The Effect of Surface Roughness and a Collar on Fixation of Cemented Femoral Stems *in vivo*

by

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Dedication

This work is dedicated to my beautiful wife Jodi, who has provided endless support and understanding for my research.

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Thesis Summary

The use of polished surfaced femoral stems of hip replacements has been reported to decrease aseptic loosening and osteolysis (Fowler et al.1988), but others report that loosening is initiated by debonding of the stem in the cement and recommend increasing this bond (Jasty et al.1991).

This thesis investigated the effect of femoral stem surface roughness and a collar on the fixation of cemented hip hemi-arthroplasty femoral stems in an *in vivo* sheep model up to nine months following implantation. Plain radiography, micromotion between prosthesis and bone during mechanical testing and histology were used. The primary hypotheses tested were:

> At nine months after implantation a polished surfaced prosthesis will show radiographic evidence of subsidence at the prosthesis-cement interface whereas a matt surfaced prosthesis will not.
>
> At nine months after implantation there is less axial micromotion between a polished surfaced prosthesis and bone than between a matt surfaced prosthesis and bone.

At nine months after implantation, subsidence of a polished surfaced femoral stem within the cement mantle was not seen and there was no difference in prosthesis-cement subsidence between a polished and a matt surfaced femoral stem ($p = 0.9$).

At nine months after implantation, there was no difference in axial prosthesis-bone micromotion between polished and matt surfaced stems ($p = 0.6$). Axial prosthesis-bone micromotion was no different between implant types ($p = 0.3$) but taken as a whole the micromotion immediately after implantation was greater than at nine months ($p < 0.001$). The representative middle value of axial prosthesis-bone micromotion was 37 μm immediately after implantation and 23 μm at nine months.

For medio-lateral and antero-posterior prosthesis-bone micromotion and axial, medio-lateral and antero-posterior prosthesis-cement micromotion, the differences

between the three prosthesis types immediately after implantation compared to at nine months, were small and not considered important.

Immediately after implantation, there was excellent interdigitation at the c-b interface. However, there were small c-b gaps that were filled with blood and bone debris and these were less than 300 μm. Debonding was not seen in the histological sections, small p-c gaps were seen immediately after implantation andat nine months due to cement mantle voids and were probably present at the time of implantation. At nine months after implantation there was evidence of bone remodelling with filling of the c-b gaps that were seen immediately after implantation; the result being increased stability of the stem. Small areas of fibrous tissue at the c-b interface did not effect the mechanical stability of stem.

Trabecularization of the distal femoral cortex and the formation of a neocortex was a common finding at nine months after implantation. Radiolucent lines at the c-b interface were found to represent this remodelling of the cortical bone rather than the presence of a complete fibrous interface which was not seen.

The fixation of cemented femoral stems studied in this *in vivo* sheep model was not influenced by the surface roughness of the stem or the use of a collar. This is important and has not previously been shown. There were no radiographic or histological findings to suggest implant loosening. Also, the results of this study suggests micromotion between cemented femoral prostheses and bone may decrease over time, resulting in improved fixation. This study has shown that a polished stem does not have significant p-c micromotion and the use of a matt surface finish with or without a collar does not improve bonding of the stem to the cement.

Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university and that, to the best of the candidate's knowledge and belief, the thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

I give consent to the thesis being made available for photocopying and loan if applicable if accepted for the award of the degree.

Scott Andrew Brumby

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Chapter 1

Cemented Hip Arthroplasty: A Literature Review

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Cemented total hip replacement is a successful operation for degenerative disease of the hip joint. However, one of the major complications is aseptic loosening of the femoral component. It has been suggested that the design and the surface finish of the femoral component may influence the incidence of aseptic loosening. Many clinical, implant retrieval and mechanical studies have been performed to assess aseptic loosening but the aetiology remains unclear.

Clinical studies can be reviewed to determine which prosthesis designs are associated with long term survival, however these studies require large numbers and long duration of follow-up. Implant retrieval studies allow more detailed analysis of implant fixation with measurement of micromotion between the prosthesis and bone together with histological analysis.

This chapter will review the clinical, implant retrieval and experimental studies that have been performed to address the problem of cemented hip replacement failure due to aseptic loosening and the discuss the importance of design features such as femoral component surface finish and a collar.

1.1. Clinical Studies

Schulte et al. (1993) report on the twenty year results of 330 cemented Charnley (polished surfaced femoral stem) hip arthroplasties performed by a single surgeon. There was an 98% follow-up and 32% of the patients were alive at 20 years from their original operation. The incidence of femoral component revision due to aseptic loosening was 2% for all patients and 3% for those alive. The incidence of femoral component definite or probable radiographic loosening and aseptic loosening confirmed at revision was 6% at 20 years. These excellent results were obtained with hand packing of the cement and without modern bone cleaning techniques.

Wroblewski reported the 15-21 year results of 116 cemented Charnley hip arthroplasties. The study group was a selection of patients who attended for regular review and had the longest follow-up available. This group may represent a select population as the original population from which these patients have come from is not documented. This was a relatively young group of patients with a mean age of 53 years (range 20-71 years). 85% were completely pain free at 15-21 years. Radiographic analysis was incomplete as some hips had radiolucent cement and definitions of the parameters measured are not present in this paper. Subsidence occurred in 29% and cement fractures in 15% of cases. The incidence of radiographic loosening and femoral component revision are not reported.

Beckenbaugh and Ilstrup (1978) report on 333 Charnley femoral stems implanted at the Mayo Clinic and found a 24% incidence of radiographic evidence of femoral component loosening at five years. Cement fractures were always associated with loosening. Femoral component loosening was attributed to the quality of cement fixation. The finger packing of cement may have resulted in variability of the cement mantle between patients.

A decade later from the Mayo Clinic, Russotti et al. (1988) report on 251 cemented Harris Design II femoral stems. They report a 1.2% definite radiographic loosening at five years using second generation cement techniques of cement pressurisation and canal brushing. The results were attributed to improved cement techniques, but, the design of the prostheses had been altered and the experience of the surgeons had improved.

Using "modern" cementing techniques and a matt surfaced, collared implant, Harris et al. (1986) reported 1.7% "definite loosening" on plain radiographs of 117 femoral components with radiographic review at five years. On the surface these results appear very good. However, data are reported on radiographs of only 114 femoral components from a series of 234 hips (49% of the original group). 100 patients were lost to follow-up, refused follow-up or had died and the percent of these patients with loose femoral components is unknown. This study highlights one of the main difficulties in performing studies with a long duration of outcome, that being loss of study patients because of incomplete follow-up. At a twelve year review (Barrack et al.1992) there were 50 patients (21% of the original group) available for follow-up and only one stem was definitely loose on radiographic assessment. The success of the cemented femoral components was thought to be due to improved cementing techniques and better stem design.

Gardiner and Hozack (1994) investigated aseptic loosening of seventeen femoral stems with surface coatings designed to strengthen the prosthesis-cement interface. Failure occurred at a mean time of thirty-seven months following insertion. Failure occurred at the cement-bone interface, the prosthesis-cement interface was solid without evidence of de-bonding. The definition of loosening used in this study was not stated, nor was the method for assessing loosening at revision surgery. There was 100% demarcation at the cement-bone interface in all post-operative radiographs and all prostheses were removed with the cement mantle intact and firmly bonded to the prosthesis.

The role of a medial cortex load bearing collar has been addressed in theoretical studies (Markolf et al.1980) and in a prospective, randomised, controlled clinical trial (Kelly et al.1993). Kelly et al. (1988) compared a "collared" implant with a "collarless" implant and investigated subsidence, lucent lines and bone resorption. The study is misleading as the "collarless" implant had a medial cement mantle load bearing collar and cannot be compared with the Exeter collarless implant which is a truly collarless implant. The correct comparison would be between a "collared" matt surfaced Harris type implant and a "collarless" Charnley low-friction arthroplasty. They found "collarless" implants had an increased incidence and width of lucent lines in zones 2 and 7 (Gruen et al.1979), and greater loss of endosteal height of the femoral neck cut. They found no difference in subsidence of the "collared" and "collarless" groups.

As there were no differences in subsidence between the groups, three conclusions could be drawn. Firstly, the techniques used to determine subsidence were not sensitive enough to detect a difference, secondly, the study numbers were not great enough to detect a difference at five years, or thirdly, the matt surface was fully bonded to the cement and therefore the effect of the collar was minimal.

The clinical experience with the Exeter hip replacement has been documented by the designers of the implant (Fowler et al.1988; Mikhail et al.1988) and others (Rockborn and Olsson, 1993). Clinical review at 15 - 20 years with clinical and radiographic follow-up has been published. Subsidence at the prosthesis-cement interface has been noted and thought to be an integral function of the hip system and not associated with failure at the cement-bone interface. Review at seventeen years found that 36.4% had no measurable subsidence, 17.5% had subsided less than 1 mm, 18.2% had subsided 1 - 2 mm and 8.9% had subsided 3 - 4 mm. The incidence of stem revision of the initial group of polished stems implanted between 1971 and 1975 was 1.64%.

The Exeter femoral stem surface finish was originally highly polished, however the design was changed to a matt surface for the period of 1976-1986 without consultation of the designers and was probably because it was common to have matt surfaces on femoral stems at that time. The possible differences in function of matt versus polished stems was not appreciated. During this period, 2968 primary hip arthroplasties were performed with a stem loosening rate of 0.47% at review in 1986-87 (Fowler et al.1988). However, the incidence of osteolysis and aseptic loosening has greatly increased such that 10% of matt surfaced Exeter femoral stems have been revised (Prof. R.S.M. Ling, personal communication). This finding is further supported by results from the Swedish Hip Registry (Ahnfelt et al.1990). The change in surface finish was thought to be a retrograde step (Fowler et al.1988) and the implant was changed back to a polished surface in 1986. This change was based on clinical observation of increased early osteolysis with the matt stems despite no documented increase in failure (compare 1.64% with 0.47%). Also the designers cited reports of laboratory studies which suggested mechanical advantages of the polished femoral stems. This change in implant design has allowed a comparison of surface finish to be made on a similar design of implant (Fowler et al.1988; Rockborn and Olsson, 1993). The other change that occurred in 1976, around the time of the introduction of the matt surfaced stem, was the introduction of cement pressurisation techniques. When the surface changed in 1976 it was noted that the subsidence did not occur (95.8% = no subsidence).

Rockborn and Olsson (1993) reviewed 143 primary matt surfaced Exeter hip replacements at a minimum of five years after implantation. The cement technique was of pressure irrigation and brushing, cement gun, distal plug and cement pressurisation. There was definite loosening of the stem in 14% and suspected loosening in 7%. These figures are greater than those reported for other matt surfaced implants which form the majority of implants currently available. The mean subsidence in the group with suspected loosening was 5 mm. Localised osteolysis was noted in 8 hips in the mid-shaft region associated with a thin or absent cement mantle. The conclusions made regarding the aetiology of loosening in this study lack supporting evidence from the data presented. The matt surface of the implant is presumed to be a cause. Failure to achieve and maintain cement pressurisation and too early insertion may have been factors. The use of too large a stem may have decreased the cement mantle.

Changes in stem design and materials may influence loosening. Dall et al. (1993) report on an increased incidence of loosening with the second generation Charnley femoral stems despite improvements in cementing techniques. They report the incidence of stem fracture was 4.1% in first generation stems and 0.5% in second generation stems, stem loosening was 3.1% and 11.4% respectively. The authors of this study believe the differences are due to changes in the cross sectional area of the second generation stems resulting in an increased flexural stiffness. The first generation Charnley femoral stems were polished and this was changed to a matt surface with the second generation stems; Dall et al. (1993) raise the question that the polished surface may contribute to the lower loosening rate. The interpretation of this study, like many others, is difficult as there were three changes made between the two study groups, implant design, implant surface finish and cementing techniques. All of these are thought to influence femoral component loosening.

Mohler et al. (1995) review 29 femoral stems with early loosening at a mean of 5 years from the index operation. They conclude that the features responsible for early loosening were both a matt surface finish combined with a geometry of a cylindrical shape distal to the proximal cobra shape. A radiolucency in the supero-lateral region developed after the clinical symptoms of loosening and was followed by a medial lucency. This is unlike the supero-lateral lucency seen by Fowler et al. (1988) which developed in the first 12 - 24 months in asymptomatic patients and was not followed by a medial lucency. The important finding in the study by Mohler et al. (1995) is that once rotational stability at the prosthesis-cement interface is lost with a matt surfaced implant, loosening is accelerated.

Gruen et al. (1979) reviewed a large number of femoral components to determine the mechanism of failure of cemented hip arthroplasty. The serial radiographs of 389 femoral components were assessed to evaluate the changes leading to failure. They identified four modes of mechanical failure. Mode 1 is pistoning of one material with respect to another; stem within cement is type 1a, stem and cement within bone is type 1b. This mode of failure is due to forces from axial loading of the femoral stem being transferred predominantly as shear stress and not as increased radial compressive loading. Mode 2 is medial mid-stem pivot. This mode is due to weak calcar support and lack of distal cement support. Mode 3 is calcar pivot. In this mode there is adequate calcar support but distal cement support is poor and the stem moves into a varus position with eventual lysis and fracture of the distal-lateral cortex. This mode is seen in failure of collared implants that are held-up on the calcar and are unable to subside when loose. Mode 4 is cantilever failure. This mode occurs when there is adequate distal support and medial deformation of the proximal stem, this eventually leads to fracture of the stem. This mode is now uncommon due to the current metal alloys being stronger.

Clinical studies have shown cemented hip arthroplasty to be well tolerated in the long term. The surface finish of the femoral component is one variable that has received considerable attention because of increasing evidence suggesting it may influence long term results. There are other variables such as femoral bone quality, surgical technique of canal preparation and cementing and femoral component geometry. These variables and a multitude of other patient dependent variables are difficult to analyse and therefore make assessment of the aetiology of loosening difficult. Both matt and polished surfaced implants have been successful in many studies, however the exact role that surface finish has in the initiation of loosening has not been answered by clinical studies to date.

1.2. Subsidence

Subsidence of a cemented femoral prosthesis with respect to the femur can occur at either the prosthesis-cement interface, the cement-bone interface or a combination of both. Harris et al. (1982) suggest that prosthesis-cement subsidence is evidence of failure of prosthesis-cement bonding and regard this as definite evidence of loosening. Fowler et al. (1988) regard subsidence of the Exeter polished femoral prosthesis within the cement mantle as an essential requirement for load transmission from the prosthesis to the bone. It is generally accepted that progressive subsidence at the cement-bone interface is associated with loosening, however the importance of early, self-limiting subsidence at the prosthesis-cement interface is unclear and might occur with some designs of femoral stems without loosening.

1.2.1. Measurement of Subsidence

Landmarks on the femoral bone such as the tip of the greater trochanter, the centre of the lesser trochanter and the cut edge of the femoral neck have been described as reference points for measuring femoral subsidence.

Loudon and Charnley (1980) measured subsidence from the distal tip of the prosthesis to the point of insertion of double wires used for reattachment of the trochanter following trochanteric osteotomy. This study was one of the first to define the errors involved in measuring migration. The study calculated the error in the measurement of migration from a single radiograph, but did not calculate the error involved in taking the radiographs due to magnification and position changes.

Loudon and Older (1989) reviewed 102 patients at 9-13 years and documented femoral component subsidence. Clinically satisfactory THR had 2.01 mm of femoral subsidence, clinically satisfactory THR with cement tip fracture on radiography had 4.40 mm of femoral subsidence, and clinically unsatisfactory THR had 8.21 mm of femoral subsidence. The majority of subsidence occurred in the first 12 months with the unsatisfactory patients showing a greater rate of progressive subsidence. Loudon (1986) later showed that subsidence of clinically successful THR usually decreases with time or stops at 5 mm. On the other hand progressive subsidence beyond this amount, and sometimes up to 20 mm at 5 years, is likely to lead to failure.

Mulroy et al. (1991) report a simple method to measure subsidence and standardise the position of the prosthesis by using measurements from a Herbert screw inserted into the greater trochanter and the shape of a proximal transverse hole in the femoral prosthesis. This had the advantage of controlling rotation and flexion/extension, and provided a reference marker for measuring subsidence. The error calculations were not included in the study and a disadvantage of the method is that it requires a prosthesis with a proximal transverse hole.

Computer based image analysis had been used in an attempt to standardise digitised measurements of prosthesis position from plain radiographs (Hardinge et al.1991). Measurements were claimed to be reproducible to ± 0.01 mm and accurate to ± 0.5 mm. The data and methods for determining accuracy were not referenced in the paper.

Liossis et al. (1992) have developed computer software to analyse hip arthroplasty position by comparing the known geometry of the prosthesis with three points of the prosthesis on plain radiographs with two bone markers. The errors in their measurements were less than 0.5 mm providing the patient did not move greater than 15° and the bone markers were implanted near specific positions.

Malchau (1995) calculated the intra and inter observer error of femoral stem subsidence from plain radiographs. Measurements were taken from the radiographs using a ruler and pencil and also with a user interactive digitiser. The intra observer error (two standard deviations) varied from 1.6 to 5.6 mm. The inter observer error (two pooled standard deviations) varied from 2.6 to 5.6 mm. Digital and manual measurements did not differ.

Prosthesis-cement subsidence has been measured by Fowler et al. (1988) using a simple technique. The distance between the curved supero-lateral margin of the prosthesis and the adjacent cement mantle in Gruen zone 1 was measured with a pencil and ruler. They were able to calculate subsidence to 0.5 mm but did not include an assessment of the accuracy of the method.

Walker et al. (1995) describe the theoretical and experimental errors involved in measurement of subsidence from plain radiographs. Their paper assesses the effect of rotation and out of plane flexion and suggested a methodology for measuring subsidence. The paper states the error of subsidence measurements with their technique of measuring from the top of the greater trochanter to the lateral stem collar was 0.37 mm with 10° of rotation; the actual range is 0.53 mm with theoretical measurements which do not account for the effect of magnification and human variability in marking the radiographs for digitisation. With their experimental study the range of values for each rotation or flexion was 0.1 to 0.32 mm such that the combined range may be up to 1 mm. Their clinical study did not report inter and intra-individual variability and found that all implants had subsided up to 3 mm in the first 12 months at the cement-bone interface. This suggests that all are loose or that there is some variability in the methodology that may be up to 3 mm due to patient positioning, radiographic variability and human error in digitising radiographs.

The paper by Walker et al. (1995) claims to measure stem-cement migration but they do not report their methodology despite publishing results. They comment on the use of a distal marker in the cement however they also suggest that distal measurements are subject to great error in the order of 4 mm.

1.2.2. Radiographic Errors

Radiographic measurement of the relationship of a prosthesis to bone is subject to errors due to differences in exposure and magnification, the effect of parallax, rotational and positional changes of the femur and changes in the bone (Goodman et al.1987; Albert et al.1991). These may have large effects when measurements in the range of one to two millimetres are made to assess subsidence . Various methods have been used in an attempt to standardise the position of the patient, the exposure and position of the radiographic equipment (Clarke et al.1976; Kirkpatrick et al.1983; Amstutz et al.1986). The errors due to position and magnification are the greatest errors and must be reduced or standardised to allow comparison at different times and with different subjects.

Clarke et al. (1976) and Kirkpatrick et al. (1983) defined many of the potential errors and attempted to correct them using a "chariot device" to standardise patient position, magnification and radiograph quality. The device has not been widely accepted (Amstutz et al.1986). Amstutz et al. (1986) subsequently used a "grid radiograph" in an attempt to standardise plain radiographs. The technique required the feet to be fixed in neutral rotation and the centre of the XR beam was adjusted using fluoroscopy and standardised over the centre of the hip joint for each patient.

The variation of femoral rotation on the appearance of the proximal femur and the femoral component with plain radiography has been assessed (Goodman et al.1987; Albert et al.1991; Engh et al.1993). Rotation changes as small as 20° can simulate changes in varus/valgus position, the density of Gruen zone 7 and the bone landmarks used for the measurement of migration. The rotation depends on the position of the stem in the femoral canal; if the stem is posterior, external rotation results in pseudo-valgus and internal rotation results in pseudo-varus. The reverse is true if the stem is located anterior in the canal. There was a 10.3% mean zonal change in the density of Gruen zone 7 with 20° of external rotation (Engh et al.1993).

1.2.3. Roentgen Stereophotogrammetric Analysis (RSA)

Roentgen stereophotogrammetric analysis (RSA) has been extensively used as a research tool to document positional changes of prostheses (Mjoberg et al.1986; Cheal et al.1992; Nistor et al.1991; Ryd, 1992; Chafetz et al.1985; Snorrason and Karrholm, 1990; Mjoberg et al.1984). Although extremely accurate (precision of between 0.2 - 0.7 mm (Snorrason and Karrholm, 1990; Cheal et al.1992)), the method is expensive, time consuming and requires insertion of multiple markers into the femur. Mjoberg et al. (1986) documented subsidence with RSA in 20 patients, recording distal migration in only 3 of 20 femoral stems at 2 years. The femoral stems moved between 0.3 - 0.6 mm distally and there was no migration in the other two axes. Their error calculations were for the x axis = ± 0.13 mm, for the y axis = ± 0.06 mm and for the z axis = ± 0.25 mm. RSA is accepted in the literature as a very accurate method of documenting subsidence but the facilities for RSA are not available at most institutions and therefore it is not relevant for the assessment of large number, long duration studies.

1.3. Implant Retrieval Studies

There are many reports on the histopathology of tissues from retrieval studies of cemented hip arthroplasties. These may be divided into failure studies (retrieved tissue from clinically loose implants taken at revision surgery or autopsy) (Linder and Hansson, 1983; Goldring et al.1983; Goldring et al.1986; Johanson et al.1987) and studies of stable arthroplasties (retrieved at autopsy) (Fornasier and Cameron, 1976; Maloney et al.1989; Jasty et al.1990; Jasty et al.1991; Kwong et al.1992; Fornasier et al.1991). Autopsy studies of stable arthroplasties are particularly important as implants may be analysed at various times from the initial operation without the late accelerated biological response seen with loosening. The implant and the intact femur can be removed for detailed mechanical, histological and radiological analysis. The initiating factors of loosening may be hypothesised from these studies but small numbers have prevented direct comparisons of individual features as the implants, cementing techniques and surgical expertise are not standardised for each specimen. There is also no control for the findings seen and it is unclear if the features seen are due to in vivo loading of the implant or whether they have been present since the time of implantation.

Although these studies are few, the information obtained is important in obtaining an understanding of the human body's response to THA and for providing direction for research.

1.3.1. Prosthesis-Cement Interface

The prosthesis-cement (p-c) interface has received little attention as most histological studies have dissolved the cement during section preparation prior to analysis of the cement-bone interface. Some studies have specifically addressed this interface to obtain a complete picture of the prosthesis - cement - bone complex (Fornasier and Cameron, 1976; Jasty et al.1991). The p-c interface has been thought by some to be the site of initiation of aseptic loosening (Jasty et al.1991) and therefore requires detailed assessment.

Fornasier and Cameron (1976) reviewed 5 stable femoral components at autopsy and found a fibrous membrane between the cement and the prosthesis which was less than 100 microns at its point of greatest thickness. This tissue was thought to be nourished by fluid which diffused from the proximal p-c interface. They postulated that the gap was produced by cement thermal contraction, thermal expansion and later contraction of the femoral stem and by any tissue or blood present on the stem at the time of insertion. The cementing technique (lack of pressurisation) may have caused these findings.

The p-c interface has been most extensively investigated by a review of 16 clinically and mechanically stable femoral components by the Harris group (Maloney et al.1989; Jasty et al.1990; Jasty et al.1991; Kwong et al.1992). The four published studies address different issues but overlap considerably. The p-c interface was examined with scanning electron microscopy, contact radiography and routine histology without removing the implant; this enabled examination of the intact p-c interface, the cement mantle and the cement-bone interface.

There was early separation of the p-c interface in some areas of all specimens, even at 15 days post-op; which suggests that this finding may have been present at the time of insertion and therefore may represent a technical problem of implantation. The term "de-bonding" used throughout the studies by the Harris group should be replaced with "never bonded" or "not bonded" as it is impossible to determine that complete bonding occurred in every case.

Many implants were collared implants and published photographs of several sections showed non-centralised insertion of some implants with deficient cement mantles. "De-bonding" was seen around sharp corners of implants and in four specimens there was a fibrous membrane of 50-100 microns at the p-c interface. Fractures were noted in the cement mantle originating at the p-c interface and from cement voids. "Debonding" at the p-c interface occurred proximally and distally.

There is no mention of whether the contralateral laboratory implanted control specimens had a debonding gap or blood at the p-c interface at the time of insertion and no mention of the micromotion of control femora. This lack of information prevents comparison of the femora at the time of insertion with that at the time of retrieval. This study with such a wealth of information lacked critical analysis of the de-bonding widths and frequencies at sequential levels down the implant, the interface tissue widths and type, the adjacent cement mantle parameters (thickness, porosity and fractures) and is therefore unable to determine the initiating factors that cause loosening.

The authors propose that the initiating factor in cemented femoral component loosening is "debonding" at the prosthesis-cement interface and therefore all efforts should be made to improve the bonding at this interface. The fact that the patients were all pain free, the radiographs showed no evidence of loosening and the implants were mechanically stable should suggest that "debonding" is associated with implant success rather than the initiation of failure. The findings of cement fragmentation around sharp corners and in areas with a thin or deficient cement mantle are important. The conclusions that should have been made from their studies are that cement fragmentation is associated with sharp corners of implants and deficient cement mantles. The role of cement fragmentation and loosening should have been explored further.

1.3.2. Cement-Bone Interface

In "stable" autopsy retrieved specimens, the cement-bone (c-b) interface has been noted to be well maintained after 17 years with an absence of fibrous tissue between cement and bone and in most specimens there was no separation of the cement and the bone with trabecular bone interdigitating with cement (Maloney et al.1989; Jasty et al.1990; Jasty et al.1991; Kwong et al.1992). These studies have found no evidence of foreign body giant cells and macrophages that have been seen with loose components (Goldring et al.1983; Goldring et al.1986; Johanson et al.1987; Lennox et al.1987) and they do not report on the presence or absence of polyethylene wear debris which has been a consistent finding in other studies (Goldring et al.1983; Goldring et al.1986; Johanson et al.1987; Lennox et al.1987; Fornasier et al.1991).

The radiolucent lines seen on plain radiographs were found to represent regions of osteoporosis of the cortical and cancellous bone and not a fibrous c-b interface (Kwong et al.1992). This study used high contrast radiographs of explanted specimens and documented "lucent lines" of 1-10 mm which is not the same as the reports by the same investigators using the same study group with normal radiographs where there was no evidence of loosening as defined by radiolucencies at the c-b interface (Jasty et al.1991). High contrast radiographs will demonstrate osteopaenia but they are not the radiographs used by the clinician for follow-up of cemented hip arthroplasty hence caution should be used when saying that all radiolucencies are osteopaenia and not fibrous tissue.

Some inconsistency is present in the work from the above investigators, as evident in the review paper from the Hip Implant Retrieval Committee of The Hip Society (Schmalzried et al.1993). In this paper the authors state:

> "The remarkable finding at the bone-cement interface on the femoral side was the paucity of fibrous tissue."
>
> "Despite the frequent occurrence of radiolucencies noted on clinical and specimen radiographs, soft tissue at this interface was rarely seen."

These comments are similar to the theme of most of the similar papers from this group (Maloney et al.1989; Jasty et al.1990; Jasty et al.1991; Kwong et al.1992). Later in the results section:

> "A distinctly different histology, however, could be found in the most proximal femoral sections. In the proximal 1-2 cm of the femoral bone-cement interface, soft-tissue interposition between cement and bone was characterised by

numerous plump macrophages laden with submicron PE (polyethylene) wear debris."

This completely different view has never been reported in their prior studies and while this view is consistent with the bulk of the literature it is of interest why this data has not been investigated further and reported in the studies: "The histology of the radiolucent line" (Kwong et al.1992) and "The initiation of failure in cemented femoral components of hip arthroplasties" (Jasty et al.1991).

Willert et al. (1974) have examined twenty-eight specimens of the c-b interface at autopsy and revision surgery to determine the progression of the interface with time. There was early necrosis around the cement (up to 3 weeks post operative) followed by repair (up to 2 years) and then remodelling. The repair stage was associated with osteonecrosis and adjacent osteoporosis and was thought to be as a result of the surgical trauma, thermal trauma and the non polymerized cement. The permanent prosthesis bed was found to consist of a 0.1-1.5 mm fibrous membrane with minimal vascularisation and fibres parallel to the cement surface. Cement pearls were found near the interface associated with foreign body inflammatory tissue. Resorption of bone and cement fragmentation were associated with loosening of the femoral component.

Fornasier et al. (1991) reviewed 14 autopsy retrieved stable hip arthroplasties. Radiographs did not demonstrate radiolucencies, displacement or fracture. The specimens were fixed and the cement dissolved, prosthesis removed and decalcified. Sections were taken at multiple levels and radial sections at the distal tip. The cement-bone membrane was composed of histiocytes with a scant background of fibrous tissue. Multinucleated giant cells were prominent as were birefringent particles, which were seen along the full length of the membrane and increased with time. The density of the histiocytes was associated with the thickness of the membrane and the duration of implantation. This study suggests that there is a multi-factorial aetiology of the membrane and includes a cellular response to polyethylene and cement debris, micro movement and accelerating factors which are not yet fully described.

Linder and Hansson (1983) has reviewed the ultrastructure of the cement-bone interface in three revision hip arthroplasties, of interest was the viable bone alternating with areas of soft tissues containing macrophages and giant cells. In all sections, there was a thin rim of connective tissue (1-3 microns) interposed between the bone and cement.

It is well established that "failed" components are associated with a large fibrous membrane at the cement-bone interface which is a combination of histiocytosis, fibrosis and necrosis and may appear like a synovial membrane (Goldring et al.1983; Goldring et al.1986; Johanson et al.1987). Particulate matter is common and may be of cement, polyethylene, bone or metal. The cement surface has been noted to be eburnated and to lack physical interlock in the failed state and be associated with small fractures of the cement extrusions (Johanson et al.1987). The distinction between biological and mechanical loosening is not clear and most likely intimately related.

1.3.3. Capsule Tissue

Mirra et al. (1976) reports the pathology of 24 hip and 10 knee arthroplasty failures with a semi-quantitative method of microscopic analysis of synovial fluid and capsule tissue. Joint infection was associated with focal and/or diffuse acute inflammation as manifested by polymorphonuclear leucocytes. Chronic inflammation (lymphocytes, lymphoid follicles and plasma cells) were associated with infection (14 of 20 cases with 2 to 3+ chronic inflammation) and large quantities of polyethylene and acrylic debris causing a "traumatic" synovitis. Mononuclear histiocytes were seen in all cases of infection and with wear particles within or surrounding the cells. Giant cells were associated with wear particles. Wear particles were not associated with an acute inflammatory response in any specimen.

1.3.4. Localised Osteolysis

Localised bone resorption has been noted adjacent to stable cemented hip arthroplasties in several studies (Jasty et al.1986; Maloney et al.1990; Anthony et al.1990). The cellular response was of macrophages and foreign-body giant cells invading the bone. Polymethylmethacrylate (PMMA) particles were abundant (10-200 microns) however the adjacent cement mantle was intact in all of the four specimens reported by Jasty et al. (1986). Further review by the same group (Maloney et al.1990) with 25 cases demonstrated in 60% of cases a defect in the cement or a thin cement mantle. Local fragmentation of the cement was seen in this study. It is uncertain if polyethylene particles were looked for specifically.

Anthony et al. (1990) noted defects of the cement mantle and found metal, PMMA and polyethylene wear debris at the site of the lytic lesions. The debris was thought to be from the joint space and transported via the p-c interface and then via cement mantle defects, unlike Maloney et al. (1990) where local debris was formed. Osteolysis is seen with loose cemented hip arthroplasty as an aggressive granulomatous reaction(Santavirta et al.1990; Santavirta et al.1990).

1.4. Experimental Studies

Draenert (1981) studied the histomorphometry of the cement-bone interface with a cement filled femoral canal without a metal implant in rabbits. This model retained the femoral head and as such changed the stiffness of the canal and the transfer of load to the cortex. The bone responses are therefore not the same as with an implant that articulates with the acetabulum.

Initially, haematoma was present in the gap between cement and bone. Gaps between 20 and 200 μm were filled directly with lamellar bone. Larger gaps were filled with woven bone, this progressed with lamellar reinforcement of the trabecular bone by the end of the third week. At the end of the fourth week the entire gap had been compacted. A layer of woven bone was seen levelling the surface irregularities of the cement. Periosteal reaction was seen after one week and the remaining cortex was interspersed with resorption lacunae.

Rhinelander et al. (1979) described the effects due to reaming and the thermal effect of acrylic cement in the proximal femora of dogs. This study has several flaws which prevent correlation with the current methods of hip arthroplasty. The cement volume and surface area was small and the metal implant was small in diameter and therefore the findings may not represent the normal trauma to bone due to a reduction in total heat generated and different thermal transfer properties. The normal procedure for hip arthroplasty involves disruption of the capsular vessels, more extensive reaming and pressurisation of the cement, therefore, the results from this study may be an under-estimate of the effects of reaming and the thermal effects of pressurised cement. The following paragraphs summarise their findings.

The effects due to reaming include transection of the nutrient arterioles resulting in devascularisation followed by revascularisation resulting in cancellous new bone formation in the necrotic areas of the cortex and endosteal new bone formation. The metaphyseal arterioles revascularise the damaged cancellous bone and six months after reaming alone, the proximal cortex was histologically normal.

The effects due to cement insertion after reaming were assessed. There was no abnormality of the proximal cortical bone as this area was not traumatised by the procedure. Immediately after cement insertion, a thin membrane exists at the cement-bone interface of initially compressed marrow elements which with time, progressed to multi-layered fibrous tissue. There was similar evidence of revascularisation and bone remodelling, however, after insertion of cement the pathway for medullary revascularisation was blocked and at 12 months necrosis of the inner layer of the diaphyseal cortex was still present. Immediately adjacent to the cement in the proximal sections were trabeculae with viable cells indicating that the thermal effects of cement did not result in necrosis. A thermistor at the cement-bone interface did not record temperatures greater than 55°C. These findings are all with a non-loaded model and can not be correlated directly with the loaded hip arthroplasty.

In the sheep, Radin et al. (1982) have viewed the sequence of histological changes seen during hip arthroplasty. At 3 weeks there was fibroblastic and woven bone adjacent to the cement, endosteal necrosis and periosteal new bone. Cortical remodelling continued throughout the period to 12 months, initially endosteal resorption followed by periosteal new bone formation with continued remodelling at the cement-bone interface. Overall a net loss of bone occurred.

Studies on cementless fixation in the human and canine studies (Cook et al.1988; Sumner et al.1992) demonstrate the same fibro-histiocytic response with particulate metal and polyethylene as well as foreign body giant cells and macrophages. The response to implantation is therefore not unique to cement fixation and the cement can not be thought to be the only factor in initiating loosening. All wear debris particles are important in the aetiology of loosening and need to be assessed individually to determine their role.

1.5. Cement Properties

Cement is a thermo-plastic polymer that exhibits time and temperature dependent deformation under constant load (creep) (Lee et al.1990). At body temperature it should not be regarded as a brittle solid that only acts as a "grout" to hold the prosthesis in position and transfer load between the prosthesis and bone directly as initially described by Charnley (1960). At body temperature, cement behaves as a visco-elastic solid and applying a load causes a small elastic deformation, followed by continuing deformation (creep) at an ever decreasing rate over time (Lee et al.1990). Lee et al. (1990) have shown in "taper constraint tests", the cement will tend to creep radially outwards into grooves in the constraint as well as distally. This has the potential to allow increased cement bone inter digitation and reduction of micromotion even after the initial pressurised insertion of the cement. There is also no reason why the cement should not creep proximally, out of the canal.

Bugbee et al. (1992) found that using current cement pressurisation methods, cement penetration into cancellous bone has a finite effect on interface shear strength and that with cement penetration between 50% and 100% there was no relationship between penetration and interface strength ($r = 0.16$; $p > 0.26$). The aim of cemented hip arthroplasty should be to achieve greater than 50% penetration of the available cancellous bone.

Ahmed et al. (1982; 1982) describe the volumetric behaviour of cement during its curing process. The change in volume may be due to bulk shrinkage due to polymerisation, bulk expansion due to trapped gas bubbles or thermal expansion followed by thermal contraction due to the exothermic polymerisation reaction. General observations have documented the changes that occur and initially there is contraction before the temperature rise and this is due to bulk shrinkage due to polymerisation (this is likely to occur while the cement is being mixed and pressurised in the canal). The expansion occurs at the time of temperature rise and may be due to either thermal or bulk expansion (both of which would enhance inter digitation of cement during prosthesis insertion). The final stage of contraction is due to thermal shrinkage. The residual stress that exists after curing can be explained on the basis of thermal expansion and then shrinkage.

Analysis of cement behaviour at the interface with cancellous and cortical bone predicts that the cement-bone interface will be under radial compression throughout the curing of the cement and that no gap will exist at this interface with either bone type. When looking at the prosthesis-cement interface in a cancellous bone model, radial tensile stresses are developed at this interface of 0.5 to 1.5 MPa during curing. If the tensile stress of the interface is not sufficient to resist these stresses (eg: polished surface) then residual gaps of 2 to 7 microns are predicted to occur where there is cancellous bone. With a cortical bone model, the stresses at the prosthesis-cement interface are always compressive and no gap is predicted.

Modern cementing techniques attempt to enhance the fixation ability of cement by increasing the inter digitation by pressurising techniques (Ling, 1980; Bugbee et al.1992; Ling, 1991; Harris and McGann, 1986), bone cleaning techniques to decrease bone, blood and fat debris at the c-b interface (Ling, 1980; Ling, 1991; Roberts et al.1986) and cement mixing techniques to improve the cement consistency (Lee et al.1973; Lee et al.1978; Linden, 1991; Russotti et al.1988).

Gharpuray et al. (1990) examined cement fracture mechanics in an experimental model (cadaver tibial components) and attempted to produce a mathematical model. Experimental studies demonstrated fractures in the cement formed and propagated within the cement itself. They occurred at the site of voids and inclusions (non-polymerised PMMA) in the cement. The cracks in the voids ran perpendicular to the implant surface and cracks from inclusions ran at variable directions from the implant but radially from the inclusions. They found the vertical cracks in the cement emanating from the voids are likely due to compressive loading of the cement. They found that the voids are the weak link in cement and therefore should be avoided.

Helmke et al. (1992) found significant porosity at the stem-cement interface (18 ± 18%, range = 1 - 90%) and theorised that this may be responsible for the "weak bond" between the stem and cement as evident by the low tensile strength of this interface. Rough surfaced implants were associated with a lower porosity and porosity was greater around corners of implants. The pore size observed was 105 ± 56 microns. They attribute the porosity at the prosthesis-cement interface to air entrained during prosthesis insertion.

Jefferiss et al. (1975) performed studies on the thermal characteristics of PMMA. They found that the dispersal of heat was greater with cancellous bone due to the increased surface area and the thermal capacity of cancellous bone may be higher due to its richer blood supply. They suggest that other factors such as mechanical and vascular trauma may be more important in the zone of necrosis seen around the cement bed. Chemical trauma due to the cement and generation of free radicals adds to this insult.

Bundy and Penn (1987) examined the strength of the metal-cement interface with different metals and surface preparations. The shear strength was calculated by measuring the twist angle after a torque was applied to a cylinder of metal cemented in a cylindrical testing mold. Interfacial strength was greatest for the coarsest surface (grit blasted, Ra = 1 μm) and the finest surface finish (polished, Ra = 0.1 μm) as compared to intermediate finishes. The authors hypothesise that interface strength results from two effects: mechanical interlock which predominates for rough surfaces and atomic interactions which predominate for polished surfaces. Therefore a strong bond can exist with either surface roughness. The limitation of this model is that it does not take into account the effect of the geometry of the metal. The results with a double tapered femoral stem are not known.

1.6. Stem Design and Surface Finish Properties

Analysis of the various aspects of stem design by Crowninshield et al. (1980) demonstrates the complex interactions between a number of factors which all influence the mechanical stability of hip arthroplasty. The use of a collar on the femoral stem has been proposed as a mechanism to transfer axial stress to the cortical bone in an attempt to conserve cortical bone proximally and to prevent distal migration of the component. With cemented components the collar may be designed to load the cement or the bone; some designs do not include a collar. The vast number of different collar designs on the market indicates that the exact role of the collar is not completely understood. To enable the collar to perform correctly, an exact collar-calcar contact must be made, and in cemented hip arthroplasty this is rarely or never achieved (Fagan and Lee, 1986).

The effect of prosthesis-cement bonding due to surface finish has been investigated by Miles (1990) by measuring axial strain in the cement mantle in a double tapered model testing with a polished stem and a grooved/matt stem. The findings were of increased axial compressive strain with a polished stem and no significant difference in cement hoop strain between the polished and grooved stem. With low interfacial shear between the polished stem and the cement, the majority of the load is transferred by radial compression of the cement. The increased hoop strain is not a clinically relevant problem unless bone quality is poor. The result is that with a polished stem there is greater radial compressive loading of the cement-bone interface.

Mann et al. (1991) investigated straight and tapered femoral stems in a laboratory model. For the straight model, global stiffness decreased as the load increased and there was continuous slip at an applied load of 7900 N (10 times B.W.), no fractures occurred. Tapered stems showed a decrease in global stiffness as loading was increased, however the taper prevented the stem from slipping through the cement column. Vertical displacement was approximately zero until an applied load of

15000 N (20 times B.W.) was administered. Failure occurred due to longitudinal fractures of the cement. At low load levels there were high strains at the distal outer cement column but lower proximally. There was large shear stress and initial slip of the stem at the distal tip which increased with loading. They suggest that slip at the p-c interface begins at the distal tip and progresses proximally. The loads that were required to result in migration are not in the physiological range and the findings should be interpreted accordingly and not extrapolated to the clinical situation.

When they compared their experimental studies with their theoretical studies, they found they could model cement using Coulomb friction interface elements at the p-c interface. At the time of completion of cement curing, there exists a residual stress in the cement, consisting of longitudinal tensile stresses. Although they did not define the surface roughness of the prosthesis used, they found no adhesive bond between the stem and the cement. They conclude that in the absence of any chemical or mechanical bond of the stem to cement, the load transfer is described by Coulomb friction at this interface.

Manley et al. (1985) investigated the effect of surface finish in a laboratory model with plastic bones. The polished implant showed irreversible subsidence and an increase in tensile hoop strain. This study found these differences at 29 kN (41 times B.W.) which is clearly not physiological loading. The experiment used only proximal fixation with no distal support to determine the effect on the distal cement mantle. The results of this study have little relevance to the current problem of surface finish.

The Exeter femoral prosthesis is a polished, collarless, double tapered stainless steel prosthesis that has been noted to move distally within the cement mantle without disruption of the cement-bone interface and retention of the medial bone stock (Fowler et al.1988; Lawes et al.1988). The biomechanical philosophy of a collarless, double-tapered, highly polished femoral stem is that the prosthesis-cement interface has a low co-efficient of friction and therefore minimal shear force is transmitted at this interface. The axial load is transferred to the cement as shear force, radial force and hoop stress (Lee, 1990). With a polished stem, the ratio of shear to radial compressive force changes with loading such that there is relatively less shear at the prosthesis-cement interface. As cement is able to creep under load the result is that cement will remain compressed into the bone as the prosthesis subsides (moves distally) within the cement mantle. The prosthesis requires a centraliser to ensure an even cement mantle around the prosthesis and this must be hollow such that the prosthesis does not load the cement via the distal tip and is therefore allowed to subside into the cement mantle.

1.7. Micromotion and Aseptic Loosening

The recent literature (Sugiyama et al.1989; Harris et al.1991; Nunn et al.1989; Burke et al.1991; Maloney et al.1989) includes many assessments of the amount of micromotion measured in explanted femoral components but little is written regarding the amount of micromotion that is detrimental to bone ingrowth into porous coated components or likely to lead to cement fracture and mechanical failure of cemented components. Micromotion at the prosthesis-bone interface is thought to be the limiting factor for bone ingrowth of cementless components and 150 μm was initially considered the upper limit of acceptable motion, based on the fact that it is half the average pore size of commonly used prostheses (Burke et al.1991). There has been no limit set for cemented femoral components.

1.7.1. In vivo Studies of Micromotion

The amount of micromotion permissible has been addressed in several in vivo studies performed in the distal femur. These studies are performed as controlled studies in the distal lateral femoral condyle in animals and therefore the results should be viewed with some reservation when comparisons are made to the human THA where complex forces are known to be present at the prosthesis-bone interface.

Burke et al. (Burke et al.1991) developed a canine model to observe further the effects of controlled micromotion in vivo. Micromotion of 40 μm resulted in excellent bone ingrowth into the porous coating, however the calcified bone in the porous mesh was not in continuity with the host bone. Motion of 150 μm resulted in no bony ingrowth and the appearance of dense fibrous tissue at the interface. Aspenberg et al. (1992) found that bone ingrowth (in a cementless model) was inhibited by 20 cycles of 500 μm movement applied during a 30 second period once daily. Soballe et al. (1992) demonstrated that 150 μm of controlled dynamic axial micromotion inhibited bone ingrowth and lead to the development of a fibrous membrane. Pilliar et al. (1986) found that bone ingrowth can occur with movement up to 28 μm, while excessive movement of 150 μm results in attachment by connective tissue.

There has not been a study that examines the amount of controlled micromotion to a cemented implant. There have been no studies that measure in vivo micromotion of cemented femoral components at either the prosthesis-cement or cement-bone interfaces during normal loading of the hip joint.

1.7.2. Ex vivo Micromotion testing

Micromotion of explanted cemented femoral components may be measured in many ways; what is common to all methods is loading the femoral head of the arthroplasty with a certain load based on predicted loading of the hip joint during certain activities and recording micromotion with respect to the bone at one or more places.

The early studies on failure of femoral components assessed failure due to axial loading of the component. More recent studies have investigated the effects of torsional forces and rotational fixation in an attempt to reproduce the physiological forces seen around the hip joint that may result in clinical failure (Sugiyama et al.1989; Harris et al.1991; Nunn et al.1989; Burke et al.1991; Maloney et al.1989). The study of torsional forces has resulted in the development of complex testing devices to reproduce and measure these out of plane forces (Maloney et al.1989; Cuckler, 1991; Page et al.1991).

Many groups are attempting to reproduce the physiological loading of the femur in the laboratory by simultaneously loading extensor and abductor straps attached to the femur to simulate the normal muscle forces acting on the femur. It is impossible to reproduce the exact loading seen by the hip joint unless all muscle groups are attached anatomically and loaded precisely. The complication of femoral shaft fracture in some studies (Maloney et al.1989; Fischer et al.1992) suggests that this loading is far from physiological. Furthermore destruction of the femur in cases of greater micromotion leading to fracture prevents further detailed histological assessment. In many cases large holes are drilled in the femoral shaft to allow distal micromotion to be measured and this prevents histological assessment in the area where the micromotion was recorded.

1.7.3. Micromotion Testing Models

The Harris group have developed a model to measure micromotion under both simulated single leg stance and stair climbing in explanted femurs (Maloney et al.1989; Burke et al.1991). The model consists of a simulated pelvis which allows application of a load acting at the centre of gravity; woven nylon straps simulate the abductor and extensor muscles, and the knee joint is represented by a non constrained knife edge joint to eliminate non physiological bending moments. Similar studies have been performed using an in vitro canine jig that loads through the explanted pelvis (Page et al.1991).

The loading apparatus is used to apply stair climbing loads (Stracher et al.1988; Burke et al.1988) and single leg stance loads (McLeish and Charnley, 1970). Micromotion was measured between prosthesis and bone using electrical displacement transducers (Extensometers, MTS Corporation, Minneapolis, USA). Clearance holes must be made in the femoral cortex to allow positioning of the device, a cylindrical metal pin was press-fitted into the prosthesis and by positioning the transducer in either a horizontal or vertical direction, both axial and transverse motion can be recorded. The device is attached 3 cm distal to the collar and as such only measures proximal motion.

Lanyon, Radin et al. (Lanyon et al.1981; Radin et al.1982) have been investigating loosening in an in vivo Sheep model for many years, comparing the biological and mechanical processes that initiate loosening. Their data has included strain data in vivo (Lanyon et al.1981) and explant mechanical tests (Radin et al.1982). Torsional rigidity was recorded using a method that also assessed the contra lateral femur as the control femur. Both femora were potted in Plastic Steel to a level below the prosthetic collar. The femoral head had a moment arm attached and the prosthesis was loaded through the moment arm and motion recorded with displacement transducers attached to the moment arm at 0.80 Newton-meter of torque (well below the animals normally imposed walking torque). Torsional rigidity was reported as a percent of the contralateral unoperated femur (rigidity ratio).

Vanderby et al. used a canine model to compare fixation stability of cemented and porous ingrowth THR (1992). Animals were sacrificed at 4 months. Control femurs were used but prostheses inserted ex vivo. Measurements were recorded with eddy current transducers in 3 axes at two positions (femoral neck and mid-shaft) but not recorded simultaneously. Static loads were applied in three directions and repeated until results were reproducible to differentiate micromotion from the initial subsidence of the cementless prostheses. The measurement device has a long arm and there is potential for error, as noted by the authors. There is a noted difference in the results from the neck and the shaft, with the neck having consistently higher readings. The conclusions from this study are that torsional forces play an important role, and like most other studies they do not give ranges of detrimental motion or normal motion which may be beneficial for the healing process.

Freeman et al. looked at the mechanical advantages of retention of the femoral neck as a promotion of the Freeman prosthesis (1989). The group measured motion in prostheses inserted into cadaver femora and loaded them anteriorly and studied the motion at the proximal interface with varied design features. Bones were mounted in steel cylinders and fixed with cement, a load was applied anteriorly and measured with a strain gauged cantilever device attached to the greater trochanter. The method only measures motion in one plane and at one position. The rigid fixation of the femur in a steel cylinder is non physiological, however, it attempts to isolate the interface and minimise the effects of bone compliance.

There are many other studies that have measured micromotion in femurs with cementless femoral components (Whiteside and Easley, 1989; Sugiyama et al.1989; Pilliar et al.1986; Engh et al.1991; Burke et al.1991; Schneider et al.1989; Phillips et al.1991; Otani and Whiteside, 1992; Otani and Whiteside, 1992; Otani et al.1993; Otani et al.1993). These have not been included as they are mainly studies investigating the effects of porous surface coating and canal fit with initial cementless stability. These studies are not relevant to this thesis, however, the methodology in these studies is similar to that described above.

1.7.4. Measured Micromotion from Ex vivo Studies

Burke et al. (1991) used laboratory implanted cemented femoral stems in cadaver femurs to measure micromotion with loading that simulated single leg stance. The mean axial micromotion of the cemented component was 11 μm (SD 15) and the mean transverse micromotion was 6 μm (SD 6). During stair climbing, the mean axial micromotion was 6 μm (SD 6) and the mean transverse micromotion was 26 μm (SD 28) with a range of 2-76 μm. The results for cementless components showed greater variation in the stability during simulated stair climbing with two of the seven components moving 200 μm or more. These findings of cadaver femurs can be regarded as the gold standard for micromotion of implants inserted into a well prepared canal without the effects of capillary blood pressure at the cement-bone interface. The results can be compared with another study performed by the same authors (Maloney et al.1989), who measured the same parameters for clinically "solid" cemented femoral components at autopsy retrieval.

In the study of eleven autopsy retrieved femurs with cemented total hip arthroplasty all components were stable clinically and radiographically at the time of death of the patient and retrieval of implants (Maloney et al.1989). The same method as described above was used to measure axial, transverse and rotational micromotion. Axial micromotion ranged from 0 - 40 μm with no consistent trends between the single stance measures and the simulated stair climbing. Transverse micromotion ranged from 4 - 90 μm for the single stance measurements and from 32 - 155 μm for the simulated stair climbing, with the stair climbing measurements being at least three times greater than the single limb stance. Rotational torque testing (171 Nm) varied from 10 - 300 μm with no trends between any of the other measurements suggesting that the three methods measure different properties of the interface.

The data suggest that out of plane forces are important for understanding the biomechanics of total hip arthroplasty. Two specimens fractured at the tip of the prosthesis during simulated stair climbing, one of these components had transverse micromotion of 90 μm during single limb stance measurements (the majority of components 10 - 20 μm).

The definition of mechanical loosening still remains unclear despite the large amount of data from the above studies (Maloney et al.1989; Burke et al.1991). The prostheses appear to be solid histologically and despite the intimate cement-bone inter digitation there is motion of 10-300 μm between the prosthesis and the bone. It is unclear whether this motion is acceptable in the long-standing prosthesis although perhaps unacceptable in the immediate post operative period to enable healing at the interface.

In these longstanding prostheses, which were stable at the death of the patient, there is no evidence to suggest that physiological loads resulted in fracture of the femoral shaft. However, the method of testing of the Harris group (Maloney et al.1989; Burke et al.1991) resulted in several femurs being fractured below the prosthesis. This suggests that non physiological loading conditions were applied and the amounts of measured micromotion were actually greater than in vivo.

Histology found trabecular bone intimately associated and interdigitated with the cement mantle, no fibrous tissue intervening, small cement fractures primarily at the prosthesis-cement interface and within cement voids. The finding of fatigue striations in the small cement fractures suggests a repetitive loading strain must have been applied, not a non physiological load such as that provided by the stair climbing device. The histological analysis noted the profound osteoporosis around the prosthesis and the development of the neocortex. Trabecular bone is easily deformed and perhaps the micromotion measured the compliance of the remodelled bone.

The main criticism of the study is that although control femurs were assessed, there is no mention of the micromotion of the control femurs. The results of the cadaver study may be compared as controls, however they are not aged matched controls.

Fischer, Carter and Maloney (1992) performed in vitro assessment on the effect of a collar in providing rotational stability. The load magnitude of the stair climbing regime was such that femoral shaft fractures occurred at 2200 N (approximately 3 times body weight). Again this loading is not physiological and provides further caution to the use of complex testing devices to resemble physiological loading. The micromotion is reported at a load of 650 N which is less than one times body weight and the values reported in this study are therefore below physiological loading and meaningless.

What still remains uncertain is where the micromotion being recorded is occurring and whether the micromotion is due to interface slip between materials, elastic deformation of the bone, cement or femoral component or more likely, a combination of all of these. The effects of tissue hydration and fixation on the mechanical properties of the bone and interface tissues are not entirely known and therefore testing the specimens fresh would be an advantage.

1.8. Summary

The incidence of aseptic loosening of cemented femoral components is variable and only now are we seeing the results at twenty years; many studies at twenty years have found the incidence of aseptic loosening to be around 5% (Mikhail et al.1988; Schulte et al.1993). The factors under control of the surgeon include selection of prosthesis type, cementing techniques and surgical craftsmanship.

Laboratory and clinical studies support the importance of improved cementing techniques which include distal canal restriction, canal cleaning with pulsatile lavage and pressurised injection of cement, however many clinical studies using first generation cement techniques have surprisingly good results (Schulte et al.1993). An inadequate cement mantle and voids in the cement appear to be associated with a higher incidence of cement fractures and production of particle debris. As initially thought by Charnley, an intact cement mantle may be well tolerated.

The selection of the type of femoral component to be implanted remains controversial. Leaving aside the choice between cemented and cementless, the main design features of femoral component cemented hip arthroplasty are the type of surface finish and the use of a medial load bearing collar. There is no strong support in the literature to suggest that maximising or minimising the bond at the prosthesis-cement interface will reduce the incidence of loosening. There are no clinical studies that show a collar is essential to prevent loosening.

The findings of the studies performed by Gardiner and Hozak (1994) and Rockborn and Olsson (1993) suggest that the matt surfaced Exeter femoral component and other components designed to improve prosthesis-cement bonding may not increase bonding and reduce the incidence of aseptic loosening. The matt surfaced femoral stems may be the cause for an unacceptable level of loosening (Ahnfelt et al.1990).

Biological and mechanical factors appear to be closely related and cannot be separated in the investigation of the aetiology of loosening. Particulate wear debris is associated with the formation of a fibrous membrane at the cement-bone interface, as is controlled micromotion in the absence of particulate debris.

Micromotion of less than 30 microns at the cement-bone interface appears well tolerated in vivo. However micromotion of 100 to 300 microns is not tolerated in a controlled setting and results in fibrous tissue ingrowth into porous coated implants. The amount of acceptable micromotion remains uncertain, however it would appear that the acceptable level is between 50 and 100 microns.

Chapter 2

Hypotheses and Study Design

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2.1. Introduction

A major controversy in cemented hip arthroplasty is whether to use a femoral stem with a polished surface that achieves little bond to the cement or to use a matt surface, with or without additional features such as a collar, to enhance bonding to cement (Harris, 1993; Ling, 1993). Surface finish of the femoral stem is thought to influence the way that load is transferred from the stem to the cement and bone and thereby loosening of the femoral component (Lee et al.1990).

Polished femoral stems have been associated with decreased loosening of hip replacements and less osteolysis at 17 years follow-up (Fowler et al.1988). The polished surface in conjunction with a collarless double tapered design is thought to be advantageous for the effective transmission of load from the femoral component to the femoral bone. A polished tapered stem is proposed by its designers (Fowler et al.1988; Lawes et al.1988) to allow subsidence of the stem within the cement mantle which is thought to enhance fixation. On the other hand, Harris (1993) regards any movement of the component from the position immediately after implantation as evidence of prosthesis loosening.

Jasty et al. (1991) propose aseptic loosening of the cemented femoral stem is initiated by mechanical failure of the stem-cement bond. Retrieved human femoral stems from clinically successful joint replacements were found to have an intact cement-bone interface with minimal fibrous tissue in all cases. Areas of "debonding" of the cement from the prosthesis and cement mantle fractures were common and increased in frequency with time after implantation (Jasty et al.1991). Jasty et al. (1991) have proposed that long term failure is initiated by "debonding" of the interface between the prosthesis and the cement.

The interpretation of the study by Jasty et al. (1991) is controversial as the findings could equally suggest that loss of stem-cement bonding is necessary for long term success. The theory promoted has been accepted on face value by the majority of the orthopaedic community without critical analysis. Because of the belief in the theory that "debonding" is the initiating factor of failure, support has been given to femoral component designs which increase stem fixation in cement and designs which include a matt surface and a collar.

Despite this controversy, polished collarless, matt collarless and matt collared prostheses are successful clinically. However, recent review of results from a national data base suggest the matt collarless tapered stem of the Exeter design may have higher loosening rates than the polished collarless Exeter prosthesis (Ahnfelt et al.1990). No clinical study to date has compared the early or late loosening of a polished and a matt surfaced finish femoral stem with or without a collar. No study has investigated the subsidence of femoral stems with different surface finish or collar in an *in vivo* model nor investigated the micromotion of femoral stems with different surface finish or collar in an *in vivo* model.

2.2. Hypotheses

This thesis examined the differences in behaviour of a polished versus a matt surfaced femoral stem. The primary hypotheses tested were:

At nine months after implantation a polished surfaced prosthesis will show radiographic evidence of subsidence at the prosthesis-cement interface whereas a matt surfaced prosthesis will not.

At nine months after implantation there is less axial micromotion between a polished surfaced prosthesis and bone than between a matt surfaced prosthesis and bone.

The following secondary hypotheses were tested by examining the differences between three femoral stem types, a polished collarless, a matt collarless and a matt collared.

Over the nine months from implantation a polished surfaced prosthesis will show radiographic evidence of subsidence at the prosthesis-cement interface whereas a matt surfaced prosthesis either with or without a collar will not.

There is less micromotion between the prosthesis and bone with a polished surfaced prosthesis than with a matt surfaced prosthesis, with or without a collar, at nine months after implantation.

There is less micromotion between a matt surfaced prosthesis, with or without a collar, and the cement mantle than between a polished surfaced prosthesis and the cement mantle immediately after implantation.

2.3. Aims

To test the hypotheses, the study was designed with the following aims:

to develop a sheep hip arthroplasty model that could be used to examine the biomechanical response to cemented hip arthroplasty;

to measure subsidence at the prosthesis-cement and cement-bone interfaces over a nine month period;

to measure micromotion at the prosthesis-bone and prosthesis-cement interfaces immediately after implantation and at nine months following implantation;

to describe the radiographic features of the cemented hip arthroplasty over a nine month period;

to describe the histological features of cemented hip arthroplasty immediately after implantation and at nine months following implantation.

2.4. Study Design

2.4.1. Calculation of Sample Size

Because a study of this type had not previously been performed in animals, the sample size required to test the first hypothesis was calculated by using the expected results based on the most relevant human study (Fowler et al.1988).

The study was based on the premise that there would be initial subsidence of the prosthesis in the cement mantle in the first nine months. Fowler et al. (1988) measured the amount of subsidence which occurs at the prosthesis-cement interface in 426 polished and 92 matt surfaced prostheses. The polished prostheses were measured to subside 1.5 ± 1.0 mm and the matt prostheses 0 mm. These measurements were used to calculate the sample size required for this study.

The type I and II errors were assigned as α = 0.05 (two-tailed) and β = 0.20. The sample size required was determined by using the t-test to compare means of continuous variables and calculated to be seven sheep per group (Hulley and Cummings, 1988). This number may be an underestimate because of the small study numbers (Hulley and Cummings, 1988), therefore a group size of at least 8 was the first estimate.

Review of the relevant literature of sheep hip arthroplasty (Phillips et al.1987; Phillips and Gurr, 1989; Lanyon et al.1981) suggested a 10 % complication rate may be expected. This would prevent the sheep from completing the treatment and so the revised sample size (N') to account for drop-outs was obtained by the following formula (Lachin, 1981).

Therefore ten animals were included in each group.

$$N' = \frac{N}{[1-R]^2}$$

N' = revised sample size N = first estimate sample size
R = drop-out rate

2.4.2. Study Animals

A flock of sheep from a single breeder was purchased for this study. This provided a uniform genetic and life background for the sheep in the study so as to ensure as little variation between the trial animals as possible. Obtaining a flock in this manner also provided a home flock for the sheep to return to, so as to enhance recovery and was thought likely to enhance consistency of rehabilitation.

2.4.3. Study Groups

Forty sheep were assigned to this study. This provided three study groups of ten sheep, those receiving a polished collarless stem, those receiving a matt collarless stem and those receiving a matt collared stem. Ten extra sheep from the same flock were available if required to replace study group sheep should the drop-out rate be higher than expected.

2.4.4. Inclusion and Exclusion Criteria

An independent veterinary surgeon examined the animals to assess physical fitness before inclusion in the study. Four-tooth mature Merino wethers were used. Standard vaccinations were undertaken. Only animals greater than 60 Kg were included in the study.

2.4.5. Stratification and Randomisation

The study groups were not stratified.

Randomisation was performed using computer generated random numbers. The last digit of each random number was used to determine the prosthesis type: if the last digit was one, two or three the sheep was assigned to receive a matt collared prosthesis, if the last digit was four, five or six the sheep was assigned to receive a matt collarless prosthesis and if the last digit was seven, eight or nine the sheep was assigned to receive a polished collarless prosthesis. The sheep were randomised until one study group contained one third of the study size and then all remaining sheep were randomised into the other two groups (Hulley and Cummings, 1988).

2.4.6. Study Logistics

The sheep were assigned a study number that was independent of the prosthesis type. Operative details and assessment data were collected using standardised forms that did not include the prosthesis type of the sheep being assessed.

All attempts were made to blind the surgeon and investigators as to the prosthesis type. The prosthesis type was determined by an independent person opening the envelope containing the prosthesis type and this person opened the prosthesis. The surgeon did not see the type of prosthesis until the time of insertion. The results were analysed without knowledge of the prosthesis type except that the collared prostheses could be identifed on the plain radiographs and the surface finish and collar identified during the mechanical testing.

2.4.7. Drop-out from the Study and use of Replacement Sheep

Prior to the commencement of the study it was decided that any of the following complications would resulted in drop-out from the study; femoral shaft fracture, unstable joint at the time of surgery or post-operative dislocation, infection, clinical evidence of pain, lameness and failure to complete the post operative program, intra-operative death or death because of unrelated causes.

At six months from the commencement of the study an independent person reviewed the complications resulting in withdrawal from the study. The number of sheep surviving with each prosthesis type was calculated. The number of replacement sheep required to ensure that seven sheep would complete treatment was calculated. Replacement sheep were randomly selected and allocated a prosthesis type.

2.4.8. Control of Bias and Study Blinding

Review of the literature relating to animal arthroplasty (Crowninshield et al.1980; Sumner et al.1988; Lanyon et al.1981; Phillips et al.1987; Eitel et al.1981), sheep cadaver dissections and laboratory studies performed prior to the commencement of the study identified several factors which might introduce bias and error to the study. To minimise bias and error, the following steps were taken;

The prostheses were made of stainless steel and all were of identical double tapered geometry.

The sheep were chosen with a similar genetic background so as to decrease variation due to skeletal size, age and bone remodelling rate. Skeletally mature sheep were used to minimise the change in skeletal size which is seen in skeletally immature animals.

A template was used for the femoral neck osteotomy and the femoral canal was prepared with a standard rasp. This increased the likelihood of a similarly shaped cement mantle for each arthroplasty.

The prostheses for assessment at nine months and those for assessment immediately after implantation were inserted under the same operative conditions. The same amount of fluid replacement was given intra-operatively.

The sheep were walked four kilometres per day, five days per week for nine months to ensure a minimum amount of exercise for each sheep.

2.5. Statistical Analysis

The data analysed statistically was continuous and independent data. Because of the small study numbers, a normal distribution could not be assumed. There were occasional missing values for each analysis, therefore some of the analysis was unbalanced. Because the study numbers were small, the data are presented in scatter plot form.

It was decided to analyse the differences for the two primary hypotheses using a single statistical test for each hypothesis. Analysis of the secondary hypotheses should allow for repeated measurements made from the same study sheep. It was decided to take the following approach to the analysis.

The first hypothesis

> At nine months after implantation a polished surfaced prosthesis will show radiographic evidence of subsidence at the prosthesis-cement interface whereas a matt surfaced prosthesis will not.

was tested with a single measurement of prosthesis-cement subsidence at nine months after implantation. Analysis was performed using a Mann Whitney U-test. A significant p-value was defined as p less than or equal to 0.05.

The second hypothesis

> At nine months after implantation there is less axial micromotion between a polished surfaced prosthesis and bone than between a matt surfaced prosthesis and bone.

was tested with a single measurement of prosthesis micromotion at nine months after implantation. Analysis was performed using a Mann Whitney U-test. A significant p-value was defined as p less than or equal to 0.05.

For analysis of the secondary hypotheses the three prosthesis types were assessed together. Statistical analysis of the differences of multiple measurements of subsidence and micromotion was performed by using an Unbalanced Repeated

Measures Model with Structured Covariance Matrices (BMDP Statistical Software, Los Angeles, USA).

The Unbalanced Repeated Measures Model determines the significance of the different variables that may have influenced the measurement taken. For subsidence, the variables are implant type and time after implantation for the different markers used to measure subsidence. For micromotion testing, the variables are implant type and whether the measurements were made immediately after implantation or at nine months after implantation for the different interfaces at which micromotion was recorded and the three different tests performed.

The statistical analysis calculates a common equation for all the data of the relevant test and then compares this equation with equations that fit the data from each of the three prosthesis type groups, time after implantation and any other effect that may be investigated. The equations calculated are represented by a linear and a quadratic component.

Statistical analysis performed on the subsidence data calculates the linear and quadratic components of the individual equations for each implant type over the nine month period from the common equation of all data. This is important for the subsidence analysis to determine any difference due to time after implantation. For the analysis of subsidence, three p-values are calculated for each created equation.

From the calculated equations, statistically predicted representative measurements (representative values) were calculated for the different measurements made with respect to each implant type and time after implantation. These values reflect the central tendancy of the data and are similar to median or mean values.

This method allows analysis of all the data and simplifies the statistical analysis by investigating differences between implant types and time after implantation in a single analysis.

2.6. Ethical Approval

Institutional ethics approval was obtained for this study based on the study design and sample size calculations above. All procedures were performed under the ethical guidlines of the institution.

Chapter 3

Sheep Hip Arthroplasty

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3.1. Introduction

The biological response to total hip arthroplasty has been investigated using animal models in the past and for this the dog has been used extensively (Vanderby et al.1992; Vanderby et al.1989; Dogan et al.1991; Sumner et al.1992; Turner et al.1986; Sumner et al.1992; Goethgen et al.1991; Manley et al.1989; Page et al.1991; Bobyn et al.1992; Jasty et al.1992; Hedley et al.1983; Hedley et al.1993). Anatomically and biomechanically, the dog hip is similar to the human hip (Bergmann et al.1984; Goel et al.1982; Bloebaum et al.1993). However, use of the dog for experimental surgery in large numbers is limited in many communities by ethical and financial considerations. Many studies have used dogs of different breeds, skeletal size and age. These variables will alter the biological response to cemented hip arthroplasty.

The sheep has a number of advantages for hip replacement studies. Sheep are readily available at low cost and may be purchased with a high degree of uniformity in breed, age and size. Their docile nature and ease of handling has been noted (Phillips et al.1987). Rehabilitation can be undertaken at a field station rather than at a specific housing facility. The biomechanical similarity of the sheep to the human femur has been noted (Bergmann et al.1984), anatomically the sheep femur is similar to the human (Bloebaum et al.1993; May, 1977), though the internal morphometry is dissimilar (Goel et al.1982). The sheep has been used successfully in a number of hip arthroplasty studies (Lanyon et al.1981; Radin et al.1982; Phillips et al.1987; Eitel et al.1981). However to date there has not been a detailed description of the model.

3.2. Prosthesis Design and Development

The prosthesis for this study was specially designed and manufactured for insertion into the sheep femur by Howmedica International (Staines, United Kingdom). The geometry of the prosthesis was based on morphometric data from ten skeletally mature Marino wethers, identical to those used in the study. Standard measurements of femoral head diameter, cortical and endosteal bone widths of the proximal femur and longitudinal length of the femur were assessed from plain radiographs (Figure 3.1).

The "Sheep Femoral Prosthesis" was based on the Exeter philosophy of a highly polished, double tapered, collarless femoral stem (Figure 3.2). The prosthesis was designed to be inserted with a cement mantle of 2 mm anterior and posterior, and 3 mm medial and laterally. The prosthesis was also designed to be used with a distal cement restrictor and a prosthesis centraliser distally. The sheep femoral head is less spherical than the human. The femoral head maximum diameter of the ten sheep measured had a range of 24-28 mm. In this study the prostheses were produced with three femoral head diameters (24, 26 and 28 mm).

The prostheses were made of forged stainless steel and three versions of the prosthesis were made. One version had a highly polished surface and was collarless (polished), the second had a matt surface and was collarless (matt) and the third had a matt surface and a medial cortex loading collar (collared) (Figure 3.3). The surface roughness assessment of the matt and polished surfaces showed over one order of magnitude difference (Polished Ra = 0.02 - 0.04 μm, Matt Ra = 1 μm). The relevant human prosthesis values are Exeter Polished Femoral Stem (Ra = 0.02 - 0.04 μm), Exeter Matt Femoral Stem (Ra = 1 μm), Precision (Ra = 6 - 10 μm).

As the polished surface prosthesis required a double tapered femoral stem geometry to theoretically allow distal migration of the stem within the cement mantle it was decided to use this shape for all prostheses. While this may not be the optimal design for a matt collarless or matt collared prosthesis, it is not detrimental as several implants are commercially available with matt surface and collar with this shape. The sheep femoral prosthesis was inserted as a hemiarthroplasty. It was decided not to use a polyethylene acetabular component as this might have complicated the histological analysis with polyethylene wear debris.

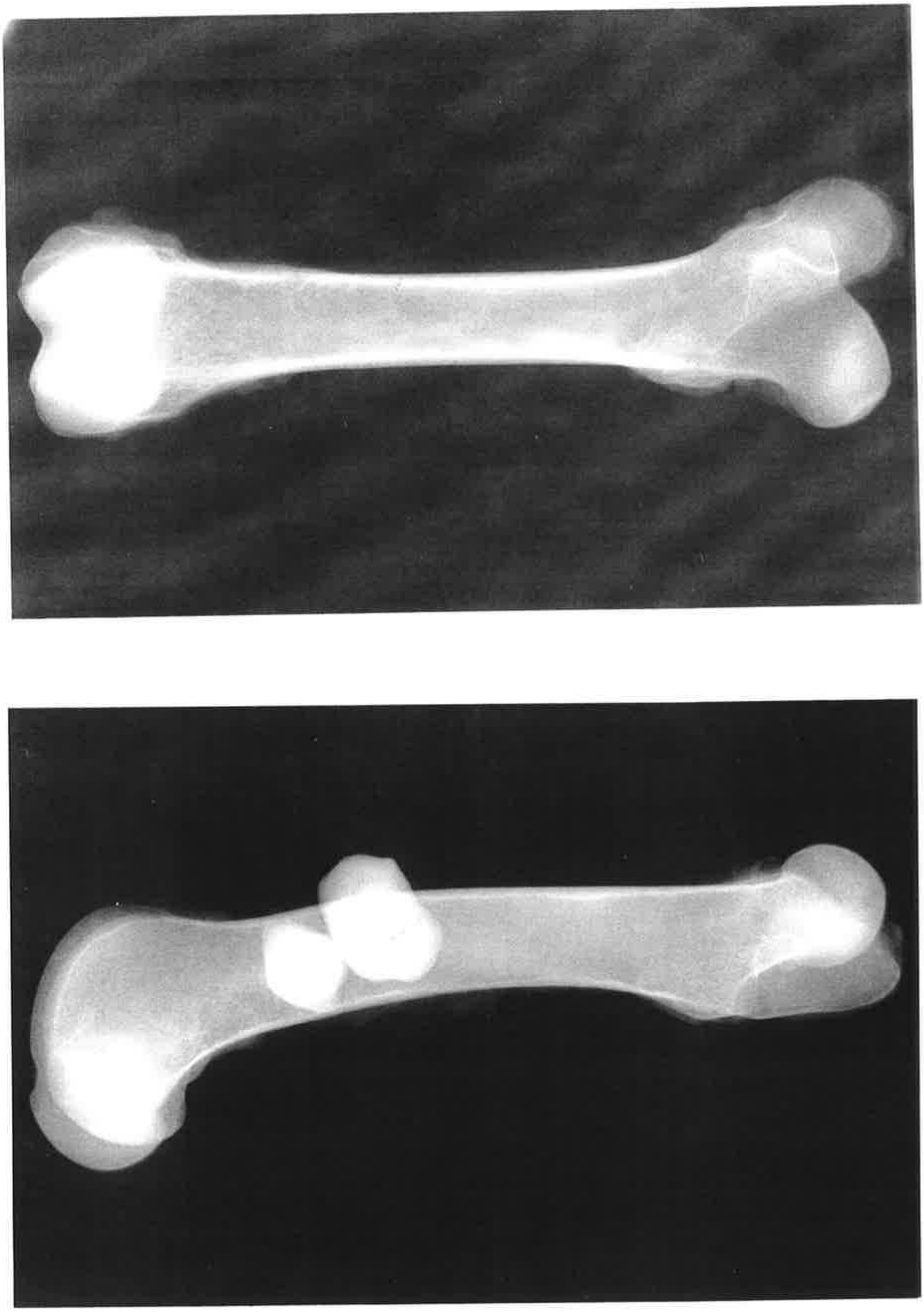

Figure 3.1. Sheep femur morphometry

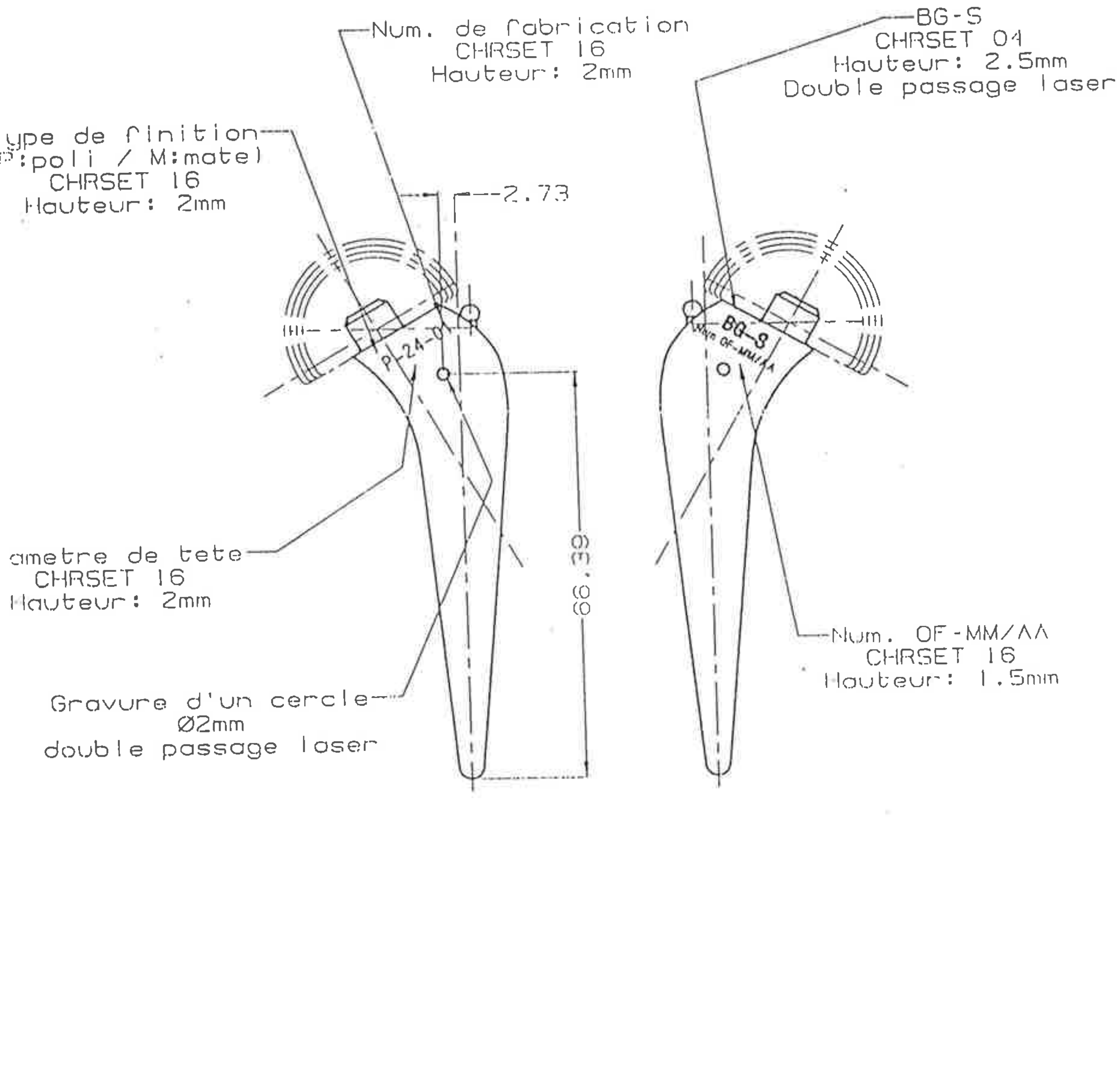

Figure 3.2(a). Design diagrams for polished and matt stems

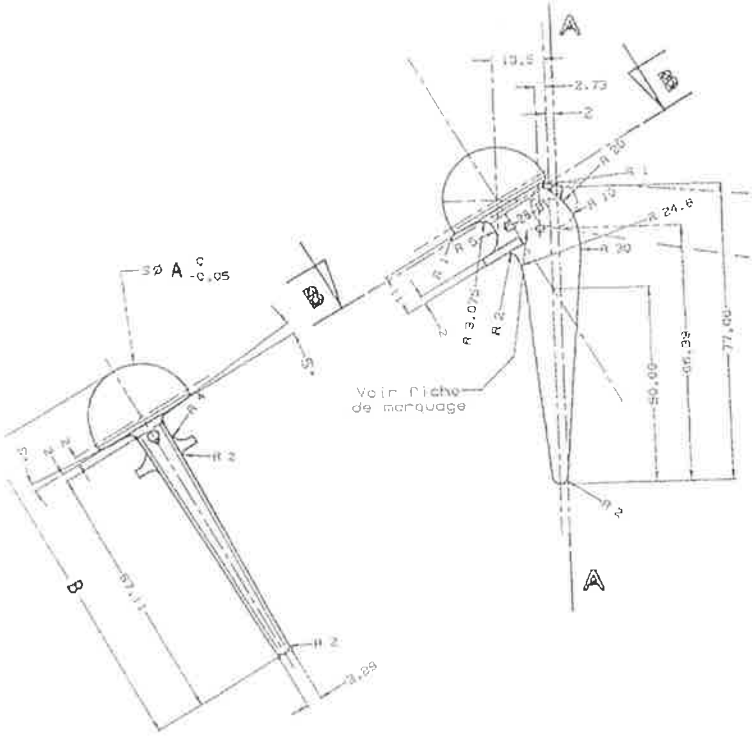

Figure 3.2(b). Design diagrams for collared stem

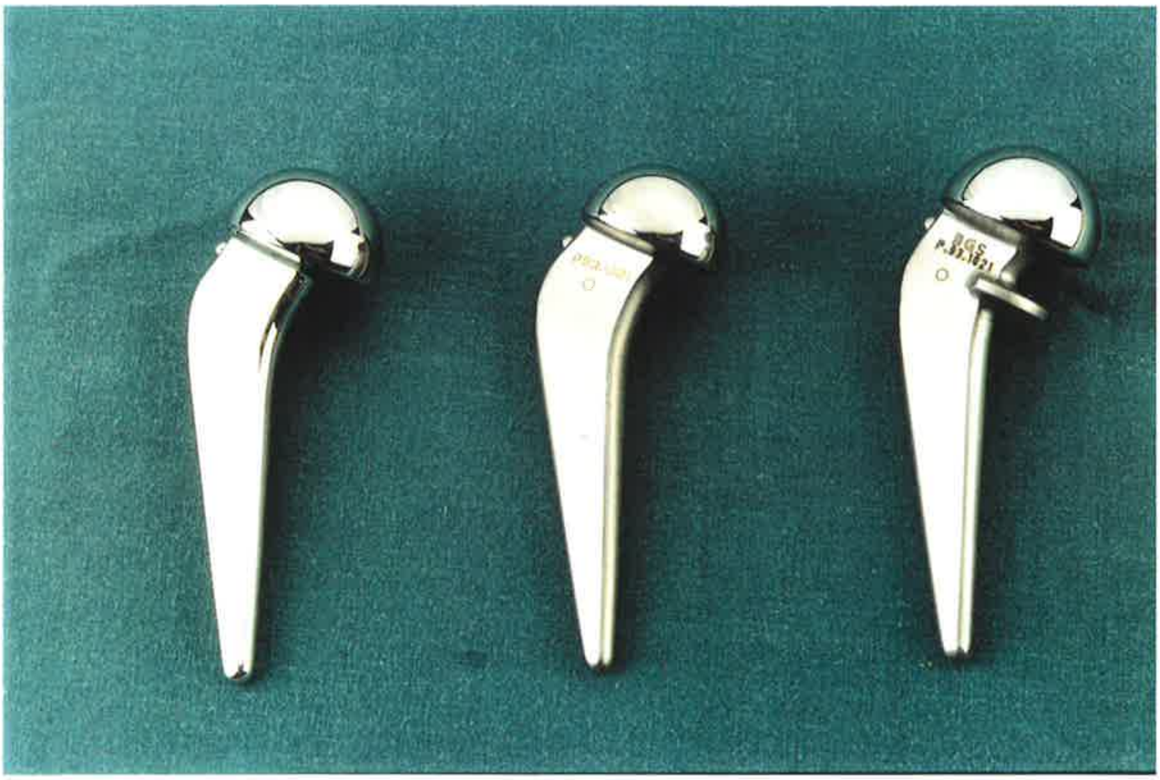

Figure 3.3. Sheep Hip prostheses (polished, matt and collared)

3.3. Materials and Methods

3.3.1. Operative Procedure

30 sheep (10 polished, 10 matt, 10 collar) and 5 replacement sheep (identical implants as described in chapter 3) underwent unilateral left cemented hip hemi-arthroplasty under general anaesthesia. This was performed by one surgeon and one assistant.

3.3.2. Anaesthesia and Antibiotics

A general anaesthetic was administered. Induction was with intravenous thiopentone 1g (Pentothal, Abbots, Australia) and the sheep was intubated but then permitted to breathe spontaneously. Anaesthesia was maintained with nitrous oxide (300 ml/min), isoflurane (1.5-2.5 l/min) and oxygen (1 l/min) through the endotracheal tube. Intra-venous fluids (1000 ml Hartmanns solution) were given intra-operatively to prevent hypovolaemia due to blood loss and hypotension during cement insertion.

Antibiotic cover was provided by Penstrep 2 ml per 50 kg (Penicillin 250 mg/ml, Streptomycin 250 mg/ml, Penstrep, Ilium, Australia), given at time of induction and twice daily for three days. Analgesia was provided as required in the post operative period with Methadone (0.1 ml per 10 kg).

3.3.3. Preparation

The sheep was placed in the right lateral position with the left hip uppermost. The hind limb was closely shaven and washed with soap and water. The skin down to the hoof was degreased with 70 % Alcohol and then prepared with povidone-iodine solution. The hind limb was free-draped with a sterile drape up to but not including the stifle joint (knee joint).

Surgical instruments were sterilised and placed on four trays and disposable equipment was opened in a sterile manner and placed on the trays (Figures 3.4 - 3.7).

3.3.4. Anatomical Exposure and Dissection

A curved skin incision (convex caudal) was made centred over the greater trochanter extending distally ten centimetres in line with the femur and proceeding six centimetres above the trochanter (Figure 3.8). The deep fascia was incised and the biceps femoris muscle identified caudally. The cranial margin of the muscle was defined and retracted caudally behind the greater trochanter (Figure 3.9). The gluteus medius running supero-cranial from the greater trochanter and vastus lateralis running inferiorly were identified and the fatty tissue lying between them was cleared (Figure 3.10). Lying in the interval between gluteus medius and vastus lateralis is a small muscle, gluteus superficialis (the human gluteus maximus analogue), which was released. Huck towels were sutured to the margins of the wound. A Charnley retractor was placed beneath the deep fascia and a self-retaining retractor was positioned to separate the gluteus medius and vastus lateralis.

Lying deep to the gluteus medius is gluteus accesorious which inserts into the neck of the femur and capsule. The white shiny fascial surface is uppermost (Figure 3.11). The vascular bundle crossing gluteus accesorious (a muscular branch of the circumflex ilium profunda artery) was ligated and divided. A stay stitch was placed into gluteus accessorius and it was released close to its insertion (Figure 3.12). Gluteus profundus was identified as a separate muscle below gluteus accessorius. This muscle was released in conjunction with the hip capsule near its insertion along the femoral neck (Figure 3.12).

The hind limb was flexed and externally rotated to 180° and the capsule cleared with a Cobb elevator. An initial capsulotomy was performed parallel to the acetabular margin allowing access for dislocation of the hip joint. The joint was distracted by the assistant. A curved, blunt tipped bone lever was inserted into the joint, with care not to damage the acetabular articular cartilage. The femoral head was levered distally and the ligamentum teres was cut from its femoral insertion with Metzenbaum scissors. This was sometimes difficult as the ligament was relatively large and holds the joint securely in place (Figure 3.13). The hip was dislocated anteriorly by flexion, adduction and external rotation. The remnant of the ligamentum teres was removed from the acetabular floor.

The capsulotomy was limited to the anterior and superior margins of the joint as a complete capsulotomy or capsulectomy may result in unacceptable instability. The tissue about the proximal femur was mobilised so that the femoral canal was well exposed and so that the leg could be externally rotated by 90^{o}. This allowed correct prosthesis positioning.

3.3.5. Femoral Preparation and Prosthesis Selection

The Charnley retractor was repositioned such that there was maximal exposure of the femoral canal and the medial soft tissues were well cleared of the canal (to enable accurate insertion of the prosthesis without pressure from the soft tissues). The proximal femur was lifted with a specially designed elevator placed postero-medially. This needed to be done with care as the cortex was fragile and was preferably placed on the inter-trochanteric ridge. The preparation of the femoral canal required that there was free access to the proximal end of the femur.

The lateral cortex was exposed proximally by placing a small Homan retractor below quadratus femoris. This cortex must be seen to enable the neck cut to be made lateral. The base of the greater trochanter was also exposed such that the groove between the neck and the trochanter was visible. The soft tissues were retracted from the medial cortex of the femur with a Homan elevator to allow an unobstructed view.

The neck cut was marked by passing the neck cutting guide/template sub muscularly along the femoral shaft with the hip flexed and externally rotated ninety degrees (Figure 3.14). The neck cut was made at 90^{o} to the sagittal axis of the femur. A step cut was made axially at the medial border of the greater trochanter as lateral as possible to release the femoral head. Bone nibblers were used to remove all bone from the neck to the base of the greater trochanter.

The head of the femur was sized by passing it through the metal template. This template has holes of diameter 24, 26 and 28 mm. The appropriate prosthesis size was selected. The femoral heads were labelled and stored for future histomorphometric, bio mechanical testing or for bone graft.

3.3.6. Canal Preparation

The soft tissues were reflected as described above to allow vision of the entire proximal femur which was lifted out of the wound with a specially designed elevator placed postero-medially (Figure 3.15). This was done with care as the cortex is fragile and may fracture with excessive leverage. An osteotome was introduced in the lateral cancellous bone, in line with the lateral shaft of the femur and a small cube of cancellous bone was removed. The narrow T-handle straight tapered awl was introduced to the 1/3 mark with lateral rasping, then seated to the 2/3 mark with reaming. The awl was moved medially to remove further soft cancellous bone.

The custom made curved broach was then introduced by hand and rasping performed by hand, concentrating on lateral, proximal cleaning of the bone until the broach was 1/2 inserted. The broach was then seated three times with minimal rasping only to allow seating of the rasp in correct alignment. The dimensions of the rasp results in a prepared canal with a 3 mm clearance around the prosthesis in the medial-lateral direction and a 2 mm clearance in the A-P direction. The rasp was then rotated 180 degrees and inserted several times to remove lateral bone such that there was an unobstructed view down the lateral cortex and to allow the lateral cement marker to be inserted. If the rasp was not able to be fully seated, the distance proud was recorded. The canal was gently curetted with a large curette to remove intra medullary fat only, no bone was removed.

A cement restrictor (Universal, Howmedica, Staines, U.K.) was placed 10 cm from the cut edge of the neck of femur. This allowed a distal cement mantle of 1 cm from the tip of the prosthesis. The canal was brushed and then cleaned with pulsatile lavage (0.9% Normal Saline with 1 g Cephalothin).

The canal was then inspected with direct vision to ensure no fat remained and to confirm, two gauze swabs were inserted with the T-handle reamer and viewed to ensure a clean canal (Figure 3.16). The canal was then packed with a hydrogen peroxide (1.5 % H_2O_2) pack. This pack was made of 5 cm ribbon gauze or similar that has been soaked in H_2O_2 and then wrung out. An infant feeding tube was placed into the canal as a drain and then the gauze was introduced into the canal using the narrow T-handle broach. This enables the gauze to be placed as far distally as possible. When the pack was fully inserted the feeding tube was connected to the suction. When the packing was complete, the cement was mixed.

3.3.7. Cementing Technique

Simplex cement (Howmedica, Rutherford, New Jersey) was mixed by hand in a bowl with 60 rotations per minute for 60 seconds and then poured into the barrel of the gun and the nozzle was trimmed to about 15 cm. The proximal half-moon cement restrictor was placed on the nozzle.

The H_2O_2 pack and drain were removed immediately before injection of the cement. At 2-2.5 minutes the cement was injected into the femoral canal. The cement was slowly introduced over 30-90 seconds in such a fashion that the gun was slowly withdrawn being pushed out by the cement that was filling the canal. As the top end of the canal was filled a thumb was held over the cement, the nozzle was cut 0.5 - 1 cm from the half-moon restrictor and held over the canal entrance to prevent the leakage of cement. Pressure was constantly applied with the gun and blood exuded from the femur and this recorded as happening.

The cement was pressurised till 4.5-5.5 minutes. Cement was introduced as the gun was removed to prevent a vacuum effect of the cement. The gun and block were removed and manual compression of the cement was performed by placing the thumb medially to act as a seal and then inserting the index finger into the cement up to the nail bed.

3.3.8. Prosthesis Insertion

The prosthesis was not touched by gloved hands and was in a pack at all times until insertion. The centraliser was placed onto the tip of the selected prosthesis. The centraliser had a small 1.2 mm stainless steel ball inserted into the base prior to cement mixing. This was the distal cement marker ball.

A thumb sealed the medial neck and kept the prosthesis lateral. The centraliser and prosthesis were inserted into the femoral canal at 5-6 minutes. It was essential that the femur was elevated in such a fashion that there was unobstructed access to the neck of the femur as obstruction by the postero-medial tissues may result in excessive anteversion. The leg should be held at the stifle joint such that the femur is flexed, maximally adducted and externally rotated by 90^{o}.

Sufficient pressure was maintained on the prosthesis to prevent change in position of the prosthesis as the cement cured and expanded and to minimise blood penetration into the cement-bone interface; this was achieved by the proximal seal. The anteversion was dictated by the anatomy of the sheep femoral neck, normally 0-5 degrees as determined by the initial positioning of the holding device. The prosthesis was inserted until the etched circle was 5 mm from the cut edge of the femur (Figure 3.17). The thumb remains over the medial cement mantle to pressurise and prevent cement extrusion and keeps the prosthesis lateral. The cement was cleared from bone. The prosthesis was then inserted the last 5 mm and held for 15 minutes with constant pressure applied.

All cement must be curetted away from the proximal end of the femur to avoid any cement lying on the medial cortex, this was to prevent any collar-like action of the cement. Cement was removed from the lateral aspect to ensure a 3 mm gap between the cement mantle and the marker ball on the prosthesis. The proximal cement marker ball was inserted using an introducer into the lateral cement mantle at least 3 mm from the stem.

3.3.9. Radiographic Markers

Three marker screws were inserted into the greater trochanter. A specially designed drill guide was attached to the femoral head of the implant. Three drill holes were made into the greater trochanter of the femur in three different planes at 90° to each other. Three screws (10 mm length, 1.5 mm diameter; Synthes) were inserted into the greater trochanter (Figure 3.18). The drill guide enabled accurate insertion of the marker screws which served as radiological reference axes as well as constant markers for direct measurements of implant migration. Direct measurements were taken with a set of micrometer callipers (Mitutoyo, Japan) between the screws and the drill guide.

3.3.10. Anatomical Closure

The acetabulum was then washed, inspected and palpated to ensure no foreign material would obstruct reduction. The joint was then reduced by traction, hip extension and internal rotation and tested for stability by flexing the joint to 90 degrees and rotating 40 degrees internally and externally. The region was washed out with the lavage equipment (0.9% Normal Saline with 1 g Cephalothin).

One 1.4 mm drill hole was made in the base of the greater trochanter to allow reattachment of the deep gluteal muscles (Figure 3.19). The hip capsule, gluteus accessorius and gluteus profundus were advanced and reattached en masse with a 1-P.D.S. modified Kessler suture (Figure 3.20). Gluteus superficialis was reattached to the fascia lata. The biceps femoris muscle was reduced over the greater trochanter and sutured to the deep fascia so that it was unable to slide posteriorly over the trochanter. The skin was closed with continuous sub cuticular 2.0 vicryl. No dressing was applied.

Radiographs were taken prior to reversal of anaesthesia.

3.3.11. Post-operative management

Post-operatively, the sheep was suspended in a canvas sling that was supported between 2 wooden poles in a small crate (Figure 3.21). The sheep was allowed free access to food and water. The height of the sling was such that the sheep could stand weight bearing or could rest in the sling. At twenty-four hours post operation, the sling was lowered by 10 cm to encourage full weight bearing and movement forwards and backwards while still providing lateral support. The sling was removed at forty-eight hours post-operation and the sheep allowed to stand unsupported. The sheep were housed in an indoor pen for 21 days. The sheep were released into the paddock at a suitable time about 3 weeks to 1 month post-operation.

At 4 weeks post operation the sheep were exercised daily to ensure consistent loading of the hip arthroplasty between individuals. The sheep were walked a distance of 4 km per day, 5 days per week and gait was observed and limp recorded by the animal handlers. This ensured a minimum daily exercise for each sheep.

Figure 3.4. Instruments for dissection, sutures for closure and instruments for inserting marker screws and balls.

Figure 3.5. Instrumentation for exposure and preparation of the femoral neck and trial insertion.

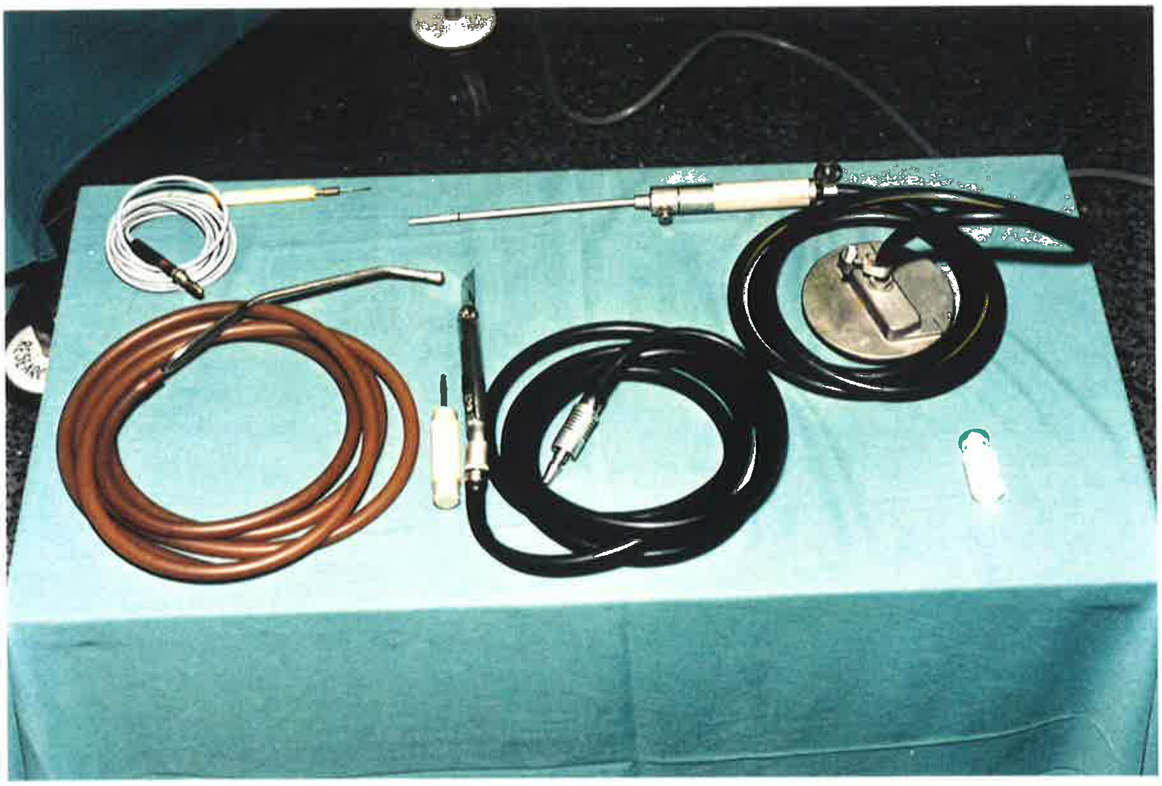

Figure 3.6. Equipment for diathermy, suction, sagittal saw and lavage.

Figure 3.7. Equipment for medullary plug insertion, canal packing, cement insertion and pressurisation and femoral implant.

Figure 3.8. Surgical incision (centred over the greater trochanter).

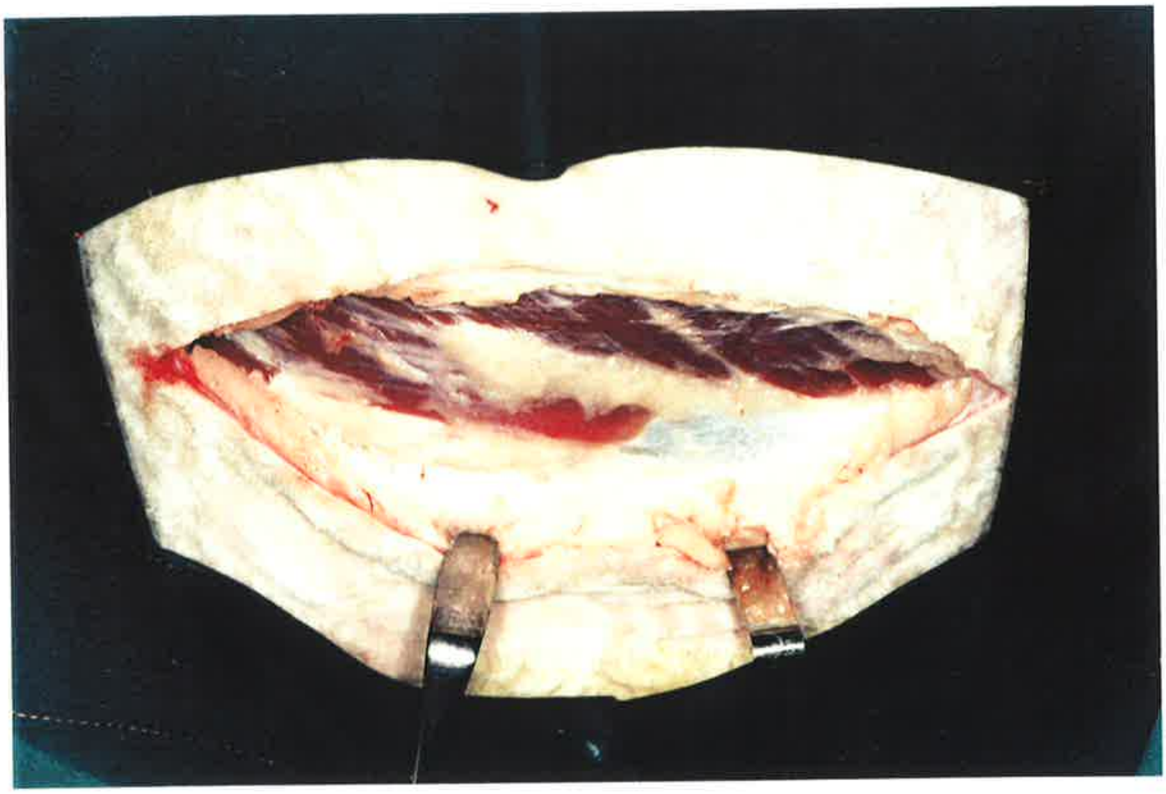

Figure 3.9. Superficial dissection and identification of Biceps femoris.

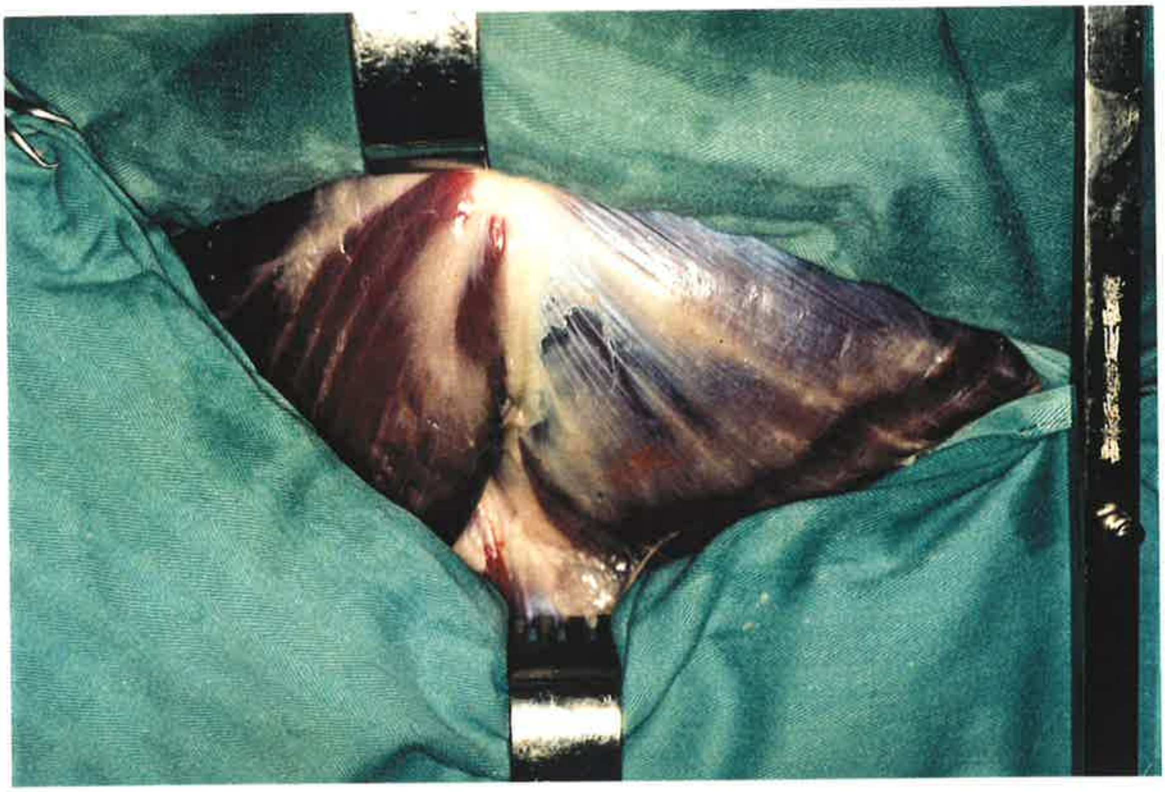

Figure 3.10. Exposure of Gluteus medius and Vastus lateralis.

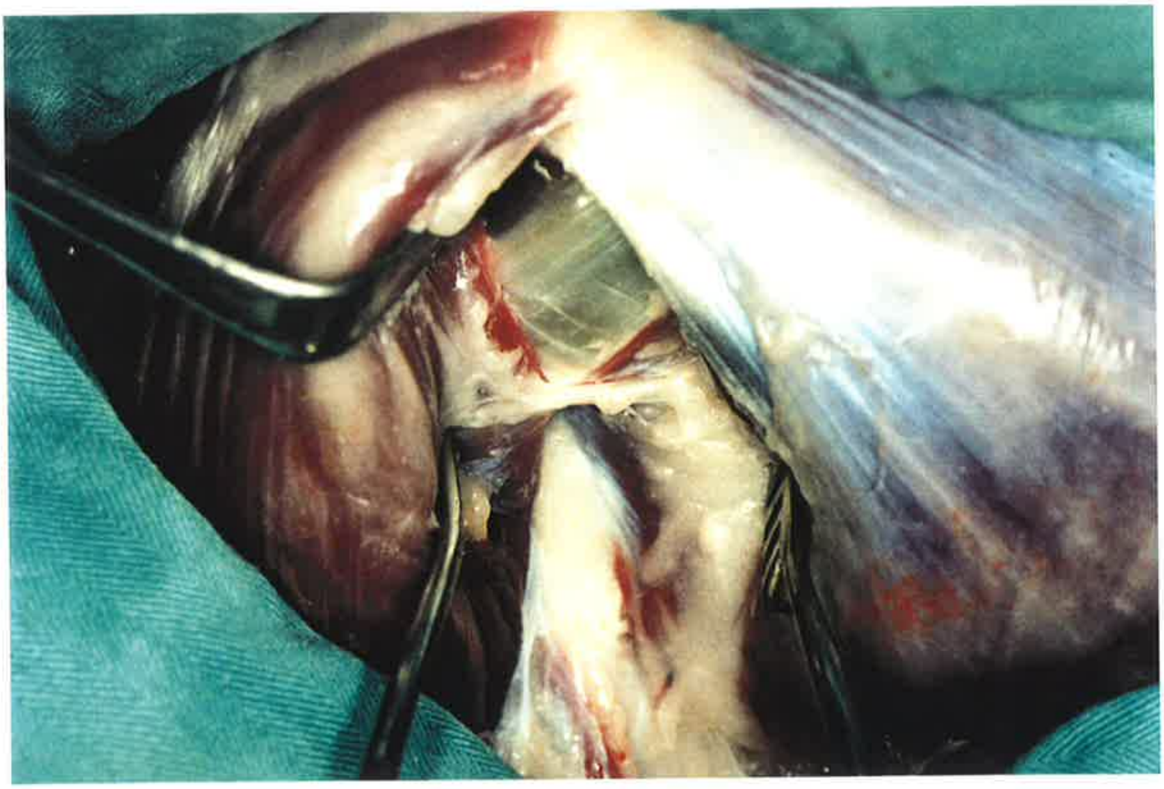

Figure 3.11. Identification of Gluteus accesorious with vascular bundle.

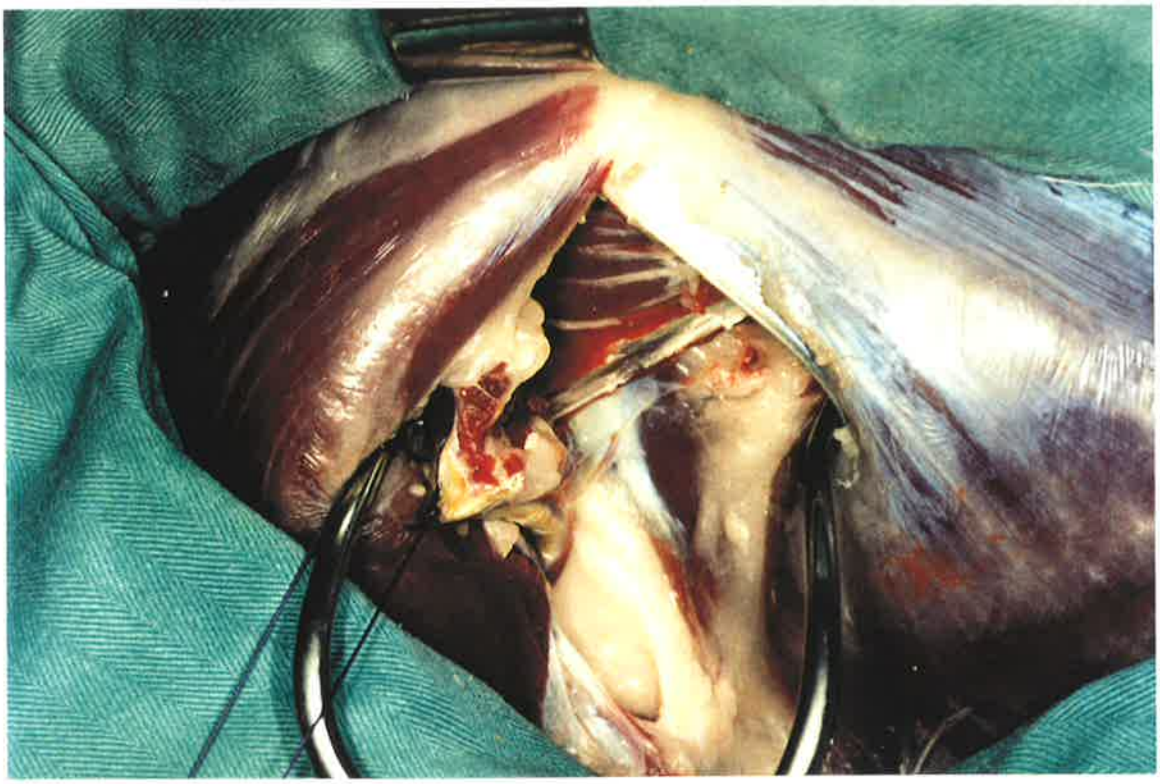

Figure 3.12. Gluteus accesorious reflected with stay stich and Gluteus profundus identified below.

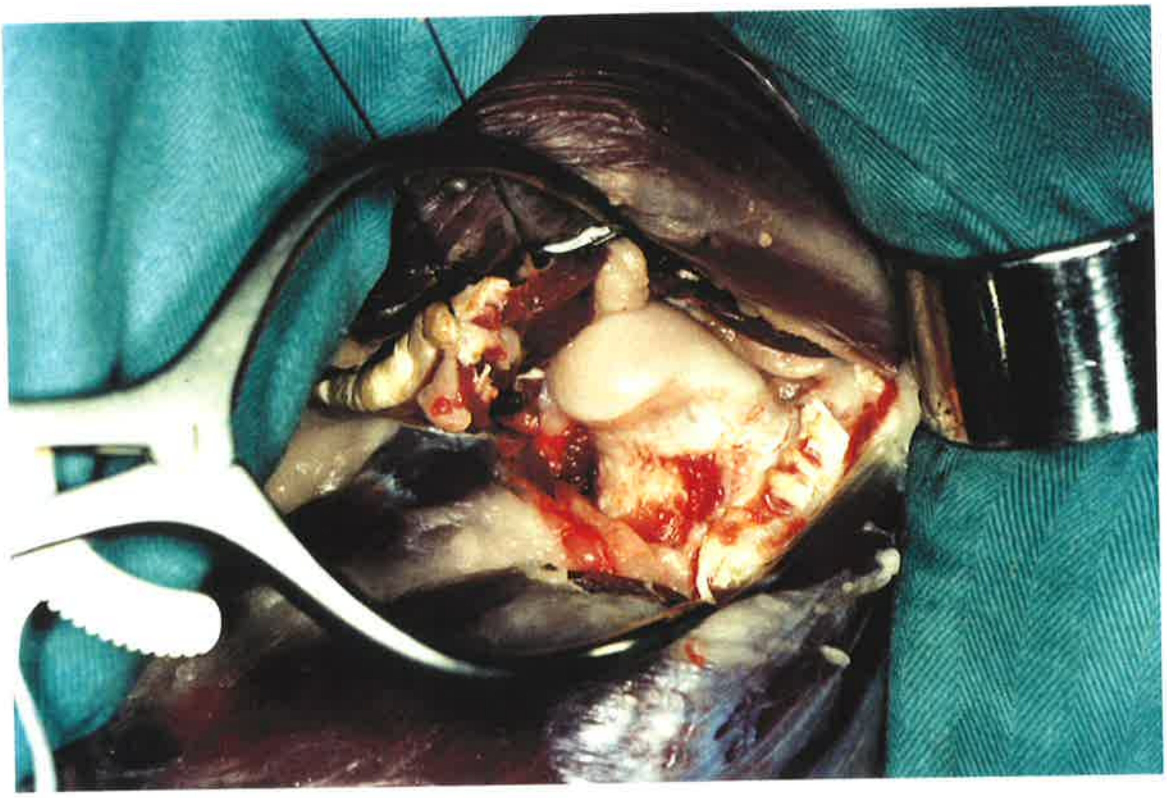

Figure 3.13. Dislocated hip joint and proximal neck exposure.

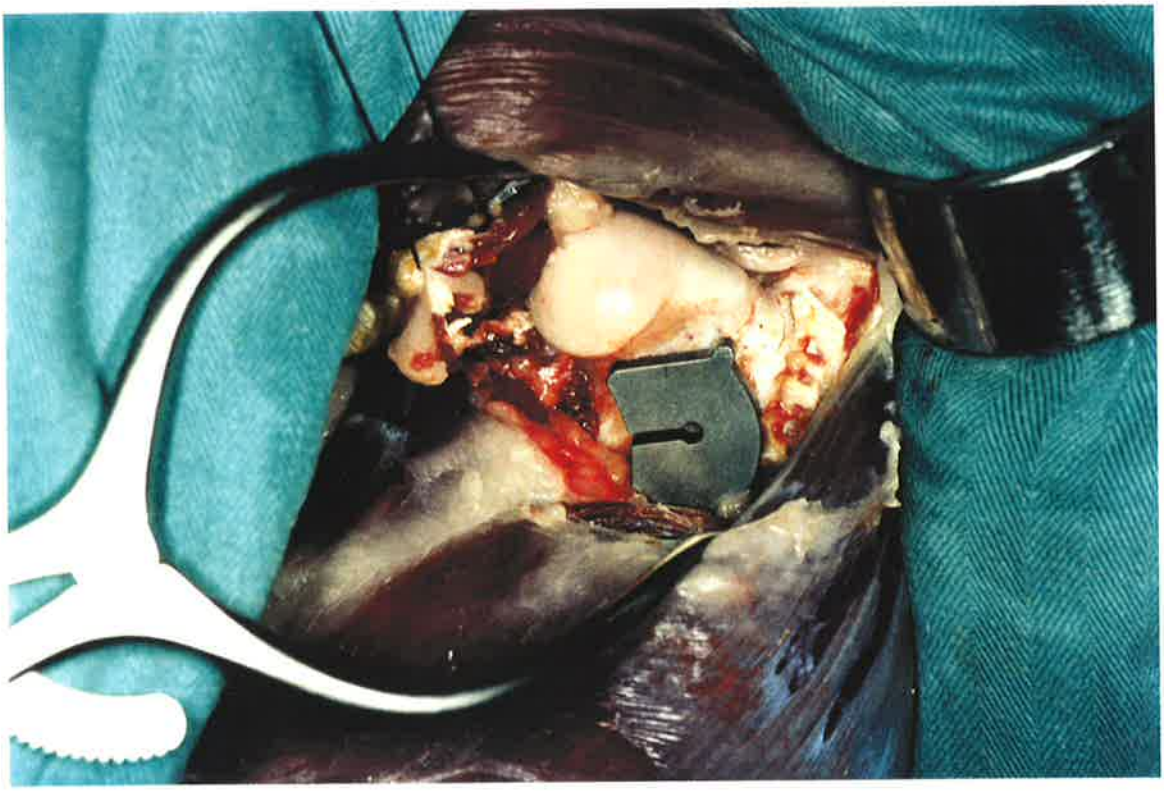

Figure 3.14. Neck cutting guide placed submuscularly along femur.

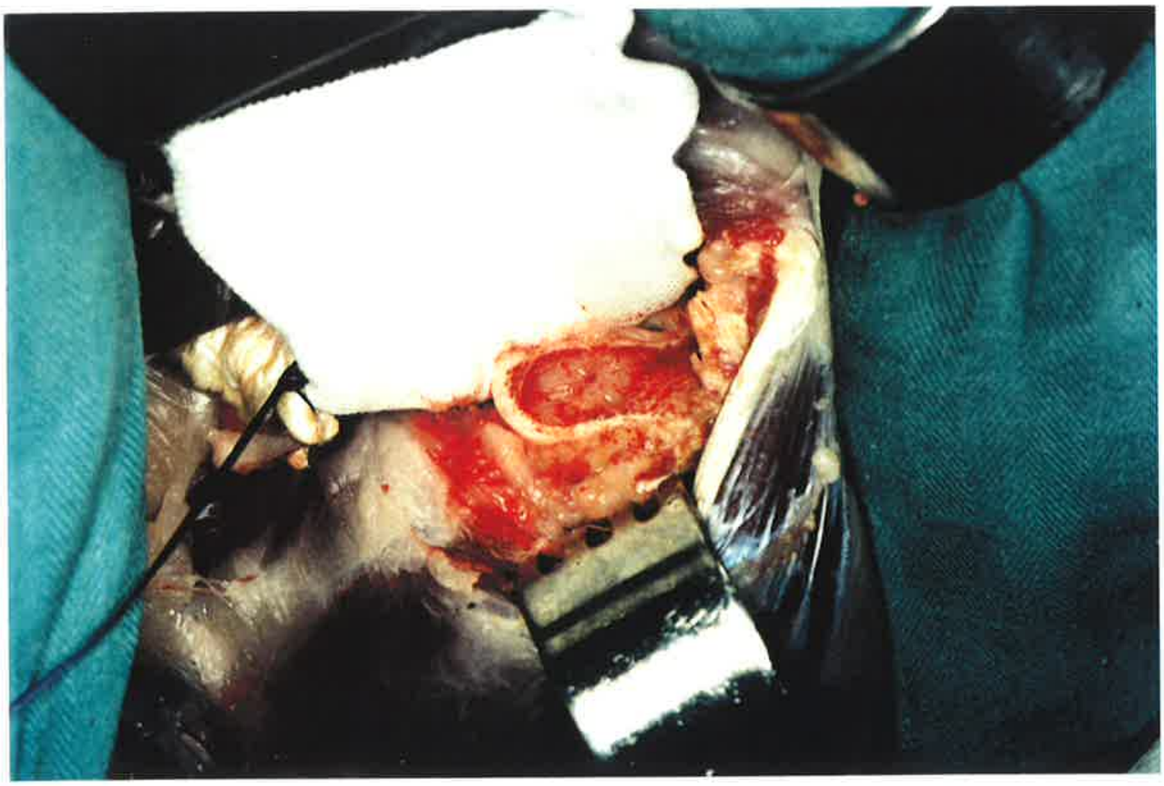

Figure 3.15. Proximal exposure of cut femoral neck.

Figure 3.16. Femoral canal after rasping, brushing and lavage.

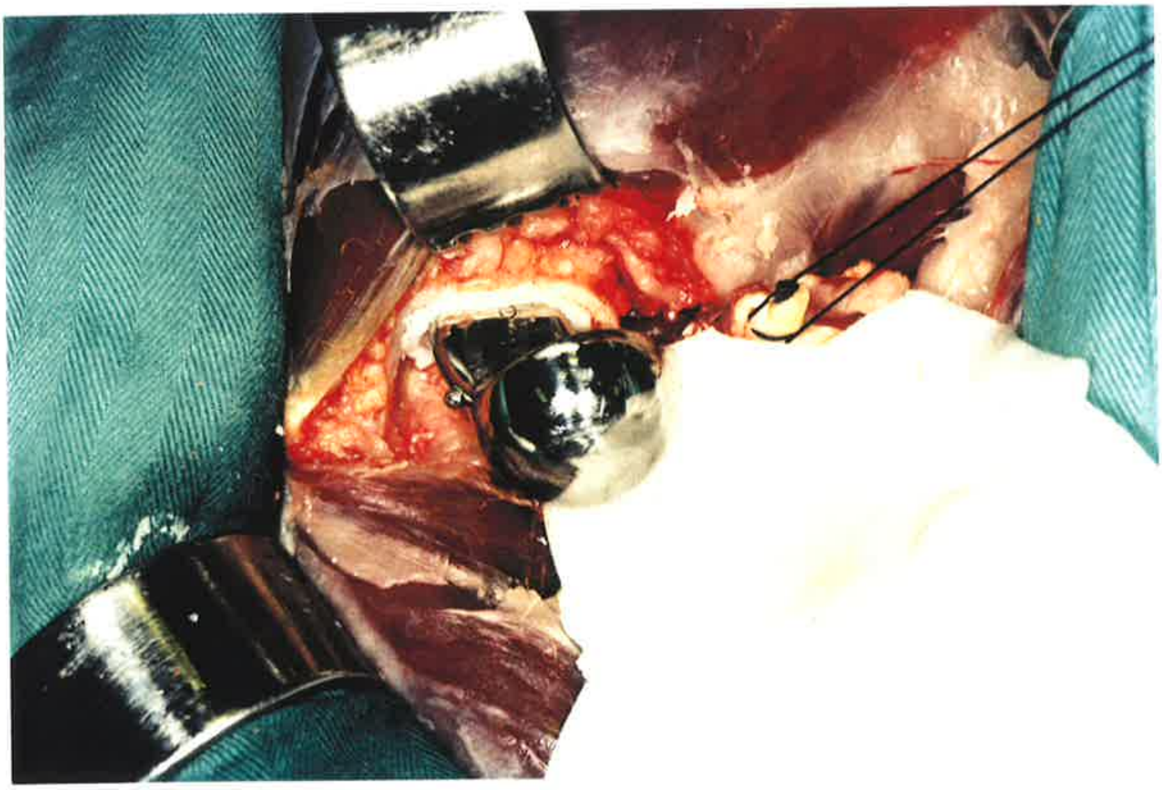

Figure 3.17. Inserted cemented femoral implant.

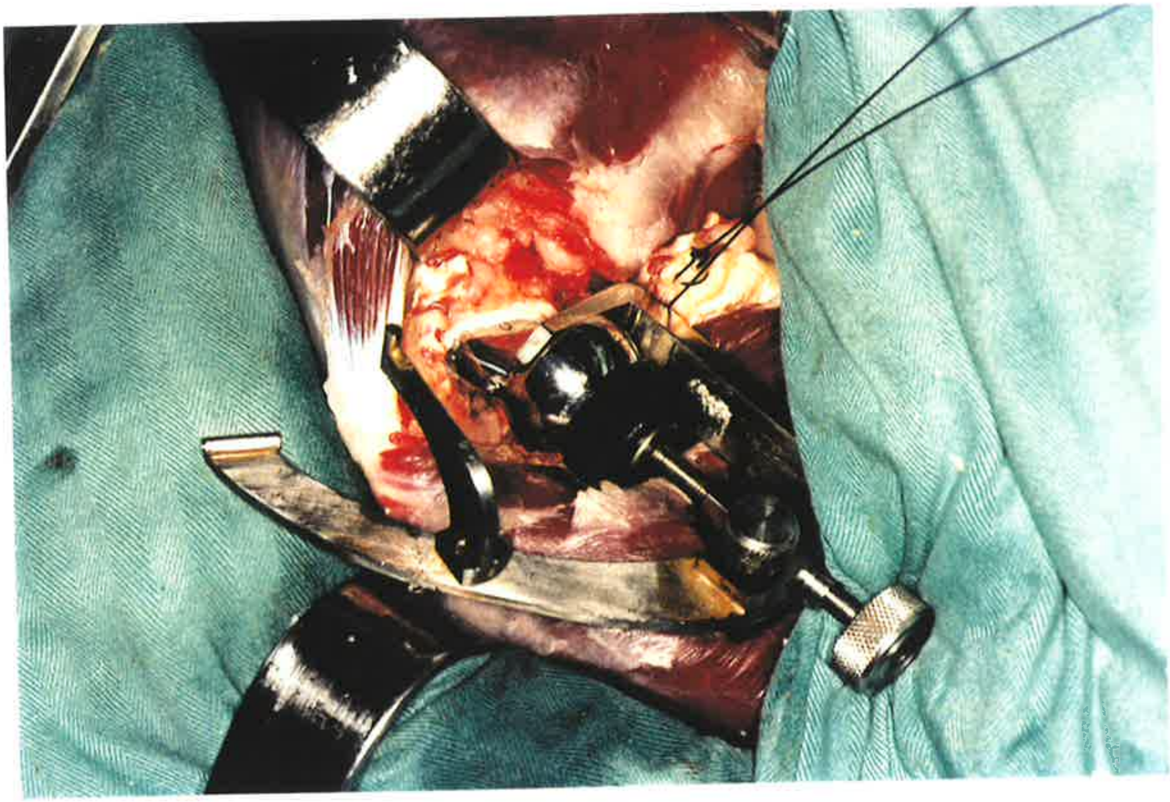

Figure 3.18. Drill guide attached to femoral implant and guide holes situated over greater trochanter.

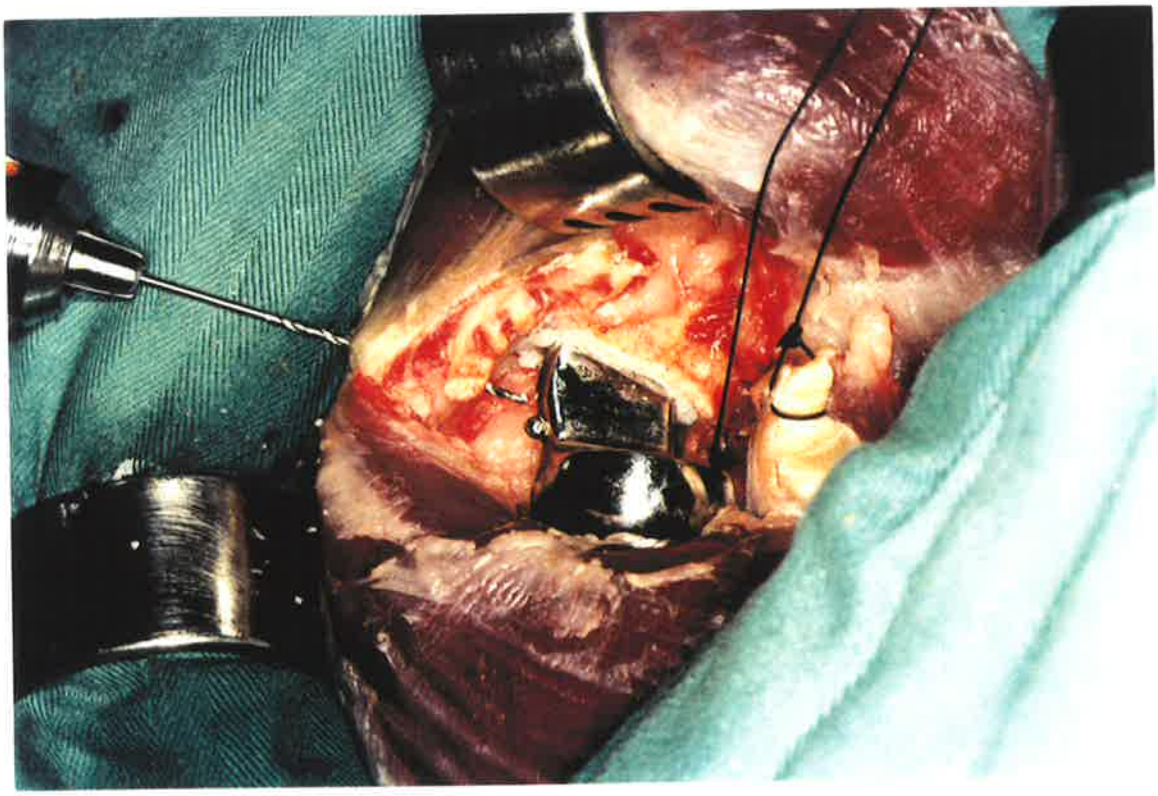

Figure 3.19. Drill holes into greater trochanter for repair of deep muscles.

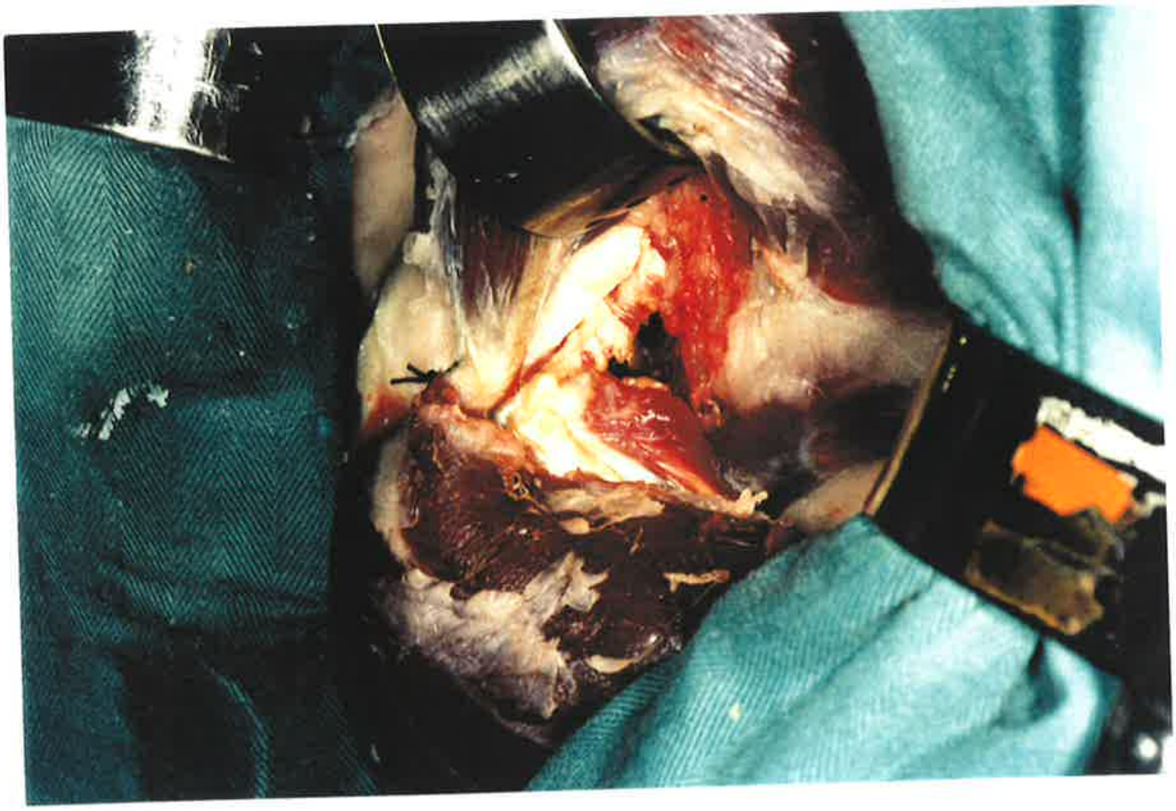

Figure 3.20. Repair of deep muscles and hip capsule.

Figure 3.21. Sheep in sling and crate.

3.4. Results

Thirty-five sheep (thirty of the initial study group and five replacement sheep) received a left cemented hip hemiarthroplasty. Twenty-one sheep (eighteen of the initial study group and three replacement sheep) completed nine months in vivo loading with daily walking. Weight bearing status and gait were assessed daily. The animals were observed to be weight bearing within forty-eight hours of surgery and to be walking with near normal gait at the time of transfer to the field station. At one month from surgery they were walking four kilometres per day and were observed to be walking with a normal gait.

Though there were no anaesthetic complications related to the initial surgery, there was one death from aspiration during a subsequent anaesthetic. This occurred whilst performing the routine radiographic assessment. We have performed over 200 radiographic assessments of sheep under intravenous barbiturate anaesthesia without intubation and this is the only mortality.

There were a total of fourteen sheep (40%) suffering complications which resulted in withdrawal of the sheep from the study group (Table 3.1).

There was one infection (3%) that occurred in one of the replacement sheep (#R2). The sheep was noticed at 3 months following surgery to be lame and refusing to weight-bear. The sheep was febrile and had a palpable trochanteric abscess. Fluid was aspirated and sent for culture and antibiotics commenced. The isolated organism was Actinomyces pyogenes, a common sheep skin commensal. The sheep remained febrile and was killed 24 hours later.

There were no superficial or deep haematomas that limited mobilisation or required surgical intervention.

Table 3.1. Details of the complications that occurred during the nine month study period that resulted in withdrawal from the study group.

Sheep number	Implant type	Post-op (days)	Complication that resulted in withdrawal from the study
1	matt	4	Dislocated (sling and repair problem)
3	matt	0	Unstable intra-operative (posterior cortex fracture)
6	polished	6	Dislocated (sling and repair problem)
8	collar	14	Fore-limb nerve palsy/dislocated (sling problem)
12	polished	80	Malnutrition (loss of dentition)
14	matt	21	Dislocated (unknown)
15	matt	70	Femoral fracture (traumatic)
18	collar	21	Dislocated (unknown)
21	collar	30	Femoral fracture (traumatic)
25	matt	120	Aspiration (XR review anaesthetic)
29	matt	50	Femoral fracture (traumatic)
30	polished	60	Dislocated (unknown)
R2	collar	90	Infection
R3	polished	90	Aseptic Loosening

There was one sheep (#R3) with clinical evidence of femoral implant aseptic loosening during the nine month course of this study (3%). The sheep was noted to be limping and not keeping up with the rest of the flock during the daily walks. Radiographic assessment showed a complete cement-bone lucency. Capsule histology did not show infection.

In 8 cases (23%) it was not possible to fully seat the curved broach due to the small antero-posterior diameter of the proximal canal at the level of the cut neck. The posterior cortex was thin in all sheep and small fractures were not uncommon when rasping the canal. The fractures were small chip fractures and there were no visible longitudinal split fractures.

There were seven anterior dislocations, four occurring in the first eight sheep in the series. These eight sheep had a different anatomical closure from that described above. A direct end-to-end repair of the deep gluteal muscles was initially used and this was occasionally tenuous. Exploration of one sheep which had dislocated showed this repair to have failed. Subsequent sheep had an advancement and deep attachment of the gluteal tendons as described in the methods section. Only three dislocations occurred in the next twenty-two procedures.

A number of additional factors contributed to the initially high dislocation rate. The initial post operative support slings used were too small, being tight around the limbs and were difficult to remove resulting in traumatic dislocation. In one sheep, a forelimb nerve palsy occurred resulting in forelimb paresis with an inability to stand and this contributed to dislocation. Larger slings were made subsequently and used without complication. Larger and stronger support poles were used to prevent pole breakage.

Treatment for dislocation was unsuccessful. Closed reduction and abduction hip spica immobilisation was attempted in one sheep which dislocated when the spica was removed. An open reduction and soft tissue repair was also attempted in one sheep without success. We adopted the policy that dislocation of the femoral implant was cause for sacrifice.

There were three femoral shaft fractures (#15,#21,#29). The fracture of sheep #15 occurred at day 70, radiography at day 60 was normal. There was a spiral fracture extending down the entire shaft of the femur. The prosthesis-cement interface was intact and there was an intact cement mantle with good penetration of cement on the cement cast left around the implant. Sheep #21 was lame on day 30 and radiography demonstrated an avulsion fracture of the greater trochanter and posterior cortex. Sheep #29 was noted to be lame on day 50 and radiography demonstrated a large trochanteric and lateral cortex fracture. All of the fractures appeared to be due to a specific event as they were mobilising normally the day before noted to be lame, however no events were documented by the animal handlers. All fractures occurred in sheep with matt surfaced implants (2 matt collarless and 1 matt collared).

One sheep (#12) was lame at day 80 and was noted to have no teeth and was therefore unable to eat. The sheep was unable to regain weight and mobility and was killed for ethical reasons.

All other sheep were killed at the planned time of 9 months after the insertion of an identical implant into the contralateral femur with no complications.

3.5. Discussion

An overall complication rate of 40% was encountered. This was attributed to the learning curve of sheep hip arthroplasty. Of the first 8 sheep, 4 dislocated and were withdrawn from the study. The complications related to the initial tenuous closure of the deep gluteal muscles and problems with slinging. Special attention to the repair and advancement of the deep gluteal muscles during closure and use of large, non constricting slings was implemented for the following sheep.

After correction of these problems, the dislocation rate decreased to 11%. Although this is greater than the human total hip arthroplasty dislocation rate, it should be noted that the sheep hip joint is inherently unstable and the majority of the stability is provided by the ligamentum teres which has to be divided during surgery.

Phillips et al. (1987; 1989; 1990) described a trans-trochanteric approach, but reported a dislocation rate of 17%. Subsequently Phillips used a posterior approach and reported a dislocation rate of 10% and this further reduced to 6% with experience (1987). Radin et al. (Lanyon et al.1981; Radin et al.1982) and Goodship (Goodship, 1991) both use the posterior approach but do not report their dislocation rate.

Fractures of the femoral shaft occurred in three sheep. These sheep fractured whilst at the field station following a period of normal mobility. Although no specific injury was noted, the fractures are likely unrelated to the initial surgical procedure.

Two complications were related to the veterinary management of the sheep. It is recommend that a veterinary surgeon regularly reviews the general care of the animals with emphasis on hoof and oral health. In addition, the use of experienced animal anaesthetic technicians will decrease the incidence of anaesthetic complications.

The anterolateral approach to the sheep hip was chosen as it is observed that sheep sit with their hind limbs flexed, adducted and internally rotated. This is the position of instability for the posterior approach. The anterolateral approach would be more stable, as the sheep seldom are seen to be externally rotating their hind limbs.

In conclusion, this chapter has described the use of the sheep as a hip arthroplasty model. The animals rehabilitated well from surgery and there was one sheep with aseptic loosening during the course of this study. The learning curve in developing the operative and post operative protocol has presented a number of complications and it is reported how these complications can be managed. With further experience and refinement of the sheep model, it is anticipated that the complication rate may decrease further.

Chapter 4

Measurement of Femoral Stem Subsidence

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4.1. Introduction

The main objective of this component of the study was to test the hypothesis that

> At nine months after implantation a polished surfaced prosthesis will show radiographic evidence of subsidence at the prosthesis-cement interface whereas a matt surfaced prosthesis will not.

In this study four methods were used to measure subsidence;

> Prosthesis-cement and prosthesis-bone subsidence was measured from plain radiographs of the sheep hip. The radiographs taken at two monthly intervals until the sheep were killed at nine months following implantation were compared with the radiograph taken immediately after implantation to calculate subsidence.
>
> High contrast contact radiographs were taken of the explanted femurs to assess prosthesis-cement radiolucency in Gruen zone 1, which may represent subsidence.
>
> Micro-photographs of the proximal prosthesis-cement-bone interfaces were assessed for subsidence by observation and direct measurement of the p-c interface gap.
>
> An intra-operative direct measurement of prosthesis-bone migration was developed that measured the distance between the prosthesis and bone at the time of implantation and repeated at the time of explantation to calculate subsidence.

4.2. Materials and Methods

4.2.1. Technique for taking Plain Radiographs

A positioning device was made to enable reproducible positioning of the sheep and thereby standardise flexion and rotation of the femora. All radiographs were taken with the sheep anaesthetised with intravenous thiopentone (1g, Pentothal, Abbots, Australia). The sheep was positioned in the positioning device supine with slight flexion of the lumbar spine.

The anteroposterior (AP) pelvis radiograph was taken with the hip joint extended and abducted, internally rotated and all other joints extended. The distal extremity was fixed to the radiographic plate holder and the stifle joints were held in internal rotation with a velcro strap (Figure 4.1). The lateral (LAT) hip radiograph was taken with the femora abducted, the stifle joint (knee) flexed, the hock joint (ankle) flexed and the distal lower limbs fixed to the radiographic plate holder (Figure 4.2).

Distances of each joint from the radiographic plate and the distances to the midline were measured to ensure symmetry and therefore similar flexion, rotation and abduction. This would ensure the similar position of the femur on all subsequent radiographs. The radiographic plate was positioned centred on the superior pubic ramus and the angle of the plate was adjusted and thereafter standardised for each sheep such that the femoral shaft was parallel to the radiographic plate. Standard settings were determined, however exposure was varied by different radiographers and different sheep sizes and weights (Table 4.1).

Table 4.1. Details of the radiographic settings used to take standardised radiographs.

	Tube-Film Distance (cm)	Voltage (KVp)	Amperage (mA)	Exposure Time (msec)
AP Radiograph	100	82	200	0.25
Lat Radiograph	100	72	300	0.08

Figure 4.1(a). Caudal view of sheep in positioning device to allow reproducible AP pelvis radiograph to be taken. Radiograph cassette and grid are placed in slot at rear of device and distal limbs are fixed to ensure standard positioning.

Figure 4.1(b). Lateral view of sheep in positioning device for AP pelvis radiograph.

Figure 4.1 (c). AP pelvis radiograph

Figure 4.2(a). Caudal view of sheep in positioning device for lateral radiograph. Radiograph cassette and grid are placed in slot at rear of device and distal limbs are fixed to ensure standard positioning.

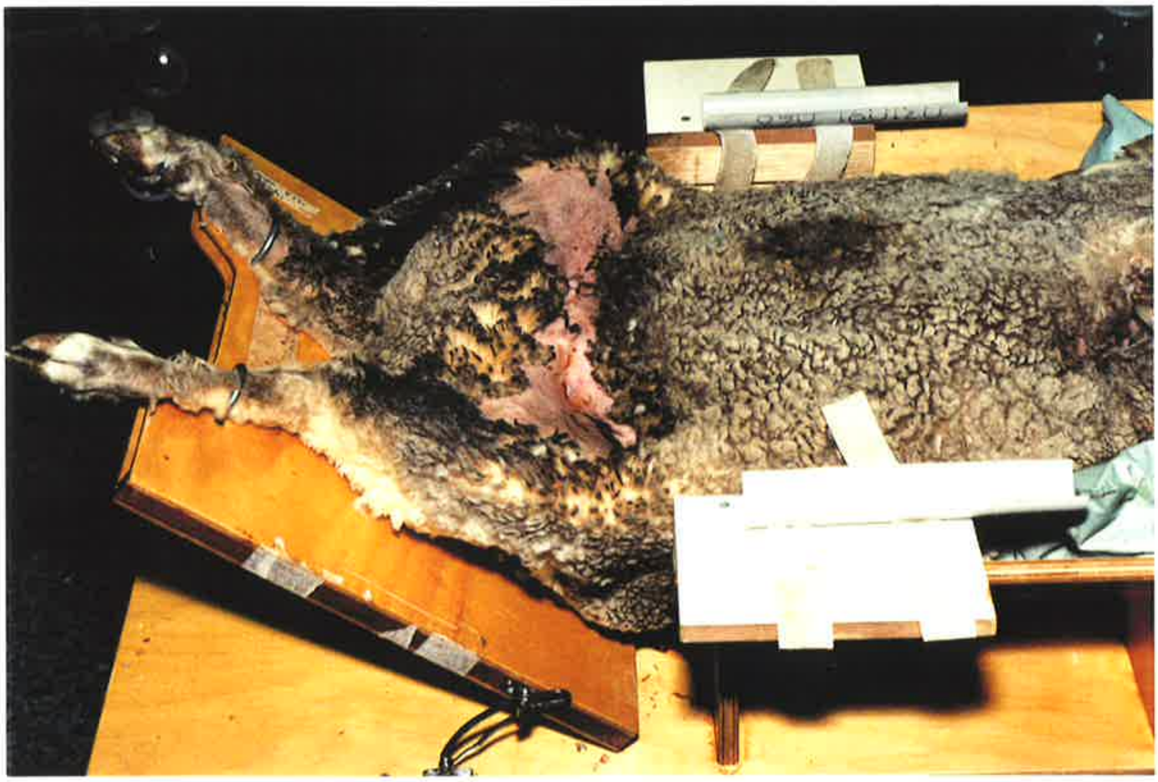

Figure 4.2(b). Lateral view of sheep in positioning device for lateral radiograph.

Figure 4.2 (c). Lateral radiograph

4.2.2. Radiographic Measurement of Subsidence

AP pelvis radiographs were taken immediately post-operatively, at two monthly intervals and prior to sacrifice. Subsidence was calculated from serial plain radiographs by taking measurements between the reference screws placed in the bone, the cement mantle marker balls and the markers on the prostheses.

All femurs had three reference screws (1.5 x 10 mm stainless steel) inserted in the greater trochanter and two marker balls (1.1 mm stainless steel) placed in the cement mantle at the time of implantation. The prosthesis was made with a marker ball (3 mm stainless steel) welded to the neck of the prosthesis.

Measurements were made from the AP pelvis radiographs using a standard light box, a lead pencil, a transparent ruler with 0.5 mm graduations and a set square. A longitudinal reference axis for measurements was defined by the longitudinal axis of the vertical screw. All measurements were made with reference to a line drawn perpendicular to the longitudinal axis from the top of the screw head (Figure 4.3). Measurements were taken to four points, the proximal surface of the proximal marker on the prosthesis, the distal tip of the prosthesis, the proximal surface of the proximal cement mantle marker ball and the proximal surface of the distal cement mantle marker ball.

The axis length of the prosthesis was measured from the proximal surface of the proximal marker of the prosthesis to the distal tip of the prosthesis to calculate a combined magnification and out of plane flexion/extension factor. The actual distance of the axis length was known from the implant design diagrams and was 77 mm. Measurements made from the plain radiographs were corrected using the following equation.

Firstly a correction factor was made to allow for magnification and out of plane flexion/extension of the femur. The correction was calculated as a function of the measured and true lengths of the femoral prosthesis (axis length) and the out of plane flexion/extension angle (θ).

$$\cos\theta = \frac{\text{axis length (measured)}}{\text{axis length (true)}}$$

$$\cos\theta = \frac{\text{distance between markers (measured)}}{\text{distance between markers (true)}}$$

Combining the two corrections allowed a corrected migration measurement to be made from the actual distances between markers measured. The actual distances were made from the tip of the vertical reference screw to the two markers in the cement mantle and the two markers on the prosthesis.

Distance between markers (true)

$$= \frac{\text{distance between markers (measured)}}{\cos\theta}$$

$$= \frac{\text{distance between markers (measured)}}{\dfrac{\text{axis length (measured)}}{\text{axis length (true)}}}$$

$$= \text{distance between markers (measured)} \times \frac{\text{axis length (true)}}{\text{axis length (measured)}}$$

Measurements made from each radiograph taken after implantation were subtracted from the measurements made from the immediate post operative radiograph to determine migration at the two monthly intervals and at sacrifice.

A further measurement was made specifically to assess prosthesis-cement subsidence. The AP pelvis radiograph was used and two measurements were made between the cement mantle markers and the prosthesis markers that were independent from the greater trochanter reference screws (Figure 4.4).

The reference axis for measurements was the longitudinal axis of the prosthesis, defined as the line drawn from the proximal marker on the prosthesis to the tip of the prosthesis. To calculate the proximal prosthesis-cement subsidence the distance between the proximal marker on the prosthesis and the proximal cement mantle marker ball was measured. To calculate the distal prosthesis-cement subsidence the distance between the tip of the prosthesis and the distal cement mantle marker ball was measured.

The measurements were corrected for magnification and out of plane flexion using the equation above. The measurements from the immediate post implantation radiograph were subtracted from all other measurements to calculate the subsidence.

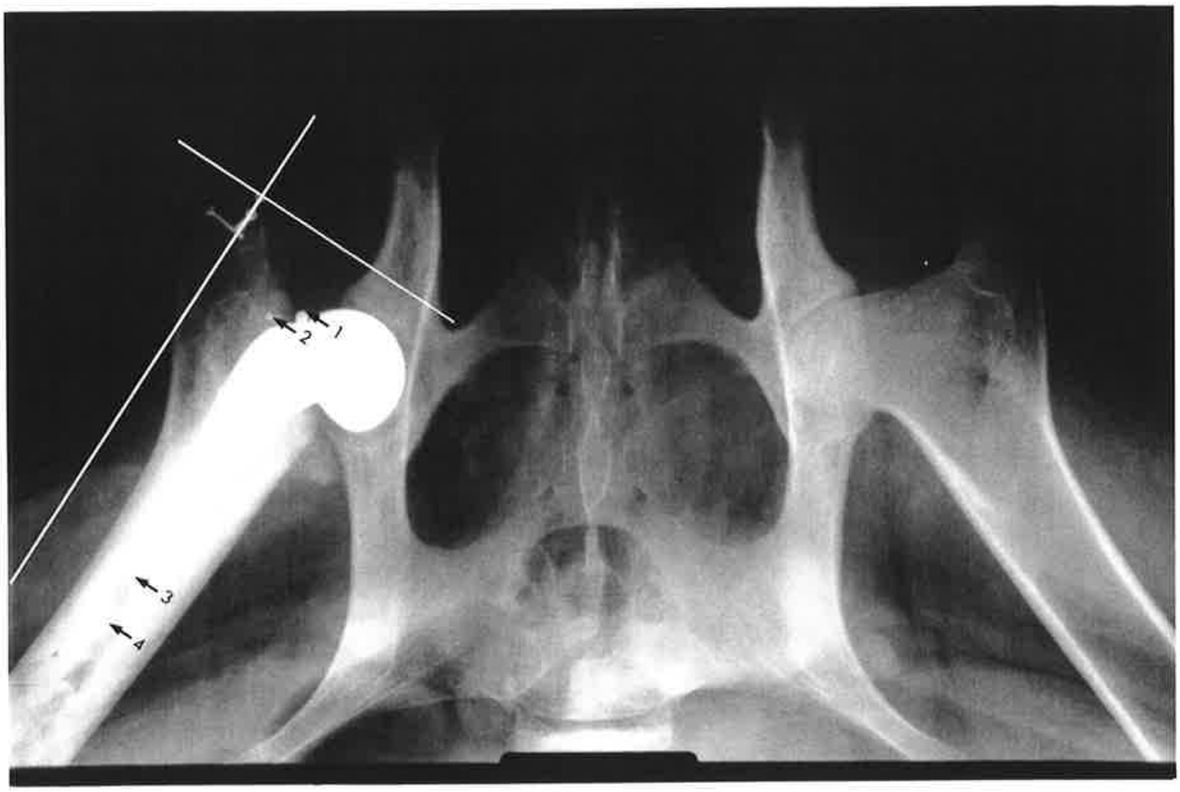

Figure 4.3. Antero-posterior radiograph with reference markers and axes used to measure subsidence of the two cement markers and the two prosthesis markers. Measurements were made to the proximal cement marker, proximal prosthesis marker, distal cement marker and the distal tip of the prosthesis from the top of the vertical screw.

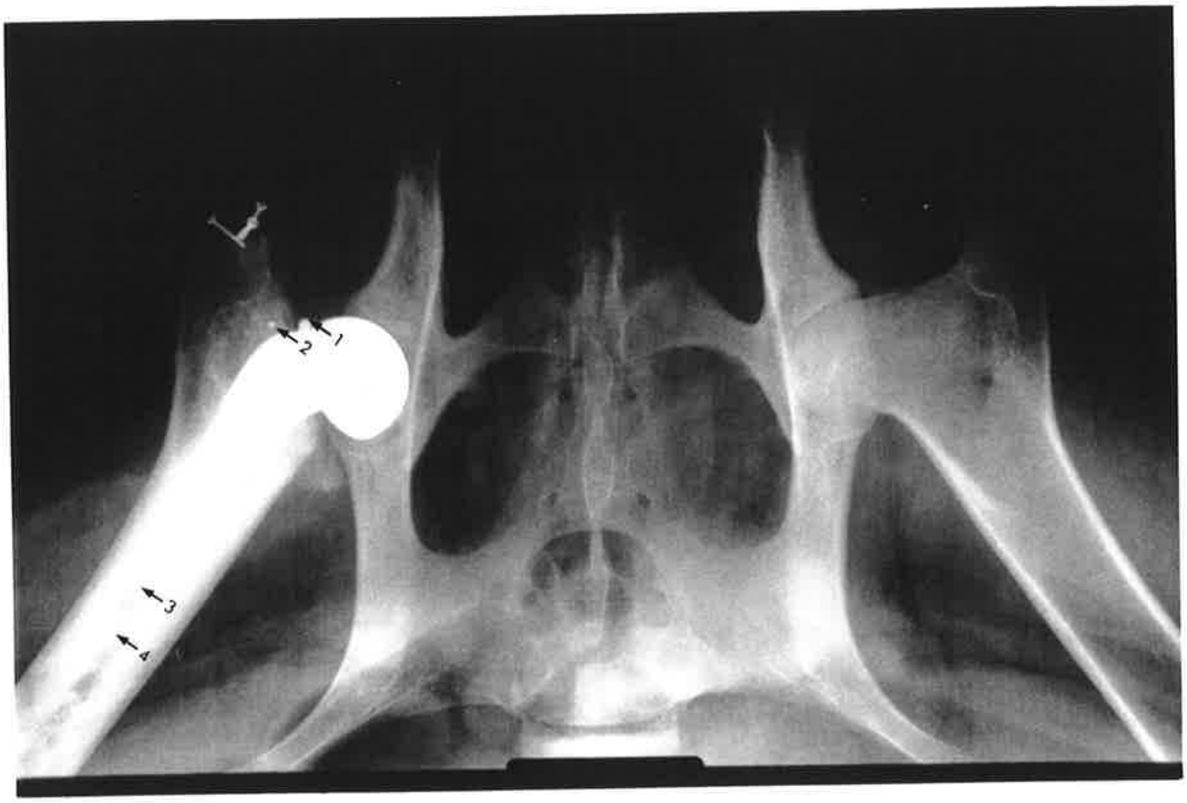

Figure 4.4. Anteroposterior radiograph with lines marked for the measurement of prosthesis-cement subsidence. Measurements were made proximally between the proximal cement marker and the marker on the prosthesis and distally between the distal cement marker and the distal tip of the prosthesis.

4.2.3. Prosthesis-Cement Radiolucency and Interface Gap

Immediately after the sheep were killed, high contrast contact radiographs of the explanted femurs were taken in a radiographic cabinet. Three radiographs were taken; the first was centred on the middle of the femur and taken in an AP direction, the second was centred on the middle of the femur in a lateral direction and the third was centred on the femoral head in the AP direction. These radiographs were used to assess prosthesis-cement lucency together with the AP pelvis radiographs.

The contact radiographs and all the plain AP pelvis radiographs were assessed for prosthesis-cement subsidence according to the method described by Fowler et al. (1988). In their paper they assessed prosthesis-cement subsidence by measuring the gap between the lateral curved neck of the prosthesis and the cement mantle in the supero-lateral femur (Gruen zone 1) (Figure 4.5) .

This feature was measured in this study on the AP pelvis radiographs, the contact radiographs of the explanted femurs and the contact radiographs centred on the femoral head.

To investigate the proximal prosthesis-cement interface further, the proximal femur was sectioned in the mid-coronal plane. This was performed after all the radiographic, mechanical and histological processing had been done. The sections were stained and photographed as described in the histology section (chapter 7). The interface tissue between the prosthesis and cement was measured if present and noted if absent. This is a direct observation of the radiolucent line as described above.

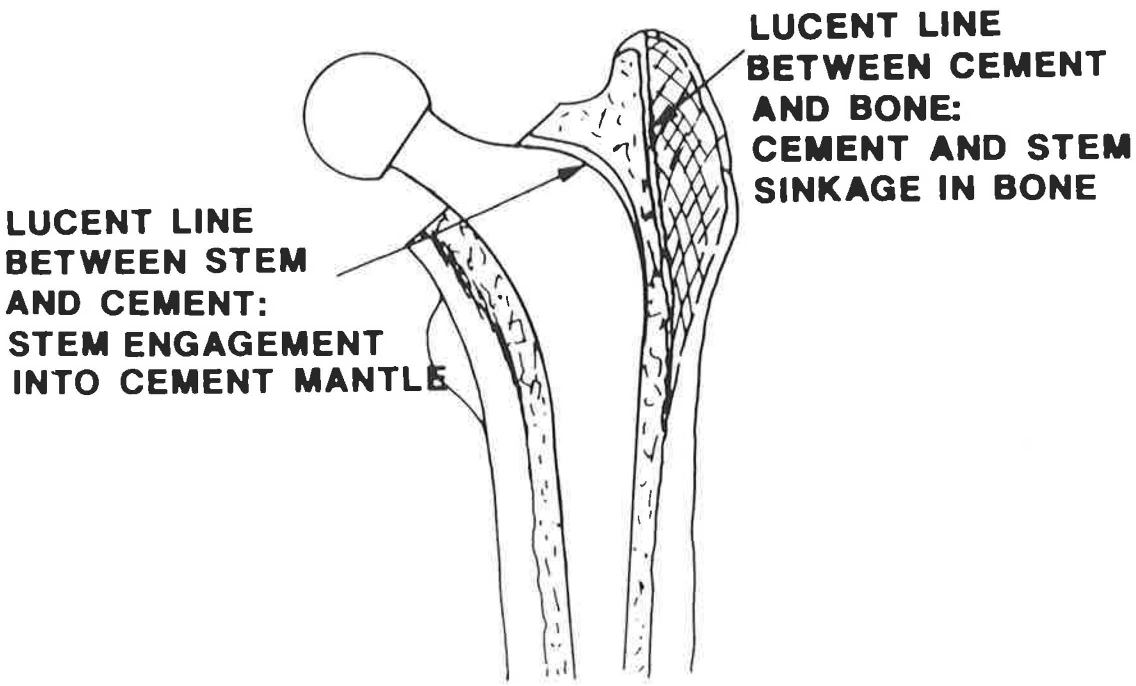

Figure 4.5. Diagrammatic representation of p-c subsidence according to the method of Fowler et al. (1988) for the AP radiograph in the supero-lateral zone (Gruen zone 1).

4.2.4. Direct Measurement of Migration

Three screws (1.5 mm x 10 mm) were inserted intra-operatively into the greater trochanter in three different planes using a specially made jig (as described in chapter 3). These screws provided a three dimensional reference for the femur and allowed for direct measurements to be made from the prosthesis to the bone.

At the time of implantation, the specially made drill guide was attached to the head of the prosthesis (Figure 4.6). Three drill holes were made at 90° to each other into the greater trochanter and three 10 mm screws were inserted. Measurements were taken between the drill guide and the heads of the screws using a set of micrometer callipers with a vernier scale capable of measuring to 0.1 mm (Mitutoyo, Japan) (Figure 4.7). At nine months after implantation, the same measurements were repeated on the explanted femur.

The subsidence of the prosthesis relative to the bone was calculated in three dimensions by subtracting the measurements made at the time of implantation from those at nine months after implantation. Vertical migration was recorded as a positive value if there was subsidence and a negative value if there was superior migration out of the femoral canal. Horizontal migration was recorded as positive if the prosthesis migrated medially and negative if there was lateral migration. Transverse migration was recorded as positive if there was posterior migration and negative if there was anterior migration.

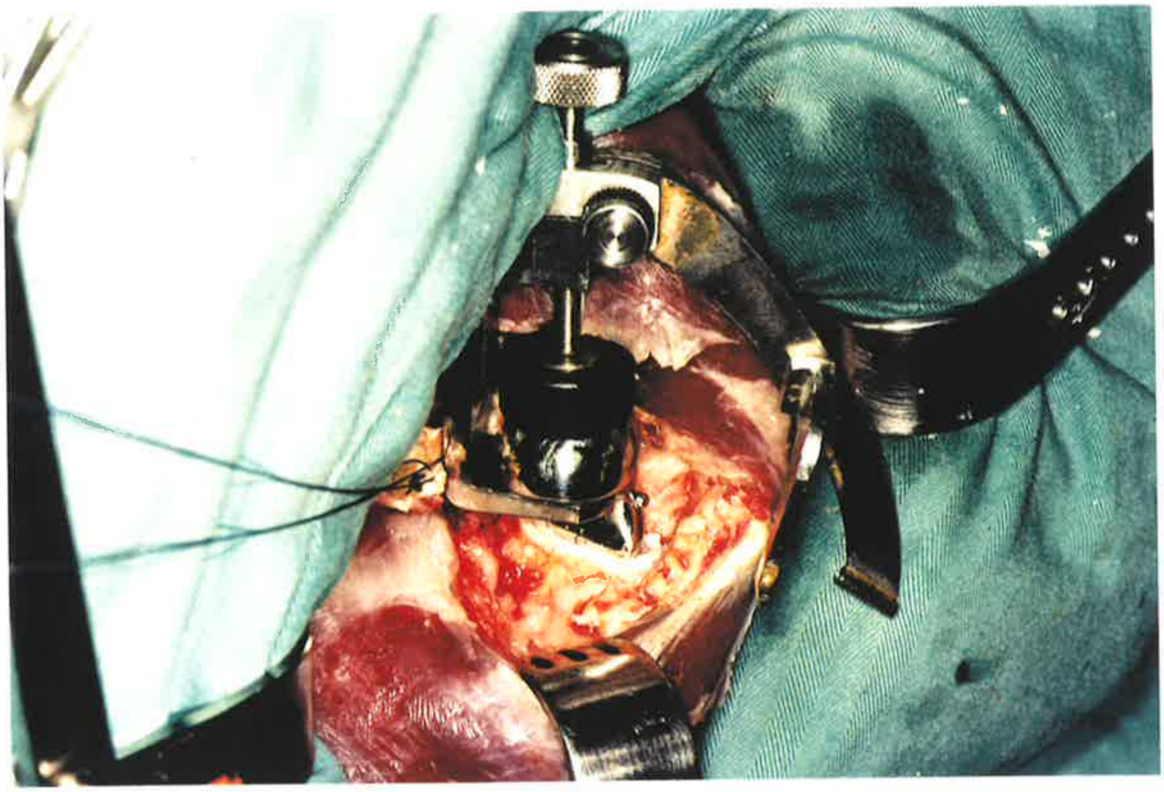

Figure 4.6. Drill guide attached to femoral prosthesis.

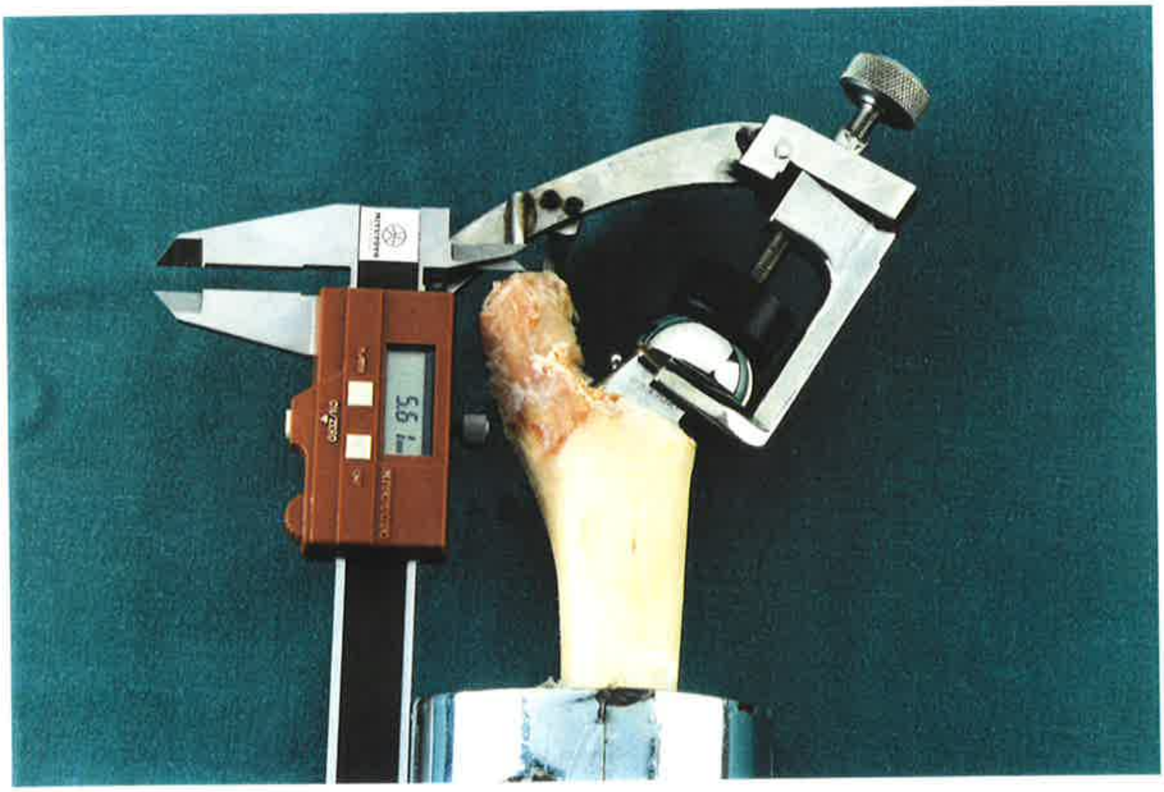

Figure 4.7. Measurement of the distance between the drill guide and marker screws.

4.3. Repeatability of Measurement Methods

Several studies were performed to assess the repeatability and error of the methods used to measure subsidence.

The repeatability of prosthesis-cement subsidence measured between the distal tip of the prosthesis and the distal cement marker ball was done. Five AP radiographs of the same sheep taken on a single day were assessed. Between each radiograph the sheep was taken off the positioning device and the radiograph machine was moved away and then re-positioned before the next radiograph was taken. Prosthesis-cement subsidence was measured 10 times from each single radiograph and the mean values were then compared for the five radiographs. The standard deviation of the distance used to measure prosthesis-cement subsidence between the distal markers was 0.1 mm. The uncorrected measured length of the femoral stem varied between 88.5 and 89.5 mm.

The repeatability of migration measurements using the intra-operative direct method was assessed by measuring 10 times the distances from the guide to the reference screw, removing and repositioning the guide between each measurement. The standard deviation of the measurements was 0.06 mm.

4.4. Results

4.4.1. Prosthesis-Cement Subsidence

The data for prosthesis-cement subsidence over the nine months after implantation is shown in Figures 4.8 and 4.9. The data for the measurement of subsidence was incomplete because the proximal marker ball was not seen on all radiographs, therefore, the implant axis length and other measurements could not be calculated for these radiographs. At nine months after implantation the data for the proximal measurement of prosthesis-cement subsidence was incomplete whereas the data for the distal measurement was complete, therefore the distal measurement of prosthesis-cement subsidence was used to test the hypothesis.

Prosthesis-cement subsidence at nine months after implantation measured between the distal tip of the prosthesis and the distal cement marker ball is shown in Figure 4.8. At nine months after implantation there was no difference between a polished surfaced prosthesis and a matt surfaced prosthesis when prosthesis-cement subsidence was measured between the distal markers ($p = 0.9$).

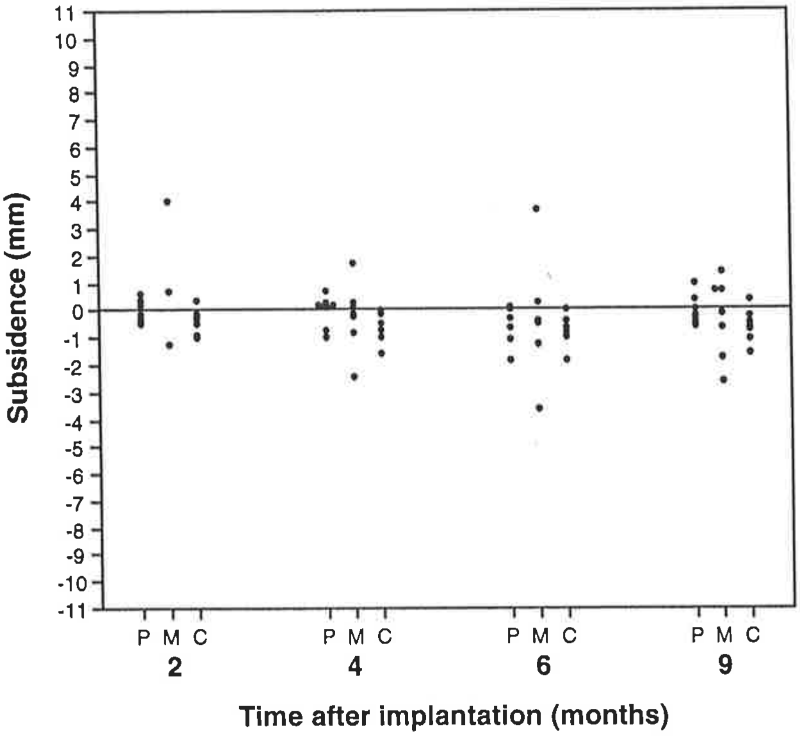

Figure 4.8. Scatter plot of the prosthesis-cement subsidence measured between the distal markers over nine months following implantation for polished, matt and collared prostheses.

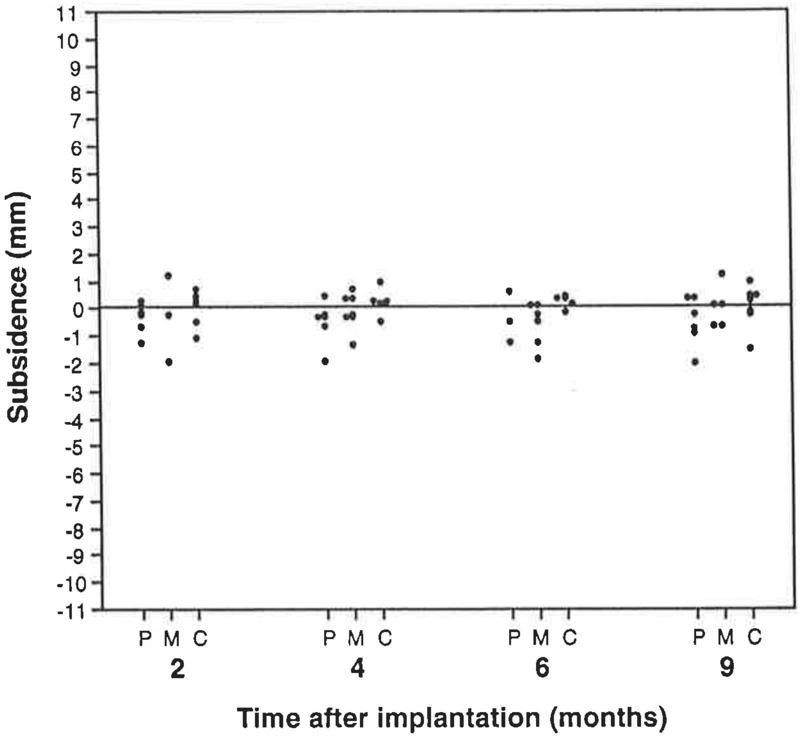

Figure 4.9. Scatter plot of the prosthesis-cement subsidence measured between the proximal markers over nine months following implantation for polished, matt and collared prostheses.

There were no radiolucent gaps seen between any prosthesis and the cement mantle in Gruen zone 1 on plain AP radiographs or the high contrast contact radiographs. This was confirmed when the mid-coronal sections of the proximal femur were assessed. In all femurs, there was no visual evidence of prosthesis-cement subsidence (Figure 4.10). Several important findings were seen with the mid-coronal sections;

New bone growth over the cement mantle was a common feature (Figure 4.11).

New bone growth over the greater trochanter was seen (Figure 4.12).

No fractures of the proximal cement were seen and there was good interdigitation between the proximal cement and bone (Figure 4.13).

The observations from the assessment of high contrast plain radiographs and mid-coronal photographs confirmed the radiographic assessment that there was no prosthesis-cement subsidence of any stem.

Figure 4.10. Mid-coronal section of proximal femur. There is direct contact between the prosthesis and cement in the supero-lateral zone (Gruen zone 1) without evidence of migration or intervening fibrous tissue.

Figure 4.11. Mid-coronal section of proximal femur. There is new bone growth over the cement mantle.

Figure 4.12. Mid-coronal section of proximal femur. There is new bone growth over the greater trochanter.

Figure 4.13. Mid-coronal section of proximal femur. There is a uniform cement mantle with no fracture and good cement-bone interdigitation.

4.4.2. Migration Measurements of the Four Markers

The data for the migration of the two cement and the two prosthesis markers referenced from the greater trochanter is shown in Figures 4.14 to 4.17. The range of calculated subsidence was very high, between -10.3 mm and +10.1 mm. Statistical analysis was not done because of the wide distribution of the data which was thought not to be accurate.

The scatter plots show there was no difference between the three implant types and there were no trends over the nine months following implantation.

Review of the plain radiographs shows that 10 mm of subsidence could not have occurred.

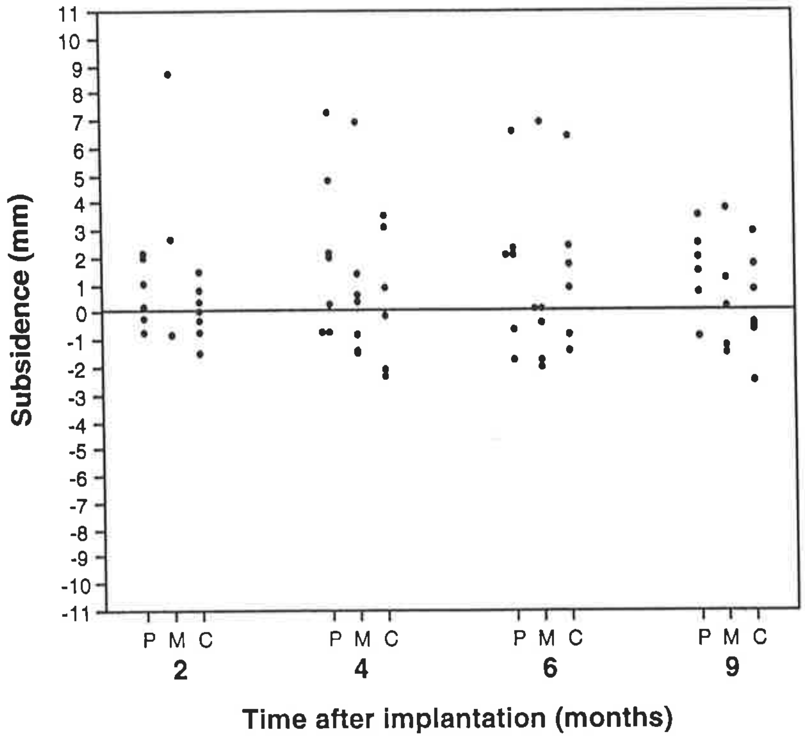

Figure 4.14. Subsidence between prosthesis and bone as measured by migration of the proximal prosthesis marker over nine months.

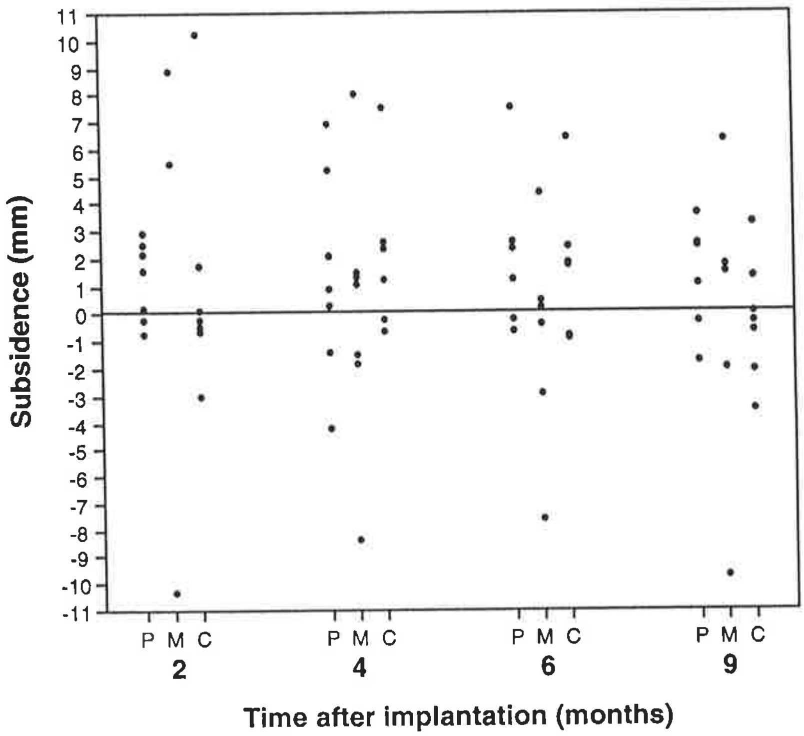

Figure 4.15. Subsidence between prosthesis and bone as measured by migration of the distal prosthesis marker over nine months.

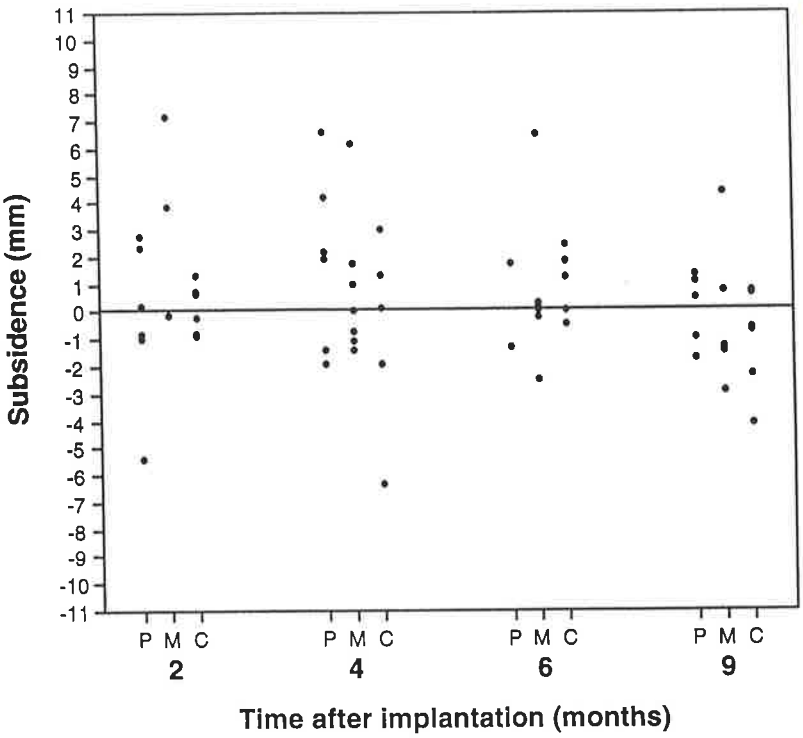

Figure 4.16. Subsidence between cement and bone as measured by migration of the proximal cement mantle marker over nine months.

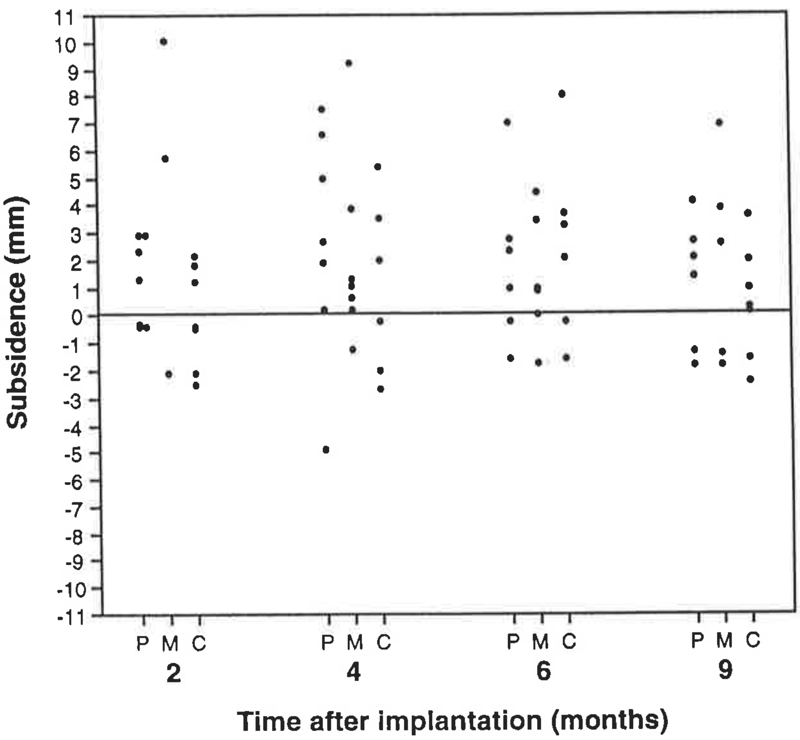

Figure 4.17. Subsidence between cement and bone as measured by migration of the distal cement mantle marker over nine months.

4.4.3. Direct Measurement of Migration

The data for the direct measurement of migration at nine months after implantation is shown in Figure 4.18. There was no difference between the three implant types and the range of measurements was high.

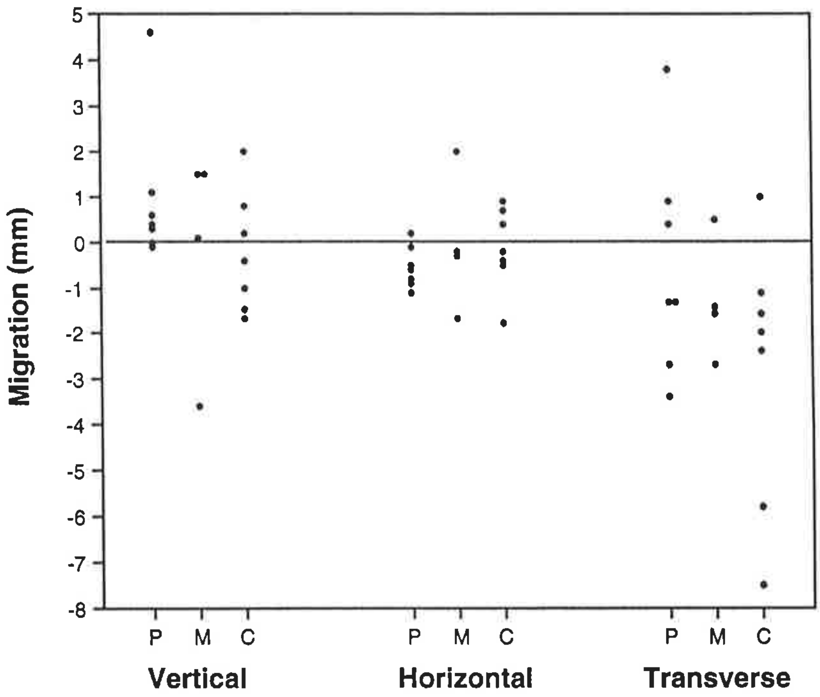

Figure 4.18. Migration at nine months after implantation taken from the direct measurements in three directions for the three implant types.

4.5. Discussion

In this study, plain radiography was unable to detect a difference in subsidence at up to nine months following implantation for the polished, matt or collared implants at either the prosthesis-cement or cement-bone interfaces. The finding that at nine months following implantation there was no difference in prosthesis-cement subsidence between a polished and a matt surfaced cemented stem allowed the hypothesis to be rejected. The power of the study was calculated from the mean and standard deviations of distal prosthesis-cement subsidence data. The power was calculated to be 27%.

In this study a lucent line or gap at the prosthesis-cement interface in Gruen zone 1 was not seen on plain radiographs for any prosthesis. The detailed assessment of the prosthesis-cement interface with high contrast radiographs and photographs of the mid-coronal sections of the explanted femurs did not demonstrate a gap in Gruen zone 1. In contrast, this prosthesis-cement gap has been a common radiographic finding with the polished surface Exeter femoral stem in the human, and is normally seen within 12 months of implantation (Fowler et al.1988). The findings of this study suggests that a double tapered cemented femoral stem does not subside in a sheep model of cemented hip arthroplasty.

The Exeter polished femoral stem inserted with first generation cementing techniques has been measured to subside up to 10 mm within the cement mantle, the majority less than 2 mm (Fowler et al.1988). The same study found no subsidence in 96% of the Exeter matt femoral stems inserted with second generation cementing techniques. No clinical study has reported the subsidence of polished Exeter femoral stems with second or third generation cementing techniques. However, Davies et al. (1996) have measured subsidence of a polished Exeter femoral stem inserted with contemporary cementing techniques into fibreglass femurs and then cyclically loaded in a joint simulator. They found that no stem had subsided more than 200 microns after 10 million cycles.

The design of the sheep femoral stem was similar but not identical to the Exeter human femoral stem. The sheep femoral stem was proportionally greater in the antero-posterior diameter and was tapered proximally, not flat like the human stem. These subtle differences in taper may have prevented subsidence of the sheep femoral stem used in this study or the use of contemporary cementing techniques may limit subsidence such that it is not measurable with standard radiographic techniques.

Loudon and Older (1989) have suggested that subsidence resulting in seating of the prosthesis will occur within the first 12 months. Therefore this study should have detected early subsidence if it was to occur.

In this study the prosthesis-cement subsidence at nine months after implantation, not separated by prosthesis type, was -0.3 ± 0.9 mm. Subsidence of the two prosthesis and two cement mantle markers as measured from a screw in the greater trochanter had a range of -10.3 mm to +10.1 mm. This variation is greater than that expected. The repeatability study of prosthesis-cement subsidence showed the standard deviation for 5 radiographs taken on the same day and measured 10 times was 0.1 mm. The difference between the repeatability of plain radiography over nine months compared to 5 radiographs on the same day may be due to several factors;

There were different radiographers taking the radiographs and although following the same instructions, the technique may have differed. There may have been differences in size and hip flexibility in the sheep over the months.

The greater trochanter may not have been a static landmark and the relative position of the reference screw in the greater trochanter may have changed with bone growth and bone remodelling due to the different forces acting on the greater trochanter after hip replacement.

The measurements in this study were corrected for magnification and out of plane flexion by a factor calculated from the known length of the implant. This factor did not take into account the differences in rotation of the implant or parallax of the x-ray beams due to centring differences and abduction of the femur. As all radiographs were compared to the radiograph taken immediately after implantation, any differences in this radiograph would have effected all other radiographic measurements.

This study together with others have demonstrated the limitations of plain radiographic assessment of migration. The main error is because of the difficulty in taking reproducible radiographs. The error of the measurement from plain radiographs has been reported to be between 0.5 and 6 mm. (Liossis et al.1992; Loudon and Charnley, 1980; Loudon, 1986; Nunn et al.1989; Sutherland and Bresina, 1992).

The use of a digitising tablet to measure subsidence from non standardised plain radiographs is not supported unless reproducible radiographs can be ensured, because the error due to positioning is greater than the error due to measurement. Future studies which specifically address the amount and rate of migration should use Roentgen Stereophotogrammetric Analysis (RSA) despite the cost and time disadvantage.

A study designed using RSA with migration of a polished prosthesis of 0.5 $\pm$ 0.5 mm and a matt prosthesis of 0 $\pm$ 0.5 mm, using an α = 0.05 and a β = 0.20 (power = 80%), would require 16 sheep per prosthesis type group. Despite the cost of RSA there would be less animal costs for such a study.

It may be criticised that the observation period of this study may have been too short to see subsidence. However, this study was designed to observe the early events that occur with cemented femoral stems in vivo. Subsidence should have occurred in this time frame if the prosthesis was engaging to a more stable position. The measurement of subsidence due to prosthesis loosening was not an aim of this study.

4.6. Conclusions

Subsidence of a cemented femoral stem was not measured at nine months following implantation with an *in vivo* sheep model. Surface roughness and the use of a collar did not effect subsidence at the prosthesis-cement or cement-bone interfaces. The poor accuracy of plain radiographs in measuring subsidence has been highlighted in this study as the limiting factor for the detection of small differences in subsidence.

RSA is essential for future research into hip arthroplasty fixation and study groups should be greater than 20 per implant type to allow for complications and ensure adequate statistical power.

Chapter 5

Micromotion Assessment of Fixation

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5.1. Introduction

The main objective of this component of the study was to test the hypothesis

> At nine months after implantation there is less micromotion between a polished surfaced prosthesis and bone than between a matt surfaced prosthesis and bone.

This study was a comparison between three stems, a polished, a matt and a matt collared stem. Micromotion was measured immediately after and at nine months after implantation. Micromotion was measured from a jig attached to the femoral head to the proximal bone, cement and stem surfaces using a single displacement transducer. Micromotion to the prosthesis stem was subtracted from that to the bone and cement to give p-b and p-c micromotion.

The relevant literature on measurement of prosthesis stability and micromotion testing has been reviewed in chapter 1.

5.2. Materials and Methods

Eighteen of the initial study group of thirty sheep and three of the replacement sheep completed nine months *in vivo* loading. The explanted femurs of these twenty-one sheep with seven polished, seven matt and seven collared stems underwent mechanical testing. The femurs were tested within 24 hours of explantation.

One replacement group sheep (#R3, polished) was killed at three months following implantation because of possible prosthesis loosening and was tested and described separately. The prostheses from the drop-out sheep that were killed because of other withdrawal criteria were not tested.

5.2.1. Femur Marking, Positioning and Fixation into the Loading Jig

The explanted femurs were placed in a positioning jig designed to allow reproducible positioning. The femurs were marked transversely at 10% and 40% of the longitudinal length from the distal femoral condyles and longitudinally along the posterior and medial aspect of the femur (Figure 5.1). The mark at 10% from the distal femoral condyles was the level at which a cut was made to enable potting of the femur. The mark at 40% was the depth to which the femur was potted in cement. The level of potting in cement ensured the entire prosthesis was above the potting cement (Figure 5.2).

A loading jig was designed and constructed to enable mechanical testing in three planes and ensure rigid fixation of the femoral prosthesis (Figure 5.3). The loading was along the principal longitudinal axis of the prosthesis for the axial test and at two axes at right angles to this axis for medio-lateral and antero-posterior tests. The longitudinal axis of the prosthesis was lateral to the centre of the head of the prosthesis; the other two axes passed through the centre of the head of the prosthesis.

The head of the prosthesis was secured in the loading jig and attached to the load cell of the Hounsfield Universal Testing Machine (Hounsfield H25KM, Hounsfield Test Equipment, Croydon, England). To fix the femur, it was then lowered into a metal holding cup until the distal cut end of the femur was at the base of the holding cup and positioned such that the head of the femoral stem was in the centre of the holding cup and the greater trochanter did not overhang the cup. Self-curing dental cement (PMMA, Hallas Dental, Adelaide, Australia) was poured into the holding cup to fix the femur in the holding cup and was inserted such that it covered the distal 40% of the femur. The potting cement did not cover the distal tip of the prosthesis or the intramedullary cement mantle one cm below the tip of the prosthesis. The potting cement was allowed to cure for one hour prior to testing. Throughout testing the femur was sprayed at regular intervals with normal saline to maintain hydration of the bone and interface tissues.

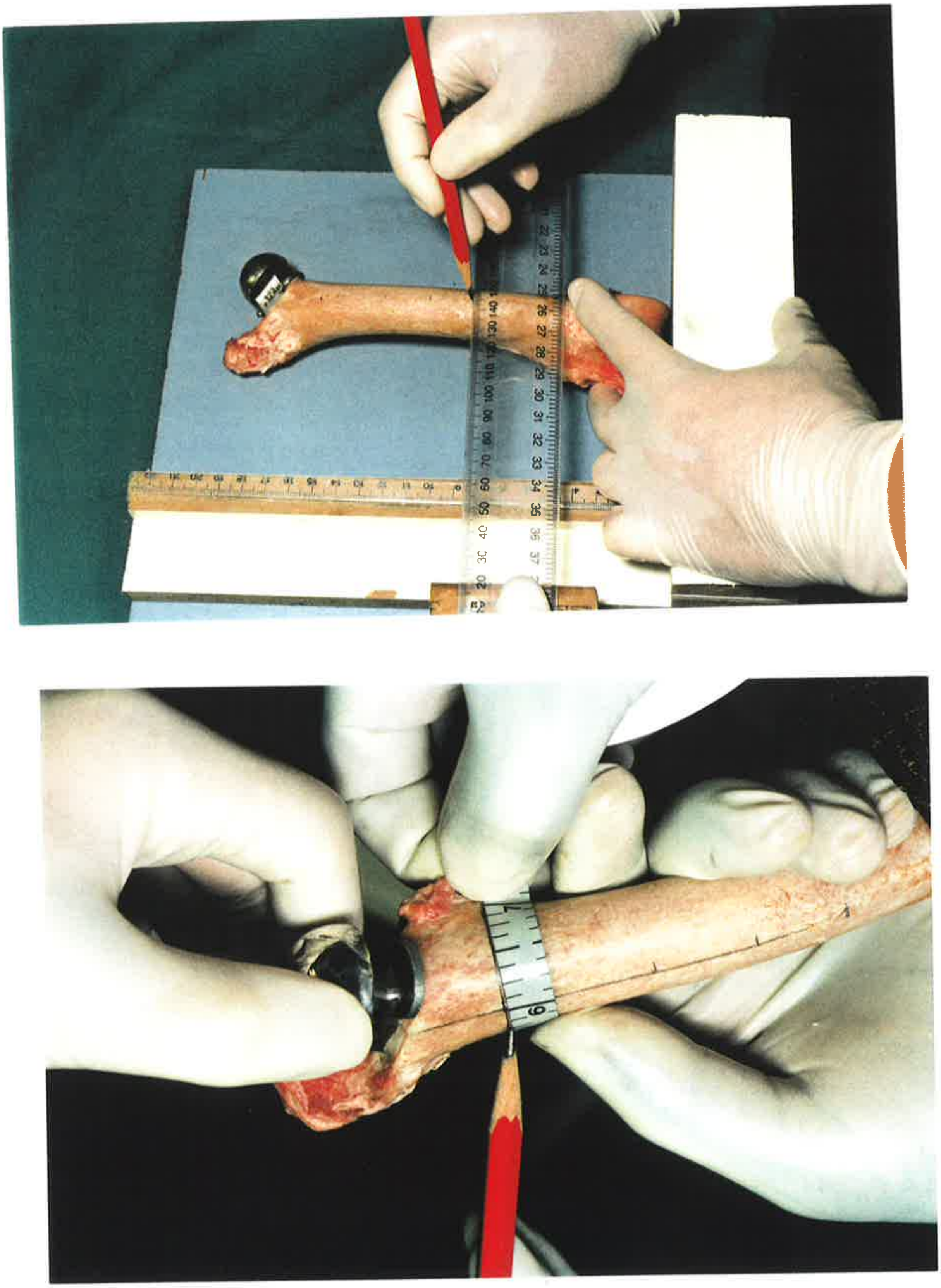


Figure 5.1. Sheep femur stripped of soft tissues placed in positioning jig to enable accurate marks to be drawn on the bone surface for sectioning and potting levels.

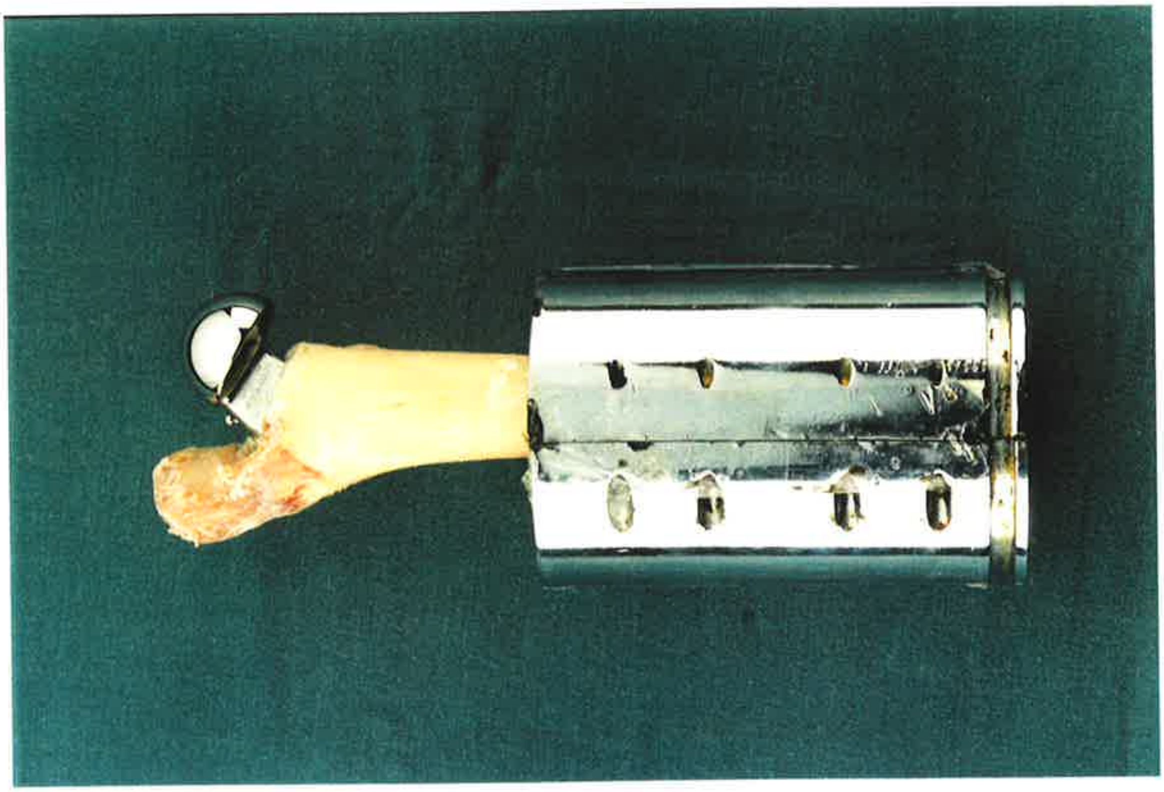


Figure 5.2. Femur potted in the holding cup.

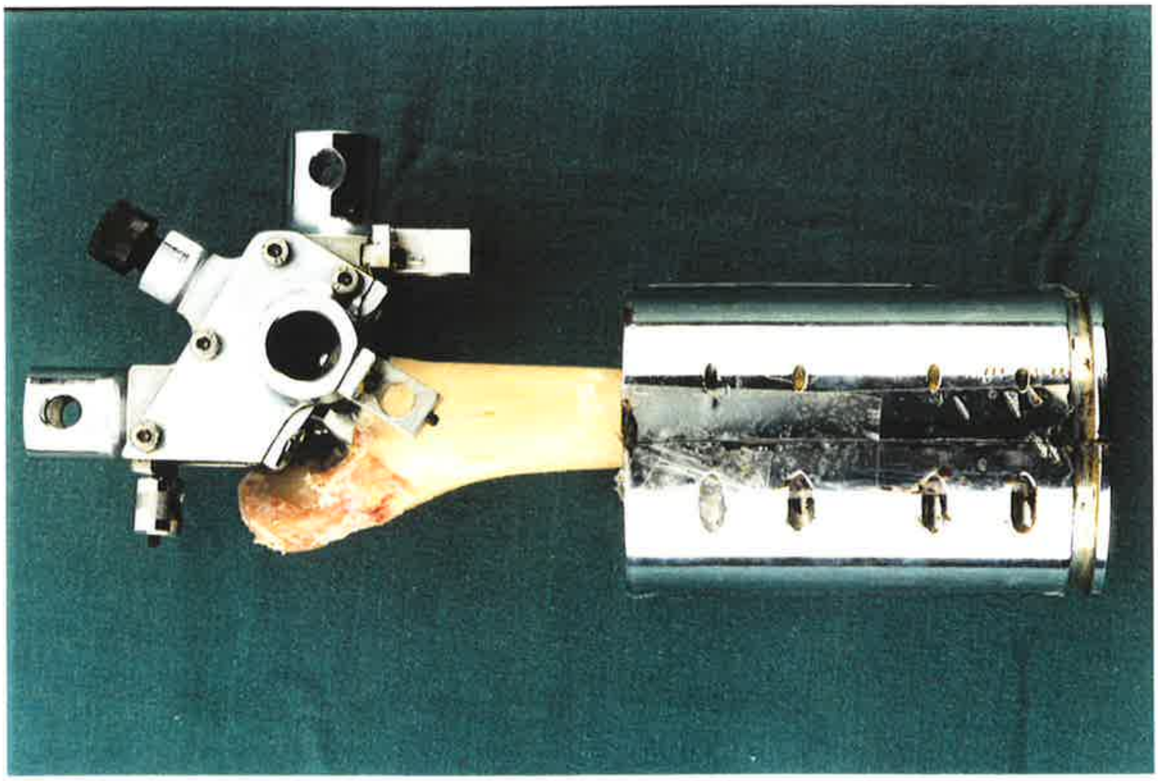
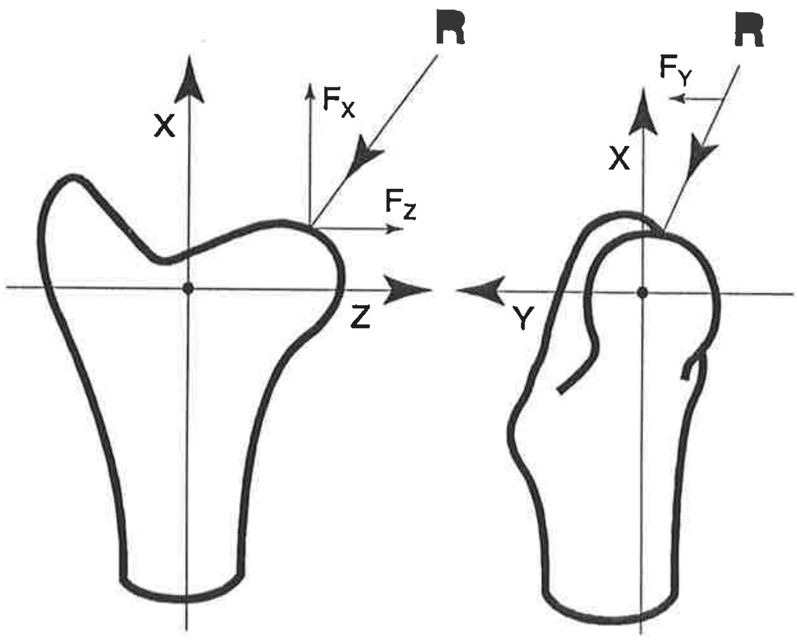


Figure 5.3. Loading jig attached to the prosthesis.

5.2.2. Calculation of Loading Force Magnitude and Direction

A reproducible, standardised loading protocol was designed. The loading forces used were based on the data from the study of Lanyon et al. (1981) who measured *in vivo* strain in sheep femurs during normal walking.

Lanyon et al. (1981) calculated that during normal walking, the resultant force (R) on the sheep hip joint was 500 Newtons (N) directed 35° laterally and 20° posteriorly for a 65 kg sheep (Figure 5.4).



R = resultant load acting on femoral head
Fx, Fy, Fz = vector loads

Fx = axial = 385 N
Fy = antero-posterior = 140 N
Fz = medio-lateral = 287 N

Figure 5.4. Resultant sheep hip joint forces (Lanyon et al., 1981)

To calculate the component forces in the axial, medio-lateral and antero-posterior directions, the resultant force was resolved into a force in each of the three planes (x,y,z). The equations below show how these forces were calculated from the above diagram and data.

$R'^2 = x^2 + z^2$
$R''^2 = x^2 + y^2$
$x = R' \cos 35$ and $R' = R \cos 20$ for the x-z plane
$x = R'' \cos 20$ and $R'' = R \cos 35$ for the x-y plane

Solving the above equations for x, y and z (for a 65 kg sheep).

$x = R \cos 20 \cos 35 = 385$ N Axial
$y = R \cos 35 \sin 20 = 140$ N Antero-posterior
$z = R \cos 20 \sin 35 = 287$ N Medio-lateral

The following calculated loads were then used for the mechanical testing of each pair of femurs. The vector loads used for testing (N) in each direction (x,y,z) are represented as multiples of body mass (kg). Loading was then calculated based on the weight of each sheep.

$x = 5.923 \times BW(kg)$ N Axial

$y = 2.154 \times BW(kg)$ N Antero-posterior

$z = 4.415 \times BW(kg)$ N Medio-lateral

5.2.3. Micromotion Measurement and Test Conditions

From a jig attached to the head of the femoral component, micromotion was measured to the proximal bone, cement and stem using a single linear variable differential transformer (LVDT) (Lucas Schaeritz, Pennsauken, NJ, USA) (Figure 5.5.). The LVDT had a resolution of 0.28 microns and an accuracy of 0.8 microns when allowances were made for the electrical noise of the testing machine and electrical equipment used in the micromotion testing.

Loading was performed in three directions, axial, medio-lateral and antero-posterior, and in each direction three measurements were made. The first micromotion measurement was prosthesis-bone and was made from the femoral head to the proximal femoral cortex. The LVDT and the femoral head were rigidly attached to the loading jig and the tip of the LVDT was positioned on an area of cortical bone that had a small drill hole made to ensure no soft tissue was interposed. Following the measurement of the prosthesis-bone micromotion, the cortex immediately below the point of measurement was drilled down to the cement mantle with a 2.5 mm drill to allow measurement of prosthesis-cement micromotion (Figure 5.6.). Following the measurement of prosthesis-cement micromotion, the cement mantle was drilled down to the stem to allow measurement of micromotion from the femoral head to the stem of the prosthesis.

For the axial test the explanted femur and holding cup was positioned in the testing machine such that an axial load of 5.923 x BW(kg) Newtons was applied through the principal vertical axis of the prosthesis (Figure 5.7.). There was no pull out test performed as this might have interfered with subsequent histological examination.

For the medio-lateral test the explanted femur and holding cup were mounted in the testing machine such that the femoral stem was perpendicular to the loading direction and the femoral head was in the centre of the loading axis. A specially made adaptor was attached to the load cell and the femoral head and was used to load the prosthesis at 4.154 x BW(kg) Newtons in a medial to lateral direction

(Figure 5.8.).

For the antero-posterior test the explanted femur and holding cup were mounted in the testing machine so that the femoral stem was perpendicular to the loading direction and the head of the prosthesis was in the centre of the loading axis. A specially made loading jig was attached to the load cell and the femoral head and was used to load the prosthesis at 2.154 x BW(kg) Newtons in an anterior to posterior direction (Figure 5.9.).

The load was applied through a loading jig attached to the load cell. Five loading cycles were applied at a rate of five mm per minute. The maximum micromotion was used for comparison between stem types.

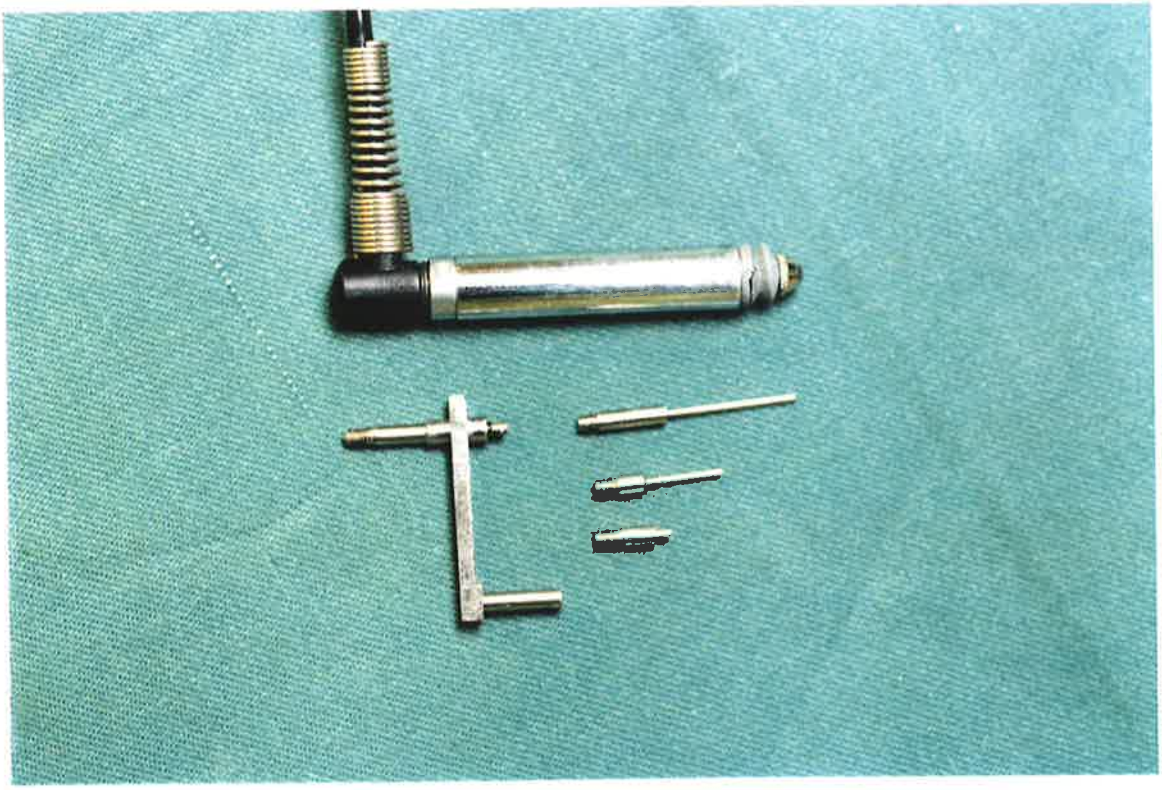


Figure 5.5. LVDT used for measurement of micromotion

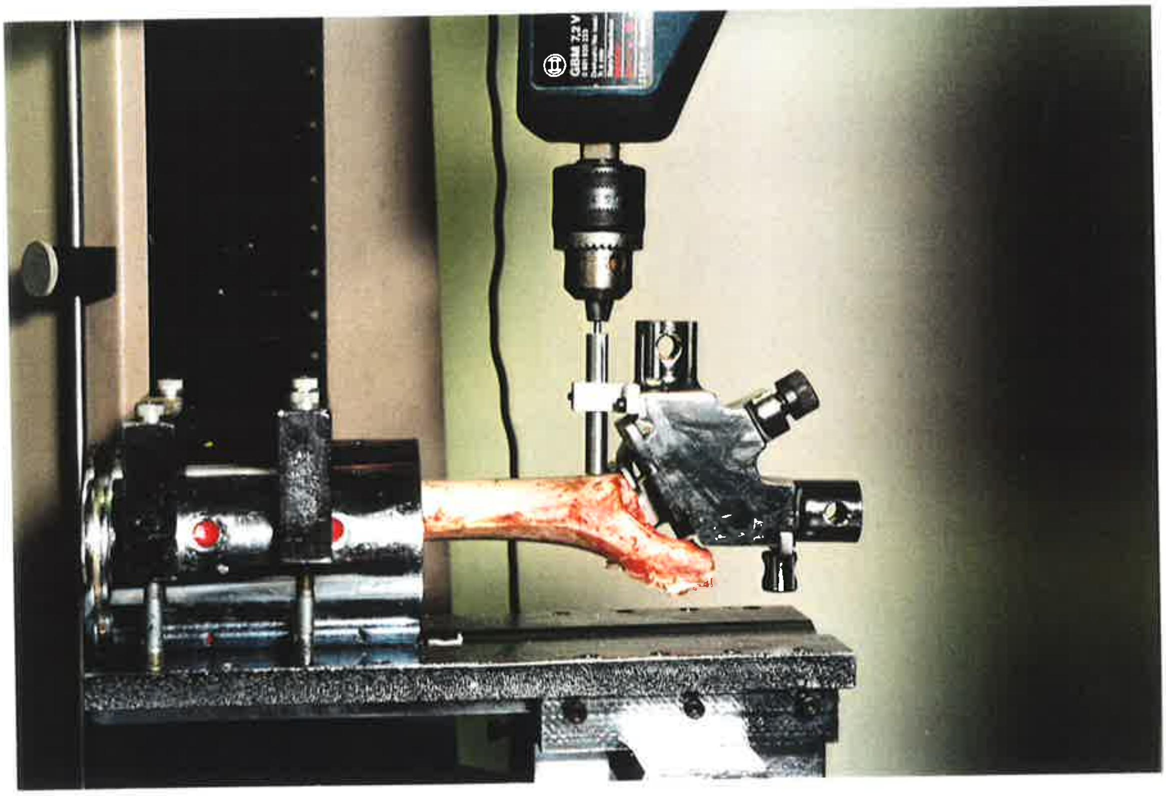


Figure 5.6. Bone being drilled down to the outer cement mantle to allow measurement of the cement mantle micromotion.

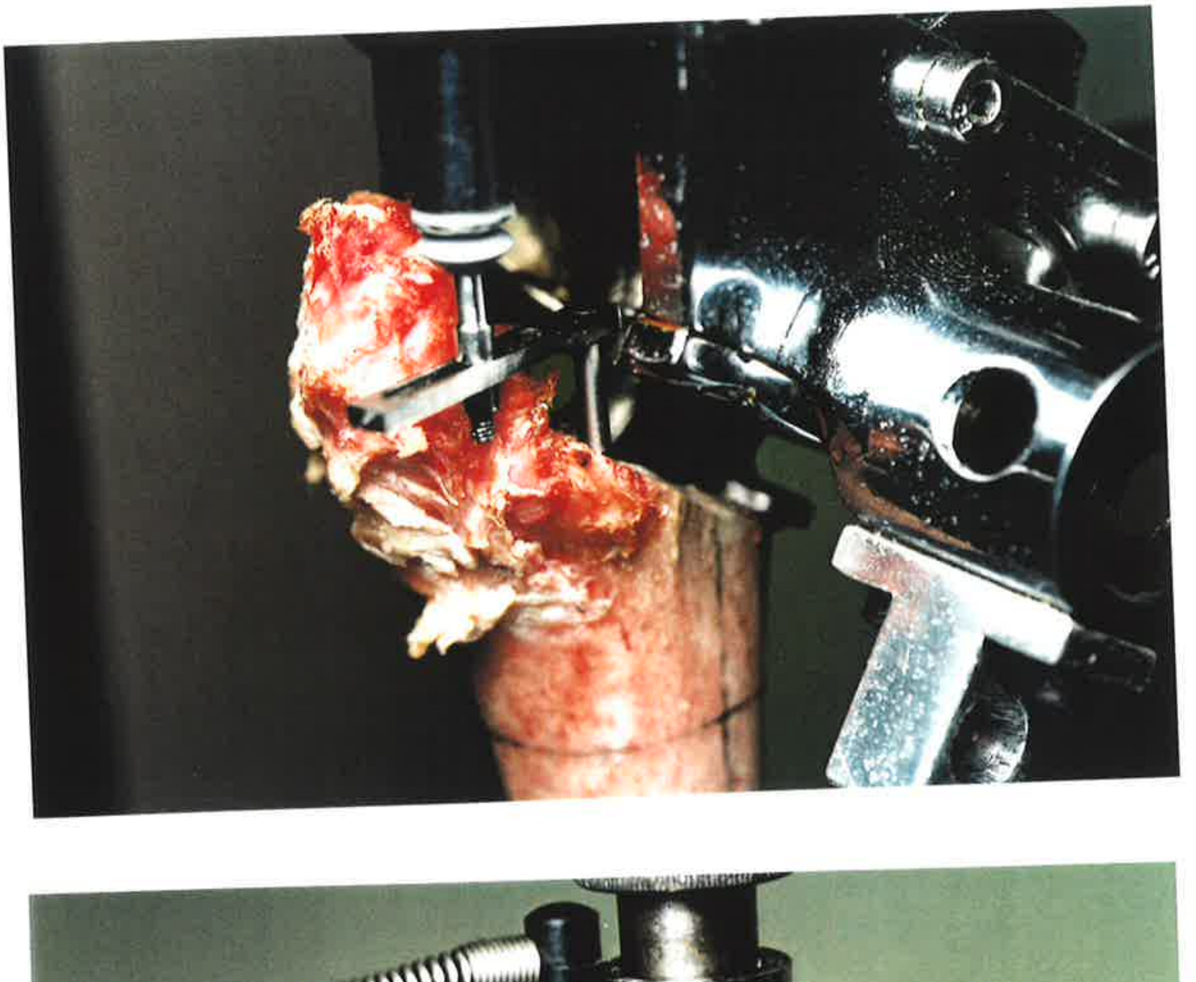


Figure 5.7. Axial Testing

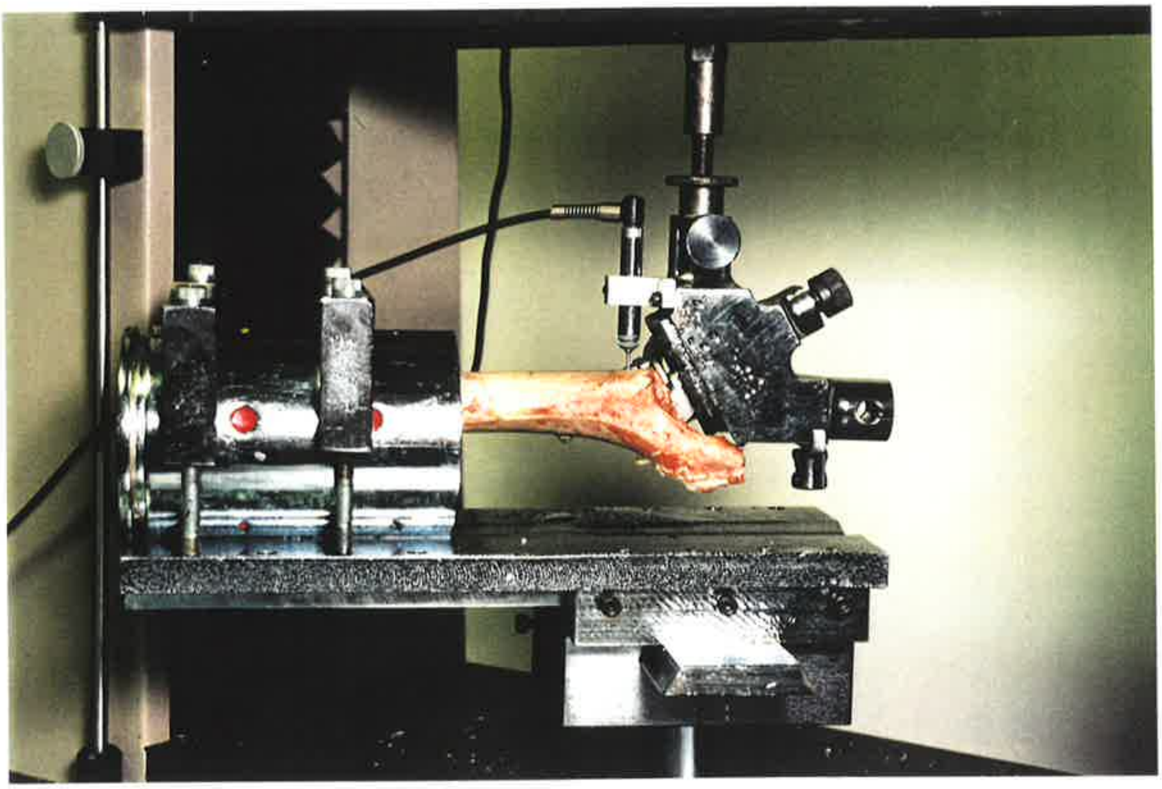


Figure 5.8. M-L Testing

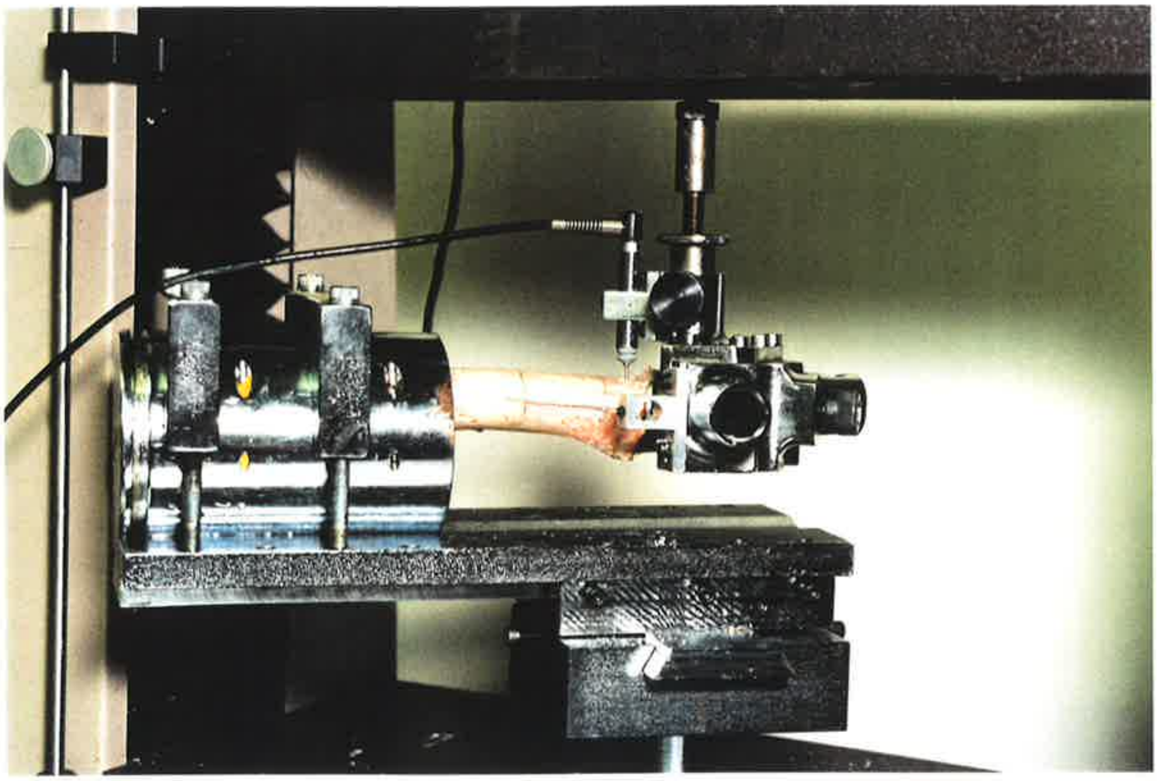


Figure 5.9. A-P Testing

5.2.4. Assessment of Micromotion

Micromotion was recorded from the jig attached to the head of the femoral component to the proximal bone, cement and prosthesis. This allowed prosthesis-bone, prosthesis-cement and prosthesis-prosthesis micromotion to be measured. The difference between the maximum and minimum value of micromotion recorded during the fifth cycle of testing was the measurement of micromotion used for the analysis.

Initially it was thought that the micromotion which was recorded between the prosthesis and prosthesis was "noise" due to micromovement between the jig and LVDT leading to experimental error for each tested femur. Because of this, in the analysis of both prosthesis-bone and prosthesis-cement micromotion the prosthesis-prosthesis micromotion was subtracted from these measurements to give a corrected micromotion measurement. For small measures of micromotion this sometimes resulted in some negative values being calculated, which should not be interpreted as negative micromotion.

Following the analysis of the corrected micromotion measurements and review of the data of prosthesis-prosthesis micromotion (Table 5.1), it was thought that this experimental error may not be as systematic as initially thought because of the large range of values recorded.

A second assessment was therefore performed on the uncorrected data of prosthesis-bone and prosthesis-cement micromotion. This data did not have the prosthesis-prosthesis micromotion subtracted and therefore had no negative values.

Table 5.1. Prosthesis-prosthesis micromotion measured for all prostheses with axial, medio-lateral and antero-posterior testing.

	Axial	Medio-lateral	Antero-posterior
Mean	13	32	18
Standard Deviation	6	19	11
Range	2 - 26	8 - 94	0 - 43

Micromotion was not able to be measured from the cement mantle with axial t in ten prostheses and antero-posterior testing in two prostheses.

Micromotion statistical analysis was performed using a Mann Whitney U-test for testing of the hypothesis and with an Unbalanced Repeated Measures Model (BMDP Statistical Software (5V), Los Angeles, USA) for the secondary hypotheses as described in chapter 2. This model analysed the axial, medio-lateral and antero-posterior micromotion as separate tests and the prosthesis-cement and the prosthesis-bone micromotion as a separate tests.

The Unbalanced Repeated Measures Model calculates representative values of micromotion for each test. These represent the central tendency of the data, much like a median or mean value. Analyses where the representative values of micromotion for any one implant type were less than one standard deviation of prosthesis-prosthesis micromotion were considered not significant, as these measurements were small and the differences between the groups were within the potential error of the method.

5.3. Results

5.3.1. Prosthesis-Bone Micromotion

Axial prosthesis-bone micromotion is shown in figure 5.10. At nine months after implantation, there was no difference in axial micromotion between a polished surfaced prosthesis and bone and a matt surfaced prostheses and bone ($p = 0.6$). The representative value of prosthesis-bone micromotion nine months after implantation was 23 μm.

Axial prosthesis-bone micromotion was no different between implant types ($p = 0.3$) but taken as a whole the micromotion immediately after implantation was greater than at nine months after implantation ($p < 0.001$). The representative values of axial prosthesis-bone micromotion was 37 μm immediately after implantation and 23 μm at nine months after implantation.

Medio-lateral prosthesis-bone micromotion is shown in figure 5.11. There was no difference between implant types and there was no difference when measured immediately or nine months after implantation. The representative value of medio-lateral prosthesis-bone micromotion was 10 μm. The representative value was smaller than the error of the method and statistical analysis was not done.

Antero-posterior prosthesis-bone micromotion is shown in figure 5.12. There was a difference in antero-posterior micromotion between the prosthesis and bone measured for the three prosthesis types ($p = 0.01$). There was also a difference in antero-posterior micromotion measured between the prosthesis and bone immediately after implantation compared to that at nine months after implantation ($p = 0.001$). However the representative values were smaller than the precision of the method and the differences were not considered important.

The representative values of antero-posterior micromotion between prosthesis and bone immediately after implantation were: polished = 19 μm, matt = 7 μm and collared = 0 μm. The representative values of antero-posterior micromotion between prosthesis and bone nine months after implantation were: polished = 2 μm, matt = 3 μm and collared = 1 μm.

There was no difference in the distribution of the data when the prosthesis-prosthesis micromotion was not subtracted.

5.3.2. Prosthesis-Cement Micromotion

Prosthesis-cement micromotion is shown in figures 5.13, 5.14 and 5.15. There was no difference between implant types for prosthesis-cement micromotion with any test condition, axial ($p = 0.5$), medio-lateral ($p = 0.5$) and antero-posterior ($p = 0.02$). There was no difference in prosthesis-cement micromotion measured immediately after implantation compared to that measured at nine months after implantation, axial ($p = 0.2$), medio-lateral ($p = 0.6$) and antero-posterior ($p = 0.97$).

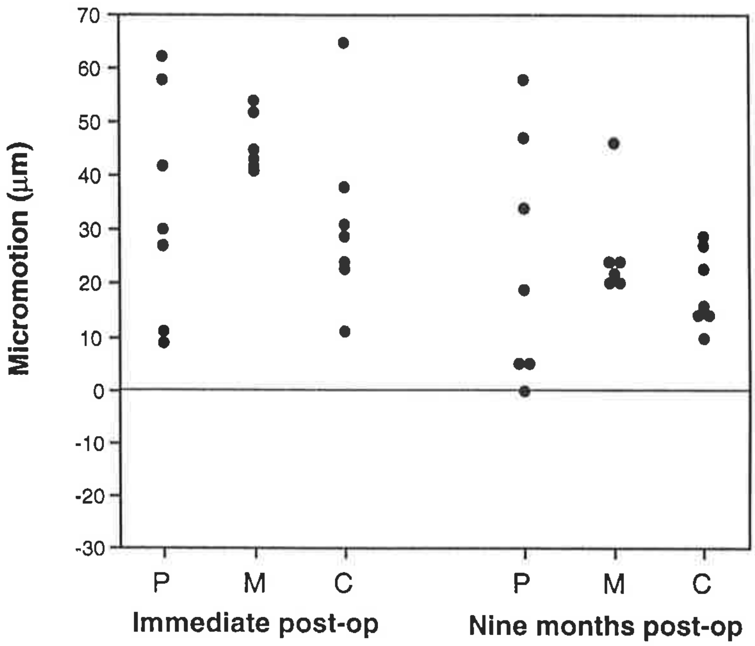
The representative values for prosthesis-cement micromotion were axial = 16 μm, medio-lateral = 2 μm and antero-posterior = 1 μm. These values were all very small and represent minimal movement at the prosthesis-cement interface.

There was no difference in the distribution of the data when the prosthesis-prosthesis micromotion was not subtracted.

5.3.3. Clinically Loose Prosthesis

One polished stem (#R3) showed possible radiographic loosening at three months (Harris et al.1982). The sheep was clinically lame and was killed according to ethical guidelines. The axial micromotion was 129 μm at the cement-bone interface, 210 μm at the prosthesis-cement interface resulting in an axial prosthesis-bone micromotion of 339 μm. The medio-lateral micromotion was 152 μm at the cement-bone interface, -6 μm at the prosthesis-cement interface resulting in a medio-lateral prosthesis-bone micromotion of 146 μm. The antero-posterior micromotion was 84 μm at the cement-bone interface, -33 μm at the prosthesis-cement interface resulting in an antero-posterior prosthesis-bone micromotion of 51 μm. This prosthesis provided an example of the micromotion seen with early loosening.

(a)



(b)

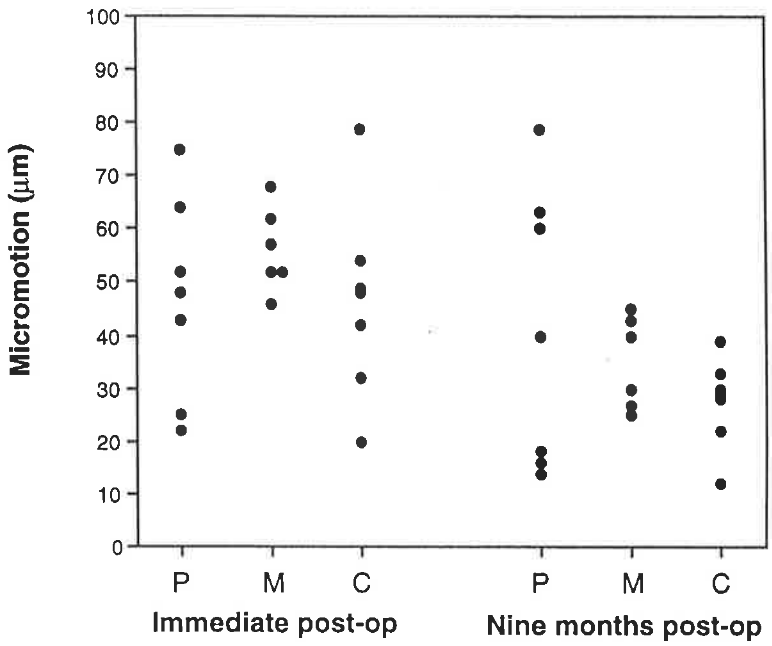
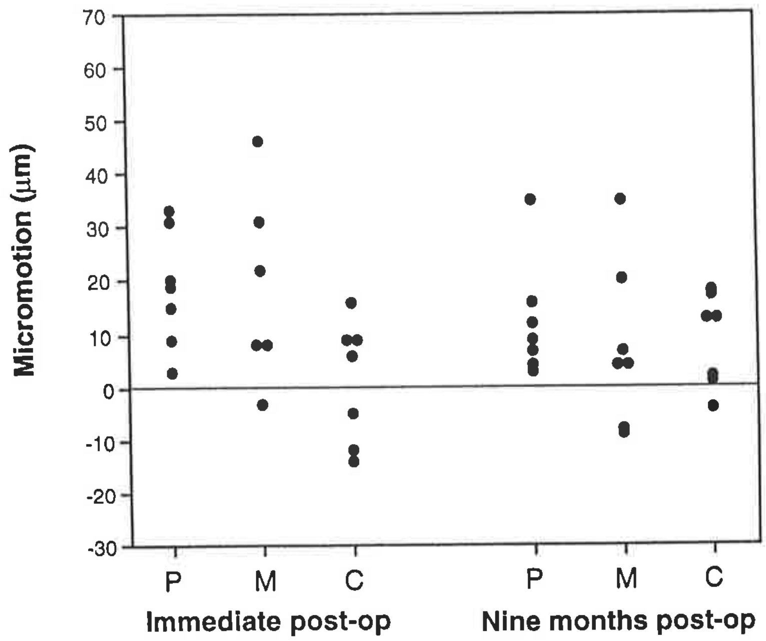


Figure 5.10. Prosthesis-bone micromotion (μm) for axial testing. P=polished, M=matt, C=collar. (a) corrected (b) uncorrected

(a)



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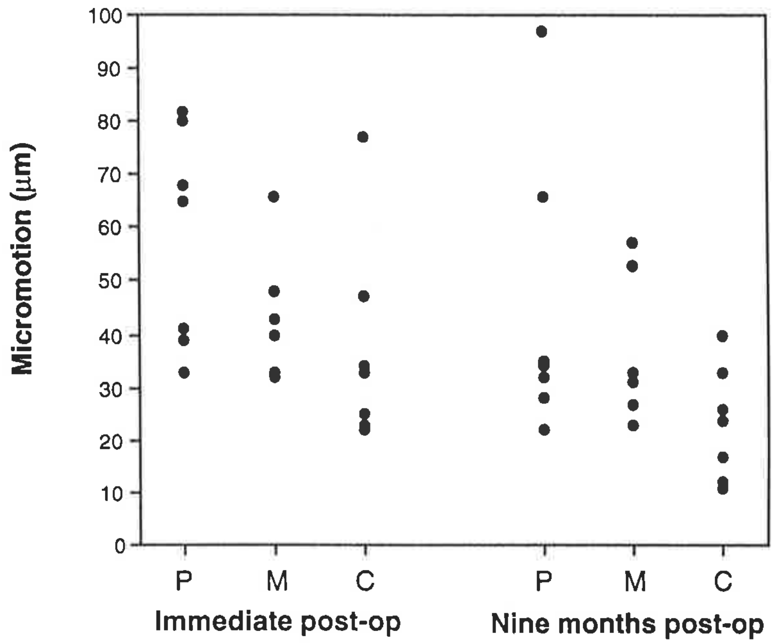
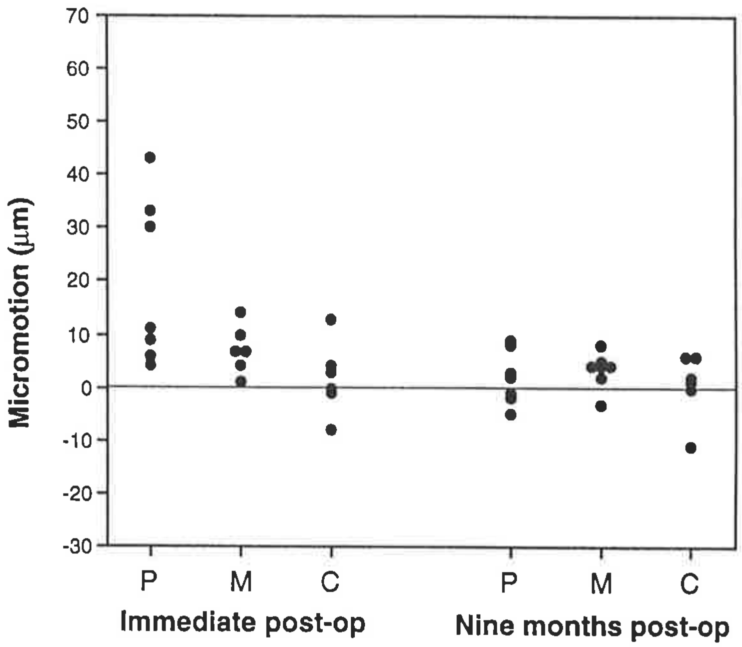


Figure 5.11. Prosthesis-bone micromotion (µm) for medio-lateral testing. P=polished, M=matt, C=collar. (a) corrected (b) uncorrected

(a)



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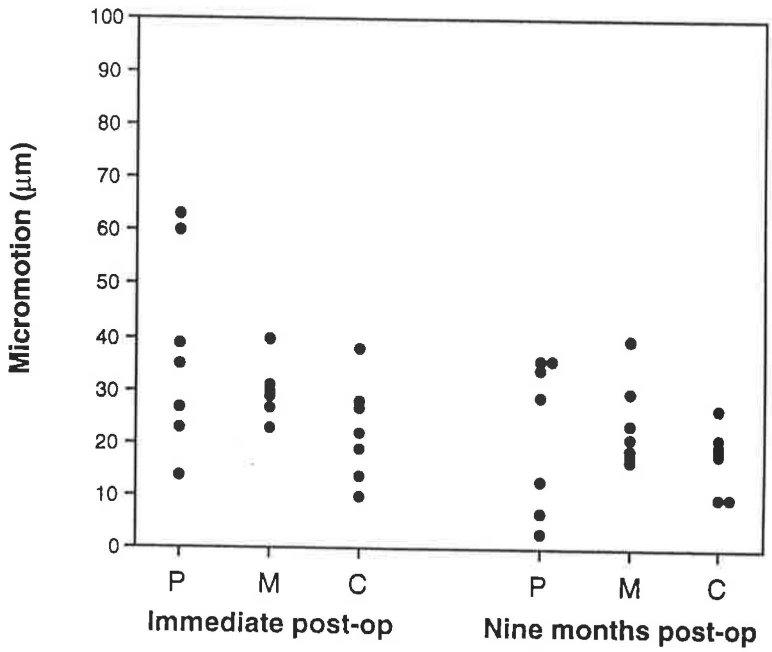
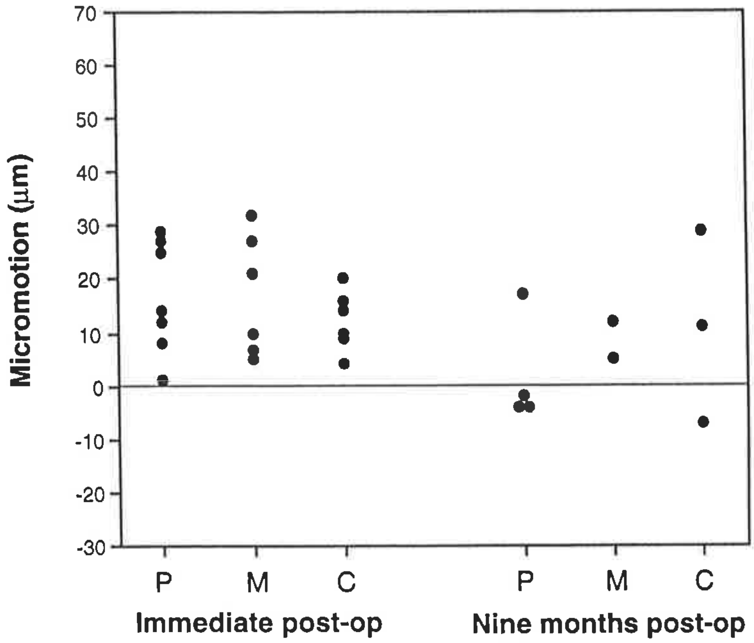


Figure 5.12. Prosthesis-bone micromotion (μm) for antero-posterior testing. P=polished, M=matt, C=collar. (a) corrected (b) uncorrected

(a)



(b)

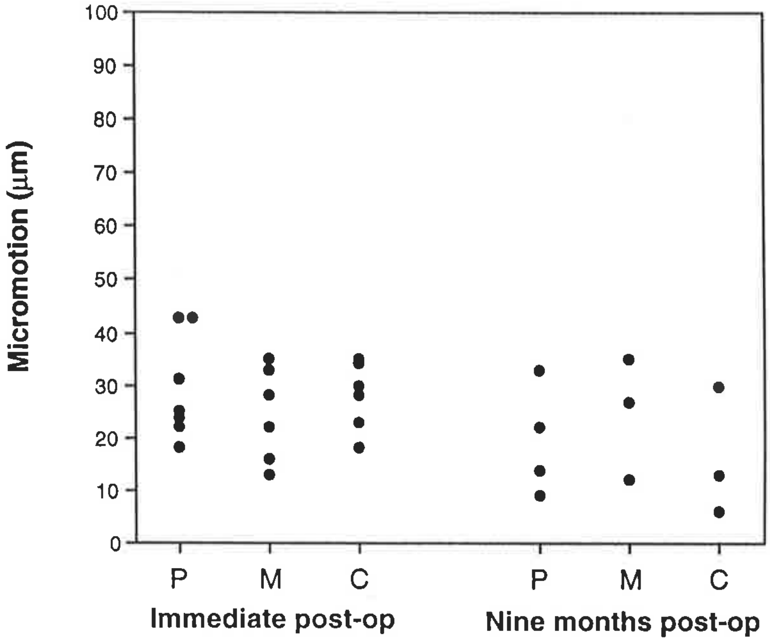
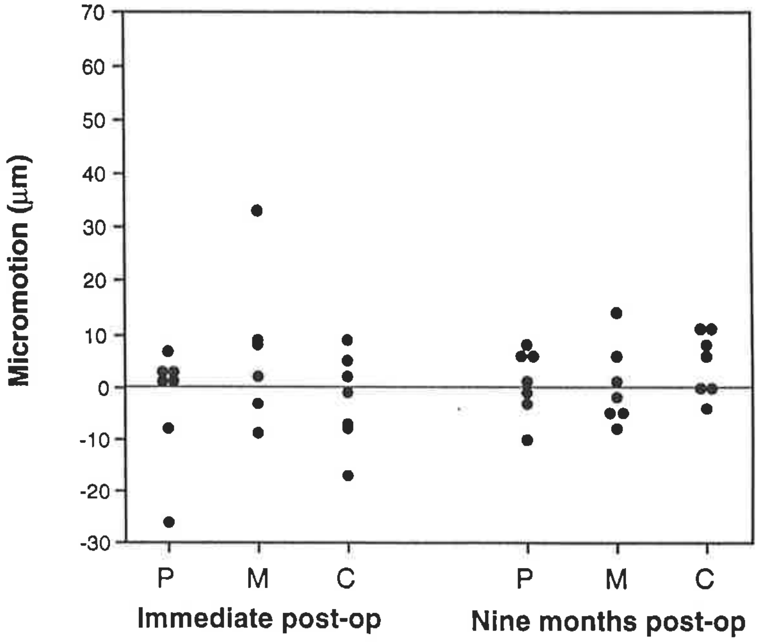


Figure 5.13. Prosthesis-cement micromotion (μm) for axial testing. P=polished, M=matt, C=collar. (a) corrected (b) uncorrected

(a)



(b)

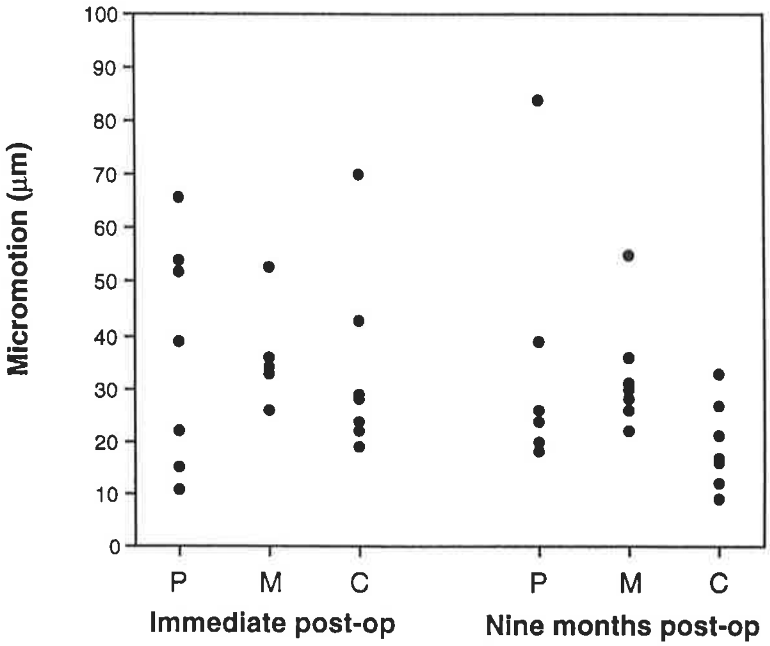
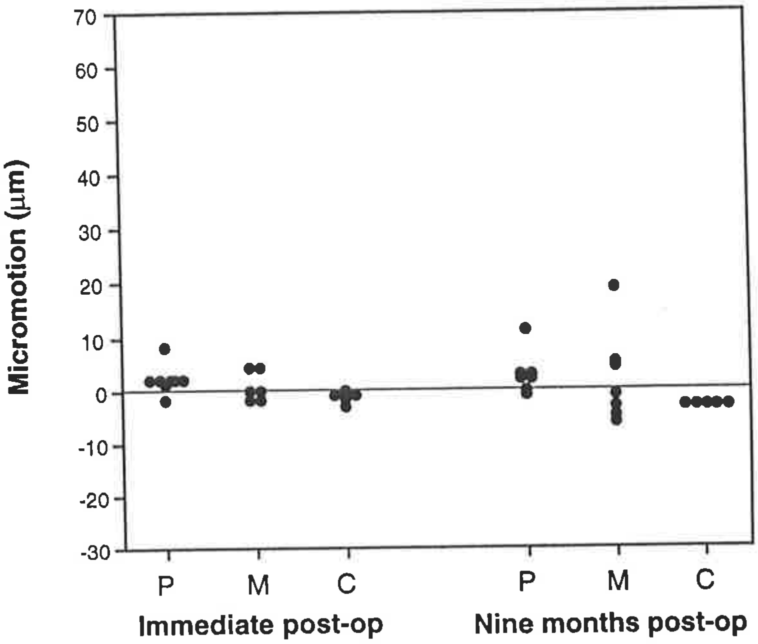


Figure 5.14. Prosthesis-cement micromotion (μm) for medio-lateral testing. P=polished, M=matt, C=collar. (a) corrected (b) uncorrected

(a)



(b)

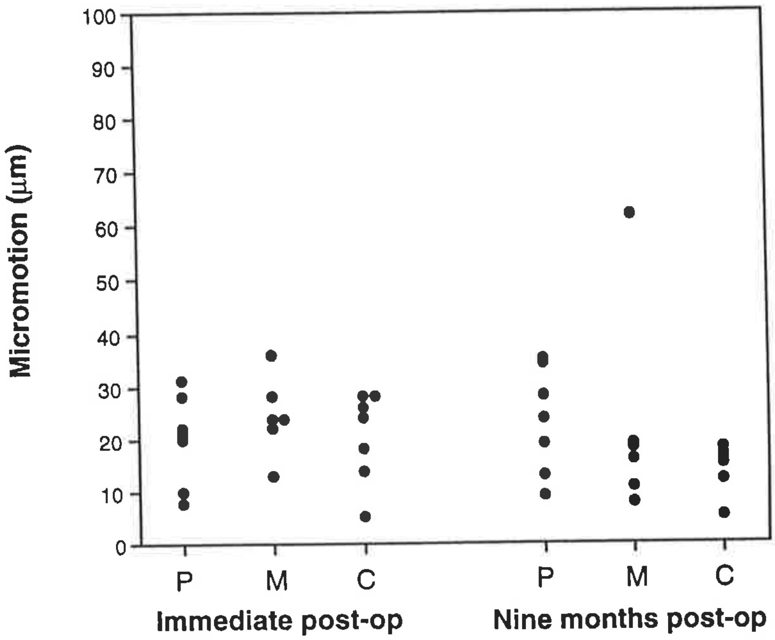


Figure 5.15. Prosthesis-cement micromotion (μm) for antero-posterior testing. P=polished, M=matt, C=collar. (a) corrected (b) uncorrected

5.4. Discussion

At nine months after implantation there was no difference in axial micromotion between prosthesis and bone of a polished surfaced femoral prosthesis and a matt surfaced femoral prosthesis ($p = 0.6$) therefore the second hypothesis was rejected. The statistical power was calculated to be 95% using the data from the hypothesis testing micromotion (polished = 24 ± 23 μm, matt = 26 ± 10 μm), the sample size of 7 per group and a two-tailed test $\alpha = 0.05$.

Axial micromotion between prosthesis and bone was less nine months after implantation compared with immediately after implantation and this difference was significant ($p < 0.001$). This difference demonstrates that the fixation of a cemented femoral stem is increased after several cycles of bone remodelling and healing following implantation. There was no difference between prosthesis types with all implant types showing this improved fixation.

This improved fixation may be a feature of a stem design with a double taper rather than surface finish, or it may represent improved fixation between the cement and the bone. Immediately after implantation there is blood, bone debris and endosteal necrosis due to reaming and the thermal effects of bone cement. Draenert (Draenert, 1981) observed that gaps between cement and bone that were between 20 and 200 μm were filled directly with lamellar bone and larger gaps with woven bone. The filling of these gaps over the nine months after implantation would lead to increased fixation in the immediate healing period after implantation.

In this study the micromotion measured between prosthesis and bone of all prostheses except the clinically "loose" prosthesis were small with all measurements below 65 μm. Several *in vivo* studies of controlled prosthesis-bone micromotion with cementless implants have shown that micromotion up to 40 μm resulted in bone ingrowth whereas micromotion greater than 150 μm resulted in fibrous tissue formation at the interface (Burke et al.1991; Soballe et al.1992; Pilliar et al.1986). The prostheses in this study can be regarded as having solid fixation providing conditions that would allow bone apposition to the cement mantle. The clinically "loose" prosthesis which had micromotion of 339 μm, an order of magnitude greater than the prostheses with solid fixation, does not represent solid fixation.

Human studies of autopsy retrieved cemented femoral stems (Maloney et al.1989) have found axial micromotion between prosthesis and bone in the order of 0 to 40 μ m and values to 300 μm with simulated stair climbing loading. The micromotion in this study compares with that recorded by Maloney et al. (1989) for axial testing for a series of cemented femoral stems that are radiologically and clinically solid.

The only testing condition that found a difference between the prosthesis types was the antero-posterior test for prosthesis-bone micromotion, however the difference was small. The micromotion of the polished stems was greater than the matt surfaced stems immediately after implantation and was not different at nine months after implantation. The polished stems had a representative value of micromotion of 19 μm which indicates solid fixation immediately after implantation. The increased micromotion recorded was not due to increased prosthesis-cement micromotion, all stems had p-c micromotion less than 20 μm. For micromotion to reduce between the prosthesis and bone without a change of micromotion at the prosthesis-cement interface, micromotion must have changed at the cement-bone interface or elastic deformation of the bone or cement must have occurred. This study could not determine which of these changes had occurred.

Although the difference seen with the polished prosthesis was small and the amount of micromotion present was not detrimental to the stable fixation of the prosthesis at nine months it is uncertain what may have caused the difference. The differences seen may represent a the combined effect of a collection of many inter-individual differences that existed between the sheep and during the testing such as femoral canal shape, femoral bone elasticity, variation in cementing technique and cement mantle, effect due to the temperature of the specimens at the time of testing and the position of the prosthesis within the cement mantle with respect to the bone. These small differences could not be assessed in this study. The difference would not appear to be clinically relevant as there was no difference at nine months after implantation where several cycles of remodelling have taken place.

However, the small differences in prosthesis-bone micromotion recorded in the antero-posterior plane warrant further study to investigate the torsional stability of tapered femoral stems.

Prosthesis-cement micromotion was not influenced by the surface roughness of the femoral components, with all components having p-c micromotion less than 40 μm. The assumption that polished surfaced femoral components such as the Exeter femoral stem do not bond to the cement and that the matt surfaced femoral components solidly bond to the cement is not true. This study has shown that all three stem types have small amounts of micromotion at the prosthesis-cement interface. The use of a matt surface with or without a collar does not provide increased bonding of the stem to the cement.

Lu et al. (1992) have demonstrated in a simple finite element model that partial debonding of the prosthesis-cement interface resulted in the lowest principal stress in the cement. The conditions of either perfect bonding or zero bonding are criticised in the study by Lu et al. and thought not to provide accurate predictions of stresses within the cement. This study would further support their conclusions that perfect or zero bonding does not exist and therefore can not be assumed in theoretical studies of cemented hip arthroplasty. Davies et al. (1996) have also found that an initial bond does form between polished stems and fresh cement and that partial debonding with cyclic loading does occur.

It is not known how prosthesis-cement micromotion can be translated to a measure of the bonding strength of the prosthesis-cement interface. The significance of a small amount of micromotion at the p-c interface is also uncertain, however micromotion of a matt surfaced femoral component against the cement mantle may result in increased wear debris production.

The method of testing in this study has not been reported previously. This method has the advantage of measuring micromotion in three known and defined planes relative to the longitudinal axis of the prosthesis. The aim of this study was to perform comparative tests between three implant types and therefore it was essential that the mechanical testing be reproducible.

A major problem with other methods is that the investigator is unsure of the loading direction as axial loading and torsional loading are combined. The muscular loading varies considerably with body shape, weight and age and is not taken into account in most other studies. There were no femoral shaft fractures in this study unlike the studies of Maloney et al. (1989) who had 2 fractures of 11 femurs tested and Fischer et al. (1992) who had 2 fractures of 8 femurs tested using complex devices to simulate stair-climbing.

5.5. Conclusions

The method of testing in this study did not result in any fractures and the standardisation of the loading protocol has allowed accurate comparative testing to be performed.

At nine months following implantation there was no difference in axial prosthesis-bone micromotion between a polished versus a matt cemented femoral stem. Also, there were no important differences in micromotion between the three stem types at either prosthesis-bone or prosthesis-cement in any direction. There was a reduction in axial prosthesis-bone micromotion with all implants at nine months after implantation compared with that immediately after implantation and this suggests that fixation in cement improved over time. An important finding was the lack of differences in prosthesis-cement micromotion between polished, matt surfaced and matt collared stems, suggesting that fixation of a tapered stem in cement is not improved by a matt surface or a collar.

Chapter 6

Radiological Assessment of Loosening

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6.1. Introduction

The selection of criteria to accurately diagnose loosening of cemented hip replacements from plain radiographs is controversial. In a review of 116 hip repalcements which were assessed using several different criteria to diagnose loosening, the reported incidence of femoral stem loosening varied between 27% to 51% depending on the criteria used (Brand et al.1986).

Cain et al. (1990) found only nine studies which report series of twenty or more patients that had radiographic findings on plain films and arthrograms correlated with surgical assessment of hip component stability. Review of 40 patients with 42 painful hip arthroplasties with surgical correlation found the best criteria for prediction of femoral component loosening were:

(1) any prosthesis-cement lucency

(2) cement-bone lucency (width 2 mm or greater)

(3) cement mantle fracture

The most widely used assessment of cemented hip arthroplasty loosening is that described by Harris et al. (1982). Plain radiographs are assessed for evidence of femoral stem migration, cement mantle fracture and radiolucent lines at the cement-bone and prosthesis-cement interfaces. The radiographs are assessed as definite, probable, possible loosening and solid fixation.

Definite loosening is defined by the single criterion of definite evidence of migration, which includes a radiolucency at the prosthesis-cement interface that did not exist on the immediate post-operative radiograph.

Probable loosening is applied to hips with a continuous radiolucency at the cement-bone interface.

Possible loosening is a radiolucency that is greater than 50% but less than 100% of the cement-bone interface.

In this study, plain radiographs were used to assess the biological response of cemented hip arthroplasty and to predict loosening. The radiographic findings were compared with the clinical status and the findings from mechanical testing of the explanted femurs.

6.2. Materials and Methods

The implants were assessed with radiographs performed immediately post-op and at two monthly intervals until the sheep were killed. Contact radiographs of the explanted femurs were also assessed. Anteroposterior pelvis and lateral hip radiographs were reported without knowledge of the time after implantation or clinical status. The polished and matt surfaced implants could not be identified, the collared implants were identified and not blinded. Radiolucent lines at both the cement-bone and the prosthesis-cement interfaces were recorded for Gruen zones 1 - 14 (Gruen et al.1979; Johnston et al.1990) (Figure 6.1) and measured in mm using a transparent ruler with 0.5 mm graduations (0, "less than 1 mm", 1 mm and thereafter to the nearest 0.5 mm).

Radiographic loosening was classified as per Harris et al. (1982) using the antero-posterior and lateral radiographs and only lucent lines greater or equal to 1 mm were assessed.

Cement fracture were documented for each Gruen zone. The cement mantle quality was defined in terms of thickness and uniformity. The cement mantle was defined as adequate if in a given zone, two-thirds of the width of the prosthesis-bone interspace was filled with cement (Tapadiya et al.1984). For zones 1 and 4, adequate cement was defined as a mantle at least 3 mm thick. Uniformity of the cement mantle was defined as per Table 6.1. for the entire cement mantle (Roberts et al.1986).

Table 6.1. Criteria used to determine the cement mantle uniformity from the immediate post-op radiograph ((Roberts et al.1986))

	Size of void		
	> 10 mm	5 - 10 mm	2 - 5 mm
Good	None	None	< 5
Fair	None	< 2	5 - 7
Poor	Any	> 2	> 7

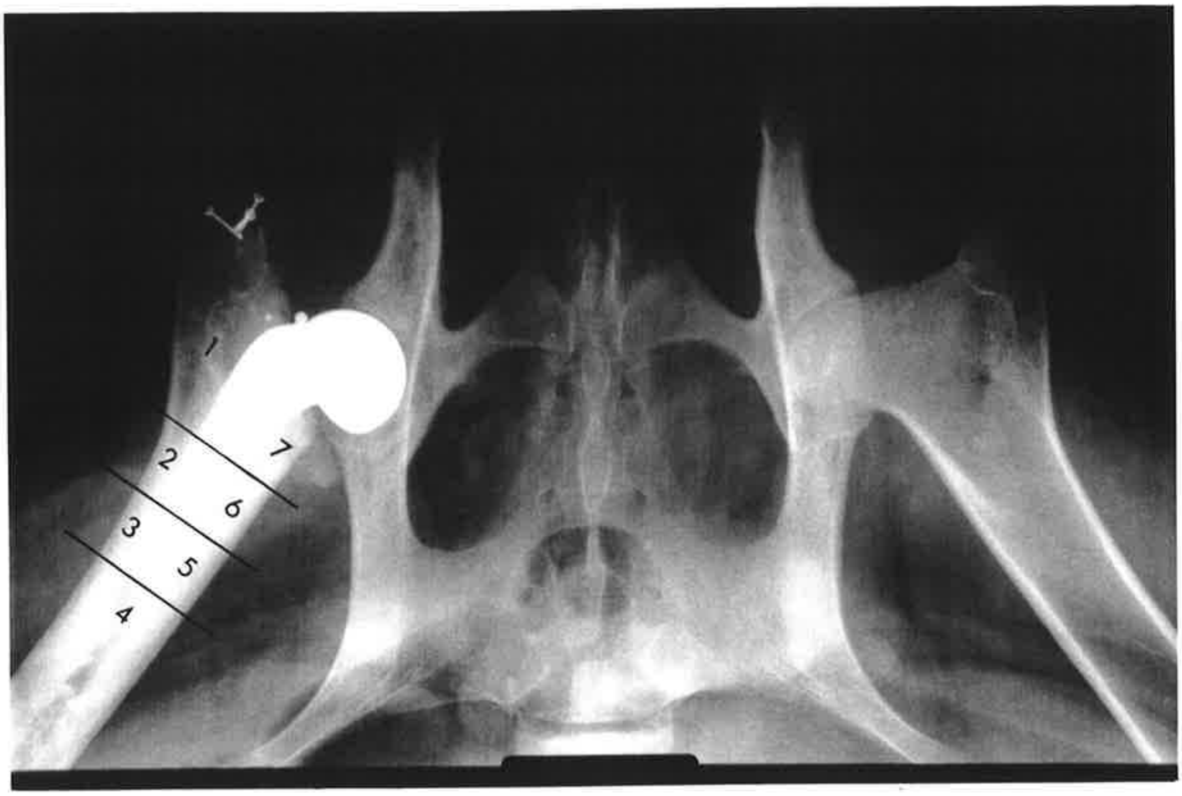

Figure 6.1(a). Standard radiograph with Gruen zones (AP pelvis).

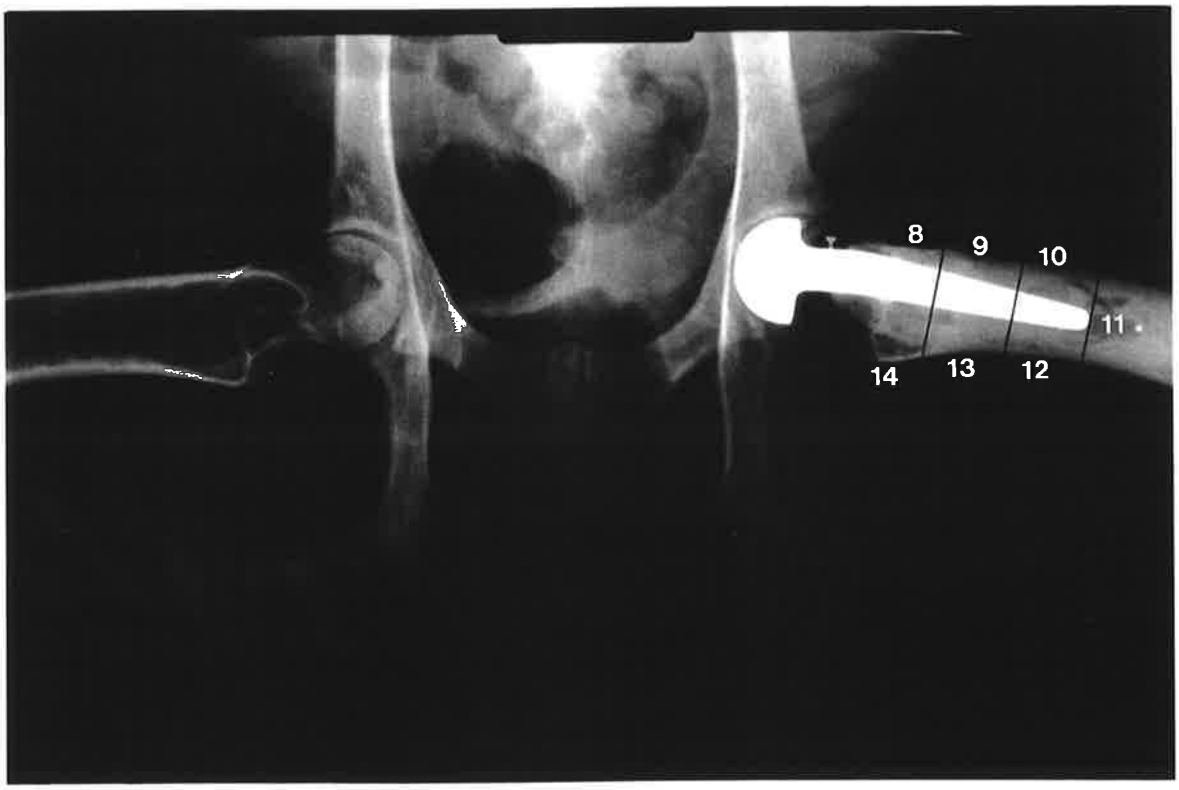

Figure 6.1(b). Standard radiograph with Gruen zones (lateral).

6.3. Results

Twenty-one sheep completed nine months *in vivo* loading and were classified as clinically "solid" and one sheep (#R3) was clinically "loose" at three months after implantation. The clinically "loose" implant will be discussed seperately.

The cement mantle was of adequate thickness on all radiographs. There were no cement mantle fractures seen on any radiograph throughout the nine month period of observation. There were five implants with large cement voids. The uniformity of the cement mantle is shown in Table 6.2. There were no prosthesis-cement radiolucent lines.

Table 6.2. Uniformity of the cement mantle as assessed on the immediate post-op radiograph ((Roberts et al.1986)).

	Good	Fair	Poor
Polished	5	1	1
Matt	6	-	1
Collar	5	-	2

Proximal cement-bone radiolucent lines (Gruen zones 1, 7, 8 and 14) were seen commonly around all implants. Lucent lines at the cement-bone interface of less than 1 mm were very common and were inconsistent in appearance on sequential radiographs; therefore only lucent lines of greater or equal to 1 mm were assessed.

6.3.1. Polished Implants

There were no p-c lucent lines or cement mantle fractures seen with any polished surfaced implant. The separation of the prosthesis from the cement in zone 1 as described by Fowler et al. (1988) for polished surfaced Exeter femoral stems was not observed in this study.

When the 9 month radiographs were analysed, there were four implants assessed as having solid fixation (#7, #10, #11, #20) and three as possible loosening (#5, #22, #23).

One polished surfaced implant (#5) with possible loosening had a large (> 10 mm) void in zone 7. The other two implants with possible loosening had good cement mantles. One implant (#23) showed marked calcar resorption and distal cement-bone lucent lines (Figures 6.2 and 6.3).

Thin (< 1 mm) lucent lines were very common around all polished surfaced implants and increased in frequency with time, some progressing to 1 mm lucent lines; these lucent lines were not evident on the high contrast explanted femur contact radiographs and their meaning is uncertain.

When c-b lucent lines greater than 1 mm were used to diagnose loosening from the contact radiographs, all seven were assessed as having solid fixation. Medial cortex remodelling and some calcar resorption was seen in all femurs (Figure 6.4).

Figure 6.2. Radiographs of the polished implant #23.
(a) Immediate post-op. (b) Nine months after implantation.

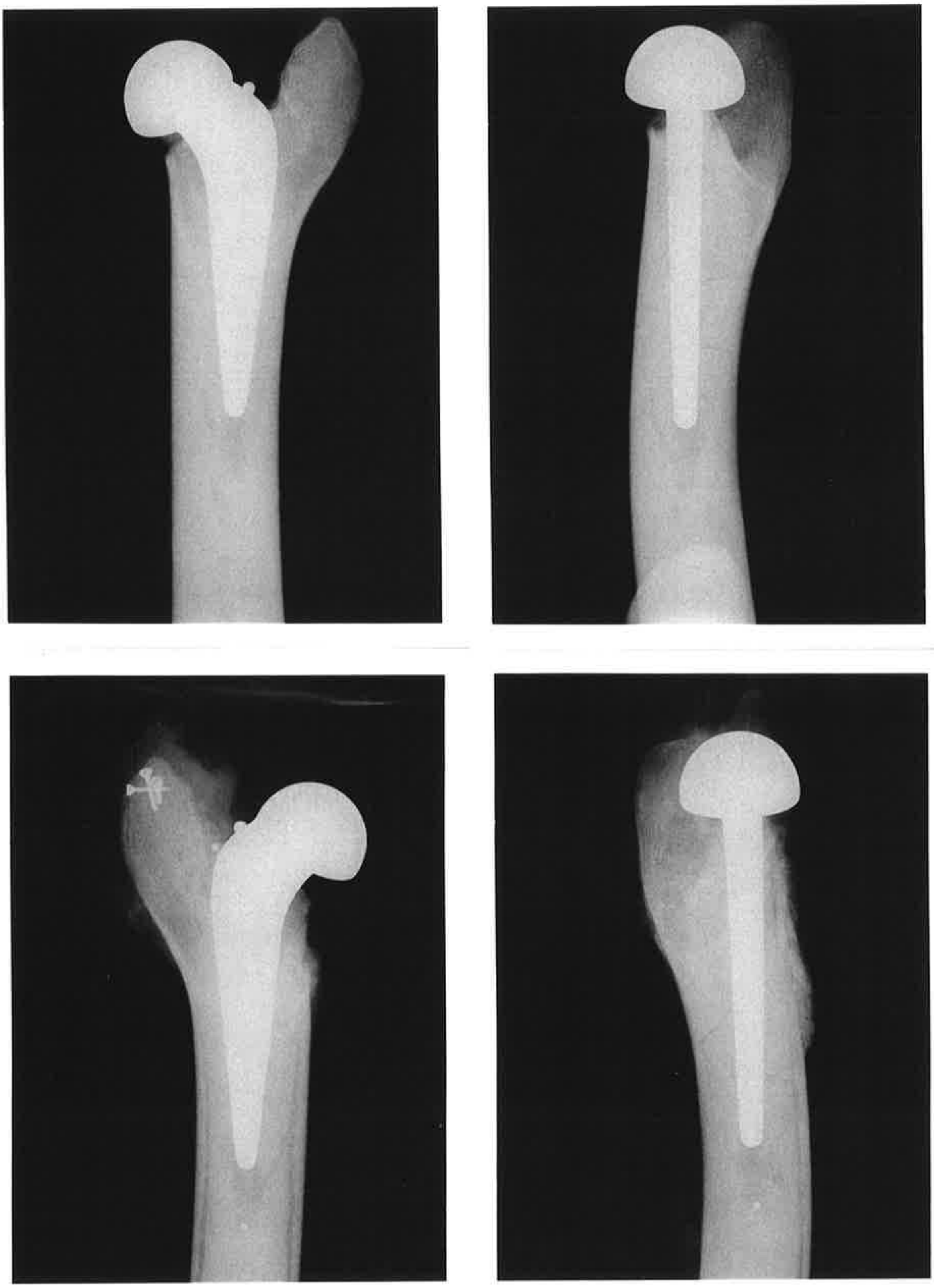

Figure 6.3. Explanted femur contact radiographs of polished implant #23.
(a) Contralateral femur immediately after implantation (AP and lateral).
(b) Nine months after implantation (AP and lateral).

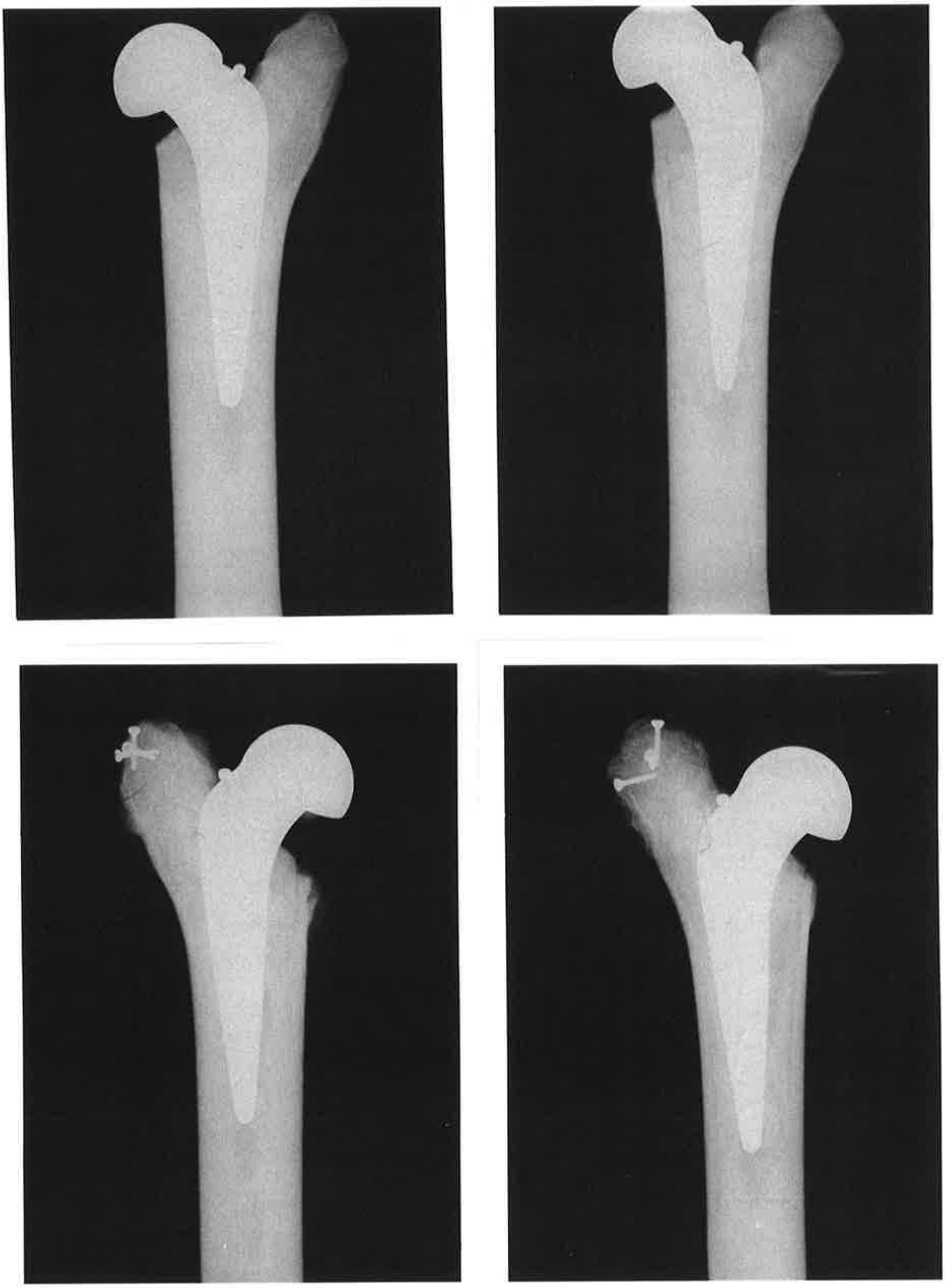

Figure 6.4. Explanted femur contact radiographs of polished implants #5 and #7 showing mild calcar resorption.
(a) Contralateral femurs immediately after implantation (AP).
(b) Nine months after implantation (AP).

6.3.2. Matt Implants

There were no p-c lucent lines or cement mantle fractures seen with any matt surfaced implant. Five implants were assessed as having solid fixation (#26, #24, #R1, #R4, #R5) (Figure 6.5). Two implants had evidence of possible loosening (#13, #27).

One matt surfaced implant (# 13) had a 1 mm c-b lucent line which were seen around greater than 50% of the interface. Lucencies in zones 2, 3 and 7 on the AP radiograph and zones 8, 9, 12, 13 and 14 on the lateral radiograph were seen on the 9 month radiograph and also on the contact radiograph of the explanted femur (Figure 6.6). There was calcar resorption seen after 4 months. The c-b radiolucent lines appeared to be progressive.

One matt surfaced implant (#27) had a 1 mm c-b lucent line in zones 4, 5, 6 and 7 at 9 months after implantation and 4, 5, 6 and 7 on the explanted femur contact radiograph and was assessed as possible loosening (Figure 6.7). There was a good uniformity and thickness of the cement mantle.

Figure 6.5. Explanted femur contact radiograph of matt implant #24 showing solid fixation..

Figure 6.6. Explanted femur contact radiographs of matt implant #13 showing calcar resorption and possible loosening.
(a) Contralateral femur immediately after implantation (AP and lateral).
(b) Nine months after implantation (AP and lateral).

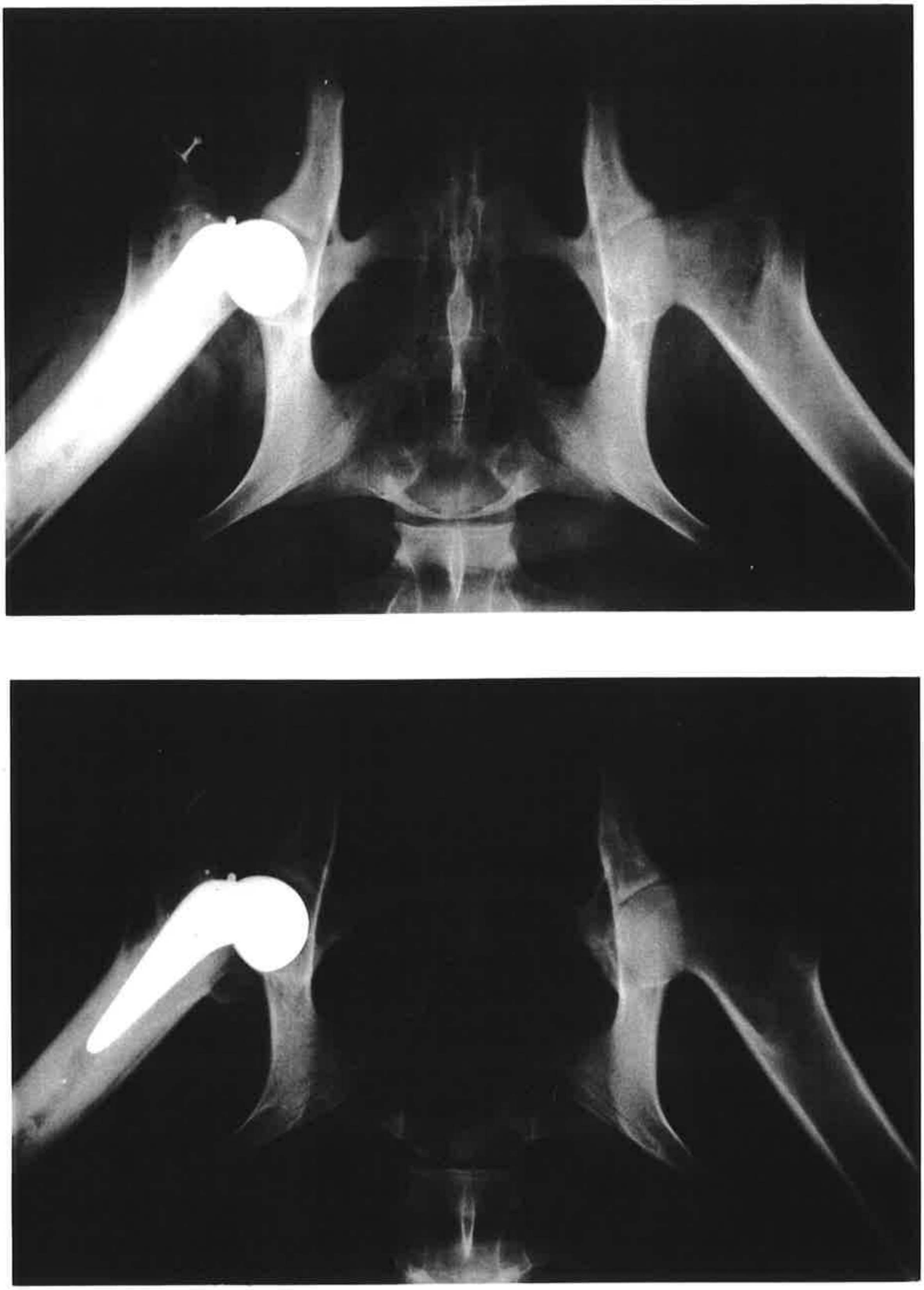

Figure 6.7. AP pelvis radiographs of matt implant #27 showing possible loosening.
(a) Immediate post-op.
(b) Nine months post-op.

6.3.3. Collared Implants

There were no p-c lucent lines or cement mantle fractures seen with any collared implant. All collared implants were assessed as having solid fixation at the c-b and p-c interfaces without disruption of the cement mantle (Figure 6.8). Greater than 1 mm c-b lucent lines were seen in five of the seven collared implants and only in zones 1, 6, 7 and 8.

Thin (< 1 mm) proximal c-b lucencies were commonly seen immediately after implantation and on all follow-up radiographs of collared implants. These thin c-b lucent lines were mainly seen proximally (zones 1, 6, 7, 8 and 14). Three of the seven collared implants had thin (< 1 mm) distal c-b lucent lines seen at 6 to 8 months, however they were not present on the explanted femur contact radiographs.

Due to exposure differences between radiographs it was not possible to detect an objective measurement of calcar resorption below the collar (Figure 6.9). Calcar resorption was seen with all implant types and not unique to the collared implants.

Figure 6.8. Explanted femur contact radiographs of collared implant #16 showing a solid cement-bone interface with calcar resorption under the collar.

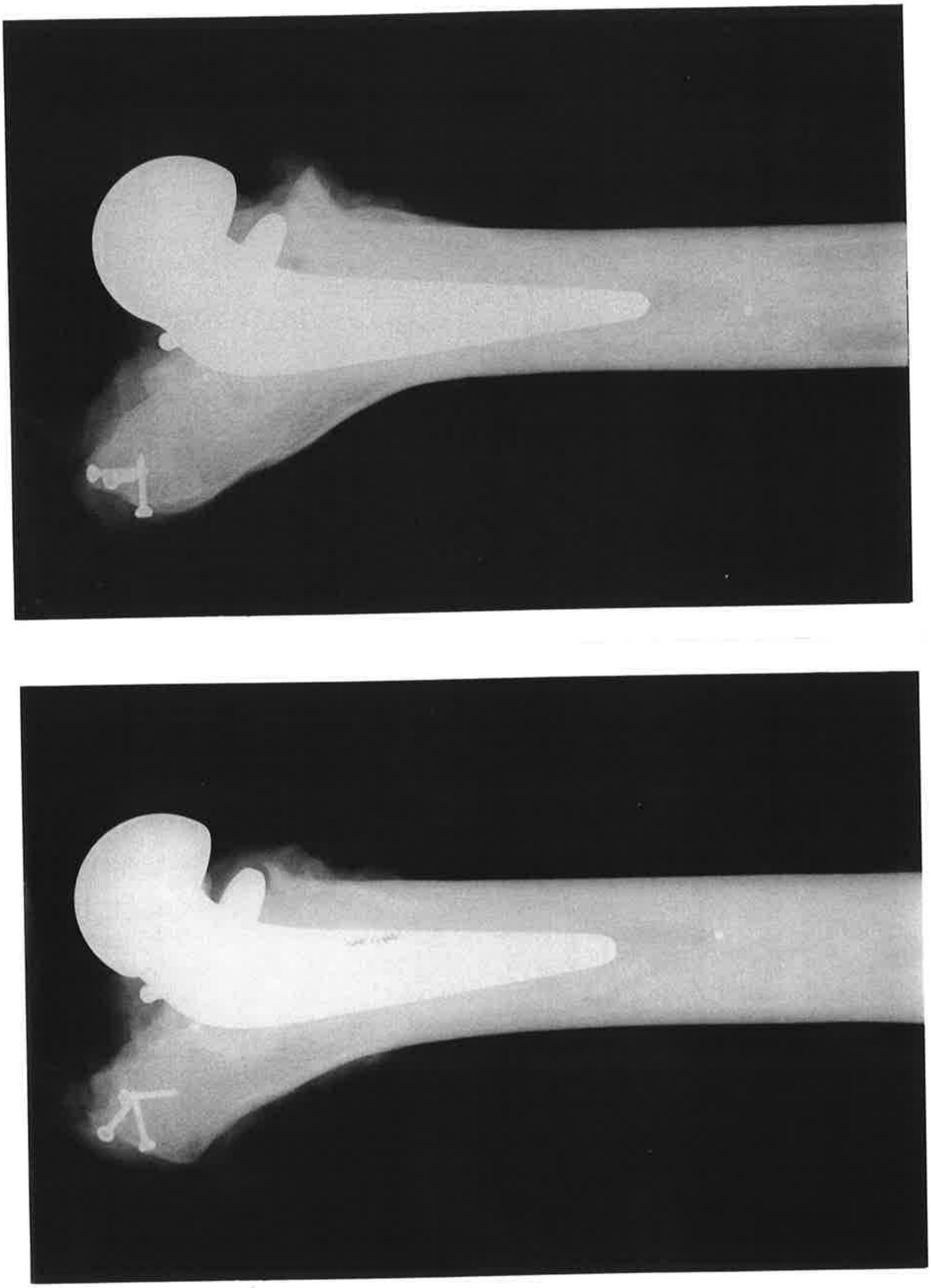

Figure 6.9. Explanted femur contact radiographs of collared implants # 9 and #28 showing calcar remodelling.

6.3.4. Summary

Plain radiographs at nine months after implantation were assessed for c-b radiolucenct lines greater or equal to 1 mm, p-c radiolucent lines of any width and cement fracture. Using the criteria of Harris et al. (1982), three polished and two matt implant were diagnosed as having possible loosening (Table 6.3). There were no implants with definite loosening at nine months after implantation.

Table 6.3. Femoral component loosening assessed from the AP pelvis and lateral radiographs at nine months following implantation according to the criteria of Harris et al. (1982).

	Solid fixation	Possible loosening	Probable loosening	Definite Loosening
Polished	4	3	-	-
Matt	5	2	-	-
Collar	7	-	-	-

Assessment of the high contrast contact radiographs showed different findings from the radiographs at nine months after implantation (Table 6.4). The majority of implants were found to have solid fixation. There was one matt surfaced implant that was again diagnosed as possible loosening. The cement-bone lucent lines were mainly along the medial cortex and they were of a greater width proximally than distally. Many of the lucent lines seen on the nine month radiographs which measured greater than 1 mm were less than 1 mm on the contact radiographs and therefore these implants were diagnosed as having solid fixation.

Table 6.4. Femoral component loosening assessed from the explant femur contact radiographs according to the criteria of Harris et al. (1982).

	Solid fixation	Possible loosening	Probable loosening	Definite Loosening
Polished	7	-	-	-
Matt	6	1	-	-
Collar	7	-	-	-

6.3.5. Clinically Loose Implant

The one clinically loose polished implant (#R3) had a complete cement-bone lucency greater than 1 mm on the lateral radiograph, and a complete cement-bone lucency on the AP pelvis radiograph that was greater than 1 mm in four zones and 0.5 mm in three zones and therefore by definition was probable loosening. The findings on the contact radiographs were similar with greater width lucent lines on the lateral radiograph.

Figure 6.10. Clinically loose implant that was diagnosed on plain radiographs as probable loosening (sheep #R3).

6.4. Discussion

At nine months after implantation assessment of plain radiographs found that there were no implants with definite loosening; there were no complete radiolucent lines at the c-b interface, there were no p-c radiolucent lines, no cement mantle fractures and no definite evidence of migration. The majority of implants were clinically asymptomatic and were assessed as having solid fixation. There was no difference between implant types. Solid fixation of all implants that completed nine months *in vivo* loading was confirmed with mechanical testing. Micromotion measured with axial loading was less than 65 microns for all implants.

Cement-bone radiolucent lines greater than 1 mm were seen more commonly in the proximal-medial zones and were progressive with time. As this study only assessed the changes over nine months after implantation, it is uncertain if these changes would have continued to progress or stabilize at some time after implantation. The c-b interface was incomplete in the majority of femurs and this suggests that an incomplete c-b radiolucent interface may still be associated with solid fixation of cemented femoral stems.

Plain radiography is a non specific method of assessing the interface between the cement and bone of cemented hip arthroplasty and will not provide true information as to the cause of a c-b radiolucent line. The c-b radiolucent lines may represent bone resorption and the formation of fibrous tissue, local osteoporosis or normal remodelling after implantation or a true gap between the cement and bone. Radin et al. (1982) found a complete c-b radiolucent line in all but one of their sheep hip arthroplasties at 12 months after implantation and histology found the interface consisted of fibrous tissue. Kwong et al. (1992) have suggested that radiolucent lines may be seen with well fixed components and may not always represent fibrous tissue at the cement-bone interface, instead they may represent local osteoporosis.

The accuracy of plain radiography correctly representing the p-c and c-b interface has been reported to be poor (Jacobs et al.1989; Jasty et al.1991; Kwong et al.1992). Plain radiographs of clinically solid cemented femoral stems reviewed by Jasty et al. (1991) did not have p-c radiolucent lines and cement mantle fractures despite being found on transverse sections. Jacobs et al. (1989) found the predictive value of plain radiographs when compared to transverse section contact radiographs to be extremely poor due to superimposition of structures and irregularities of the endosteal surface of the cortex. In this study, p-c radiolucent lines and cement mantle fractures were not seen on plain radiographs. Histological assessment and correlation with the radiography of the p-c and c-b interface is essential and will be described in the following chapter.

Calcar resorption was seen as a progressive feature in some implants from all groups, however, the presence of a collar did not reduce this finding. Differences in rotation and exposure prevented an accurate objective measurement of calcar resorption. Calcar resorption was seen around polished surfaced implants with good cement mantles in zone 7, this appearance was thought by Fowler et al.(1988) not to occur with the Exeter design. Other factors such as bone quality, implant design and cementing technique rather than surface finish and collar appear to be responsible for changes in the bone of the calcar and proximal femur.

To diagnose loosening in this study, radiolucent lines at the cement-bone interface that were greater than 1 mm in width only were assessed. Maxwell et al. (1993) have found that visual measurements of radiolucent lines are only reliable when the lines are 2.5 mm and greater. If radiolucent lines greater than 2.5 mm only were assessed then no lucent lines would have been recorded and all implants would have been graded as having solid fixation. The precision of measurement of radiolucent lines and migration can be improved with computer assisted analysis, however the greatest errors are found in the taking of reproducible radiographs over long term studies.

6.5. Conclusions

Review of plain radiographs found that the majority of components had solid fixation and there was no difference between implant type. There was no implant with definite loosening on plain radiography. Thin (<1 mm) radiolucent lines were commonly seen at the cement-bone interface and were thought to represent bone remodelling rather than loosening. An incomplete c-b radiolucent line was associated with axial micromotion of less than 65 microns and therefore thought to represent solid fixation.

In this study, the surface finish of the femoral stem and the presence of a collar did not appear to influence the development of calcar resorption. Other features such as bone quality, implant design and cementing technique may have been responsible.

Chapter 7

Histological Assessment

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7.1. Introduction

Harris and his colleagues (Maloney et al.1989; Jasty et al.1990; Jasty et al.1991; Kwong et al.1992) have extensively assessed the implant-bone interface and their findings are discussed in Chapter 1. Their studies provide the most detailed assessment of the histology of cemented hip replacements and their conclusions form the current theory of the initiation of failure of cemented femoral components. The key histological features from their studies were:

1. Early separation of the prosthesis-cement interface, particularly around sharp corners of implants, and this was thought to be the initiating factor in aseptic loosening.

2. Cement mantle fractures were found to originate at the prosthesis-cement interface and from cement voids.

3. Radiolucent lines seen on plain radiographs were seen to represent regions of osteoporosis of the cortical and cancellous bone and not a fibrous cement-bone interface.

In this study, the histology of cemented hip hemiarthroplasties immediately after implantation and at nine months after implantation is described. The histology provides some explanation for the findings seen with plain radiography and mechanical testing.

7.2. Materials and Methods (Section Processing)

7.2.1. Femur Preparation

Prior to the mechanical testing, the femur was marked at a distance of 50% and 75% from the distal femoral condyles to allow similar sections to be made for all femurs (Figure 7.1). After the completion of mechanical testing, the femurs were prepared for sectioning. The femurs were sectioned fresh.

Photographs were taken of the intact femur before sectioning to document the gross histology and the distance markings. The greater trochanter, proximal cement mantle and implant were fixed in PMMA cement to prevent any differential movement of the interfaces during sectioning.

During preparation and sectioning, the sections were sprayed regularly with water to prevent dehydration. A shallow longitudinal cut was made on the posterior and medial aspect of the femur to assist with orientation of the sections.

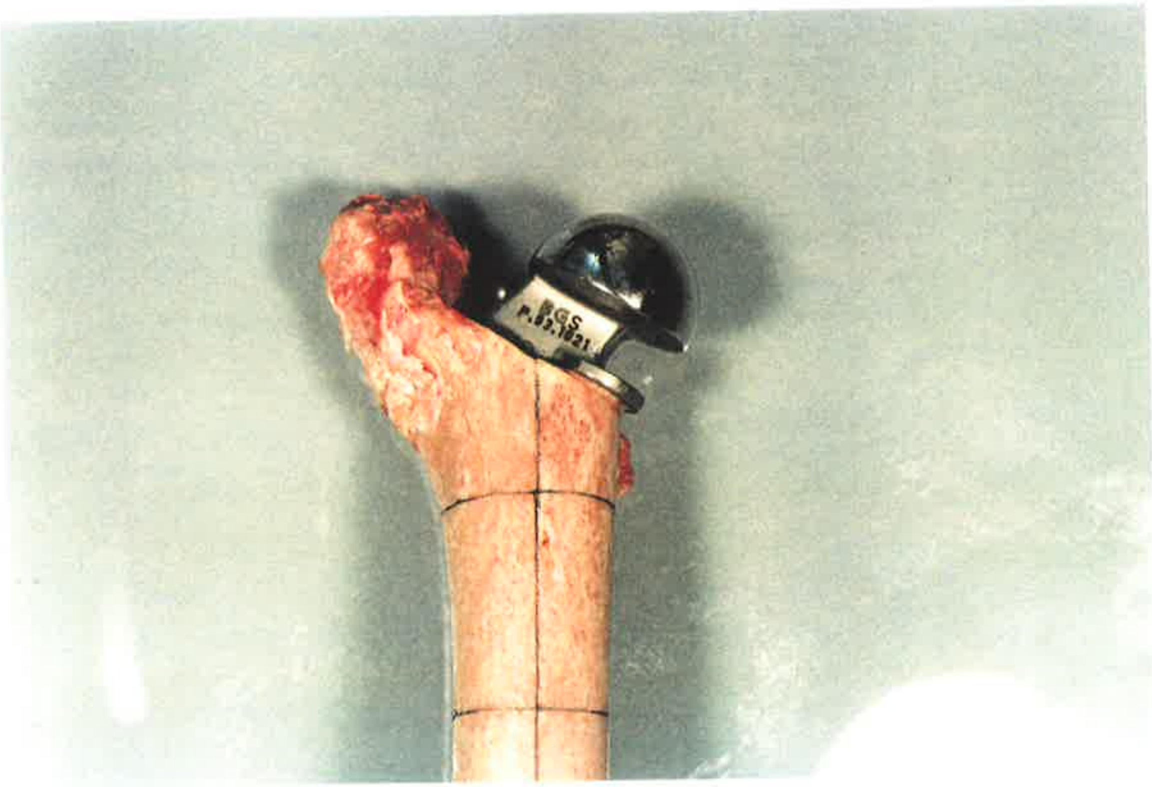


Figure 7.1. Marking of femur prior to sectioning.

7.2.2. Sectioning and Photography

The sections were made using an Exakt band saw (Exakt Apparatebeura, Germany) using constant water irrigation, blade speed = 6 and a force of 0.5-1.0 N acting on the specimen to draw it through the saw. The proximal femur was positioned in the holding device of the saw and aligned with the longitudinal axis of the femur perpendicular to the saw blade (Figure 7.2).

The first section was made at 50% from the distal condyles and the distal section was placed in formalin and not assessed further. The remaining part of the femur with the implant was then sectioned. Distally, 6 sections were made every 3 mm and labelled sequentially from #1. These sections were to assess the distal prosthesis-cement interface and cement mantle. There were extra sections made to ensure that there were four sections with metal implant present. The sections were labelled #1 to #6 and extra sections #6a, #6b etc.

Sections were than made every 10 mm up to the 75% mark from the greater trochanter. If extra sections were made, the length of bone cut was subtracted from the first 10 mm section (eg. if 2 extra sections were required, then 6 mm extra was cut, therefore the first "10 mm section" would only be 4 mm in this case). The sections were labelled #7, #8, #9.

The proximal femur had 6 sections made every 3 mm from the 75% mark. These were to assess the proximal cement-bone interface membrane. There were extra sections made up to the medial cut surface of the neck. The sections were labelled #10 to #15 and extra sections #15a, #15b etc.

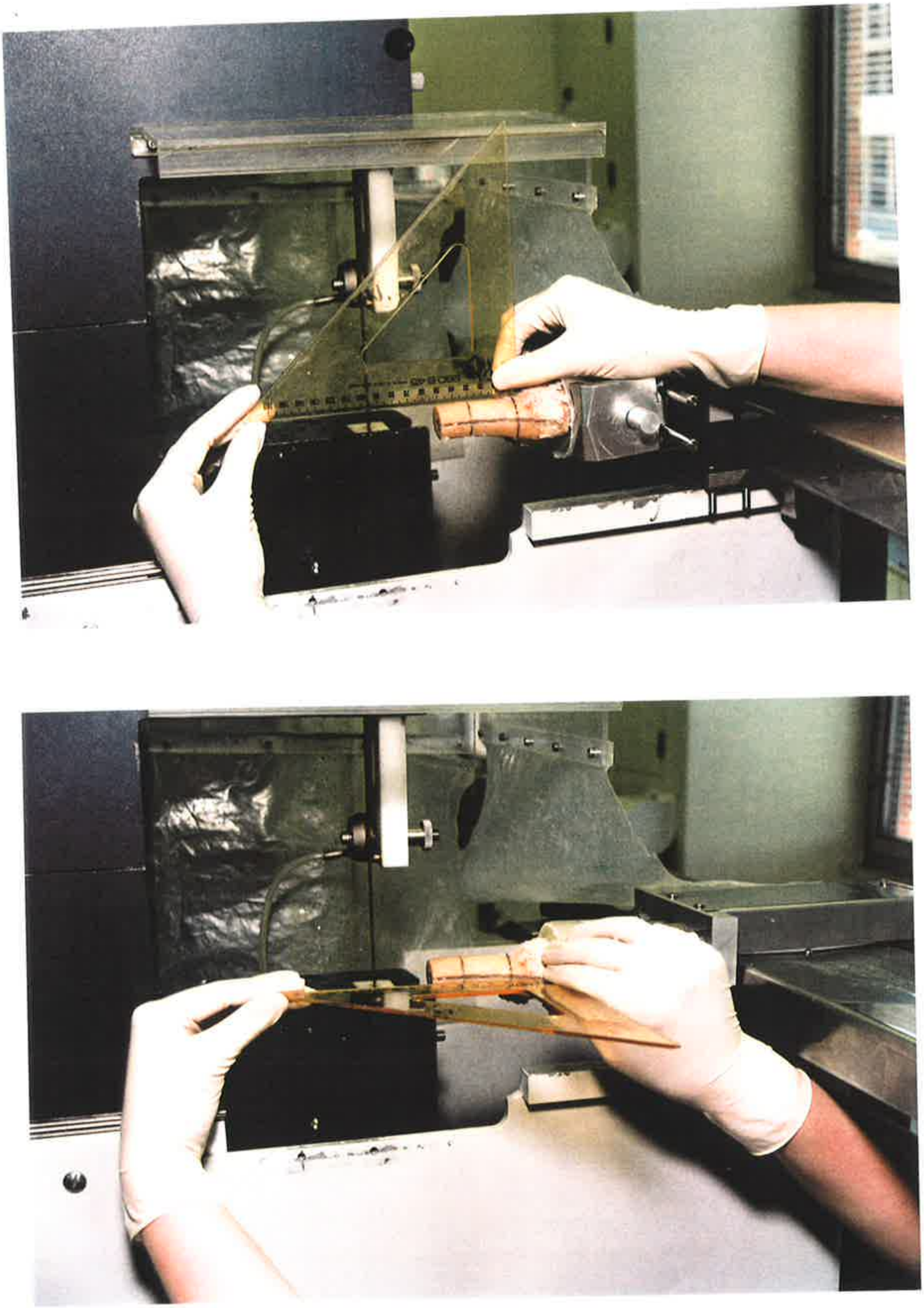


Figure 7.2. Femur positioned and held for sectioning.

After every section, micro-photographs were taken of the cut surface (Figure 7.3). A Nikon automatic camera with micro lens was positioned on the band saw housing and Halogen lights illuminated the cut surface of the bone-implant complex. A scale and label was used with all photographs. Each section was photographed with and without stain using an apperture priority setting on the camera with shutter speed of 1/125 second. The unstained photograph was taken to allow the entire section to be viewed and was taken at a distance ratio of 1.6:1. The section was stained with a light green stain and photography taken at a distance ratio of 1.2:1 to observe the two interfaces. Extra photographs at 1:1 were taken of intersting areas.

After photography the sections were immersed in 10% neutral buffered formalin for 2-3 days for the 3 mm sections and 1-2 weeks for the 10 mm sections.

Alternate sections from the proximal and distal regions were processed for decalcified and undecalcified histology.

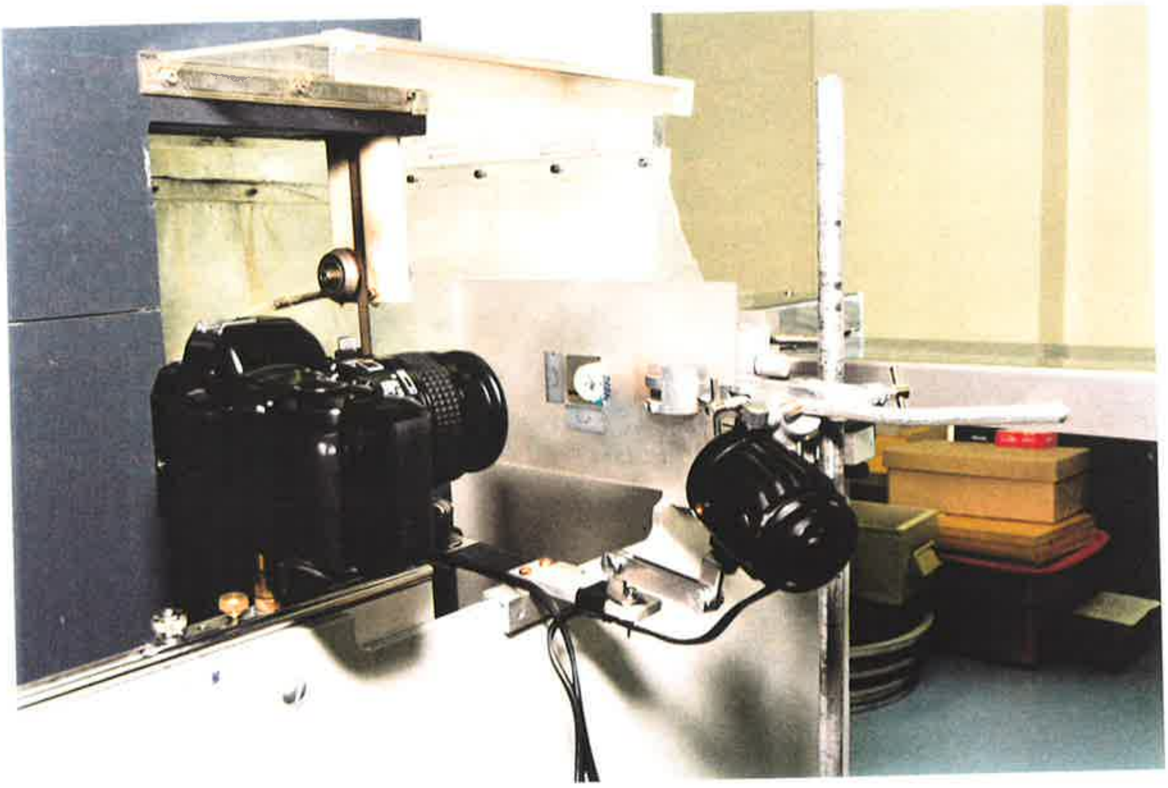


Figure 7.3. Micro-photography of sections, using halogen lights.

7.2.3. Thin Section Contact Radiographs

Following sectioning, micro-radiographs were taken of all 3 mm sections using high speed mammography film. Proximal and distal sections were taken on the same film at two different exposure settings to assess the cement mantle and the bone.

7.2.4. Undecalcified (Thick or Ground) Sections

Following fixation the sections were dehydrated in graded ethanol which was followed by dehydration over CaCl granules for 5 hours.

70% EtOH 24 hours under vacuum at room temperature
85% EtOH 18 hours under vacuum at room temperature
95% EtOH 18 hours under vacuum at room temperature
100% EtOH 7 hours under vacuum at room temperature
100% EtOH 18 hours under vacuum at room temperature

The sections were then embedded in Spurrs Epoxy Resin (Taab Laboratories, U.K.). Each section was placed on a prepolymerized layer of resin, then placed in an Epovac vacuum impregnation unit (Struers, Denmark) and evacuated for 60-90 minutes. The unit vacuum was then reduced to 50-60 mm Hg and using a plastic tube, the resin was siphoned to cover the section. The unit was re vacuumed to remove air from the resin for 5 minutes. The vacuum was then released to allow impregnation to take place. The section was then turned and resin poured over the top. The specimen block was left overnight at room temperature and then cured at 70°C. After curing, the block was removed from the mould .

The surface of the block was then ground using ascending grit papers (paper grits = 60, 120, 240, 400, 800, 1200) on a Beuhler bench top grinder with water irrigation (Beuhler, Germany) such that the surface of the bone was exposed. The surface was then polished with one micron alpha alumina polish (Beuhler, Germany) using a polishing cloth. The polished surface was adhered to a flexible poly carbonate slide using 5 Min Araldite (Selley, Australia). Weights were attached to ensure complete contact with the slide. Using the 60 grit abrasive paper the bulk of the section was ground. Ascending grit papers were used as above to obtain an 80-100 micron section, and then polished as above.

The section was then stained using a modified Toluidine Blue stain (personal communication: Linda Jenkins, Rhodes Engineering Unit, S. Carolina, USA).

7.2.5. Decalcified (Thin or Paraffin) Sections

Alternate sections for decalcification were placed in separate containers of 2.5% phosphate buffered EDTA. This solution was changed every two days and the end-point of decalcification was monitored by daily radiography. When complete sections were placed in a neutralising solution (6% aqueous sodium sulphate with methylene blue as indicator). An extended, automated dehydration, clearing and paraffin infiltration cycle was used to process the specimens, which were subsequently embedded in paraffin.

Sections of 5 microns were taken using a Leitz microtome (Leitz, Germany) and stained with either haematoxylin and eosin or haematoxylin/van Geisson.

7.2.6. Hip Capsule Specimens

Three specimens (5 mm x 5 mm x 3 mm deep) were taken from anterior, posterior and superior hip capsule at the time of explantation. The tissue was fixed in 10% neutral buffered formalin for exactly 2 hours. The tissue was then dehydrated, cleared and embedded in the routine manner. Five micron sections were taken as described above and stained with haematoxylin and eosin. Hip capsule tissue was assessed to determine the cellular response to hip arthroplasty using a semi-quantitative method (Mirra et al.1976).

7.3. Materials and Methods (Assessment)

7.3.1. Microphotographic Assessment

Colour slides of ten selected sections (4 distal, 2 mid-stem and 4 proximal) were magnified 10 times with a slide projector onto a white wall. Measurements were taken manually with a pencil and ruler. The magnification was such that 1 mm on the screen represented 100 microns. The following data were collected for each section;

The number, size (recorded in mm) and distribution (p-c involvement, cement only, c-b involvement) of cement fractures.

The number, size (<1mm, 1-5mm, >5mm) and distribution (p-c involvement, cement only, c-b involvement) of cement voids.

The prosthesis-cement and cement-bone interfaces were described with respect to gaps and tissue at the interfaces. The distribution and maximum thickness (measured in mm) was recorded from the medial, lateral, anterior and posterior quadrants of each section.

7.3.2. Thin Section Contact Radiographic Assessment

In selected cases based on the findings from the micro-photographic sections, contact radiographs were used to assess the bone, the cement mantle and the p-c and c-b interfaces.

7.3.3. Histological Assessment

In selected cases based on the findings from the micro-photographic sections, the ground and paraffin sections were used to provide a more detailed assessment of the p-c and c-b interfaces. The ground sections were used to study the p-c interface and the paraffin for the c-b interface.

7.4. Results

7.4.1. Immediately after Implantation

The majority of sections showed excellent interdigitation of the cement with the bone (Figure7.4). In all sections there were small gaps between the cement and the bone. The c-b gaps were found at all levels and in all quadrants of the sections. The c-b gaps were filled with blood and bone debris and were less than 300 μm in the majority (Figure 7.5). The c-b gaps were complete (circumferential) in 7 of 21 femurs and in 20 of 211 sections. In one femur (#10, polished) the c-b gaps were greater than 1 mm in two of the proximal sections (Figure 7.6). In several sections, the c-b gaps were due to voids in the cement mantle that were at the c-b interface (Figure 7.7).

Prosthesis-cement gaps were seen in four femurs immediately after implantation (#10, polished; #16, collar; #17, collar; #19, collar). These gaps were less than 100 μm, seen over short distances and were in the mid-stem and proximal sections (Figures 7.8 - 7.11). The gaps were not seen at the corners of the prosthesis but along the edges. Examination of the p-c interface on the ground sections and the thin section contact radiographs provided explanations for the gaps as artefact rather than debonding or lack of bonding.

Several sections had many small voids along the p-c interface which collected bone and metal debris and these stained strongly (Figure 7.12) and were seen on the thin section contact radiographs (Figure 7.13).

There was one cement mantle fracture seen in two proximal sections of one femur (#485, polished, Figure 7.14). This was associated with a void that extended to the proximal cement surface and was thought to be a sectioning artefact. Voids were common within the cement mantle and varied in size from less than 1 mm to 30 % of the cement mantle area in several sections (Figure 7.15).

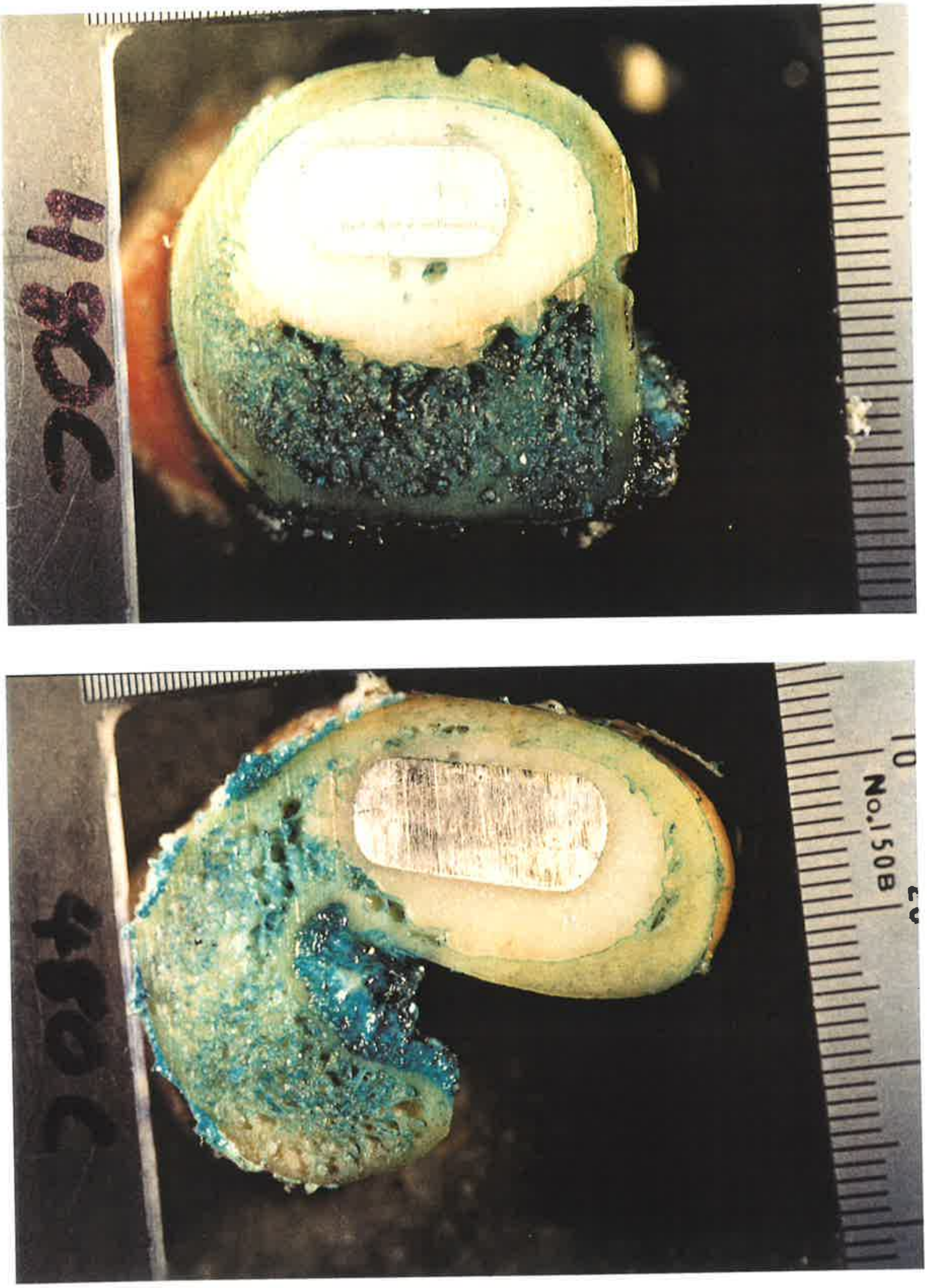


Figure 7.4. Microphotograph of proximal section showing excellent cement-bone interdigitation.

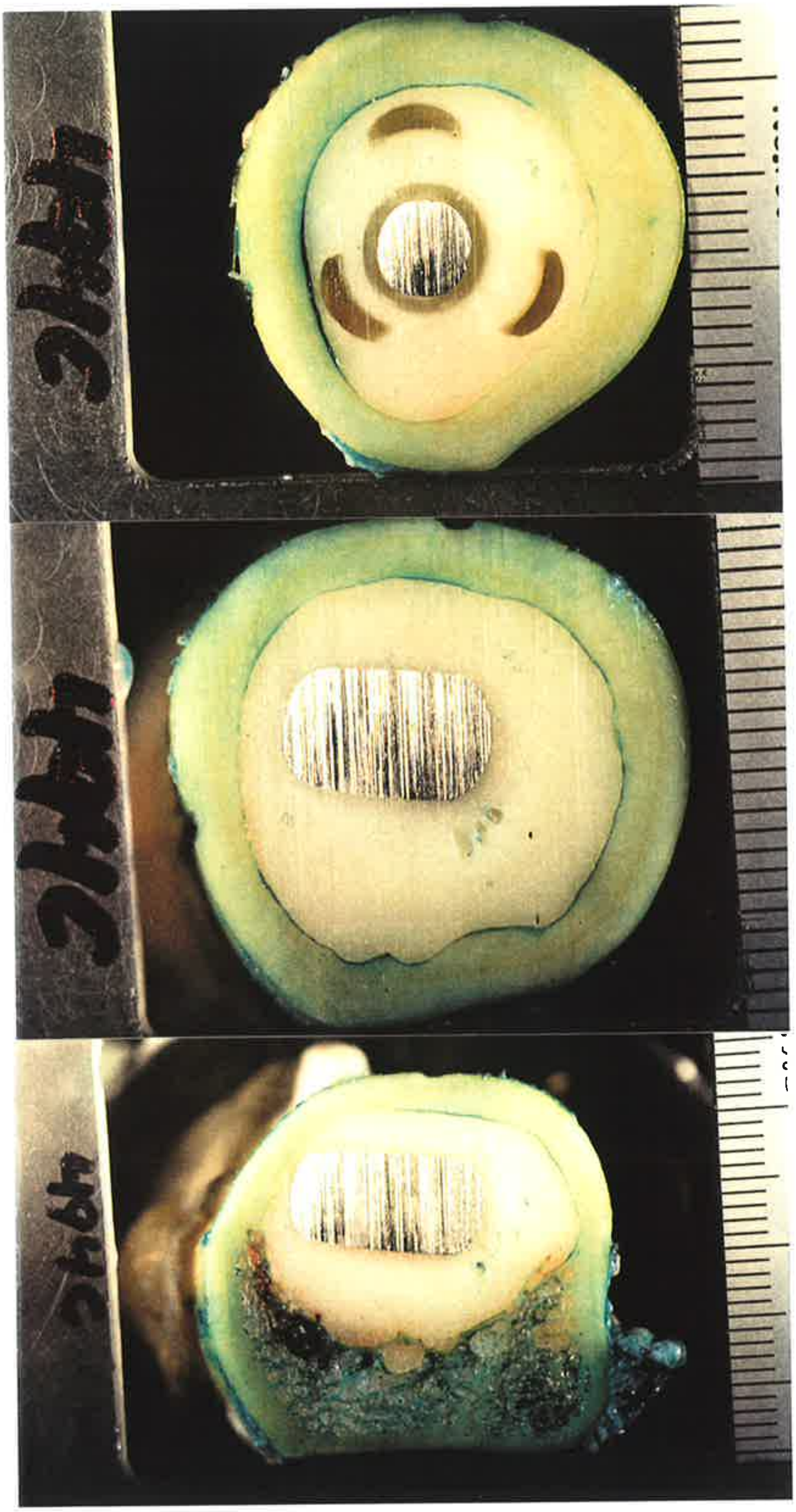


Figure 7.5. Microphotographs of distal, midstem and proximal sections showing small c-b gaps.

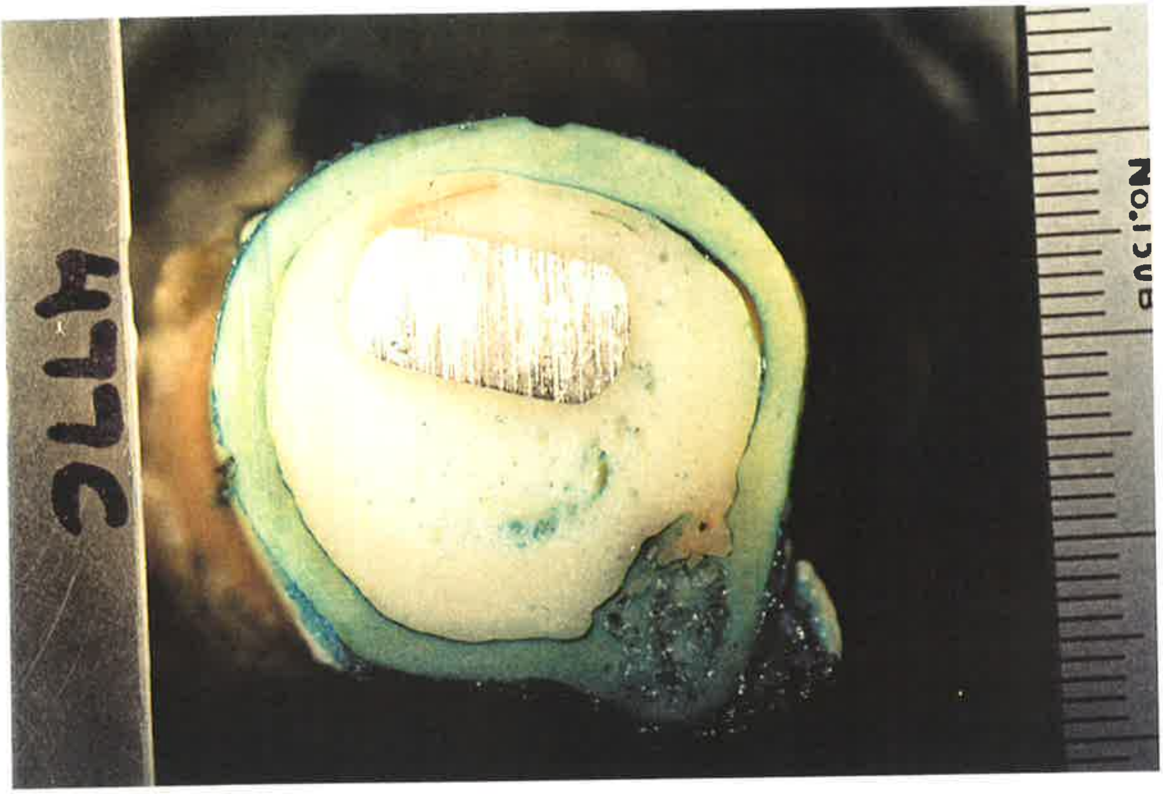


Figure 7.6. Microphotograph showing large proximal c-b gaps.

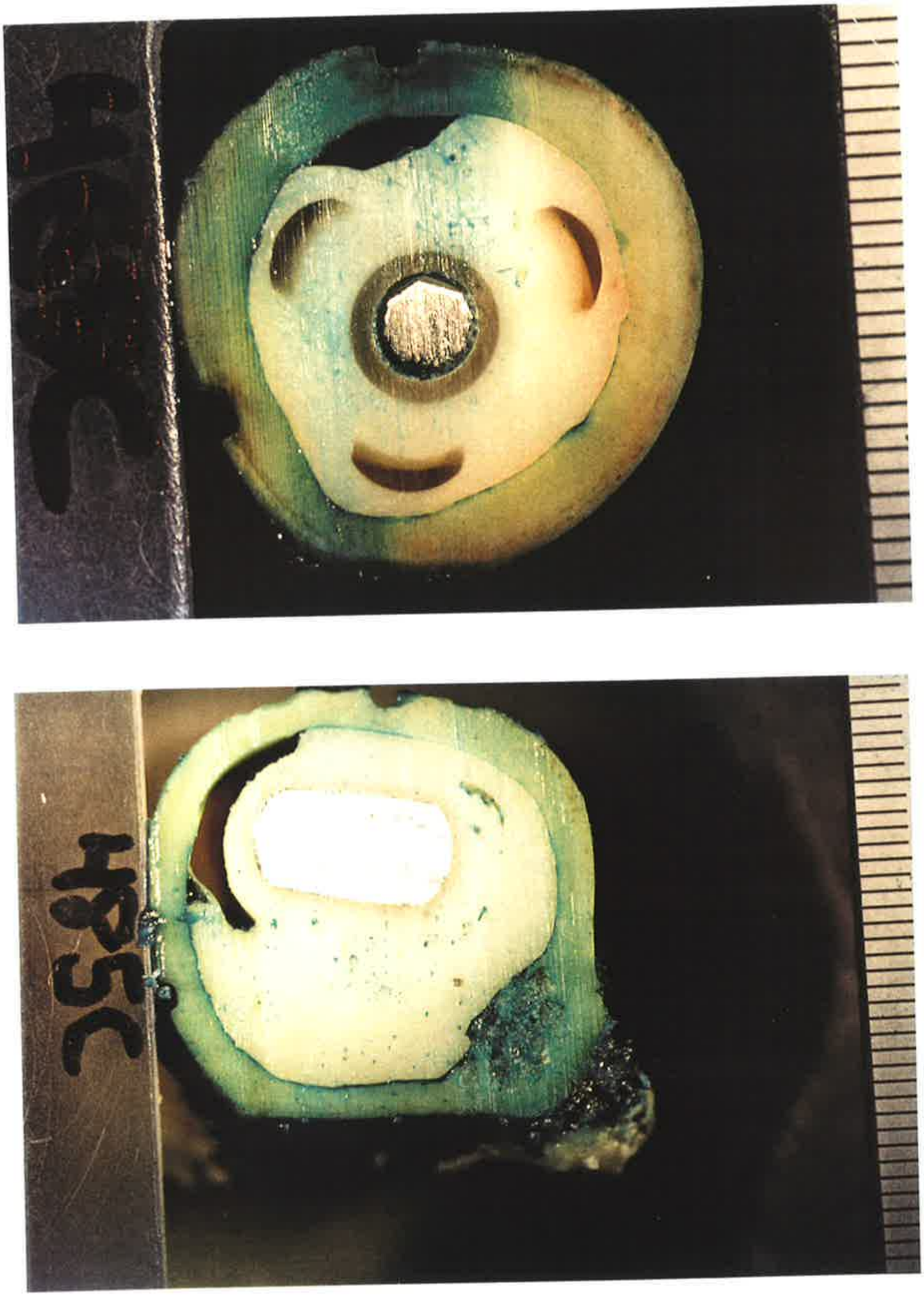


Figure 7.7. Cement mantle voids at the c-b interface.

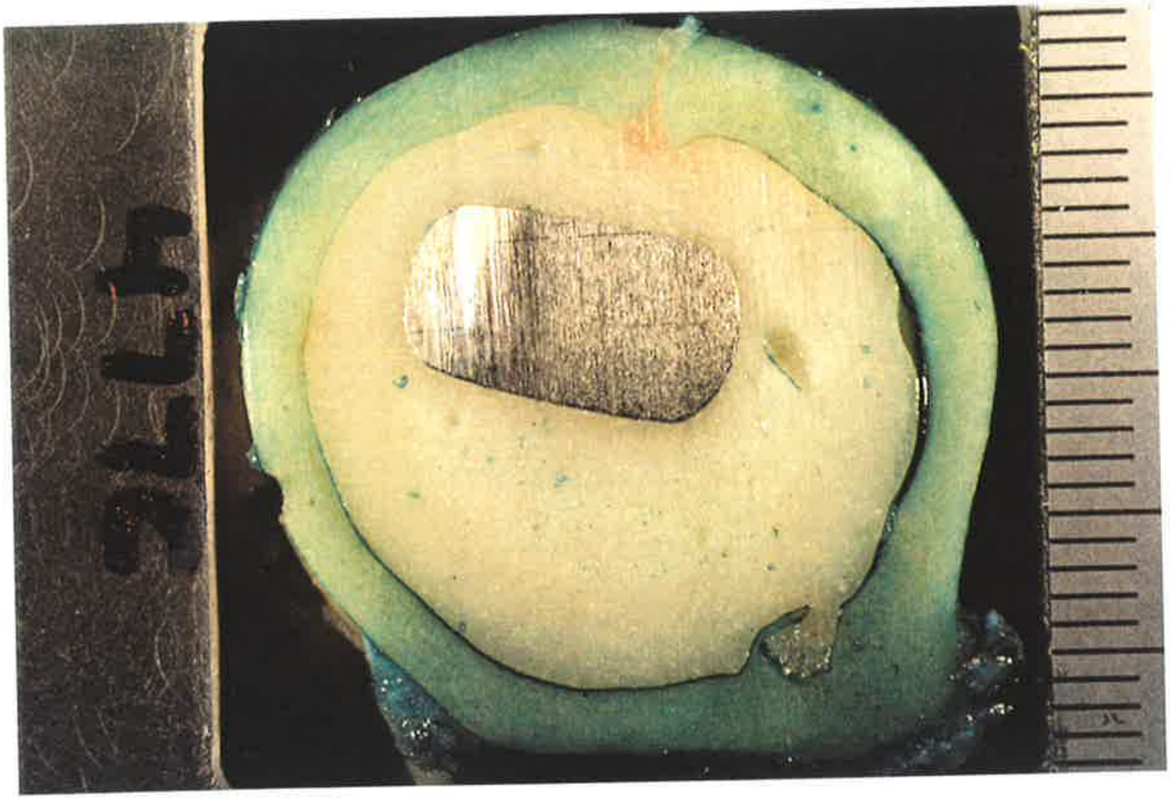


Figure 7.8. Microphotograph of p-c gap (sheep # 10, polished).

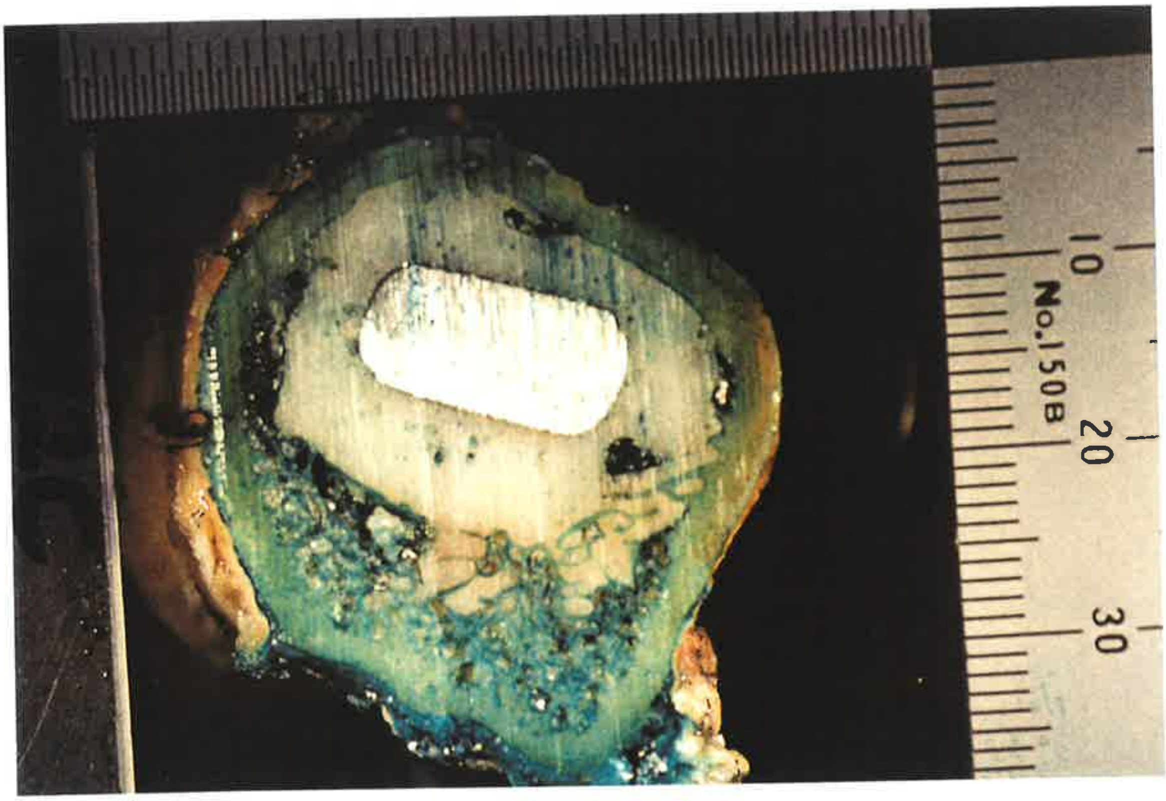


Figure 7.9. Microphotograph of p-c gap (sheep # 16, collar).

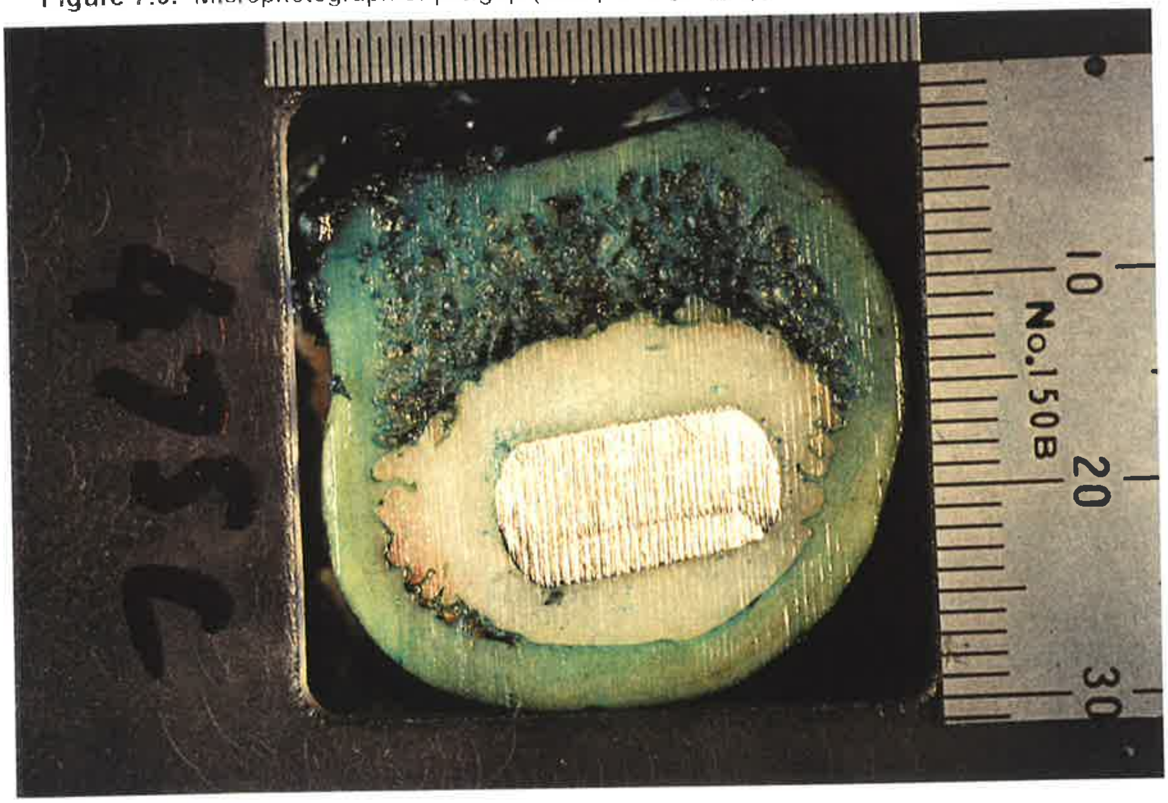


Figure 7.10. Microphotograph of p-c gap (sheep # 17, collar).

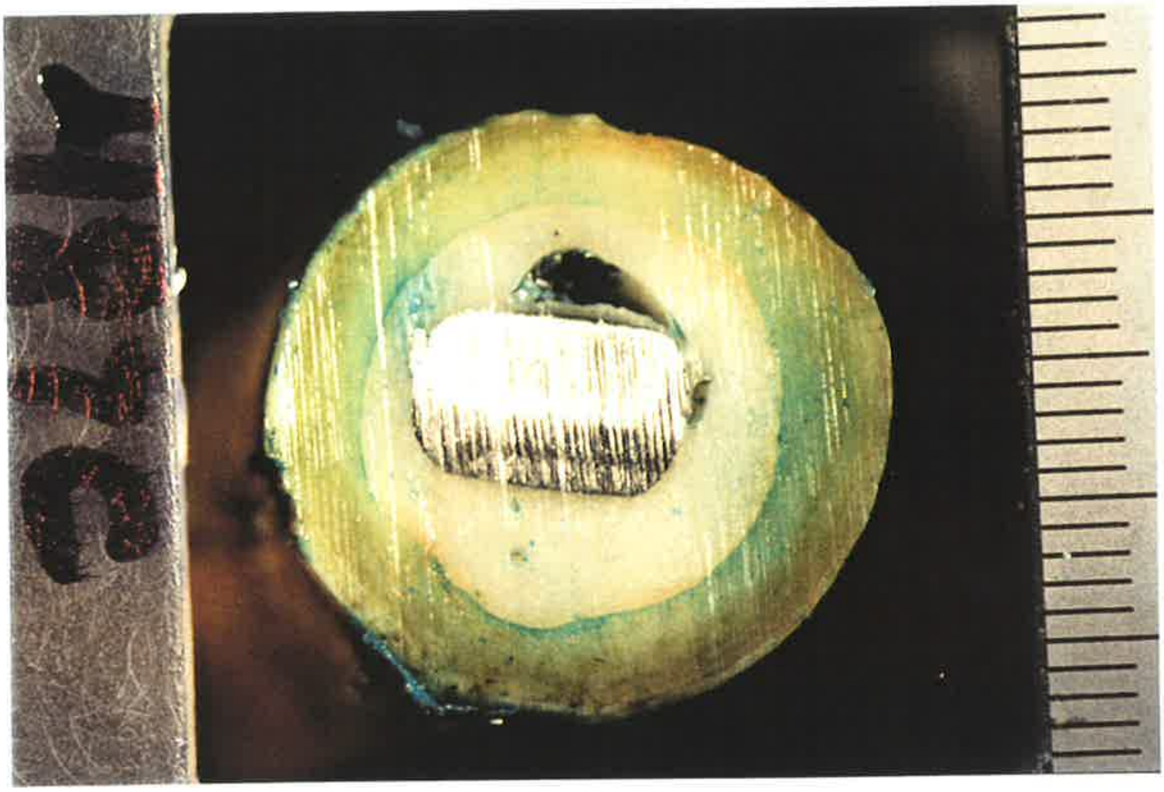


Figure 7.11. Microphotograph of p-c gap (sheep # 19, collar).

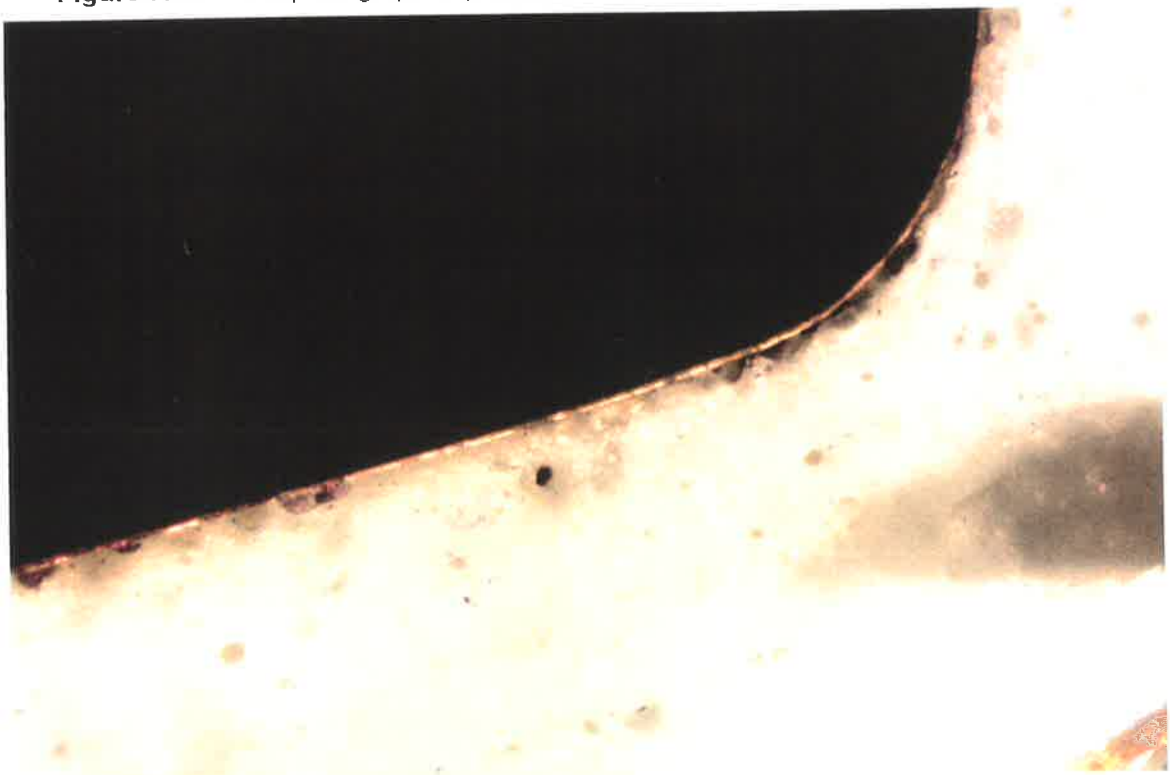


Figure 7.12. Ground section of p-c gap due to voids and debris

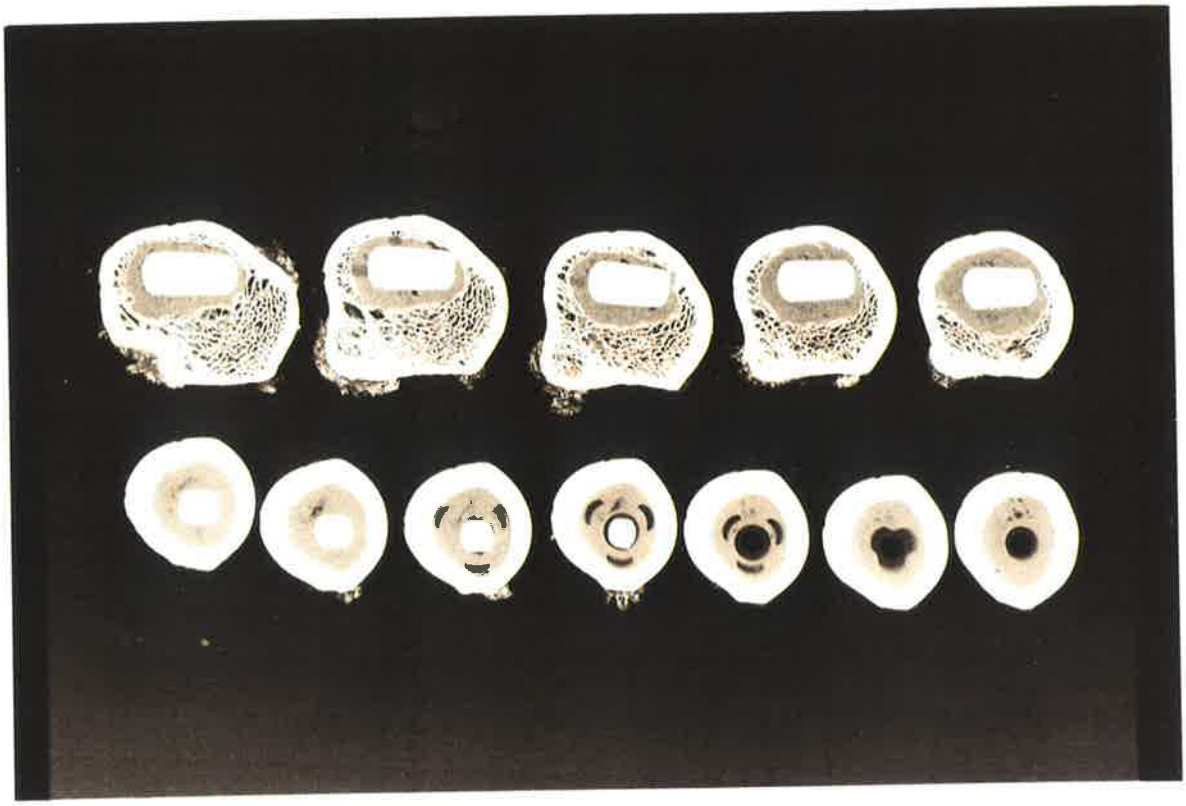


Figure 7.13. Thin section contact radiograph showing p-c gaps due to voids at the p-c interface and metal debris at the p-c interface.

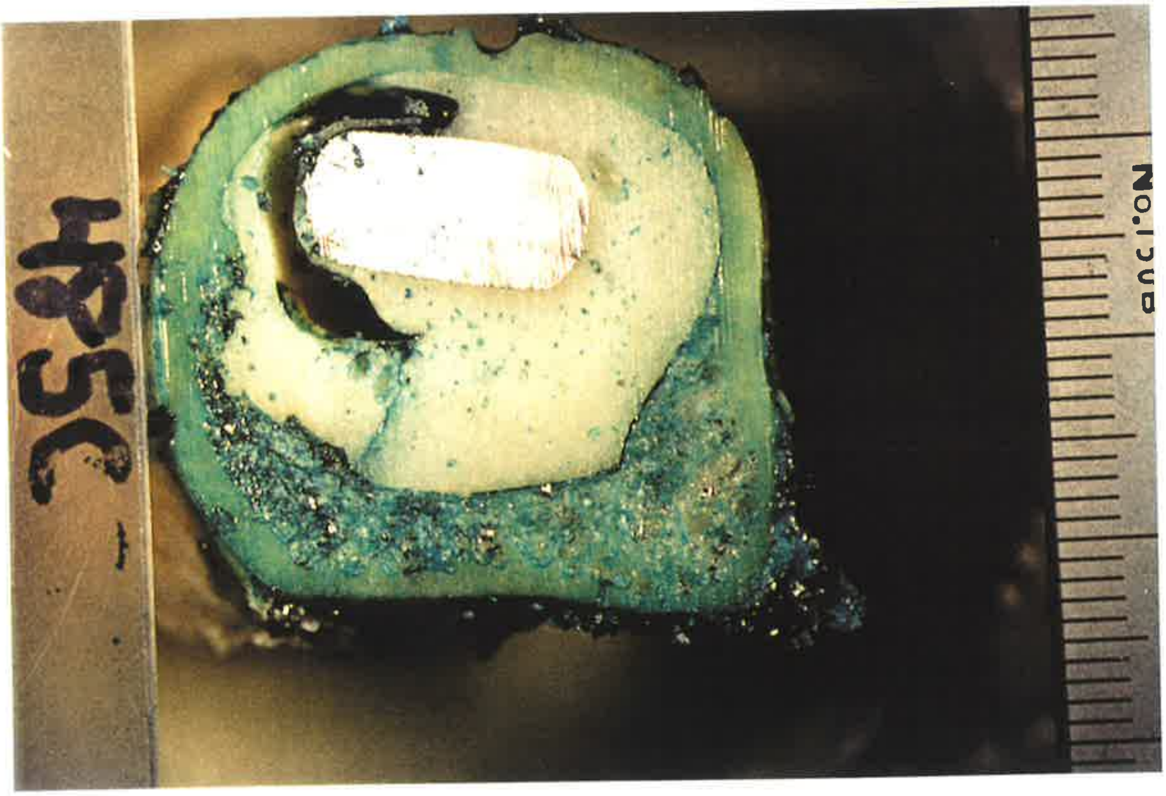


Figure 7.14. Microphotographs of cement mantle fractures.

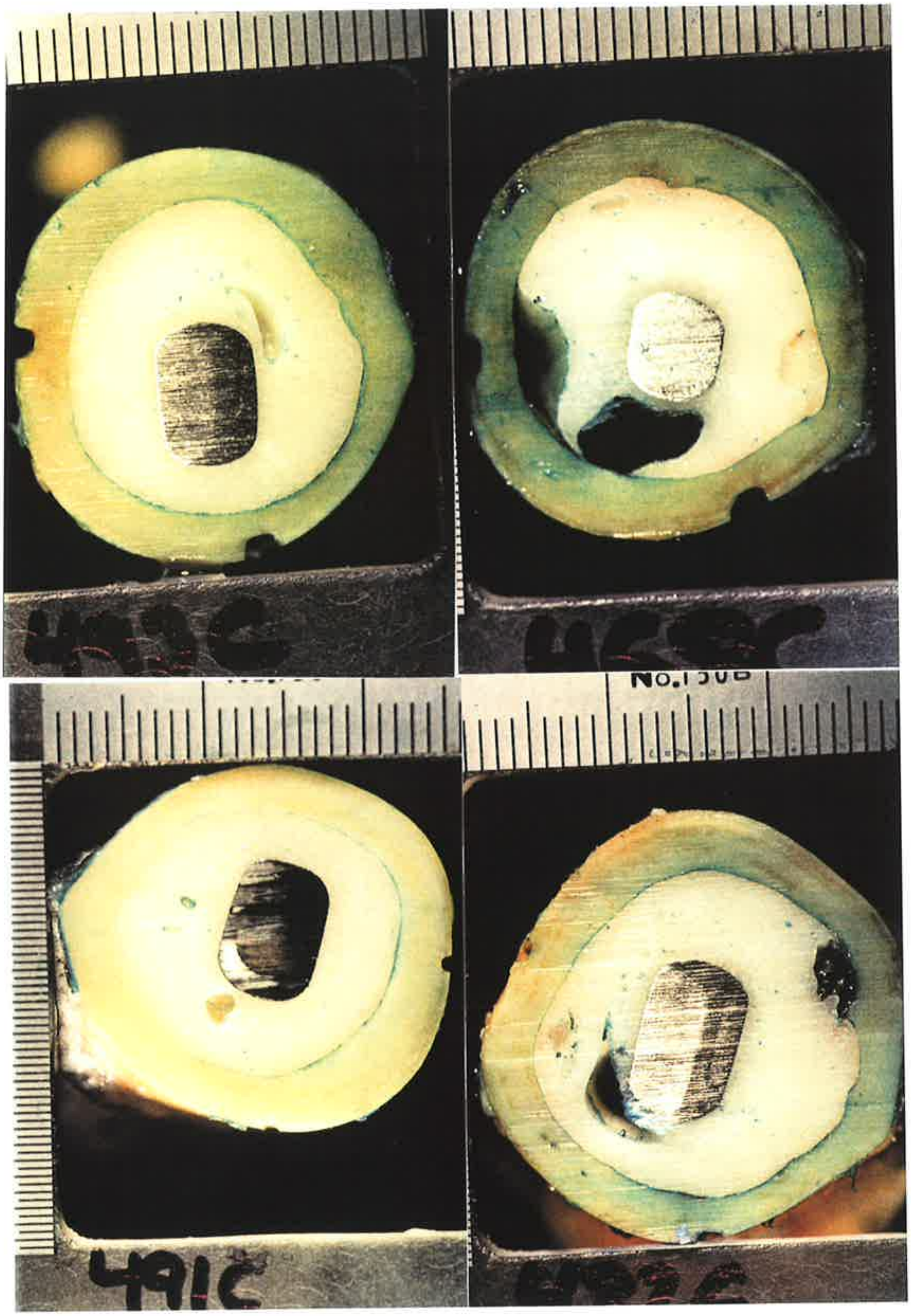


Figure 7.15. Microphotographs of cement mantle voids.

7.4.2. Nine months after Implantation

At nine months after implantation the distribution of cement-bone interface tissue was different from that immediately after implantation. No c-b gaps were seen in any section, any separation between the cement and bone was with a fibrous tissue interface. Most sections had intimate contact with cement and bone with small areas of fibrous tissue in most sections with the thickness being greatest in the proximal sections.

The distal sections had minimal fibrous tissue, with only 2 of 21 femurs (sheep #28, collar; sheep #11, polished) and 3 of 84 sections having a thin complete c-b interface, the maximum thickness was 400 μm (Figures 7.16 - 7.17).

Trabecularization of the distal femoral cortex was a common finding, seen in 6 polished, 5 matt and 3 collared stems. The changes were more prominent in the polished stems (Figure 7.18). Femurs that had prominent trabecularization in the distal sections did not have greater proximal c-b fibrous tissue than femurs without distal trabecularization. The formation of a neo-cortex was associated with the trabecularization distally and was also seen with the cancellous bone proximally (Figure 7.19 - 7.20).

The proximal sections had mainly intimate cement-bone contact (Figures 7.21). Fibrous tissue between cement and bone was common in all proximal sections. This fibrous c-b interface was complete in 5 of 21 femurs and 9 of 76 sections. In 18 of 76 sections in was greater than 75% of the circumference of the c-b interface, being deficient mainly laterally. The maximum thickness varied from 0.0 up to 2.3 mm, the majority being between 0.5 and 1.5 mm (Figure 7.22).

Heterotopic bone was prominent around the medial cortex of the most proximal sections in all implants (Figure 7.23).

There were 5 femurs which had gaps at the p-c interface (#11, polish; #23, polish; #13, matt; #16, collar; #17, collar). All of these sections were associated with a cement mantle void that was adjacent to the stem (Figure 7.24 - 7.26). These areas did not represent debonding as the void never allowed bonding to occur at the time of implantation. The adjacent cement mantle was without fracture and the c-b interface at the respective level was no different than other levels.

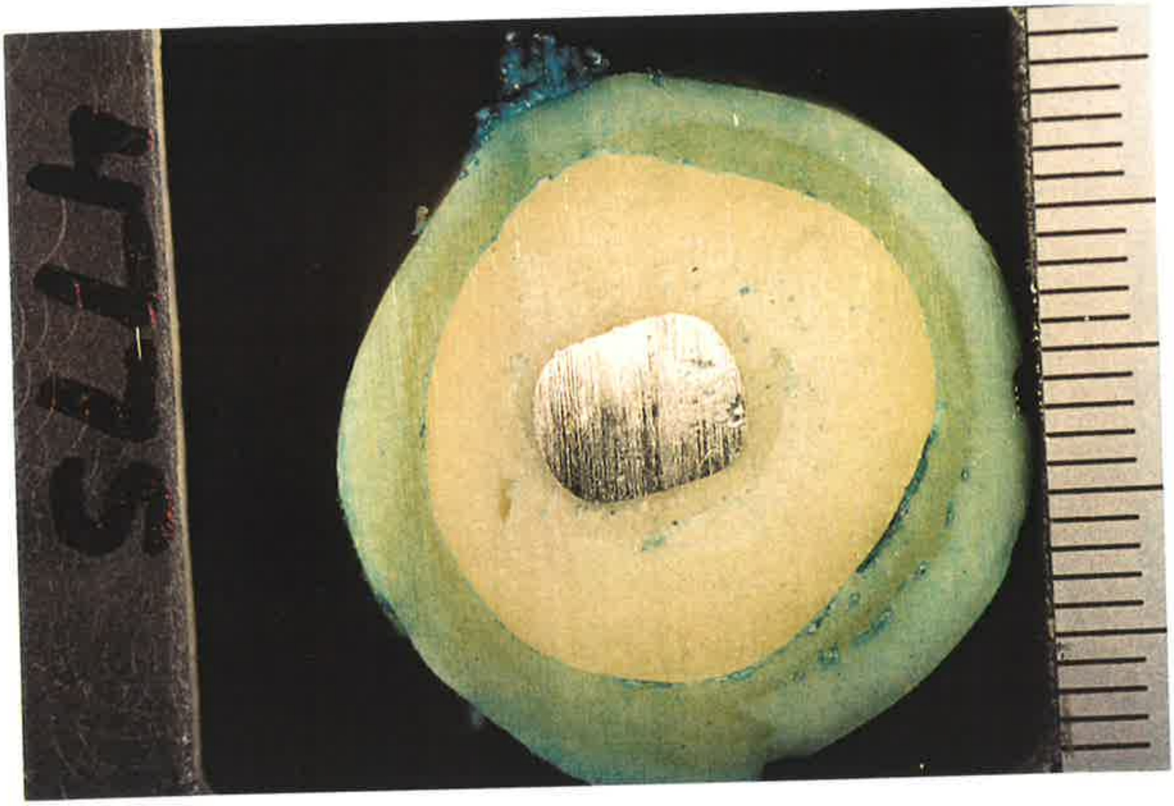


Figure 7.16. Distal section showing minimal fibrous tissue at c-b interface (sheep #10, polish).

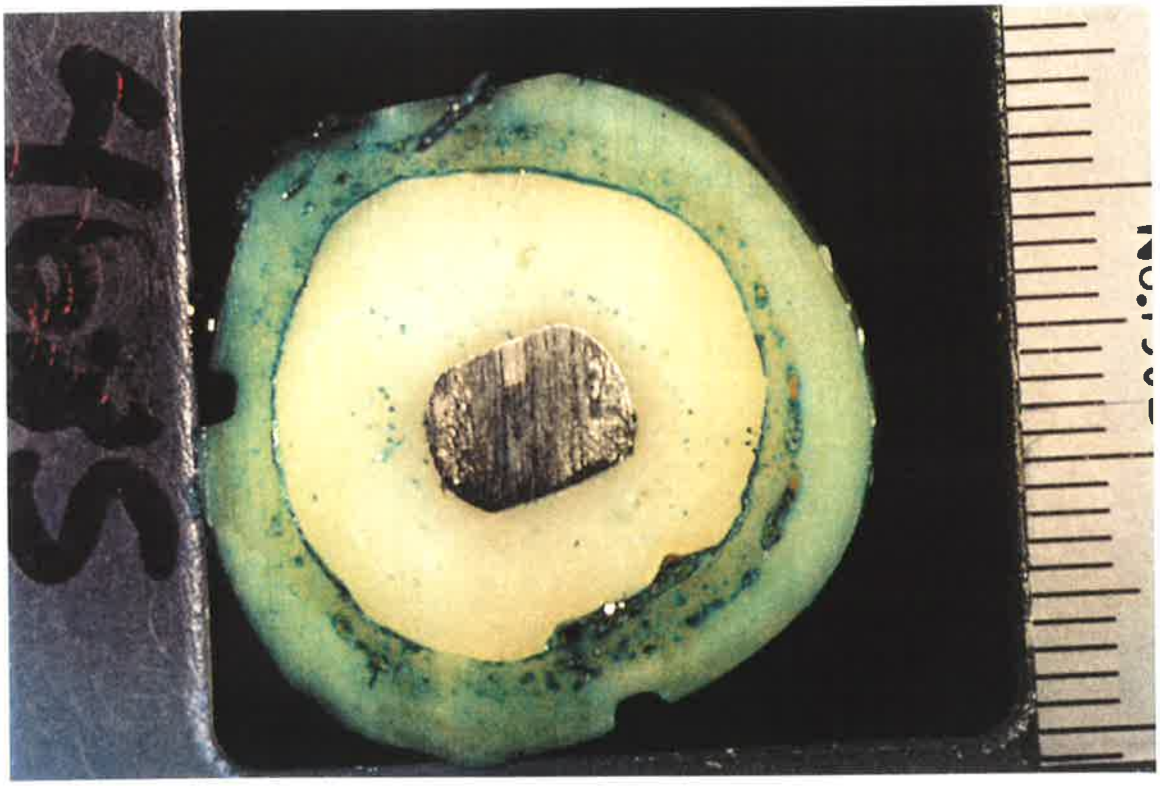


Figure 7.17. Distal section with c-b fibrous interface (sheep #28, collar)

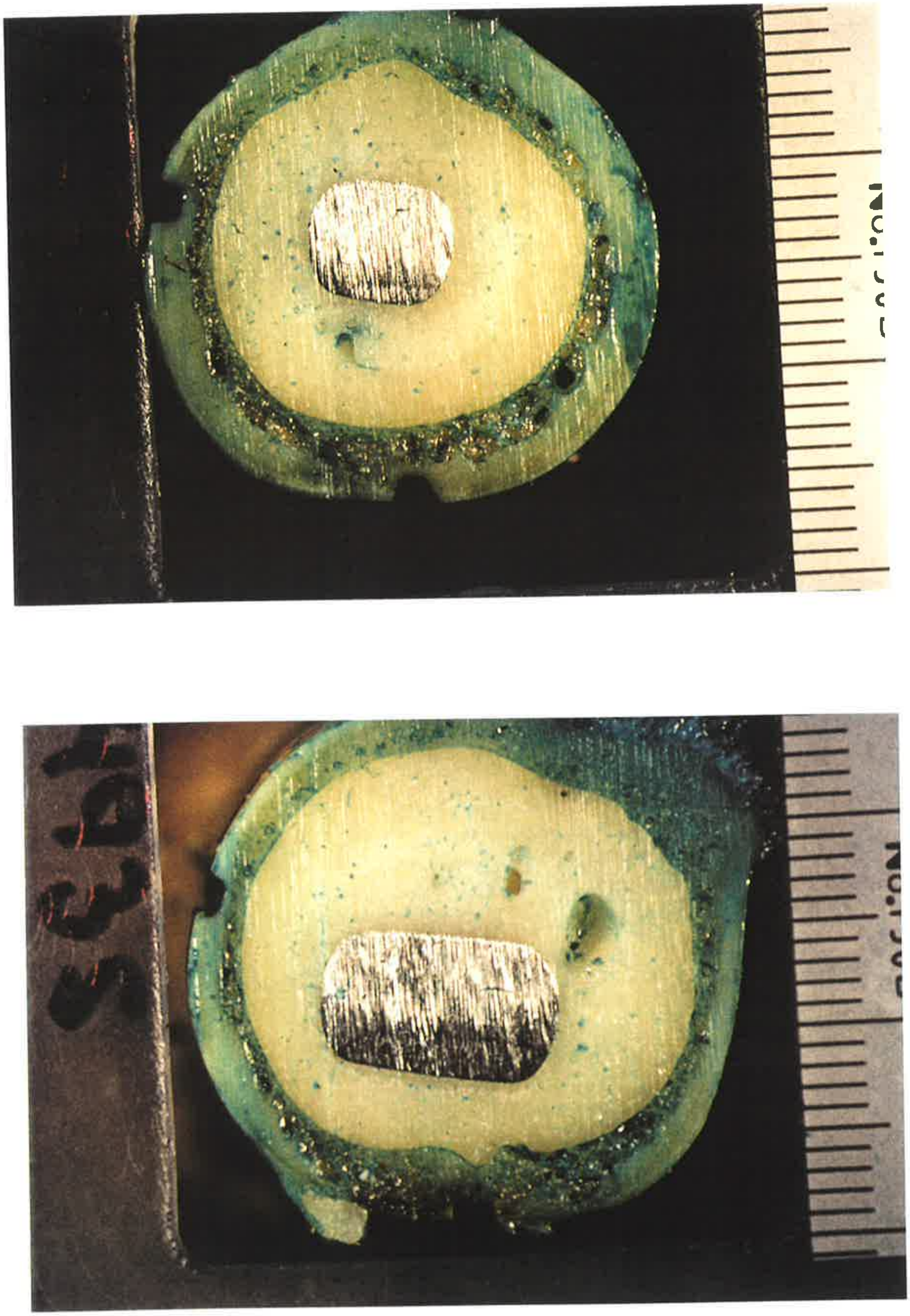
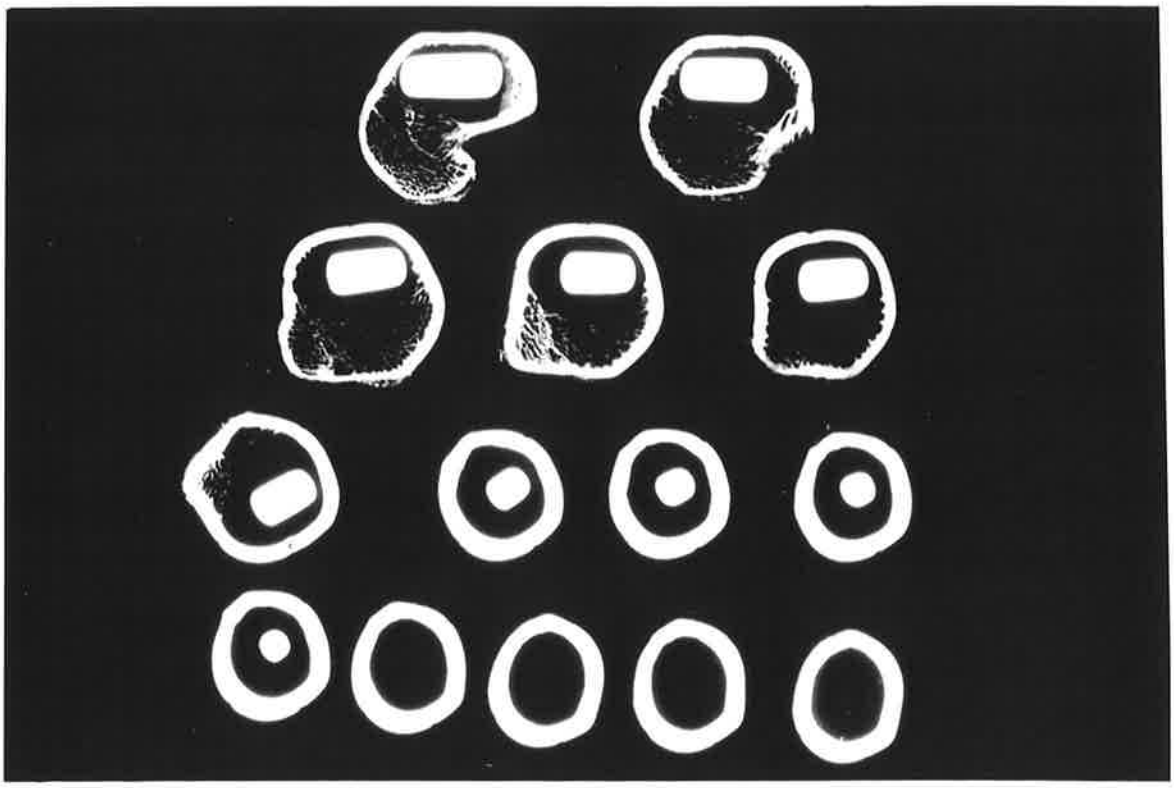


Figure 7.18. Trabecularization of distal cortex (sheep #23, polish).

(a)



(b)

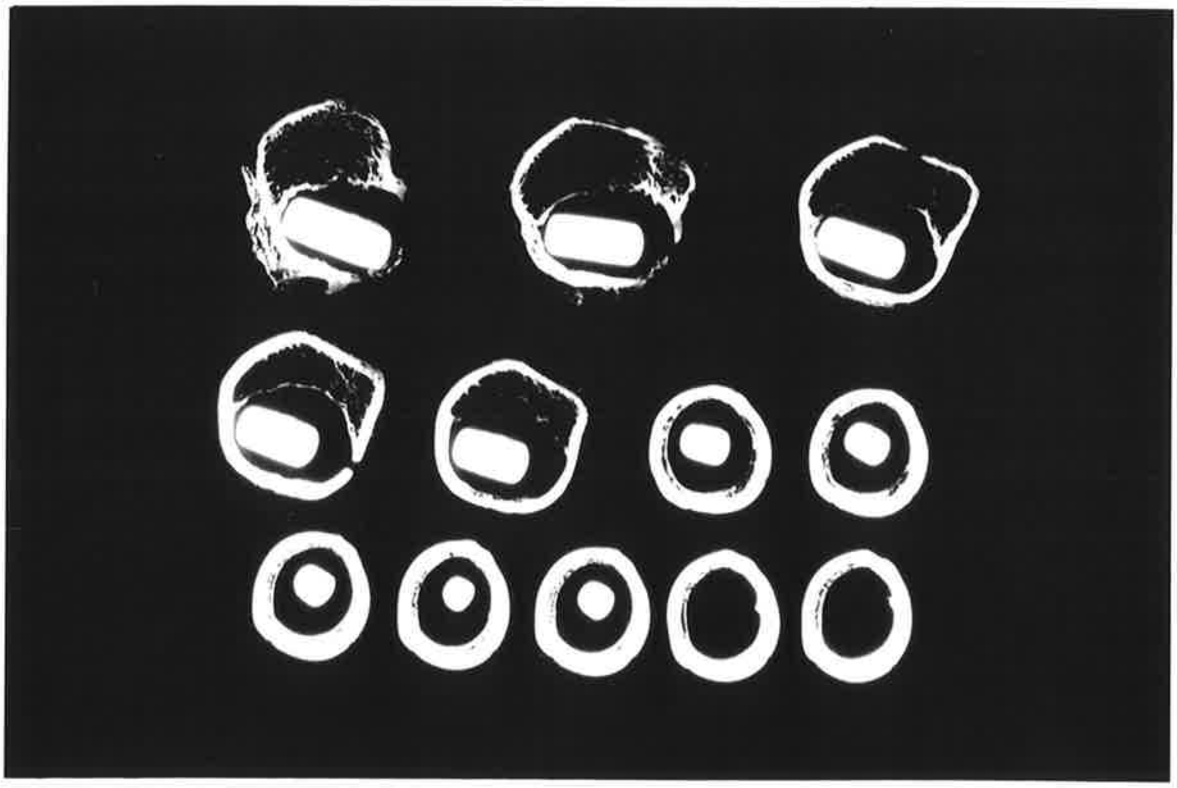
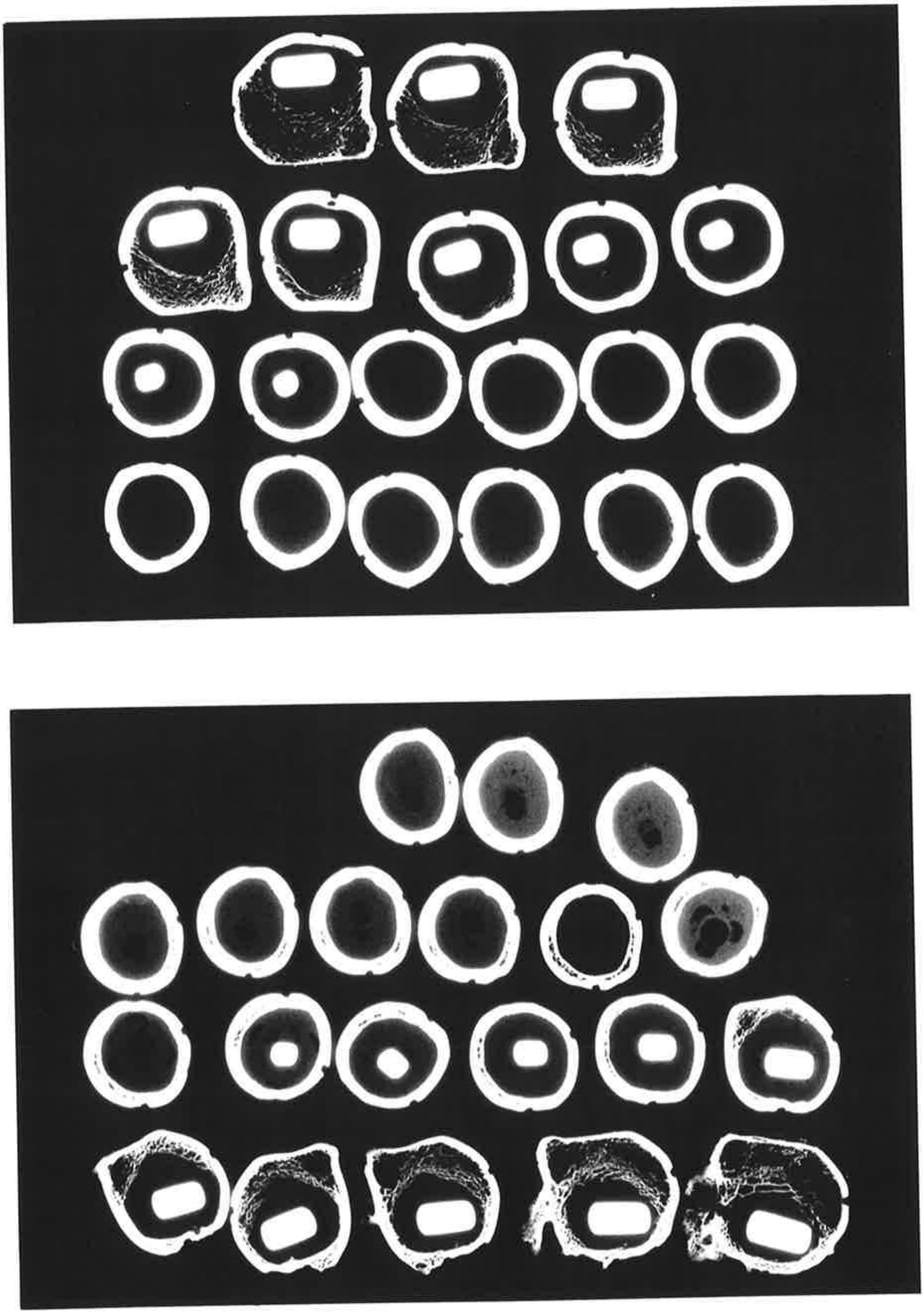


Figure 7.19. Contact radiographs of sections from femur (a) immediate and (b) nine months after implantation that shows trabecularization and neocortex (sheep #5, polish).

(a)



(b)

Figure 7.20. Contact radiographs of sections from femur (a) immediate and (b) nine months after implantation that shows trabecularization and neocortex (sheep #27, matt).

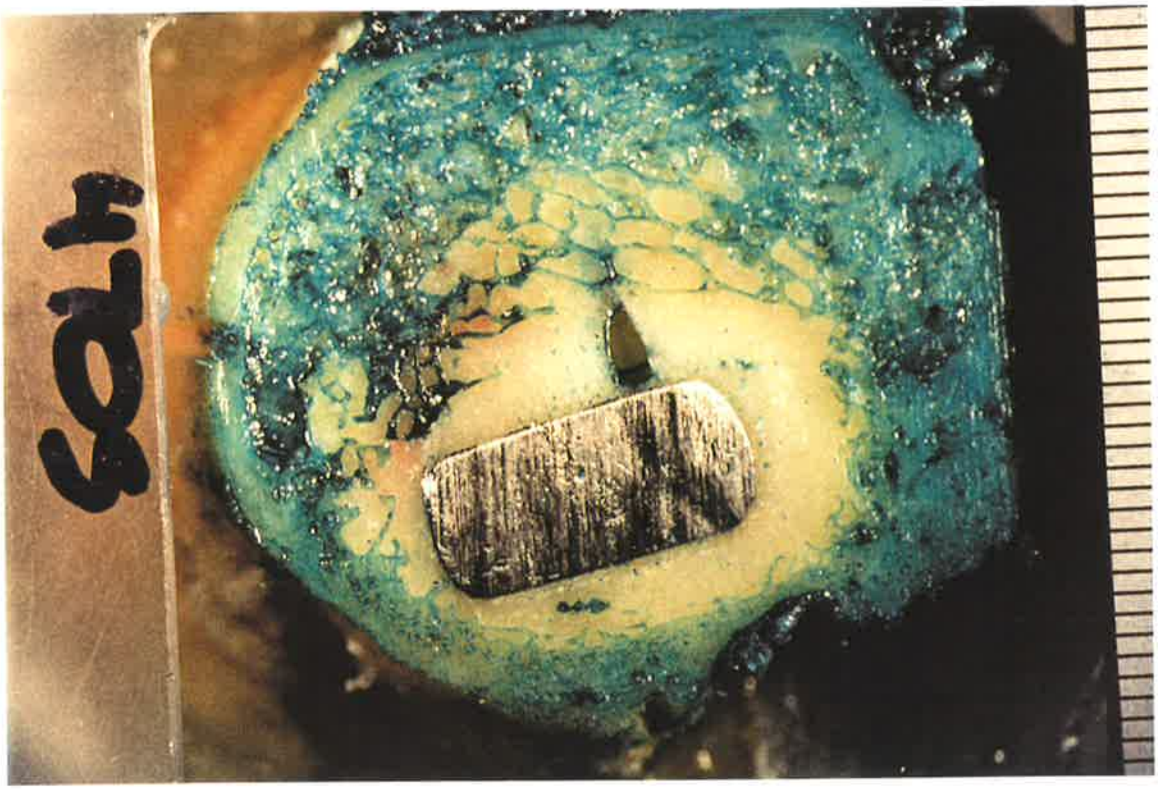
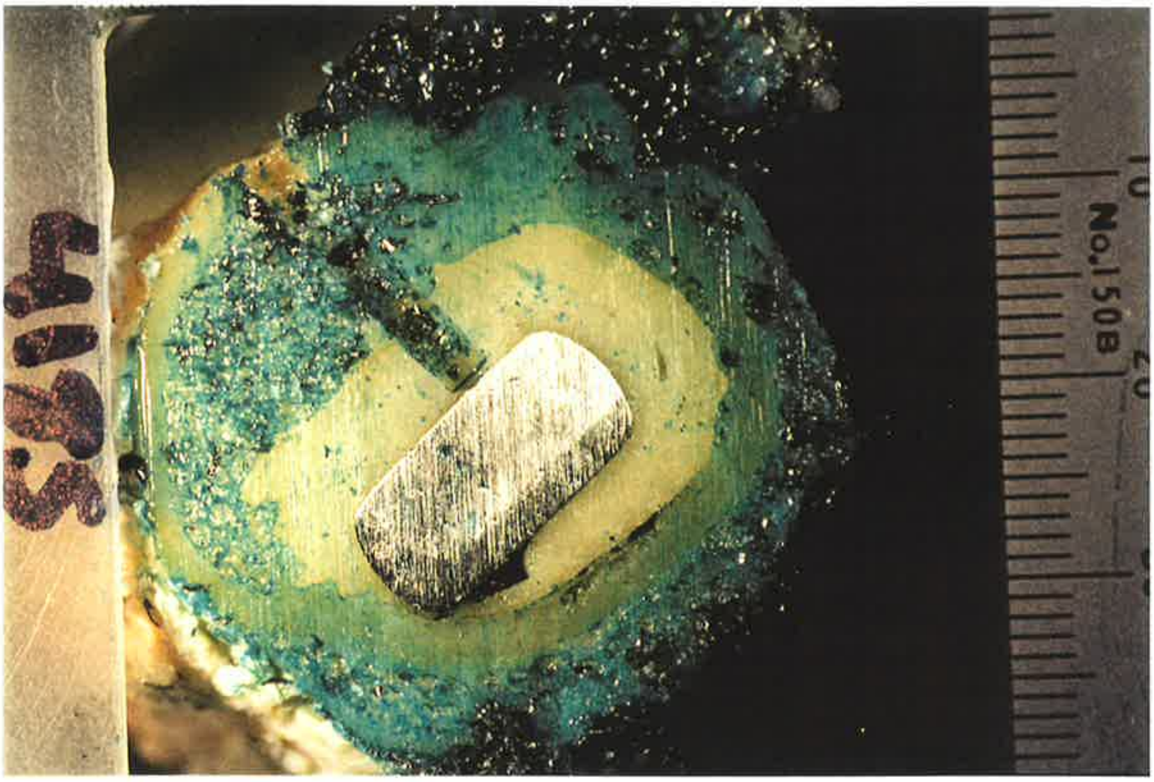


Figure 7.21. Proximal c-b interface at nine months after implantation (sheep #27, matt).

Figure 7.22. Proximal c-b interface at nine months after implantation (sheep #7, polish).

(a)



(b)

Figure 7.23. Proximal heterotopic bone (a) sheep #11, polish. (b) sheep #R2, matt..

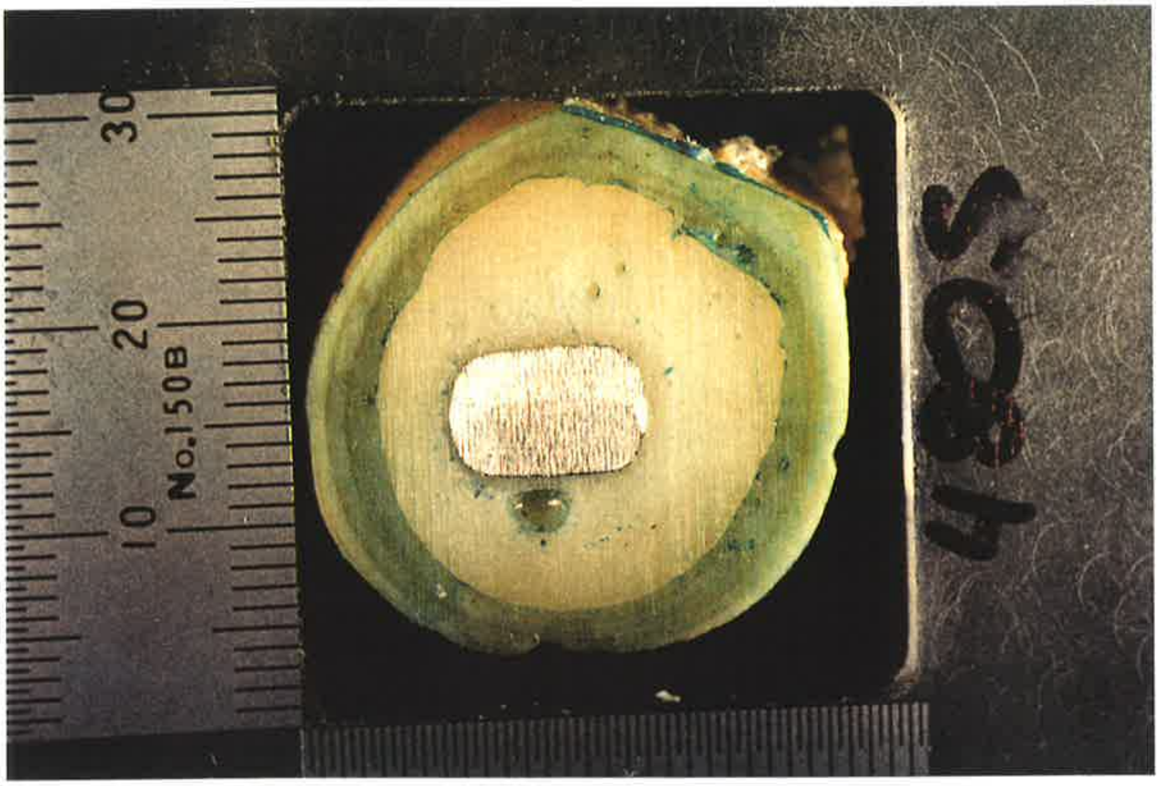


Figure 7.24. Microphotograph of thin section contact radiograph of p-c interface gap (sheep #11, polish).

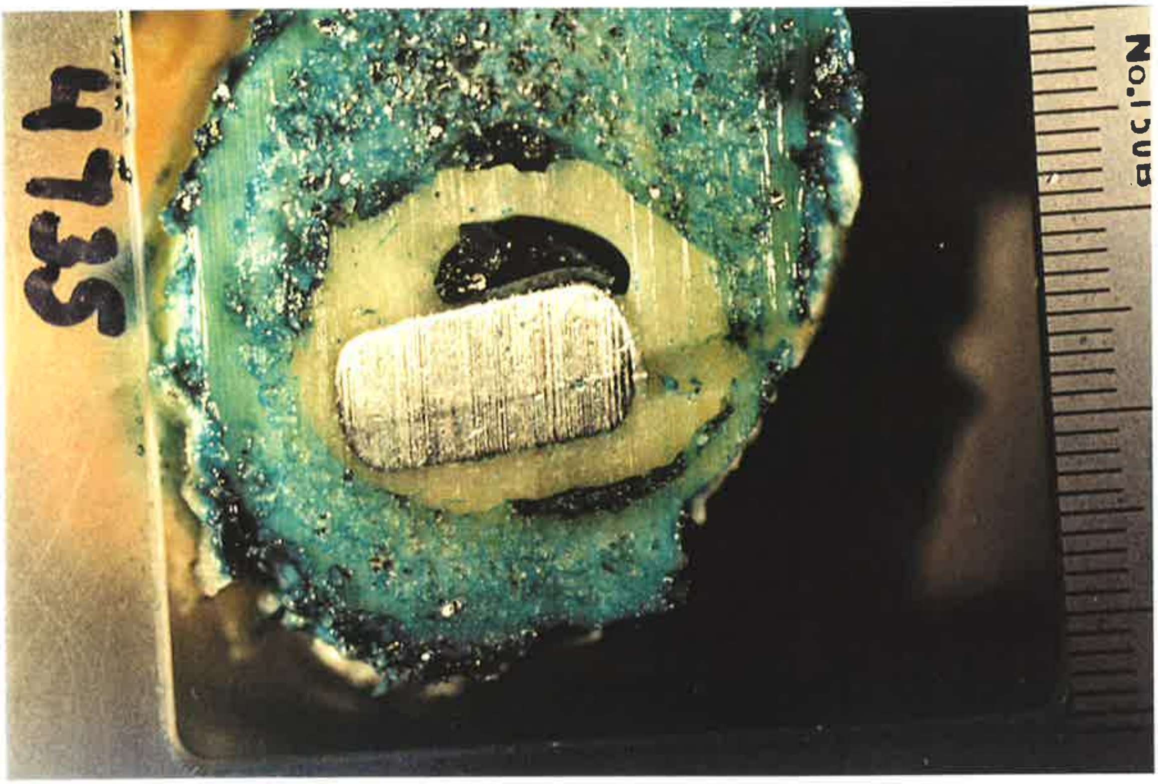


Figure 7.25. Microphotograph and thin section contact radiograph of p-c interface gap (sheep #13, matt).

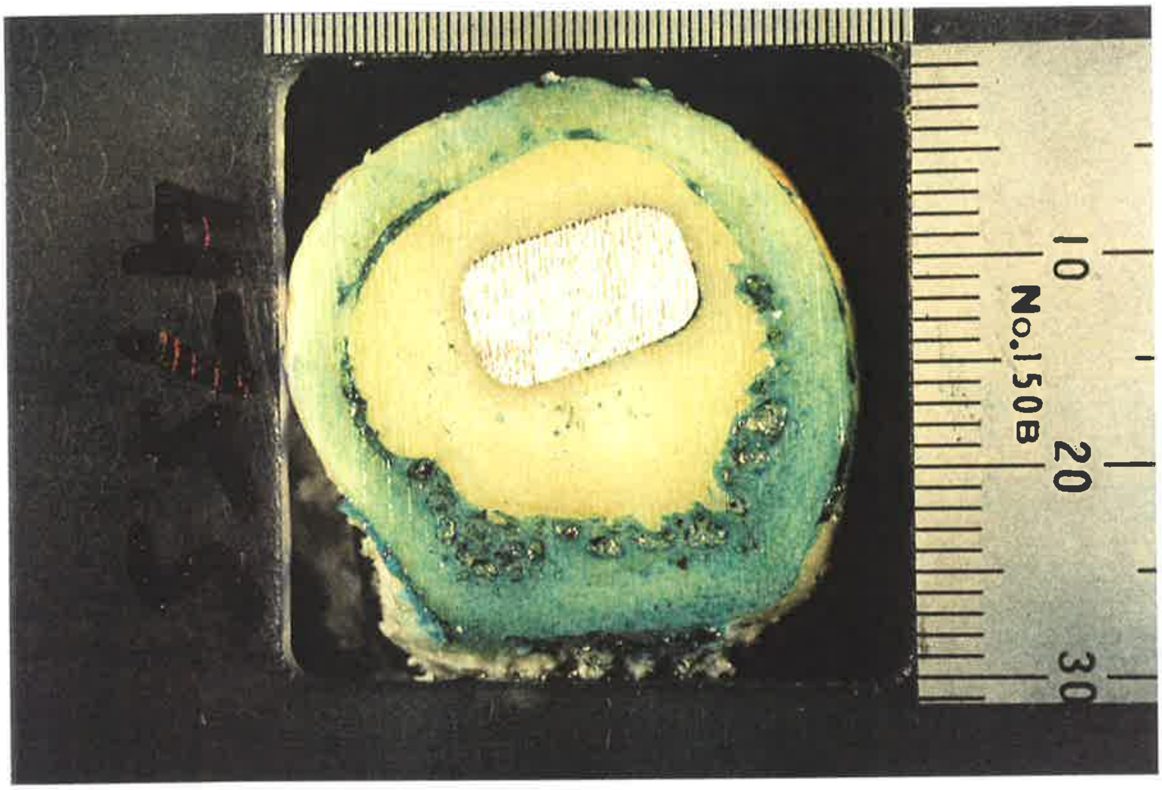


Figure 7.26. Microphotograph and thin section contact radiograph of p-c interface gap (sheep #16, collar).

7.5. Discussion

Immediately after implantation there were gaps up to 300 μm at the c-b interface that contained blood and bone debris. Draenert (Draenert, 1981) observed gaps present immediately after implantation between the cement and bone that were between 20 and 200 μm and attributed them to reaming and the thermal effects of bone cement. Draenert found that with time these gaps were filled directly with lamellar bone and larger gaps with woven bone. At nine months after implantation the c-b interface was characterised by intimate contact of cement with bone and small intervening areas of fibrous tissue.

It is suggested that the filling of these gaps over the nine months after implantation would lead to increased fixation in the period after implantation. In this study, axial micromotion between the prosthesis and bone was found to be less nine months after implantation compared to that immediately after implantation suggesting that this remodelling has occurred.

Trabecularization of the cortex and the formation of a neocortex was seen in the majority of femurs. The neocortex adjacent to the cement will not be seen with plain radiography and the intervening trabecular bone will appear radiolucent. The lack of a wide fibrous c-b interface suggests that the radiolucent lines seen with plain radiographs represent remodelling rather than bone resorption and replacement with fibrous tissue. This finding has also been noted by Draenert (1981) and Kwong et al. (1992). This finding highlights the importance of thin section histology or contact radiography to accurately investigate the c-b interface.

Debonding at the p-c interface was not seen in this study. Gaps at the p-c were seen immediately after and at nine months after implantation and were caused by voids in the cement mantle adjacent to the stem. There was no evidence that combined axial and rotatory movement of the stem was present resulting in the debonding that was seen by Jasty et al. (1991). Debonding may be a finding that is associated with stems that have a triangular cross section with or without poor cement mantles as shown in the paper of Jasty et al. (1991). Cement mantle void, deficient cement mantles because of non centralised components and stems with triangular cross sections may be the initiating factors of loosening. Strengthening the bond between the stem and the cement with a matt surface finish will not prevent "debonding" if a cement mantle void prevented the stem from bonding at the time of implantation.

7.6. Conclusions

The histology of the p-c and c-b interface was not different between implant types.

Immediately after implantation the c-b interface was characterised by incomplete gaps up to 300 microns filled with blood and bone debris. Gaps at the p-c interface were due to voids in the cement mantle and therefore represented areas where the stem was never bonded to the cement. The term "debonding" coined by Harris should be replaced with "never bonded". In the absence of cement mantle voids there were no gaps at the p-c interface. The use of a matt surface and a collar will not improve this bond.

At nine months after implantation the majority of the bone was in direct contact with the cement. Fibrous tissue at the c-b interface was incomplete and thicker proximally. Trabecularization of the cortex and the formation of a neocortex was common and it is suggested that the c-b radiolucent lines seen on plain radiographs represent this remodelling.

Chapter 8

Conclusions and Further Research

This study has investigated the effects of femoral stem surface finish and a collar with a double tapered cemented femoral stem implanted in a sheep. The findings can not be directly compared with the changes which may occur in the human. However, this study was performed as a comparative study to determine the effects of surface roughness and a collar on the fixation of cemented femoral stems *in vivo*. The differences seen reflect the differences in surface roughness and the use of a collar.

Immediately after implantation there was bonding of the stem to the cement except in a few areas that were associated with cement mantle voids. Micromotion between the prosthesis and cement was less than 40 microns and was not different between implant types. The use of a matt surface finish with or without a collar did not improve the initial fixation of the stem to the cement.

At nine months after implantation the prosthesis-cement interface was unchanged with no evidence of debonding. There was no evidence of subsidence of the stem within the cement mantle. Micromotion at this interface remained less than 40 microns. The findings of this study suggest that in a sheep model, changing the surface roughness of a double tapered cemented femoral stem from an Ra = 0.02-0.04 μm to an Ra = 1 μm with or without a collar does not alter fixation between the stem and cement at nine months after implantation. Polished femoral stems implanted using modern cementing techniques may not subside within the cement mantle. Early self limiting prosthesis-cement subsidence may be related to cementing technique and not due to the surface finish of the femoral stem as previously thought.

Immediately after implantation there was micro-interlock of the cement and bone, however there were many gaps between the cement and bone that were filled with blood and bone ebris. These gaps were not seen with plain radiography and this highlights the limitation f plain radiographic assessment of the cement-bone interface. There was no difference etween implant types in micromotion measured between the prosthesis and bone during ıxial or medio-lateral loading. However, antero-posterior loading resulted in greater nicromotion of the polished stems compared to the matt surfaced stems. This difference vas small and the significance uncertain.

At nine months after implantation there was remodelling of the cortex with rabecularization and the formation of a neocortex. This was seen as an incomplete adiolucent line on plain radiographs. A complete fibrous cement-bone interface was seen n only a few sections. The micromotion measured between the prosthesis and bone with axial loading was less than that immediately after implantation. This suggests that the illing of cement-bone gaps with bone and remodelling of the cortex with trabecularization and the formation of a neocortex is associated with increased stability. There was no difference in fixation between implant types at nine months after implantation.

The findings from this study should again be compared with the extensive work by Harris and his colleagues on sixteen femurs retrieved at autopsy from patients with asymptomatic cemented hip replacements (Maloney et al.1989; Jasty et al.1991; Kwong et al.1992).

The findings from this study agree with those of Maloney et al. (1989) who found solid fixation with axial micromotion less than 40 μm associated with a cement-bone interface that was well maintained in the absence of cement fragmentation. Allowing for differences in loading conditions, micromotion of less than 100 μm should be regarded as solid fixation.

The findings from this study disagree with those of Jasty et al. (1991) who found evidence of prosthesis-cement debonding in all femurs. In this study early debonding was not seen and there was no difference between a polished and a matt surfaced stem. Debonding may be a feature of stems that have a triangular cross section or a reflection of a poor ement mantle. The use of stems that have an increased surface roughness or a collar re not supported by the findings of this study.

'he histological features of the radiolucent line described by Kwong et al. (1992) are imilar to the features seen in the sheep femur with this study. This study supports the iew that radiolucent lines can occur with well fixed cemented femoral stems and may epresent remodelling with local osteoporosis rather than a fibrous interface.

'his study has highlighted the problems involved in the radiographic assessment of emented hip replacements. Firstly, measurement of subsidence is subject to many rrors, mainly due to the difficulty of taking reproducible radiographs. The use of RSA for urther studies is highly recommended. Secondly, recording and grading radiolucent lines ind calcar resorption is subject to observer bias and poor accuracy because of non eproducible radiographs and subjective measurements. The use of digitised radiographs ind computer assisted measurements of bone density and interface width may improve he accuracy but the taking of reproducible radiographs is more important.

urther research of cemented hip replacements requires a reproducible, relevant animal nodel. This study has shown that the sheep is a suitable model for comparative studies of cemented hip replacement.

In this study there was no difference between a polished and a matt surfaced femoral stem of identical geometry. The Charnley femoral stem has been made with different surface finishes and cross sectional geometry; small changes in the incidence of loosening have been noted between the first generation and subsequent-generation stems (Dall et al.1993). A difference in the incidence of loosening has also been noted between the polished and matt surfaced Exeter femoral stems (Fowler et al.1988; Ahnfelt et al.1990). The stems used in this study had a different taper angle and geometry from the Exeter stems. The effect of femoral stem taper angle and the relationship with different surface features requires further study. The correct matching of surface finish with stem geometry may be more complex than initially thought.

Minor changes in the bone histomorphometry were seen at nine months after implantation in this study. The detailed assessment of this bone was beyond the scope of this thesis. A detailed analysis of the trabecularized cortex and neocortex may provide valuable information on the difference in the way the bone is loaded from cemented femoral stems of different surface finish and a collar. Minor differences may have an effect on the late loosening of femoral stems. Analysis of the bone histomorphometry is being planned at present. As well, comparison and validation of these findings with a finite element model of cemented hip replacement may allow further designs to be rapidly assessed.

This thesis has addressed early loosening of cemented femoral stems from a mechanical view point. The cause of late loosening is controversial and may be a result of mechanical failure, the response to wear debris or a combination of factors. The response to wear debris is complex and determined by particle type, size, shape, number of particles, rate of generation and probably many other factors. Current research of wear debris is being performed with wear particles in cell culture and small animal models. To examine the combined interaction of wear debris and mechanical factors, a large weight bearing animal model is essential. The sheep model described in this thesis can be modified to assess the factors that may be implicated in the aetiology of cemented hip arthroplasty loosening.

In conclusion, initial and early fixation of a cemented double tapered femoral stem in bone is not effected by femoral stem surface finish or a collar. Micromotion between a polished surfaced femoral stem and cement is small and not reduced by increased surface roughness or a collar. With modern cementing techniques, there is minimal subsidence of a polished femoral stem without debonding of the prosthesis-cement interface. Loss of early fixation and subsequent loosening may be due to the effect of the stem geometry and the cementing technique. The implication of this knowledge for the arthroplasty surgeon are that the selection of a prosthesis with documented excellent long term results and the payment of special attention to the cementing technique are the two prime factors that will give confidence for the long term outcome of total hip arthroplasty.

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Chapter 1

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