reaction to wear particles is not only a simple inflammatory process but also a complex immune response (Willert 1999). Patients will respond differently to different stimuli such as the mechanical and inflammatory stimulus delivered to the endosteal bone at the point that the cement mantle is defective. It may be possible that these response are normally distributed across a population. Alternately it may be possible that some patients develop a hypersensitivity to certain particles which will accelerate the development of osteolysis. The biological differences between patients are not well defined but it is almost certain that they play an important role in the development of osteolysis.

11.5 Surface finish and stem geometry

The polished Exeter stem clinically is believed to always subside at the stem-cement interface. The principle aim of the work on subsidence and fluid movement presented in chapter 10 was to show that subsidence does not open the stem-cement interface of this design of polished stem to fluid and debris. Experimentally component subsidence was able to improve the seal at the stem-cement interface in all cases and every increment in subsidence improved the seal at the stem-cement interface. Thus it is believed that the principle aim was achieved.

Whether component subsidence would be as beneficial for polished stems which do not function as a true taper is not clear. Furthermore it is not certain as to whether subsidence is essential to maintain the seal at the stem-cement interface clinically or if the resistance of the polished surface to fluid movement is sufficient to provide this seal. A highly polished femoral component will produce limited debris at the stem-cement interface when it debonds and this may be sufficient to prevent the development of osteolysis. It is the authors belief that subsidence of the tapered stem will improve component stability and the seal at the interface. As will be discussed below it is probable that all polished stems subside at the stem cement interface and the low but recognised cases of focal osteolysis with the polished Charnley stem suggest that it is sealing the stem-cement interface less effectively than a double tapered component such as the polished Exeter.

Any structural excrescence (collar, flange, ridge etc.) or localised depression on any part of the stem surface, or an anatomical shape for the stem, will interfere with the ability for a stem to function effectively as a taper. Moreover, no stem that is 'end-bearing' in the cement can function as a self-locking taper (Archibald 1991) explaining why so many Exeter stems which have been in situ for long periods without hollow centralisers have been associated with fractures of the cement mantle (Chapter 3).

For femoral components that aim to secure a tight bond to the cement mantle (to function as a composite beam) a collar offers the theoretical advantage of decreasing component subsidence. Proponents of a collar believe that its use will allow loading of the medial femoral neck and retention of bone where it is loaded (Harris 1992), though it is doubtful that this can be achieved reliably in practice (Crowninshield 1981). It is not the aim of this thesis to debate, beyond the influence of differences in surface finish at the stem cement interface, the taper-slip versus composite beam theories of femoral component fixation. However the use of a collar with highly polished stems, such as the Classic (Smith and Nephew), suggests a mixing of philosophies. It remains unclear how the use of a collar with a polished stem could be considered advantageous and the fact that the collar, if it functions as designed,

will limit stem subsidence, means it may prevent the sealing of the stem-cement interface that occurs with a polished stem which functions as a taper.

That stem design can have a marked effect on component subsidence, and thus on the way a stem functions, was highlighted in a study by Loudon and Charnley (Loudon 1980). They looked at a series of 100 round back Charnley stems and compared them with 75 Cobra stems (Charnley stems expanded laterally into a collar) looking at subsidence and cement mantle fractures. Subsidence was 4 times greater with the non flanged (roundback) stems and 26% of patients had fractures of the cement mantle with the roundback stems compared to none of the flanged stems. The addition of the flange had a profound effect on the way that the stems behaved. By decreasing subsidence it was possible to prevent cement mantle fractures but this meant that the stem was now behaving more as a composite beam than a taper. The fundamental behaviour of a flanged Charnley stem is thus completely different from the original stem design and is another example of how design changes to an implant may have effects beyond those expected. These design changes may partially explain the worse outcome of the Charnley stem observed with newer designs of this component (Dall 1993).

The original polished Charnley had a small collar and was tapered only in one plane. In spite of this it is associated with good long term results. It may thus be argued that surface finish may be enough alone to prevent osteolysis because so little debris is produced at the stem-cement interface with debonding. Indeed the author believes that the fact that the stem was polished is critical to the fact that it has been associated with such low rates of osteolysis. However in one reported series, which only considered osteolysis seen on AP radiographs and so probably underestimated its true incidence, the polished Charnley stem showed a 3.5% incidence of focal osteolysis at a 3- 11 year follow-up. This is a low incidence but the question is would it have been prevented altogether if the stem was of a different geometry.

RSA work, previously discussed, suggests that the matt Charnley stem subsides at the stem-cement interface early after implantation. It has also been noted that there is a

high instance of cement mantle fractures with the polished Charnley stem (Weber 1975) suggesting component subsidence at the stem-cement interface. In a separate study 33% of polished Charnley stems subsided at the bone cement interface radiographically (almost certainly an underestimation of the true rate of subsidence). These facts would suggest that it is probable that the polished Charnley stem always subsides at the stem-cement interface and that its collar is not preventing a small amount of subsidence. Radiographically apparent subsidence does not appear to be detrimental to the survival of the polished Charnley stem, compared to those that showed no subsidence, whereas subsidence of more than 2 mm was a risk factor for failure (Berry 1998). Clearly the interaction of stem geometry and surface finish on the development of osteolysis and component failure is complex.

11.6 Future studies

It is believed that the clinical and experimental work presented here provides strong evidence that the stem-cement interface is an important pathway along which fluid and ultimately debris may pass. Furthermore the surface finish and the design of the stem fundamentally alter the behaviour of fluid at this interface. This can explain the low incidence of osteolysis around the polished Exeter stem observed clinically and the increased incidence of focal osteolysis around rough stems.

As well as answering a number of important questions, as previously outlined, this thesis raises a number of further questions, the answers to which are unclear. Firstly it suggests that many finite element studies, particularly those that consider debonding at the stem-cement interface, should be repeated, allowing for altered boundary conditions at this interface. If as predicted in theory (Persson 1999) the bond strength at the stem-cement interface is weakened by a factor of 10 due to the presence of fluid, many fundamental assumptions made with regards to the design of cemented femoral components will need to be made.

The next important question suggested by this study is the relative importance of component design and surface finish to the sealing of the stem-cement interface under different conditions which more closely approximate those encountered in vivo. Within the limits of this study it appears that a polished tapered stem maintains and improves the seal at the stem-cement interface with debonding. This simple model can now be expanded to test different conditions. Experiments could be initiated which looked at cyclical loading, different designs of stem, and different loading regimes. It should be emphasised that the author believes that the only true way to study what occurs in vivo is to carefully follow clinically and radiographically the outcome of THR. Attempts could be made to approximate this behaviour, but it is important that any loading regime takes into account the time-dependent properties of PMMA. In vivo, loads are applied at around 0.5-1 Hertz at 37 degrees centigrade with long periods of rest. Attempting to accelerate this loading in the laboratory means there is a risk of reaching wrong conclusions.

Fluid has been shown to be able to penetrate the stem-cement interface of well fixed rough stems and it is predicted that this will contribute to debonding. However it is clear that mechanical factors are involved in the debonding of the stem from the cement. It is not clear if the presence of fluid weakens the interface sufficiently to allow debonding to occur under load or if, in vivo, it is only after debonding, that significant amounts of fluid move along the interface. At what stage, and under what conditions, does the stem-cement interface open sufficiently to allow pressure fluctuations and debris to be transmitted along this interface. Furthermore once the interface opens to fluid and debris how does stem-geometry and surface finish influence the way in which debris and fluid move.

The stems in this study were not subjected to a rotational moment. Studying the influence of such a force on component stability and the integrity of the stem-cement interface with stems of different geometry and surface finish may provide further insights as to the development of osteolysis. How fluid moves and what forces are generated at the stem-cement interface with the 'paddling' effect of loose stems may provide further insights into the pressure versus particle debate.

As outlined in section 11.4 retrieval studies of matt surfaced stems show surface damage indicating that they have been rotationally unstable at least during some period of their implantation. It would be interesting to pursue this phenomenon in the laboratory in an attempt to reproduce this pattern of damage. If the same pattern of damage to stems could be reproduced a more realistic picture of the forces applied to stems during their implantation would be gained. This would allow more realist forces to be applied in the laboratory to other studies concerned with the femoral component in THR, and also allow more realist forces to be modeled with finite element studies.

It is clear that this body of work leaves many questions unanswered. However as this is one of the first attempts to study in depth the importance of the stem-cement interface in cemented THR it is believed that it offers important insights into this subject. Upon this background more complicated studies could be established which may provide further insights on this subject. It is hoped that any conclusions they reach are consistent, as the studies here are, with what is observed clinically. If they are not, then these conclusions should be questioned.

11.7 Conclusion

In conclusion the author believes that osteolysis may occur as a progressive erosive process which extends along the bone-cement interface. However focal osteolysis distant to the joint articulation and lysis adjacent to fractures in the cement mantle cannot be explained in this way. Focal osteolysis occurs as a response to fluid, with or without particles, being pumped along the stem-cement interface, and accessing the endosteal bone via defects in the cement mantle.

Rough, and smooth surfaced stems will eventually debond from their cement mantles and it is probable that the presence of fluid at the stem-cement interface, of rough components contributes to this process. From the time that the stems debond the effects at the stem-cement interface for rough and highly polished stems are completely different.

Rough surfaced stems will, through micromotion and abrasive wear, produce cement and metal debris at the stem-cement interface. This will gradually expand the interface and thus the pathway for fluid and wear debris produced not only at the stem-cement interface, but also at the articulation between the bearing surfaces of the femoral and acetabular components. Micromotion of the stem, within the cement mantle, will cause the stem to act as a paddle generating large pressures at the stem-cement interface. These pressures will drive fluid and particles into defects in the cement mantle where they may gain access to the endosteal bone of the femur producing focal osteolysis. This osteolysis will occur anteriorly at the middle of the stem and posteriorly at its tip as these are the points at which cement mantle defects will occur. An intact cement mantle will protect the distal femur from focal osteolysis.

For polished tapered stems, debonding at the stem cement interface produces a different outcome. A polished tapered collarless stem will maintain, and even improve, the seal at the stem-cement interface which will prevent the migration of fluid and any debris being produced at the articulation of the femoral head and the acetabular component. The time dependent properties of polymethylmethacrylate in conjunction with the subsidence of a loaded polished tapered stem explain why this interface becomes even more tightly sealed with loads encountered in vivo. Some debris, mostly oxide, is produced at the stem cement interface of polished stems due to fretting damage. This damage occurs below the surface of the stem with the majority of it being retained where it is produced. The absence of fluid from the stem-cement interface helps to explain why even debris produced at the stem-cement interface does not pass along this interface to defects within the cement mantle. The fundamental differences in the behaviour of rough and polished stems are believed to explain why the polished Exeter stem is very rarely associated with focal osteolysis, even in the presence of cement mantle defects and fractures.

APPENDIX

RELATED PUBLICATIONS /PRESENTATIONS

PUBLICATIONS

1. R Crawford, M Evans, R Ling, D W Murray. In vitro investigation of fluid flow around model femoral components of differing surface finish. Acta. Orthop. Scand. 1999 (In press).
2. Crawford R, Psychoyios V, Gie G, Ling R, Murray D. Incomplete cement mantles in the sagittal plane- an anatomical explanation. Acta. Orthop. Scand. 1999 (In press).
3. Crawford R, Ling R. Cement fracture does not necessarily progress to osteolysis. Acta. Orthop. Scand. (Submitted 1999).
4. Crawford R, Gie G, Ling R. An 8 to 10 year clinical review comparing matt and polished Exeter stems. J Bone Joint Surg. (Submitted 1999).
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PRESENTATIONS / ABSTRACTS

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