AN IN-VITRO EVALUATION OF VIBRATION AS A DIAGNOSTIC TOOL IN THE LOOSENING OF THE FEMORAL COMPONENT OF TOTAL HIP REPLACEMENT

Thesis submitted for the degree of
Doctor in Medicine
at the University of Leicester, June 1995

by

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ABSTRACT

An in-vitro evaluation of vibration as a diagnostic tool in the loosening of the femoral component of Total Hip Replacement

by

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Introduction: Traditional methods of diagnosing aseptic loosening of total hip arthroplasties, such as radiography, scintigraphy and arthrography are unreliable. In 1989, Rosenstein et al at Oxford suggested that it was possible to detect loosening at an early stage using a vibration technique. However, the models they tested were probably very loose and would have been detectable by plain radiography, thus obviating the need for vibration testing.

Aim: To find out if vibration technology is able to detect early loosening.

Methods: Several models of loosening were created in-vitro. These included:
1. Late loosening whereby macromovement is present between bone and implant
2. Early mechanical loosening whereby the interlock between cement and trabecular bone is lost
3. The presence of soft tissue at the bone-cement interface
4. Early stem-cement debonding due to fatigue fracture of the cement mantle

Each of those models was submitted to vibration testing and the output signal was analysed using the following methods:
1. Frequency (amplitude) response
2. Spectral analysis using the Fourier Transform

Results: For late loosening, the vibration technique had an excellent diagnostic accuracy with a sensitivity and a specificity of 100% (19 specimens). However only 3 out of 8 specimens showing early mechanical loosening were correctly diagnosed (sensitivity 37.5%). The presence of a layer of soft tissue at the bone-cement interface was vibrationally undetectable provided there was no associated mechanical instability. Finally, fatigue fracture of cement was also vibrationally undetectable in the absence of instability at the bone-cement interface.

Conclusions: The vibration technique can diagnose late loosening with a high degree of accuracy. However, this is likely to be clinically and radiographically apparent without the need to resort to vibration testing. Results for early loosening have been less satisfactory and further work may be required to improve the sensitivity of the test.
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Declaration of originality

This thesis is submitted in fulfilment of the requirements for the degree of Doctor in Medicine at the University of Leicester, U.K.. All work recorded in this thesis is original unless otherwise acknowledged in the text or by references. No part of it has been submitted for any other degree, either to the University of Leicester or to any other University.

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June 1995
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To my parents,
for their constant encouragement to seek education

and

To Dominique for her forbearance
Acknowledgements

As the first Orthopaedic Research Fellow sponsored by the St Cross NHS Trust, I approached my task with some trepidation but also much determination not to disappoint those who had shown faith in me. In this respect, I was lucky to benefit from the goodwill of many people around me, all of whom wished me to succeed. To them, I wish to record my appreciation. First, I would like to thank my supervisors, Professor PJ Gregg and Professor NB Jones for their advice and guidance throughout my research. Their wisdom and experience have been invaluable in making a potentially treacherous journey go smoothly. Special credit is also due to the forward-thinking consultant Orthopaedic surgeons at the hospital of St Cross in Rugby (Messrs SN Deliyannis, AW Hughes and MJ Margetts) who strove to obtain funding for my Research Fellowship. It is to be hoped that their effort will be emulated by others and that further Research Fellowships fully funded by NHS Trusts, will in future be available to deserving young Orthopaedic surgeons.

A warm thank you from the bottom of my heart to my friends and fellow students, Tuan Tran and Paul Goodyer for helping me with the computer and making me think like an engineer. I shall miss those relaxed and enlightening coffee breaks with them. I also wish to record my thanks to Mr Colin Morrisson for his unfailing cooperation and his invaluable advice in setting up my experiments. To Nurse Miller of St Cross Hospital, I owe a debt of gratitude for conscientiously saving all those packets of unused cement for me.

Finally, I would like to thank my wife for her unconditional love and support, for her understanding during those weekends spent writing away from her.

Patrick Li, June 1995
About 800,000 Total Hip Replacements are performed throughout the world every year and this number is likely to rise with the introduction of this immensely successful operation to third world countries. The most common long-term complication of the operation is aseptic loosening of the artificial joint and it may surprise quite a few people to learn that there is at present no reliable method of diagnosing this problem, particularly at an early stage.

In 1989, a group of Engineers and Orthopaedic surgeons at Oxford suggested that Vibration could be used to detect implant loosening. The models they used were of late loosening, and it seemed to us that there would be no advantage in further developing vibration technology unless it showed itself to be effective in the diagnosis of early loosening because this is the area where traditional tests such as plain radiography are unreliable. To this effect, we created several laboratory models of early loosening and analysed their effect on a transmitted vibration signal using signal processing techniques described in Chapter 7.

This thesis can broadly be divided into 2 main sections: The first 6 chapters provide an introduction into the evolution of Total Hip Replacement and its complications, particularly aseptic loosening. In addition, the current role of vibration in orthopaedics is briefly outlined. The second part of the thesis deals with the experimental methods, discussion of the results and the conclusions derived from them.

I have enjoyed writing this thesis and would like to thank everyone who has contributed to make it so.

PLTW, June 1995
CHAPTER 1

History and evolution of Total Hip Replacement

1. Introduction

Total hip replacement (THR) is perhaps the major post-war surgical development. Since Charnley introduced his low-friction arthroplasty in the early 1960's, over five million total hip replacements have been performed worldwide (Harris, 1992). A recent estimate suggests that 800,000 THR are performed annually throughout the world, more than 40,000 in the United Kingdom alone (Hashemi-Nejad, Birch & Goddard, 1994). With the progressive introduction of this successful operation to third world countries, it is likely that these figures will increase. The commonest indication for THR is severe pain resulting from osteoarthritis which is a degenerative disease of the hip articular cartilage affecting 10-15% of all individuals over the age of 55 years (Kellgren, 1961). To many patients with this condition, THR has brought untold benefits in terms of pain relief, increased mobility, and an improvement in their quality of life. To some it has allowed the fruitful resumption of employment.

Evolution of Total Hip Arthroplasty

2. The early days

The concept of hip arthroplasty arose early in the 19th century, or even before, because of the many joints stiffened by pyogenic or tuberculous infection or by severe injury. The first THR was probably performed by Thermostoles Gluck in Germany around 1890 using a prosthesis made of ivory and fixed to the upper femur with steel screws and using cement which consisted of a mixture of pumice powder, plaster and glue (Gluck, 1890). Although not a success, Gluck's was the first documented attempt
at hip replacement. It is likely that no-one earlier dared attempt the feat due to the disastrous consequences of implanting foreign material in the human body in the pre-Listerian era. It is only after Lister had expounded his principles of asepsis and antisepsis that implantation surgery really took off.

In 1923, Hey-Groves in England devised a treatment of the osteoarthritic hip, in which he excised the femoral head and rounded the stump of the neck before covering it with surrounding soft tissue.

During the second and third decades of this century, Smith-Petersen in America, performed a famous series of interposition studies which led to the evolution of mould arthroplasty of the hip (Smith-Petersen, 1948). He removed the articular surface of the femoral head and of the acetabulum and then covered the femoral head with synthetic material in such a way that it was not truly fixed to the head, but was free to move over the ball and within the socket during hip movement. Smith-Petersen thought that this would cause the bone adjacent to the synthetic material to undergo metaplasia into a new smooth fibrocartilage and that he could eventually remove the synthetic material leaving behind a smooth gliding joint. He was proved correct but, removal of the mould often proved impractical or unnecessary. Smith-Petersen himself found vitallium to form the best mould after trying various materials over a period of 15 years. Long-term results showed that mould arthroplasty was only partially successful in relieving pain, improving motion and correcting deformity. Because of this, mould arthroplasty fell gradually into disuse and with historical perspective, the operation can be regarded as temporary makeshift while the search was on for a more definitive treatment.

3 Hemiarthroplasty of the hip

It would be appropriate at this point to briefly mention hemiarthroplasty of the hip which was first developed by Austin-Moore in 1942 in the U.S.A. (Moore and Bohlman, 1943). The operation involves replacing the femoral head and the main indication is for high femoral neck fractures. Thompson, also from the U.S.A. developed
an essentially similar prosthesis about the same time as Moore. Although hemiarthroplasty has been therapeutically tried in osteoarthrosis, it has been disappointing because of the lack of congruity between the head and the acetabulum.

The Judet brothers in 1946 introduced a new form of hemiarthroplasty (Figure 1) which made an enormous impact because the immediate results were exceptionally good (Judet et Judet, 1952). In fact, their operation was so successful initially that, for many years, attention was diverted from the development of a total hip prosthesis on which Philip Wiles in London had already performed pioneering work. The Judet operation took the form of a "resection-reconstruction" of the osteoarthritic femoral head, in which the femoral head was replaced by a knob of polymethylmethacrylate incorporating a plastic stem passing axially down the neck. However, after the initial success, came the disappointment when the prosthesis was found to fail, in many cases only a few months after the operation. The reason was the lack of appreciation of the stresses involved in a weight-bearing joint such as the hip and not surprisingly, the acrylic head was usually worn and fissured, the stem broken or the whole implant loose at re-exploration.

Fig 1 Judet prosthesis: a) Acrylic femoral head, b) Acrylic stem with metal core
4 Total Hip Replacement

4.1 The Wiles prosthesis

Although Gluck was the first to perform total hip replacement, the first real predecessor to the modern arthroplasty of the hip must be credited to Philip Wiles at the Middlesex hospital in London. He performed six THR's for the effects of Still's disease, using metal on metal prostheses. The cup was screwed to the acetabulum and the femoral head connected by a stem in the neck to a plate bolted to the outer side of the shaft. Wiles had reasonable long-term success with his implant and one of his bilateral cases had excellent function after 13 years (Wiles, 1958).

![Fig 2: The Wiles prosthesis (Wiles, 1958)](image)

4.2 The McKee prosthesis

Although Wiles had introduced his prosthesis in the early 1930's, further progress on this front was arrested for two reasons: The second World War and the aforementioned diversion of interest by the Judet prosthesis. While Orthopaedic interest worldwide was focused on the Judet prosthesis, two of Wiles's followers in England were advancing their programmes of total hip arthroplasty: McKee in Norwich and Charnley in Manchester.
McKee in conjunction with Watson-Farrar produced his THR prototype as far back as 1940 (McKee, 1970). This was a metal-metal prosthesis made of vitallium, and although not as popular as the metal on plastic prosthesis later developed by Charnley, produced excellent results.

4.3 The Charnley Low-Friction Arthroplasty

John Charnley is perhaps the individual most responsible for the present success of total hip arthroplasty. Whereas McKee’s prosthesis had a metal femoral head articulating with a metal cup, Charnley decided very early that he needed a metal femoral component and a plastic acetabular cup. He developed the concept of "low-friction" arthroplasty. Charnley argued that synovial fluid had a very minimal role in the lubrication of the hip joint and that this occurred by the phenomenon called "boundary lubrication" rather than fluid lubrication. In boundary lubrication, the solid surfaces are only partially separated by an extremely thin lubricant layer of molecular dimensions. The fact that boundary lubrication does not completely eliminate wear indicates that the solid surfaces are not completely separated. If synovial fluid did little to lubricate a normal hip joint, it would have little effect on the coefficient of friction of a metal-metal prosthesis, he argued. The high frictional force between a metal head moving within a metal cup would lead to torsional forces on both components, thus causing loosening. For this reason, it had to be a metal head articulating with a plastic cup, a combination with a low coefficient of friction.

Fig 3 Charnley prosthesis
The plastic initially used by Charnley was polytetrafluoroethylene (PTFE, Teflon) and his initial results were good. However, the wear rate of PTFE was very high (2.4-3.6 mm/year) (Weightman, 1977) and long-term success therefore remained elusive. Charnley had almost lost heart when one of his engineers discovered that the high density version of PTFE, known as high molecular weight polyethylene (HMWPE) had a substantially lower wear rate. From this HMWPE, Charnley manufactured his cups which turned out to be so successful with an average wear rate of 0.13 mm/year (Weightman, 1977).

The other salient features of the Charnley prosthesis apart from its HMWPE cup were the small size of the femoral head and the use of polymethylmethacrylate (PMMA) cement for its fixation. First the question of the size of the femoral head; in the original Charnley prosthesis, this was 22 mm, which is small compared to other prostheses. The advantages of having a small head are:

1. Decreased volumetric rate of production of wear particles which Charnley believed to be implicated in loosening (Livermore, Ilstrup & Morrey, 1990).
2. The cup can be made of a thicker layer of HMWPE with resultant prolongation of life-span in the face of linear wear.
3. Reduced torque exerted by the head on the cup during movement. This would presumably decrease the tendency of the components to loosen.

On the matter of fixation, Charnley settled on the use of PMMA which he first encountered during a visit to California where he saw it being used as a self-curing acrylic cement in dentistry. When cast in-situ, it filled the gap between the prosthesis and the bone and eliminated slip between them (Charnley and Kettlewell, 1965). Charnley himself thought of PMMA as a grouting agent which penetrated the interstices of cancellous bone allowing interlock between the implant and bone. In addition to interlock, the cement mantle allows the forces acting on the femoral component to be evenly dissipated over a wide surface area at the bone-cement interface thus avoiding focal areas of excessive stress.
Charnley's other great innovation was the introduction of the clean air theatre system and the body exhaust system that is still used by many of his followers to combat the risk of infection. Since Charnley designed his prosthesis, a multitude of other prostheses have flooded the market (and we shall briefly consider some of those in the next section), but to this day, Charnley's cemented total hip arthroplasty is still widely considered as the gold standard.

5. Methods of fixation

Since Charnley introduced his total hip prosthesis in the 1960's, a multitude of other implants to replace the hip joint has been developed by a dozen or so companies around the world (Bulstrode, Murray, Carr et al, 1993). The motivation behind this constant development of new prosthetic design is to seek improvement in their durability and function. The classic Charnley prosthesis itself underwent several modifications in design to improve its strength (Charnley, 1979). It would be difficult to document the exact number of different hip prostheses that have been used up to now and perhaps a more reasonable approach would be to classify the various implants not by details of design but by the technique of their fixation. The establishment of fixation of implants at the hip involves an interlock between the implant and the bone. The interlock is of 3 basic types (Lee and Ling, 1982):

1. Mechanical interlock using acrylic bone cement.
2. Non-cemented mechanical interlock relying on an initial interference fit of all or part of the implant with the bone. (Press-fit fixation)
3. Non-cemented mechanical interlock stabilised by bone and soft tissue ingrowth into the implant.

5.1 Cemented prostheses

In the vast majority of THR's, cement is used for fixation of the components. The only cement so far widely used is polymethylmethacrylate (PMMA) which was
introduced into orthopaedic practice by Chamley. The cement is cast in-situ to fill the gap between a prosthetic component and the bone, allowing the two to form an accurate fit and thus locking the implant into the medullary canal. An additional effect of such an accurate fit between prosthetic component and bone is to distribute load over the largest possible contact area and so give the lowest possible contact stresses. The use of bone cement has allowed an acceptable fixation to be regularly achieved which may not be the case for uncemented prostheses.

Chamley thought of cement as a grout because it is able to penetrate the trabecular spaces of cancellous bone and so improve the mechanical interlock between the implant and the bone. Miller and coworkers (1981) coined the term "micro-interlock" to describe essentially the same phenomenon whereby the mechanical interlock between cemented implant and bone is improved by cement penetration of the pores of trabecular bone. These authors made this distinction from the "macro-interlock" which results from cement acquiring the gross shape of the medullary cavity. It is important to note that the distinction is purely one of size and does not imply any kind of atomic or chemical bond forming between the cement and the bone. Nevertheless, the term "micro-interlock" has gained wide acceptance and is often used in the orthopaedic literature to denote what John Charnley had many years before called the "grout" property of cement.

This "grouting" property is vital to the long-term success of a cemented THR. This was initially not very well appreciated by orthopaedic surgeons and indeed the results of THR using "first generation" cementing techniques showed a high incidence (30-40%) of loosening of the femoral component (Stauffer 1982, Sutherland, Wilde, Borden et al, 1982). This stimulated efforts directed at improving the use of cement, pioneered by Miller and Harris (Miller, Krause, Krug et al 1981, Harris, Mc Carthy & O'Neill 1982). Much of these efforts were aimed at improving the cement interlock with trabecular bone by the introduction of lavage techniques that produced a bone surface free of blood and marrow debris, and at the same time, improved pressurisation of the cement was made possible with the combined use of a canal plug to restrict cement flow.
distally and a proximal seal. Not surprisingly, the figures for loosening rates have fallen dramatically since the implementation of these newer cementing techniques. Mulroy and Harris (1990) have reported a loosening rate of 3% at 10 years for femoral components inserted using "second generation" cementing techniques. This represents at least a ten-fold reduction as compared with Stauffer and Sutherland. It is important to note that, subsequent to the advances in femoral component cementing reviewed by Mulroy and Harris, further major improvements have been made in cement handling. These so-called "third-generation" cementing techniques include reduction in cement porosity using centrifugation or vacuum mixing, pulsatile lavage, the use of adrenaline-soaked sponge to reduce bleeding in the femoral canal, and pre-coating and roughening of the surface of the femoral component. It is probable that these additions to cementing technique will further improve the long-term fixation of cemented femoral components.

CEMENT BIOCOMPATIBILITY

In the mid-1970's, a great deal of concern focused on the biocompatibility of PMMA cement. Early studies concerning bone tissue response to PMMA indicated that a technically well-fixed THR implanted with the use of cement would not cause adverse tissue reactions, and that it would be an inert biomaterial (Charnley, Follaci & Hammond, 1968). However, in 1976, Harris and coworkers reported on 4 patients who had aggressive granulomatous reactions around femoral components which had been inserted with cement (Harris, Schiller, Scholler et al, 1976). The radiological appearance of this form of localised osteolysis resembled the changes seen in infection, but the authors could find no microbiological evidence of this condition. They attributed this extensive localised bone resorption to a foreign-body type tissue response to particles of bone cement arising from fragmentation of the cement mantle. Histological examination of the granulomatous tissue showed sheets of macrophages, a few giant cells and multiple small fragments of a birefringent material, but no inflammatory cells as would be expected in infection. With this first hint of a biocompatibility problem, came further reports confirming an alarming incidence of progressive femoral lysis around cemented femoral components.
components (Jones and Hungerford, 1987). Bone cement was perceived to be the cause of this problem and fragmented cement particles could be seen radiologically and microscopically around loose stems. Jones and Hungerford coined the term "cement disease" as an implication of the understanding of the culprit. Since cement was considered to be the cause for failure of THR's, there was widespread expectation that the lytic process could be eliminated by avoiding its use. Efforts were therefore directed at the development of non-cemented techniques in the early 1980's.

As follow-up studies of the cementless designs became available, it became clear that they too suffered from the problem of femoral lysis (Clarke, Campbell & Kossovsky, 1992). "Cementless disease", "bead disease" and "particulate disease" were terms added to the surgeon's vocabulary. The data presently available shows that femoral lysis occurs around cementless implants at an earlier time period, at a higher incidence and in more extensive amounts than with cemented femoral components (Mulroy and Harris, 1990). All these data suggest that bone lysis is not "cement disease" but "particle disease". As such, it can be caused by cement, plastic or metallic particles. Bulk cement does not lead to lysis.

The great improvement in the results of THR with the use of modern cementing technique together with the relatively good biocompatibility of PMMA are the two major factors that currently favour its use by the majority of Orthopaedic surgeons.

5.2 Press-Fit prostheses

In 1968, only a few years after Charnley had introduced his low-friction arthroplasty, Ring, at the Redhill hospital in Surrey, performed his first complete replacement of the hip without using cement (Ring, 1968). The original Ring prosthesis (Fig 4) was all-metal and consisted of a femoral component which in design was rather similar to the straight-stemmed Austin-Moore prosthesis. The acetabular cup was conical in shape and was secured to the pelvis by a long screw-thread. The design of the
Ring prosthesis has since undergone several modifications, the main one being a switch from a metal to a plastic (HMWPE) cup.

Fig 4 Original Ring prosthesis (Ring, 1989)

Ring’s device is an example of a press-fit prosthesis. Press-fit fixation is defined as any technique which permits the implant to be directly and immediately stabilised in an appropriately shaped skeletal cavity. This can be done:

1. By driving a parallel-sided prosthesis into a pre-drilled hole (as if it were a dowel being driven into a hole in a piece of wood).
2. By driving a tapering prosthesis into the bone.
3. By inserting the prosthesis as a screw.

In practice, it demands precision of bone cutting by the surgeon in such a way that the prosthesis and its cavity form a good match allowing maximum contact between the implant and the bone thus minimising stresses at the interface.

Ring has reported on the medium and long-term results of his press-fit prostheses and notes that "on the acetabular side there is evidence that the implant will give results that are certainly comparable with the cemented counterpart. On the femoral side press-fit components have the merit of simplicity. They may have an increased risk of mechanical loosening, but this can be balanced against the ease of exchange." He quotes
a failure rate of 1% per annum for the first 10 years but admits the risk may increase subsequently (Ring, 1989).

5.3 Prostheses depending on biological ingrowth

In the late 1970’s, when cement was thought to be the cause of failure of THR, efforts were made to develop implants whose fixation did not depend on cement but on bony ingrowth into the prostheses. Initially, the basic Austin-Moore design was widely used except that the fenestrations were eliminated in favour of smaller pores (Engh, 1983). Since that time, new prostheses have proliferated, some porous-coated, others hydroxyapatite-coated, but all aiming to achieve fixation by bony or biological ingrowth.

There are two disadvantages associated with these cementless implants. First, they have to achieve instant stability once inserted into the medullary canal. Micromovement of more than 140 microns allows only fibrous ingrowth whereas micromovement of less than 50 microns is required to allow bony ingrowth (Bobyn, Pillar, Cameron et al 1980, Cameron, Pillar & Mc Nab 1973, Engh, O'Connor, Jasty et al 1992). This degree of stability requires an accuracy in the preparation of the bone bed which is probably difficult to repeat on a regular basis. The second disadvantage of biological-ingrowth prostheses is the development of severe proximal femoral atrophy due to stress shielding. Currently, two classes of femoral components are available: straight-stemmed prostheses, which tend to be long and achieve stability in the diaphysis, and anatomically-shaped prostheses, which are considerably shorter and rely upon maximising fill in the metaphysis. It is in the former type, ie those implants that rely on diaphyseal ingrowth, that the phenomenon of stress shielding is seen and can result in severe proximal bone atrophy thereby rendering future revision operations very difficult. In addition, the concentration of load at the diaphysis may explain the high incidence of thigh pain seen in patients with cementless prostheses.

Presently available data suggest that the results of cemented THR's are better than those of cementless implants (Havelin, Espehaug, Vollset et al, 1994).
Nevertheless, in the quest for a truly durable hip, there are those who believe that the future lies with biological-ingrowth prostheses (Hungerford & Jones, 1993).

6. Conclusion

There is little doubt that THR in its various forms is a very successful operation. The matter of which type of arthroplasty is superior is still the subject of debate. Given that 800,000 THR are now performed annually world-wide, many would find it hard to believe that total replacement arthroplasty of the hip was a procedure virtually unknown prior to the early sixties. It has brought enormous benefit in terms of increased mobility, pain relief and an improvement in the quality of life to vast numbers of patients. To some, it has allowed the resumption of fruitful employment. In a sense, the success of the operation has been its own worst enemy. Because of its capacity to produce such dramatic and rapid results, it spread like wildfire before the significance of some of its complications was recognised. The complications of total hip replacement, particularly wear, because of its perceived role in loosening, are discussed in the next chapter.
CHAPTER 2

Complications of total hip replacement

1. Introduction

Total hip replacement (THR) is undoubtedly a successful operation. In the first 24 years of low-friction arthroplasty, only 3% of 20,588 implanted hips are known to have been revised (Wroblewski, 1989). No other procedure employed for the treatment of the painful hip has enjoyed such spectacular success. Nevertheless, like all operations, and in particular because it is a major procedure involving several distinct steps, THR carries with it the risk of complications, including death. The complications of THR are summarised in this chapter. From the clinical standpoint, it would be appropriate to discuss complications in the chronological order in which they can be expected to arise: i.e. intraoperative, early post-operative and late post-operative and in each of these groups, complications may be either local or general (systemic).

2. Intraoperative complications

Local complications

Local technical problems which may occur during the operation of THR include:
1. Acetabular over-reaming and pelvic perforation.
2. Fracture of the femur.
3. Socket malposition.
4. Femoral component malposition.
5. Stem protrusion.
7. Leg length discrepancy.
Acetabular over-reaming

It is standard practice during the implantation of the artificial socket to ream the medial wall of the acetabulum and to drill holes so that the socket can be firmly anchored in it with the help of acrylic cement. Through and through perforation of the medial acetabular wall is common and deliberate in the Charnley technique (a "tin-hat" being used to prevent cement protrusion into the pelvis) and does not normally lead to serious complications. However, dramatic complications have occurred and Mallory (1972) has described one case where the common iliac vein was completely avulsed when a powered reamer penetrated the antero-medial part of the pelvic wall. Similar injuries to the iliac artery have been reported (Nachbur et al, 1979).

Fracture of the femur

Fractures at the base of the neck or in the upper shaft seem to occur most frequently in the patient whose proximal femur is smaller than normal, in particular the patient who has had old congenital dislocation of the hip. In this group of patients, Dunn and Hess (1976) report an incidence of femoral shaft fracture of 27.2%. In these patients, the upper shaft is frequently small enough that a conventional femoral component cannot be inserted and a smaller custom-made prosthesis has to be used.

Intra-operative distal shaft fractures are usually associated with the use of long-stem implants, for example during revision procedures for failed previous surgery (Lowell, 1976). Most long-stem prostheses have a length of approximately 30 cm, which is more than enough to prevent them from following the natural curve of the femur of a person of short stature.

Socket malposition

Socket malposition may result in instability and subsequent dislocation. Too much retroversion is most frequently associated with a posterior approach to the hip and too much anteversion with an anterior approach. Old fractures of the acetabulum with a
deficient posterior rim or previous mould arthroplasty, during which a portion of the posterior rim has been excised, can lead the surgeon into positioning the acetabular component in retroversion if his attention is focused too keenly on the acetabular margin alone as his point of reference.

Femoral component malposition

The problems of femoral component malposition, like those of socket malposition, are frequently determined by the surgical approach chosen. The posterior approach tends to be followed by retroversion of the prosthesis and the anterior approach by anteversion.

Stem protrusion

Stem protrusion seems to occur most frequently when total hip arthroplasty is done for failed previous surgery, such as osteotomy or hip nailing and it occurs more frequently when the anterior approach rather than the posterior approach has been used. It is also seen when hip motion is limited pre-operatively and if trochanteric osteotomy is not performed.

Ectopic cement

The appearance of cement within the pelvic cavity as a result of perforation of the medial wall of the acetabulum has already been mentioned. It is important to remove surplus cement from the margins of the acetabulum and from the edges of the resected femoral neck after insertion of the components of a THR. Failure to do so leaves "cementophytes" that may compromise movement or become loose and intrude between the articulating surfaces.
Leg length discrepancy

Inequality of leg lengths after THR, although undesirable, is not an uncommon occurrence. Length loss due to previous disease can sometimes, but not always, be restored by prosthetic selection and placement. When more than 1.0 or 1.25 inches is made up, sciatic palsy must be recognised as a possible sequela. If the technique of THR enables one to make up shortening, it also carries the potential of creating excessive lengthening. The feel of the soft tissue tensions about the hip after placement of the trial components is not always a good guide in preventing this complication. Careful use of templates pre-operatively with markings on the radiographs of the desired location of the acetabular and femoral components is helpful to prevent this problem.

General intra-operative complications

The most serious of the intra-operative complications is death. The mortality rate associated with THR is 1.07% within 1 month of operation (Ling, 1982) and this is usually due to the inability of the patient to sustain major anaesthesia. In this context, one should remember that the patient selected for THR usually comes from an age group in which concurrent disease is common. In addition to the problems associated with any anaesthetic, there is a special problem incurred with the use of PMMA cement. The occurrence of acute hypotension and cardiac arrest after bone cement application has caused a lot of concern among clinicians (Hyderally and Miller, 1975). Some investigators believe that hypotension is always clinically significant. Various hypotheses have been proposed to explain hypotension after cement, particularly during the insertion of the femoral component:

1. The blood pressure changes may only reflect the response normally seen to a noxious stimulus.
2. Monomer may leak from the cement and cause hypotension by directly suppressing myocardial activity or by causing peripheral vasodilatation.
3. Surgical interference with the bone marrow may lead to embolisation of fat and marrow to the lungs thus causing a release of vasoactive amines and other local hormones.

4. Pre-existing hypovolaemia at the time of cement insertion is an exacerbating factor.

    Each of these possibilities appears to be real and the best method of prevention would appear to be careful quantification of blood loss during the operation and concomitant adequate replacement; careful timing of the insertion of the polymerising cement into the femur so that it is tacky, not liquid, and venting of the medullary cavity by placement of a small tube down the shaft, which will be removed after the cement has been inserted.

3. Early post-operative complications

    For the purpose of the following discussion, early means the first 3 post-operative months. As in the previous section, the early complications can be classified either as local or general complications.

Local complications

    The early local complications of THR include:

1. Peripheral neuropathy
2. Haematoma formation
3. Infection
4. Dislocation
5. Problems related to trochanteric osteotomy such as non-union, avulsion and trochanteric bursitis.
Peripheral neuropathy

The incidence of peripheral neuropathy after THR varies from 0.7% (Weber et al, 1976) to 3.7% (Wilson and Scales, 1973). In the study of Weber et al at the Mayo clinic on a series of 2,012 THR, 14 cases of neuropathy were documented and of these, 7 were sciatic, 3 femoral, 3 combined (Sciatic and Femoral) and 1 obturator. No cases of lateral popliteal palsy were found in the Mayo clinic series although this is a recognised complication as reported by Eftekhar and Stinchfield (1973) in another large series.

Haematoma

A wound haematoma may complicate any THR and its incidence is higher among patients given prophylactic anticoagulation. Despite this, many believe that concern for the safety of the wound must be balanced against the risk of fatal pulmonary embolism and that anticoagulation is more beneficial than it is harmful. A serious potential danger of a wound haematoma is infection which can have disastrous consequences for the patient with an artificial joint as discussed below.

Infection

Infection is one of the most dreaded complication of THR and may have disastrous consequences for the patient. It can occur at any time after the operation and is not restricted to the early post-operative phase. Cases up to 17 years after the operation have been reported. It is traditional to classify infection after THR either as superficial or deep.

Superficial infection is defined as infection in the tissues superficial to the deep fascia, i.e. it is essentially a wound problem and its major importance is that it may lead to contamination of the deeper tissues around the artificial joint. Because of this, superficial infection should be avoided if possible, and where it has already occurred, it should be treated vigorously with antibiotics and surgical drainage as necessary.
Deep infection is a serious matter for both patient and surgeon and is defined as infection involving the tissues adjacent to the implant, cement or other adnexa such as trochanteric wires (Elson, 1982). The reported incidence of deep wound infection varies from 0.4% for primary arthroplasty of the hip (Eftekhar and Stinchfield, 1973) to 17% in cases of revision arthroplasty (Dandy and Theodorou, 1975). The offending organism may be implanted at the time of surgery or may reach the implant via the haematogenous route from a distant septic focus, for example an infected toe. Also, as mentioned previously, superficial infection can lead to deep infection. The practical importance of deep infection is its tenacious chronicity and its end-results, i.e. mechanical loosening and consequent pain. Although deep infection is more commonly encountered in its chronic form, it can also be acute and fulminating and may be accompanied by a severe toxic state. The management of deep infection is a challenging problem and when the situation is recognised and appropriate microbiological cultures have been taken, the surgeon may elect to initiate treatment with massive and prolonged antibiotic therapy, but if response is not prompt, then the wound may be widely opened, debrided and closed over a drainage system. This should be covered with large doses of antibiotics. When the infection is established, the prosthesis should be removed either permanently or replaced only after the wound has been quiescent for up to 6 months and then only under further intensive antibiotic coverage. (It should be noted however that one-stage revision for deep infection under heavy systemic and topical antibiotic cover is also commonly practiced nowadays (Elson, 1982).) Thorough debridement is crucial to the success of any replacement procedure.

Because it is so difficult to eradicate established deep infection, it is perhaps wise to invest time and energy to avoid its occurrence. The measures used in the prevention of infection during THR include:

1. The patient has at least one antiseptic/soap wash in the 24 hours prior to surgery.
2. The whole leg is twice prepared with tincture of iodine prior to draping.
3. During the operation, all doors are kept shut to restrict the number of personnel and hence minimise the risk of air-borne pathogens infecting the wound.
4. The operating room is fitted with a sterile air enclosure to provide near total air sterility and the surgeon, his assistant and scrub nurse wear body-exhaust gowns as recommended by Chamley.

5. The patient is given an intravenous dose of antibiotics at the time of induction of anaesthesia and this is usually continued at regular intervals over the first 2 post-operative days. The choice of antibiotics may vary according to the clinician's preference as firm recommendations are difficult to make (Elson, 1982).

6. The cement used for implant fixation is antibiotic-loaded (mostly with gentamicin). This was first introduced by Buchholz and Engelbrretch in 1970 and has conclusively been shown to reduce the incidence of deep infection (Elson, 1982).

7. Finally, as in any operation, the risk of infection can be minimised by atraumatic, expeditious surgery, careful haemostasis to avoid haematoma formation, and thorough cleaning of the wound with normal saline or sterile water irrigation.

Dislocation

Dislocation of the femoral head from the acetabular cup is a dramatic but fortunately infrequent early complication of THR. Contributing factors include:

1. Malalignment of either acetabular or femoral component
2. Congenital or acquired laxity of the surrounding soft tissues, in particular the gluteal muscles. An example of congenital laxity is Ehlers-Danlos syndrome and acquired laxity can result from repeated surgical trauma to the muscles or trochanteric avulsion.

Dislocation can usually be treated by closed reduction followed by protection of the hip in traction for a period of about 3 weeks. If however, there is gross component malalignment, revision surgery may be necessary to correct the problem. When the components are correctly positioned, the complication of dislocation does not seem to be greater with the Charnley prosthesis with its 22 mm head than with femoral implants of larger head diameter.
Complications related to trochanteric osteotomy

Trochanteric osteotomy is performed by many surgeons during the operation of THR because it allows improved access to the joint and thereby ensures more accurate alignment of both the acetabular and the femoral component. This in turn reduces the risk of post-operative dislocation. Set against this undoubted benefit, there are complications (which may occur early or late):

1. Increased blood loss and prolongation of operating time.
2. Trochanteric non-union. The incidence is estimated at 5-10% (Boardman et al, 1978) and is usually due to the breakage of the wires, usually affecting the vertical wires first. It is important to point out that in the group of patients with trochanteric non-union, about half heal by fibrous (rather than bony) union and only in the other half is there true trochanteric separation. It is in the latter group that problems such as pain on weight-bearing or a positive Trendelenburg gait are observed (Hamblen, 1982). The treatment in such cases is difficult and may involve re-attaching the detached trochanter using special techniques which will not be discussed here.
3. Trochanteric bursitis. This is usually associated with the wires used to fix the trochanter and the diagnosis can be confirmed by a trial injection of local anaesthetic or steroids into the bursa. If confirmed, the condition can be treated by removal of the wires.
4. Neurological damage.
5. Paradoxically, for a manoeuvre performed in order to avoid dislocation of the prosthesis, it can occasionally predispose to dislocation as a result of abductor weakening.

To avoid the problems related to trochanteric osteotomy, many surgeons prefer to adopt a different surgical approach, exposing the hip joint by cutting through soft tissues only. Nevertheless, even these surgeons will admit to the superior access afforded by trochanteric osteotomy and may use this approach in difficult situations such as revision total hip arthroplasty.
General complications

The general complications of THR occurring in the first 3 post-operative months are those that can occur after any major surgical procedure: atelectasis and chest infection, pulmonary oedema, paralytic ileus, gastrointestinal bleeding, urinary retention, urinary tract infection, depression, psychosis, myocardial infarction, deep vein thrombosis and pulmonary embolism.

4. Late complications

Late complications, defined as those occurring more than 3 months after THR include infection, dislocation and problems related to trochanteric osteotomy, all of which have been discussed already. In addition to this list will be aseptic loosening, the diagnosis of which forms the basis of this thesis, wear of the components which is thought to contribute to this problem, stem fracture, cement fracture and ectopic ossification.

Aseptic loosening

Aseptic loosening of the components of total hip replacement is the most common complication of this operation and as its investigation forms the subject of this study, it will be discussed in some detail in the next 3 chapters.

Wear (Fig 1)

This particular complication of THR is discussed in some detail because of its contribution to the process of loosening. All types of materials, when used as the articulating surfaces of prostheses, release wear particles into the surrounding tissues. The early Mc Kee-Farrar prosthesis used cobalt-chrome alloy articulating against itself and resulted in the accumulation of metal debris in the tissues. Charnley's initial choice of polytetrafluoroethylene (PTFE) for his cup led to early failure because the rapid wear
of this material generated particulate debris which resulted in granuloma formation. The switch to ultra-high molecular weight polyethylene (UHMWPE) improved the situation but did not eliminate the problem completely. In metal on polymer articulations, attempts to make the polymeric component convex resulted in greater wear rates of the polymer. Recently, considerable attention has been given to the problem of metal particles, and particularly, generation of wear particles from the articulating surface of titanium alloy prostheses and from the femoral stem (Agins et al, 1988).

It is important to realise that wear particles are not generated only at the articulating surfaces of a THR. Movement at the metal-cement or cement-bone interface also results in the release of metal and cement debris. Migration of these wear particles to the cement-bone interface is thought to be a crucial step in the genesis of loosening.

The following terms are often used in the discussion of wear:

1. "Two-body" wear occurs when the femoral head slides over the cup resulting in the removal of material from both surfaces.
2. "Three-body" wear is said to occur when hard particles (e.g., cement) are trapped between the sliding surfaces, become attached to one surface and plough through the other.
3. "Linear" wear refers to the depth wear (of the polymeric cup).
4. "Volumetric" wear refers to the volume of wear debris generated at the articulation.

Two-body wear is inevitable and is a universal occurrence in prosthetic joints. With metal on plastic articulations, most of the wear debris is generated from the plastic component, with a very small amount from the metallic component. The contribution from each component appears to be inversely proportional to the hardness of the material (Weightman, 1977). The polymer with the best wear characteristics is UHMWPE. Clinical experience with other polymeric materials such as polyester has been disappointing. In this context, it is worth mentioning that previous attempts to use a
polymeric ball and a metallic cup resulted in greater wear of the polymer than the present configuration of a metal ball in a polymeric cup.

Three-body wear is particularly troublesome because it accelerates the wear process due to abrasion of the articulating surfaces by small particles trapped in the joint. Various particles have so far been identified that contribute to this process: metal, cement, bone and even hydroxyapatite in those implants that have been coated with the latter. The particles can be generated as a result of two-body wear at the articulating surfaces or they can also arise from micromotion of the metal or cement against bone. In addition, any small particles of bone or cement left in-situ at THR may exacerbate the problem.

Linear wear (depth wear) of the acetabular component of THR's is to a large extent dependent on the diameter of the femoral head. On theoretical grounds, the rate of depth wear is inversely proportional to the head diameter, so that the smaller the femoral head, the greater the rate of depth wear (Weightman, 1977). This has not been entirely borne out in a recent study comparing the rate of depth wear of the cup when articulating with femoral heads of various diameters (Livermore et al, 1990). These authors found a significantly lower rate of depth wear for prostheses with 28 mm femoral heads, whereas prostheses with 22 mm heads had the highest rate of depth wear (consistent with theory). Femoral heads of 32 mm diameter which might have been expected to produce even less depth wear than 28 mm heads, in fact led to more depth wear. Using UHMWPE as example, the mean rate of depth wear quoted in the literature for the Charnley Low-Friction arthroplasty is 0.10 mm per year (Livermore et al, 1990). On this basis, even an acetabular cup with an outside diameter as small as 40 mm should have sufficient wall thickness for around 90 years of service if the femoral head diameter is 22 mm. However, as linear wear progresses, a secondary problem is caused by the penetration of the femoral head into the polyethylene acetabular cup. This results in a reduced range of movement of the hip due to earlier impingement of the prosthetic neck.
on the cup. Increased stresses are then transferred to the interfaces and this may eventually contribute to the loosening process.

The *volume* of polymeric wear debris produced per year (volumetric wear) is an important consideration as it is generally accepted that they contribute directly to the loosening process (Chapter 4). Unlike linear wear, volumetric wear is directly proportional to the head diameter, i.e., the larger the femoral head, the greater the volume of wear debris produced every year (Weightman, 1977). This was confirmed by the study of Livermore and coworkers who showed that volumetric wear was greatest in THR's with 32 mm femoral heads, intermediate with 28 mm heads and least with femoral heads of 22 mm diameter. They also made the observations that volumetric wear was increased by greater body weight and that osteolysis of the proximal femur was more marked with increasing volumetric wear rate. The positive correlation between volume of polymeric debris and resorption of the proximal femur is noteworthy as it suggests the former have an important biological role in the process of osteolysis and loosening.

Fig 1  Top: Radiograph showing wear in the supero-lateral part of the socket. Bottom: Acrylic cast of retrieved socket (Wroblewski, 1989)
Stem fracture

Charnley first reported on fractures of the femoral prosthesis in 1975, more than a decade after he had introduced his low friction arthroplasty. In his series, the incidence of stem fracture was 0.26% (17 out of 6500 THR) although a much higher rate of 11% had been reported by Martens et al (1974).

Cement fracture

Fractures of the acrylic cement in relation to the stem of the femoral prosthesis may be evident as early as 6 months post-implantation. Weber and Charnley (1975) reported the incidence of cement fracture to be 1.5% in a radiological survey of 6,649 THR's. The majority of those patients with cement fracture remained asymptomatic and in 70% of cases, there was subsidence of the prosthesis to a new position of stability. The effect of an acrylic cement fracture depends upon its influence on the support conditions of the stem. For instance, a fracture in the calcar region will impair proximal medial support for the stem and may precipitate it into Gruen's mode 4 failure leading to fracture of the stem (see Chapter 4). In Weber and Charnley's series, the fracture occurred at the distal 2 cm of the prosthetic stem in 98 out of 99 cases. A fracture here may have relatively little effect on the implant since it subsided to a new position of stability. Such fractures are thought to carry a good prognosis and are not an indication for revision surgery.

Ectopic ossification

Ectopic ossification, also sometimes known as myositis ossificans, is the deposition of bone in the muscles around the implanted prosthesis. Histologically, the new bone does not develop in the muscle fibres, but in the connective tissue surrounding them. In the most severe form of the disease (fortunately rare), the total volume of soft tissue surrounding the hip becomes ossified producing virtual ankylosis. The cause of ectopic bone formation is thought to be the trauma caused to the muscles at the time of
surgery. Men are more likely than women to develop the condition and ankylosing spondylitis is a well recognised predisposing factor.

5. Conclusion

The growing number of THR's performed worldwide since the 1960's testifies to its success in treating degenerative joint disease. However, it has to be remembered that THR is an operation performed not to save life, but to improve quality of life, and that it is a major surgical procedure with potentially serious consequences as outlined in this chapter. The most common of these complications is aseptic loosening and it is with the investigation of the latter that we shall now turn our attention.
CHAPTER 3

Aseptic loosening: Definitions

1. Introduction

The rate of aseptic loosening generally increases with increased duration of follow-up and also in the particular situation when the operation is applied to the more active patient in the younger age group (Chandler et al, 1981). However, even when these factors are taken into account, the incidence of loosening reported in the literature varies considerably. For instance, the reported rate of femoral component loosening using first-generation cementing technique varies between 0-40% (Table 1). Similar variation has been reported for the acetabular component (Mjoberg, 1986). Most of the studies on loosening rates involve surveys of post-operative radiographs and this introduces a problem as there is no consensus as to what radiographic criteria constitute loosening (Table 2). Brand and coworkers (1986) applied the definitions previously used in the literature to a group of 116 non-infected THR's in order to demonstrate how much a definition of loosening could affect the loosening rate. They found that the incidence of femoral component loosening varied by a factor of greater than two, depending on which definition was used. This study confirmed what was already widely suspected: ie, it is difficult to compare rates of loosening from one report to the next as long as there exists no uniformity of thinking as to what constitutes loosening, or what variables should be measured, and with what degree of accuracy (Galante, 1985). This chapter is devoted mainly to the discussion of those radiographic criteria perceived to signify loosening and, in addition, the clinical and operative definitions of this important entity are briefly discussed.
<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Follow-up duration (years)</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eftekhar and Chamley</td>
<td>1971</td>
<td>7-8</td>
<td>0%</td>
</tr>
<tr>
<td>Chamley</td>
<td>1973</td>
<td>9-10</td>
<td>1%</td>
</tr>
<tr>
<td>(Same group as above)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Beckenbaugh and Ilstrup</td>
<td>1978</td>
<td>4-7</td>
<td>24%</td>
</tr>
<tr>
<td>Stauffer</td>
<td>1982</td>
<td>10</td>
<td>30%</td>
</tr>
<tr>
<td>(Same group as above)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand et al</td>
<td>1986</td>
<td>9</td>
<td>35%</td>
</tr>
<tr>
<td>Sutherland et al</td>
<td>1982</td>
<td>10</td>
<td>40%</td>
</tr>
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</table>
Table 2: Radiological criteria indicating loosening of femoral component.

   Progressive change in the width and length of radiolucency zones at either the bone-cement or stem-
   cement interface.
   Widening of cement fracture gap.
   Stem fracture.
   Gross movement of the femoral component.

   Complete radiolucent line more than 1 mm wide at the bone-cement interface.
   Presence of any radiolucent line at the stem-cement interface not present on the original post-operative
   radiograph.
   Any change in position of femoral component.

   Definite loosening: Appearance of a radiolucent line at the stem-cement interface that had not been
   present on the immediate post-operative radiograph.
   A change in the position of the femoral component or the cement mantle.
   Cement fracture.
   Stem fracture.
   Probable loosening: Continuous (100%) radiolucent line at the cement-bone interface without evidence
   of migration (width not specified).
   Possible loosening: Incomplete (50-99%) radiolucent line at cement-bone interface (width not specified).

   Separation of stem from cement mantle due to subsidence or varus migration. Radiographically
   manifested as lucency at proximal, lateral edge of stem-cement interface.

   Any lucency ≥ 2 mm.
   Any position change ≥ 4 mm
   Any cement fracture.
2 Clinical definition

Loosening following THR is suspected on clinical grounds if the patient complains of hip pain for which other causes such as infection can reasonably be excluded. Investigations that may be helpful in the exclusion of infection include blood serology (WBC, ESR, CRP), scintigraphy, hip aspiration and culture studies. These will be further discussed in Chapter 5.

3 Operative definition

The direct examination of the implant at surgery is regarded as the gold standard for the identification of loosening (Lyons et al, 1985). If a component is loose, then visible movements can be induced by applying force to it (O'Neill and Harris, 1984). O'Neill and Harris acknowledged the difficulty even with this very basic operative definition of loosening. They described the following protocol for evaluating looseness at operation and candidly admitted that "although these tests for loosening were the best available, they must be regarded as somewhat limited ". Their protocol for determining looseness of the femoral component consists of applying manual force to the prosthesis with the help of an impactor if the component did not move at the time of dislocation of the hip. They subjected the prosthesis to "strong" rotational and varus stresses manually and then observed the bone-cement and prosthesis-cement interface for any motion or the extrusion of blood with pressure. Either the presence of motion or the extrusion of blood was considered proof of loosening. Clearly, the forces applied in this manner were much smaller than the forces acting on the hip during gait.
It has been seen above that even the direct naked-eye diagnosis of loosening at the time of revision surgery is often not an easy matter. In practice, the situation is even more complicated because loosening is a diagnosis which the clinician must make before contemplating a revision operation. Apart from the odd exception, there is no place for routine exploratory surgery in patients with painful total hip arthroplasties for the sole purpose of diagnosing loosening. It is thus clear that for practical purposes, an operative definition of loosening is not very useful in the vital preliminary assessment of the suspected loose prosthesis. The pre-operative diagnosis of loosening relies on a number of techniques which will be discussed in this chapter and also in chapter 5. The diagnostic criteria used to define loosening are far from settled whichever of those techniques is chosen.

4 Radiological definition

Plain radiography is the most commonly used investigation to assess mechanical loosening. A review of the diagnostic criteria of loosening in conventional radiography reveals a plethora of definitions: in fact, there are as many definitions as
there are authors (Table 2). The common diagnostic criteria of loosening on plain radiography are:

1. Change in component position (migration). Component migration is generally accepted as a certain sign of loosening (O'Neill and Harris, 1984, Gruen et al, 1979). However this statement merits clarification. Swanson (1977) has pointed out that some movement is bound to occur between a metal femoral implant and the femur with each cycle of weight-bearing. This is because the bone to which the component is fixed is itself elastic, and deforms and recovers its shape under each application and removal of load. Since deformation occurs within the bone and since the prosthetic component also deforms elastically, but to a different extent because its material has a different stiffness from that of the bone, some deformation at the bone-prosthesis interface seems inevitable and not necessarily harmful. The important question is how much movement is acceptable and what constitutes loosening. Swanson suggested that provided the amplitude of micro-movement does not steadily increase with successive applications of a constant load and does not cause pain or indeed damage the bone, then it was perfectly acceptable. Experimental evidence for this came from Markolf et al (1980) who showed that the application of a load of 2000N to a femoral prosthesis implanted in a cadaveric femur caused a relative movement between them of the order of 0.1 mm, i.e., the diameter of a human hair. These displacements were fully recovered as the loads were taken off and do not signify loosening.

Bearing in mind the above remarks, there is no doubt that the best radiological evidence of component loosening is a change in its position detected on serial radiographs. With regard to the femoral component, a change in its position can be manifested as:

a. Subsidence (Fig 2).
b. Angular shift (usually varus).
c. Cement fracture and subsequent widening of cement fracture gap (due to subsidence).
d. Stem fracture.
Migration can occur by movement either of the cement mantle with respect to bone or of the femoral component within the cement mantle. How much movement is required to signify loosening? Mjoberg (1986) claims that this should be more than 0.2 mm in the vertical plane (subsidence). In a Roentgen Stereophotogrammetric study of 20 hips, he found that 11 acetabular and 3 femoral components had migrated more than 0.2 mm two years after operation. In most of these cases, there had been an initial period of rapid migration, after which most components migrated more slowly. Using conventional radiography, it is not possible to detect implant movement of that order. Indeed, Brand and coworkers (1986) came to the conclusion that femoral subsidence of less than 4 mm could not be reliably interpreted on serial radiographs. It is obvious from these studies that even if loosening rates were to be judged by implant migration alone, considerable difficulty may be encountered in comparing data between studies because of the lack of a standardised method of evaluating radiographic appearances.

![Image](image.png)

**Fig 2** Migration (subsidence) of the stem over a period of 10 years: Note the space between the lateral convex surface of the stem and the bone (Wroblewski, 1989)

Although migration is generally regarded by most authorities as being synonymous with loosening, other surgeons such as Ryd (Ryd et al, 1984), argue that the amount of migration has no relation whatsoever with the degree of instability of a
prosthetic component. Indeed, many prostheses achieve a position of greater stability after having migrated. There is no better example of this than the situation with collarless tapered femoral stems. Such stems may be more strongly fixed after migration than before, owing to the wedging effect of the tapering stem in the tapering medullary canal. In other words, the migration is self-limiting, culminating in a new position of stability.

In addition to movement in the vertical direction (which for the femoral component usually means sinking or subsidence), varus angulation of the stem (Fig 3) also points to loosening (Stauffer, 1982, Lyons et al, 1985).

Whereas migration or subsidence of the stem can be measured from serial radiographs, Harris et al (1982) have pointed out that indirect evidence of migration often exists on a single plain radiograph. Those indirect pointers of migration are the presence of a crack in the cement mantle (Fig 4) or a fracture of the stem (Fig 5). They are therefore unequivocal indicators of loosening on the same terms as gross migration.
2. RADIolucent lines. Apart from migration, the radiological appearance generally assumed to be part of the picture of loosening is the presence of a radiolucent line at the bone-cement interface (Fig 6) or the prosthesis-cement interface. This statement requires elaboration as radiolucency is not always synonymous with loosening.

The presence of a radiolucent line at an interface such as between bone and radio-opaque cement can be due to the following:
a. The presence of osteoporotic bone adjacent to the cement mantle, as for instance due to stress shielding (Tigges et al., 1994).
b. The "Mach" effect; i.e., the presence of an apparent but not real, lucency at the interface of two materials of greatly different radiographic density (Lane et al., 1976).
c. The presence of a radiolucent material such as debris and blood clots interposed at the interface if such a line was present on the first post-operative film.
d. In later follow-up films, a lucent line generally signifies the presence of fibrous tissue at the bone-cement interface (Lee and Ling, 1982). In such circumstances, the implant may still be solidly fixed to the bone. In their 5-year review of 255 hips, Beckenbaugh and Ilstrup (1978) found that the vast majority demonstrate some radiolucent zone formation at the bone-cement interface around one or both components, and yet, only 20-24% of these hips were assessed as being loose. Furthermore, the reporting of radiolucent lines depends on how carefully they are searched for and is also influenced by radiographic technique (Lee and Ling, 1982). In this respect, it is worth noting that at least two views in perpendicular directions are necessary as a single view may only reflect the situation in one plane of the interface.

The foregoing emphasises the fact that the mere presence of a radiolucent line does not always mean prosthetic loosening. Conversely, the absence of the radiolucent zone does not rule out loosening of the prosthesis: Apart from the difficulty of determining the presence and the degree of radiolucency, the zone may gradually be obliterated by the migrating component (Mjoberg, 1986). Having outlined the difficulties encountered in the interpretation of the radiolucent zone, it now becomes pertinent to attempt a description of the degree and extent of lucency that is currently believed to signify loosening of the prosthetic component.

It is generally agreed that a progressive increase in the width of a radiolucent line at the cement-bone interface in successive follow-up films indicates the onset of loosening (Gruen et al., 1979, Harris and Mc Gann, 1986). This is held to mean that there has been progressive destruction of bone or migration of the implant away from the bone surface, or both (Lee and Ling, 1982). In such circumstances, the femoral
component becomes unstable due to the loss of mechanical support in its own bed and as this happens, the amplitude of movement between cemented prosthesis and the bone increases with each application of load. This leads to a vicious cycle in which the increased stresses on the bone (due to the increasing amplitude of movement) causes further bone destruction thus making the implant even more unstable. Similarly, the development of a radiolucent zone at the stem-cement interface which was not present on the original post-operative film indicates that the coupling between the prosthesis and the cement has been breached.

Whereas there is general agreement that a progressive increase in the width and extent of the radiolucent line heralds mechanical loosening, it is by no means certain what the width and extent of this line should be to establish a diagnosis of frank loosening. Brand et al (1986) believe that a lucency less than 2 mm in width is subject to enough error as to be questioned. They, and most other authors conclude that only a lucent line equal to or greater than 2 mm in width can be reliably interpreted. Even then, actual measurement of the lucent line can be subject to much inter-observer variation. Using computer technology, Maxwell et al (1993) showed that only lucent bands greater than 2.5 mm could be reliably measured by visual methods using a transparent rule. There is no consensus whatsoever as to the extent of the lucent zone around the cement mantle that is required to be diagnostic of loosening. This fact is made obvious by reference to Table 2.

To summarise a complex situation, it would seem that most clinicians agree that definite loosening is present if there is migration of the components, progressive complete radiolucency at the bone-cement interface, or complete radiolucency exceeding 2mm in width or fracture of the stem or of the cement mantle. However as succinctly put by O'Neill and Harris (1984), "many components with a minimum radiolucent zone have been proved to be loose at operation, and a few components with an extensive radiolucent zone have been shown to be well-fixed at operation. Therefore, if there is no migration, the extent, thickness, and progression of the radiolucent zone are not fully reliable predictors of loosening of a component." This was confirmed in a study by
Mjoberg et al (1986) who found that 21 out of 40 components studied were non-migrating (and therefore secure) and yet had developed a radiolucent zone at the bone-cement interface whereas some of the migrating components had no lucent line.

Fig 6: 18 months post-operatively there is gross bone resorption around the cemented prosthesis giving rise to a lucent zone (Lee & Ling, 1982)
CHAPTER 4

Mechanisms and causes of Aseptic loosening

1. Introduction

The aetiology of aseptic loosening is very complex and is not fully understood. It involves a large number of diverse factors such as mechanical stresses on the implant, foreign body (biological) reactions, surgical technique and metal sensitivity. In any specific case of loosening, it is often difficult to ascertain the relative importance of any one factor in causing failure of the fixation. The situation at a macroscopic level is rather better understood and was described by Gruen et al in their classic paper of 1979. In that paper, the authors identified 4 modes of failure of the cemented stem-type femoral component by retrospective analysis of the serial radiographs of 56 patients with progressive loosening. It was also suggested that faulty cementing technique was the main reason leading to the failure of the implanted prostheses. The paper was a significant contribution because it allows one to predict the likely fate of a failing implant and to take action accordingly.

2. Modes of failure of cemented stem-type femoral implants

Gruen and his colleagues were able to work out the various modes of loosening of a femoral implant by studying serial radiographs (taken over a period of 6 years post-operatively) of 389 THR's. To facilitate the radiographic assessment of the femoral component, the proximal femur was delineated into 7 zones (Fig 1):
Each of these zones was carefully assessed for the presence of fractured acrylic cement, and an interface gap such as a radiolucent zone at the stem-cement or at the cement-bone interface. In the authors’ assessment, a prosthesis is loose if any one or more of the above occurs in any of the zones described.

By those criteria, 76 out of the 389 (19.5%) hips were loose after an average follow-up of 3 years. The zonal distribution of the radiographic evidence of looseness is illustrated in figure 2.
The authors then studied serial radiographs of the 76 "radiographically loose" prostheses and found that 56 of those had progressive femoral component loosening and these were classified into 4 modes.

2.1 Mode 1: Pistoning behaviour

Mode 1 failure is characterised by pistoning of the prosthesis within the acrylic sheath (Mode 1a) or of the acrylic encapsulated prosthesis within the bone (Mode 1b).

Mode 1a indicates subsidence or slippage of the stem within the acrylic sheath due to loss of proximal acrylic support and often results in a punch-out fracture of the acrylic cement at the tip of the stem as a result of axial loading. It is a clear example of loosening at the stem-cement interface and is radiographically characterised by stem sinkage, the presence of a radiolucent line in the proximal-lateral zone (zone 1) and cement fracture at the tip of the stem (Fig 3).

![Fig 3 Mode 1a: Subsidence of prosthesis within acrylic sheath "opening" up distal tip cement fracture](image)

Mode 1b is radiographically characterised by a radiolucent zone around most if not all of the cement-bone interface (Fig 4). It was suggested that in Mode 1b, the applied mechanical stresses on the implant disrupt the mechanical bond at the cement-bone interface with subsequent loosening. This was the most common mode observed
by the authors who stated that it may be brought about "by inadequate interdigitation of acrylic cement into cancellous bone." Thus poor cementing technique was implicated for this mode of failure. There is support for this theory as half the cases of Mode 1b failure occurred in revision operations for failed hemiarthroplasties and in most of these cases, the radiolucent zone at the cement-bone interface was observed in the immediate postoperative radiograph, thus implying insufficient removal of the fibrous tissue that had encapsulated the previous prostheses. In those circumstances, the cement will not adequately penetrate cancellous bone to achieve sound mechanical fixation. Current thinking favours a different view for Mode 1b loosening: It is believed that particulate wear debris (polyethylene in particular) generated at the joint bearing are able to migrate to the bone-cement interface where they induce a chronic inflammatory reaction which results in bone resorption around the cemented implant. This would account for the lucent line around the cement mantle.

Fig 4 Mode 1b: Significant bone resorption has occurred and the prosthesis together with its cement mantle has subsided into the femoral canal (Gruen et al, 1979)
2.2 Mode 2: Medial midstem pivot

This mode is radiographically characterised by medial migration of the proximal stem coupled with lateral migration of the distal stem tip (Fig 5). It is caused by a combination of weak calcar support and lack of distal acrylic support. The radiograph below illustrates an example of Mode 2 failure: The characteristic medial migration of the proximal stem has resulted in a radiolucent zone along the proximal-lateral (convex shoulder) surface of the stem. Here too, deficient cementing technique seems to be the main factor causing failure of fixation.

![Radiograph of Mode 2 failure](image)

Fig 5 Mode 2: Note medial migration of proximal half of stem and lateral migration of distal half (Gruen et al, 1979)

2.3 Mode 3: Calcar pivot

This mode is the result of insufficient distal acrylic support and results in the distal stem pivoting on the calcar (Fig 6). The prosthesis may have adequate proximal support or "hang-up" on the medial femoral neck upon which it pivots. Gruen et al counted only 3 such cases (out of 59 cases of loosening) and concluded that it is easier to obtain or maintain rigid fixation in the distal femur than proximally. Mode 3 is analogous to the loosening of uncemented Austin-Moore prostheses where the large
head of these prostheses pivoted upon the transected femoral neck and the distal part of the stem was able to move within the femoral cavity.

Fig 6 Mode 3: There is no evidence of proximal loosening but distal motion is present

2.4 Mode 4: Bending cantilever fatigue

This mode is characterised by loss of proximal acrylic support with subsequent medial migration of the proximal stem while the distal end remains securely fixed in acrylic cement (Fig 7). This mode is the most threatening with respect to stem durability and accounted for stem fracture in two of Gruen's patients. When the proximal stem loses its acrylic support and is then subjected to cyclic bending stresses, this creates a region of high stress at the junction of mobile proximal stem and fixed distal stem eventually leading to fracture of the stem at that point.

Apart from defective cementing technique, Gruen et al suggested another aetiology for Mode 4 failure. They postulated that it could result in cases where there was disuse atrophy of the proximal medial femoral neck (calcar resorption), which would result in a decrease or loss of proximal-medial support of the stem. As a result, the poorly supported proximal stem is able to rock on the securely fixed distal stem thus increasing the likelihood of fatigue fracture.
3. The causes of aseptic loosening

While Gruen's modes of failure provide an adequate description of the mechanical pattern of loosening, the question of aetiology was not tackled to any depth. It was the authors' firm belief that defective cementing technique was the main cause of loosening whereas a review of the literature revealed a much broader view: the situation is indeed complex because multifactorial. For the sake of convenience, those aetiological factors will be discussed under the following headings:

1. Biological reactions to wear particles.
2. Mechanical stresses on the implant and the bone.
3. Surgical technique.
4. Physiological factors.
5. Iatrogenic factors.
3.1 Biological factors

The biological mechanisms involved in loosening are of 2 types:

a. The foreign body reaction in response to particulate wear debris.

b. Metal sensitivity.

The foreign body reaction to particulate wear debris

The biological theory holds that loosening occurs not as a result of the mechanical stresses on the implant but because of bone resorption secondary to the formation of wear particles in the artificial joint. Vernon-Roberts and Freeman (1977) were among the first to suggest this theory and proposed the following mechanism: All prostheses having bearing surfaces release particulate wear products into the joint cavity surrounding the articulating components. For the commonly used prostheses with a metal femoral component and a plastic cup, the wear debris would consist mainly of plastic and also much smaller quantities of metal. However, further amounts of metal salts are released into the joint by the chemical process of corrosion and this adds to the total load of intra-articular metal. Additionally, in cases where bone cement has been used, acrylic debris are likely to be present in the joint cavity. Those particulate debris (plastic, metal and acrylic) are carried into the capsular tissues and got rid of via the perivascular lymph vessels. But if the amount of wear debris exceeds the eliminating capacity of the joint capsule, the excess particles will eventually migrate to the bone-cement interface through cracks present in the cement mantle (Howie et al, 1993). Once there, they provoke a foreign-body reaction with activation of bone macrophages (histiocytes). This leads to a chronic inflammatory reaction whereby the macrophages ingest the particles but are unable to digest them. Various enzymes and cytokines (eg prostaglandin E2, interleukins, and tumour necrosis factor) are produced in the process and these are thought to be directly responsible for bone resorption in the vicinity of the prosthesis. This process ultimately leads to loosening.
The clinical evidence for the biological theory of loosening relates to the use of Teflon (PTFE) cups by Charnley in his early days. These cups had a relatively high rate of wear resulting in the formation of large amounts of debris. The latter led to florid foreign-body reactions which spread to the cement-bone interface, producing destructive granulomata thus causing loosening (Charnley, 1979) (Fig 8). These florid types of lytic reaction are nowadays less commonly seen with the present Ultra-high molecular weight polyethylene cups which have a much lower rate of wear.

Humphreys et al (1991) provided indirect evidence for the biological theory when they discovered that they could not loosen a femoral prosthesis subjected to 5 million cycles of loading up to 6 times body weight. They concluded that "the hypothesis that loosening occurs as a result of fatigue failure or plastic deformation of the bone or cement, due to mechanical effects alone, appears to be incorrect."

![Fig 8 High density polyethylene granulomas: Uncemented stem (left), cemented stem (right)](image)

**Metal sensitivity**

There is some evidence that the biological mechanisms outlined previously are accentuated in patients who develop metal sensitivity as a result of the formation of large amounts of metal debris in the joint cavity. Evans et al (1974) were able to
demonstrate an association between late loosening of a component and a demonstrable epicutaneous skin sensitivity to metal. They skin-tested 38 patients and found that out of 14 patients with loose prostheses, 9 had a positive skin test. By contrast, all 24 patients with securely fixed prostheses were not sensitive to metal. Subsequent work by other authors supported these findings (Benson et al, 1975). Since metal-on-metal articulations such as the McKee prosthesis generate much more metal debris than Charnley-type metal-on-plastic prostheses, it would be expected that patients with the former type of prostheses will have a higher incidence of metal sensitivity - a finding confirmed by Benson et al.

The other highly significant finding in these studies is the very high incidence of metal sensitivity (70%) in patients with unexplained loosening of prostheses, and this suggests that there is a causal relationship between metal sensitivity and loosening.

The mechanism by which metal sensitivity causes loosening is thought to be immunologically mediated. The metal itself or its salt is recognised as a foreign antigen by lymphocytes and the latter initiate an immunological attack that leads to a rapid proliferation of macrophages and giant cells which as well as ingesting the metal particles, are also responsible for bone destruction around the prosthesis, a process mediated via the release of cytokines.

3.2 Mechanical factors

The main effects of mechanical stresses occur at the interfaces; either the bone-cement interface or the stem-cement interface.

Mechanical stresses at the bone-cement interface

Paul (1976) has shown that the magnitude of the resultant force on the hip joint during walking is around 5-8 times bodyweight. As the direction of the joint force changes during the gait cycle, this imparts torsional stresses on the femoral component in addition to axial loading and bending moments. These represent a major mechanical
challenge to the fixation of an artificial joint during what is seemingly an innocuous activity.

Some authors believe the major effect of these mechanical stresses is at the bone-cement interface (Lee and Ling, 1982). Where the initial bone-cement interlock is grossly inadequate, the stresses may exceed the static strength of the host bone. Early mechanical failure ensues and allows micromovement of the implant. This produces bone destruction by mechanical abrasion, especially where cement has been used. In addition, the fibrous membrane that is often present at the bone-cement interface is capable of bone resorption when stimulated by micromovement thus making the situation worse (Goldring et al, 1983).

The correlation between mechanical overstress and loosening is borne out in clinical practice where it is evident that young, overweight or overactive patients are those most likely to develop loosening. Chandler et al (1981), reporting on a group of patients having undergone THR under the age of 30 years found that 57% of those had real or incipient problems of loosening. Lindberg and Carlsson (1983) found that loose stems were significantly more common in men. Excessive physical activity was regarded as the most important single factor contributing to the loosening. Once loosening starts, a vicious cycle is frequently created that will lead to progressive destruction of the interface and eventually gross clinical loosening. This vicious cycle can only be arrested by substantial reductions in the stresses applied to the fixation. In practice, this means a reduction in the level of physical activity, often requiring the use of sticks or crutches.

Mechanical stresses at the stem-cement interface

As outlined above there are some authorities who believe that loosening is a problem that begins at the bone-cement interface (Lee and Ling, 1982). However Stauffer (1982), in his 10-year radiological follow-up of 231 THR, found that the most common (58/69) type of loosening resulted from failure at the stem-cement interface due to splitting of the cement mantle. Why does cement fracture? Due to the polymerisation
process, the cement on cooling, develops locked-in internal stresses. Certain of these stresses are oriented circumferentially and constitute so-called hoop stresses, analogous to the tensile stress that develops in a metallic hoop that has been heated, placed around a wooden barrel and allowed to cool and shrink. The degree of hoop stress is directly proportional to the shrinkage characteristics of the polymer and has been found to be between 4 and 8 MPa (Miller et al, 1978). In addition to these locked-in stresses, much higher hoop stresses are developed during axial loading of the tapered, wedge-shaped femoral component. When the sum of those hoop stresses exceed 30 MPa (the maximum tensile strength of the cement), the cement mantle begins to split, a crack starting proximally and propagating distally for a variable distance before ending as a crack oriented in the horizontal plane (Stauffer, 1982). Because of the location, irregularity, and out-of-plane orientation of the vertical parts of the cement cracks, they are not generally visible on plain films of the hip. They can nevertheless be clearly seen at the time of revision when the component is removed. As in the case of bone-cement interface failure, the only way to prevent cement fracture is by a reduction in physical activity and weight if obese.

3.3 Surgical factors leading to loosening

Bone death around an implant

Vernon-Roberts and Freeman in 1976 found that early loosening (i.e. loosening within 2 years of implantation) was "usually associated with the death of more bone than appears to be the case with non-loose prostheses which have been implanted for the same period of time". This association between bone death and loosening suggested a causal relationship.

The cause of the death of bone at the bone-cement interface is uncertain, but three factors have been implicated:

1. The trauma and heat generated by cutting and reaming the bone.
2. The heat generated by the polymerisation of PMMA cement.
3. Leakage of toxic monomer from the cement mass into surrounding bone before polymerisation is completed.

Rough handling causes bone death by direct trauma and also by damaging its blood supply. That atraumatic handling of bone is important has been demonstrated by Linder and Lundskog (1975) who claimed to show that if the operative technique was sufficiently gentle, direct contact could be achieved and maintained between living cortical bone and a metallic implant. So close can this contact be that considerable forces may be required to extract even smooth-surfaced implants.

PMMA generates significant heat when it polymerises so that thermal necrosis is theoretically a possibility. However, doubt has been cast on the extent to which this occurs in practice since flowing blood and metallic implants may both act as effective heat sinks to reduce the surface temperature of the cement mass at operation (Jeffersiss et al, 1975). The highest temperature at the bone-cement interface measured in-vivo was 46 degrees centigrade (Vernon-Roberts and Freeman, 1777) which is well below the temperature at which protein denatures (56 C). As such, many authorities do not believe thermal trauma to be a significant cause of bone death.

Monomeric methyl methacrylate is toxic and diffuses from the cement mass into the bone before full polymerisation. That it may cause toxic necrosis of the adjacent bone is therefore possible but as yet unproven. In summary, of the 3 factors which might be responsible for the initial death of bone at the bone-cement interface, surgical trauma seems to be the most likely and the factors specific to PMMA cement the least likely.

With a dead layer of bone at the cement-bone interface, the sequence of events that eventually leads to loosening of the prosthesis is as follows. Dead bone is weaker than living bone and is therefore more fatigue-prone. Thus, it is likely that the dead cancellous bone adjacent to the cement mass undergoes fatigue fracture in the face of the repetitive loads applied in everyday life. The longer the period for which the bone is loaded, the more likely this is to occur. The fracture of dead bone at the interface may lead to an actual loss of the interlock between living bone and cement rather than merely
to fibrous replacement of a zone of dead bone (Vernon-Roberts and Freeman, 1977). This scenario would be consistent with early loosening.

A second sequence of events is possible in which the death of a substantial zone of bone adjacent to the implant results over a period of years, in the development of an unusually thick layer of fibrous tissue at the bone-cement interface. Since soft connective tissue is relatively weak in tension and in shear, this may predispose to loosening by rupture of the fibrous tissue (rather than by fracture of the bone as in early loosening). Support for this view comes from the fact that tears, haemorrhages and fibrinous exudates have been observed in the fibrous tissue of the implant bed in cases of loosening occurring more than 2 years after implantation (Willert et al, 1974). This scenario, in which the implant becomes loose as a result of rupture of the fibrous tissue of the implant bed, would be consistent with late loosening.

Thus excessive bone death caused by surgical trauma may be responsible for both the phenomena of early and late loosening.

Poor cementing technique

The use of acrylic cement for implant fixation in replacement arthroplasty of the hip is the method of choice for most Orthopaedic surgeons. With cement, many consider that sound fixation of an implant is strongly dependent on an adequate cementing technique and that loosening is more likely to occur if the prosthesis has been poorly cemented. Factors pertaining to cementing technique considered significant in the pathogenesis of loosening are of 2 types (Lee and Ling, 1982):

1. Those which weaken the cement itself.
2. Those which adversely affect the quality of the interlock between cement and bone.

Factors which weaken the cement

Acrylic cement is weakened by the presence of porosities, voids and laminations. Porosities and voids are due to the presence of air in the cement and can be avoided by using centrifugation or vacuum mixing, which form part of the protocol for
so-called third-generation cementing techniques. Laminations can be avoided by using the cement relatively early, when its viscosity is low. The presence of blood within laminations can decrease the mechanical strength of cement by up to 80%. However, the most critical factor affecting the mechanical behaviour of cement is that it must be fully constrained or supported by bone. Cement that is not properly constrained by bone cannot give adequate support to an implant (Figure 10: Lee and Ling, 1982).

The addition of antibiotics such as Gentamicin to cement in order to prevent or treat infection does weaken it to some degree. However, provided that the amount added is not excessive (ie, less than 2 grams for every 40 grams of powder), the mechanical strength of PMMA cement is not significantly reduced. Similar principles apply to the other usual additives such as barium and zirconium salts as well as chlorophyll.

Fig 10 The cement above the calcar is unconstrained and provides no support to the stem with the result shown

Factors which affect the quality of the interlock between cement and bone

A. Presence of blood clots and debris at bone-cement interface.

During a histological examination of the canine bone-cement interface, Miller et al (1978) observed the presence of blood and debris interposed between the cement and the bone, and speculated that this may lead to a "significant reduction in the integrity of cement fixation to bone." They found that thorough mechanical cleansing of the bone surface using a brush combined with lavage and suction could reduce the thickness of the...
interposed layer of blood and debris from 100-1000 microns to 10-20 microns. Mechanical testing showed that the presence of blood and debris at the bone-cement interface reduced its tensile strength by up to 57%. Several other workers have since confirmed the benefit of thorough cleansing of the bone surface and nowadays, it is common practice to use high pressure pulsed lavage of the bone surface before application of the cement.

B. Cement pressurisation.

Oh et al (1978) have shown that the quality of interlock between cement and bone can be improved by using a methacrylate intramedullary plug. They demonstrated that plugging the medullary canal increased the pressure in the cement at the insertion of the femoral component compared with non-plugged femora. They showed improved distribution of the cement throughout the medullary canal into the interstices of the cancellous bone and consequently, increased strength of the cement-bone interface (Fig 11). Using this cement pressurisation technique, Harris and Mc Gann (1986) reported a lower incidence of loosening of the femoral component compared with other series.

Fig 11 Left: cement cast from a plugged femur, Right: cast from unplugged femur (Oh et al, 1978)

As the cement is being applied to the bone, it is necessary to maintain the pressure on it so that bleeding at the bone surface does not push cement off the bone
(Lee and Ling, 1982). Persistent and repeated digital packing is required, or the use of a proximal femoral occluding device to stop the cement running out of the proximal end of the femur. The anaesthetist may contribute in minimising bleeding by using hypotensive anaesthesia.

Before leaving the subject of cement technique, a few other points are worth mentioning. Cement fracture (thought by some to be the initial stage of loosening) can be reduced by avoiding varus insertion of the femoral component and by assuring an adequate layer of cement around the prosthesis (Miller et al, 1978). To protect the stem-cement interface, the prosthesis must be kept absolutely still during the final stages of polymerisation of acrylic cement (Gruen et al, 1979).

3.4 Physiological factors: Age-related bone loss

In tubular bones such as the femur, bone deposition is periosteal and resorption endosteal. From the fourth decade onwards, the rate of periosteal apposition declines, whereas resorption continues and may even increase. Consequently, there is not only a reduction in bone mass, but also an increase in the diameter of the medullary canal. The contribution of the increase in diameter of the femoral canal to loosening is difficult to assess. One of its earliest effects would be to produce increased stresses and allow an abnormal degree of micromovement at the bone-cement interface which would in turn activate the macrophage and giant-cell response with consequent bone resorption (Goldring et al, 1983). If this scenario were to be accurate, it would have grave implications in the performance of THR in the relatively young patient.

3.5 Iatrogenic factors

It has been postulated that drug-induced inhibition of bone remodelling at the bone-cement interface after THR may lead to increased interfacial stresses and micromovement which in turn activate the cellular response leading to bone resorption with consequent loosening. Although this mechanism is as yet unproven, several drugs
in common use are well known to inhibit bone formation. Such drugs include corticosteroids and non-steroidal anti-inflammatory agents such as indomethacin and aspirin. The latter group also have analgesic properties and the suppression of pain that they cause may allow unrestrained physical activity on an implant which may already be starting to loosen.

4 Conclusion

The foregoing illustrates the complexity of the aetiology of aseptic loosening. It is probable that most of the factors mentioned, i.e. biological factors, mechanical stresses, and surgical technique, contribute to the fate of an implanted prosthesis. Their relative importance undoubtedly varies from case to case and their roles in leading to failure of the implant are often intimately linked, e.g. excessive mechanical stresses at the bone surface will provoke a biological reaction leading to bone resorption. Conversely, biological mechanisms have mechanical effects, since the removal of bone at the interlock must lead to increased stresses on the bone and other junctional tissues that remain. The exact sequence of events that lead to loosening is also far from settled. Some believe that the events at the bone-cement interface initiate the process of loosening while others believe they are merely the result of preceding failure at the stem-cement interface. Whatever the true situation may be, the surgeon has to deal with the problem of loosening based on his understanding of the process. In practical terms, this usually means careful patient selection (e.g. avoidance of obese patients), the establishment of fixation of maximal possible strength using meticulous surgical technique (which includes attention to cementing technique), and sensible advice to the patient regarding his activity level.
Chapter 5

The investigation of the painful THR

1. Introduction

Aseptic loosening of a total hip replacement is usually manifested as pain and to this day, there is no ideal method of evaluating a painful replacement arthroplasty (Lieberman et al, 1993). Loosening is not the only cause of hip pain in the patient with a THR, but it is undoubtedly the most common. This was vividly expressed by W. Harris thus: "Without any question, the number one problem in total hip replacement is loosening. It is not wear, not sepsis, and not anything else; it is loosening." (Harris, 1978). In a review of 91 revision arthroplasties performed in patients with a painful primary THR, Van Rens and Slooff noted that 65% were due to aseptic loosening, 29% to sepsis and 5% were due to various other causes such as ectopic ossification (Van Rens and Slooff, 1982).

The investigation of aseptic loosening is really the investigation of a painful THR. It involves a process that not only excludes the other causes of pain (particularly sepsis), but also yields positive evidence of mechanical loosening. As in all clinical medicine, this process begins with a careful history and an adequate physical examination which are supplemented as necessary by further investigations. The investigations in common use for the investigation of the painful THR are:

1. Haematological parameters: WBC, ESR, Plasma Viscosity, CRP.
2. Plain radiography.
3. Roentgen stereophotogrammetry (RSA).
4. Isotope studies.
5. Arthrography.
7. Tissue Biopsy.
2. Clinical assessment

This consists of the history followed by physical examination.

A. The history

Pain after replacement arthroplasty of the hip can conveniently be classified into 3 categories (Van Rens and Slooff, 1982):

1. Patients in whom the pain is arising directly from the replacement arthroplasty e.g. from loosening, sepsis or fracture of the stem.
2. Patients in whom the pain is an indirect consequence of the arthroplasty, e.g. trochanteric bursitis or ectopic ossification.
3. Patients in whom the pain is nothing to do with the arthroplasty, and is arising elsewhere, usually in the spine.

The salient features to enquire about in the history and which will help to distinguish between those 3 categories are:

1. The time and mode of onset of the pain.
2. The site and radiation of the pain.
3. The aggravating and relieving factors.

The time and mode of onset of the pain

Pain persisting unchanged following operation suggests either the original pain was not arising in the hip, or gross defects of fixation of the implant components at the original surgery, with or without infection.

Pain arising from the arthroplasty and of gradual onset following a post-operative pain-free period of variable duration suggests either mechanical loosening, deep infection, or a combination of both.

Pain arising from the arthroplasty and of sudden or relatively sudden onset following a post-operative pain-free period of variable duration suggests either
mechanical loosening, stem fracture or a fatigue fracture of the pelvis. The latter is unlikely until some years have passed following surgery (Mc Elfresh and Coventry, 1974).

The site and radiation of the pain

Pain felt in the groin, the upper thigh, over the greater trochanter and in the lateral part of the buttock is often found with cup loosening either with or without deep infection.

Loosening or infection of the femoral component is more often associated with a deep boring pain in the whole thigh.

Pain purely over the greater trochanter suggests trochanteric bursitis or a painful un-united trochanteric osteotomy. The main complaint in such cases is an inability to rest and sleep on the affected side.

Pain arising in the lumbar spine, especially when associated with entrapment or irritation of one of the upper lumbar nerve roots, may mimic very closely pain arising in the hip. Root pain may be accompanied by variable paraesthesiae and complaints of subjective numbness. These do not occur with hip pain. Where the pain has a spinal origin, careful questioning may sometimes elicit a history of low back pain.

Aggravating and relieving factors

The more or less immediate production of pain by weight-bearing on the affected limb strongly suggests that the pain is arising directly from the hip. Pain felt for the first two or three steps after starting to walk following a period of sitting is by no means uncommon, especially in the early months after operation. Such pain subsides with further walking and as a rule, disappears altogether within 6 months of operation. If it persists, and especially if it becomes progressively worse, eventually being unrelieved by walking, loosening is the likely cause, with or without infection.
Rest pain and night pain, aggravated by weight-bearing should raise the suspicion of sepsis (Evans and Cuckler, 1992). It can also be due to malignant disease (Van Rens and Slooff, 1982).

Pain arising from lumbar root irritation may be aggravated by weight-bearing, but as a rule, the aggravation is not so immediately apparent as it is when the hip is responsible. Lumbar root pain may be exercise-related, especially when associated with spinal stenosis, and may then have characteristics of intermittent claudication. Pain of this type raises the question of obliterative arterial disease, and further investigation may then be needed.

Physical examination

The physical examination of the patient with a painful arthroplasty should be similar to that performed on all patients with hip pathology. Some particular points require emphasis:

1. Clinical evidence of present or past inflammatory change, e.g. a healed sinus, strongly supports the diagnosis of infection.

2. Local tenderness over the greater trochanter is found with trochanteric bursitis, and pain may be produced with forced adduction of the hip (Van Rens and Slooff, 1982). Similar findings may be present with a painful non-union of the greater trochanter following trochanteric osteotomy, or when a projection of acrylic cement extends laterally out of the track of a previously removed blade plate (following intertrochanteric fracture or osteotomy).

3. Gait examination: the presence of a normal gait and negative Trendelenburg sign may suggest sources other than the total hip arthroplasty as the source of pain.
4. Limb length inequality, particularly when progressive shortening can be documented, suggests mechanical failure in fixation (Evans and Cuckler, 1992).

5. The range of motion of the hip within reasonable limits should be painless. Pain in the hip with passive motion suggests mechanical dysfunction of one or both components. Van Rens and Slooff claim that a constant finding in their cases of loosening, whether due to infection or not, was pain with forced passive internal rotation of the limb.

6. Where the pain is suspected of having a spinal origin, the careful interpretation of the findings on performing the straight leg-raising and femoral nerve stretch manoeuvres may give very valuable information.

7. With exercise-related pain, attention must be given to the state of the peripheral circulation, and to the possibility of spinal stenosis with root entrapment.

8. Finally, as in all cases, a comprehensive general examination of the patient looking for potential sources of infection, such as the feet, or any areas of ulceration, abscess, or skin breakdown. Abdominal, rectal and pelvic examinations should also be considered in the absence of a clear relationship between the total hip arthroplasty and the pain syndrome.

3. Haematological investigations

Haematological parameters in patients with painful total hip replacements may be used to distinguish between sepsis and aseptic loosening. The tests commonly used are:
a) White cell count (WBC).
b) Erythrocyte sedimentation rate (ESR).
c) Plasma Viscosity (PV).
d) C-Reactive protein (CRP).

A White cell count and differential

There is general agreement that WBC has little value in the evaluation of the painful arthroplasty in the absence of fulminant sepsis (Evans and Cuckler, 1992). Van Rens and Slooff (1982) found that they were usually normal in their cases that were subsequently proved to have infections at the time of operation. Lindberg had previously reported similar findings (1979).

B Erythrocyte sedimentation rate (ESR)

The ESR is undoubtedly of greater value than the WBC in the evaluation of the painful THR (Evans and Cuckler, 1992). A high ESR is suggestive of infection whereas a normal value is in favour of aseptic loosening. Taking the upper limit value of ESR as 30 mm in the first hour, Kamme and Lindberg (1981) found that 34 out of 38 infected cases had an elevated ESR (sensitivity 90%), two of the four who did not had received prolonged antibiotic treatment prior to exploration, and the other two had infections with organisms of low virulence. However, in a later study, using similar criteria, Sanzen and Carlsson (1989) found that only 14 of 23 infected THR's had a raised ESR (sensitivity 60%). There is similar variation in the reported specificity of the test, i.e. its ability to exclude infection in the presence of a normal ESR. Cuckler et al (1991) have averaged the specificities in 5 studies, (including their own) and found this to be 77%. Despite these variations, most orthopaedic surgeons would regard a persistent elevation in or an increasing ESR as highly suggestive of infection. It is of course less valuable in patients with rheumatoid disease, who usually have a persistently elevated ESR as a result of background disease.
There are some difficulties in interpreting ESR values. First, the value of the ESR in normal individuals varies with age and gender and is higher in the elderly than the young and higher in women than men of similar age. Second, in the specific context of THR, the ESR can remain elevated for as many as six months following an uncomplicated hip replacement (Forster and Crawford, 1982). Several later studies have confirmed that the decline in the ESR after uncomplicated THR is indeed a protracted event that lasts between 6 weeks to one year (Larsson et al, 1990, Aalto et al, 1984). This slow decline is a distinct disadvantage to the value of the ESR as a predictor of post-operative sepsis in THR and many authors have advocated the use of another haematological parameter; namely the C-reactive protein level (see later).

C Plasma Viscosity

Although it is generally assumed that the ESR and the Plasma Viscosity (PV) increase in parallel under the influence of factors such as infection and inflammation, these tests are not truly identical. The ESR depends on Rouleaux formation (red cell aggregation), which in turn depends on the relative concentrations of fibrinogen and globulins in plasma. Weight for weight, fibrinogen has a greater viscosity than globulin, which in turn has a greater viscosity than albumin. It is nowadays generally agreed that plasma viscosity measurement is a better indicator of the change in plasma protein composition that occurs in response to inflammation than the ESR (Eastham, 1984). Choudhry et al (1992) have demonstrated an additional advantage of PV over the ESR in the context of joint replacement: they showed that PV had returned to normal levels within 2 months of joint replacement compared to 6 months for the ESR and this therefore made early post-operative interpretation of the test easier if infection were suspected. In many contemporary laboratories, the plasma viscosity is gradually replacing the ESR as an index of inflammation (Eastham, 1984).
D The C-Reactive protein (CRP)

C-Reactive protein is one of the so-called "acute phase reactants". It is thus named because of its affinity for the C-polysaccharide of pneumococcus. It is present in increased quantities in the serum of patients with infection, inflammation, trauma and occasionally those with malignant disease.

A review of the literature reveals a consensus of opinion that CRP measurement is a valuable supplement to the ESR in the monitoring of infection after THR. Van Rens and Slooff (1982) report that the CRP was always abnormal in their infected cases but sadly they did not specify their chosen normal value and did not comment on their rate of false-positives. In a more detailed study, Sanzen and Carlsson (1989) measured both the CRP and ESR in 23 patients with infected THR's before revision and found a raised CRP in 18 patients (78%) and a raised ESR in 14 (61%). In only 1 infected patient were both the CRP and ESR normal. The authors repeated the same tests on 33 patients with aseptic loosening and found that both their ESR and CRP remained within the normal range. In the light of their results, they suggested that CRP measurement complements ESR measurement in the monitoring of infection following THR. The fundamental reason for this complementary behaviour of CRP and ESR is that although both become raised during sepsis, the CRP increases first and peaks earlier than the ESR. The latter rises afterwards and remains elevated while the CRP level is already declining.

Although CRP levels, like ESR, increase following uncomplicated THR, they consistently return to normal within 3 weeks of the operation (Aalto et al, 1984, Larsson et al, 1990). This compares favourably with the duration of the fall in ESR which can last up to a year following THR. In the study of Larsson et al, 103 of 109 patients (95%) had regained a normal CRP value 21 days after uncomplicated elective surgery and all had normal CRP levels 42 days post-operatively. This led the authors to conclude that routine CRP determinations for detection of bacterial infections complicating THR are probably much more valuable than the routine measurement of ESR.
4 Plain radiography

Plain radiography is part of the first-line investigation of any patient with a painful THR. The difficulties in interpreting X-ray appearances of loosening are set out in detail in Chapter 3 and will not be discussed again here. The other radiological features to look for which may suggest a cause other than aseptic loosening include:

1. Scalloped endosteal bone resorption and laminated periosteal new bone: these are strongly indicative of infection according to Lyons et al (1985). However most other investigators have been unable to differentiate aseptic from septic loosening on the basis of the findings of plain radiography (Evans and Cuckler, 1992).

![Image of infection: Scalloped endosteal resorption in the femoral shaft (Lyons et al, 1985)](image)

Fig 2 Infection: Scalloped endosteal resorption in the femoral shaft (Lyons et al, 1985)

2. Ectopic ossification: This is a well recognised complication of THR which in the early stage (3-6 weeks post-operatively), is radiographically characterised by a haze of calcification, usually in the abductor muscles. Later as the bone matures, its radiological density increases, but the volume deposited does not exceed that outlined by the calcification at 6 weeks (Hamblen, 1982).

3. The position and extent of any extra-osseous cement should be noted. Bowman et al (1979) have reported a case in which intrapelvic cement was responsible for entrapment of the obturator nerve with relief of pain after removal of the cement mass.

67
5 Roentgen Stereophotogrammetry (RSA)

RSA is a special radiographic technique that allows small changes in the position of prosthetic components to be measured. Since change in component position is commonly accepted as a sign of loosening, the advocates of RSA claim that this technique is capable of detecting prosthetic loosening at an early stage (Mjoberg et al, 1985). Essentially an RSA investigation has four distinct parts:

1. Implantation of several radio-opaque markers (usually tantalum balls) into the bone around the implant.
2. Stereoradiography at regular post-operative intervals using two simultaneous X-ray beams and a "reference" plate.
3. Measurements on the radiographs: This is usually done by television camera.
4. The data obtained is finally processed using special software packages to calculate component displacement with respect to bone.

There is no doubt that in centres well versed in the performance of RSA, prosthetic migration can be assessed with a high degree of accuracy (of the order of 0.1 mm) and as such, this investigation holds great promise for the detection of early loosening. However, in most places, RSA is not available or at best is still in its developmental stages. At present, there is probably still too little data available to assess the reliability of RSA in the diagnosis or prediction of implant loosening.

6 Isotope studies

Radioactive isotopes are often used in the assessment of the painful THR as the results of clinical examination and plain radiography are often inconclusive. The main isotopes available for clinical use are Technetium-99m methylenediphosphonate (Tc-99m MDP), Gallium-67 citrate (Ga-67), Strontium-87 (Sr-87) and Indium-111 (In-
The principle of those tests is essentially similar and is best illustrated using the Tc-99m MDP bone scan as example.

A The Tc-99m MDP bone scan

The introduction of Tc-99m labelled phosphate compounds by Subramanian et al in 1971 resulted in a great improvement in the degree of anatomical resolution which could be achieved by nuclide scanning. In addition, the very low levels of radiation dosage associated with these agents made bone scanning safe for the investigation of benign as well as malignant conditions.

During the test, the isotope is injected as a bolus intravenously. The phosphate group to which the radioactive technetium is attached tends to preferentially accumulate in areas of increased osteoblastic activity such as around a loose prosthesis (where there is constant bone remodelling due to the presence of the micromobile prosthesis). The exact mechanism of diphosphonate bonding is unknown, but it probably represents a direct exchange with components of the hydroxyapatite crystal (Kaye et al, 1975). The radioactive technetium so accumulated around the loose prosthesis is a gamma emitter and can readily be detected using an external gamma camera.

The Tc-99m bone scan used in this manner is undoubtedly a very sensitive test of loosening. The problem is its complete lack of specificity: an increased uptake may not only mean loosening but may indicate the presence of infection, a stress fracture, non-union of the greater trochanter or para-articular ossification (Van Rens and Slooff, 1982). In addition, Utz et al (1986) have shown that up to 20% of asymptomatic patients had a persistently increased uptake of Tc-99m around the prosthesis 1 year after THR. This can cause considerable difficulty in interpreting bone scans performed within a year of the original operation and indeed many authorities would not perform this scan during this period. The main value of the Tc-99m scan therefore resides in its sensitivity; i.e. with a normal bone scan there is little chance that a component is loose (Lyons et al, 1985).
Fig 3 Technetium scan showing increased activity around loosened right hip

B The Gallium-67 Scan

The foregoing has highlighted the chief shortcoming of the technetium bone scan; namely its lack of specificity. In the evaluation of a painful THR, the key question to answer is: "Is there deep infection or is it aseptic loosening?". A Tc-99m bone scan on its own cannot differentiate between septic and aseptic loosening (Merkel et al, 1984). However as shown by Rushton et al (1982), a Ga-67 scan performed sequentially after a Tc-99m scan can help to differentiate between infection and aseptic loosening. The mode of action of Gallium is due to its incorporation into leucocytes which then migrate to the area of infection (Gelrud et al, 1974). In Rushton's study, every infected hip in which Technetium and Gallium scanning were sequentially performed, the findings were positive. Sixteen cases with aseptic femoral loosening diagnosed by Tc-99m scans had normal gallium scans. These results tend to suggest that the Tc-99m/Ga-67 sequential scanning is an ideal test for infection with a sensitivity and a specificity of 100%. Unfortunately (but more realistically), subsequent workers have found that
although the specificity of the test is indeed very high (approaching 100%), the sensitivity is low. Thus, a positive study is strongly suggestive of an infection, whereas a negative study provides little information to help determine the presence of sepsis in a patient with a painful THR (Evans and Cuckler, 1992).

C The Strontium-87m scan

The first isotope used in the diagnosis of skeletal disorders was Strontium-87. In principle, the Sr-87 scan is much similar to the Tc-99m scan. Although now superseded by the latter, Van Rens and Slooff (1982) claim that it has a substantially greater accuracy than the Tc-99m scan. However, it suffers from a similar lack of specificity.

D Indium-labelled WBC scan

Like the Ga-67 scan, the In-111 WBC scan utilises the natural movement of leucocytes to produce intensified radioactivity in areas of sepsis or inflammation. Blood is taken from the patient to allow labelling of the leucocytes. The latter are injected intravenously, accumulate in local areas of infection and can then be detected by scanning. Although this method should in theory be extremely helpful in establishing the presence of an infected THR, in practice it has proved disappointing except in cases where the diagnosis is obvious on other grounds (Van Rens and Slooff, 1982).

7 Arthrography

Theoretically, arthrography can be helpful in assessing the stability of implants and in addition, it permits the opportunity to aspirate the hip and to send a specimen for culture (Fig 4). It has been claimed that when the prosthesis is loose, contrast medium seeps into the cement-bone interface, producing a thin, contrast-filled space, and that is "conclusive proof of looseness" (Salvati et al, 1971). Most authorities today would not agree with this contention. In a paper on this subject, Murray and
Rodrigo (1975) showed that over 20% of asymptomatic hips had arthrographic evidence of loosening. Furthermore, the loosening shown by arthrography could be confirmed in only 7 of 12 painful THR that were subsequently explored. The authors therefore questioned the value of arthrography in the investigation of the problem. Subsequent workers in this field have experienced similar difficulties in interpretation and have largely abandoned it (Van Rens and Slooff, 1982).

The diagnostic accuracy of arthrography can be substantially improved by the application of colour subtraction techniques (Fig 5). Lyons et al (1985) report that in comparison with both plain films and scintigraphic studies, subtraction arthrography was superior in the diagnosis of loosening. However the technique is not available in many centres.

Fig 4 Demonstrating technique of arthrography: The needle is positioned fluoroscopically at the junction of the neck and the lateral collar, several centimetres from the femoral vessels. The needle is directed downward, perpendicular to the prosthesis, until a metal to metal grating is felt.
8 Hip aspiration

Hip aspiration to obtain material for culture is usually performed at the time of arthrography before the instillation of contrast material. It may be useful in identifying the presence or absence of infection. However, false-negative and false-positive results can be obtained (O'Neill and Harris, 1984). Also, the organisms obtained by aspiration do not always correlate with those obtained at the time of operation (Gristina and Costerton, 1985). Skin flora are frequently the pathologic organisms in an infected arthroplasty and are also frequent contaminants further complicating the evaluation of aspiration results. Despite these confounding factors, aspiration of the hip is a key element in the evaluation of the painful THR (Evans and Cuckler, 1992).

9 Capsular biopsy

Non-invasive techniques such as those mentioned above cannot reliably distinguish aseptic loosening from the infected THR. It has therefore been advocated that all cases of failed hip replacements should have a capsular biopsy before revision (Elson, 1982) and at the time of revision surgery (Roberts et al, 1992). Multiple
biopsies are usually taken in theatre, promptly taken to the microbiology laboratory for homogenisation and subsequent culture. Even then, it may be difficult to differentiate between contamination of the specimens and true infection. Kamme and Lindberg (1981) recommended that 5 biopsy samples be taken at different spots from each suspected hip and stated that "growth in one or two of five biopsy samples was a strong indicator of contamination, while growth in five out of five biopsy samples of one or two bacterial species strongly indicated an infection." The organism most commonly involved in the study of Kamme and Lindberg and that of Roberts et al was Staphylococcus epidermidis, which is a skin commensal and an organism of low virulence. A conclusive diagnosis of infection even at such a late stage is still useful because it allows the surgeon to plan his post-operative antibiotic regimen (which is likely to be prolonged) on the basis of the microbial sensitivity results.

10. Conclusion

The evaluation of the painful THR, and of loosening in particular, is a complex endeavour that has a dramatic impact on the treatment of the individual patient. None of the investigations available today are 100% sensitive or specific. This was the impetus behind our experiment which attempts to define the role of vibration as a diagnostic technique in the investigation of the loose femoral stem. Vibration testing is already employed in engineering to determine the integrity of laminated structures. It is felt to be superior to ultrasound in testing for delamination, and is especially useful in testing complex composites. Loosening of the femoral stem can reasonably be regarded as a form of delamination either at the cement-bone interface or at the cement-implant interface. It is therefore conceivable that the diagnosis of loosening may be possible using a vibration technique.
CHAPTER 6

Current use of vibration in Orthopaedics

1. Introduction

Lippman in 1932 was among the first to use a vibration method to study an orthopaedic problem. He percussed one end of a long bone and, by listening at the other end with a stethoscope, he analysed how the presence of a fracture affected the transmission of a sound wave. However, it is not until more recently that there has been renewed interest in the application of vibration techniques in the analysis of various orthopaedic conditions. In fact, most of the important papers on this subject have only been published in the 1970's and after. The vast majority of this work concerns the use of vibration in the study of the rate of fracture healing. However, there are also multiple references in the literature on the use of vibration analysis in the study of several other orthopaedic conditions. These include:

a. The detection of osteoporosis.
b. Screening for congenital dislocation of the hip in the newborn.
c. The enhancement of bone cement penetration into cancellous bone during total hip replacement
d. The detection of prosthetic loosening.

Each of the above will now be discussed in more detail.

2. Assessment of fracture healing

Fracture healing has traditionally been assessed on clinical and radiographic grounds. Clinical symptoms such as pain on weight-bearing and instability of the fracture on manual stressing are generally taken to mean that the fracture has not united. Radiography allows the orthopaedic surgeon to see an image of the developing callus on
the road to union, but since that image relies for its production on the mineralisation of the callus, the radiographic appearance lags behind the actual evolution of the callus mass. Because clinical examination remains subjective and radiography is an unreliable predictor of fracture union, there is a place for a technique that provides a more objective measurement of fracture healing.

In the human skeleton, the bone that lends itself particularly well to vibration analysis is the tibia. This is partly because of its subcutaneous nature hence making it easily accessible to instrumentation. In addition, fractures of the tibia are very common and problems such as delayed union or non-union are frequently encountered. For these reasons, it is perhaps understandable that most of the work on the use of vibration in the assessment of fracture healing has been performed on the tibia.

There are essentially two ways in which vibration analysis can be applied to the study of fracture healing. The first involves measurement of the amount of attenuation of a vibration impulse across the fracture site as compared with transmission in the intact contralateral tibia (Nokes et al, 1985). Nokes and coworkers studied 3 groups of people:

a. Patients with intact tibiae.
b. Patients with a unilateral tibial fracture.
c. Patients with established non-union of the tibia.

In each patient, a standard impulse was applied to the tibial tubercle by dropping a small steel ball onto it and the resulting tibial acceleration was measured at two standardised sites (one proximal and one distal to the fracture site) using pre-loaded accelerometers. The ratio of the maximal amplitude of the distal accelerometer signal to the maximal amplitude of the proximal accelerometer signal was calculated. This ratio was called the “attenuation factor” (AF). The authors found that the AF value in normal tibiae was constant at around 0.57. In a fresh fracture, vibration transmission is initially poor, giving AF values of around 0.10. As healing occurred, signal transmission across the fracture increased so that the amplitude of the distal accelerometer signal increased, giving higher AF values. In fractures that went on to clinical and radiological union, the
AF value approached that of the normal contralateral tibia (0.57). In those patients with established non-union, extremely low AF values (0.1) were observed 6 months post-injury. Nokes and coworkers thought that the attenuation factor could be a useful predictor of the rate of fracture healing at a time when the callus had not yet become mineralised and was therefore invisible on radiographs. The theoretical basis for the use of this particular test is simply that vibration transmission in bone is dependent on its mechanical integrity and therefore high AF values reflect high mechanical integrity and thus fracture union.

The second way in which vibration analysis has been used in the assessment of fracture healing is by measuring the resonant frequency of the fractured bone and comparing it with the unfractured contralateral side. This particular method was first reported by Markey and Jurist (1974) who found a high correlation between time since fracture and the square of the frequency ratio of the injured to uninjured tibia. The theoretical basis for using resonant frequency measurement to monitor the progress of a healing fracture is that the resonant frequency of a bone such as the tibia, is proportional to its stiffness. It is also dependent on other material variables such as length, density and support conditions, but in a fractured leg, it is presumed that these variables remain constant and the main influence on the resonant frequency is the diminished stiffness of the bone resulting from the presence of the fracture. Cunningham et al (1990) have been among recent investigators of this particular technique. These authors studied a group of patients with tibial fractures treated non-operatively. They introduced an impulse to the tibia at the medial malleolus using a force-instrumented hammer and the resulting acceleration was measured at two pre-determined points on the tibia. The input force from the hammer and the output signal from the accelerometers were submitted to Fourier Transform analysis and the transfer function was calculated. From this frequency response transfer function, the tibial resonant frequencies were calculated. For each patient, serial measurements were carried out at each visit to the clinic. For those fractures that progressed to complete clinical union, it was found that the resonant frequencies for the fractured legs progressively increased in value until nearly reaching
the value of those for the unfractured contralateral limbs. This was true for all the modal frequencies investigated. These findings were entirely consistent with the theoretical prediction that in a fractured bone, the resonant frequencies will be proportional to the amount of coupling or healing between the fractured ends. As healing progresses, the resonant frequencies of the fractured bone increase to approach those of the unfractured contralateral bone and thus provide a quantitative measure of fracture healing. As expected, the vibration results in delayed healing showed that all modalities of resonant frequencies were significantly lower in the fractured bone than the normal contralateral side 20 weeks post-injury. The authors concluded that resonant frequency analysis indicated complete union when all of the modal frequencies of the fractured tibia were greater than 90% of those of the intact tibia.

Among the advantages quoted for the vibration techniques in the assessment of fracture healing are:

1. A pre-determined objective end-point corresponding to complete clinical union can be identified, e.g., in the study of Nokes et al, this was the attainment of an attenuation factor of around 0.55 and in the study of Cunningham et al, a resonant frequency equal to or greater than 90% of the contralateral unfractured bone.

2. The rate of fracture healing can be measured from an early stage by observing the rate of increase in the value of the attenuation factor or the resonant frequency. In this respect, vibration analysis holds a distinct advantage on radiographic images which are relatively slow at demonstrating callus. In this way, treatment designed to augment healing (e.g., bone grafting) can be instituted without delay.

3. It is possible to compare rates of healing between different groups of patients, for instance, to determine the effect of differing treatments or grade of injury.

The drawbacks of the vibration technique include:

1. By measuring an indirect parameter of healing such as attenuation factor or resonant frequency, it could be argued that they do not give a measure of the functional ability of a fracture to withstand the loading placed upon it.
2. In the immediate post-injury situation, the amount of soft tissue swelling may interfere with the quality of the signals obtained.

3. Although easy to perform, the vibration experiments usually require experienced personnel and special software to process and interpret the data obtained.

4. It has been shown that the particular technique of resonant frequency analysis was not applicable in fractures of the proximal fourth of the tibia or those fractures treated by external fixation or interlocking nails. However, tibial fractures treated by unreamed, unlocked nails seem to be amenable to resonant frequency analysis (Tower et al, 1993)

3. The detection of osteoporosis

Osteoporosis is a major health care problem and is responsible for a rising incidence of fractures, particularly of the proximal femur, distal forearm, and vertebrae. Current quantitative methods of detecting individuals with osteoporosis and hence at increased risk of fractures rely on assessing changes in bone mineral density using various methods such as single or dual photon absorptiometry and quantitative computerised tomography. Whereas these methods measure bone mineral content, they may not give a true indication of bone strength which usually but not always decrease in parallel with bone mineral content (Burr and Martin, 1983).

Jurist (1970) observed a direct relationship between the resonant frequency of the ulna in vivo and the degree of osteoporosis. The author measured the product of ulnar resonant frequency and length (FL) in normal men and women at various ages to establish normal values of this parameter as a function of age and sex. He then compared the FL value obtained in patients with established osteoporosis and found that this was 44% lower than that of normal subjects. Based on these results, Jurist suggested that ulnar resonant frequency measurement was a promising approach in following the development and progress of osteoporosis in the elderly. The theoretical basis for Jurist's findings is that the resonant frequency of a beam such as the ulna is
proportional to its stiffness. The latter in turn correlates highly (0.96) with bone strength which is reduced in osteoporosis (Jurist and Foltz, 1977). Thus, with progressive osteoporosis, the bone weakens and the resonant frequency decreases.

Not all those who investigated vibration of bones agreed with Jurist. Assuming simple uniform beam theory with homogeneous boundary conditions, the natural frequency \( F \) of the ulna is given by the equation:

\[
F = \frac{C}{L^3} \sqrt{\frac{EI}{W}}
\]

Where \( C \) is a constant,

- \( L \) is the ulnar length
- \( EI \) is the flexural rigidity (stiffness)
- \( W \) is the ulnar weight (Doherty et al, 1974).

In osteoporosis, the flexural rigidity \( EI \) decreases, but so does the ulnar weight due to bone loss. Therefore, the ratio \( EI/W \) may indeed not change very much in the process and as a result, the resonant frequency \( F \) may not be a sensitive index of osteoporosis. A recent study by Cunningham and Kershaw (1992) seems to confirm this theoretical consideration. These authors studied the tibial resonant frequencies of normal young women and those of older women with established osteoporosis and found no significant difference in resonant frequencies in the two groups. Thus, the use of resonant frequency alone appears to be of limited value in the diagnosis of osteoporosis.

4. Screening for CDH in neonates

Children born with Congenital Dislocation of the Hip (CDH) have an unstable hip joint which can easily be reduced if the hip is abducted. This causes a
clunking noise which can be detected by accelerometers positioned on the skin around the hip and this information is then fed to a computer able to confirm the diagnosis after analysing the signals (Kemohan and Mollan, 1983).

5. Enhancement of bone cement penetration during Total Hip Replacement

Good cementing technique is of vital importance to safeguard against premature loosening in total hip replacement. One of the salient features differentiating good from poor technique is the quality of interlock achieved between cement and trabecular bone. Lee and Ling (1982) have documented those factors perceived as being important to achieve good mechanical interlock.

Thomas et al (1991) suggested that the application of a vibrating force to the femur during total hip replacement may enhance the penetration of bone cement into the trabecular spaces of cancellous bone. They stated that the transmission of energy at the interface between cement and bone allowed the former to flow more efficiently into the small "pores" of the bone. However, this practice has yet to gain wide acceptance by orthopaedic surgeons.

This brief overview of the applications of vibration in orthopaedics now brings us to the subject of this thesis which is a study of the role of vibration in the diagnosis of loosening of total hip prostheses.

6. The use of vibration to diagnose loosening- Review of the world literature.

There is little in the literature on the application of vibration techniques to the field of prosthetic loosening. Chung et al at the Massachusetts Institute of Technology (1979) were the first to report the development of a vibration system to follow the change in the resonant frequency of a femur-prosthesis composite during the
curing of bone cement. They found that as the cement matured, improving the coupling between the implant and the femur, there was a gradual decrease in the resonant frequency of the composite system. This led them to comment that it may be possible to use resonant frequency as a means of detecting loosening of the femoral component. However, actual testing of THR at any stage of loosening was not carried out. One of the interesting features of Chung's paper was that they were able to provide a mathematical model of the vibrational behaviour of the composite system which closely matched their experimental observations.

Rosenstein et al (1989), at Oxford used a different approach when they carried out their experiment on implanted femoral prostheses. Instead of using resonant frequency as suggested by Chung et al, they performed a frequency analysis of the vibration signal output using a spectrum analyser (see later chapter on signal processing). They applied a sinusoidal excitation to the femur-prosthesis composite and found that when the prosthesis was secure, the output waveform was smooth and sinusoidal and frequency analysis revealed only one major frequency. On the other hand, after they had deliberately loosened the prosthesis, the output waveform became distorted and frequency analysis revealed multiple harmonics.

Rosenstein's study was essentially an in-vitro one, but they confirmed their findings in a limited in-vivo experiment.

The main drawback of the Oxford experiment is the manner in which loosening was simulated. Loosening at the cement-implant interface was achieved by removal of proximal cement and separation of the implant from its cement mantle. To simulate loosening at the cement-bone interface, the cement mantle was allowed to cure on a prosthesis before inserting it into a prepared femur. In clinical practice, this situation would be equivalent to "late-stage" loosening when massive loss of bone stock may already have occurred and when the diagnosis would be obvious clinically and radiologically thus obviating the need for vibration testing. Another criticism is that although resonant frequency measurements were fleetingly referred to, there was no
attempt to document the manner in which the magnitude of the response differed in the secure and the loose situations.

7. Conclusion

The work of Rosenstein et al suggests that vibration is a potentially useful technique in the diagnosis of prosthetic loosening. The method is based on the fact that when the prosthesis is secure, the femur-implant unit vibrates in unison whereas when loosening occurs, the separated elements of the composite respond separately. In the event of a time-dependent force (eg sine-wave) being applied to this system, it starts vibrating. Because the loose implant has only partial contact with the inner walls of the femur, it can readily be imagined that as the latter reverses acceleration, the prosthesis continues to move in an opposite direction until it strikes the femur. We believe that such "disharmony" of motion should be detectable by vibration analysis. The two techniques we intend to use to analyse the vibration signals are:

1. Amplitude response analysis.
2. Spectral analysis.

These are described in Chapter 7.

Although it has obvious drawbacks, an in-vitro setting has been deliberately chosen as this allows complete control of the interface situation and therefore allows us to attribute the various vibration patterns to the different states of loosening. Clearly, this would not be possible in-vivo. Further advantages of the in-vitro experiment are set out in the next chapter.

The only previous study of vibration in the detection of prosthetic loosening was restricted in analysis technique and limited in its models of loosening (Rosenstein et al,1989). Before considering the transfer of vibration technology into clinical practice, further work is required to evaluate its possibilities. Such work should seek to identify as many differences as possible in the vibration pattern of the secure and the loose prostheses for subsequent exploitation. In this respect the use of two different analysis
techniques is clearly preferable to just one, as in the Oxford study. Furthermore, the ability of vibration to detect early stage loosening must be examined because it is in this area that traditional methods such as radiography and arthrography are usually unreliable. In this context, it is necessary to construct various models of early loosening and submit them to vibration testing.

It is the aim of this study to evaluate the possibilities of vibration technology in the detection of aseptic loosening along the lines suggested above. The experimental set-up and methods are described in the next chapter.
CHAPTER 7

Experiment design and methods

1. Purpose of experiment

Rosenstein et al at Oxford (1989) have already suggested that it is possible to distinguish between a secure and a loose prosthesis by the distortion in a sinusoidal wave occurring in the loose situation. What then, motivated this new study? There are two basic reasons. The first being that the methods of signal analysis should be as comprehensive as possible so as to identify the maximum number of differences between secure and loose prostheses. By solely doing frequency analysis of the output waveform, the Oxford study lacks documentation of the difference in the intensity of the response between the secure and the loose situations. The second and more important reason is the fact that waveform distortion in the Oxford study was generated from prostheses that were probably very loose. While this in itself is a useful finding, it does not constitute a true evaluation of the technique in the diagnosis of loosening. We believe that a proper evaluation of vibration as a diagnostic tool in loosening must examine its capability in conditions where there is no macromovement (or little macromovement) between prosthesis and bone such as when a prosthesis is gradually loosened by cyclic loading or when there is a layer of soft tissue at the bone-cement interface. These and other models of early loosening as described in this chapter present to the technique of vibration a challenge to its sensitivity.

2. Experiment setting - Why in-vitro?

The purpose of this research is to evaluate the potential of vibration as a diagnostic tool in loosening of the femoral component of total hip arthroplasties. Although it would be possible to conduct an in-vivo study, this is potentially time-consuming given that the basic principles of vibration analysis in the presence of
impending loosening or frank looseness have not been fully established in previous research. It was thus felt inappropriate to subject patients to vibration analysis at a stage when comprehensive documentation of the expected results are not available and the researcher is unaware of what to look for exactly. An in-vitro study on the other hand, is more expedient and generally speaking, a good in-vitro experiment can be made to work in-vivo after appropriate modifications. However, if a technique has clearly been shown not to work in-vitro, it is unlikely to work in-vivo, and both the patient and the researcher would have been spared unnecessary trouble. The great advantage of the in-vitro set-up in this study is that it allows direct naked-eye observation of the prosthesis and the interfaces which is not possible in clinical practice unless the patient were to undergo revision surgery. Furthermore, one part of our experiment involves a longitudinal study of the change in vibration pattern of an implanted prosthesis after it has been submitted to several million cycles of loading which in clinical practice would be equivalent to several years of walking and therefore well beyond the time scale allowed for this study.

3. Aims

In simple terms, the femur can be regarded as a cylindrical tube with its own characteristic modes of vibration. If a metal prosthetic component with entirely different mechanical properties from bone is then cemented into the proximal femur, the two entities will then form a composite system coupled by acrylic cement. This coupling is very strong because the cement forms a perfect mould of the bony cavity and locks the prosthesis in the bone. This mechanical interlock is improved as cement penetrates the trabecular spaces of the cancellous bone thus providing extra stability to the implant. Because the femur now becomes so intimately linked with the prosthesis, it can be expected to vibrate differently from its natural modes. As the prosthesis becomes loose, the coupling between it and the femur weakens and the femur will presumably regain some of its freedom to vibrate in its own natural manner. Furthermore, the loose
prosthesis might be expected to vibrate independently inside the medullary cavity of the
vibrating femur thus producing a more complex vibration pattern than in the secure
situation.

The aim of our experiment is to identify these differences in the transmission
of vibration by a femur as its contained prosthesis becomes loose. It would seem
sensible to proceed in two stages thus:

1. Firstly to establish what the differences in vibration transmission are when the
prosthesis is definitely loose (with movement of the order of 2 mm between prosthesis
and bone). This part of the experiment would constitute a test of feasibility, i.e. whether
the vibration technique is indeed capable of differentiating the secure from the loose
prosthesis. If it is, as the Oxford study has suggested, it would be necessary to
document as comprehensively as possible (not just by frequency analysis as previously
done) the differences in vibration signal between the secure and the loose situation. The
methods intended to be used to highlight those differences are:

a) Frequency (amplitude) response of the composite when provoked by a sinusoidal
force _ this represents a study of intensity or magnitude of response.

b) Spectral analysis of the transmitted vibration signal_ this represents a qualitative
study of the waveform pattern.

These methods of signal processing will be discussed in greater detail in Section 5 of this
chapter.

2. In the second stage of the experiment, it is intended to test the sensitivity of the
technique in situations when the implant is not yet loose, but where impending loosening
is likely. This part of the experiment can only proceed after the basic differences in
vibration pattern in the secure and loose situations have been fully established. Models
of impending loosening to be created in the laboratory would include:

a) The presence of a thick layer of fibrous tissue at the bone-cement interface as it is
thought that this impairs the mechanical support around the prosthesis and predisposes
to its loosening.
b) The loss of mechanical interlock between cemented prosthesis and bone due to failure of cement to interdigitate with the trabecular spaces of cancellous bone. This may represent a form of early mechanical loosening and in practice would allow some degree of micromovement between implant and bone. According to Goldring et al (1983), this may in turn activate the cellular reaction leading to bone resorption and frank loosening.

c) A longitudinal assessment of the change in vibration signal as an initially secure prosthesis is submitted to fatigue testing by cyclical loading until component or cement failure.

The manner in which these three models of loosening are made in the laboratory will be described in the next section.

4. Experiment design

For the sake of convenience, the experiment design will be discussed under 2 main headings:

1. A description of the vibration equipment and the related data recording apparatus.
2. The production of laboratory models of loosening to be tested by the vibration technique.

4.1 Vibration equipment and data collection apparatus

This part of the experiment is concerned with the input of a vibration signal to the distal end of a model or cadaveric femur containing an implanted Charnley prosthesis and the detection of the transmitted signal at the proximal end near the trochanteric region. The instrumentation set-up is illustrated in Figure 1:
A sine-wave generator with an in-built amplifier is connected to a shaker inducing the latter to vibrate at a frequency determined by the setting on the generator. This setting can be manually controlled allowing the frequency of vibration of the shaker to vary in an appropriate range. The shaker is applied to the distal end of a femur containing an implanted Charnley stem. Contact between shaker and bone is constantly maintained. Distally, the femur is held in a clamp whereas proximally, the head of the prosthesis lies in a Charnley cup. The frequency of vibration of the system is varied through the range 100-1200 Hz since it was found that the bone-implant composite vibrated optimally in this particular range. Lower frequencies produced coarse vibrations and higher frequencies led to small amplitude vibrations with significant noise contribution from the supporting system.

As the femur-prosthesis composite vibrates, the input sinusoidal force and the output waveform were observed and recorded by means of accelerometers (Ach 01, Atochem) placed on the shaker and at the greater trochanter respectively. The signals from the accelerometers were relayed to a cathode ray oscilloscope (CRO) and also to a
computer with a digital signal processing board. These signals are displayed in real-time on the CRO whence the relative amplitudes of the input and output signals can be calculated and the presence of any distortion in the output waveform noted. The signals were stored in the hard-drive of the computer for subsequent spectral analysis.

Three specific points in the experimental design deserve special comment:

1. Method of excitation. We deliberately chose a sine-wave instead of an impulse (as for instance resulting from a strike with a force-instrumented hammer) because the former allows the input of a single frequency at any one time whereas the latter entails the introduction of a number of independent fundamental frequencies per impulse. This could make subsequent frequency analysis more difficult particularly since there is no satisfactory theoretical model to predict whether the femur-prosthesis composite behaves in a linear or non-linear manner. The study of Rosenstein et al seems to indicate that the loose system behaves non-linearly and that would render an impulse stimulus inappropriate for this type of analysis.

2. Boundary conditions. Proximally, the head of the prosthesis lies in a Chamley socket whereas distally, the femoral condyles are held in a retort clamp. Whether the latter is an accurate representation of the true situation at the knee has yet to be determined. So far as we are aware, there is no consensus in the literature as to what boundary conditions constitute the best model of the in-vivo situation. Thomas et al (1991) suggested that the ligamentous structures of the knee could be simulated by passing a wire through the distal femoral condyles and holding the femur down onto a flat surface by applying a tensile force to the wire. No evidence was provided to support the validity of this model although it seems quite an attractive one. In an in-vivo study of the human tibia, Cornelissen (1986) found that fixed end conditions were approximated if the leg were supported near the medial malleolus and the tibial tuberosity. Although there has been no similar study of the human femur, this paper seems to provide indirect evidence that provided the leg is supported, fixed end conditions can be assumed. However, if the knee is held slightly flexed and the tibia is left unsupported, free-free boundary conditions are thought to exist (Van der Perre and Van Audekercke, 1983). Although it is difficult
to extrapolate from the findings concerning the tibia, Cornelissen's study seems to indicate that provided the knee is externally supported, the boundary condition at the distal femur may be considered fixed. This situation was convenient for our study as otherwise, it would have been difficult to support the femur in such a way that it remained in permanent contact with the shaker.

3. Position of accelerometers. For each femur, the input was recorded by an accelerometer placed on the shaker and the output waveform was measured using an identical accelerometer applied to the greater trochanter. For successive recordings in the same specimen, the accelerometers were fixed in these positions. This is important as the amplitude of the output waveform depends on the distance of the point at which it is measured from the point of input (i.e., shaker position). The shape of the output waveform however, is identical for any given specimen, whatever the position of the output accelerometer relative to the shaker.

We intended to construct our experiment in such a way that it could readily be translated into clinical practice should the vibration technique be successful at diagnosing loosening. An anatomical fact that restricted our experimental design is that the point of input of the vibration force and the point of its subsequent detection must be subcutaneous. There are just two such points for the femur in-vivo: the greater trochanter and the femoral condyles. This was the rationale behind the location of the shaker and of the output accelerometer. All the results that we will later report are with the accelerometers placed in these positions. In practice however, it matters little where the accelerometers are placed as long as the points of measurement for a given femur are fixed. For instance, if the output accelerometer is placed at a point closer to the shaker, the amplitude of the output waveforms in successive measurements will be greater but there is in fact no relative increase in successive readings.
Fig 2  **Experimental set-up**: The input force (via the shaker) is at the distal third of the femur and the output force is detected by an accelerometer near the greater trochanter.

Fig 3  Bottom: The **sine wave generator** with an in-built amplifier, Top: Frequency counter.
Fig 4 The Sensor: ACH-01 accelerometer. This is a relatively inexpensive device with good performance characteristics particularly in the frequency range 100-1200 Hz. The larger box at the top of the picture is its interface amplifier.
Fig 5 **Data display:** Cathode Ray Oscilloscope. Top signal: The input sinusoidal force  
Bottom: The output signal

Fig 6 **Data display:** Spectrum analysis of a non-sinusoidal output signal in the case of a loose prosthesis. Note multiple harmonics
4.2 Laboratory models of loosening

The purpose of the experiment is to assess the ability of vibration to detect loosening. Since in practice, there exists a wide spectrum in the degree of loosening ranging from early loosening with a thin layer of fibrous tissue at the bone-cement interface to frank looseness when movement is present between prosthesis and bone, it is necessary to develop laboratory models resembling those situations and then present the challenge of detection to the vibration technique. It is proposed to develop 4 models of loosening:

1. Definite looseness where movement of the order of 2 mm exists between prosthesis and bone.
2. Impending loosening with the presence of a 2 mm layer of fibrous tissue at the bone-cement interface, but no movement between prosthesis and bone.
3. Early mechanical loosening in which the cement mantle has lost its interdigitation with trabecular bone but still provides a good fill of the gross shape of the medullary canal. In this way, the prosthesis with its cement mantle forms a good "press-fit" of the bony cavity.
4. Loosening induced by failure of the cement mantle due to its fracture.

4.2.1 Definite looseness

Definite looseness in this experiment is taken to mean the presence of macromovement between the prosthesis and the bone. This movement which is of the order of 2 mm was created in 2 ways:

1. Acrylic cement is applied as a mantle around the stem of a Charnley prosthesis. While the cement is still soft, the prosthesis is inserted into the medullary cavity of a prepared femur. As the acrylic cement is still soft, it acquires the shape of the medullary canal and if the prosthesis is rocked (using the calcar as fulcrum) before the cement hardens, a gap develops between the bone and the cement. This gap was measured with a micrometer and found to be about 2 mm for each specimen femur in stage I (see...
previous Aims section) of the experiment. Since achieving gross loosening is the aim here, we found this rather unsophisticated method of producing a "gap" satisfactory.

Fig 7 A gap develops at bone-cement interface as the prosthesis is rocked before the cement hardens. Excess cement extrudes at the mouth of femoral neck

2. A second way of creating macromovement at the bone-cement interface is to widen the medullary cavity around the cemented prosthesis: the lining of the medullary cavity is first sprayed with a non-stick material such as Teflon. In those conditions, cement will not stick to the bone and the prosthesis can be pulled out again with an intact cement mantle which is a perfect mould of the bony cavity. The latter is subsequently over-reamed using the drill shown in figure 9. The size of the drill is chosen so that it is just larger than the size of the diaphyseal part of the canal. Enlargement of the proximal femur relies on cutting each of its walls in turn with the side-cutting drill. The new medullary canal is now wider than the previous tight-fitting one circumferentially. If the prosthesis with its surrounding cement mantle is now replaced into the medullary canal, it lies loose in it (Fig 8). Realistically, overreaming in this manner is not exactly reproducible in each case and different amounts of bone may be taken from successive
Fig 8 Prosthesis with cement mantle lying loose inside over-reamed femoral cavity
Fig 9 The jig used to over-ream the femoral canal
specimens. However, the main aim of this exercise is to create a grossly loose situation and as such this method was satisfactory. Figure 10 represents a silicone mould of the new cavity.

4.2.2 Impending loosening: The presence of a thick layer of fibrous tissue at the bone-cement interface

Most surgeons agree that radiographic evidence of a lucent line more than 2 mm thick at the bone-cement interface around the whole of the cement mantle is evidence of probable loosening although the prosthesis itself may not be loose yet because it is encapsulated by a thick layer of fibrous tissue. The latter is able to support the prosthesis but not to the same extent that bone does because the soft tissue is relatively weak in shear and in tension. It is presumed that looseness eventually results from tears or rupture of the fibrous tissue as observed by Willert et al (1974).

This situation is created in the laboratory by introducing a complete layer of silicone rubber between the cement and the bone in the following manner. As in section 4.2.1(2), the prosthesis with its intact cement mantle is pulled out of the medullary cavity after a perfect mould is obtained. The femoral canal is then reamed using the jig shown in figure 9 such that it is made about 2 mm wider circumferentially. Thus the general shape of the cavity is maintained but only it is larger. Liquid silicone is then poured into the medullary canal and the prosthesis (with its cement mantle) re-inserted. The silicone rubber will then occupy the extra space between the cement and the bone and as it dries up, it mimics the soft fibrous tissue at the bone-cement interface. Using maximal manual force in the laboratory, there was no movement between prosthesis and bone and it was not possible to pull the prosthesis out of the medullary cavity.
Fig 10 Retrieved silicone mantle at the bone-cement interface of one of the prostheses
4.2.3 Early mechanical loosening

It is the bone at the interface which is under maximum shear strain and, under conditions of excessive loading, the interlock between cement and bone may be progressively lost. In the initial stages of this process, the cement mantle loses its interdigitations with cancellous bone. This may result in excessive micromovement at the interface and thus represents early mechanical loosening.

This situation can be simulated in-vitro by spraying the lining of the medullary canal with Teflon before inserting the prosthesis with its cement mantle still soft. The latter acquires the shape of the cavity as shown in figure 11 but because it is not allowed to penetrate the trabecular spaces, there is no interdigititation. Because the medullary canal has a regular tapering shape, it is possible to pull the prosthesis out with its cement mantle.

4.2.4 Loosening by fatigue fracture of the cement mantle

All the models of loosening described so far represent failure at the bone-cement interface analogous to bone resorption in-vivo. Some authorities (Stauffer, 1982) have reported that cement failure was much more common as a cause of loosening than cement-bone interfacial failure. In order to produce failure at the stem-cement interface in-vitro, it is necessary to cause fracture of the cement mantle by repeated cyclic loading of the prosthesis using forces around 3-5 times body-weight. In the living situation, the cracks produced in the cement would inevitably lead to increased stresses at the bone-cement interface leading to bone resorption and hence secondary failure of this interface. It is probable that this loss of osseous support around the fractured cement mantle allows the latter to collapse somewhat into its bed and produce looseness at the stem-cement interface. In the laboratory, the biologically mediated process of bone resorption cannot occur and therefore we can reproduce a situation of pure cement failure by cyclic fatigue loading of a cemented prosthesis.
Fig 11 Early mechanical loosening: The cement mantle around the prosthesis forms a good mould of the medullary cavity but does not interdigitate with trabecular bone.
For the purposes of the fatigue experiment, a Charnley prosthesis is cemented in the standard fashion into a transparent model femur so that any cracks that develop after loading can be seen. The prosthesis is then submitted to cyclic loading using forces around 4 times body-weight until the cement mantle fractures. Although it would theoretically be possible to apply a stress cycle to the implant which accurately mimics the natural stress cycle at the hip in-vivo, in practice this was not possible for our experiment because the available fatigue machine does not apply load in the conventional $x$, $y$, and $z$ directions independently. To buy a new machine would have been prohibitively expensive, and we elected to use the available fatigue machine (Losenhausen) which only applies compressive loads to the implant. Each applied loading cycle was of the shape of a sine-wave from a minimum load of twice body-weight to a maximum of 4 times body-weight. This cycle was repeated at a frequency of 10 Hz. While this does not necessarily reflect the in-vivo situation accurately, it is probably satisfactory because the primary objective is to disrupt the cement mantle.

The setting of the fatigue experiment is illustrated in the figure 12. It is worth noting that the prosthesis was angled in such a way that the direction of the compressive load occurred in the same direction as the resultant force acting at the hip joint (about 17 degrees from vertical). Because the artificial femur tends to bend under the large compressive loads used, it is necessary to support it with a cylindrical metal tube as shown in the photograph.

The femur-prosthesis composite is vibration tested prior to fatigue testing and then after various number of cycles to see if there is a progressive change in the vibration signal. The exact number of loading cycles required to failure is difficult to predict, but is probably of the order of several million cycles. To illustrate how time consuming this process can be, it would require 278 hours of continuous loading at 10 Hz to achieve 10 million cycles.
Fig 12 Fatigue experiment by cyclic loading
5. Experiment organisation

Section 4 formally described the experimental set-up. We shall now concentrate on the practicalities of achieving the aims set out in section 3 using the available equipment. In the first phase of the experiment, the priority is to establish differences between loose and secure prostheses and therefore, the vibration signals to compare are those of femora with securely cemented implants and those of the same femora containing definitely loose prostheses. At regular intervals during testing, the same specimen was tested at different points in time to make sure that the results obtained at any one sitting were reproducible. Since human cadaveric femora are not readily available, the major part of this experiment was carried out on model femora, but it is intended to validate the results thus obtained by repeating the experiment on a limited number of cadaveric human femora.

In the second stage of the experiment, the aim is to see whether it is possible to detect any of these differences for the various models of loosening described in section 4.2. In all of those models except that of definite loosening, macromovement is not present between prosthesis and bone and it is extremely hard to drive the implant out of its bed without damaging the femur. It is nevertheless essential to preserve the bone intact to allow direct "horizontal" comparison between the various models of loosening and the following plan was therefore adopted. First the prosthesis is implanted into the teflon-coated femoral canal allowing the still soft cement mantle to fit exactly into the space of the cavity but not being able to penetrate into the trabecular spaces. This model of early mechanical loosening is then vibration tested. The prosthesis with its cement mantle is then pulled out and the medullary canal is widened circumferentially. The prosthesis is replaced into the widened canal and this model of definite loosening is also vibration tested. Subsequently, liquid silicone rubber is poured into the medullary cavity to occupy the extra space between the cement and the bone. When dry, this forms a complete layer of "soft tissue" at the bone-cement interface and this is again submitted to vibration testing. Finally, the prosthesis is again removed from the femoral canal and the silicone rubber curetted out. The prosthesis is now firmly implanted using additional
cement and the vibration signal of this secure prosthesis is obtained. This scheme allows a direct comparison between models of loosening as the femur is identical for each set of measurements. The transparent bone models of the fatigue experiment are vibration-tested separately.

One point in the above scheme deserves further discussion. This is the justification for the use of model femora to perform the vibration experiment. Assuming the femur is a uniform beam under standard support conditions, the relationship between the natural frequency (F) on the one hand and flexural rigidity (EI), mass per unit length (μ) and length (L) on the other hand is described by the equation:

\[ F = \frac{\alpha}{2\pi} \sqrt{\frac{EI}{\mu L^2}} \]

in which \( \alpha \) is a dimensionless factor, having a specific value for each resonant mode. For real femora and artificial models, the values of the flexural rigidity and mass per unit length will be different, thus giving rise to resonant frequencies which may be widely different. In our experiment, however, we are not concerned with the absolute values of the resonant frequencies, but rather with the change in the number of resonances as the prosthesis becomes loose. The composite femur-prosthesis system is a complex one and is not really amenable to simple beam theory. However, we are not aware of any previously successful mathematical modelling of this system and therefore, we have chosen this simplified model above to illustrate our point. In our experiment, each femur acts as its own control and any change in the number of resonances can be solely attributed to the changes at the interface due to loosening. As such, it would not really matter whether real or artificial bone is used.

Because artificial bone is lighter than real bone, one may argue that in any femur-prosthesis composite, the prosthetic mass will be much more predominant if artificial bone is used. Again, it is difficult to predict the effect of this factor on mathematical grounds due to lack of a working model. However, empirical evidence for the validity of
using model femora will be presented by repeating the tests on a limited number of cadaveric human femora.

6. Methods of signal processing

In order to detect any differences in the vibration of the femur when the contained prosthesis becomes loose, it is necessary to analyse the output signal. (The input force applied to the bone is a pure sinusoidal wave whose frequency and amplitude can readily be controlled by switches on the sine-wave generator: thus it is a known quantity in terms of its "quality" and its "intensity"). Two aspects of the output signal lend themselves to analysis:
1. The change in its intensity in response to varying the frequency of the input force.
2. Its shape and frequency composition. Such an analysis of waveform is referred to as spectral analysis.

6.1 Intensity response of the femur: The frequency response curve

In our experiment, a sinusoidal driving force which we have chosen to call the input force, is administered via a shaker, and is maintained at a fixed point on the femur. The latter is thus forced to vibrate at the frequency of the driving force and the magnitude of the forced vibration can be measured by the trochanteric transducer and displayed on the C.R.O. Generally speaking, the greater the input force, the greater is the intensity of the output, and therefore the ratio Output amplitude/Input amplitude is a better indicator of the intensity response of the femur at a given frequency than the output force amplitude alone.

As the frequency of the sinusoidal input force is changed along the range 100-1200 Hz, the frequency of forced vibration of the femur-prosthesis composite changes accordingly. At certain frequencies, the amplitude of vibration increases tremendously yielding high values for the ratio Output amplitude/Input amplitude. In Engineering, when this phenomenon occurs, it is termed "resonance", whereby a
relatively small driving force produces a large response from a target system. A vivid example would be that of the high-pitched voice of a soprano setting the structure of a wine glass in motion and shattering it. The vibration of any composite structure is a complex affair dependent amongst other things on the mechanical properties of the individual components and on the interface conditions. Nevertheless frequency response curves for the system can be obtained, first with the prosthesis secure and then when it is loose.

In order to obtain the frequency response curve, the ratio Output amplitude/Input amplitude (O/I) of the composite system is obtained at intervals along the stated range 100-1200 Hz. This ratio is then plotted as a function of frequency to yield the frequency response curve. Such a hypothetical curve is illustrated in figure 13 containing two discrete peaks whereas the remainder of the plot is relatively flat. These peaks denote the frequencies at which the response of the system is maximal, and by direct comparison of the curves for the secure and the loose situations, it may be possible to detect any differences in the intensity response caused by the changing interface conditions brought about by loosening.

It should be pointed out that such frequency response plots should strictly be limited to systems behaving in a "linear" manner, i.e. those that produce the same output waveshape as that of the input. While the secure prosthesis can reasonably be expected to do so, such is not the case when the prosthesis becomes loose. In this situation, when the output waveform has been distorted and is not sinusoidal, the output intensity will be taken to be the peak-to-peak amplitude of the distorted wave. In this manner, it would be possible to develop an empirical technique which showed the resonances in the loose situation.
Fig 13 Hypothetical frequency-response curve. The system responds maximally at frequencies $f_1$ and $f_2$.

To illustrate the manner in which the frequency response curves were obtained in our experiment, an example of an actual data sheet with its corresponding frequency response curve are shown in the next 2 pages (Figs 14 and 15).
## DATA SHEET

### FEMUR4

### SECURE PROSTHESIS

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<th>Frequency (Hz)</th>
<th>Input Amplitude (V)</th>
<th>Output Amplitude (V)</th>
<th>Output/Input ratio</th>
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</tr>
</tbody>
</table>

Fig 14 Example of a data sheet
FREQUENCY RESPONSE CURVE

FEMUR4: SECURE PROSTHESIS

Fig 15 Frequency response curve obtained using the results from figure 14
6.2 Frequency (Spectral) analysis

As previously mentioned, the input force is a sinusoidal wave of variable frequency. The output force however, may or may not be sinusoidal depending on the state of looseness of the prosthesis. Rosenstein et al (1989) found that in the secure situation, the output signal retained a sinusoidal shape, but when the prosthesis became loose, the output signal became distorted. This tends to suggest that the secure system with the prosthesis firmly implanted behaves in a linear manner and that when loosening occurs, the system behaves non-linearly. The reason for the non-linearity of the loose system may be that the prosthesis is to a certain extent free to rock inside the vibrating bone thus distorting the fundamental vibration pattern imposed on the bone by the sinusoidal input force. The general mathematical formulae that describe these modes of behaviour for a given input force \( F = A \sin 2\pi ft \) are:

Linear system: Output force \( F' = B \sin (2\pi ft + \phi) \)

Non-Linear system:

Output force \( F'' = B_1 \sin (2\pi ft + \phi_1) + B_2 \sin (4\pi ft + \phi_2) + B_3 \sin (6\pi ft + \phi_3) + \ldots \)

The corresponding output waveforms in response to a pure sinusoidal input force is illustrated for both the linear and non-linear system:

![Fig 16: Linear versus non-linear response](image-url)
The waveform signals shown above are in the time domain. A better way of assessing the waveforms is to transform the signals from the time domain to the frequency domain so that their frequency contents can be analysed. The transformation process can be carried out using the Fourier integral (Brigham, 1988). The Fourier integral of a continuous time signal is defined as:

\[ X(f) = \int_{-\infty}^{\infty} x(t) e^{-j\omega t} dt \quad \omega = 2\pi f \]

where \( x(t) \) is the continuous time domain signal

\( X(f) \) is the Fourier transform of \( x(t) \)

The Fourier transform was performed in our experiment by computer using a modified but much more efficient algorithm known as the Fast Fourier Transform (FFT). Thus, performing an FFT of the two signals shown in figure 16 may give the following results shown in figure 17:

![Amplitude vs. frequency graph for linear system with no harmonics](image1)

![Amplitude vs. frequency graph for non-linear system with multiple harmonics](image2)

**Fig 17: Frequency analysis of linear and non-linear systems**

This example vividly illustrates how frequency analysis by FFT can so clearly demonstrate the frequency contents of what may otherwise have been mistaken for a
completely erratic signal by the uninitiated eye. This tool (FFT) was used in our experiment to help compare the output signals arising from the secure and the loose prostheses.
CHAPTER 8

Results and discussion

1. Introduction

The data obtained on a series of femora containing an implanted Charnley prosthesis using the methods described in the previous chapter are presented here. The order of presentation will be in accordance with our stated aims:

1. Comparative data for the secure versus definitely loose prostheses so that all the differences in vibration pattern between the secure and loose systems can be identified. Most of the femora used will be artificial models but a small subset in this group will be cadaveric femora to test the validity of using artificial femora.

2. Vibration data for various models of early loosening will be presented to establish whether it is possible for the vibration technique to distinguish these situations from the secure state. As a reminder, the models to be tested include:
   a) The presence of a soft tissue layer at the bone-cement interface.
   b) Early mechanical loosening with loss of cement interlock with trabecular bone.
   c) The fatigue fracture of the cement mantle after cyclic loading.

2. Data acquisition: Specimen femur.

In this section, we present comprehensive data obtained in each specimen using one particular femur as example. This particular femur was chosen because the results obtained reflect accurately the pattern that will later be seen to evolve from the whole series of femora. It will be apparent that it is neither necessary nor practical to present similarly comprehensive results for all femora. For the remaining femora, only a selected number of graphs are necessary to demonstrate the underlying trend.

During the vibration experiment, each femur-prosthesis system was vibrated in the frequency range 100-1200 Hz. A series of graphs was obtained during this exercise as follows:
1. Frequency (Intensity) response curves.

These curves demonstrate the way in which the intensity of vibration of the system changes as the frequency of the input force is changed in the range 100-1200 Hz. The magnitude of the output wave relative to the input force was measured at several frequencies along this frequency range. This value (output/input) was then plotted as a function of frequency and the graph obtained shows the frequency response of the femur under test. The curves for the illustrative femur, first when the prosthesis is secure and then, when loose are shown in figure 1. These show that the number of peaks or resonances increase with loosening, a trend which is consistently observed in most specimens as discussed later.

**SECURE**

---

**LOOSE**

Fig 1: Intensity response curves of secure v/s loose system showing an increase in the number of peaks in the loose system

2. Shape of output waveform.

The input waveform is always sinusoidal and it is therefore not necessary to record this. During the course of the experiment, it was noted that the shape of the
output wave became irregular or distorted at certain particular frequencies of excitation. This consistently occurred in the case of loose specimens but not in the secure ones. In the latter, the output waveform remained sinusoidal at all excitation frequencies thereby indicating linear behaviour. This is illustrated by the graphs in figure 2 which were obtained at two different excitation frequencies during vibration of the illustrative femur. For the loose systems, the output trace remained sinusoidal throughout most of the range tested, but at certain particular frequencies, wave distortion was observed and these waveforms were recorded and stored on computer hard-drive (Fig 3). The significance of waveform distortion at those particular frequencies is discussed in the next section when data for all femora are considered.

3. Spectral analysis.

The output waveforms as shown in figures 2 and 3 are in the time domain. We found it helpful to transform these signals from the time domain to the frequency domain in order to demonstrate their spectral contents. This transformation process was carried out using the Fast Fourier transform by sampling at 10 kHz and then using a 1024 point transform. At least 100 waveforms were averaged for each transform. Figure 4 shows such spectral analyses performed on the time signals for the secure implant shown in figure 2. Since these time signals are sinusoidal, a single peak is observed in each case. On the other hand, spectral analyses of the distorted waveforms (for the loose implant) shown in figure 3 yield graphs shown in figure 5. It will be noted that more than one peak is present in each case. The fundamental frequency in each spectrum corresponds to the particular excitation frequency at which the bone was being vibrated. The additional peaks or harmonics, were multiples of the fundamental frequency. The significance of harmonics is discussed when the results for all femora are considered.
Fig 2: Characteristic sinusoidal output waveforms for secure system. In this case the excitation frequencies were 130 Hz (top) and 535 Hz (bottom).

* ms: millisecond
Fig 3: Typical distorted output waveforms of loose system. In this particular example, waveform distortion occurred at 325, 340, 548 and 644 Hz.
Fig 4: Characteristic spectra of a secure system at two different excitation frequencies (130 & 535 Hz) reveal a single peak with no harmonics.
Fig 5: Typical spectra of loose specimen revealing the presence of harmonics. In this particular case, harmonics were generated at the following excitation frequencies: 325, 338, 548 and 644 Hz.
3. Comparison of vibration data between secure and definitely loose prostheses (all femora)

For each femur tested, comprehensive data as documented in section 2 was obtained. However, for ease of analysis when all femora are considered, only a subset of those graphs is required. For instance, if the output waveform had remained sinusoidal throughout the frequency range tested, only one such waveform and its corresponding spectral analysis need be shown. Similarly, if waveform distortion had occurred for a particular specimen at five different excitation frequencies, only one such representative waveform need be shown. In this way, the vibrational characteristics of a particular femur-prosthesis composite can be illustrated by a relatively small number of graphs and this undoubtedly makes cross-specimen comparison easier.

In this section, vibration spectra of secure prostheses are compared with those of definitely loose prostheses (Fig 6 - Fig 14). The left-sided column shows the graphs for the secure specimens and the right-sided column shows results for the loose specimens. Each column has three rows. The top row is the intensity response curve, the middle row shows the shape of a typical output waveform at a particular excitation frequency and the bottom row shows the spectral content of the output waveform.

The results for 9 model femora are presented here to demonstrate the differences in vibration pattern of the secure and loose systems. Additionally, the data obtained from two cadaveric femora will be presented to demonstrate the reproducibility of the experiment when using human bone.

3.1 Differences in the frequency response curves

Inspection of the 9 pairs of frequency response curves shows that the graphs of the loose systems contain more resonances (peaks) than those of the secure systems (Fig 6 - Fig 14). If one were to draw an arbitrary line parallel to the frequency axis through an output/input ratio of 1.0 and then count the number of peaks in each graph lying above this line, one would find that in 8 out of 9 cases, there are more peaks in the
loose system compared to the secure one. In only one case (femur 9), was the number of peaks before and after loosening the same (two). There was no instance in which the number of peaks had decreased with loosening.

Having made the general remark that the number of peaks increases when the prosthesis becomes loose, it is pertinent to note that the number of peaks in the secure situation varies between 0 and 2, not exceeding 2 in any instance while the curves for the loose systems exhibit between 2 and 5 peaks, and in 7 out of 9 cases there were more than 2 peaks. Another general finding is that the height of the peaks for the loose system tend to be greater than in the secure situation.

To find out whether the increase in the number of peaks observed with loosening is significant and to exclude that it may simply be a chance finding, a Student's t test was performed. For this statistical analysis, additional data from 8 femora in Section 4 are included to increase sample size. We make the null hypothesis that there is no difference in the number of peaks before and after loosening and proceed to calculate its likelihood:
Table 8.1: Number of peaks before and after loosening: paired comparison

<table>
<thead>
<tr>
<th>Femur</th>
<th>Number of peaks</th>
<th>Difference</th>
<th>(D = L - S)</th>
<th>(D^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Secure (S)</td>
<td>Loose (L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>7</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>4</td>
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<td>11</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>4</td>
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<tr>
<td>14</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>16</td>
<td>1</td>
<td>6</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>17</td>
<td>1</td>
<td>6</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>19</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>20</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>21</td>
<td>1</td>
<td>5</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>22</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>23</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Total \(\Sigma S = 22\) \(\Sigma L = 63\) \(\Sigma D = 41\) \(\Sigma D^2 = 133\)

Mean of the differences \(\overline{D}\) \(\Sigma D/N\) where \(N\) is the number of samples

Square of the sum of the differences \(\Sigma D^2\)

The standard deviation \(S\) \(\sqrt{\frac{\Sigma D^2 - (\Sigma D)^2}{N-1}}\)

The standard error \(S_a\) \(\frac{S}{\sqrt{N}}\)

Substituting figures for symbols, one obtains \(S_a = 0.35\)

The standard normal variable \(t\) \(\frac{\overline{D}}{S_a} = 6.9\)
Entering the table of the \( t \) distribution at 16 degrees of freedom (that is, \( N-1 \)), we find that this value is greater than 4.015. Reading off the probability value, we see that \( P<0.001 \). Therefore the probability of the null hypothesis being true is less than one in a thousand and we can reasonably conclude that loosening causes an increase in the number of significant peaks in the frequency response curve. Repeating the above calculations using the distribution-free Wilcoxon signed rank test gives a \( P \) value of the same order of magnitude.

Another variable which may be subjected to similar statistical scrutiny is the difference in the length of the frequency response curves in the secure and loose situations. Because the length of the curves is closely related to the number of peaks, it is to be expected that the difference in length would be significant to the same degree of confidence as that found above.

3.2 Differences in the output waveforms

With the prosthesis secure, the output waveform remained sinusoidal throughout the frequency range (100-1200 Hz) in all nine cases (fig 6-fig 14). This suggests that the secure femur-prosthesis composite behaves in a linear fashion. With loosening, the output waveform became distorted at several particular excitation frequencies in the range 100-1200 Hz and this could be clearly seen on the oscilloscope. These frequencies at which wave distortion occurred were not always resonances but probably represent situations when the movement of the bone and that of the loose implant are significantly out of phase thereby resulting in frequent impaction of the prosthesis against the inner wall of the femur. This would lead to waveform distortion as was observed in all nine loose specimens here. These findings are consistent with those of Rosenstein et al (1989).
3.3 Differences in the Spectrum analysis

Spectral analysis of the output waveforms by Fast Fourier Transform (FFT) reveals spectra as displayed in the last row (fig 6-fig 14). As much as possible, spectra at similar excitation frequencies are presented for secure and loose systems. However this was not always possible as the frequencies at which harmonics were generated were not predictable and may not coincide with the previously recorded frequencies of the secure systems.

In all nine secure cases, the spectrum reveals a single frequency which confirms that the output waveform is sinusoidal and that the system is linear. Conversely, in all nine loose systems, spectral analysis reveals the presence of harmonics with frequencies that are multiples of the fundamental frequency. This suggests the presence of wave superimposition and is characteristic of the behaviour of non-linear systems.

3.4 Discussion

The results obtained from this group of 9 femora suggest that:

1. The number of peaks (resonances) in the frequency response curves increases with loosening of the prosthesis. The presence of more than 2 peaks is strongly suggestive of looseness and in no instance of looseness were there less than 2 peaks. Conversely, the presence of less than 2 peaks strongly suggests that the prosthesis is secure and in no instance of security was there more than 2 peaks. The consistency of these findings is confirmed in a further series of 8 femora tested as part of the second phase of this study (see section 5). If those 8 femora are taken into consideration, giving a total of 17 specimens and therefore 34 frequency-response curves, the overall findings are as follows:

a) The frequency response curve has more than 2 significant peaks: 14 loose implants, no secure implants.
b) The frequency response curve has less than 2 significant peaks: 10 secure implants, no loose implants.

c) The frequency response curve has 2 peaks: 7 secure and 3 loose implants.

Thus with the proviso that results with 2 peaks are excluded, the frequency response curve would have a sensitivity and a specificity of 100% for detecting security or looseness of an implant. However, this is not practical and all the results must be considered.

Assuming the diagnostic criterion that the presence of more than 2 peaks signifies loosening and the presence of 2 peaks or less to indicate probable security of the prosthesis, one can calculate the sensitivity and specificity of the frequency response analysis. We use the following definitions:

\[
\text{Sensitivity} = \frac{\text{True positive}}{\text{All with disease}}
\]

\[
\text{Specificity} = \frac{\text{True negative}}{\text{All without disease}}
\]

Disease in this context means loosening, a positive test is one with more than 2 peaks and a negative test is one with 2 peaks or less. We construct a small table to help us calculate the numerator and denominator in the above equations:

<table>
<thead>
<tr>
<th></th>
<th>Loose</th>
<th>Secure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive test ((&gt;2) peaks)</td>
<td>True positive</td>
<td>False positive</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Negative test ((\leq2) peaks)</td>
<td>False negative</td>
<td>True negative</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>17</td>
<td>34</td>
</tr>
</tbody>
</table>
From this table, we obtain

\[
\text{sensitivity} = \frac{14}{17} \times 100 = 82\% \quad \text{and} \\
\text{specificity} = \frac{17}{17} \times 100 = 100\%
\]

Thus, assuming the diagnostic criterion enunciated above, the frequency response test will miss a loose prosthesis 18 times out of a hundred but it will not mistake a secure implant for a loose one.

2. The second and perhaps more conclusive finding from this first set of data is that the output waveform remained sinusoidal at all frequencies tested in the secure systems whereas all the loose prostheses caused distortion of the sinusoidal waveform at certain particular frequencies, indicating non-linear behaviour. Spectral analysis revealed the presence of harmonics in all the 17 loose systems while they were absent in the 17 secure ones. By this test therefore, and without any proviso, the vibration technique has both a sensitivity and a specificity of 100%.

The probable explanation for the increased number of resonances observed in the frequency response curves and for waveform distortion of the output signal (and hence the presence of harmonics in the spectra) is as follows: the loose implant has poor contact with the inner wall of the femur. It is therefore to some extent capable of independent movement within the medullary canal. During excitation of the femur-prosthesis unit, the femur and the prosthesis behave as a composite system with non-linear and time-dependent coupling. As the femur reverses acceleration, the prosthesis continues to move in an opposite direction until it impacts the femoral wall. We believe it is such impacts that are responsible for the generation of extra resonances and for the observed wave distortion. Waveform distortion was observed only at certain particular excitation frequencies in the range tested. This is probably because these particular frequencies represent situations where the acceleration of the bone and its contained
implant are significantly out of phase with one another thereby resulting in frequent impaction of the prosthesis against the bone.

We attempted to provide a mathematical model to account for the observed behaviour of this complex system but have not succeeded. A review of the literature was also unproductive in that respect. However, the results shown in this section are consistent with linear vibrating beam theory and what might be expected if two such beams were jointed by a coupling system which was a strongly non-linear function of the relative motion of the two beams.

We conclude from the results of this first set of data that when the prosthesis is definitely loose, with the presence of macromovement at the bone-cement interface, the vibration pattern as assessed by both frequency response and spectral analysis is sufficiently different from that of the secure system to allow a confident diagnosis of loosening. However, such an advanced degree of loosening is likely to be clinically manifest as pain and disability and could probably be detected by more conventional investigations such as plain radiography. This argument therefore brings us to the next phase of the experiment which is to test the ability of the vibration technique to diagnose early loosening. Before that however, the results obtained from 2 cadaveric femora are presented to demonstrate the reproducibility of results and thus validate the use of model femora for most of the experiment.
Fig 6: FEMUR4

**SECURE**

- Frequency (Intensity) response curves

**LOOSE**

- Output waveforms

- Spectral analysis of output waveforms
Fig 7: FEMUR5

SECURE

O/I

LOOSE

O/I

Frequency (Intensity) response curves

TIME ANALYSIS

Output waveforms

SPECTRA ANALYSIS

Spectral analysis of output waveforms
Fig 8: FEMUR6

Frequency (Intensity) response curves

Output waveforms

Spectral analysis of output waveforms

132
Fig 9: FEMUR7

Frequency (Intensity) response curves

Output waveforms

Spectral analysis of output waveforms
Fig 10: FEMUR8

**Frequency (Intensity) response curves**

**TIME ANALYSIS**

**Output waveforms**

**SPECTRA ANALYSIS**

Spectral analysis of output waveforms
Fig 11: FEMUR9

SECURE

LOOSE

Frequency (Intensity) response curves

Output waveforms

Spectral analysis of output waveforms
Fig 12: FEMUR10

**SECURE**

![Frequency (Intensity) response curves for SECURE](image)

**TIME ANALYSIS**

![Output waveforms for SECURE](image)

**SPECTRA ANALYSIS**

![Spectral analysis of output waveforms for SECURE](image)

**LOOSE**

![Frequency (Intensity) response curves for LOOSE](image)

**TIME ANALYSIS**

![Output waveforms for LOOSE](image)

**SPECTRA ANALYSIS**

![Spectral analysis of output waveforms for LOOSE](image)
Fig 13: FEMUR11

Frequency (Intensity) response curves

Output waveforms

Spectral analysis of output waveforms
Fig 14: FEMUR14

**SECURE**

**LOOSE**

Frequency (Intensity) response curves.

Output waveforms.

Spectral analysis of above waveforms.
4. Cadaveric femora

4.1 Results

The principles of vibration of a rod such as the femur would be the same whether the rod is made of real bone or some other artificial material. Although the mass, density and stiffness of real bone are quite different from that of model bone, this should be reflected only in the absolute value of the resonant frequencies. In our study, we have been more concerned with the change in the number of peaks than in the absolute values of the resonant frequencies. Therefore, as discussed in section 5 of Chapter 7, minor differences in mechanical properties should not affect the results of vibration analysis.

To demonstrate this point, we have conducted a limited study on 2 cadaveric human femora obtained from different cadavers. The data for secure and loose prostheses follow an identical pattern to that obtained using model femora: namely more peaks for the frequency response curve of the loose system, the presence of output wave distortion and the presence of harmonics in the spectra (fig 15 & 16).

4.2 Transmission loss

The only notable difference in the results obtained using cadaveric femora is that the peaks attained in the frequency response curves are much lower than those obtained using model femora. Thus, even when we consider the frequency response of the loose cadaveric system which has the higher peaks, the maximum Output/input ratio attained is about 1.2-1.6. This is due to the phenomenon of transmission loss whereby the more massive a structure is, the greater its opposition to vibration. Thus, because the cadaveric femora were heavier than the model femora (average mass 435 grams v/s 270 grams), the peaks obtained were lower. This has important implications because the mass of human femora vary greatly depending on patient size, sex and age. We can anticipate that tall patients with heavy femora will produce relatively low peak values (≤1.0) even when their prostheses become loose. Thus, if our arbitrary line is fixed at an
O/I value of 1.0, no significant peak may be recorded. This begs the question as to what we mean by a significant peak and how to decide the level of the arbitrary line. This is discussed below.

4.3 Discussion

The foregoing highlights the difficulty encountered in deciding the level above which a peak is to be considered significant. Because of transmission loss, heavy femora will produce smaller resonances than light femora and therefore the arbitrary line should be set at a lower level for them. Furthermore, if one is to transfer the experiment to a clinical setting, it is likely that the soft tissues around the femur will cause damping of the signals and therefore attenuate the resonances even further. Because of the wide variation in patient height, size and weight, it would not be sensible to choose a single cut-off level and hope that this will have universal relevance.

There is only one practical solution to this problem and that is to use each individual as his own control. Thus the diagnosis of loosening by frequency response studies would require that all patients undergoing THR have their frequency response curves recorded in the immediate post-operative period when the implant is secure. If they should later become symptomatic, the test can be repeated and the newly obtained curve compared with the original post-operative graph. In this way, the presence of additional resonances which were not previously present can be identified.

On the other hand, no such baseline data is required during frequency analysis: A single measurement taken in time would suggest loosening in the presence of harmonics and security of the prosthesis if no harmonics were present. Together with the fact that frequency analysis has a superior sensitivity (100% v/s 82%), it would seem to be the better test out of the two.
Fig 15: CADAVERIC FEMUR

**SECURE**

Frequency (Hz)

- Frequency (Intensity) response curves

**LOOSE**

Output waveforms

Spectral analysis of output waveforms
Fig 16: CADAVERIC FEMUR2

Frequency (Intensity) response curves

Output waveforms

Spectral analysis of output waveforms
5. Vibration pattern in early loosening

5.1 Introduction

In the previous sections, the differences in vibration pattern of the secure and definitely loose systems have been clearly established. It is probable that "definite looseness" as we mean it (i.e. with macromovement between prosthesis and bone) represent such an advanced degree of loosening that it would have been diagnosed by clinical and radiological means and one would not have to resort to a sophisticated technique such as vibration analysis for its diagnosis. The transfer of vibration technology to the clinical setting for diagnostic purposes would require substantial investments in terms of financial, technological and manpower resources. There may also be potential sources of inconvenience to the patient such as having his femur vibrated (albeit using a small force) and the possibility that one may have to place a micro-transducer (not yet developed) at the greater trochanter for signal detection as some patients have too thick a layer of fat there to permit cutaneous placement of the transducer. Because of these problems, the introduction of vibration technique into clinical practice would not be justified unless it showed itself to be superior to well established, inexpensive and non-invasive techniques such as plain radiography. In this section, we will assess the in-vitro ability of the vibration technique to diagnose early loosening. This represents the situation where traditional methods are usually unreliable and is therefore the area in which any new technology such as vibration would have to demonstrate its superiority. The in-vitro setting provides the ideal environment for vibration to show its potential since there is no soft tissue to attenuate the transmitted signal.

5.2 Results

In this section, we present the results obtained from 8 model femora at various stages of the loosening process (Fig 17-Fig 24). For each set of graphs, the femur is kept constant so that any differences that appear in the pattern of vibration can
be attributed solely to the quality of the bond between the prosthesis and the bone. For each femur, the vibration pattern of the securely cemented prosthesis is compared with those of:

1. The prosthesis with a complete silicone "soft tissue" layer at the bone-cement interface.
2. The prosthesis with a cement mantle which fits exactly into the bony cavity but with absent cement interdigitation with trabecular bone.
3. The definitely loose prosthesis where macro-movement is present between the prosthesis and the bone.

For convenience, the format of data presentation is identical as in the previous sections except that we have omitted to include the output waveforms because the information they convey can be inferred from the results of frequency analysis in the bottom row.

5.2.1 Results for the secure and the definitely loose systems

These results were included in the discussion in section 2 and this will not be repeated here. Suffice it to say that the number of resonances increased with loosening and frequency analysis for the loose system showed the presence of harmonics in all specimens.

5.2.2 Prosthesis with silicone layer at bone-cement interface

5.2.2.1 Results

Examination of the frequency response curves of all 8 specimens with a complete silicone layer at the bone-cement interface shows them to be almost identical to the graphs for the corresponding securely cemented prosthesis. Frequency analysis showed complete absence of harmonics, as in the secure cases. From this, we conclude that the vibration technique is not sensitive enough to detect the presence of a thick layer of silicone at the bone-cement interface.
Fig 17: FEMUR15

SECURE

SILICONE LAYER

O/I

Frequency (Hz)

Frequency (Intensity) response curves

SPECTRA ANALYSIS

Spectral analysis of output waveforms
FEMUR15

EARLY MECHANICAL LOOSENING

LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 18: FEMUR16

SECURE

SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR16

EARLY MECHANICAL LOOSENING  LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 19: FEMUR17

SECURE

SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR17

EARLY MECHANICAL LOOSENING  LOOSE

O/I  O/I

4.00 — 1
3.00 —
2 .0 0  —
1 .0 0  —
0 .0 0  —

0.00 400.00 800.00 1200.00
Frequency (Hz)

Frequency (Intensity) response curves

SPECTRA ANALYSIS

File: 17-2.2
FFT Length: 1024

SPECTRA ANALYSIS

File: 17-3.2
FFT Length: 1024

Spectral analysis of output waveforms
Fig 20: FEMUR19

SECURE

SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR19

EARLY MECHANICAL LOOSENING

LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 21: FEMUR20

SECURE

SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR20

EARLY MECHANICAL LOOSENING

LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 22: FEMUR21

SECURE

SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR21

EARLY MECHANICAL LOOSENING

LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 23: FEMUR22

SECURE  SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR22

EARLY MECHANICAL LOOSENING LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 24: FEMUR23

SECURE

SILICONE LAYER

Frequency (Intensity) response curves

Spectral analysis of output waveforms
FEMUR23

EARLY MECHANICAL LOOSENING

LOOSE

Frequency (Intensity) response curves

Spectral analysis of output waveforms
5.2.2.2 Discussion

In this experiment, the layer of silicone rubber was able to couple the cemented prosthesis and the bone very firmly. This is witnessed by the fact that we were unable to dislodge the prosthesis by using manual force in tension and in torsion. The silicone was poured in the liquid phase to fill the gap between cement and bone and as it cured, it adhered to both the cemented prosthesis and the medullary canal thus mechanically coupling the two components of the system. Whether the fibrous tissue in-vivo would provide such a strong degree of coupling is unknown. Another potential problem with this model is the fact that the material properties of the in-vivo fibrous tissue may be completely different from those of silicone rubber. It may be possible in practice to match the properties of silicone rubber more closely to the in-vivo fibrous tissue by varying the composition of the elastomer but this would require prior knowledge of the material properties of the latter. It is difficult to predict how these material properties might affect the transmission of a vibration signal but they may well be relevant.

Our experiment has shown that vibration analysis is not sensitive enough to detect the presence of a layer of soft silicone rubber at the interface assuming there is no prosthetic instability. However, the validity of using silicone as a model for the interfacial fibrous tissue is not yet determined. Should later studies confirm the validity of this model, then our results suggest that the fibrous tissue is not vibrationally detectable.

5.2.3 Early mechanical loosening: Loss of interlock

5.2.3.1 Results

Examination of the graphs for the 8 specimens in which the cement mantle of the prosthesis forms a perfect (or near-perfect) mould of the gross bony cavity but does not interdigitate with trabecular bone, reveals more variety of response.
First we consider the frequency response curves. If we abide by the diagnostic criterion mentioned in section 2.4 that loosening is diagnosed by the presence of more than 2 peaks and stability is likely with 2 peaks or less, we find that all 8 frequency response curves for the systems representing early mechanical loosening have 2 peaks or less. (In fact most of them have just 1 peak). Therefore, on the basis of the frequency response test, this system behaves as if it were secure.

On the other hand, the results of frequency analysis were more variable. Out of the 8 specimens, 5 behaved as if they were secure producing no harmonics (femora 15,16,21,22,23) and the other 3 behaved like the loose system in generating harmonics (femora 17,19,20).

5.2.3.2 Discussion

Although macromovement between the prosthesis and the bone is absent in this model of loosening, it is likely that micromovement does occur because the interlock is not completely secure. To a certain extent therefore, this model is probably the best in representing early stage mechanical loosening. The magnitude of this micro-movement depends on the "goodness" of fit of the cement mantle in the bony cavity. In our experiment, although all the 8 specimens were prepared with equal care, the final quality of "press-fit" probably varied from specimen to specimen just on the basis of the natural variation that is so ubiquitous in life. Therefore, the extent of micro-movement can be expected to be slightly different in all eight specimens.

The results of the frequency response test suggests that it is not sensitive enough to detect micro-movement as it failed to differentiate this model from the secure one in all 8 cases. It therefore seems to be of no value in the detection of early mechanical loosening.

The results of spectral analysis, although better than those of frequency response studies, are also disappointing because of the low rate of detection of early mechanical loosening. Only 3 out of 8 specimens of this early model of mechanical...
loosening were correctly diagnosed. This corresponds to a sensitivity of 37.5% although the specificity remains high at 100%. It is likely that the 3 specimens that were correctly diagnosed as being loose were those in which there was relatively more movement between prosthesis and bone. Despite the low sensitivity obtained in this experiment, the fact that spectral analysis correctly diagnosed early mechanical loosening in three cases does offer some hope for future workers. Perhaps with the advent of more sensitive transducers as well as more advanced signal processing techniques and the development of improved models, it may be possible to diagnose early loosening more reliably.
6. Prostheses with fatigue fracture of the cement mantle

6.1 Results

We were unable to produce mechanical loosening by cyclic loading of the prosthesis using a compressive force varying between 2-4 times bodyweight. In both specimens tested, it was noted that a circumferential crack had developed at the tip of the prosthesis after $2 \times 10^5$ cycles of loading (Figs 27 and 28). However, despite continued fatigue loading, up to 12 million cycles for Femur18 and 2.5 million cycles for Femur2, no further signs of cement failure occurred and the prosthesis remained securely fixed in the medullary canal.

Examination of the frequency response curves of both femora shows them to be identical before and after cycling with just 1 significant peak in each case (Fig 25 & 26). Frequency analysis showed no harmonics. These findings are consistent with security of the prosthesis and were expected given the failure to produce mechanical loosening.

6.2 Discussion

There are many who believe that long-term failure of the fixation of cemented femoral components is primarily a mechanical problem, starting with debonding at the interface between the cement and the prosthesis, and continuing as slowly developing fractures in the cement mantle (Jasty et al, 1991). Weber and Charnley (1975) first reported on a large series of 6,649 patients, 99 of whom had developed a circumferential fracture of the cement mantle. In all but one of those patients, the fracture occurred at the distal 2 cm of stem tip - just as in our experiment. The authors believed that the distal tip cement fractures arose because the stem had become loose in the cement mantle giving rise to a pistoning effect of the stem within the cement mantle with each cycle of weight-bearing. As a result of this looseness, the prosthesis induces tension in the distal part of the cement when load is applied. This causes the cement to fracture and the prosthesis may then subside down the femoral canal.
canal. Our experimental observations suggest a more simple mechanism which in fact was considered by Weber and Chamley before they discarded it: with both femora tested, a loud crack was heard after about $2 \times 10^5$ cycles when the bone was bending under the applied load. The proximal part of the femur does not bend as much as the part distal to the prosthesis because the presence of the implant there stiffens it. The strain at the junction is therefore very high and may account for the cement fracture here.

Weber and Chamley noted that most of the cement fracture in their series had occurred within 6 months of implantation and subsequent follow-up showed that most had a good prognosis. This is consistent with our finding that cement fracture occurred relatively early in the cycling process (after only $2 \times 10^5$ cycles) and thereafter continued loading to 12 million cycles had no additional effect.

The findings of the fatigue test lead us to believe that although mechanical factors are responsible for the fracture of the cement mantle and may indeed be the initiating event in aseptic loosening as postulated by Jasty et al (1991), those factors alone cannot entirely account for the loosening process. It is almost certain that biological mechanisms have an important role either because of the foreign body reaction that accompanies the passage of particulate debris to the bone-cement interface at the fracture site or it may be that the cement fracture allows a greater degree of micromotion between prosthesis and bone which in turn activates the macrophages and giant cells found in the membrane at the bone-cement interface. In either case, this would lead to bone lysis around the cement mantle with resulting loss of support and hence loosening of the prosthesis. Biological mechanisms such as those do not occur in-vitro and this may explain why we were unable to produce loosening despite cycling up to 12 million times.

One particular point in the above experiment design is probably worthy of further discussion. This concerns the fact that single-plane loading was applied to the prosthesis in an attempt to disrupt the fixation. Although this would adequately transmit compressive and shear forces to the interfaces, torsional forces are negligible. This point may be corrected in future studies by applying multi-plane loading either by using a
modern hip simulator or simply by adjusting the angle of the prosthesis in relation to the direction of the applied load in both sagittal and coronal planes. The appropriate angles have previously been documented (Paul, 1976).
Fig 25: FEMUR2

NO CYCLES  2.5x10^6 CYCLES

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 26: FEMUR18

NO CYCLES

12x10^6 CYCLES

Frequency (Intensity) response curves

Spectral analysis of output waveforms
Fig 27  Left: Circumferential cement fracture at the tip of femoral stem (confirmed by radiograph shown in figure 28).  Right: Close-up view of the fracture
Fig 28  Radiograph of specimen from fig 27 confirming the site of cement fracture at prosthetic tip
CHAPTER 9

Conclusions and future work

1. Introduction

This study of vibration as a diagnostic technique in the loosening of THR has explored its possibilities and exposed its limits to an extent not accomplished before. After previous suggestions that vibration could perhaps become a useful diagnostic tool in clinical practice, the results we obtained on models of early loosening force us to adopt a more cautionary view. Every opportunity was given to the technique to succeed; in particular the in-vitro setting allowed the signals to be transmitted without the damping which would occur in-vivo due to the surrounding soft tissues. The accelerometers used were among the most sophisticated presently available and finally, we combined the signal processing methods of frequency response and frequency analysis which was not done in previous studies. Despite this effort, early loosening proved to be exceedingly difficult to diagnose using vibration. The following are the final conclusions we derive from our study.

2. Late loosening

The diagnosis of late loosening (defined as the presence of macromovement of the order of 2 mm between prosthesis and bone) was achieved with a sensitivity and specificity of 100% by spectral analysis. The results using the intensity response technique were also good with a sensitivity of 82% and a specificity of 100%. Overall, the results in "late loosening" were very encouraging although one might argue that this degree of loosening would be clinically or radiologically apparent.
3. Early mechanical loosening

In the presence of early mechanical loosening, when the cement loses its interdigitation with trabecular bone, looseness was vibrationally detected by spectral analysis in three out of eight specimens (sensitivity 37.5%). Using intensity response, a diagnosis of security was falsely made in all eight specimens. Although disappointing, these results are perhaps a reflection of the relative security of our model as we could not detect any movement at the bone-cement interface with the application of manual force to the prosthesis. It may well be that vibration analysis is not able to reliably detect this degree of loosening. However, the fact that three out of eight specimens were correctly diagnosed as loose by spectral analysis offers hope that the sensitivity could be bettered by future improvements in experimental design, signal analysis techniques and transducer technology.

4. Fibrous tissue at bone-cement interface

Using silicone rubber as a model for fibrous tissue, it was not possible either by spectral analysis or intensity response studies to detect its presence in all eight specimens when there was no associated mechanical instability. As discussed in Chapter 8, it is possible that our model may not be an accurate representation of the interfacial fibrous tissue. Nevertheless, our results lead us to believe that if the prosthesis remains stable, the presence of soft tissue at the interface is not detectable.

5. Fatigue fracture of cement

Fracture of the cement occurred relatively early in the fatigue cycle ($2 \times 10^5$ cycles). On the basis that fractured cement is the initial event in the loosening process as some authorities believe (Jasty et al, 1991), then this is the earliest possible form of loosening. In our study, it was not possible to detect the presence of cement fracture by vibration in the absence of mechanical instability.
The fatigue experiment led us to two additional conclusions. The first being that mechanical factors alone cannot produce loosening as we failed to notice any compromise in the stability of the implant after $12 \times 10^6$ cycles. Other studies, for instance that of Humphreys et al (1991) led to the same finding. This suggests that biological events, possibly activated by PMMA debris from the fracture site, are essential in the genesis of mechanical instability by causing bone lysis thereby leading to a collapse of the bony support around the implant.

The second "by-product" of the fatigue test was that it allowed us to deduce a simple mechanism to explain the circumferential cement fracture that is so frequently observed at the tip of the femoral prosthesis. As previously noted, Weber and Charnley made the hypothesis that the distal tip cement fracture occurred due to pistoning of the prosthesis inside the cement mantle. This presupposes that the prosthesis lies loose inside the cement almost from the time of implantation (Weber and Charnley, 1975). In our experiment, there was no evidence of stem-cement looseness that could lead to pistoning. At an early phase of fatigue cycling (around $2 \times 10^5$ cycles), the cement was heard to crack as the femoral shaft bent under loading. The crack almost always occurs near the tip of the stem (98 out of 99 of Weber and Charnley's cases) because the proximal femur is rendered stiffer by the contained implant and does not bend as much as the part that is distal to the prosthesis. The junctional region is therefore under maximal bending strain and this may explain cement fracture in this region. An additional piece of evidence in favour of our mechanism is the early onset of the fracture: less than 6 months post-implantation in Weber and Charnley's series and around $2 \times 10^5$ cycles in our experiment. For Weber and Charnley's mechanism to hold true, one must accept that stem-cement looseness occurs very early, in fact almost immediately post-implantation so that subsequent pistoning can lead to cement fracture within 6 months. We believe this is extremely unlikely whereas our experimental evidence suggests that bending of the femoral shaft is the likely cause of distal tip circumferential cement fracture.
6. Limitations of present study and scope for future work

The work of this thesis shows that advanced loosening can reliably be diagnosed in-vitro by vibration analysis. It has been more difficult to detect earlier forms of loosening, and indeed only three out of eight specimens of early mechanical loosening were identified as loose. On the basis of the results obtained, one cannot yet justify the large scale introduction of vibration technology into clinical practice. Further improvement in the sensitivity of the test is required. These improvements may in future be brought about in the following areas:

1. Experiment design
2. Transducer technology
3. Signal processing

Progress in the last two will naturally come from continuing advancement in the field of electronic engineering. It is in the experimental design however, that we feel able to make constructive suggestions for future workers. For instance, our models of early loosening, particularly the use of silicone rubber to mimic soft tissue may not be truly representative of the in-vivo situation (Ch 8, Section 5). The use of a different material with no adhesive properties or perhaps the use of material retrieved at revision surgery may be more realistic. We might have been more successful at disrupting the fixation of the prosthesis using multi-plane loading rather than single-plane loading during the fatigue tests (Ch 8, Section 6). However even then, one must be prepared to be unsuccessful because the biological mechanisms that contribute to failure do not come into play in-vitro. We are not aware of any proven model of the boundary conditions at the distal femur in the human (Ch 7, Section 4). However, previous work on the human tibia has shown that provided the leg is supported, the situation at the knee can be considered fixed (Cornelissen, 1986). In this light, our use of a clamp is probably justified and carries the additional advantage that a steady-state sine-wave vibration can be applied to a suitably pre-loaded femur. However, further work may be required to test the validity of this model. Finally, although we feel that the use of model femora is
justified, we would have preferred to perform more cadaveric experiments had human femora been more readily available.

In view of the clear differences in the vibration signals of the secure and the definitely loose prostheses, future controlled trials to test the accuracy of the test in the clinical situation are probably justifiable. These trials may be of two types:

1. Prospective studies.

In this type of study, a population of patients undergoing THR is followed prospectively over a number of years from the time of surgery. All patients are clinically assessed at regular intervals, preferably in a special clinic. Ideally, the clinic is staffed by a clinician as well as an engineer or technician proficient in the use of specialised vibration equipment. At each visit, radiographic as well as vibration data as described in this thesis are obtained. The latter, for instance the number of resonances or the presence of harmonics are compared as they evolve over the follow-up period and this data is correlated with the clinical and radiographic findings. In the majority of cases, the fixation of the implant is likely to remain secure and one might expect serial tests to show the number of resonances to remain unchanged and spectral analysis to reveal an absence of harmonics. For a minority of patients however, the implant will become loose. This may manifest itself clinically as pain and, in addition there may be radiological features such as change in component position to re-inforce the diagnosis. It is in such patients that it would be interesting to observe the evolution of the vibration signals. It is to be hoped that as loosening progresses, the vibration signals will change to mirror the changes seen in the clinical and radiological state of the fixation.

2. Study of patients prior to revision for aseptic loosening.

Prospective studies as above can take many years to complete because loosening is usually a slow process. It may be possible to obtain valid data in a shorter time scale by choosing as study group, a population of patients who on the basis of symptoms have been listed for revision surgery. All such patients could be seen in a special clinic before their scheduled revision and vibration spectra are obtained by a technician adept at the technique. Ideally all the data should be collected by the same person as this would add
consistency to the readings. Revision surgery is then carried out by a surgeon unaware of the results of vibration analysis. He records his operative findings in the notes, for instance whether the prosthesis was grossly loose, how much force was required to extract the implant and how much fibrous tissue was at the interface. The vibration data and operative findings are then analysed by a third independent party. In this way it may be possible to show that the vibration signals of those implants that have been shown to be loose at operation are clearly different from those that were relatively secure as was the case in our in-vitro study. If such was to be the case, vibration analysis may even be used as a predictor of the ease or difficulty of a particular revision operation, prior knowledge which is often helpful to the surgeon.

We believe that in-vivo studies can be conducted using the basic set-up described in this thesis. A few minor alterations need to be made however. For instance, an automatic swept sine-wave will allow more efficient and rapid data collection than manual control of the frequency range. The shaker should be hand-held and must include a device that allows a constant preload to be applied to the femoral condyle. Nevertheless, the major challenge in-vivo is undoubtedly the soft tissue envelope around the femur. This can influence both the transmission and the detection of the vibration signal. Cornelissen et al (1986) have demonstrated that the muscles around a long bone such as the tibia increases damping of the transmitted signal and decreases the resonant frequency. The latter would not compromise studies such as ours because we are mainly concerned with the relative change in the number of resonances rather than their absolute frequency values. Damping can cause problems because it reduces the amplitude of the output signal and thus makes it more difficult to detect. However, this problem can be overcome by using sensitive transducers. The skin and fat overlying the greater trochanter theoretically decreases the coupling between accelerometer and bone and can pose problems in signal detection especially in obese patients. This can be overcome by using needle-mounted accelerometers and injecting the needle under local anaesthetic through the soft tissue until firm contact is made with the bone (Ziegert and Lewis, 1979). In thin patients, a small mass accelerometer, preloaded against the skin will
reliably measure bone acceleration, avoiding the need to use needle-mounted accelerometers. Thus although the soft tissues present a challenging problem in-vivo, this is not unsurmountable.
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