



**FEMORAL BONE REMODELLING
FOLLOWING CEMENTED HIP ARTHROPLASTY
IN A SHEEP MODEL**

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TABLE OF CONTENTS

Table of contents	i
Abstract	vii
Publications	ix
Acknowledgements	xi
Dedication	x
Chapter 1 INTRODUCTION	1
Chapter 2 LITERATURE REVIEW	4
2.1 Femoral Component Design Controversies	4
2.1.1 The Rationale for the Collared Matt Finished Femoral Stem Design	4
2.1.2 Clinical Results of the Collared Matt Finished Stem	5
2.1.3 The Case against Collared Stems	5
2.1.4 The Case against Matt Finish	7
2.1.5 The Rationale for the Collarless Polished Femoral Stem Design	8
2.1.6 Clinical Results of the Collarless Polished Stem	9
2.2 Femoral Cortical Strain Analysis	12
2.2.1 In Vitro Strain Studies	12
2.2.2 Ex Vivo Strain Studies	14
2.2.3 Principal Strain Analysis	16
2.3 Bone Morphometry	18
2.3.1 Femoral Canal Preparation	18
2.3.2 Effect of Cementation	19
2.3.3 Bone Remodelling Effects	21
2.3.4 Quantitative Bone Remodelling Studies	24
2.3.5 Canine Bone Morphometric Studies	26
2.4 Densitometric Evaluation of Bone	30
2.4.1 Radiographic Densitometry	30
2.4.2 Dual Energy X-Ray Absorptiometry (DEXA)	31
2.4.3 DEXA Clinical Studies - Cementless THA	32

2.4.4	DEXA Clinical Studies - Cemented THA	34
2.5	Animal Models for Total Hip Arthroplasty	36
2.5.1	General Principles	36
2.5.2	Biomechanical Aspects	36
2.5.3	Anatomical Aspects	38
2.5.4	Rehabilitation of Animals Following THA	39
2.5.5	Ovine Studies of THA	40
Chapter 3	A SHEEP MODEL FOR TOTAL HIP ARTHROPLASTY	42
3.1	Introduction	42
3.2	Choice of Animal Model	42
3.3	Study Design	43
3.3.1	The Study Group	43
3.3.2	Calculation of Sample Size	44
3.3.3	Randomisation to Treatment Groups	46
3.3.4	Withdrawal Criteria	47
3.3.5	Selection of a Control	47
3.4	Sheep Implant Design	49
3.5	Operating Room Set Up	52
3.6	Anaesthesia	52
3.7	Surgical Protocol	52
3.7.1	Surgical Exposure	52
3.7.2	Femoral Canal Preparation and Implant Insertion	54
3.7.3	Radiographic Markers for Implant Subsidence (An Independent Study)	56
3.7.4	Surgical Closure	56
3.7.5	Post Operative Radiography	57
3.7.6	Post Operative Management	58

3.8	Results of Surgical Protocol	59
3.9	Sacrifice Protocol	63
3.10	Discussion	63
Chapter 4	CONTACT RADIOGRAPHY	72
4.1	Introduction	72
4.2	Hypothesis	72
4.3	Methods and Materials	72
4.3.1	Radiolucent Line Evaluation	73
4.3.2	Subsidence Evaluation	73
4.3.3	Other Radiographic Features	74
4.4	Results	75
4.5	Discussion	76
Chapter 5	CORTICAL STRAIN ANALYSIS	80
5.1	Introduction	80
5.2	Null Hypothesis	81
5.3	Strain Gauge Instrumentation	81
5.3.1	Introduction	81
5.3.2	Bone Preparation	81
5.3.3	Strain Gauge Application	81
5.3.4	Strain Gauge Positioning Protocol	82
5.3.5	Femoral Mounting	84
5.3.6	Application of Load	84
5.4	Reproducibility Study	92

5.4.1	Introduction	92
5.4.2	Method and Materials	92
5.4.3	Results	93
5.4.4	Conclusion	93
5.5	Sheep Intact Femur Study	94
5.5.1	Introduction	94
5.5.2	Method and Materials	96
5.5.3	Results	97
5.5.3.1	Cortical Strain Distribution in the Intact Femur	97
5.5.3.2	Left-Right Variability in Cortical Strain	98
5.5.4	Conclusions	106
5.6	Sheep Retrieval Studies: Methodology	106
5.6.1	Explant Protocol	106
5.6.2	Explant Study vs Control Group Analysis	108
5.6.3	Explant Intergroup Analysis	108
5.7	Sheep Retrieval Studies: Results	108
5.7.1	Descriptive Changes	108
5.7.2	Cortical Strain Analysis: Study vs Control Groups	113
5.7.3	Intergroup Analysis	116
5.8	Discussion	118
Chapter 6	BONE MORPHOMETRY	133
6.1	Introduction	133
6.2	Hypothesis	133
6.3	Methods and Materials	133
6.3.1	Bone Sectioning Protocol	133
6.3.2	High Resolution Radiography	135
6.3.3	High Resolution Radiographic Bone Morphometry Protocol	135
6.3.4	Reproducibility Study of Bone Morphometry Protocol	136

6.4	Results: Study vs Control	141
6.4.1	Cortical Width	142
6.4.2	Cortical Porosity	143
6.4.3	Trabecular Density	143
6.4.4	Discussion	144
6.5	Results: Analysis of Intergroup Difference	153
6.5.1	Cortical Width	153
6.5.2	Cortical Porosity	153
6.5.3	Trabecular Density	154
6.5.4	Discussion	154
Chapter 7	CLINICAL LONGITUDINAL EVALUATION OF THE EXETER STEM USING DEXA	165
7.1	Introduction	165
7.2	Methods and Materials	166
7.3	Results	167
7.4	Discussion	172
Chapter 8	GENERAL DISCUSSION	178
8.1	Sheep Hip Arthroplasty Model	178
8.1.1	Was the Sheep Model Appropriate for Bone Remodelling Studies?	179
8.1.2	Study Design and Methodology Issues	180
8.1.3	Accept the Null Hypothesis	181
8.2	Directions for Future Research	182
8.3	Concluding Remarks	183

APPENDICES

Appendix 1	Hip Arthroplasty Instrumentation: Exposure	185
Appendix 2	Hip Arthroplasty Instrumentation: Implantation	186
Appendix 3	Calculation of Explanted Hip Loading Forces	187
Appendix 4	Cortical Strain: The Intergroup Comparisons	189

BIBLIOGRAPHY

198

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ABSTRACT

Total Hip Arthroplasty (THA) involves insertion of an implant into the proximal femur to replace the femoral head. Implantation of the femoral prosthesis radically alters the loading pattern of the proximal femur. Adaptive bone remodelling occurs and subsequent clinical radiographs demonstrate periprosthetic bone resorption or deposition.

This thesis examined the effect of implant design on the femoral bone remodelling response. A sheep cemented hip arthroplasty model was developed. Three implant design groups were studied: a highly polished collarless stem, a matt finished collarless stem, and a matt finished collared stem, all of the same double tapered geometry. Following ten months in vivo, an analysis was performed of retrieved matched pairs of femurs. The hypothesis of the study was that the adaptive bone remodelling response would be no different between implant groups.

The results indicated that up until the time of sacrifice, no sheep had developed lameness or clinical signs of hip implant loosening. High contrast contact radiographs of retrieved femurs indicated that no hip implant was definitely or probably loose. Femoral cortical strain analysis was performed under axial, medio-lateral, and antero-posterior directed loads of physiological magnitude. The results indicated that implantation of a femoral prosthesis of any design substantially reduced principal compressive strain and principal tensile strain compared to non implanted femurs subjected to equivalent loads. Comparison of study side implanted femurs with the contra-lateral implanted control femur, indicated that cortical strain had not recovered with in vivo bone remodelling. Contrary to adaptive bone remodelling theory, cortical principal strain in many instances was less following bone remodelling than at equivalent sites in the control femur.

The implant design variables of a collar and surface finish had no significant effect on the pattern of cortical strain changes which had occurred with remodelling. Specifically the collar did not continue to load the proximal medial cortex with compressive strain. Also the collarless polished stem did not show clear evidence for increased loading of the proximal femur with hoop strain, via its capacity to subside into the cement mantle.

Femoral bone morphometric analysis was performed on matched pairs of transverse sections. The results indicated external bone remodelling with reductions in cortical width, as well as

internal bone remodelling with reductions in cortical porosity and trabecular density. The matt collarless group demonstrated the greatest overall resorptive remodelling but there were no significant differences in the skeletal response for the collared or the polished groups.

Variations in cortical strain and bone morphometry were large within implant groups, even with the relative uniformity of size and genetic background of the subjects studied. Large inter-individual variation has also been observed in the skeletal response to total hip arthroplasty in human studies. Biological factors, notably the presence of osteoporosis have previously been shown to increase the magnitude of femoral bone loss after hip arthroplasty in matched pair autopsy retrieval studies. This thesis included a clinical study where dual energy X-ray absorptiometry changes were evaluated longitudinally around the “Exeter” hip. Single photon absorptiometry scan of the dominant wrist identified a sub-group of subjects who were osteoporotic at the time of surgery. The results indicated that osteoporotic subjects lost significantly more periprosthetic bone at 12 months after surgery than non osteoporotic subjects.

In this thesis, the design variables of a femoral collar and surface finish could not be shown to influence the adaptive bone remodelling response to hip arthroplasty in the short term in a sheep model. The implant altered the loading environment of the proximal femur so profoundly that normal homeostatic mechanisms for restoration of cortical strain were lost. Relatively subtle implant design features could not significantly alter this abnormal mechanical loading environment.

The clinical section of this thesis also indicated the importance of biological factors in the femoral bone remodelling response. Osteoporosis at the time of surgery significantly increased the magnitude and rate of periprosthetic bone remodelling in the short term following total hip arthroplasty.

PUBLICATIONS

1. Wang, A., Howie, D., Percy, M. Dual Energy X-Ray Absorptiometry Analysis of Femoral Remodelling after Exeter Total Hip Replacement. *J Orthop Surg.* 5(1): 29-32, 1997.
2. Wang, A., Schultz, C., Chatterton, B., Howie, D., Percy, M. Osteoporosis Increases the Magnitude of Proximal Femoral Bone Loss after Total Hip Arthroplasty. *Clinic Orth Rel Res*, submitted December 1997.

ABSTRACTED PUBLICATIONS

1. Wang, A., Schultz, C., Howie, D., Percy, D. Evaluation of Femoral Bone Mineral Density in Cemented Total Hip Replacement using DEXA Scanning. *Orthop Proc Suppl II, J Bone & Joint Surg* 76B: 100, 1994.
2. Schultz, C., Wang, A., Chatterton, B., Howie, D. Functional Image vs Conventional Gruen Analysis of Total Hip Arthroplasty. *Europ J Nucl Med* 21(10): 854 Oct 1994.
3. Wang, A., Nawara, N., Brumby, S., Percy, M., Howie, D. The Effect of a Calcar Collar and Surface Finish on Femoral Cortical Strain after Remodelling in a Sheep Hip Arthroplasty Model. *Orthop Proc Suppl IV, J Bone & Joint Surg* 79B: 385, 1997.
4. Barker, D, Wang, A., Yeo, M, Nawana, N, Percy, M., Brumby, S., Howie, D. An in vivo and Numerical Analysis of the Effect of Femoral Stem Surface Finish on Cortical Strain in Cemented Hip Replacement. *Proc Third Int Symp on Computer Methods in Biomechanics and Biomechanical Engineering*, Barcelona, May 1997.

POSTER DISPLAYS

1. Wang, A., Howie, D., Schultz, C., Percy, D. Evaluation of Femoral Bone Mineral Density in Cemented Total Hip Arthroplasty. A Study using DEXA. American Academy of Orthopaedic Surgeons, Orlando, Feb 1995
2. Brumby, S., Howie, D., Wang, A., Percy, M., Nawana, N. The Effect of Surface Roughness and a Collar on Fixation of Cemented Femoral Stems in vivo. Orthopaedic Research Society, Atlanta 1996

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DEDICATION

To my Mother

BICKLEEN NG WANG

CHAPTER 1: INTRODUCTION



The number of total hip arthroplasties (THA) performed annually has been steadily increasing, with currently more than 800,000 operations performed worldwide (Malchau *et al* 1993). THA has proven to be a successful operation for the relief of pain and improving function in the elderly patient disabled with arthritis.

Aseptic loosening of the femoral component remains one of the major complications of THA, and is one of the most common causes for revision surgery. Early studies of cemented THA have indicated that loosening rates of the femoral component varied from 20% to 40% in the medium term (Beckenbaugh *et al* 1978, Sutherland *et al* 1982, Stauffer *et al* 1982). More recently femoral component survival has improved with the introduction of contemporary cement techniques (Mulroy & Harris 1996, Ballard *et al* 1994, Poss *et al* 1988). However these studies cover only a 10 to 20 year period, which is still less than the average life expectancy of many patients undergoing THA. Therefore innovations continue in an attempt to improve the survival of the femoral component. Current research has focused on the development of non-cemented femoral stems (Mallory *et al* 1995, Engh *et al* 1990, Heekin *et al* 1993), and resurfacing arthroplasties (Howie *et al* 1990, Amstutz *et al* 1987). However current data suggests that a cemented femoral stem still gives the best overall survival and the use of cement for femoral fixation is regaining popularity (Joshi *et al* 1993, Schulte *et al* 1993, Sullivan 1994).

Currently there are a huge number of femoral stem designs available for cemented application in THA. The majority of these implants have a short clinical track record and minimal scientific input into their design (Morris 1996 Murray 1995). Joint replacement registries indicate that not all femoral implant designs perform equally well, and there is currently a drive in a number of countries to establish arthroplasty registers to track the clinical performance of these various femoral implant designs (Havelin *et al* 1997, Sochart *et al* 1996, Malchau *et al* 1993).

The design of cemented femoral implants is polarised around two basic and mutually exclusive design concepts. These are:

1. a femoral implant with a matt finish and a broad medial collar,
2. a femoral implant with a highly polished surface finish and no collar whatsoever.

Implants of both these basic designs are in widespread clinical use, and perform equally well in medium term clinical studies (Malchau *et al* 1993). Each design represents not only an alternative approach for implant fixation, but also for the implant to transfer weight bearing loads to bone. The presence of the femoral implant in the intramedullary canal will reduce the loads normally applied to bone of the proximal femur, resulting in periprosthetic bone resorption. Ongoing stress shielding and progressive bone resorption may occur, and with the expectation of THA remaining in situ for 25 or more years, the extent of bone resorption may become clinically important. Thin “eggshell” femurs are at risk for periprosthetic fractures during revision surgery and the lack of bone stock especially sturdy cancellous bone in the proximal femur makes subsequent reconstruction more difficult. Kershaw *et al* (1991) reported that cemented revision into poor bone stock was associated with a higher failure rate than revisions into normal or reduced bone stock. Biological fixation after interference fit of cementless stems is also less sound when bone stock is porotic and weakened (Lord *et al* 1988, Engh *et al* 1988b, Mallory 1988). Finally bone made more porotic by stress shielding related resorption may also be more susceptible to wear debris related osteolysis, and aseptic loosening (Prittchett 1995, Hoffmann *et al* 1989).

The problem of periprosthetic bone loss is made more difficult by the risks of bone stock reconstitution with allograft bone. Following second or third revision surgeries, femoral bone stock commonly requires reconstruction with either bulk structural allograft (Head *et al* 1987, Oakeshott *et al* 1987) or impacted morselised allograft (Gie *et al* 1993, Ling *et al* 1992). Allograft bone, though subject to rigorous donor screening procedures and sterilisation, still carries the potential for transmission of infection (Buck *et al* 1989). Preservation of bone stock is a fundamental principle in orthopaedic surgery. The skeletal response of the femur to THA has therefore been the subject of numerous radiographic, densitometric and autopsy retrieval studies. However, to date there has been little data on the comparative bone remodelling response to femoral implants of different designs. The question as to whether femoral designs features, specifically collared matt finished designs, or a collarless polish finished design, can influence the bone remodelling response, remains unanswered.

This experimental work studied the femoral design controversy in an in vivo animal model. A sheep model for THA was developed and a hindlimb implanted for experimental studies. After 10 months of remodelling, the contralateral limb was implanted prior to sacrifice and used as a control for studies on the implanted femur. Quantitative methods were applied to determine the relative differences in femoral bone parameters after remodelling around three stem designs: a collarless polished stem, a collared matt stem and a collarless matt stem, all of the same basic double tapered geometry. Specifically the objective was to examine differences in the pattern of load transfer to bone using high resolution contact radiography, cortical strain analysis, and bone morphometry after a period in vivo. The central hypothesis of this matched pairs animal retrieval study was that there is no important difference in the skeletal remodelling response around cemented femoral implants of a collarless polished, a collarless matt finished, or a collared matt finished design.

This work includes a clinical study of femoral bone remodelling changes using dual energy X-Ray absorptiometry (DEXA). Femoral bone remodelling was measured in a 12 month longitudinal study of the “Exeter” (Howmedica) collarless polished tapered stem, with a focus on what **patient** variables may affect the magnitude of the remodelling response.

The experimental work is presented in five chapters, each with its own introduction, methods and materials, results, and discussion. The thesis concludes with a general discussion of the relevance of the results to the study aims and hypothesis, the limitations of the study, and a summary of the conclusions from this work.

CHAPTER 2: LITERATURE REVIEW

2.1 FEMORAL COMPONENT DESIGN CONTROVERSIES

2.1.1 The Rationale For Collared Textured Femoral Stem Design

A cemented femoral stem with a textured surface and a broad proximal collar is widely employed in clinical practice. This basic design has been adopted by a variety of manufacturing companies (eg Zimmer: "Harris Precoat"; Howmedica: "Precision"; Smith and Nephew: "Spectron").

The rationale for the collar has been described by Fagan and Lee (1986), Kwong *et al* (1990), Harris (1992). The collar is designed to sit flush against the femoral neck osteotomy. Axial loads are transmitted from the implant head via the collar to the proximal medial femoral cortex reducing stress shielding and bone resorption. In addition a well seated collar can reduce micromotion and increase stability of the implant on torsional loads (Markolf *et al* 1980). Once flush against the femoral neck, the collar may also reduce the stress in the proximal medial cement mantle by up to 60-70% (Crowninshield 1980b). Using strain gauges placed within the cement mantle, O'Connor *et al* (1996) showed a collar may reduce strains within the proximal cement especially during stair climbing. This may decrease the risk of progressive cement fracture and implant loosening.

The stem texturing and matt surface finish also improves the prosthesis cement bonding strength (Ahmed *et al* 1984). Jasty *et al* (1991), in a histomorphometry analysis of cadaver retrieved cemented stems, found that de-bonding at the prosthesis cement interface was associated with cement mantle fractures. Jasty *et al* suggested that a matt surface finish, by strengthening the cement prosthesis interface, will decrease cement fracturing and decrease the passage of polyethylene wear particles from the articulating surface via the fracture line to the bone cement interface, where osteolysis occurs. A matt surface finish would therefore decrease implant loosening.

2.1.2 Clinical and Radiological Outcome of Collared Stems

Recently a number of medium term outcome studies of femoral stems with large collars and matt surface finish have been reported. In the Swedish National Hip Arthroplasty Register Malchau *et al* (1993) reported a 99% 9 year survival of 939 “Spectron” Hips, when used with an all polyethylene socket. From the same Registry, the “Scan” collared hip had a 97.2% 10 year survival. Interestingly the Scan collarless hip performed worse with an 8 year survival of 93.9%.

Kelley *et al* (1993) performed a randomised prospective radiographic analysis of otherwise identical collared and collarless cemented implants. His study indicated that a well positioned collar continued to function and load the proximal medial femoral cortex. At 5.5 years post operatively femurs with collared implants had undergone significantly less calcar resorption. Loss of femoral neck height at the endosteal side was 1.7mm, compared to 3.4mm in the collarless group. Notably when collar calcar contact was poor, loss of femoral neck height was 2.6mm, compared to 0.7mm when collar contact with bone was considered good.

In an unpublished series high rates of collar calcar contact have also been noted and this was preserved over time (Harris 1992). Using a collared stem of his own design and using a calcar reamer to shape and angle the femoral neck cut, Harris initially achieved excellent calcar contact in 91% of cases. In those cases, calcar contact was maintained in 88% at 5.8 years.

There is therefore evidence that the calcar collar is effective at preserving the calcar bone, and there are excellent medium term clinical results of implant designs using a collar with a matt finished stem.

2.1.3 The Case Against Collared Stems

There are numerous clinical studies which show the collar is not consistently effective at loading the calcar and preventing calcar resorption. O'Hara and McMinn (1991) studied 51 hips of the Link SP design at 2 years. 26 demonstrated greater than 2 mm of resorption. At 4 years none were loose but all those reviewed had greater than 2mm of resorption. Richards and Duncan (1986), using the HD-2 prosthesis, found 76% lost

collar calcar contact over a 2 year period. Thomas *et al* (1986), in a medium term study of the CAD implant, reported calcar resorption in the range 2-20mm, with a mean of 6.5mm in 42% of cases. Cotterill *et al* (1982), with a 6 month to 11 year follow up, reported 71% of 166 Charnley Muller stems showed evidence of calcar resorption. Therefore a degree of bone resorption under a collar still commonly occurs. There are a number of reasons why this is so.

Firstly doubt has been raised that contact between the collar and calcar can be reliably achieved. Markolf (1980) noted that if the opposing calcar and collar surfaces were not flat and parallel to the tolerance of the diameter of the human hair (0.075mm) then incomplete contact will occur. He considered that such a level of precision could rarely be achieved intra operatively. Richards and Duncan (1986) and Thomas and Salvati (1986) demonstrated adequate collar calcar contact could only be achieved in 78% of cases. Kelley *et al* (1993) using a rigid definition of collar calcar contact found contact could only be achieved in 47% of cases.

In the operating room with the practical limitations of surgical technique, it is likely that the collar is in contact with only localised areas of cortical bone, leaving a gap between the metal collar and bone in the remaining areas. These gaps are inevitably filled with cement which extrudes as the stem is finally seated. Crowninshield (1980b) found that 2-5mm of cement intervening between the collar and calcar produced a 20% reduction in longitudinal stress within the proximal medial femoral cortex.

In addition to attenuating load transfer from collar to bone, this thin intervening layer of cement is subjected to compressive forces of a magnitude 5-7 times body weight in stair climbing (Burke *et al* 1988). This interposed cement is unconstrained and may fracture producing wear debris and this may result in calcar osteolysis (Crowninshield *et al* 1980a, O'Hara and McMinn 1991, Markolf *et al* 1980). Both these factors therefore combine to result in the collar losing intimate contact with the underlying bone and thus being defunctioned.

Biological factors are also active to decrease or eliminate collar calcar contact even if it were initially achieved. Thermal necrosis from the power saw used to osteotomise the femoral neck (Lundskog 1972, Jefferiss *et al* 1975), vascular disruption (Blackner and Charnley 1978) and cement monomer toxicity (Linder 1976) all may cause bone

resorption at the femoral neck. Blacker and Charnley (1978) considered a degree of calcar resorption was inevitable after femoral neck osteotomy. They considered any resorption less than 3mm an amputation stump phenomenon and not indicative of stress shielding related resorption. Any minor resorption however is sufficient to decrease collar calcar contact and defunction the collar in its role of transmitting load to bone.

The weight of evidence suggests that even with careful use, collared components are frequently associated with a degree of calcar resorption and therefore dissociation between the collar and calcar occurs. By axially loading the now unsupported proximal cement mantle the collar would tend to cause distal displacement of the whole implant cement composite with eventual shear disruption of the bone cement interface and generation of wear particles which may lead to osteolysis. The presence of a collar may therefore be considered deleterious. With any degree of bone resorption the collar loses its ability to provide long term useful load transmission to the calcar. It is then poised to disrupt the bone cement interface should any subsidence subsequently occur.

2.1.4 The Case Against Matt Finish

The matt finish may be considered deleterious for 2 reasons. Firstly micromotion is inevitable at the prosthesis cement interface and occurs secondary to the high loads (5-7 x Bodyweight) which occur on single legged stance and stair climbing (Burke *et al* 1988, Anthony *et al* 1990). A matt surface potentially will produce a greater volume of cement wear particles by fretting against the inner surface of the cement mantle, compared to a smooth surface finish. Hale *et al* (1990) used talysurf studies of matt and satin femoral components and showed burnishing of the implant surface with removal of an average of 0.5 microns of metal. Examination of the cement mantle confirmed the burnishing was due to abrasion of matt stems against the inside of the cement mantle. Anthony *et al* (1990) showed that localised areas of osteolysis occurred with well fixed matt stems of the double tapered design. Revision surgery indicated no loosening of the implant but these focal osteolytic lesions occurred in association with wear debris and cement fractures. Jasty *et al* (1986b, 1990) and Maloney *et al* (1990b) confirmed this finding with matt collared stems.

The second reason why a matt surface is deleterious is its adverse effect on load transmission producing a relative increase in shear and relative reduction in compressive

forces (Miles *et al* 1990). This is especially a concern with stems of a double tapered geometry. Subsidence of a matt stem tends to carry the cement with the stem thus creating a shear force within the cement mantle and at its interfaces and this may lead to failure.

The clinical importance of surface finish has been demonstrated in both the “Charnley” (Depuy) and the “Exeter” (Howmedica) hip. Dall *et al* (1993) reported lower rates of aseptic loosening in the polished first generation Charnley stem than from subsequent generations of Charnley stems which had a matt and textured finish. He suggested the polished finish contributed to the lower loosening rates of the Charnley stems by reducing shear and increasing compression at the cement bone interface. For the Exeter hip, two reports from the Swedish Registry (Malchau *et al* 1993 and Rockborn and Olsson 1993) both showed markedly poorer results and higher revision rates with the matt finished Exeter compared to the otherwise identical polished finished Exeter stem.

2.1.5 The Collarless Polished Femoral Stem - The Rationale

A diametrically opposite concept for load transfer by the femoral implant has been proposed. It is represented by the “Exeter” hip (Howmedica) the “CPT” hip (Zimmer) and the “Mirror” hip (Smith and Nephew). The design is totally collarless with a highly polished surface finish. In addition the stem is tapered in both coronal and frontal planes. The taper is designed to subside distally with time into the cement mantle. This subsidence is self limiting and is accommodated by time dependent deformations of the cement which “creeps” around the implant without splitting or disrupting the bone cement interface. A collar and matt surface finish would impair the ability of the stem to subside. The originators of the Exeter hip claim that the subsidence of the collarless polish tapered stem has a favourable effect on the mechanism of load transfer. Subsidence of the taper transfers a relatively greater proportion of the load of weight bearing as radial compressive forces to the cement mantle, its interfaces, and bone, with a relatively low shear component (Miles *et al* 1990, Fowler *et al* 1988).

Another cited advantage of the collarless polished design is potentially decreased production of wear debris. As the taper subsides and engages the cement mantle, micromotion occurring at the prosthesis cement interface may decrease and with the polished finish, may not generate wear debris as much as matt surfaces which have a

higher coefficient of friction. Finite element analysis indicates that low prosthesis to cement bonding strength is an advantage. Lu *et al* (1992) showed that maximum cement stress occurred with perfect prosthesis cement bonding and that partial interface debonding caused minimum cement stress. His study indicated that the maximum fatigue life of the cement mantle would be obtained with less than perfect prosthesis cement bonding.

2.1.6 Clinical Results of Collarless Polished Stem

The collarless polished tapered stem implant was first used in 1976 in Exeter, United Kingdom. The results from this centre have been reported on a number of occasions (Black *et al* 1979, Fowler *et al* 1988, Timperley *et al* 1993, Gie *et al* 1990). Fowler *et al* (1988) reported the excellent long term results of the original 426 hips. Clinical outcome at 11 to 16 year follow up showed aseptic stem loosening of only 1.64%. Long term stability of the radiographic appearances of the bone cement interfaces and bone stock were also the striking features.

A radiographic analysis at 5-10 years follow up, Fowler *et al* (1988) reported a less than 2% incidence of calcar resorption greater than 3mm. At 11 to 15 years follow up calcar loss was nil in 77.7%, 2mm or less in 13.7% and 3mm or more in 7.5%. Radiolucent line formation was analysed by Gruen zone (Gruen *et al* 1979). Radiolucent lines in the presence of an otherwise well fixed implant have histologically been shown to indicate a zone of osteoporosis (Kwong *et al* 1992). At 11 to 16 years follow up, the incidence of radiolucent lines in the calcar region zone 7 was 5.9%, and in zone 1, 20.5%. Thus in the proximal femur there is striking preservation of bone stock at medium to long term follow up. The authors attributed this relative lack of bone resorption to the ability of the Exeter stem to subside into the cement mantle, and in almost every case, the subsidence was into valgus alignment (Fowler *et al* 1988). At 11 to 16 years, 66% of stems had subsided 1mm or more. In 52.2% of those cases diaphyseal bone hypertrophy was also noted radiographically.

This series was renewed again at 15 to 20 years follow up (Timperley *et al* 1993). Of the original series, 100 patients survived to 15 to 20 years review. The revision rate of the stem was 14 hips (4 of which were already revisions). Radiographic appearances were remarkably benign. 62% were entirely free of radiolucent lines at the cement bone

interface and 77% showed no loss of calcar height at 15-20 years. Thus resorptive remodelling of bone as indicated by radiolucent lines and calcar resorption was remarkably stable with time.

Notably these excellent results using the Exeter stem were achieved when the surgery was performed by multiple surgeons, some still in training, and first generation cement techniques were utilised. These early cement techniques have been associated with higher rates of loosening (Harris *et al* 1982, Harris and McGann 1986) and have now been abandoned for more sophisticated techniques.

Fowler *et al* (1988) reviewed a smaller series at 4 to 5 years follow up using contemporary cementing techniques. Measurable subsidence of the stem into the cement was virtually obliterated as was radiographic diaphyseal hypertrophy. The relative absence of radiolucent lines and calcar resorption however were again evident. 95.6% had no radiolucent lines, 2.17% had incomplete less than 1mm lines, and 2.17% had complete less than 1mm lines. 60.4% had no loss of calcar height and only 4.16% had 1mm or more resorption. Malchau *et al* (1993) reported the Swedish experience with the Exeter hip and at 4 years confirmed Fowler's findings.

The question arises whether the clinical success of the Exeter hip is due to the collarless double tapered stem geometry alone or the polished surface finish as well. The Exeter group used a matt surface double tapered collarless design between 1980 and 1985 (Gie and Ling 1994). This matt finish proved to be a retrograde step with results significantly inferior to the polished finish. Malchau *et al* 1993 reported the 8 year Swedish Multi Centre revision rate for matt Exeter stems at 10.3%. Rockborn and Olsson (1993) also reported unacceptably high failure rates with the matt Exeter stem. Thus the stem geometry alone was inadequate to provide the excellent results achieved with the polished Exeter hip.

Thus two diametrically opposite concepts for stem geometry and surface finish of cemented femoral stems have been described and the clinical performance of each stem design reviewed. Each design aims to optimise load transmission to bone minimising stress shielding while protecting the cement mantle and its interfaces. Both designs have been associated with satisfactory clinical outcomes in the medium term. The issue of load transfer with stress shielding of bone however remains controversial and in an

effort to resolve the conflict in design philosophy it is helpful to review laboratory studies on bone remodelling. These studies are considered under strain analysis, bone morphometry and more recently densitometric evaluation.

2.2 FEMORAL CORTICAL STRAIN ANALYSIS

In vitro experiments and finite element analyses have demonstrated the effect of implantation of a femoral stem on the cortical strain distribution in the proximal femur (Oh and Harris 1978, Suh *et al* 1992, Otani *et al* 1933, McBeath *et al* 1980, Langkamer *et al* 1992, Hua and Walker 1992, Weinans and Huiskes 1993). The loads applied to the femoral head are borne principally by the implant and a massive reduction in bone strain characteristically occurs in the proximal femur.

The design of the femoral stem affects the transmission of load to the bone and therefore the magnitude of strain reduction. Design features include the modulus of elasticity of the implant (Langkamer *et al* 1992a, O'Connor *et al* 1993), the diameter of the implant (Engh and Bobyn 1988), cross-sectional geometry (Fowler *et al* 1988, Crowninshield *et al* 1980b) and the presence of a calcar collar. A collar has been recommended to reduce strain shielding and resorptive remodelling of calcar bone.

2.2.1 In Vitro Strain Studies

Oh and Harris (1978) studied the effect with varying sizes of calcar collars on the strain distribution in fresh human cadaver femurs implanted with cemented femoral stems. They used uniaxial strain gauges which consisted of a strain sensitive grid. Strain gauges measure deformation on that part of the cortical surface which the strain gauge is attached and measure only deformation parallel to the direction the grid is aligned. Oh and Harris oriented the uniaxial strain gauges longitudinally to detect changes in longitudinal cortical strain under axial load. They found implants which had a large collar directly in contact with the cut surface of the medial femoral neck recorded a calcar strain which was 30-40% of that seen in the intact femur. Stems with no collars recorded calcar strains of approximately nil. On the basis of this laboratory study the authors recommended the use of femoral implants with the calcar collar to transfer longitudinal load to the proximal medial cortex.

However the use of a static vertical load and uniaxial strain gauges aligned longitudinally is open to criticism. The loads on the human hip are maximal in the stair climbing mode which involve a large torsional component (Burke *et al* 1991). The proximal femur also is irregular in shape and anisotropic in composition. Deformation of bone in response

to applied load will therefore be not only longitudinal but bone will be strained circumferentially and obliquely as well. Bone will remodel to all strains imposed on it. Measurement of only longitudinal strain and only to an axial loading mode clearly cannot adequately describe the complex changes in strain which occur in the proximal femur after implantation of a femoral stem.

McBeath *et al* (1980) studied the effect of a longitudinal load on both circumferential, as well as axial strain in three pairs of embalmed human femurs. They used biaxial strain gauges at three locations medially and three laterally. The intact femur recorded a compressive longitudinal strain of 1,000 micro strain and a tensile circumferential strain of 140 micro strain in the calcar.

Implantation of a Charnley stem in varus caused compressive longitudinal strain to decrease to 200 micro strain and circumferential tensile strain to increase to 250 micro strain in the calcar. Valgus positioning of the implant caused a compressive longitudinal strain of 40 micro strain and a compressive circumferential strain of 100 micro strain. For neutral alignment no circumferential strain recording was recorded, though longitudinal strain was compressive and recorded 130 micro strain.

The study by McBeath *et al* suffers in that few specimens were studied, there was no consideration given for the effect of muscle contraction acting on the femur, the specimens were embalmed and embalming may have altered the pattern and magnitude of strain recorded, and results from only one site in the femur (the calcar) were reported. However, this study does show that circumferential strain occurs in the intact femur and following implantation. Moreover circumferential strains can exceed the longitudinal strains in magnitude. Clinically the importance of circumferential strain is well recognised in performing cementless THA. Press fit implants produce high circumferential (hoop) stresses in the proximal femur and occasionally this causes fractures of the upper femur during implantation.

The effect of torsional as well as axial loads on strain have been examined. Otani *et al* (1993), in a study of 21 intact human femurs, first confirmed the finding of McBeath *et al* with axial load that circumferential strain normally is relatively low in magnitude in the calcar region. In addition they reported circumferential strain was tensile medially and compressive laterally in the proximal femur. However, more distally

circumferential strain was tensile. Circumferential strain was 6.8% of the magnitude of longitudinal strain values in the calcar, but more distally circumferential strain values increased to 37% at the mid diaphysis level. Under torsional load, recorded circumferential and longitudinal strain values were of smaller magnitude proximally but increased distally. The study by Otani *et al* raises the question of how circumferential strain magnitude will vary by site when the proximal femur is implanted with different stem designs.

This issue was addressed in part by Suh *et al* (1992). They investigated the effect of a collared and non collared implant on axial, oblique and hoop strain in a small series of 5 pairs of human cadaver femurs. When collar calcar contact was good, axial loads caused a significantly greater longitudinal strain in the proximal cortex than non collared implants of identical design; in agreement with Oh and Harris(1978) and Crowninshield (1980a). However, there were no differences in longitudinal strain in the anterior and posterior cortices at the calcar level. Moreover, the longitudinal strain in the distal femur and the hoop and oblique strains in all locations of the femur were not significantly related to the degree of collar calcar contact.

2.2.2 Ex Vivo Strain Studies

The above in vitro studies provide no indication of how cortical strain will vary with time following implantation. Adaptive bone remodelling theory (Huiskes *et al* 1992) predicts that following implantation, strain shielded bone will undergo resorptive remodelling. Mechanical stimuli integrated with hormonal, genetic and metabolic factors regulate the rate of relative bone apposition and resorption. Strain shielded bone resorbs and becomes more porous (internal remodelling) and/or becomes thinner (external remodelling) (Sumner *et al* 1992). This process would continue until the bone mass had decreased sufficiently to restore the strain pattern to normal. This adaptation of periprosthetic bone to its new mechanical environment is an expression of Wolff's Law.

Maloney *et al* (1989) however could not demonstrate that bone remodelled to achieve a strain equilibrium. They recorded the strain characteristics of 11 autopsy retrieved human femurs with cemented femoral stems. These stems had been in situ for between 3 weeks to 17 years. All implants were clinically performing well at the time of death

and none were radiologically loose. Only two intact contralateral femurs were retrieved and together with three additional intact femurs, these formed a control group. The control group may therefore be considered suboptimal. Maloney *et al* positioned 12 triaxial strain gauge rosettes in the proximal femur. Each rosette comprised three completely independent strain gauge grids oriented longitudinally, transversely and obliquely. Loads were applied to the implant head and in stair climbing and single legged stance mode (Burke *et al* 1991). Maloney *et al* reported only the results of longitudinal strain measurements. He found strain values remained well below the corresponding strain values in the intact femur. Though an increase in calcar strain did occur with time to approximately 50% of the intact femur, there was no clear correlation of recovery of strain with time since surgery. The study by Maloney *et al* could not substantiate the concept of periprosthetic bone being lost to re-establish a normal strain pattern around the cemented implant.

Engh *et al* (1992), in a more recent autopsy retrieval study, also found no evidence that a homeostasis between strain and bone mass occurred. They performed strain gauge analysis on 12 femurs with uncemented AML implants. Nine contralateral femurs were available for study. They found, after up to 7.5 years post surgery, the longitudinal strain in the calcar region recorded less than 50% of that in the intact femur. This strain reduction had persisted despite extensive disuse osteoporosis causing up to a 78% loss of bone mineral content on DEXA scan.

While Maloney *et al* and Engh *et al* both showed the reduction in longitudinal strain persisted following remodelling, it cannot be assumed that the longitudinal axis is the maximal vector of strain in the proximal femur. Both authors made no analysis of transverse or oblique strain changes recorded by the transverse or oblique strain gauges of each rosette. Also, it cannot be assumed that in any in vitro or ex vivo retrieval study the maximal vector of strain will lie parallel to the longitudinal, transverse or 45° oblique strain gauge grid. This is especially so in the proximal femur with its irregular shape and anisotropic composition, and the complex loading pattern on the human hip. Analysis of cortical strain changes using the concept of principal strain and its magnitude and direction will be discussed.

2.2.3 Principal Strain Analysis

When bone or any other solid object is loaded, it deforms. It will compress in one direction and stretch in a direction 90° to the direction of compression. Thus, in the proximal femur at any point on the cortical surface, there will be two directions at 90° to each other; one in which strain is purely compressive and one where it is purely tensile. These strain vectors are called principal compressive and principal tensile strains. In any other direction than the principal direction, there is an oblique component. The maximum strain vector is at 45° to the principal strain direction.

The principal strain magnitude and principal strain direction can be calculated at each rosette location from the strain recorded at each of the longitudinal transverse and oblique strain gauges (Debastrani 1992). The changes in principal strain magnitude and direction give a more complete description of strain reorganisation following implantation, than unidirectional strain magnitude recordings alone.

Principal strain has been examined in a number of in vitro and in vivo studies. Lanyon *et al* (1981) recorded in vivo principal strain at two locations of the proximal femur in 8 sheep. Cortical strain was recorded in the intact femur, and with the femur implanted with a femoral stem. The mean peak principal compressive strain in the proximal medial cortex of the intact femur was 704 micro strain with the direction being through the articular surface of the femoral head. One week following implantation with a collared cemented femoral stem, the sheep were reported to be walking without lameness. Further in vivo cortical strain records showed peak principal compressive strain fell to less than 50% of the intact femur. The mean angle of direction of principal compressive strain changed by only 2° . The principal tensile strain had increased to 131% of normal in the proximal femur.

In a laboratory study, Page *et al* (1991) examined the effect of implantation on principal strain magnitude and direction. They used cementless collared total hip replacements in a canine model. They applied load to simulate a single legged stance and found principal compressive strain in the femoral calcar fell to an average of 22% of that of the intact femur. In the mid prosthetic level principal compressive strain fell to approximately two thirds of that in the intact bone and there was no significant difference at the distal end of the implant. The orientation of the principal strain did not

change appreciably at any level following implantation. Peak principal tensile strain decreased following implantation in the calcar and the mid lateral location.

The vector of principal strain changes on implantation, and this concurs with earlier studies of longitudinal strain changes. However it is unclear how principal strain magnitude and direction would change with time dependent changes, such as stem subsidence or loss of calcar collar contact. The principal strain changes in the proximal femur after remodelling around implant designs with different mechanisms of bone loading were therefore examined in this thesis.

2.3 BONE MORPHOMETRY

Early bone changes around a cemented femoral stem in THA may occur secondary to the independent effects of reaming and preparation of the femoral canal; of fixation of the implant with cement; and the effect of altered load distribution in the proximal femur brought on by the presence of the implant. The effect of each of these on bone remodelling were considered separately.

2.3.1 Femoral Canal Preparation

Rasping of the femur and evacuation of the intra-medullary contents are performed in preparation for cementing a femoral implant. This process in itself initiates bone changes by disrupting blood supply to the femur. Long bones receive a major proportion of the blood supply from an intra-medullary arterial system (Trueta and Caladiaz 1964, Rhinelander 1972, Rhinelander *et al* 1979). This system is formed by anastomosis between the nutrient artery, entering the medullary space via the nutrient foramen in the diaphysis, and proximal and distal metaphyseal arteries. Together the arterial network supplies the inner two thirds of the bony cortex. This intra medullary vascular network is destroyed by preparation of the femoral canal.

There is a third source of blood supply to the proximal femur. Periosteal arterioles enter at fascial attachments especially posteriorly along the linea aspera. They supply only the outer one third of the cortex where they enter. They cannot supplement the medullary arterial supply. When the medullary arterial supply is destroyed this periosteal source undergoes reactive hypertrophy to meet the ischaemic demands.

This basic pattern of long bone blood supply is common to all mammals. However, age and species have an effect on the relative importance of each source of blood supply.

Eitel *et al* (1981), using microangiography, fuchsin stained ground sections and polychrome sequential labelling, found that the rabbit, sheep and rat have a higher proportion of cortical bone and relatively less endosteal bone. This was associated with a relatively more prominent osseous blood supply from the periosteal surface. In contrast, the dog and human have relatively higher proportions of endosteal bone and have proportionally a greater dependence on the endosteal blood supply. It therefore

may be expected that intra-medullary reaming in the sheep will have less of a devascularising effect on bone than intra-medullary reaming in humans and a dog model. However with such a profuse periosteal system, any intra-medullary reaming may cause a greater increase in the reactive periosteal blood supply and periosteal bone formation, compared to the dog or human. These details of femoral vascular supply are pertinent to the choice of an animal model for THA and interpretation of bone remodelling changes which occur.

Danckwardt-Lilliestrom (1969) demonstrated this effect in the rabbit and canine femur. Following evacuating the intra-medullary canal, the periosteum was seen to react in all animals. The periosteal blood vessels increased in calibre, filling massively on angiography. The vascular reaction began at one week and began to decline at four weeks. It appeared to be greatest and persisted the longest in those periosteal areas where the area of cortex had been affected most by reaming from the inside. This hypervascularity was accompanied by subperiosteal new bone formation. This process was very active during the first few weeks post-operatively. The subperiosteal bone was woven bone, and formed up to 15% of the total area of original cortex. The amount of subperiosteal new bone formed, however, was highly variable between animals. Danckwardt-Lilliestrom (1969) postulated that subperiosteal bone formed not only from periosteal hyper vascularity but from intra-medullary bone marrow emboli being forced through the cortex to the subperiosteal surface. Importantly over two to eight weeks post-operatively the subperiosteal bone was quite rapidly reabsorbed. Revascularisation of the cortex occurred quickly and was almost complete by four to six weeks by regeneration of branches of the nutrient and metaphyseal arteries.

Draenert (1981) in rabbits, and Richany (1965) in adult cats, confirmed this sequence of periosteal vascular reaction, subperiosteal new bone deposition and cortical revascularisation.

2.3.2 Effect of Cementation

Introduction of cement into the femoral canal may induce morphological changes in bone in addition to those occurring from interruption of the intramedullary blood supply. The effects of cementation of bone are both thermal and chemical. Polymethyl methacrylate polymerises at 80°C (Lundskorg 1972). Denaturation of collagen fibres in bone may

occur at temperatures as low as 45°C when exposure is prolonged (Jefferiss *et al* 1975). Curing of cement therefore may cause thermal necrosis of the bone at the cement interface, (Draenert 1981). Jefferiss *et al* (1975), however, believes significant thermal necrosis of bone from curing cement does not occur. Inter-digitated cement creates a large surface area for the dispersal of heat from the curing monomer. In addition, the porous nature of cancellous bone, its more profuse blood supply, and the presence of inter-trabecular fat enables a high thermal conductivity and high thermal tolerance of cancellous bone. Collagen is also protected from heat denaturation by the calcified elements in bones.

The histomorphometric response of bone following canal preparation and insertion of a cement column has been studied in depth by Draenert (1981) in a rabbit model. Following curettage of intra-medullary contents and lavage, the cement bolus was injected and impacted into bone. The cement column was non-loaded. Killing of the rabbits was performed at intervals ranging from days, weeks, months and up to two and a half years from surgery. The bone remodelling response to surgery and the ensuing sub-periosteal bone changes were studied by a microangiography, light microscopy, electron microscopy, and polychrome sequential labelling.

Draenert found that the sub-periosteal new bone formation was more vigorous than the response reported in dogs following intra-medullary reaming alone (Rhineland *et al* 1979, Danckwardt-Lilliestrom 1969). When the intra-medullary canal was completely filled with cement, Draenert reported extensive periosteal new bone formation beginning at one week post surgery and by four weeks the periosteal new bone had exceeded the thickness of the original cortex in some cases, as revealed by polychrome labels. Draenert did not report whether this periosteal bone was resorbed as reported by Rhineland *et al*. The addition of cement more completely destroyed the intra-medullary blood supply than reaming alone. The endosteal blood supply takes longer to regenerate and the periosteal reaction is more prolonged.

Charnley (1970) retrieved human femurs and described a necrotic zone 0.5mm thick around a cemented implant. Willert *et al* (1974), in a study of autopsy retrieved femurs, also observed a necrotic layer of tissue up to 3mm thick at the bone cement interface. This layer was reported to have formed within the first two to three week period following surgery.

Following this initial necrosis stage, a process of bone repair occurs and coincides with revascularisation of the cortex. Draenert (1981) reports by the end of the fourth week the inner half of the cortex was interspersed with resorption lacunae. Necrotic bone was being replaced or remodelled, and osteons were already being formed in the inner third of the cortex. After six weeks and definitely after six months the osteonecrosis had been replaced by remodelling units.

Willert *et al* (1974), in 11 well fixed autopsy retrieved femurs and five surgical biopsies of the human bone cement interface, reported early repair also beginning by the third post-operative week and continuing for one to two years. Necrotic bone was remodelled by apposition of newly formed lamellae on necrotic lamellae, and by osteoclastic resorption of necrotic lamellae.

2.3.3 Bone Remodelling Effects

Starting from the eighth post-operative week Draenert (1981) reported a specific pattern of remodelling of the inner third of the cortex in the rabbit. Trabeculae of new bone were condensed around the cement column with no intervening fibrous membrane. New medullary spaces were formed between this condensation of bone and the endosteal surface of the original cortex. By six months this process was very distinct. The temporal sequence of remodelling was described more fully recently in a canine cemented study by Paul and Barger (1986) using disulfide blue intravital dye. The entire canine cortex had revascularised by 3 months. Fluochrome labels showed a high level of cortical and endosteal bone remodelling with periosteal activity having decreased but bone activity adjacent to the bone cement junction persisting representing the trabecular condensation at the interface.

Draenert (1981) reported that gaps between the bone and cement were filled in by bone by a process he called gap healing. Gaps up to 80 microns were filled in by lamellar bone. Larger gaps were bridged by a frame work of woven bone which underwent lamellar reinforcement as early as the second week. By the fourth week the gaps had all been filled in by compacted bone. Draenert considered but did not prove that gap healing occurred when force transmission across the Bone Cement Interface was optimal. Gaps between the bone and cement, however, persisted when tensile forces

acted on the interface.

By nine months post-surgery the formation of a mature "neocortex" of lamellar bone surrounding the cement mantle was complete. Trabeculae could be seen projecting deeply into the irregularities of the cement in some cases. The bone therefore was intimately apposed to the surface of the cement column without any interposition of fibrous tissue. Marginal to the neocortex, large well defined medullary spaces had formed with thin trabeculae spanning the neocortex and the endosteal surface of the outer cortex. Draenert (1981) termed this a "secondary medullary cavity" and the endosteal vascular system had begun to regenerate in this newly formed narrow space by the end of the 4th week.

The stimulus to formation of the neocortex and secondary medullary cavity is very strong and occurs across species (Rhineland *et al*, Dog, 1979; Trueta and Caladias, Rabbit, 1964). Sund and Rosenquist (1984) used polymethyl methacrylate implants inserted into adult rat femurs. A calcium deficient diet was commenced in one group of rats at 16 weeks post surgery. The rats were all killed at 31 weeks post surgery and micro radiography of sections performed. In both diet groups a neocortex and secondary medullary cavity had formed. The neocortex formation in the calcium deficient group was no different from the normal diet group. However, in the calcium deficient group extensive intra cortical resorption of the operated femur had occurred and the secondary medullary cavity formation was more marked than the normal diet group. This study shows that the stimulus to formation of the neocortex was strong and could occur despite a calcium deficient diet. Also, formation of the secondary medullary canal was more variable and apart from diet raises the question of the influence of loading of bone by different implant designs.

Charnley and Crawford (1968) and Charnley (1970) reported their observations in the human situation and initially did not describe the neocortex and secondary medullary cavity formation. They examined a series of autopsy retrievals obtained between 1 month and seven years post-surgery. They believed that direct contact between cement and bone was uncommon and that at least initially fibrous tissue intervened. At longer follow up periods fibro cartilage was seen to be in close apposition to the cement. Charnley believed that fibrous tissue underwent metaplasia to fibro cartilage then bone under the force of weight bearing and only by this process was permanent mechanical

and anatomical contact between bone and cement achieved.

Subsequently Charnley (1979) changed his views. Fibrous membrane formation was not thought to be intrinsic to the cementing process and Charnley proposed that well fixed implants have direct apposition of cement to bone and that the degree of fibrous membrane formation was inversely proportional to the security of fixation of the implant. The presence of a fibrous membrane at the bone cement interface in the initial stages following total hip replacement reflected poor initial pressurisation of cement into the interstices of bone. Early cementing techniques utilising thumb packing of doughy cement into the intermedullary canal have since been superseded by second generation cementing techniques where pressurisation of cement and microinterlock into bone is more readily achieved.

Recent studies have found fibrous membrane formation uncommon or absent altogether in the early postoperative stage after THA. Paul and Bargar (1986) in a canine study of cemented total hip replacement used current cementing techniques. They observed no fibrous membrane at the proximal bone cement interface. Recent histological studies of retrieved human cemented total hip replacements also confirmed that fibrous tissue formation is uncommon when the implants were well fixed. (Jasty *et al* 1990, 1991, Malcolm 1990, Blunn and Wait 1991, Kwong *et al* 1992).

Malcolm (1990) reported on 78 autopsy retrievals of Charnley total hip replacements done by Charnley himself. All were functioning well at the time of death and had been implanted between 8 and 22 years prior to death. Malcolm reported no evidence of fibrous membrane intervening between the bone and cement mantle in 60 of the 78 specimens. When fibrous membrane was present, macrophages and large numbers of ultra high weight polyethylene was also observed. Osteoclasts were observed resorbing bone immediately under the fibrous membrane altogether indicating an early stage of implant loosening. In the majority of specimens viable lamellae of bone were organised into a neocortex tightly apposed to the cement mantle in an "osseo integrated manner". Remodelling of medullary trabeculae was observed with bone struts oriented radially between the cement and the endosteum "along lines of new stress placed upon the bone by the implant".

Jasty *et al* (1990) confirmed this long term skeletal response to cemented THR. In 13

autopsy retrieved femurs, 40 months to 210 months post surgery, Jasty *et al* described a similar pattern of a neocortex of dense cortical bone tightly applied to the cement mantle and a secondary medullary cavity of thin trabeculae merging with the endosteal surface of the outer cortex which was often remodelled with large resorption cavities.

Kwong *et al* (1992) correlated the histological findings with the radiographic appearance of the bone cement interface. He demonstrated that a radiolucent line, defined as any region of decreased density at the cement-bone interface, was rarely associated with a fibrous membrane in well fixed specimens. Osteolysis secondary to wear particle granuloma was also very uncommon. In most instances, a radiolucent line, even when progressive, represented the secondary medullary canal with diffuse osteoporosis and cancellisation of the endosteal cortex and thinning of bony trabeculae.

The above human and animal studies on femoral bone changes after THA have been descriptive only. To determine if implant design variables have an effect on bone loading and remodelling, quantitative histological studies are required.

2.3.4 Quantitative Bone Remodelling Studies

Maloney *et al* (1996) noted that many factors can potentially influence the extent of bone remodelling including age, gender, weight, diagnosis, activity level, disease state, medications and duration of implantation. However it is widely accepted that the mechanical loading environment is a major factor (Woo *et al* 1981, Tonino *et al* 1976) in the bone remodelling response.

Quantitative bone morphometric studies have been performed and are required to describe the skeletal response to femoral components. In general these studies have quantified the bony changes which have occurred with remodelling by comparing various bone parameters to the opposite side.

Torchia and Ruff (1990) performed a quantitative assessment of cross-section cortical bone remodelling on three uncemented Austin Moore and one cemented Thompson hemiarthroplasty. The opposite intact femur was available for comparison in all cases. All four specimens were from elderly female patients with time from surgery at least 40 months. Three of the four patients were mobile but it is unclear if they were

symptomatic from the arthroplasty or not. Twelve sections were taken from the tip of the lesser trochanter to the distal diaphysis. An image analysis system was employed. Torchia and Ruff observed that sub-periosteal area and endosteal area decreased in the diaphysis relative to the opposite side but in a non-statistically significant manner. In the two proximal sections between the lesser trochanter and base of the femoral neck, endosteal area and subperiosteal area increased in the prosthetic femur associated with cortical thinning. These changes approached statistical significance.

This study suffers in that few specimens were examined, they were mostly uncemented and in addition, two implants were loose. Though this study was a quantitative analysis, no conclusion can be made on quantitative bone remodelling around firmly fixed cemented implants. Also there was no analysis of cortical porosity or trabecular density changes and no observations of the neocortex, all of which are important parameters of how bone remodels to applied mechanical loads.

Maloney (1990a) related stress shielding as measured by cortical strain to the amount of disuse osteoporosis as quantified by scanning electron microscopy. 17 autopsy retrieved femurs with a variety of cemented implant designs were studied at 0.5 months to 210 months after surgery. There were only four specimens with intact contralateral femurs for use as a control. In specimens implanted long term, stress shielding was marked and resorptive remodelling was especially severe in females. The mean cortical thickness proximo-medially was less than 1mm and in some instances was absent altogether. Proximal bone loss was not confined to the medial cortex but occurred circumferentially. Less extensive bone loss was noted in the diaphysis. On average, the proximal cortical bone was 46% thinner compared to the intact opposite femur, middle cortical bone was 26% thinner, and the distal cortical bone 8% thinner than the intact opposite femur. Internal bone remodelling was also examined and the cortical porosity had doubled in the implanted femur at all three levels. In the proximal femur cortical porosity was 15% in the intact femur and 29% in the test femur: at the mid level intact 8% versus test side 17%; at the distal level intact femur 8% versus test side 18% cortical porosity.

Maloney's study is important. It described for the first time in a quantitative manner the mechanical changes and structural adaptations of bone to implanted cemented femoral stems in the human. However, a criticism of this study is that only four contralateral

intact femurs were available for comparison. Six other non paired intact femurs were analysed, but considerable inter-individual variation exists between femurs and no indication was given whether the six non-paired femurs were matched for age and sex. There was no description of medullary area and trabecular bone density and no comment on the extent of neocortex formation. Also a large number of implant designs were studied with variable post-operative interval and multiple surgeons were involved. The study gave no indication of how the quantified variables varied with respect to specific implant design features.

Maloney (1996) reported a more extensive bone morphometric study of 48 paired femurs with unilateral hip replacements. He quantified the skeletal response to remodelling around both cemented and cementless stems at a period of followup varying from 12 to 191 months. Bone remodelling was quantified using cortical thickness, cortical bone area, and bone mineral density. The pattern of skeletal remodelling was described but again there was no indication on how bone remodelled with respect to implant design variables. This issue will therefore be examined further in this thesis.

2.3.5 Canine Bone Morphometric Studies

Detailed femoral morphometric studies after total hip replacement have been reported in canine models (Boby 1989, Sumner *et al* 1992, Turner *et al* 1986b). The implants were cementless but the analytical method they employed was detailed and pertinent to the cemented situation.

Turner *et al* (1986), and Sumner (1992c) investigated the effect of three types of porous coating on bone ingrowth and bone remodelling. Bone remodelling was studied by contact x-rays of the intact specimen, contact x-rays of transverse sections and undecalcified histology of ground sections. Sections were taken from only four levels and the same relative location in the implanted and contralateral non-implanted femur was established by referencing from bony landmarks and percentages of the bone's length. Contact radiographs of 2mm transverse sections were enlarged and analysed by a digitiser and image analysis system to determine cross sectional bone changes. Periosteal reactive bone was radiographically common, unlike in the study by Bobyn *et al* (1987). In 13 of the 16 cases periosteal reaction was relatively minor, less than 500 microns thick, present only at the most proximal level, and thought to be related to the

neck osteotomy. In the other three cases, one of which had an undisplaced fracture, periosteal new bone was present at all levels and ranged in thickness from 500 microns to 1500 microns thick.

Bobyn *et al* (1987) studied bone remodelling changes after canine cementless THA using undecalcified histology. They examined relatively few section levels, three levels at or proximal to the lesser trochanter and one level at the tip of the stem. Sections were ground to 50 plus or minus 10 microns in thickness. The undecalcified sections were stained with paragon. A computerised image analysis system was used to determine the remodelling parameters in the cortical and trabecular bone by paired sections.

Bobyn *et al* (1987) found at 36 months that gross bone resorption had occurred with 44% reduction in cortical area proximally. Also at this time sub-periosteal resorption had occurred. In 13 of the 16 section pairs, perimeter measurements showed that the implant containing section was 1 to 5mm less than that of the non-implanted corresponding section. The average decrease in perimeter was 2.6mm (equivalent to 4% of the average perimeter) which was significant.

Sumner *et al* (1992b) examined the remodelling effect of different porous coatings in 22 dogs with follow up extended to two years. They examined paired sections by quadrants using sections, 100 microns in thickness with undecalcified histology (anterior, medial, posterior, lateral). They determined sub-periosteal area, cortical area, medullary area, and calculated cortical porosity and medullary bone density. Clinically all dogs rehabilitated well beginning weight bearing within one week of surgery and appeared to have normal function within two weeks and this continued throughout the course of the study. The weight bearing status of the operated limb was investigated with dual photon absorptiometry of the tibia at two levels, 2cm distal to the tibia tubercle and at 75% of the length of the bone as measured from the proximal end. Tibia bone mineral content of the treated limb was 5.8 +/- 1.6% less than the non-operated limb, indicating a slight degree of sub-clinical favouring of the operated limb.

As with the study by Bobyn *et al* (1987), bone changes occurred early but appeared to have stabilised by six months. Sub-periosteal area decreased proximally and between 15 and 20% of the cortical area was lost adjacent to the porous coating. Sub-periosteal area significantly increased at the tip of the stem. Cortical porosity increased from a

mean of $2.2 \pm 0.1\%$ in the control to $3.5 \pm 0.2\%$ in the operated femur but the changes were most pronounced proximally with no significant difference in porosity near the tip of the stem. Medullary bone area increased more distally and was 10% greater than the control side at the mid-level of the stem. Medullary bone density increased overall for all quadrants and for all sections from the mean of $9.6 \pm 0.8\%$ in the control to $20.1 \pm 1\%$ in the operated femurs.

Overall Sumner *et al* (1992b) observed that in the proximal levels there was a net non-significant decrease in total bone mass (from loss of cortical bone but gain in medullary bone); in the mid-section levels there was a significant net loss of bone (due to decrease in both cortical and medullary bone); and at the tip there was a net gain in bone due to an increase in medullary bone. It is apparent that porosity changes due to internal remodelling at the haversian surface play only a minor role in the net gain or loss of bone compared to changes occurring at the sub-periosteal and endosteal surfaces.

Calcar atrophy beneath the collar was a common finding. It varied between animals with no constant trend when implant design or period of implantation were considered (Bobyne *et al* 1987). Calcar atrophy in the study by Sumner *et al* (1992b) was initially seen radiographically at three months and did not progress after six months.

There are a number of possible sources of error in the reported animal studies of bone morphometry. Firstly in any bone morphometric study where the study femur is compared to the control femur, there is the uncertainty that comparisons are being made between sections which are taken at exactly the same relative level. Bobyne *et al* (1987) estimated that paired sections could be displaced 2mm proximally or distally. The difference in cortical area between two adjacent sections 2mm apart was never greater than 10% suggesting 10% was the upper limit of error for cortical area measurement. Secondly, the use of 2mm thick sections and contact radiography and even 50-100 micron sections with undecalcified histology would have projection errors in the measurement of bone parameters, due to overlap from deeper layers of tissue (Bloebaum *et al* 1990).

A more advanced technique for quantitative histology is back scatter electron microscopy. (Bloebaum *et al* 1990, Bachaus and Bloebaum 1992). This technique relies on a beam of high energy electrons which strike the specimen surface and are then

reflected back to a back scatter electron detector. The number of electrons reflected is proportional to the average atomic number of the specimen, with high atomic weight elements reflecting a greater fraction of electrons. This is recorded as a whiter back scatter electron image. Conversely, low atomic weight elements reflect fewer electrons and display a darker back scatter image.

The advantages of BSEM are increased accuracy of histomorphometric parameters by decreasing the error caused by projection effects. Back scatter electrons penetrate only the superficial one to five microns of the specimen's surface. The errors due to projection from deeper layers of tissue superimposed on the superficial layer of interest are therefore reduced. Other histomorphometric techniques using light microscopy or contact radiography utilising ground sections 20 microns or thicker have greater projection errors from the deeper layers of tissue.

The technique of BSEM has great potential in accurate histomorphometric analysis of bone but widespread application is still in its developmental phase. However the techniques are currently available only in a few specialised facilities.

2.4 DENSITOMETRIC EVALUATION OF BONE

2.4.1 Radiographic Densitometry

Radiographs are insensitive at detecting changes in bone density which occur with bone remodelling. Ardran (1951) found that a 30% loss of cancellous bone is required before radiographic recognition is possible. Lachman (1955) reported that a loss of 30-50% bone calcium is required before resorption can be detected on radiographs.

Visual evaluation may be more sensitive when there is a high ratio of trabecular to cortical bone (O'Keeffe 1981, Lachman 1955). This situation occurs in the metaphysis and lesser trochanteric region of the proximal femur. Black *et al* (1979) applied a quantitative radiographic technique to detect bone density 5 to 7 years after Exeter THA. He reported a "total absence of absorption, cavitational cystic change in the calcar". 29% had shown a small increase in bone density, 4% no change and 67% a decrease in density.

West *et al* (1987), however, found that quantitative assessment of bone remodelling by radiographs was unreliable when done retrospectively. Routine orthopaedic radiographs are made under varying conditions. Many variables may affect radiographic bone density, including type of film used, exposure setting, source to film distance, variability of X-ray field, and the orientation of the limb. West used a densitometer to quantify radiographic cortical bone density around uncemented total hip replacements. He found quantitative assessment of osseous changes from serial radiographs could not be made as all the variables affecting radiographic bone density could not be standardised and accounted for simultaneously.

Engh *et al* (1993) have described a technique of image digitisation and computerised video densitometry to retrospectively quantify bone density from the films of uncemented total hip replacement. An attempt was made to compensate for the technical variables affecting image brightness by applying a technique of logarithmic histogram equalisation. This technique was useful in confirming the known pattern of bone density changes around cementless stems of varying diameters. Engh *et al* indicated this technique was useful for retrospective analysis of radiographs but was not a substitute for dual energy densitometric techniques.

2.4.2 Dual Energy X-Ray Absorptiometry

Dual Energy X-ray Absorptiometry (DEXA), has been developed recently to quantify bone mineral density. DEXA has been used extensively to clinically evaluate osteoporosis in the spine (Lilley *et al* 1991, Wahner *et al* 1988, Kroeger 1992, Harris 1992, Sievanen *et al* 1992), distal radius (Larcos *et al* 1991), and the femoral neck (Johanson *et al* 1992). It has been also used to quantify bone formation associated with leg lengthening procedures (Eyres *et al* 1993).

DEXA uses x-ray absorption to determine the amount of bone in a specified skeletal region of interest (ROI). A narrow collimated x-ray beam is filtered to allow two energies to be emitted; 38 and 70KeV. These two energies attenuate differentially in soft tissue and bone and the transmitted radiation is measured by a scintillation detector. The beam is passed through the bone and the amount of bone in the path of the beam is calculated as bone mineral content. This BMC is divided by the area of the regions of interest to calculate bone mineral density.

The accuracy (similarity between measured value and actual value) of DEXA in measuring BMD has been studied. Kiratli *et al* (1992b), and Kilgus *et al* (1993) scanned Bone Phantoms made of Hydroxy apatite of known mineral density. In both studies the accuracy of DEXA in measuring BMD was approximately 99%. The accuracy of DEXA was confirmed by Mazess *et al* (1989). Using Hydroxy apatite Phantoms, Mazess found bone mineral content measured by DEXA scanning was linearly related to the amount of Hydroxy apatite, with a correlation coefficient of greater than 0.99.

Using clinical material, Ho *et al* (1990) measured bone mineral content of 31 human lumbar vertebrae by both DEXA and mineral Ash weights. A high correlation was obtained ($r=0.963$). The accuracy error in determining bone mineral content in lumbar vertebrae with DEXA was reported as 8.9%.

The precision (similarity among repeated measurements on the same subject) of DEXA in measuring BMD around cementless THA has been evaluated. Kiratli *et al* (1992b) serially scanned 6 cadaver femurs containing press fit titanium implants. Five scans were done of each femur with no repositioning between scans. The precision error

defined as the coefficient of variation (Standard deviation divided by the mean of the sample) was approximately 1% and this was consistent across the four ROI examined. The effect of rotation of the implanted femur five degrees in either direction from the neutral was examined. The error and recorded BMD was site dependent. In the greater trochanter region the precision error in BMD was approximately 2%. However medially around the lesser trochanter the measured precision decreased substantially. Rotation of five degrees caused a 9% error in the area of bone recorded in the ROI and approximately a 5% difference in the bone mineral density compared to the neutral position.

Precision studies of DEXA in the clinical context have been performed. Kilgus *et al* (1993) performed a precision study on ten patients who had undergone cementless total hip replacement. The implanted femurs were scanned four times in succession each time with repositioning of the patient and the leg in the standard scanning position. The overall reported precision error for the ten patients was 3.8% with a standard deviation of 1.2%.

Kiratli *et al* (1992) performed in vivo precision studies on five patients scanned five times each, and thirty patients scanned twice each. Each patient was repositioned between scans. The precision error reported in all four zones was less than 5%. These results have been confirmed by other studies (Williams *et al* 1995, Laitinen *et al* 1991).

DEXA therefore has been shown to be accurate and reproducible in measuring BMD. DEXA scanning is appropriate as a clinical and investigative technique for serial hip scans on the same patient or comparing scans between different patients.

2.4.3 DEXA Clinical Studies - Cementless THA

The use of DEXA is well established in measuring resorptive bone remodelling about cementless total hip replacement. (Kiratli *et al* 1991a, 1991b, Kiratli 1992, Richmond *et al* 1991, Kilgus *et al* 1993, Engh *et al* 1992, Hughes *et al* 1995). Bone resorption is common and occurs to the degree that it is radiographically apparent. DEXA, with its ability to accurately measure BMD, can quantify the magnitude and pattern of periprosthetic bone loss and the rate at which it occurs.

Kiratli *et al* (1992) followed 12 patients with cementless titanium alloy total hip replacements (Biomet) on a prospective basis. A rapid loss of BMD had occurred in the proximal femur by 3 months. A plateau of bone loss had occurred between 6 months and 1 year at which stage the loss of BMD was 25 to 32%. The maximal bone loss occurred proximally and medially with less resorption occurring in the greater trochanter region. No analysis of BMD was done in bone in the middle and lower periprosthetic zone.

Kilgus *et al* (1993) retrospectively studied 72 patients with AML femoral stems at 1 to 6 years follow up. Only 34 patients had a contralateral non operated femoral scan as a control. The bone of the proximal one third of the femur underwent the greatest resorptive remodelling. Excluding the most proximal one centimetre of the medial femoral neck which underwent cortical round off as an amputation stump phenomenon, BMD decreased by 20 to 25% compared to the corresponding region in the control. The middle third showed approximately 15% loss with no significant loss of bone at the distal end of the implant. Small progressive decreases of BMD had continued for 5 to 7 years after implantation.

Engh *et al* (1992b) quantified BMD at longer follow up. He found bone loss can be extreme in the proximal femur in some cases. Engh scanned 5 autopsy retrieved AML implanted femurs and their contralateral unoperated femurs. The implants had been in situ for 17 to 84 months. The magnitude of bone loss as measured by DEXA was greater than in Kilgus's study. In the proximal third of the femur a mean decrease in bone mineral content of 45% had occurred with a maximum BMC loss of 83% compared to the control side. In the middle third average loss was 32% compared to the control site with a maximum loss of 67%. Engh found that the percentage decrease of bone mineral content was inversely proportional to the BMC of the control femur suggesting that the more osteoporotic the femur was at the time of surgery, the greater the degree of resorptive remodelling.

The above studies demonstrate that resorptive remodelling around cementless implants occur to a marked degree especially in the proximal periprosthetic zones.

2.4.4 DEXA Clinical Studies: Cemented THA

DEXA has also been used to study resorptive remodelling in cemented total hip replacement. Initial studies (McCarthy *et al* 1991, Markel *et al* 1993, Pritchett 1995, Wang *et al* 1994) showed DEXA is difficult to apply and errors in measuring bone mineral density may be great due to the inability to exclude reliably cement from the analysis of bone.

Markel *et al* (1993) examined the relative errors in measuring BMD around cementless and cemented hips. He implanted 8 canine femurs initially with an uncemented titanium stem. Each femur was scanned 5 times and the precision error in measuring periprosthetic BMD was calculated as 1.8%, consistent with the above precision studies. The implant was then removed and reimplanted with cement using standard cement techniques. Each femur was rescanned 5 times and the precision error was reported to increase to 7.2% (range 1.1%-12.6% variable by Gruen zone). The loss in precision on cementing was attributed to a “partial volume effect”, whereby pixels at the cement-bone interface could not be reliably identified as containing solely bone or solely cement, or containing a partial volume of both. While metal has an unphysiologically high density and can be reliably distinguished from bone and excluded from analysis of bone density, bone cement which contains barium can not be reliably distinguished from bone on a DEXA scan. Cement-bone interface pixels might therefore be included in the analysis of bone on an inconsistent basis and this caused a greater precision error in Markel’s study.

Within the limitations of DEXA application to cemented THA, initial studies have suggested that the pattern and magnitude of resorptive bone loss is equivalent to stiff extensively porous coated cementless implants, and that it is progressive with time (Pritchett 1995, McCarthy *et al* 1991). These studies have been cross sectional studies where the non implanted contralateral femur served as a control for the implanted femur under study. This study design is not optimal. Cross sectional studies introduce bias due to survival (Jones *et al* 1994). Furthermore the contralateral hip is not an ideal control for bone remodelling changes which have occurred in the implanted hip, as the BMD may not be equivalent to the BMD of the implanted femur at the time of surgery, especially if it is involved in arthritis or if there is favouring of either limb for whatever reason. McCarthy *et al* (1991) estimated the L-R difference in hip BMD to be 6.4%.

A further problem with many DEXA studies of cemented THR was that bone was sampled from a limited number of sites in the periprosthetic cortex and that the placement of the regions of interests (ROI) was somewhat arbitrary with respect to level and in the horizontal axis within cortex. McCarthy *et al* (1991) examined two ROI positioned in the medial cortex; Pritchett (1995) examined 2 sites, Wang *et al* 1994 examined 6 sites to correspond to the Gruen zones. In the latter study, the placement of ROI was improved by positioning the ROI using x,y coordinates referenced from bony landmarks. This ensured that comparable bone loci were being sampled between study and control sides and also between different subjects. However the problem remained that only a small proportion of bone was being analysed, and the bone remodelling changes such as neocortex and secondary medullary canal formation occurring at the bone cement interface, were being missed.

Cohen and Rushton (1995) in a 12 month longitudinal densitometry study of Charnley stems, included cement in the analysis of bone, under the reasonable assumption that cement would not change its density over time. They therefore could measure bone changes occurring from the endosteal to subperiosteal cortical surfaces. However they made the further assumption that recorded BMD changes in Gruen zones which included cement, would reflect the true changes in bone density alone. This incorrect assumption is erroneous; the volume of cement scanned would proportionately decrease the changes in the mineral density of the bone scanned. Cohen and Rushton reported BMD losses at 12 months of less than 10% and this is markedly less than that reported in any other cemented or cementless studies. The value of their work, however, is that this was the first longitudinal study of cemented THR where all periprosthetic bone could be analysed. Bone was not merely “sampled” with a limited ROI analysis, but bone changes occurring at the endosteal cortex were also included in the analysis.

2.5 ANIMAL MODELS FOR TOTAL HIP ARTHROPLASTY

2.5.1 General Principles

An important consideration in selecting an appropriate animal model is the similarity to the human species with respect to the subject being investigated (Roach and Shearer 1989). Ethical and financial considerations prevent the extensive use of primates for studies involving experimental surgery. Smaller animals eg. rabbits and guinea-pigs, though more readily available, are far removed from humans in the evolutionary scale. Intuitively these small animals are anatomically and physiologically too different to enable valid extrapolation to the human situation. In particular the rate and potential for bone repair is inversely related to age and position on the evolutionary scale (Schmitz and Hollinger 1986), and small animals would therefore be a poor model for bone re-modelling studies of the human situation. The interpretation of results cannot go beyond the limitations imposed by the model. An animal model which is similar to the human with respect to the response being investigated is required to predict the ultimate outcome in the human situation.

2.5.2 Bio-mechanical Aspects

Man is the only truly bipedal mammal with no reliance on the fore limbs for ambulation (Goel *et al* 1982). Selecting a quadruped eg. dog or sheep as a model for Total Hip Arthroplasty studies will necessarily involve loading the hip joint in a manner different from human. Differences in proximal femoral morphology, local action of muscle groups and ligaments, and locomotor pattern, all act together to load the hip differently between species (Bloebaum *et al* 1993).

Bergmann *et al* (1984), using cortical strain gauges bonded onto implanted femoral prostheses, determined that the load orientation at the hip in dog and sheep is similar to man. He concluded that for the consideration of load orientation either the dog or sheep is equally well suited for testing new endoprosthetic designs in humans.

However the magnitude of hip joint reaction forces is different between human and quadruped species. Grelsamer *et al* (1989) reported that the canine centre of gravity is located in the vertebral column at 40% of the distance from the shoulder to the pelvis.

Therefore proportionally more weight is carried by the fore limbs than the hind limbs. Page *et al* (1988b) and Allan *et al* (1989) confirmed this and showed that dogs typically place at least two times more weight on the forelimb in normal gait. Bergmann *et al* (1984) using strain gauge data from an instrumented endoprosthesis determined in both sheep and dog that the maximum hip joint forces were up to 100% of bodyweight. Allan *et al* (1989) determined the weight distribution in the canine hip using foot floor reaction force measurements. He showed that the hind limb receives approximately 0.35 body weight during stance which corresponds to a hip reaction force of 0.9 body weight. Grelsamer *et al* (1989) concluded that as a walking dog commonly has three paws on the ground simultaneously, the peak load on the dog hip does not approach anywhere near the loads on the human hip (5-7 times body weight in single legged stance and stair climbing modes) (Burke *et al* 1988). He recommended that to increase the load on the hip joint dogs must be vigorously exercised to have a gait where only two paws are on the ground simultaneously.

In sheep, Lanyon *et al* (1981) estimated the resultant load acting on the femoral head by applying strain gauge rosettes to the femoral cortex and measuring the in vivo strain changes as the sheep walked at 1 metre per second. He calculated a resultant force which was assumed to act solely through the femoral head as 413-509N in a sheep weighing between 59-79Kg. The advantage of Lanyon's in vivo derived experimental data is that the manner of bone loading was physiological. Muscle and ligament forces normally acting on the bone were all present and were acting on bone in an approximately normal manner. Bone is an irregular anisotropic, non-homogeneous structure and is not readily modelled by in vitro or theoretical studies. However Lanyon made the assumption that the resultant load from walking acts solely on the femoral head. Also the calculation of resultant load was based on a series of assumptions in particular the elastic modulus ratio of sheep bone in the longitudinal and transverse directions. Furthermore the data was derived from sheep in the early post operative period, and favouring of the test limb may have occurred reducing the femoral head loads. Lanyon's calculation of 500N of load on the femoral head during walking at 1 metre per second must therefore be considered an estimate only. However it does correspond to the calculations by Bergmann *et al* (1984) and Allan *et al* (1989) of approximately one body weight of hip reaction force in the dog.

2.5.3 Anatomical Aspects

Goel *et al* (1982) compared the external and internal femoral anatomy of the dog, sheep and baboon to the human, with the aim of determining the most appropriate anatomical model for hip implant studies. Numerous parameters of external anatomy were examined. The baboon and dog showed the greatest similarity to the human femur in external anatomy. The sheep has significantly less anteversion of the femoral neck (5.3° versus human $7-14^\circ$, Hoaglund and Low 1980), proportionately greater intertrochanteric distance, greater neck diameter, and sheep also have relatively greater sub-periosteal width at the isthmus. The external anatomy of the sheep proximal femur bears the least resemblance to the human of the three animal models studied. Goel *et al* (1982) believes that the use of a scaled down replica of a human hip implant in a sheep would be less likely to simulate the human in vivo loading situation than the dog or baboon which are more anatomically similar.

In internal anatomy the sheep proximal femur is also dissimilar to the human, baboon and dog. The endosteal surface of the diaphysial cortex is relatively smooth with little cancellous bone. The mean ratios of the extent of proximal cancellous bone to the length of the standard femoral shaft for the human, dog, baboon and sheep are 0.43, 0.77, 0.70, 0.25 respectively. Thus relatively less cancellous bone is available in the sheep for cement fixation of an implant compared to the human or dog.

The anatomical basis for preferentially using a canine model for arthroplasty studies is further supported by (Sumner *et al* 1990). In a study of 15 adult male mongrel dogs, the similarity in external proportion in proximal femur between the dog and human were again noted. In addition Sumner *et al* (1990) believed the canine hip is a particularly good model for bone remodelling studies. The canine femoral medullary canal is relatively larger than the human femoral medullary canal, and the canine has relatively thinner cortical bone. Sumner noted that a canal filling implant in a dog would therefore be relatively much bigger and much stiffer with respect to the bone than a canal filling implant in a human. Thus the degree of cortical stress shielding was relatively greater in the dog than the human. Resorptive bone loss would be expected to be relatively greater in the dog and the dog would therefore represent a relatively accelerated model of bone loss after total hip replacement.

2.5.4 Rehabilitation of Animals Following Total Hip Replacements

The dog has thus been established as an appropriate animal model for prosthetic hip studies on the basis of similarity to the human in external femoral geometry and cancellous bone distribution. However loading through the canine hip has been shown to be markedly less in relative and absolute terms in the human. Another important issue for determining whether quadrupeds are an appropriate model for total hip arthroplasty studies is the rehabilitation following surgery. Post-operative favouring of the operated limb by redistribution of load to the other three limbs will impact on bone remodelling studies.

Bagley *et al* (1988) used forced plate analysis to quantify gait in normal and hip implanted Greyhounds 15-25 months post surgery. The dogs were studied at walking pace. There were no significant differences in gait pattern between the control and implanted groups. The study confirms the clinical impression of others (Jasty *et al* 1986a) that animals rapidly become weight bearing and fully functional following hip replacement surgery.

Goethgen *et al* (1991) studied the changes in tibial bone mass as an index of recovery of limb function after uni-lateral cementless total hip replacement. Bone mineral content was measured using a dual photon absorptiometer. Each pair of tibiae were positioned in a standardised manner in a water bath and scanned at two sites. The proximal site was 2cm distal to the tibial tubercle, and the distal site was 75% of the total tibial length measured from the proximal end. A reproducibility study of BMC analysis showed a high level of precision using this technique. Control animals which had not undergone hind limb surgery had bilaterally symmetrical bone mineral content of the tibiae. Dogs with primary cementless total hip replacements showed no left right differences in tibial bone mineral content at six months post surgery. By two years post surgery, left right differences were approximately 5-6% though no clinical favouring of the operated limb was detectable. However dogs with radiological failure of cemented total hip replacement and clinically impaired function of the operated limb developed marked left right differences (more than 20%) in tibial bone mass within 6-12 months of surgery. Following cementless revision of these failed cemented stems, bone mass was recovered and left right differences were diminished. The changes in bone mass were attributed to loss on the operated side with or without a gain in bone mass on the contra-lateral side.

The endosteal surface was the main contributor to bone loss with endosteal cortical resorption and medullary enlargement; there was a lack of change at the periosteal surface.

2.5.5 Ovine Studies Of Total Hip Arthroplasty

The sheep has also been used as a model for total hip replacement. Phillips *et al* (1990) reported on the use of female Suffolk sheep, 6-8 years old, weighing 60-70Kg. A resurfacing arthroplasty via a trans-trochanteric approach was utilised. The acetabulum was not implanted to avoid problems of polyethylene wear debris and cement fragmentation from this side of the joint. Also a hemiarthroplasty avoided the problems of increased instability from the increased surgical dissection. A rapid recovery and low instance of post-operative complications was reported. The animals were noted to assume a four legged gait usually by the first day after surgery with rapid recovery to full activity after two weeks. However there were no force plate or bone mineral content studies to confirm this clinical impression of sheep rehabilitation after total hip replacement.

Reported complications were low. There were no infections and no dislocations in the twelve sheep of this series though in their early experience Phillips *et al* reported three dislocations in a series of eighteen operations. Acetabular erosion was reported and developed to a depth of 1-3mm within the first 3-12 months. The only animal followed to the second year post-operatively showed no further medial erosions.

Radin *et al* (1982) performed uni-lateral cemented total hip replacement in 36 adult Hampshire cross ewes, all 5-8 years old and weighing 60-80Kg. A posterior approach was employed, the neck was cut with a template to secure the correct angle of osteotomy. The acetabulum was reamed and implanted. A high complication rate was encountered. Radin *et al* reported four post-operative infections despite seven days of prophylactic antibiotic treatment. Three sheep died post-operatively from unrelated causes, one had a femoral fracture. No dislocations were recorded. The sheep were rehabilitated in stalls for six weeks then exercised on a cemented floor for two hours per day for five days per week. All sheep demonstrated radiological signs of loosening with calcar lysis by twelve months post-operatively.

Bergmann *et al* (1984) used the posterior approach (caudolateral approach) in 6 sheep. Postoperatively, 2 sheep walked with noticeable internal rotation secondary to division of the posterior short external rotator tendons. One sheep was noted to walk irregularly and this invalidated analysis of the sheep's data.

Phillips *et al* (1987, 1990), in selecting an animal model for hip arthroplasty studies noted several advantages in the use of a sheep over a dog. There was relative ease in obtaining sufficient numbers of consistently aged and consistently sized sheep at low cost. In contrast most canine studies have used mongrels usually within a specific weight range. However with dogs the uncontrolled variable of age, height and breed make it difficult to perform well controlled randomised experiments. In addition daily maintenance costs during the post-operative period are low in sheep and maintenance could be undertaken in a farm rather than a special cage or in individual runs as is necessary for dogs (Sumner *et al* 1992, Turner *et al* 1986). Phillips *et al* (1987, 1990) noted the relative ease of handling of sheep. Their docile nature enables fewer problems administering the anaesthetic and they recovered well from surgery.

Though there are anatomical dissimilarities to the human situation the sheep is also especially well suited for short to medium term bone remodelling studies. The sheep have a relatively large medullary canal and relatively thinner cortices compared to the human. Goel *et al* (1982) reported the ratio of total medullary area to total sub-periosteal area in the sheep, the dog and human as 0.865, 0.84, 0.73 respectively. A cemented stem in the sheep would be relatively much bigger and stiffer with respect to bone than a cemented stem in a human femur. The degree of cortical stress shielding would be relatively greater and resorptive remodelling of bone accelerated in a sheep model.

CHAPTER 3: A SHEEP MODEL FOR TOTAL HIP ARTHROPLASTY

3.1 INTRODUCTION

The aim of this chapter is to develop the merino sheep as a model for hip arthroplasty. This section developed a new surgical approach, post operative management program, radiography technique and the complications and rehabilitation from surgery are discussed.

3.2 CHOICE OF ANIMAL MODEL

Human studies on femoral bone remodelling have been performed for both cemented and cementless hip arthroplasty. These studies have included clinical investigations utilising radiographic or densitometric analysis of *in situ* implants (Commadoll *et al* 1988, Black *et al* 1979 Engh *et al* 1993, Kiratli *et al* 1992, McCarthy 1991, Kilgus *et al* 1993). However clinical studies can only give an indication of bone remodelling changes. The interpretation of the data is limited by the limitation of the radiographic or densitometric technique in the clinical setting (West *et al* 1987, Kiratli *et al* 1992, McCarthy *et al* 1991).

Human studies on femoral bone remodelling have also included laboratory investigations of implanted femora retrieved at autopsy (Maloney *et al* 1989, 1996, Torchia *et al* 1991, Engh *et al* 1992, Sychterz *et al* 1996). These post-mortem studies have allowed not only radiographic and densitometric analysis but also have enabled correlation with biomechanical properties of the remodelled bone and morphometry of bone sections. They therefore have enabled a more complete understanding of bone remodelling after total hip replacement. However human retrieval studies have been hampered by limited numbers of femurs available for study and the variables of implant design, post operative interval and surgical technique were uncontrolled.. difficult to correlate the effect of implant design features with skeletal remodelling in these circumstances. Moreover, inter-individual variables including variation in sex, age, post-operative activity level and ethnic background need to be considered in interpreting bone remodelling changes.

Animal models for total hip replacement can circumvent the deficiencies in clinical and autopsy retrieval studies. A prospective randomised controlled trial can be performed using a predetermined number of animal subjects per test group. The canine model has been commonly used for hip arthroplasty studies and though the canine hip has been shown to be biomechanically and anatomically similar to the human hip, there are however practical limitations in the use of the canine model. Availability of a sufficient number of dogs of similar size, age, breed and activity level for experimental surgery is limited by Ethical concerns in many communities. In studies where the skeletal response to different implant designs is being examined, inter-individual variation of subjects must be minimised to validly describe the treatment effect. The use of canine subjects obtained from municipal pounds therefore has its shortcomings, and the use of a purebreed animal model is required.

The sheep has been successfully used in several total hip replacement studies (Phillips *et al* 1987, 1990, Bergmann *et al* 1984, Radin *et al* 1982). The relatively large medullary canal of the sheep femur, and thin bone cortices make for an accelerated model of bone remodelling around femoral implants (Sumner *et al* 1992). Therefore short-term studies of bone remodelling in a sheep hip replacement model would appear valid.

The sheep has the advantage of being very readily available in a primary producer society such as Australia. Sheep of the same breed can be obtained from the same flock ensuring a high degree of size, age and genetic uniformity. These inter-individual variables which may impact on bone remodelling are therefore reduced. Preliminary clinical observations indicate that sheep tolerate the hip replacement well and begin weight bearing early. The post operative management of sheep after major hip surgery had not been elucidated as clearly as in the dog. Thus techniques were developed for the use of sheep for these experimental studies.

3.3 STUDY DESIGN

3.3.1 Study Group

The study group comprised 50 skeletally mature Merino Wethers, aged between 3 and 4 years, and weighing between 55-70Kg. The sheep were all obtained from the same flock, thus ensuring as little variation between the trial animals as possible. Obtaining

sheep in this manner also provided a home flock for the sheep to return to post-operatively, to the members of which the sheep was familiar, thus facilitating consistent rehabilitation.

An independent Veterinary Surgeon examined all sheep for physical fitness prior to the inclusion in the study. Ongoing veterinary care particularly of the hooves and oral cavity were performed as necessary throughout the course of the study.

3.3.2 Calculation of Sample Size

Three treatment groups were studied; sheep with polished collarless implants, matt collarless implants, and matt collared implants. All implants were of the double tapered design and were identical except for the variables of surface finish and the presence of a collar. The number of subjects per treatment group was pre-determined by predicting differences in resorptive bone remodelling between groups. When anticipated differences are large and the variability in data is small, the subject number per group can be small to show a significant or clinically relevant difference. As a bone remodelling study for cemented femoral stems has not been performed previously, the predicted differences in this study were based on clinical studies addressing bone resorption as well as a previously reported sheep THA study (Radin *et al* 1982).

Radin *et al* (1982) found that 100% of the 26 sheep with collared cemented femoral stems had a degree of calcar resorption accompanied by radio lucent line formation by 12 months post-surgery. This resorption may have occurred due to a loosening rather than remodelling response. The cementing technique was not optimal by contemporary standards and the implants were deliberately inserted into a valgus position rather than neutral. Also a polyethylene acetabulum component was inserted in every case raising the possibility of polyethylene wear debris causing osteolysis. The authors however believe polyethylene wear was minimal at the 12 month post operative stage (Radin Personal Communication 1992) and that calcar resorption was not due primarily to a loosening process.

Therefore a conservative prediction of radiographically apparent bone resorption in the proximal femur with collared matt stems in the current sheep study after a nominated ten month in vivo period is 80%. This resorption may not necessarily be associated with

radiographic signs of loosening. Clinical studies of matt collared stems confirm this predicted incidence of bone resorption. Cotterill *et al* (1982), Richards *et al* (1986) and O'Hara and McMinn (1991) predicted a 71% to 100% incidence of significant calcar resorption in the medium term.

The null hypothesis is that the matt-collarless implants behave in a similar manner to matt-collared implants. They both lack the ability for the taper to subside. Thus the predicted incidence of resorptive bone changes in the matt collarless stems is also 80% at 10 months post-surgery.

For the polished stems, the predicted rate of bone resorption was derived from clinical studies. Fowler *et al* (1988) reported a 7.23% incidence of radiographically apparent calcar resorption greater than 1mm at 5-10 years follow-up in over 400 Exeter total hip replacements. Black *et al* (1979) performed a radiographic densitometric analysis of the first 112 patients with a polished stem. He reported a 0% incidence of resorption, cavitation and cystic change in the calcar at 5-7 years follow-up. A conservative prediction of radiographically apparent bone resorption for the polished collared stem in the sheep after 10 months in vivo is 10%.

Thus with the prediction of a 70% difference in bone resorptive remodelling changes between the polished, and the matt-collared and matt-collarless groups, the sample size per test group can be calculated.

The assumptions were made that the distribution of bone resorption in each implant group was normally distributed and conformed to a bell-shaped curve. An alpha value of 0.05, and a beta value of 0.20 were nominated. A two-tailed unpaired t-test was applied to the difference between each test group. For a predicted 70% difference between the polished and other two treatment groups, 7.2 sheep were required per group to demonstrate this difference.

Radin *et al* (1982) reported a complication rate of 22% necessitating withdrawal of those sheep from their study. In the current study an allowance was therefore made for 3 sheep per test group to suffer complications which would require withdrawal from the study. Thus the calculated minimum number of sheep per study group was 10 animals. Ethical and financial considerations required using the minimum number of animals to

show the predicted difference in treatment effect.

Radiographically apparent bone remodelling, either resorption or apposition is only one indication of the remodelling response to the presence of an implant. It is also a relatively late occurring response requiring approximately a 30% loss of bone mineral before the change is radiographically apparent (Ardran 1951, Lachman 1955). Changes in bone as determined by cortical strain analysis and morphometric analysis and DEXA parameters occur earlier than radiographically detectable bone resorption. The calculated numbers per study group should therefore be sufficient to detect significant changes in these parameters between test groups as well.

Recent bone remodelling studies in canine cementless hip replacement studies have been performed utilising similar numbers. Sumner *et al* (1988, 1992a) assigned 7 dogs to each of three implant design study groups. Turner (1986) assigned 10 dogs to each of the three design study groups.

3.3.3 Randomisation to Treatment Groups

The choice of animal model and study design meant that the only variable likely to influence the results was implant type. The study sheep were randomly allocated to matt collared, matt collarless, or polished collarless treatment groups.

A coloured and numbered ear tag from number 450-500 was fastened to the left ear of all sheep. Thirty sheep for the study group were selected at random. Individual cards for each of the 30 study numbers were placed in a box, shuffled, and 10 cards were withdrawn from the box and assigned to the matt group. Ten cards were withdrawn from the box and assigned to the polished group and the remaining 10 sheep were assigned to the collared group. This ensured a random allocation of 30 of the 50 study animals to one of the three treatment groups. The 30 cards with the study number and implant designation were placed in individual sealed envelopes. The envelopes were identified only by the study number labelled on the outside.

The 30 sheep forming the study group were permitted to roam freely in a closed off paddock in a research farm facility. Individual sheep were selected for surgery in a random manner. At the time of surgery the appropriate sealed envelope was opened

only at the time of cement mixing, revealing the type of implant to be inserted. Therefore no operator bias in the treatment (surgical exposure, neck osteotomy, canal preparation) could possibly be introduced.

In the collection and analysis of data, the observer was blinded as much as possible from the treatment group of each animal. All data were recorded on standardised forms which contained only the sheep identification numbers. Thus in contact radiography surface finish of the collarless implants types was unknown to the observer, minimising bias. In the bone morphometry, collared or collarless implants were indistinguishable from the cut sections and observer bias was again avoided.

3.3.4 Withdrawal Criteria

In this study the number of 10 subjects per group was strictly adhered too. This number anticipated a complication rate of 30% which might require withdrawal of the subject from the study. Anticipated complications requiring withdrawal of subjects from this study included intra-operative or post-operative death from anaesthetic problems, dislocation of the hemiarthroplasty, femoral fractures, infection, aseptic loosening of the implant, and any problems unrelated to the hip joint for which an independent veterinary surgeon requested euthanasia for ethical reasons.

There were no replacements for withdrawn subjects once treatment had commenced. Treatment was deemed to have commenced at the time of randomisation to treatment groups.

3.3.5 Selection of a Control

In this study the right hip served as an internal control for analysis of the left (study hip). Immediately prior to sacrifice, the sheep was anaesthetised and the right hip was surgically implanted with an identical prosthesis as the left side. The right hip was implanted in strict adherence to the operative protocol (Chapter 3.7) used in the implantation of the study side. In particular the femoral canal was meticulously prepared, and the sheep was alive at the time of prosthesis insertion, with back bleeding from endosteal bone. Thus the potentially deleterious effects of blood at the interface are applicable in the control as well as in the study side. A laboratory implantation of the

control is an idealised situation and would not have suffered from the above limitations.

The use of the contra-lateral femur as a control has disadvantages, and the issues may be summarised in the following:

- 1) left-right variability between femurs. No studies of bilateral symmetry have been done in the Merino sheep femur. However such studies have been done in the human femur (Miller and Protrowski 1977) and in the dog femur (Sumner *et al* 1988), and L-R variability has been reported to be small. Miller and Protrowski found no significant left-right differences in cortical area in humans. Sumner reported that dogs have a high degree of bilateral symmetry with left-right differences at corresponding sites in subperiosteal area, endosteal area, and cortical area of approximately 1%.
- 2) Sumner *et al* (1988) concluded that the contralateral canine hip is an appropriate control for bone remodelling studies in which one limb is treated and the other untreated, only if the treatment has no effect on the control limb. If the test femur were to fail, the sheep might favour the test femur enough to load the contra-lateral hind limb greater than normal. In that case the contra-lateral femur would suffer a treatment effect of its own and would not be equivalent to the test femur at treatment time zero.
- 3) The control femur at sacrifice has 10 months more bone aging effects than the test femur had at the time of implantation. The right femur cannot therefore be considered a time zero control for the test femur. The magnitude of age related bone changes occurring over 10 months in a skeletally mature sheep have not been reported. However age related bone changes in human have been studied and noted to be small over a short period of time (Van Gerven *et al* 1969, Ruff and Hayes 1982). Over the age range 20 years to 60 years, subperiosteal area expansion in a male averages 7%, and a female 11%.

Despite the above considerations the use of the contra-lateral femur as a control is well established in many previous animal and human studies. The dominant factor causing differences in bone parameters between the left and right sides is the treatment effect ie. the remodelling effect of the cemented stem in situ. The relatively short time course of

the study allows sufficient time for bone remodelling to occur, as indicated by earlier dog and rabbit remodelling studies (Sumner *et al* 1992, Turner *et al* 1986, Dancke Lilliestrom 1969). However the time course is not so long that an aging effect becomes important, or aseptic loosening has caused favouring to have occurred to an important degree. The effect of left-right variability cannot be minimised by study design. However inter-individual variability is substantial (Hoagland and Low 1980, Maloney 1991) and using the femur from another animal even of the same age and flock as a control, would entail more variability than using an internal control. From the above considerations, it can be concluded that the contralateral femur is a suitable control for this study.

3.4 SHEEP IMPLANT DESIGN

In collaboration with Howmedica, an Orthopaedic implant manufacturer, three implant designs were custom made for use in this study (Fig 3.1). All implants were made from orthinox, a high grade stainless steel. The implants shared a basic double tapered geometry. Total length was 80mm with a maximal width of 25mm and a maximal stem thickness of 6mm. The width and thickness dimensions decreased in a linear manner distally creating a double taper in the coronal and sagittal plane. The dimensions of the tapered stem were calculated to allow for a minimum cement mantle thickness of 2-3mm around the stem when implanted in the sheep femur.

The implant head sizes were available in 24mm, 26mm and 28mm diameter. A sizing template was used intra operatively to size the excised femoral head and thus select the most appropriate head size for each sheep.

A marker circle was inscribed on the anterior aspect of the implant along the midline axis of the implant and 1cm below the base of the implant head. This marker circle indicated the depth to which the collarless implants were seated with respect to the femoral neck osteotomy. The marker circle also corresponded to the level of the collar so that when the collar was resting flush against the calcar, the marker circle was also at the level of the femoral neck osteotomy (Fig 3.1).

The three implant types differed in their surface finish. The smooth implants had a highly polished surface finish identical to that available on the commercially available

'Exeter' human implants currently in wide spread clinical use. The surface roughness was 0.02 - 0.04 microns. The matt implant had a surface roughness identical to the matt finished 'Exeter' implants used in the early 1980s and since discontinued in favour of the polished finish. The matt finish had a surface roughness of 1 micron and was equivalent to the surface finish of many of the matt femoral stems of other designs currently in clinical use.

The third implant type was the collared stem with a matt finish. The matt finish was identical to the matt collarless stem. The collar was designed to rest flush against the femoral calcar when the stem is fully seated up to the inscribed marker circle.

The collar dimensions were determined from contact radiographs of 2mm thick transverse sections taken from the sheep proximal femur at a level just distal to the femoral neck osteotomy. The collar dimensions were such that the proximal cement mantle and cortex were covered by and therefore supported the collar when the implant was inserted in neutral version. The collar dimensions determined were; medial, 8mm; anterior, 6mm, posterior, 6mm; thickness 2mm (Fig 3.2).

The collar angle of inclination was parallel to the base of the implant head and the collar was positioned 1cm below the base of the implant head. Therefore when the implant was seated to the marker circle, the collar contacted and covered the femoral calcar.

Two other instruments were custom made for this study. A femoral neck osteotomy guide was used to facilitate cutting the femoral neck at the correct level and correct angle of inclination (Fig 3.3). Such osteotomy guides are common in clinical total hip arthroplasty sets and have been used in previous sheep total hip replacements studies (Radin *et al* 1982).

This guide has a tapered geometry identical to the implants. The guide is placed sub-muscularly and flush along the anterior aspect of the femur with the top of the guide subjacent to the femoral head articular surface. A marker hole in the guide corresponds to the marker circle of the implant. A medial slot in the guide extends from the medial edge to the marker hole. A line is marked with the cutting diathermy blade through the slot in the osteotomy guide and is extended laterally into the greater trochanter. The femoral neck osteotomy is made along this line.

The second custom made instrument is the broach for shaping the intra-medullary canal of the proximal femur. (Fig 3.3) When seated this broach was designed to allow a complete 3mm thick cement mantle around the implant. Only the one size of broach was used in this study. In some sheep, a larger broach could have been seated, and in the occasional sheep this broach was slightly over-sized and could not be fully seated by up to 10mm. This was due to a very thin posterior cortex extending 5mm distal to the femoral neck osteotomy. Attempts to fully seat the broach in these cases occasionally caused a non propagating fracture of the thin posterior cortex.

In addition the fragile posterior cortex prevented the use of a calcar reamer. Contemporary total hip arthroplasty instrumentation (Howmedica Precision; Smith and Nephew Spectron; Zimmer Precoat) for collared femoral stems utilises a broach with a detachable handle, and a trunion on which can be placed a circular power driven reamer. This rasp can remove any irregularities or correct any slight malinclination of the femoral neck osteotomy which would compromise collar calcar contact. Harris (1992) reported that the use of this calcar reamer has enabled improved collar calcar contact, with excellent contact being achieved in 91% of clinical cases.

In this study a calcar reamer was not used. The configuration of the thin proximal posterior cortex occasionally prevented the broach from being fully seated. Thus the reamer would not have consistently contacted the bone calcar. In addition the action of a power driven calcar reamer on the thin and fragile proximal posterior cortex would risk cortical fracture. Therefore collar calcar contact was achieved by the careful use of the femoral neck osteotomy guide alone.

A series of cadaver operations was performed prior to the onset of this study to familiarise the operating team with the instrumentation. Using the neck osteotomy guide, reproducible neck cuts and collar calcar contact was achieved (Fig 3.4).

Every femoral stem was inserted with a polymethylmethacrylate centraliser placed on the distal end. The centraliser ensured central placement and neutral alignment of the stem in the canal and a consistent 2-3mm cement mantle around the stem. In addition the centraliser was an integral component of the Exeter philosophy of stem subsidence. The stem was able to subside into the cement mantle and into the PMMA centraliser without

end bearing of the tip which may cause cement fracture (Charnley 1979)

3.5 OPERATING ROOM SET-UP

Surgery was performed in an established animal research operating room. Four personnel were involved with every procedure: two surgeons, one of whom was the author, a research assistant, and an animal technician who supervised the anaesthetic. The standard operative instrumentation for human total hip replacement was available for each procedure. The instrument set-up is documented in Appendix 1 and 2.

3.6 ANAESTHESIA

A general anaesthetic was administered for each procedure. Intravenous access was gained via a subcutaneous neck vein. Induction was with 1gm of intravenous Thiopentone (Pentotal, Abbotts, Australia). The sheep was intubated but permitted to breath spontaneously. The anaesthetic was maintained with nitrous-oxide (300ml/min), Isoflurane (1.5-2.5L/min), and oxygen (1L/min) endotracheally throughout the operative procedure.

No haemo dynamic monitoring was performed intra-operatively. A sixteen gauge Angiocath was placed in the subcutaneous neck veins and 1000cc of a balanced salt solution was infused over the course of the operation, to main haemo dynamic stability. The average duration of surgery was approximately 90 minutes.

Antibiotic prophylaxis was used. Two grams of Penstrep (comprising Penicillin 250mg/ml; Streptomycin 250mg/ml, Ilium, Australia) was given intra-muscularly at induction of anaesthesia and continued daily for 3 days.

3.7 SURGICAL PROTOCOL

3.7.1 Surgical Exposure

The following stages of the operation were performed by the author. The sheep was placed in the right lateral position with the left hip uppermost. The left hind quarter was

closely shaved from the dorsal spine to the hoof. It was then washed with Chlorhexidine and water. This was followed by 70% alcohol as an additional degreasing and disinfecting measure. Finally the hind quarter was prepared with aqueous Povidine-Iodine solution.

The hind limb was free draped with a sterile drape up to but not including the stifle joint (knee joint). Sterile drapes were applied leaving the left thigh and hip joint exposed.

An anterolateral approach was made to the hip joint. A curved incision was made centred over the greater trochanter extending distally in the line of the femur, towards the stifle joint and proximally proceeding 4 finger breadths dorsal to the greater trochanter. The deep fascia was incised in line with the skin incision. The gluteus medius proximally and the vastus lateralis distally was identified as they converged to a common insertion in the greater trochanter. Lying in the interval between these two muscle bellies was a small muscle, the gluteus superficialis, which was sharply released at its insertion (Fig 3.5).

At this stage the superficial dissection was complete. Huck towels were placed, folded deep to the wound edges and secured in place with towel clips. A Charnley self-retaining retractor was placed to separate the wound margins. A further self-retaining retractor was positioned to separate the muscle bellies of gluteus medius and vastus lateralis. Lying in the deep tissue layers lies a large muscle running approximately parallel to the gluteus medius muscle. The silver tendinous insertion of the muscle into the base of the greater trochanter was uppermost and clearly identifiable (Fig 3.6). This muscle was the gluteus accessorius and it was inserted into the anterior aspect of the femoral neck. A constant leash of blood vessels running transversely across the tendinous insertion was coagulated to improve the exposure. The hind limb was then externally rotated 90° and flexed. A vicryl stay suture was placed into the gluteus accessorius tendon which was then sharply released 1cm proximal to its insertion. The tendon and muscle belly of gluteus accessorius was then swept back from the femoral neck with a dry swab revealing the tendinous insertion of gluteus profundus muscle fusing with the anterior capsule of the hip joint.

With the hind limb still held in 90° of external rotation and flexion, a 180° anterior capsulotomy was performed parallel to the acetabular margin. The joint was distracted,

and a curved mini Cobb elevator was inserted into the joint. Care was taken not to damage the articular cartilage with this instrument. The Cobb elevator was used to lever the joint open increasing access to the femoral head. The ligamentum teres was divided with metzenbaums scissors. This was occasionally difficult as this ligament is large and holds the joint securely located. The ligament was divided at its insertion into the femoral head. A scalpel and bone rongeurs were used to excise the ligamentum stump from the acetabulum.

The neck cut was made with the neck osteotomy guide. With the hind limb still held 90° externally rotated, the mini Cobb elevator was used to strip the vastus lateralis muscle off the medial and anterior aspect of the femur. The guide was placed submuscularly such that the long axis of the guide coincided with that of the femur. The guide sat flush and without tilt or wobble on the anterior femoral cortex when it was correctly positioned (Fig 3.7). The superior edge of the guide was parallel and subjacent to the articular surface of the femoral head. The neck cut was made after marking the bone with a diathermy blade placed through the slot of the neck cutting guide.

The neck cut was made using the Hall micro-surgical oscillating saw (Zimmer, Warsaw, Indiana, USA) the saw blade was irrigated with 10cc of syringed saline to decrease thermal necrosis of bone (Toksvig-Larsen *et al* 1992). A step cut was made laterally at the base of the greater trochanter to release the femoral head.

The head of the femur was sized by passing it through the metal template. This template has holes of 24mm, 26mm, 28mm in diameter.

The proximal femur was lifted out of the wound with a modified femoral elevator. This elevator has hooks which were placed against the thick cortical bone of the posterior calcar. The bone surface was protected from damage by the elevator with an intervening pack. The exposure of the proximal femur gained was now such that there was unrestricted access to the proximal end of the femur.

3.7.2 Femoral Canal Preparation and Implant Insertion

This section of the operation was performed by the other attending surgeon. The bone

at the base of the greater trochanter was removed with a narrow osteotome and mallet. The T-handled straight tapered broach was introduced to a level of 10cm. The curved broach was then introduced by hand and rasping performed, concentrating on the lateral cancellous bone and the greater trochanter. A collared trial implant was now inserted, assessing adequacy of cement mantle, and in particular if the collar would sit flush against the cut surface of the femoral neck. If not the femoral neck was trimmed by the author.

The femoral canal was prepared for cementing in the standard manner, consistent with current clinical practice (Ling 1991). Distal occlusion was achieved with a cement restricter (Universal, Howmedica, Staines, UK) which was placed 10cm from the cut edge of the femoral neck. This gave a distal cement mantle of approximately 1cm. The canal was then brushed and cleaned with pulsatile lavage of normal saline. A paediatric feeding tube was placed in the femoral canal as a suction drain. The canal was then packed with a 5cm wide ribbon gauze soaked in 1.5% hydrogen-peroxide. Packing was performed in a retrograde manner. The effervescence of the hydrogen peroxide further served to lift blood clot from the interstices of bone and thus increase the mechanical interlock of cement into the bone.

At this stage the research assistant opened the sealed envelope revealing the implant type to be inserted. The implant type of the appropriate head size was then prepared for insertion, and a polymethylmethacrylate centraliser placed on the implant tip.

Two mixes of Simplex cement (Howmedica, Staines, UK) were mixed by hand with care to achieve an even consistency. At 60 seconds the cement was poured into a disposable cement syringe (Howmedica) with care to avoid bubble formation. At 2 minutes after commencement of mixing, the cement was injected into the intra-medullary canal of the femur in a retrograde manner using an injection gun (Howmedica). The half-moon rubber seal (Howmedica) was placed onto the syringe nozzle and applied to the top of the intramedullary canal. Firm pressure was applied to the half-moon seal, thus occluding the canal and stopping cement leakage and also increasing cement pressurisation in the canal. Pressure was maintained until 4 minutes from the onset of mixing.

The hind limb was held at the stifle joint such that the femur was flexed, adducted, and

externally rotated by 90°. The implant and centraliser were inserted into the femoral canal at 4 minutes and 30 seconds after commencement of mixing. The implant was inserted in 0° of ante-version. Even though the anatomical ante-version of sheep femur is 5.3° (Goel 1982) zero degree of ante-version was chosen as this version can be judged intra-operatively on a consistent basis. In addition a femoral stem in neutral version is more stable than ante-version when inserted from the antero-lateral approach (Fig 3.8).

All cement was curetted away from the proximal cut surface of the femoral neck to prevent any collar like action of the cement (Ling 1992b). Firm pressure was maintained on the implant until the cement was fully cured.

The wound was copiously lavaged out with normal saline. The acetabulum was washed out, inspected and palpated to ensure no foreign material would obstruct reduction. The joint was then reduced by traction and internal rotation.

3.7.3 Radiographic Markers for Implant Subsidence (An Independent Study)

Implant subsidence and its detection and measurement were studied in an otherwise separate project by another research worker. The experimental protocol called for placement of radiographic metallic markers from which implant subsidence were measured from serial in vivo radiographs. A 1mm metal ball bearing was inserted into the proximal lateral cement mantle as it cured. Linear subsidence measurements were referenced from this marker to a metal ball bearing welded onto the lateral implant neck. A further 1mm metal ball bearing was press fit into the PMMA centraliser with linear measurements referenced from the tip of the implant stem. In addition, 3 x 2 mm metal screws were inserted via a drill guide jig in the tip of the greater trochanter. These screws were a further reference to measure progressive subsidence and alignment changes on serial in vivo radiographs.

3.7.4 Surgical Closure

This stage of the surgical procedure was resumed by the author.

With the hind limb held extended, internally rotated, and abducted, the hemiarthroplasty was deeply reduced into the acetabulum. The hip capsule was repaired with 1-PDS interrupted sutures. In the first 10 study animals the gluteus accessorius tendon was repaired end to end with vertical mattress sutures of 1-PDS. This repair was occasionally tenuous and some instances of early post-operative dislocation occurred. The subsequent 20 sheep therefore had a modified surgical closure. A 2mm drill hole was made at the base of the greater trochanter. A 1-PDS suture was passed through the drill hole and through the free cut end of the gluteus accessorius tendon as a modified Kessler suture. The tendon was then advanced superiorly and distally from its anatomical position and secured at the drill hole to the base of the greater trochanter. The resting tension in the gluteus muscle belly was therefore increased and the tendon formed a superior buttress to antero-superior dislocation (Fig 3.9). The principle of decreasing the risk of dislocation by gluteal tendon advancement is analogous to the technique of trochanteric advancement used to treat recurrent dislocation in the clinical setting (Kaplan *et al* 1987).

The interval between gluteus medius and vastus lateralis were closed with 1-PDS sutures. The deep fascia and gluteus superficialis were closed with continuous 1-PDS sutures. The subcutaneous layer was closed with 2-O vicryl sutures. The skin was closed with continuous subcuticular 2-O vicryl sutures. The wound was swabbed with betadine. No dressing was applied.

3.7.5 Post Operative Radiography

Radiographs were performed immediately post-operatively prior to reversal of anaesthesia. A standardised method of radiographic evaluation was developed. The sheep was positioned supine in a specially designed wooden sheep holder such that the ventro-dorsal axis was vertical. The x-ray cassette was placed in a bracket positioned under the ischium. The bracket was rotated such that it was parallel with both femurs.

The lateral x-ray was taken with the sheep in the "frog lateral" position (Figs 3.11, 3.12). The hind limbs were flexed and externally rotated 90°. The hooves were fixed together with clamps to the holder and the limbs positioned such that they were symmetrical. The transverse axis of the stifle joint was perpendicular to the x-ray cassette.

The antero posterior x-ray was taken with the sheep remaining supine resting on its dorsal spine (Fig 3.13, 3.14). The lower limbs were maximally flexed and the hooves secured to the holder via velcro straps. The longitudinal axes of the hind limbs were collinear with the sagittal axis of the body.

All radiographs were taken using the same radiography unit. The X-ray beam was centred over the pubis. The tube to cassette distance was 1 metre. The voltage was 74kVP. The exposure was 6mAs.

Follow-up antero-posterior and lateral radiographs were performed in the above manner at 2 monthly intervals from surgery under general anaesthetic. The X-ray findings noted at each occasion were:

- 1) enlocation of the hip implants;
- 2) signs of fractures around the hip implant;
- 3) signs of gross loosening of the implant;
- 4) signs of gross bony remodelling.

Detailed radiographic assessment was not possible in vivo due to overlying soft tissue folds which obscured fine radiographic detail. The purpose of performing in vivo radiographs was to exclude any major complication which ethically would require euthanasia of the subject and withdrawal from the study.

3.7.6 Post Operative Management

Following radiography the sheep was placed in a canvas sling that was supported by two wooden poles. The sheep was suspended by the sling in its pen while it recovered from anaesthesia, usually approximately thirty minutes (Fig 3.10). This arrangement was such that the sheep could stand full weight bearing on the operated limb or could rest fully supported by the sling.

Intra-muscular narcotic analgesia was given post-operatively in accordance with Animal Ethics guidelines. The sheep was allowed to eat and drink when it was able, commonly

this was within the first one to two hours of surgery.

Twenty-four hours after surgery, the sling support was lowered encouraging the sheep to full weight bear more of the time. However the sheep could still rest fully supported in the sling. At 48 hours post surgery the sling was removed and the sheep allowed to mobilise within the confines of the pen. At 72-96 hours after surgery the sheep was released into a larger pen where it could mingle with other animals of the study group which had either undergone surgery or were about to undergo surgery.

At one week the sheep was discharged to the animal research farm where it was confined to a paddock with other study sheep at the same stage of rehabilitation. At three weeks after surgery if the wounds had healed well and the sheep was noted to be walking well, an exercise program was commenced. A shepherd herded the post-operative study sheep around a 4Km dirt road at the periphery of the animal research farm 5 days of the week. This vigorous exercise program was adopted to ensure the sheep did adequately load the operated hip. Grelsner *et al* (1989) has shown that a quietly walking dog experiences peak hip joint loads well below that of a human hip joint. Lanyon *et al* (1982) has estimated the hip joint loads in the sheep and noted them to be similar to that of a dog. Thus this exercise program was adopted in an attempt to load the rehabilitating sheep hip replacement to a similar level as a post-operative human hip replacement.

3.8 RESULTS OF SURGICAL PROTOCOL

The anaesthesia and the surgery were generally well tolerated by the sheep. The sheep recovered quickly usually beginning to feed within 1-2 hours post-operatively and standing on the operative leg by 6 hours. By Day 2 sheep were commonly fully weight bearing and walking backwards and forwards by sliding the sling along the wooden poles.

Of the 30 sheep entering the study, 18 sheep survived until the ten month stage when sacrifice was performed. These 18 sheep comprised 7 matt collared, 7 polished and 4 matt collarless subjects. 12 sheep (40%) suffered complications at some stage requiring withdrawal from the study.

The most common complication was dislocation. Seven sheep suffered an anterior dislocation of the test hip. This occurred in 6 cases within the first three post-operative days.

In 3 of the 6 cases of early dislocation, the dislocation was a secondary event. In case 498, dislocation was secondary to a technical error during surgery. The broach was inserted too forcibly into the femoral canal causing a 12mm x 7mm fragment of the posterior femoral cortex to fracture off. This fragment included the insertion of the thick Gemellus (Bassett 1965) tendon postero-laterally. The Gemellus is an important stabiliser of the hip joint, preventing the proximal femur from translating anteriorly. Following cortical fracture, the hip joint could not be rendered stable by capsular and tendinous repair and this sheep was euthanased under the same anaesthetic.

In case 495, one of the wooden poles supporting the canvas sling broke. The sheep was found collapsed on the ground with a dislocated hip. Stouter wooden poles were used following this complication, and pole breakage did not recur.

In case 478, dislocation occurred secondary to an associated complication in the forelimb. The forelimb holes in the sling were relatively too small for this particular sheep, and pressure from the edge of the hole impinged at the axilla. A drop paw deformity developed on the same side as the operated hind limb. This situation is analogous to the drop wrist condition in humans secondary to a radial nerve compressive palsy at the axilla. The sheep could not extend his paw to place the hoof flat on the ground. The sheep therefore could not support itself stably on the left side. A plaster cast holding the paw in extension was applied but poorly tolerated. On removal of the sling, the sheep could not stand unsupported, and in its attempts to do so the hip joint dislocated. The sheep was euthanased. Autopsy examination of the axilla of the forelimb revealed ecchymosis secondary to pressure and oedema in the tissue surrounding the peripheral nerves, consistent with a compressive nerve lesion. Following this complication only slings with large limb holes were used.

In the case of the remaining three sheep (#1,#14,#18) early dislocations occurred soon after sling removal. The sheep were resting on the ground but in the ensuing struggle to get back onto their feet, dislocation occurred.

Early dislocation was initially treated by a closed reduction, readily ascertained by a palpable clunk and restoration of leg lengths. However dislocation rapidly recurred as the sheep was unsteady on its feet. It frequently staggered and the test hind limb lapsed back into adduction and flexion, which is the position of instability.

Closed reduction with application of a "broom-stick" plaster splint was attempted. These splints are similar to the broom-stick abduction splint worn by young human patients to maintain reduction of the femoral head in the acetabulum in Legg-Perthes disease (Apley and Solomen 1982). Velband padding was applied to both stifle (knee) joints over which a roll of 4 inch plaster was applied. The plaster incorporated a transverse broom-stick thus holding the hind limbs in abduction. While this splint was successful in holding the dislocation reduced, the sheep could not ambulate nor lie down. The orthosis was removed after 48 hours to allow the sheep to rest, but dislocation recurred.

An open reduction of the dislocated hip joint was attempted in one case. The femoral head was found antero-superior to the acetabulum with the end to end repair of the gluteus tendons disrupted. A reduction with an imbricating repair of the gluteus tendons was performed but early post-operative dislocation recurred.

Following these poor results of treating dislocations, subsequent dislocators were automatically withdrawn from the study and sacrificed.

Of the 6 early dislocations, 5 occurred in the first 10 cases where a simple end to end capsule and gluteus tendon repair was performed. Following the modification of closure where the gluteus tendon was advanced to a drill hole in the antero-lateral base of great trochanter, only two dislocations occurred in the next twenty cases. The increased stability achieved by gluteus tendon advancement was considered the key to this decreased dislocation rate.

Of the 7 dislocations only 1 (No. 472) occurred late in the field. The two month routine radiograph incidentally revealed anterior dislocation with the femoral head articulating with a pseudo-acetabulum in the ilium. The sheep was still mobile but was sacrificed.

Three fractures occurred requiring euthanasia. Sheep 479 (matt) was noted to be lame at

Day 70 and x-ray revealed a femoral shaft fracture. Sheep 490 (matt) was noted to be lame at Day 55, with a spiral fracture of the femoral shaft distal to the implant. Sheep 484 (collar) was lame at Day 30. An x-ray revealed a fracture through the base of the greater trochanter.

The aetiology of these fractures is unclear. The two shaft fractures at greater than 2 months post surgery probably were unrelated to the surgical technique of implantation. Any hair line fractures occurring during the preparation of the femoral canal would have displaced causing symptoms sooner. Extreme resorptive remodelling with spontaneous fracture through weakened bone is also unlikely at such an early stage post operatively. Radiographs did not show evidence for this extreme bone resorption. More likely an accident in the field either a fall during herding or a direct blow to the femur from another sheep or from a swing gate would have been responsible for the fracture.

One sheep (459 matt) suffered an anaesthetic complication during the 6 month radiographs. This sheep regurgitated a recent feed during the anaesthetic, aspirated and could not be resuscitated. Clinical and radiographic progress had been satisfactory up until this stage.

One sheep (489 polished) experienced severe dental decay resulting in tooth loss and inability to feed. It could not maintain its body weight and was sacrificed on veterinary advice at Day 101 post surgery. The clinical and radiographic performance of the hip joint was satisfactory until that stage.

There were no cases of aseptic loosening in this series causing a clinical limp or inability to manage the daily 4Km walking regime.

There were no clinical infections in this series. All wounds had healed within one to two weeks post surgery. No significant wound haematomas were noted.

All sheep without complications rehabilitated quickly following surgery. They managed the 4Km walk well. Veterinary input during the 10 months of the study was minimal and at the time of sacrifice the sheep were all in good physical condition.

3.9 SACRIFICE PROTOCOL

Ten months after surgical implantation, a general anaesthetic was administered and the right hip was surgically implanted with an identical prosthesis as the test side, with strict adherence to the operative protocol. In vivo radiographs were repeated. The sheep was then euthanased with a lethal dose of sodium pentobarbitone, in accordance with Institutional Animal Ethics Guidelines.

3.10 DISCUSSION

The objective of this study was to determine the appropriateness of the sheep as a model for hip replacement studies.

The advantages of the sheep have been outlined in the Introduction. This chapter described a protocol for THA including a new surgical approach for implantation, and rehabilitation. Also the study documented the difficulties encountered and suggested solutions to these problems. In the course of the study minor modifications to the surgical closure were made but these would not impinge on the primary objective of this project, that of determining the effect of implant design on bone remodelling.

The most common complication was dislocation occurring in 7 of the 30 cases (23%). The sheep hip is intrinsically more unstable than the human hip as the head is non-spherical and the acetabulum is relatively shallow. An important stabiliser of the sheep hip is the ligamentum teres, a thick fibrous band 0.5cm in diameter. Goodship (Personal Communication 1991) remarked on the size of this stabiliser and how a specially designed curved scalpel was required to divide it in order to dislocate the hip. Hip joint replacement involves division of the ligamentum teres and therefore loss of an important intrinsic stabiliser of the hip joint. Goodship (Personal Communication 1991) described a posterior approach for the sheep hip but did not report his dislocation rate. Radin *et al* (1982), in 36 total hip replacements through the posterior approach including acetabular implantation, reported no dislocations, however he did not report his method of closure.

We initially believed the posterior approach would be more unstable than the antero-lateral approach. Sheep tend to sit and lie on their hind limbs with the hind limb fixed,

abducted and internally rotated underneath them. This is the position of instability for a posterior approach. In humans the posterior approach is also associated with a higher incidence of dislocation in arthroplasty studies than the lateral approach (Morrey, 1992).

Turner *et al* (1981) and Sumner *et al* (1992) both used a cranio-lateral approach (equivalent to antero-lateral approach) in dogs and reported no dislocations. Their success was the incentive to develop the antero-lateral approach to the sheep hip replacements. This approach allowed good exposure of the proximal femur and acetabulum. With the gluteus accessorius tendon advancement, a stable closure was achieved allowing rapid rehabilitation and an acceptable dislocation rate. We would recommend the anterolateral approach in future sheep arthroplasty studies.



Fig 3.1 Femoral Implants for Sheep Arthroplasty
Polished, Collared Matt, Collarless Matt Designs
plus stem centraliser

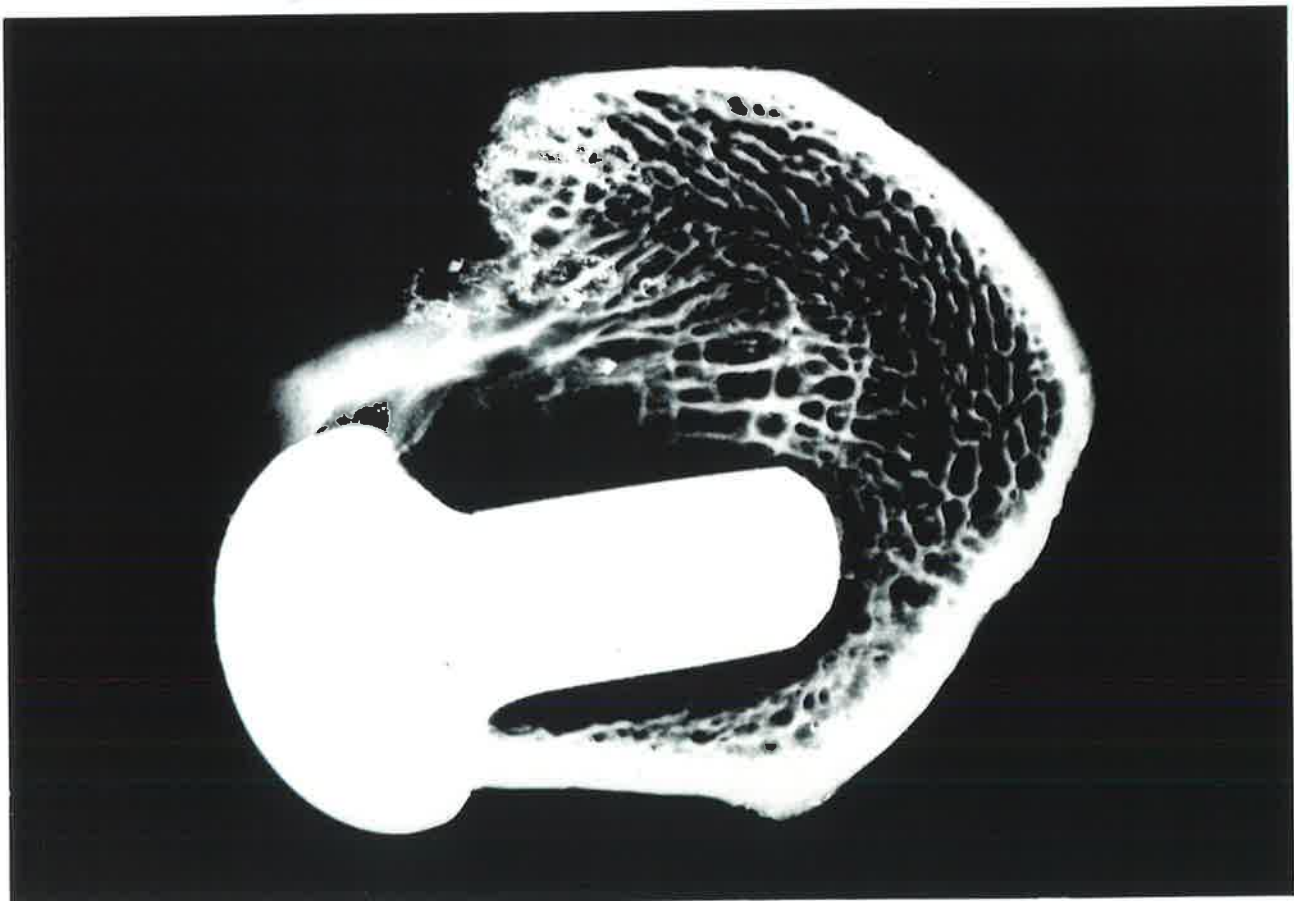


Fig 3.2 Cross section of a collared implant at the femoral neck osteotomy level
The dimensions of the collar allow complete coverage of medial and
some anterior bone cortex

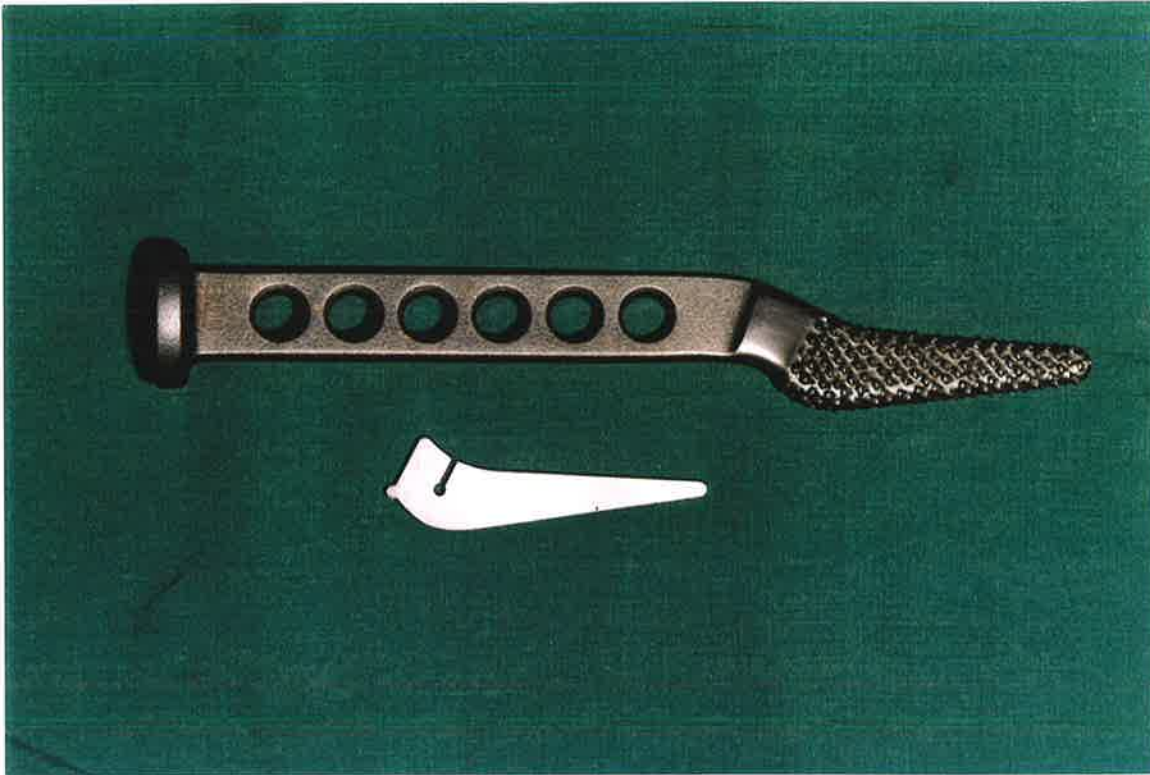


Fig 3.3 Femoral Neck Osteotomy guide and femoral broach custom made for sheep arthroplasty

Fig 3.4 Ex Vivo contact radiograph of the control femur (#482) indicating a high level of precision in femoral neck osteotomy and calcar coverage by the collar was achieved



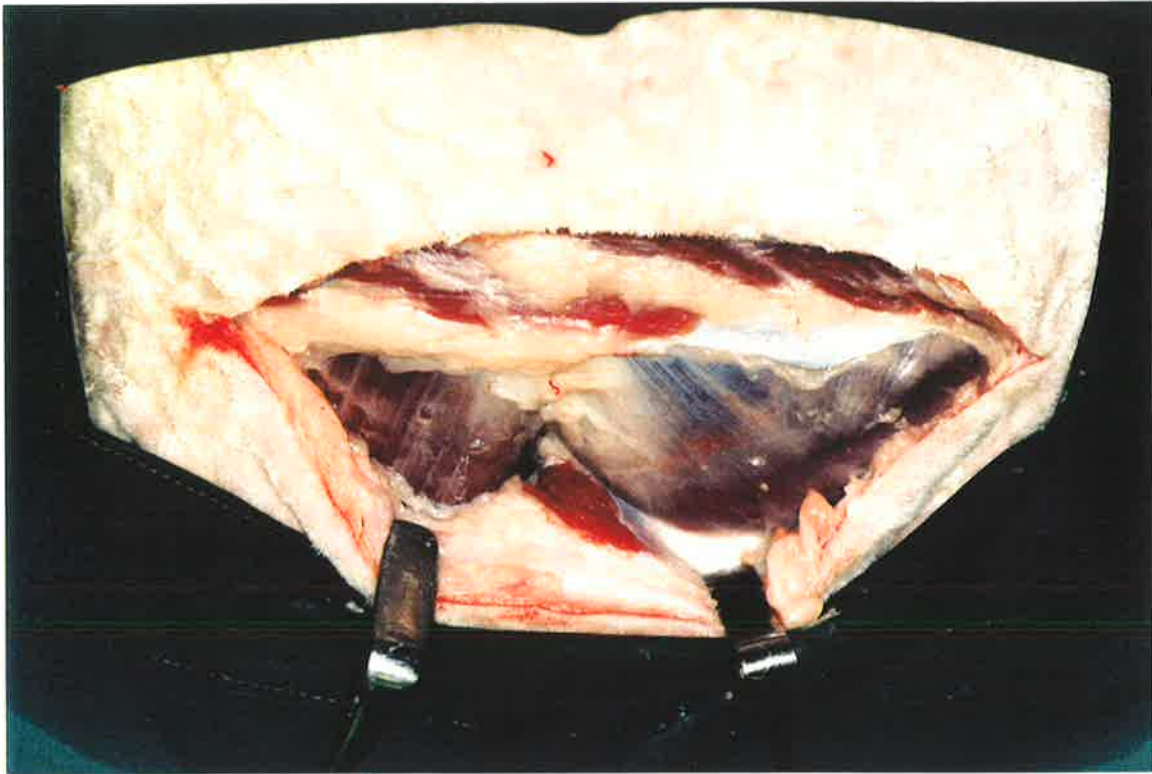


Fig 3.5 Surgical Exposure: superficial dissection through gluteus superficialis

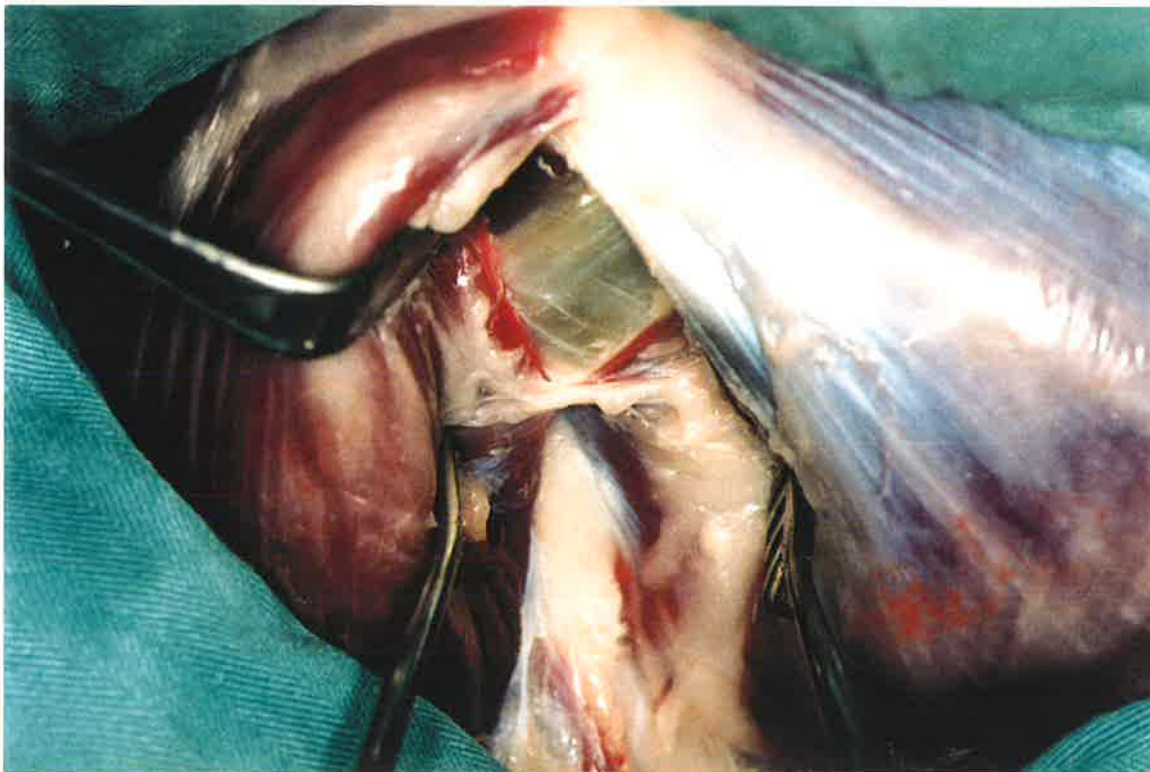


Fig 3.6 Surgical Exposure: deep dissection exposing gluteus accessorius

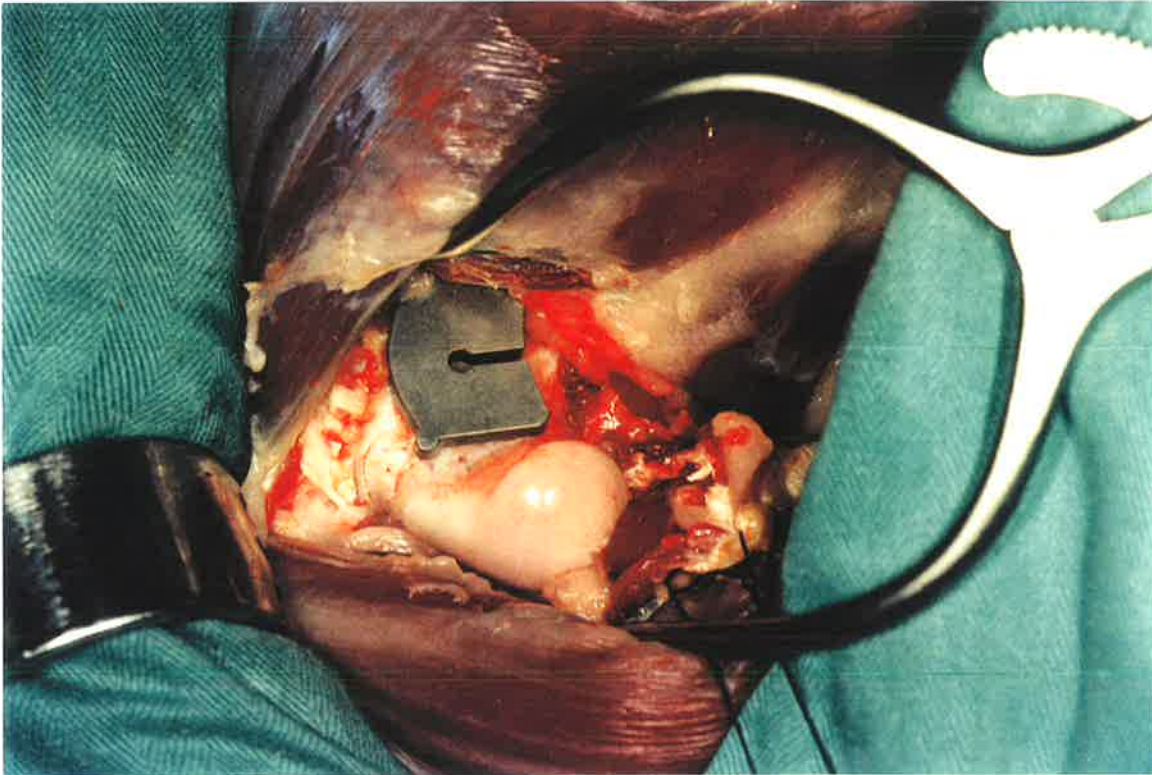


Fig 3.7 Femoral Head dislocated and cutting guide positioned for neck osteotomy

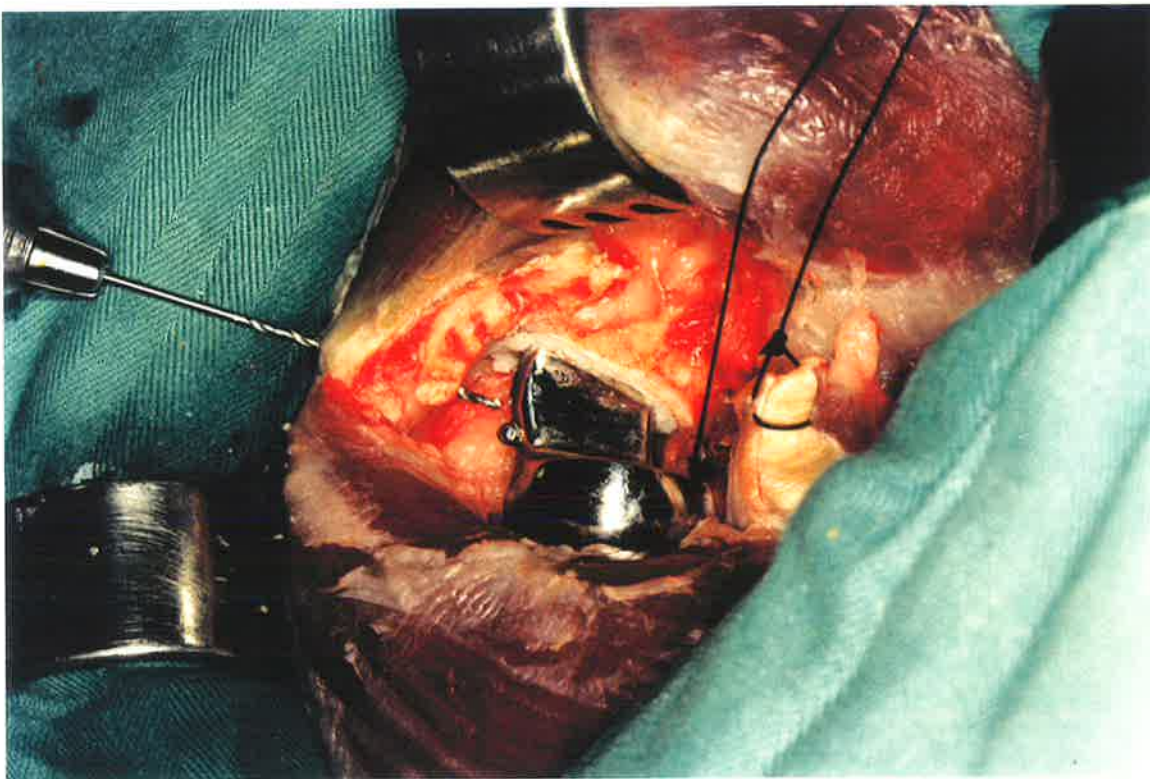


Fig 3.8 Femoral Implant inserted in neutral anteversion

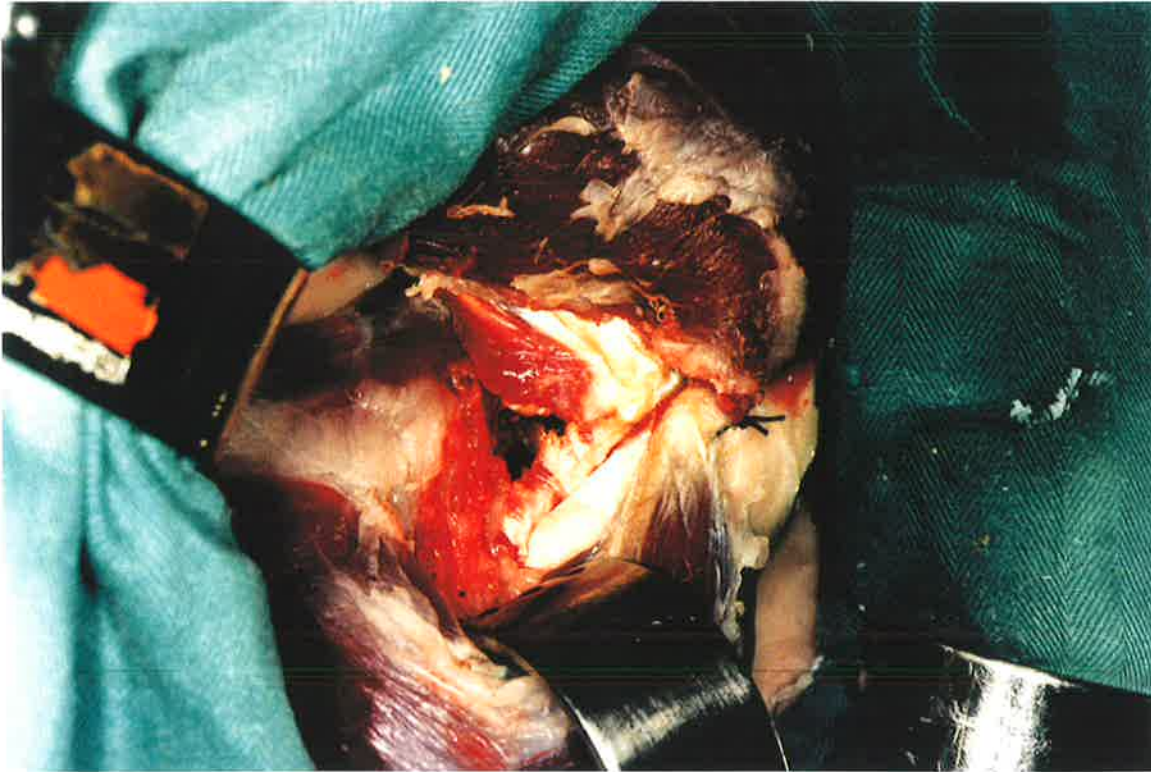


Fig 3.9 Gluteus accessorius tendon advanced and secured via a transosseous suture to the base of the greater trochanter



Fig 3.10 Sheep was recovered from anaesthetic by being suspended from poles in a sling



Fig 3.11 Sheep positioned in X-ray box for AP radiography of the operated hip



Fig 3.12 Post operative AP radiograph

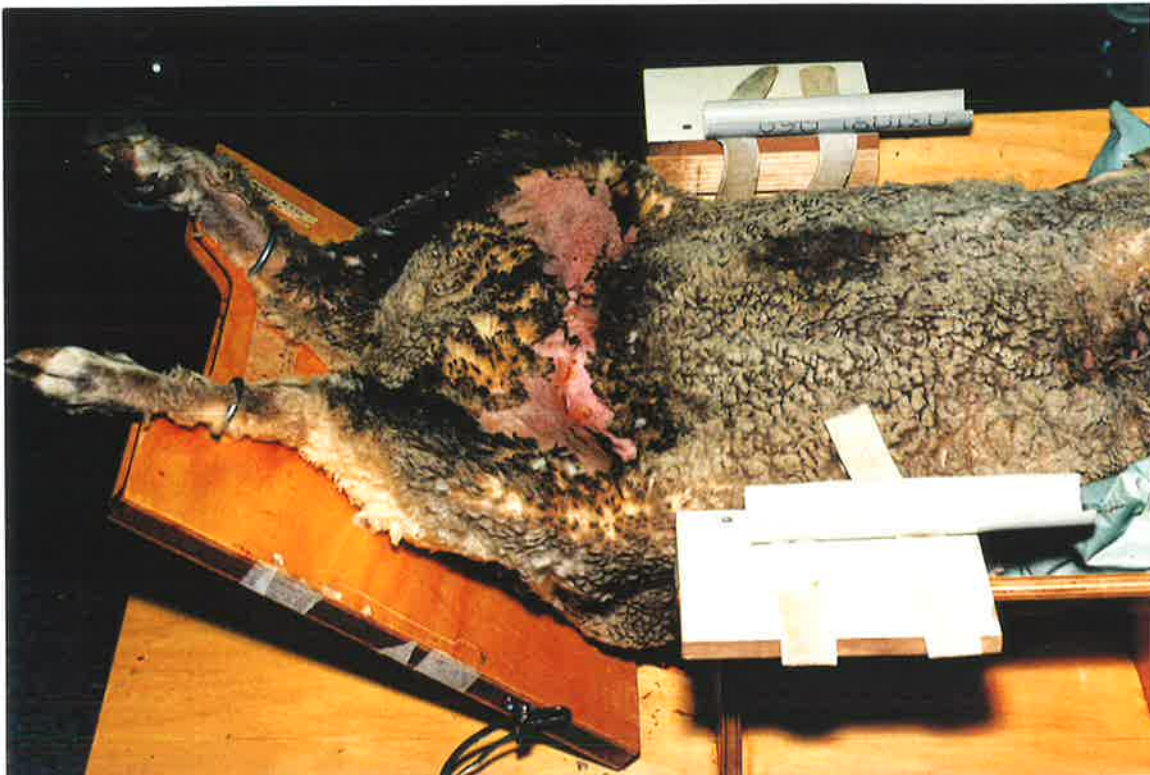


Fig 3.13 Sheep positioned in the frog leg lateral position for lateral radiograph of the operated hip

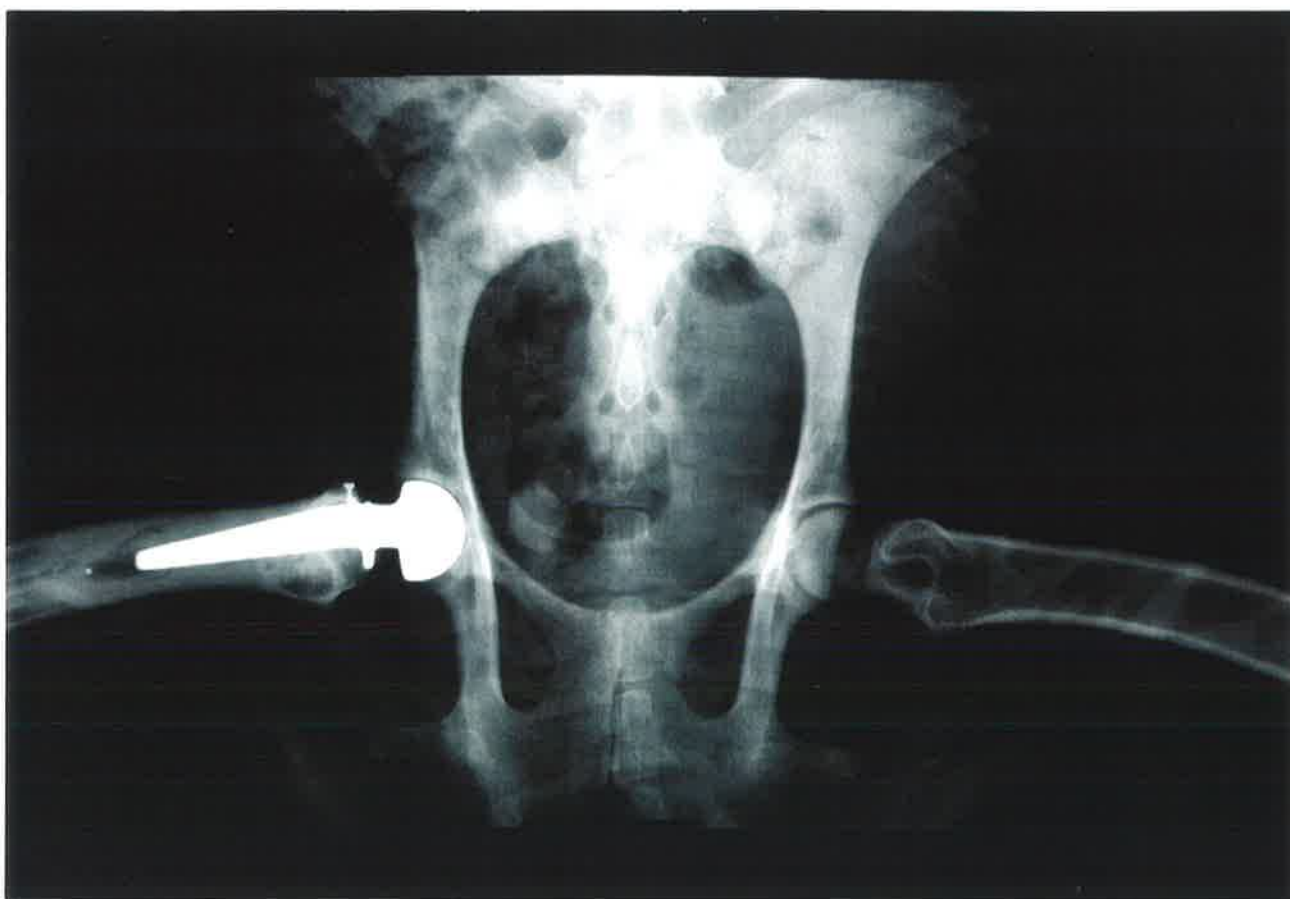


Fig 3.14 Post operative lateral radiograph

CHAPTER 4: CONTACT RADIOGRAPHY

4.1 INTRODUCTION

Radiographic analysis is the most important clinical tool in the evaluation of loosening in total hip replacement (Mulroy and Harris 1991). Radiographic criteria for loosening have been defined by Harris *et al* (1982) and have been widely adopted. A prosthesis is possibly loose when a new cement bone radiolucent line of any width is present at 50-100% of the interface, irrespective of width. Probable loosening is defined as a continuous radiolucent line at the cement bone interface. Definite loosening is defined as migration of the prosthesis, the presence of cement fractures or prosthesis fracture. The criterion of stem migration is controversial in the context of the Exeter philosophy with a polished double tapered cemented stem. In addition, a stem can be loose but not migrated to a measurable degree. Stem migration is commonly into a varus alignment in the femur and this is usually accompanied by calcar resorption.

This chapter describes an end stage radiographic examination of the outcome of cemented hip arthroplasty using the three femoral implant designs. All 18 surviving sheep were functioning satisfactorily on the 4km daily walk at the time of sacrifice. The aim of this study was to determine the incidence of radiographic categories of loosening in each of the three groups.

4.2 HYPOTHESIS

At 10 months after surgery there is no difference in the incidence of loosening in any of the groups.

4.3 METHODS AND MATERIALS

Ex vivo radiographs were taken for analysis of implant loosening. Following sacrifice, both control and study femurs were explanted and stripped of soft tissue. Contact radiographs of the bones were performed in a high resolution Faxitron (Hewlett Packard) radiographic unit. Technical specifications were voltage 70kV, exposure 4mAs, exposure time 18 seconds and Kodak film was used. Radiographic details such

as radiolucent lines, cement fracture etc could be optimised by the use of these high resolution Faxitron radiographs. Also the femurs could be accurately placed in the AP and lateral position directly onto the x-ray cassette, thus minimising magnification and projection errors.

An AP x-ray was taken with the femur supported on the film by the posterior aspect of the greater trochanter and posterior aspect of the femoral condyles. A lateral x-ray was taken with the femur placed on its medial side, supported by the medial femoral condyle and implant head, and rotated such that the line between the posterior femoral condyles was perpendicular to the horizontal. The femur was fixed in this lateral position by plasticine moulded around the distal end of the bone.

Radiographic evaluation was performed by one observer (the author) in all cases.

4.3.1 Radiolucent Line Evaluation

Radiolucent lines at the bone cement interface were measured using a transparent plastic ruler calibrated by 1mm increments. The midline of the femoral stem was marked on both AP and lateral projections and 3 transverse lines drawn perpendicular to the midline demarcating Gruen's zones 1 to 14. (Gruen *et al* 1979). The presence or absence of a radiolucent line in each Gruen zone was recorded, irrespective of width. Radiographs were examined for continuous radiolucent lines at the cement bone interface, and those radiolucent lines extending 50-100% of the cement bone interface.

4.3.2 Subsidence Evaluation

At the outset of this study, it was planned to measure subsidence by reference to two 1mm marker ball bearings. One was inserted in the proximal lateral cement mantle and implant subsidence could be determined from measuring the distance between it as a fixed point, and a marker ball welded on the lateral implant neck. The 2nd 1mm marker ball was embedded in the tip of the stem centraliser. Subsidence of the stem into the centraliser would be measured by the decrease in distance between the stem tip and the marker ball on serial in vivo radiographs. It became apparent however that both these 2 techniques would not be useful. The marker ball was occasionally obscured by thick folds of soft tissue. Also standardising the position of the femur for serial in vivo

radiographs was difficult even using the x-ray box. Errors in linear measurement would occur from the variable angle of radiographic projection and magnification factors.

In this study, subsidence was measured as the gap between the convex shoulder of the prosthesis and the adjacent cement mantle (Charnley 1979, Fowler *et al* 1988). In the clinical setting this technique also has its limitations due to difficulty in standardising the position of the femur. The variation in angle of radiographic projection, and the effect of magnification from the variable tube to target distance, will alter the width of radiolucent gap measured at the implant cement interface. Charnley (1979) believed the technique is only useful to detect subsidence of 1-2mm in magnitude.

With high resolution contact radiography of ex vivo specimens, the projection errors and magnification errors are minimised and this method of measuring subsidence has greater applicability. When the implant is seating intra operatively to the level of the marker circle, cement extrudes around the convex lateral shoulder of the implant. Any subsequent in vivo subsidence of the stem from this cement margin may be detected and measured as a radiolucent gap on the high resolution Faxitron radiograph.

4.3.3 Other Radiographic Features

The presence of cement fractures were documented by Gruen zone (Fig 4.1, 4.2). Radiographs were examined for any areas of Osteolysis which were measured and documented by zone.

The alignment of the stem within the intramedullary canal was examined. A line drawn down the longitudinal axis of the implant was measured against a line drawn down the longitudinal axis of the proximal femur. A goniometer with 2° increments was used. Varus of valgus malalignment was measured to the nearest 2°.

Gross changes in the bony calcar were recorded. A line along the medial femoral neck osteotomy was drawn and a perpendicular line drawn inferiorly to this, alongside the calcar. The degree of calcar resorption or new bone formation were measured in mm along this line from the level of the femoral neck osteotomy.

4.4 RESULTS

No hip demonstrated definite radiographic signs of loosening at 10 months post surgery. No migration or subsidence of the implant was noted, and no cement fractures were apparent on either the AP or lateral radiographs (Fig 4.1, 4.2).

Using Harris's other criteria, none of the implants were probably loose. No hips had a continuous radiolucent line at the bone cement Interface on either the AP or lateral radiographs.

Two hips were possibly loose with radiolucent lines extending 50-100% of the bone cement interface. Hip 493 (polish) had incomplete 2mm lines in Gruen zones 3 to 6 on the AP radiograph. This was associated with 18mm loss of calcar, though there was no radiographic evidence for implant subsidence malalignment or cement fractures (Fig 4.3). This situation however indicates imminent loosening of the stem with the potential of the stem to eventually subside into varus.

Hip 473 (matt) also had 1mm or less than 1mm radiolucent lines in 4 of the 7 Gruen zones on the AP radiograph and 4 of 7 zones on the lateral radiograph. There were no other adverse features to indicate loosening.

Nine other hips: Polished (496, 494, 477, 485), collared (475,482,486) and matt (470,486) had sporadic 1mm or less than 1mm radiolucent lines observed.

7 study femurs (4 collared 499, 491, 476, 487; 2 polished 480, 481; 1 matt 460) showed no radiolucent line formation at all.

Calcar bone changes were variable. Only 1 hip (493 polish) demonstrated radiographically apparent calcar absorption. The area of osteolysis measured approximately 18mm in length and was associated with an incomplete radiolucent line to indicate possible loosening on Harris's criteria.

Every other study femur showed some signs of calcar bone hypertrophy or periosteal new bone formation (Fig 4.4). This was most commonly 0.5cm-1cm of poorly trabeculated bone at the neck osteotomy level. However occasionally discrete beaks of

well trabeculated bone were noted below the level of the neck (Fig 4.1).

4.5 DISCUSSION

The pattern of bony hypertrophy and deposition at the femoral neck osteotomy can be attributed to artefacts of two aspects of surgical technique. Firstly in preparation for femoral neck osteotomy, a periosteal elevator was used to elevate capsule and periosteum medially. This would stimulate a poorly trabeculated periosteal new bone reaction at the osteotomy site. Secondly, to enable canal preparation the femur was elevated from the wound using a Hohmann elevator with the pointed tip placed postero-medially on the calcar. The cortical and periosteal injury caused by the Hohmann would stimulate formation of an additional densely trabeculated spike of new bone seen in the calcar region.

The objective of this chapter was to determine on radiographic grounds if any implant was loose. This analysis of post sacrifice radiographs followed clinically accepted guidelines for radiographic evaluation of loosening. As these radiographs were contact x-rays taken in a high resolution Faxitron unit with the XR beam centred over the proximal femur, the detection and evaluation of subtle radiographic signs of loosening was superior to clinical in vivo x-rays taken centred on the symphysis pubis.

The technique to detect subsidence employed in this study was relatively crude compared to the more complex and unwieldy method of RSA (roentgenographic stereographic assay). This technique involves implanting a number of metal marker balls and subsequent computer assisted analysis (Chafetz *et al* 1984, Mjoberg *et al* 1986). Migration as little as 0.2mm can be detected. Subsidence has also been measured from implanted screws or trochanteric wires to an implant reference point (Mulroy *et al* 1991). These techniques are not in widespread clinical use and also require reproducibly positioned radiographs taken at two different time points (Amstutz *et al* 1986).

The measurement of subsidence was not central to this study. Though Harris's criteria for definite loosening included migration of the implant, this criterion is controversial in the context of the polished double tapered stem which is designed to subside at the prosthesis cement interface.

The significance and interpretation of radiolucent lines with respect to loosening is also not clear cut. Radiolucent lines may also be due to bone remodelling and secondary medullary canal formation in the endosteal cortex (Kwong *et al* 1991). This occurs with stably fixed implants and is not in itself associated with a loosening process. Lucent lines may be due to other phenomenon apart from loosening and fibrous membrane formation at the bone cement interface. Slender lucent lines may be attributable to the Mach Effect (Lanc *et al* 1976). This occurs at an interface where radiographic density abruptly changes (such as at the bone cement interface). This sudden density change is perceived as a radiolucent line. In addition a bone cement interface radiolucency may be due to poor cement technique where the injected cement is not pressurised onto the endosteal bone surface, leaving an interface void. This cement mantle defect may predispose to subsequent aseptic loosening, but its presence does not necessarily imply that the implant is loose.

Using Harris's radiographic criteria only 2 hips 493 (polish) and 473 (matt) were possibly loose. Sheep 493 additionally had a marked degree of calcar lysis. Though not considered in Harris's criteria, this lysis together with an incomplete but extensive 2mm wide lucent line indicates a poor prognosis for eventual implant loosening in this subject.

All the other hips were soundly fixed at the bone cement interface by Harris's radiographic criteria. Thus after 10 months of loading, no hip from any of the 3 implant groups was definitely or probably loose on radiographic criteria. The way is now clear to examine bone remodelling changes around cemented implants without the confounding effects on bone resorption due to a loosening process. The responses of the sheep femur to the implantation of femoral stems are described in Chapter 5 and 6.

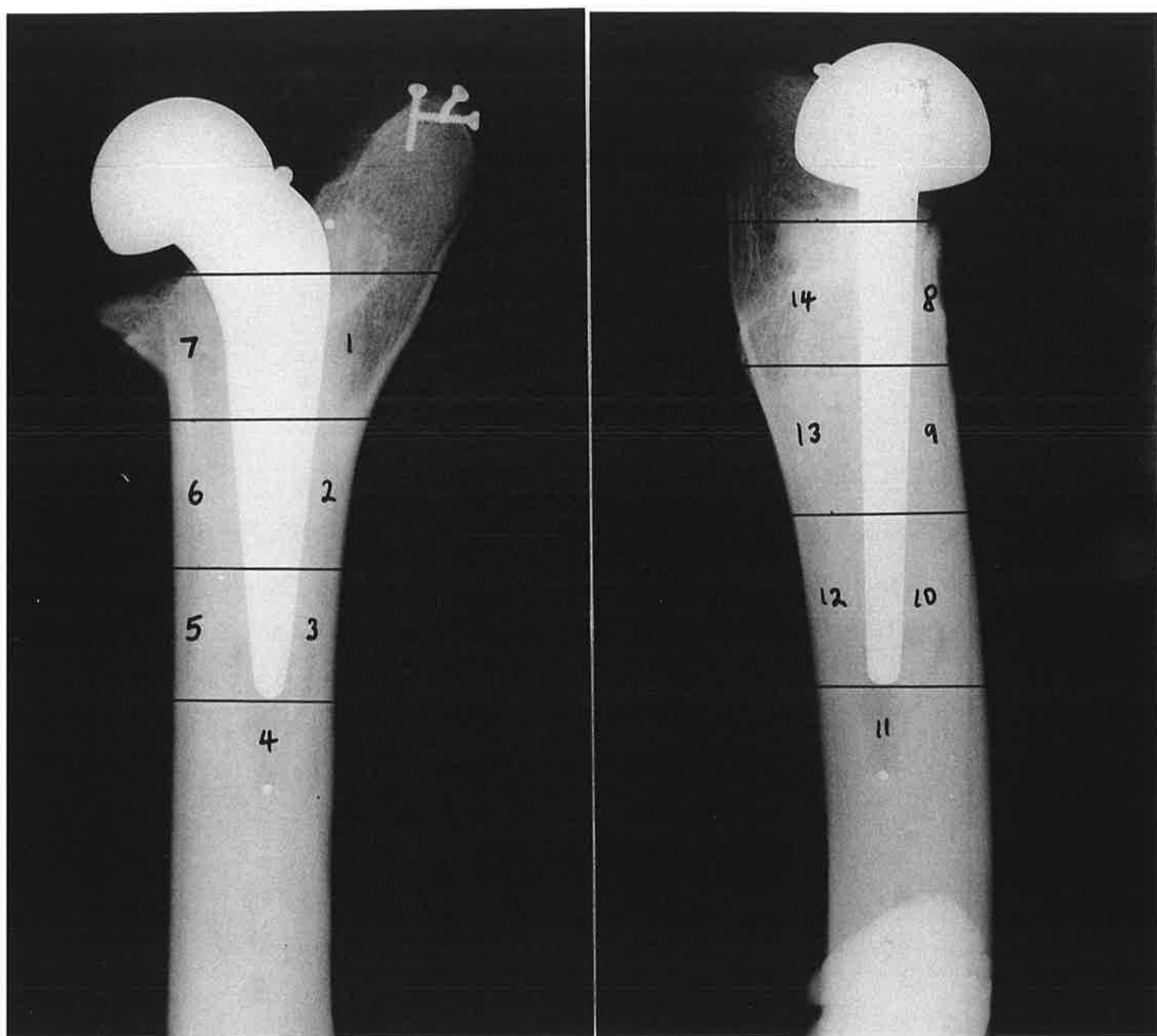


Fig 4.1 Fig 4.2 Sheep 485 Study (polished implant)

AP and lateral high resolution contact x-rays illustrate high degree of radiographic detail achieved. Gruen zones 1-14 are shown. Sporadic radiolucent lines were observed but no subsidence cement fractures or malalignment. Poorly trabeculated new bone occasionally formed at the calcar, as illustrated here. This was probably related to artefacts of surgical exposure.

Fig 4.3 AP contact radiograph 493 Study (polish)
Radiolucent line extending 50-100% of Bone Cement Interface indicating possible loosening. Extensive calcar lysis herald loosening of this implant

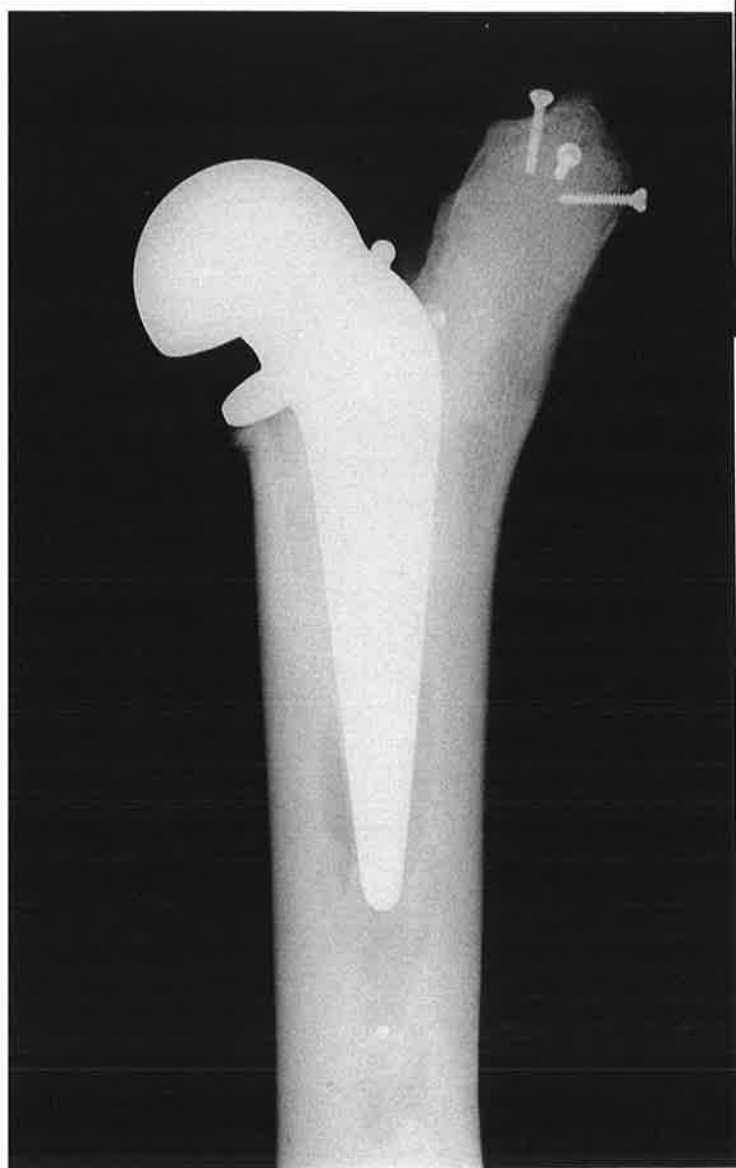


Fig 4.4 AP contact radiographs 482 Study (collared)
Poorly trabeculated periosteal new bone formation at the calcar most probably related to artefacts of surgical exposure

CHAPTER 5: CORTICAL STRAIN ANALYSIS

5.1 INTRODUCTION

Strain reorganisation occurring over time may vary with the design of implants. Previous in vitro studies have shown the immediate effect on cortical strain of insertion of collared and collarless femoral stems. These observed strain patterns may not however persist with in vivo loading as the implants subside or the collar is defunctioned by calcar resorption.

These dynamic changes in cortical strain have been incompletely studied to date. Retrieved cadaver implants (Maloney *et al* 1996, Engh *et al* 1992) have shown the dramatic strain shielding, which persists with time. Cortical strain magnitudes did not return towards normal as has been predicted by adaptive bone remodelling theory. The specimens however were sporadic retrievals with uncontrolled variables of implant type, duration of implantation, and patient factors.

The understanding of the changes in cortical strain following remodelling around femoral implants of different designs, therefore, remains unclear. In the following experiments, a protocol for cortical strain measurement in the proximal femur was developed and validated. The protocol was applied to analyse cortical strain differences after remodelling in each implant group. Triaxial strain gauge rosettes were used to fully describe the changes in strain patterns in the proximal femur after multiplane loads of physiological magnitude were applied.

The objectives of this study were firstly to examine the validity of adaptive bone remodelling theory for each implant group, in a more controlled situation than is possible with retrieval studies.

The second objective was to examine via an intergroup analysis if the variables of implant design have a bearing on strain changes which occur following in vivo loading. Specifically does the collar continue to load the calcar axially with strain? Also does the polished tapered stem with the capacity to subside, load the proximal femur with more hoop strain than the matt or collared designs?

5.2 NULL HYPOTHESIS

The change in cortical strain pattern with remodelling around a polished double tapered cemented stem is no different from a matt collared or matt collarless tapered stem.

5.3 STRAIN GAUGE INSTRUMENTATION

5.3.1 Introduction

In this section the instrumentation for recording cortical strain of an explanted sheep femur is described. Also the technical details of preparing the femur, positioning and applying strain gauge rosettes, and loading the bone are described.

5.3.2 Bone Preparation

Both left (study) and right (control) femurs were harvested from the sheep after sacrifice. All soft tissue was sharply removed from the bone with a scalpel and periosteal elevator. The cortex was polished with fine grit sandpaper, then the cortex was defatted, cleaned and dried with methanol (Oh and Harris 1978, Page *et al* 1991).

Precautions were taken to prevent dehydration of bone during the testing process. Dehydration increases the degree of brittleness compared to wet bone (Debestani 1992). The bone was therefore sprayed every five minutes throughout the duration of the testing procedure with an aerosol of isotonic saline solution. All testing was done with bones at room temperature (20°C) though ambient humidity was not controlled (Oh and Harris 1978).

5.3.3 Strain Gauge Application

Triaxial strain gauge rosettes (KFW-D17 Kyowa Japan) were used. Each rosette comprised three separate strain gauges aligned to measure strain in the longitudinal, transverse and 45° oblique directions respectively. These rosettes were available pre-wired and encapsulated in a water proof sheath. These features enabled minimising handling of the strain gauges and increased the ease of bonding of the strain gauge to the

curved and irregular bony surface. The waterproof sheath in addition protected the strain gauges from becoming debonded from bone during the wetting of the bone with saline.

The rosettes were fixed to the prepared cortical surface of the proximal femur with cyanoacrylate cement (CC33 Kyowa Japan). Finger pressure was applied for 30 seconds. The cement was allowed to harden for 5 minutes before any mechanical testing commenced.

Rosettes can record strain only from the immediately underlying bone surface. Debestani (1992) recommended that the number and distribution of rosettes should be adequate to provide an accurate indication of the strain pattern in bone, allowing for its non homogeneous and anisotropic character. In human femoral strain gauge studies, between 6 and 16 strain gauge rosettes have been positioned on the peri prosthetic cortex (Oh and Harris 1978, McBeath *et al* 1980, Maloney *et al* 1989). These rosettes were placed on anterior, posterior, medial and lateral surfaces of the bone at up to four levels. In a canine hip arthroplasty model, Page (1991) used 6 strain gauge rosettes in the proximal femur, three medially, two laterally and one anteriorly. Bobyn *et al* (1992) in a cementless canine hip arthroplasty model used 16 rosettes positioned at four levels.

None of the above authors, however, used waterproof rosettes which are significantly larger due to the enclosing plastic sheath. As extensive and time consuming strain studies require regular saline wetting of bone, the plastic sheath was indispensable for this study. The size of this sheath limits the number of rosettes which may be applied to the proximal femur of the sheep. Langkamer (1992a) measured in vivo cortical strain following THA in sheep. He did not specify if they were encased in a waterproof sheath but only 3 rosettes were used. We chose to use 4 triaxial rosettes per femur, 2 medially, 2 laterally; at one proximal and at one distal level.

5.3.4 Strain Gauge Positioning Protocol

Accurate definition of the position for each rosette is important to enable valid comparison of strain gauge recordings from corresponding locations between left and right femurs. In this study, these rosette sites were located by referencing from the femoral anatomy. The implant was not used as a reference point as the implant may have subsided into a relatively different position from the control side after 10 months of in

vivo loading.

The femur was placed in a right angled jig such that it rested on the posterior aspect of the femoral condyles and the posterior aspect of the greater trochanter. These posterior anatomical features defined the coronal plane (Goel *et al* 1982). The distal femoral condyles both made contact with the horizontal arm of the jig. The total length of the femur from the tip of the greater trochanter to the distal end of the condyles was measured. A mark was made on the anterior femoral cortex at 75% of its length from the distal end. A further mark was made on the anterior cortex at 40%, 50% and 60% from the distal end (Fig 5.1). Using a sliding block ruler, a horizontal line was drawn, perpendicular to the vertical arm of the jig, at the 75% and 60% marks. The medio-lateral mid point of the femur was marked at these two levels using a two point digital calliper micrometer (Miyamoto, Japan). The micrometer was held horizontally with the aid of a spirit level. An anterior line was drawn between these two medio-lateral mid points. This line therefore defined the longitudinal axis of the proximal femur and would have approximated the longitudinal axis of the implant unless the implant had been inserted in varus or valgus. When the implant position was central in the femoral intramedullary canal, then this longitudinal line would also correspond with the longitudinal axis of the implant.

The circumference of the femur was measured at the 75% and 60% marks and the two circumference lines were drawn onto the cortical surface at 90° to the anterior line. 20% of each circumference measurement was calculated and this distance from the anterior line was marked on the medial side, ie. along the medial cortex. 30% of each circumference measurement was marked from the anterior line onto the lateral cortex. A longitudinal line was drawn between the two medial marks and the two lateral marks, at the 75% and 60% levels (Fig 5.2).

The 4 strain gauge rosettes were placed on the anterior edge of the medial and lateral longitudinal line at the level of the 75% and 60% circumference lines. The proximal medial strain gauge rosette (rosette 1) was therefore at approximately the same transverse level as the base of the lesser trochanter, 1cm distal to the level of the medial cut surface of the femoral neck (Fig 5.3). The proximal lateral strain gauge rosette (rosette 2) was placed at the junction of the proximal femoral metaphysis with the flare out into the greater trochanter (Fig 5.4). The distal two rosettes (rosette 3 medially and

rosette 4 laterally) were positioned approximately 5mm proximal to the tip of the implant.

Strain gauge rosettes were connected to strain amplifiers, the signals from which were sent to an A-D card (Fig 5.5). The data were analysed by a custom written computer program. For each rosette the longitudinal, transverse and oblique strain was recorded and used to calculate the principal compressive strain magnitude and direction, and the principal tensile strain magnitude and direction (Debastani 1992).

5.3.5 Femoral Mounting

Following strain gauge application the femur was mounted and prepared for mechanical testing. The femur was fixed and potted in methylmethacrylate cement. The vertical position was defined by the longitudinal axis of the implant and the femur was suspended in the vertical position by a custom made loading jig. This jig had a slot which slid and secured over the implant neck and rigidly clamped the undersurface of the implant head. Radiographically all of the control or study implants were in neutral alignment in the femoral canal (Chapter 4). The femur thus vertically aligned was lowered by the loading jig into a metal pot containing liquid dental cement (Halas). The distal 40% of the femur was submerged in cement. The cement was allowed to cure for 40 minutes. During this time, the femur was wrapped in saline soaked gauze to prevent dehydration.

5.3.6 Application of Load

Loads were applied to the femoral head of the implant in three planes; axial, coronal and sagittal. Three separate planes of loading were performed as the resultant maximal vector of force acting on the sheep hip joint is unknown. In humans, peak loads through the hip joint are known to occur in stair climbing (Burke *et al* 1991), and human femoral strain gauge studies have utilised complex loading jigs simulating these loading modes. Cables have been used to simulate the vectors of force acting on the femur by the abductor and extensor muscle masses (Maloney *et al* 1989, Engh *et al* 1992, Burke *et al* 1988). Similar complex loading systems have been utilised in canine hip arthroplasty strain studies. (Page *et al* 1988, 1991).

In sheep, Lanyon *et al* (1981) has calculated the in vivo resultant load acting on the proximal femur via the femoral head during walking. This resultant force was the sum of muscle and ligament actions as well as the hip joint forces from weight bearing. It was decided to resolve this resultant force into its axial, coronal, and sagittal components and to measure strain changes to each of these load vectors independently. This therefore makes it unnecessary to design complex loading jigs simulating the pelvis and estimating force vectors from the various muscle groups around the proximal femur.

The axial load applied in Newtons was $5.92 \times$ the body weight measured in kg. The antero-posterior (AP) load applied was $2.15 \times$ the body weight (kg); and the medio-lateral (ML) load applied was $4.15 \times$ the body weight (kg) (Appendix 3). These force vectors are equivalent to those the sheep hip undergoes in vivo during the walking cycle.

Loads were applied to the implant head by a custom made loading jig. The jig remained clamped rigidly around the implant neck and underside of the femoral head. The loading jig was bolted to a Hounsfield universal testing machine (H25KM). A load cell of 2000 Newtons capacity was utilised. Loading was in the dynamic mode. 5 cycles of load were applied in each plane at a cross head speed of 5mm per minute. The first 4 cycles were disregarded to exclude any viscoelastic response which may have occurred in bone. A stable conditioned response to load was thus achieved. Deformation of cortical bone under load generated a voltage recording in the overlying strain gauge. This voltage was converted to microstrain. Fig 5.6 illustrates the typical micro strain recording under load for all 12 strain gauges.

Axial loading was performed first. The base of the metal pot holding the cemented distal end of the femur was supported by a ball bearing resting on a flat metal base plate (Fig 5.7). Any off axis error in potting the femur would therefore have a minimal effect on preloading the femur, compared to if the pot was supported but not flush against the metal base plate. Prior to application of cortical load, the 12 strain gauges were zeroed, eliminating any prestrain.

Antero-posterior (AP) loading to the implant was in the sagittal plane and was performed by the metal pot being placed on its side such that the anterior aspect of the femoral head was uppermost and the implant neck (inserted in neutral version) was horizontal as indicated by a spirit level. The pot was locked into position on a custom-made grooved

metal baseplate and the femoral head was loaded by the loading jig (Fig 5.8). The test (left) hip was loaded with the loading jig pulling upward on the implant head. The control (right) hip was loaded with the loading jig applying an equal downward force on the implant head. Thus load was always directed from the implant towards the proximal femur anterior cortex.

Medio-lateral (ML) loading to the implant was in the coronal plane and was performed by the metal pot being rotated 90° on its side while on the grooved metal base plate such that the implant neck was vertical. The pot was then clamped rigidly into the groove. The medial aspect of the femoral head was loaded by the disc and loading jig, applying a valgus stress to the implant (Fig 5.9).

Clamping of the pot into the grooved base plate occasionally caused a preload with a small prestrain being registered prior to the onset of any ML load. This prestrain was eliminated by re-zeroing.

Fig 5.1 Strain Gauge Positioning
Protocol
Marking Reference
Levels

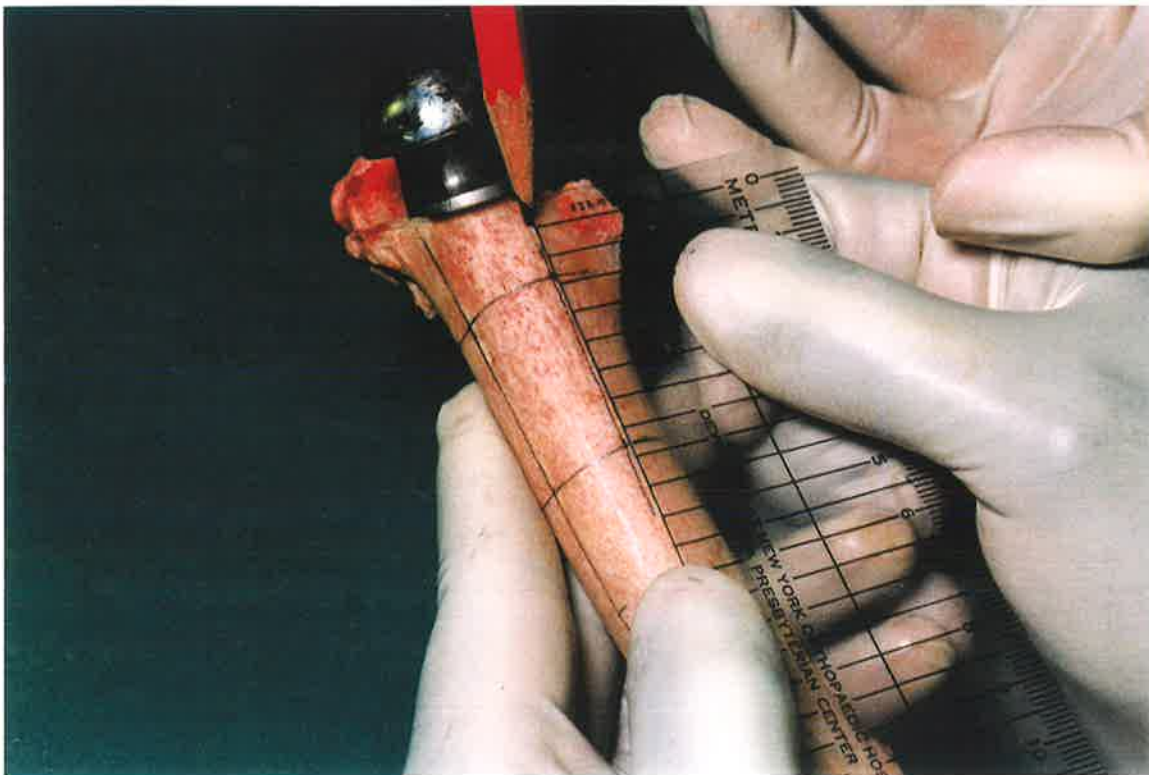
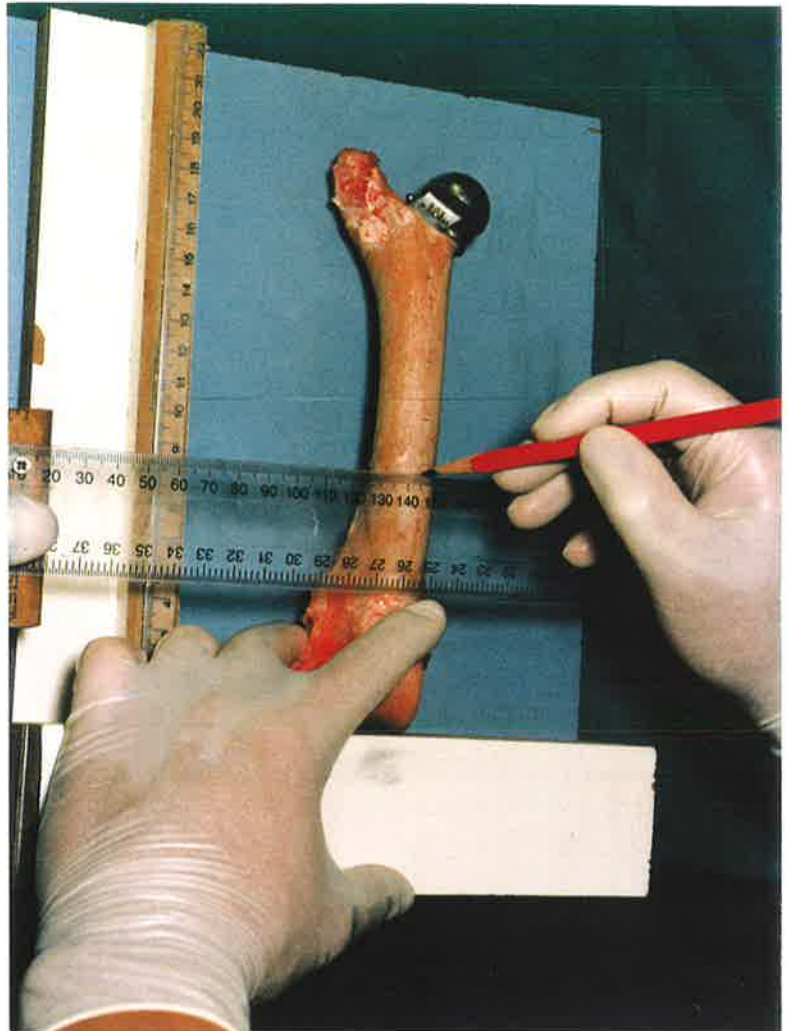


Fig 5.2 Strain Gauge Positioning Protocol
Marking Reference Lines

Fig 5.3 Strain Gauge Positioning Protocol
Medial Aspect (Study Femur)

rosette 1
(strain gauges 1-3)

rosette 3
(strain gauges 7-9)

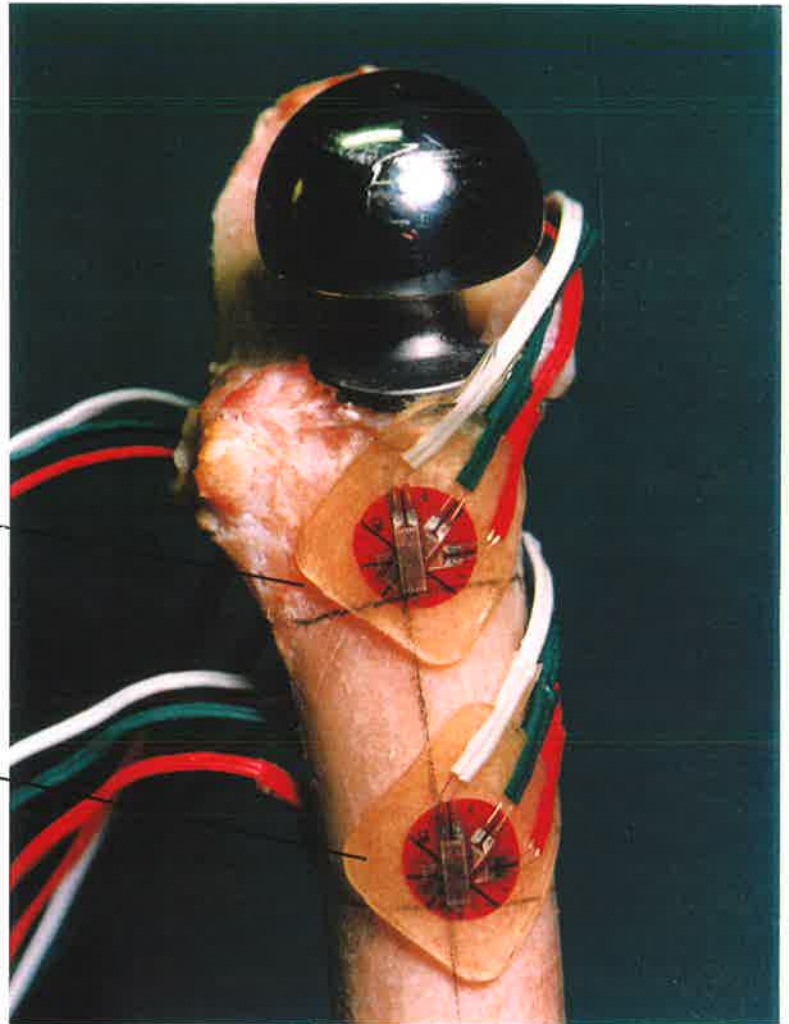


Fig 5.4 Strain Gauge Positioning Protocol
Lateral Aspect (Study Femur)

rosette 2
(strain gauges 4-6)

rosette 4
(strain gauges 10-12)

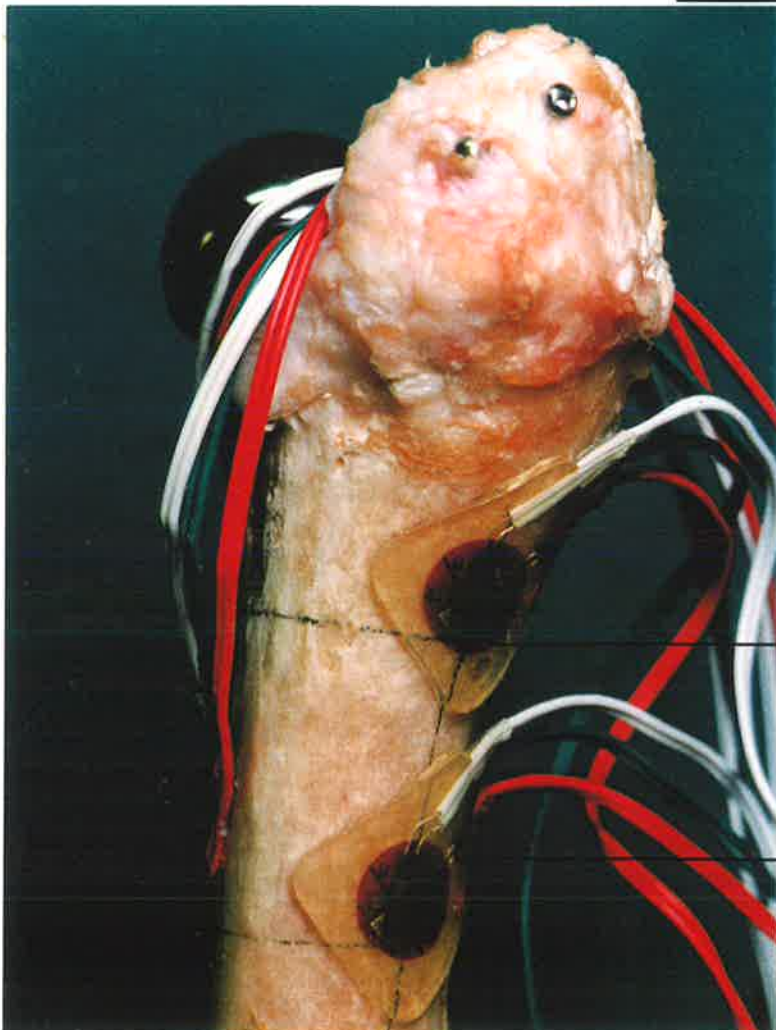




Fig 5.5 Cortical Strain Measurement

1 - Loading Jig

2 - Testing Machine

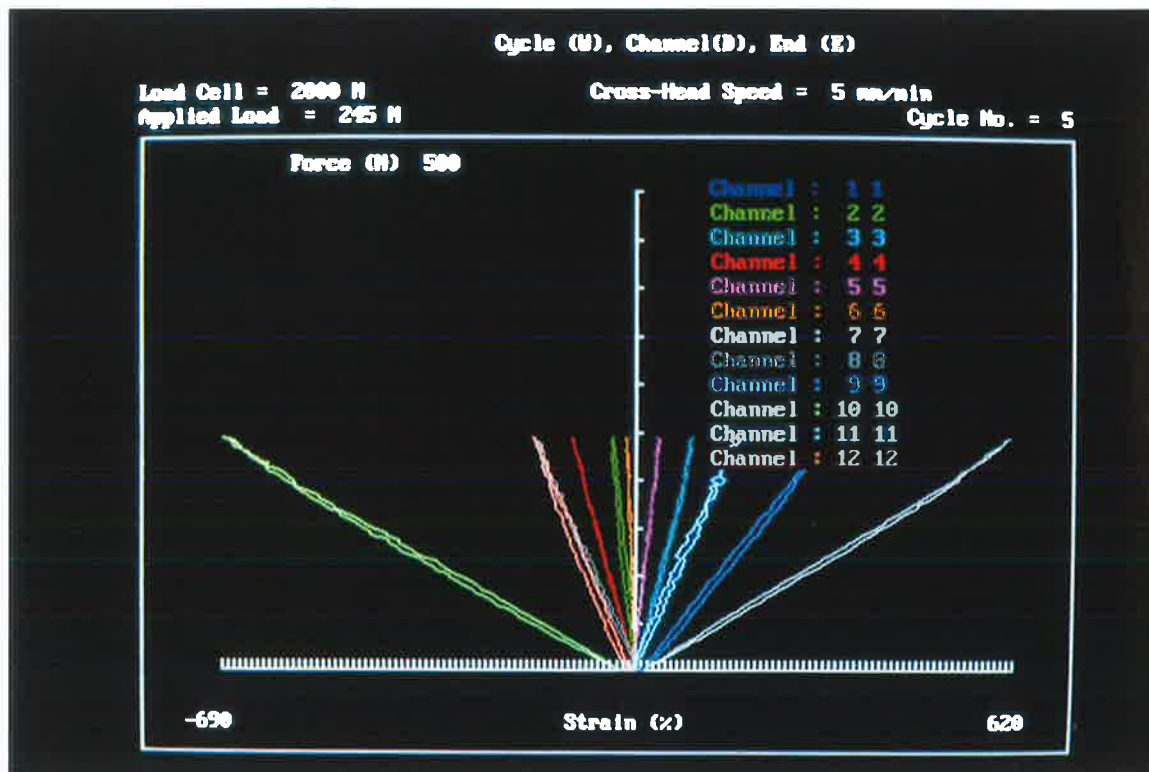


Fig 5.6 Microstrain Recording From 12 Strain Gauges Under Load

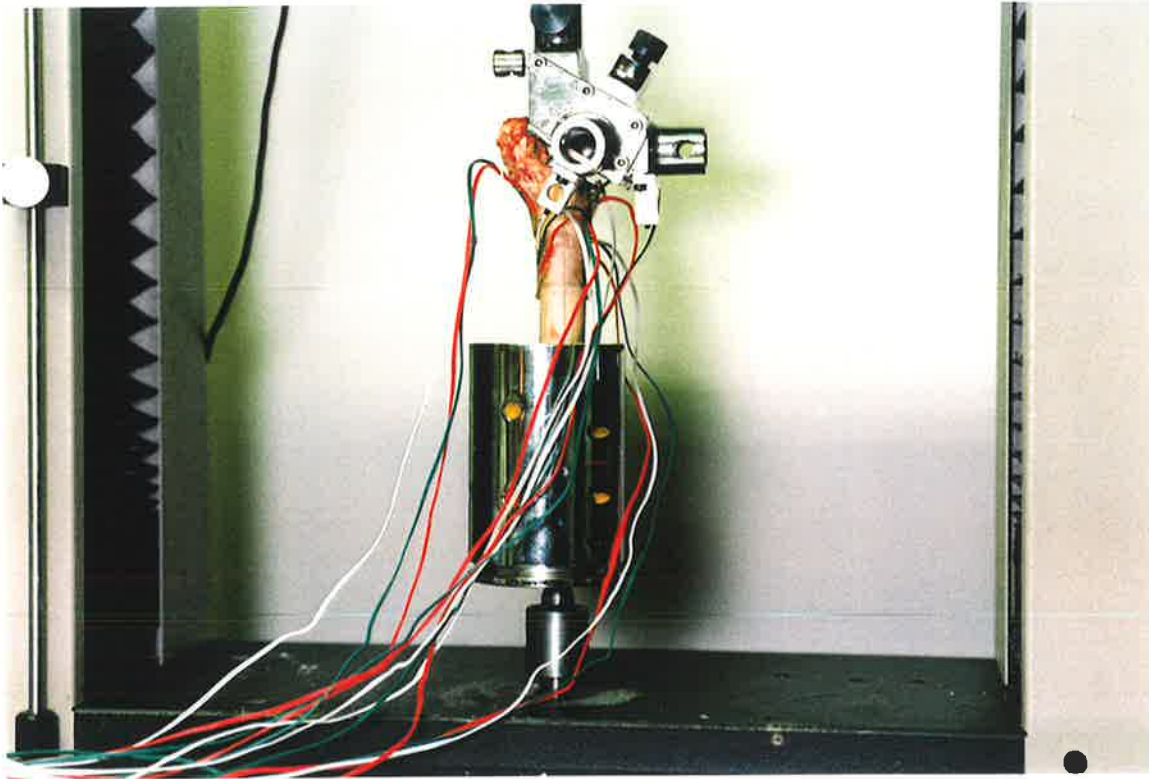


Fig 5.7 Axial Loading

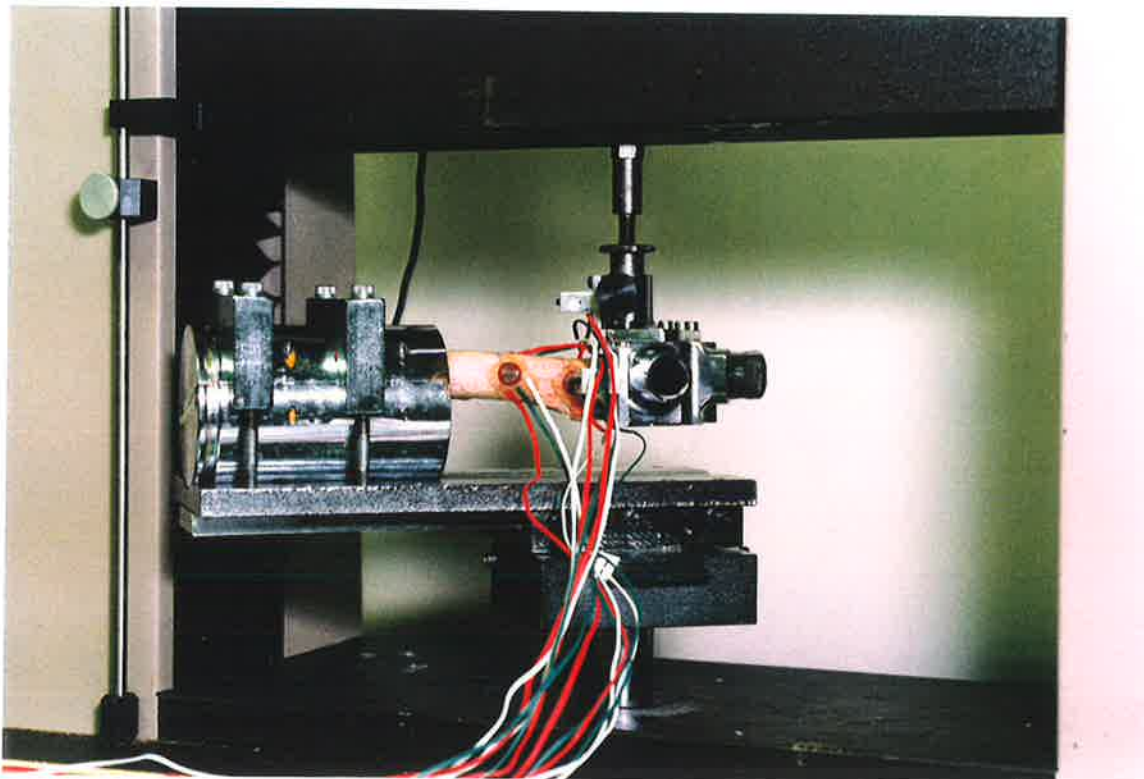


Fig 5.8 Antero-Posterior Loading

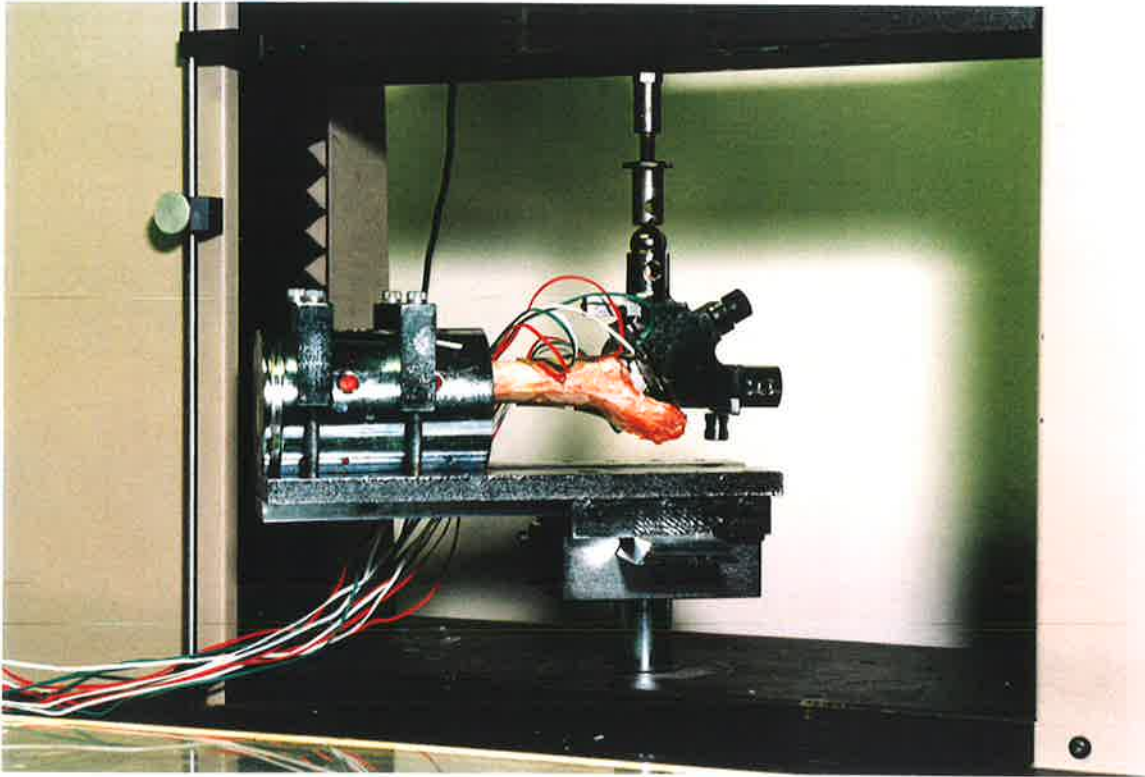


Fig 5.9 Medial-Lateral Loading

5.4. REPRODUCIBILITY STUDY

5.4.1 Introduction

Comparison of strain values between study and control femurs require the strain gauge rosettes to be positioned in exactly corresponding sites on the femoral cortex. As the proximal femur is irregular in contour and the bone is anisotropic in composition, a small error in rosette placement between study and control sides, could potentially cause a large difference in strain recorded from a rosette which had been precisely positioned. In a reproducibility study in a canine hip arthroplasty model, Page *et al* (1991) reported that cortical strain measurements from repeated loadings varied by <10%. The aim of this current study was to determine the precision error in strain measurement of the protocol for positioning of strain gauge rosettes on sheep bone (Ch 5.3.4). This reproducibility study also included instrumentation errors associated with the equipment.

5.4.2 Method and Materials

A fresh left Merino sheep femur was implanted with a cemented collared femoral stem. The cortical surface was prepared for application of cortical strain gauges. Anterior and transverse and longitudinal reference lines were marked on the cortical surface with a soft pencil, as described in the positioning protocol. The strain gauge rosettes were applied at the designated cortical sites with cyanoacrylate cement.

The femur was clamped to the loading jig and mounted in the vertical position in the Hounsfield universal testing machine (Chapter 5.3.5). However for the purpose of this validation study, the distal femur was not potted in cement. The femur was lowered so that the distal ends of the femoral condyles were 2cm above the metal base plates. Anatomically the lateral femoral condyle was seen to project approximately 5mm more distally than the medial condyle. A 2cm thick cement spacer was made with moulding to the convexity of the distal condyles. This spacer enabled both medial and lateral condyles to bear weight equally via the cement spacer and horizontal base plate upon axial loading.

An axial load of 300 Newtons was applied at a cross head speed of 10mm per minute. 5 cycles of load were applied at each trial. The strain of the last cycle from each of the four

rosettes was recorded as the strain for that trial. This completed the first trial.

The femur was then removed from the testing jig. The strain gauge rosettes were removed and discarded. A scalpel blade was used to sharply remove any residual cement from the cortical surface. The pencilled reference lines were completely removed with a soft eraser. The femur was sprayed with an aerosol of saline solution and wiped so all traces of pencil markings were removed. The cortex was then lightly sanded with fine grit sand paper and methanol was used to clean and dry the bone surface.

The femur was then replaced in the right angle positioning frame and fresh anterior, transverse and longitudinal lines redrawn with a soft pencil. The four sites for rosette placement were located and 4 new strain gauge rosettes were applied with cyanoacrylate cement in the standard manner. The femur was remounted in the loading jig and strain testing performed in the previously described manner. A total of 5 axial loading trials were done with care to completely erase the pencil reference markings between each trial.

5.4.3 Results

The mean and standard deviation of principal strain (PS), magnitude measured in microstrain ($\mu\epsilon$); and principal strain angle (measured in degrees) for each rosette are reported in Table 5.1. This reproducibility study conducted over 5 trials shows that the coefficient of variation ($CV\% = SD/mean \times 100\%$) for principal strain magnitude in general is approximately 10%. The exception is in rosette 3 where the precision error for principal compressive strain is 32.78%. The CV% in principal strain direction in general is less than 15%.

5.4.4 Conclusion

The data from this reproducibility study indicates that principal cortical strain magnitude and direction can be recorded from axially loaded femora with a moderately high degree of reproducibility. The reproducibility of AP and ML loading modes were not studied, due to the expense of non reusable rosettes. In these loading modes the precision error from instrumentation and rosette repositioning is unchanged from the axial position.

However error may or may not increase from re-positioning the femur in the AP or ML position. In general this source of error is likely to be small with the use of the spirit level referencing off the implant neck.

5.5 SHEEP INTACT FEMUR STUDY

5.5.1 Introduction

This section describes the cortical strain characteristics of intact Merino sheep femurs when loaded using the mechanical loading protocol described in Chapter 5.3. The aims of this section are:

1. to determine the pattern and magnitude of cortical strain under Axial, AP and ML loads in the intact sheep femur;
2. to determine the variation in cortical strain parameters between left and right sides.

Table 5.1 Cortical Principal Strain Magnitude and Angle Measurement:
Reproducibility of Rosette Positioning and Instrumentation
Over 5 Trials, under Axial Loads

Rosette		Strain		
		Mean	SD	CV%
1	PTS	119.47 $\mu\epsilon$	7.499	6.28
	PCS	-137.99 $\mu\epsilon$	6.6734	4.84
	PTA	20.51°	1.8204	8.87
	PCA	110.51°	1.8204	1.65
2	PTS	77.668 $\mu\epsilon$	6.1042	7.86
	PCS	-70.128 $\mu\epsilon$	7.8073	11.13
	PTA	-31.37°	4.0462	12.9
	PCA	-121.37°	4.0462	3.33
3	PTS	40.148 $\mu\epsilon$	2.9289	7.3
	PCS	-45.228 $\mu\epsilon$	14.8261	32.78
	PTA	21.47°	3.3236	15.48
	PCA	111.47°	3.3236	2.98
4	PTS	70.658 $\mu\epsilon$	2.4749	3.5
	PCS	-166.06 $\mu\epsilon$	18.0099	10.85
	PTA	-13.59°	4.5429	33.42
	PCA	-103.59°	4.5429	4.39

Definitions

PTS - Principal Tensile Strain (microstrain $\mu\epsilon$)

PCS - Principal Compressive Strain

PTA - Angle of Tensile Principal Strain (degrees)

PCA - Angle of Compressive Principal Strain

5.5.2 Method and Materials

Four Merino sheep (100,101,102,103) were sacrificed for this study. Ideally any study of the variability in a group of subjects should employ a large sample number especially if the predicted variability is high. However logistical and financial constraints restricted the number of sheep to this relatively small number. The four sheep were obtained from the original study flock of fifty Merino animals, thus ensuring a high degree of morphological similarity to the test sheep in the explant study. Both femurs were excised from each sheep.

Biomechanical testing of the four left and four right femurs was performed in the fresh state with the bones at room temperature, and care taken to prevent dehydration. The cortical surface of each bone was prepared, longitudinal and transverse reference lines drawn, and four strain gauge rosettes applied using the protocol described in Section 5.3.

As there was no implant to help position the femur, the femur was potted in the vertical position as defined by the anterior longitudinal line being perpendicular to the horizontal plane. Load was applied to the intact femoral head via a rigid metal cylinder. Point contact was made via the cylinder with the superior aspect of the femoral head for axial loading, medial aspect for ML loading, and for AP testing, a compressive load was applied to the anterior aspect of the femoral head. A body weight of 65Kg was assumed for all four sheep, so the load magnitudes applied were the same for all pairs of femurs. Axial load applied was 380N, ML load was 100N and AP load was 140N. Five cycles of load were applied for each loading mode and the strain magnitudes of the fifth cycle only recorded.

For each femur, the cortical strain magnitude was recorded from each of the twelve strain gauges. Rosette 1 comprised SG 1-3 (longitudinal, transverse and oblique positions respectively; Rosette 2 comprised SG 4-6; Rosette 3 comprised SG 7-9 and Rosette 4 comprised SG 10-12. Data from each rosette's 3 strain gauges were used to calculate principal compressive strain (PCS) and angle (PCA) and principal tensile strain (PTS) for each location. Left-right difference of each strain parameter was determined for each bone pair and tested for significance using a paired two tailed t test.

5.5.3 Results

The cortical strain data for the four pairs of femurs for each loading mode are presented in Figs 5.10-5.15.

5.5.3.1 Cortical Strain Distribution in the Intact Femur

Axial Load (Figs 5.10, 5.11)

Under axial loads, a bending moment is created and the medial aspect of the proximal femur undergoes a high level of compressive strain.

The mean principal compressive strain under axial load (A-CS) is greatest in the calcar (Rosette 1: $-396.94\mu\epsilon$), though the more distal medial location records a similar level of strain (Rosette 3: $-359.23\mu\epsilon$). The two lateral sites record a markedly lower level of principal compressive strain (Rosette 2: $-41.87\mu\epsilon$; Rosette 4: $-70.6\mu\epsilon$) due to their relatively greater lateral distance from the axis of loading.

The mean principal tensile cortical strain under axial load (A-TS) is the converse of compressive strain measurements - the lateral sites record greater principal tensile strain than the medial sites due to their greater lateral distance from the axis of applied load.

The principal compressive angle at all rosette locations is approximately 90° and is therefore parallel to the axis of axial load applied.

Analysis by individual strain gauge (SG) confirms this strain pattern (Fig 5.11). Compressive strains are noted in the longitudinally oriented strain gauges (SG 1,7) of the two medial rosettes but at the lateral rosettes, a nett tensile strain in longitudinal strain gauges (SG 4,10) is noted. The transverse strain gauges correspondingly record a tensile strain medially (SG 2,8) but laterally the transverse strain gauges SG (5,11) record a small compressive strain. The oblique strain gauges have compressive strain medially (SG 3,9) but tensile laterally (SG 6,12) in a similar pattern to but to a lesser magnitude than the longitudinal strain gauges.

Medial-lateral Load (Figs 5.12, 5.13)

When a medial-lateral force is applied to the femoral head, a valgus bending moment is created in the femur. A high level of principal compressive strain is seen in the lateral rosettes especially at the more distal site (Rosette 4: $-923.74\mu\epsilon$) which, being furthest from the point of load application has the greatest force moment acting on it.

Relatively less principal compressive strain is seen at the medial rosettes with very little at Rosette 1 which is closest to the point of application of the ML load. These 2 medial sites record correspondingly greater principal tensile strain than the lateral rosettes. The PTS is greatest at the more distal medial site (Rosette 3: $PTS=792.77\mu\epsilon$) where the force moment is greatest.

The principal compressive angle under the load is close to 90° at all 4 rosette locations but differs more at the distal sites than the proximal sites due to greater distance from the axis of loading.

Anterior Posterior Load (Fig 5.14, 5.15)

When an antero-posterior force is applied to the anterior aspect of the femoral head, a combined bending moment and a rotational moment is created. A low level of principal compressive and principal tensile strain is seen at all rosette locations. Individual strain gauge analysis reveals that a tensile force is seen in all 12 gauges, indicating that they are all positioned anterior to the mid coronal plane of the femur.

The angle of principal compressive strain is approximately 60° - 70° for all rosette locations indicating the off axis nature of loading.

5.5.3.2 Left Right Variability in Cortical Strain

Left-right variation in strain parameters is relatively small when graphically analysed (Fig 5.10-5.15). However the small number of bone pairs examined ($N=4$) substantially reduced the power of the statistical tests in detecting a L-R difference in

cortical strain characteristics. The power of statistical tests was frequently <0.1 . Though a significant ($p<0.05$) difference was seldom found, a Type II error may exist where the study numbers were too small to detect a significant L-R difference.

The bar graphs indicate that there was a moderately high degree of symmetry between left and right sides, in strain parameters under axial loads. Notably for axial principal compressive strain measurement, mean difference between sides was very small with a $p = 0.86$ at the calcar. A statistically significant L-R difference was found only in Axial Compressive Angle at rosette 3 (mean difference 7.32° , $SD=3.48$, $p=0.024$). In the obliquely orientated strain gauges (SG: 3,6,9,12), mean differences were moderately high, though SD were also high, and no significant L-R differences were observed.

For ML loading, a moderate degree of symmetry in strain parameters is noted. A statistically significant L-R difference is found in Principal Compressive Angle at rosette 4 (mean difference -8.04° , $SD=3.85^\circ$, $p=0.025$); and strain gauge 12 (mean difference = $66.38\mu\epsilon$, $SD=31.4\mu\epsilon$, $p=0.024$). High mean L-R differences were noted in the other oblique strain gauges (SG 3, 9, 12).

For AP loading, the degree of L-R symmetry is only fair. Significant L-R differences were found in;

1. Principal compressive angle at rosettes 2, 3, 4.
2. Strain gauge magnitudes at gauges 6, 7, 9, 12.
3. Principal tensile strain at rosette 3.

These L-R differences indicate that individual femurs differ relatively more in their torsional characteristics than their bending characteristics.

Fig 5.10 Intact Femur Studies of Cortical Strain Pattern (N=4)

Principal Strain Magnitude and Angle measured from each of the four rosettes under **Axially** oriented physiological load. The variation in cortical strain parameters between left and right sides is also demonstrated.

(Error bars denote one standard deviation)

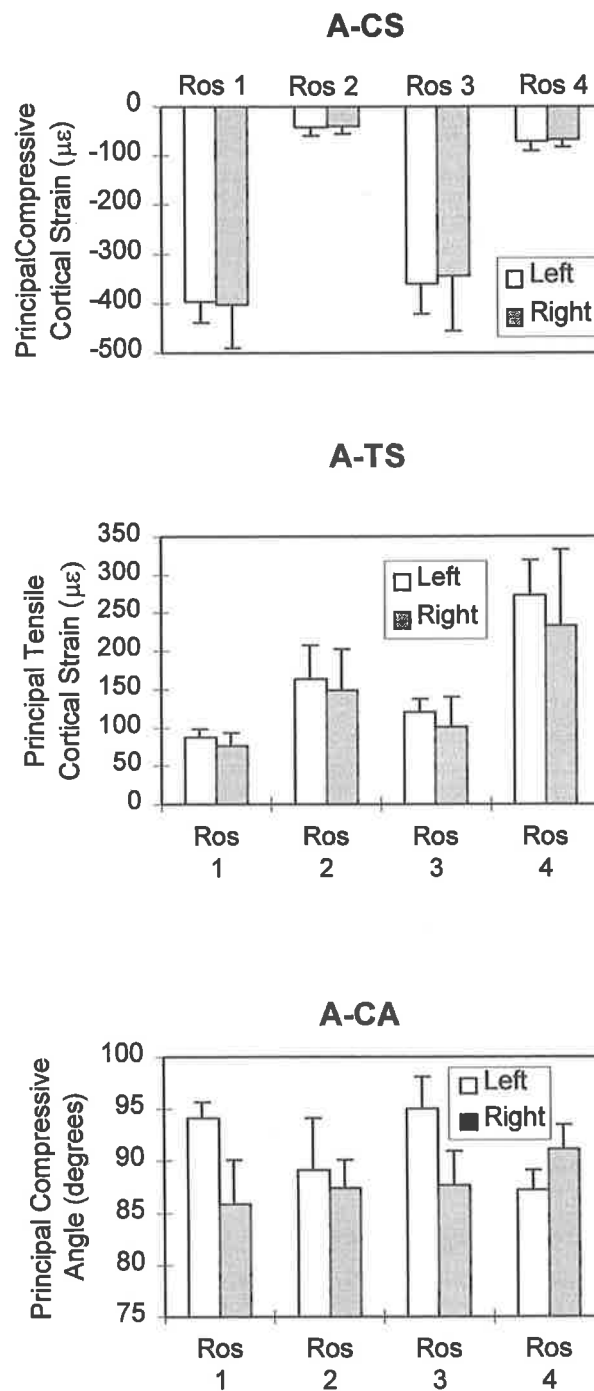


Fig 5.11 Intact Femur Studies of Cortical Strain Pattern (N=4)

Individual Strain Gauge (SG) Cortical Strain Measurement under **Axially** oriented physiological load.
The variation in cortical strain parameters between left and right sides is also demonstrated.

(Error bars denote one standard deviation)

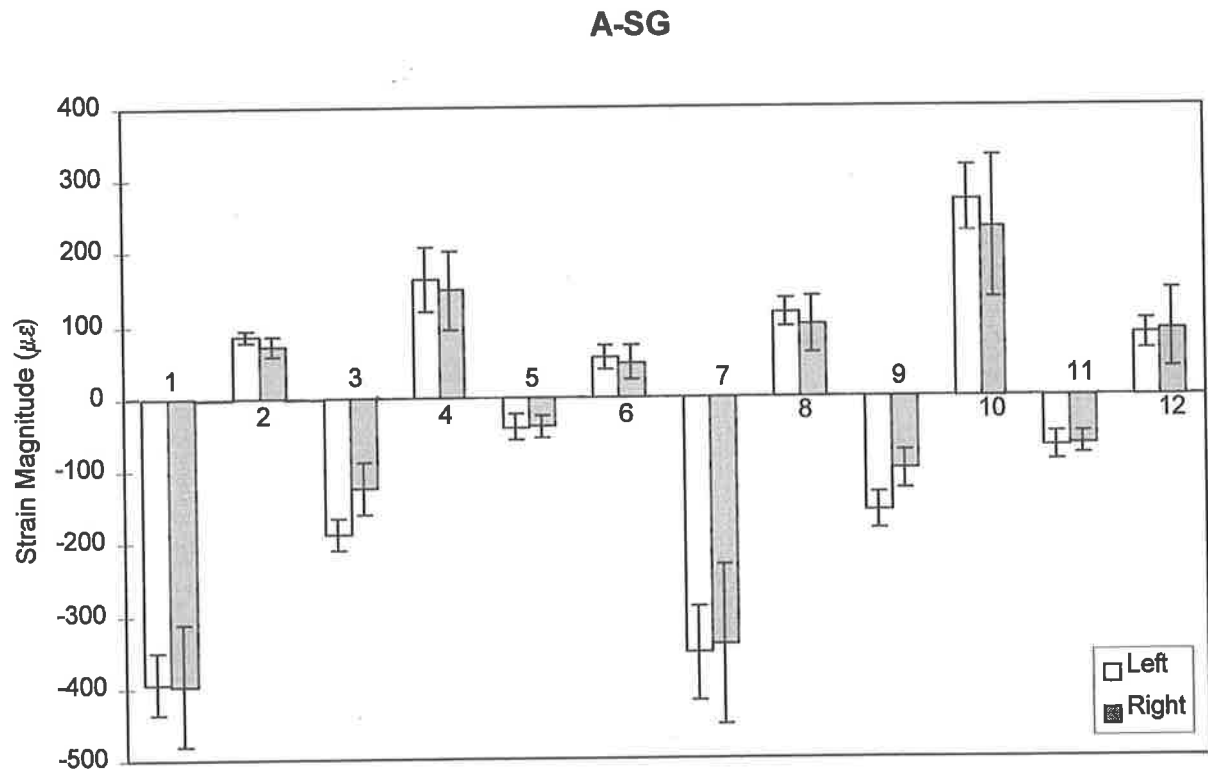


Fig 5.12

Intact Femur Studies of Cortical Strain Pattern (N=4)

Principal Strain Magnitude and Angle measured from each of the four rosettes under **ML** oriented physiological load. The variation in cortical strain parameters between left and right sides is also demonstrated.

(Error bars denote one standard deviation)

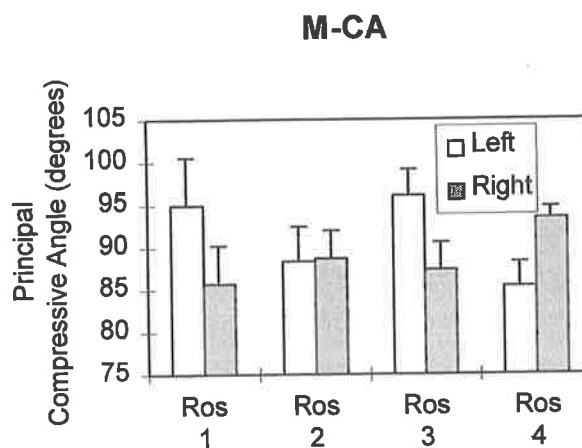
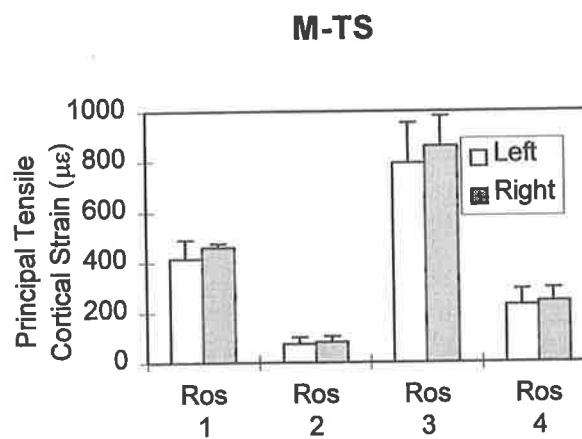
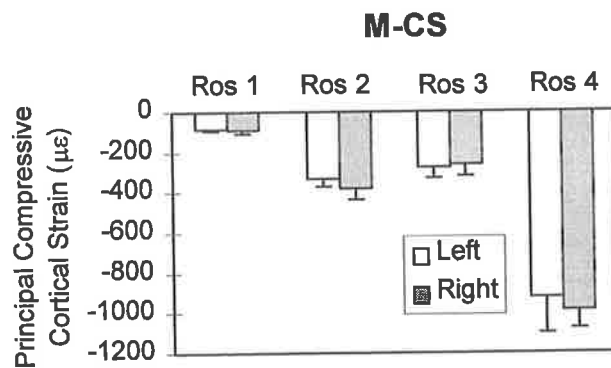


Fig 5.13 Intact Femur Studies of Cortical Strain Pattern (N=4)

Individual Strain Gauge (SG) Cortical Strain Measurement under **ML** oriented physiological load.
The variation in cortical strain parameters between left and right sides is also demonstrated.

(Error bars denote one standard deviation)

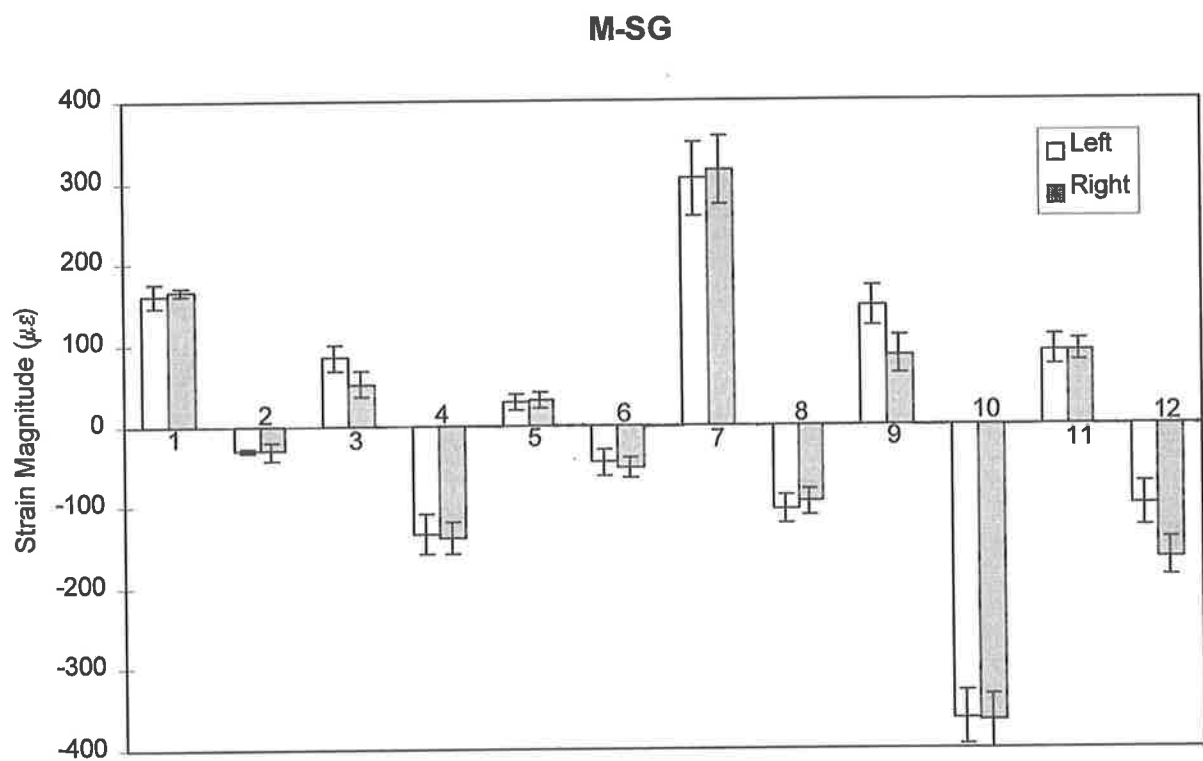


Fig 5.14

Intact Femur Studies of Cortical Strain Pattern (N=4)

Principal Strain Magnitude and Angle measured from each of the four rosettes under **AP** oriented physiological load. The variation in cortical strain parameters between left and right sides is also demonstrated.

(Error bars denote one standard deviation)

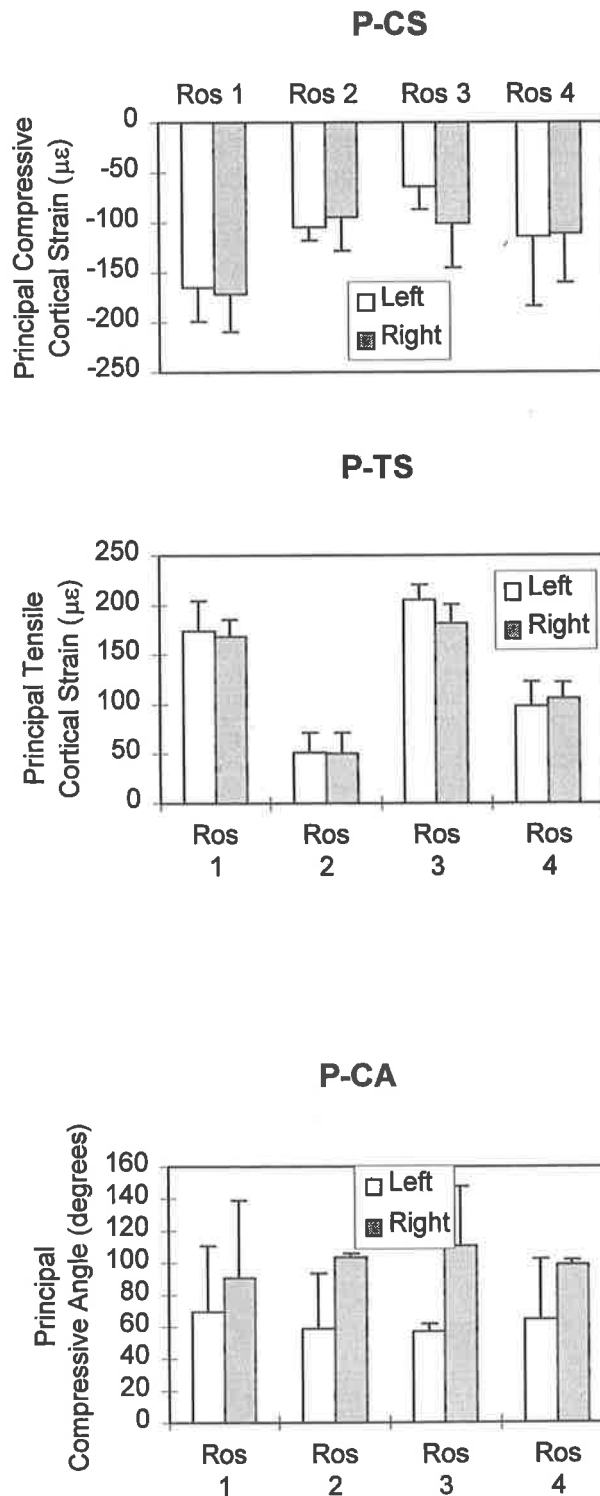
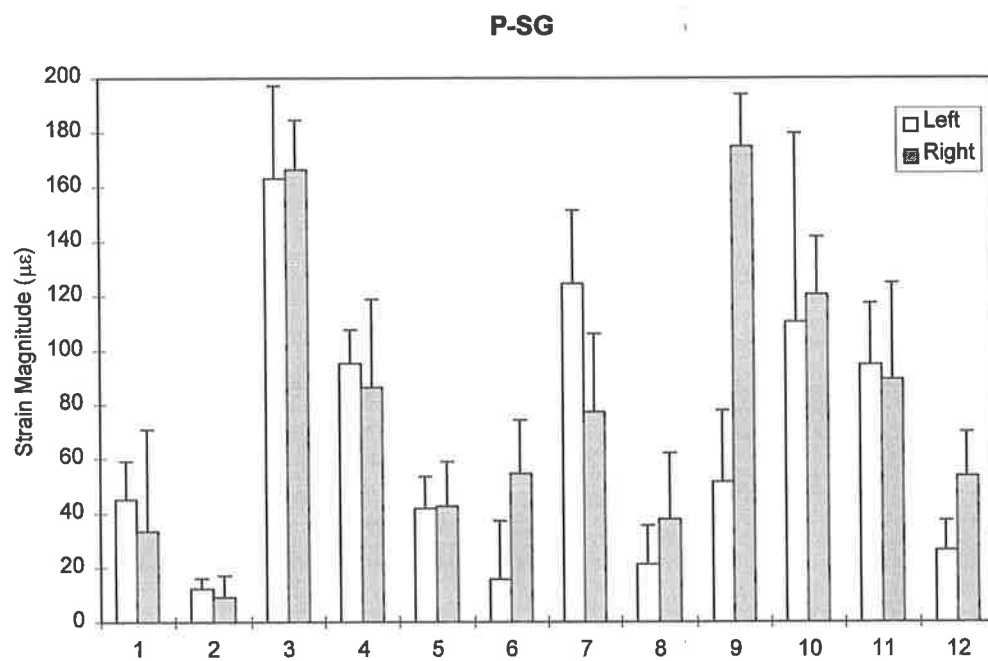


Fig 5.15 Intact Femur Studies of Cortical Strain Pattern (N=4)

Individual Strain Gauge (SG) Cortical Strain Measurement under **AP** oriented physiological load.
The variation in cortical strain parameters between left and right sides is also demonstrated.

(Error bars denote one standard deviation)



5.5.4 Conclusions

This study has described the cortical strain pattern of intact sheep femurs to axial, ML and AP loads of physiological magnitude. Maximal strains of 800-900 $\mu\epsilon$ were recorded.

The L-R study of intact pairs of femurs indicate a moderately high level of symmetry for all strain parameters especially under axial and ML loads. Under AP loads, L-R symmetry was only fair, indicating that femurs differ relatively more in their torsional than their bending characteristics. The bar graph analysis of L-R strain differences supports the use of the right femur as a control for the left femur especially for strain magnitude measurement under Axial and ML loads. The cortical strain parameters of the right femur can validly be used as a comparison for the remodelling changes in cortical strain that have occurred in the left femur.

5.6 SHEEP RETRIEVAL STUDIES: METHODOLOGY

5.6.1 Explant Protocol

10 months following implantation the sheep were anaesthetised and the contralateral right femur was surgically implanted with an identical implant as the test side. The sheep were then sacrificed with a lethal intravenous injection of phenobarbitone. Both femurs were explanted and all soft tissue removed.

Biomechanical testing of both femurs was performed in the fresh state. Overnight storage in a 4° refrigerator was occasionally necessary. The femurs were then returned to room temperature (20°C) while wrapped in a saline soaked towel, for two to three hours. (Oh 1978).

The cortical surface of the study and control femurs were prepared in the manner described in Chapter 5.3. It was apparent that most of the explanted test femurs had undergone a degree of proximal periosteal new bone formation. This bone had formed distal to the femoral neck osteotomy and was especially prominent medially and anteriorly. Photographs were taken of the proximal medial and anterior aspect of each explanted femur for subsequent descriptive analysis. The periosteal ossification was

classified as minor, moderate or severe, indicating that new bone formation was seen extending from 1 to 5mm, 5 to 10mm and greater than 10mm, from the femoral neck osteotomy respectively.

This periosteal new bone formation occasionally extended distally enough to prevent the strain gauge rosettes from being placed above the 75% transverse line. In these instances, the rosettes were placed immediately below the 75% line for both test and control femurs (Sheep No.480, 481, 482, 493).

The implant version was recorded. The femur was placed on a firm horizontal surface such that it was supported on the posterior aspect of the distal femoral condyles and the posterior aspect of the greater trochanter. Implant version was judged using the flat surface of the implant neck. The implant was in anteversion if the plane of the neck was angled above the horizontal plane, and retroverted if it was angled below the horizontal plane. The degree of version was measured using a goniometer and recorded to the nearest 5°.

For collared components, the degree of collar calcar contact was graded for both study and control femurs. Plain radiographs, being only a two dimensional representation are inadequate to assess the degree of collar calcar contact (Kelley *et al* 1992). Visual inspection could evaluate collar contact with the medial cortex as well as the anteromedial and posteromedial cortex. Inspection indicated if two thirds or more of the collar area was applied to bone (Grade 1), one third - two thirds (Grade 2) and one third or less (Grade 3) collar calcar contact was achieved.

Following application of strain gauge rosettes, control and study femur pairs were potted and subsequently loaded in axial, coronal and sagittal planes as per the loading protocol in Section 5.3. The magnitudes of load applied were resolved from the resultant force acting on the femoral neck and calculated using each individual sheep's body weight in kg (Lanyon *et al* 1981).

For each loading mode and for each rosette, longitudinal, tensile and oblique strain were recorded and the principal compressive and principal tensile strain magnitude and direction were calculated.

5.6.2 Explant Study vs Control Group Analysis

A left-right comparison of cortical strain was performed for each implant group. This analysis determined if 10 months of remodelling had brought about a significant change in cortical strain distribution in each implant group. As this analysis was a L-R comparison, with L-R differences in strain shown to be small, this analysis was valid for detecting remodelling changes within each group.

A mixed model ANOVA test was applied to the control and study groups for each loading mode and each implant type.

5.6.3 Explant Intergroup Analysis

The L-R differences in cortical strain parameters were compared between implant groups. This analysis therefore determines if the time dependent remodelling effect on cortical strain is different between groups. In this way, the different mechanisms of bone loading which have been applied over 10 months can be compared. Has subsidence of the polished stem effected a different cortical strain pattern from the collared stem which predominately has loaded axially, or from the matt stem which has had the ability to do neither? A mixed model ANOVA analysis was performed and the difference between groups tested for significance.

5.7 SHEEP RETRIEVAL STUDIES: RESULTS

5.7.1 Descriptive Changes

Gross Bone Changes

All explanted study femurs demonstrated a degree of periosteal new bone formation at the level of the femoral neck osteotomy (Table 5.2). This new bone was an irregular fibro-osseous thickening, often not intimately apposed to the cortical bone (Fig 5.16). In some instances, this periosteal bone reaction could be elevated and stripped off the cortical surface as a separate layer. In 8 cases, this periosteal new bone was minor extending between 1-5mm from the level of the cut neck. In 10 cases, it was graded moderate and measuring 5mm to 10mm from the femoral neck.

In addition to the fibro-osseous thickening, discrete bony prominences were occasionally noted (480, 482, 485) in the calcar region (Fig 5.17). These spurs were dense bone and unlike the periosteal bony reaction were firmly in continuity with the original bony cortex. Both the bone spurs and the periosteal reactions were due to artefacts of the surgical exposure, where periosteal elevation of hip joint capsule and cortical infraction from the tip of the femoral elevator would have stimulated this new bone formation.

Only one study femur had macroscopic evidence for bone resorption (493 polish). This femur had 18mm of anteromedial cortical resorption (Fig 5.18) associated with a non propagatory 5mm fracture of the cement mantle at the anteromedial edge of the implant. Only fibro-osseous thickening was present at the femoral neck osteotomy. This implant had been graded “possibly loose” on radiographic grounds (Chapter 4).

Version

In 14 of the 18 study femurs, the implant was in neutral version (Table 5.2). Two cases (482, 493) were anteverted 5° or less, while 2 cases (476, 491) were retroverted 5° or less. In 12 of the 18 control femurs, the implant was in neutral version with six femurs anteverted or retroverted by 5° or less. In all implants however a complete 2mm thick cement mantle surrounded the implant. A minor rotational malalignment into ante or retroversion did not compromise the integrity of the cement mantle except in one study femur (493 Fig 5.18) where the cement mantle was obviously fractured, and this anteromedial fracture was associated with 5° anteversion of the implant.

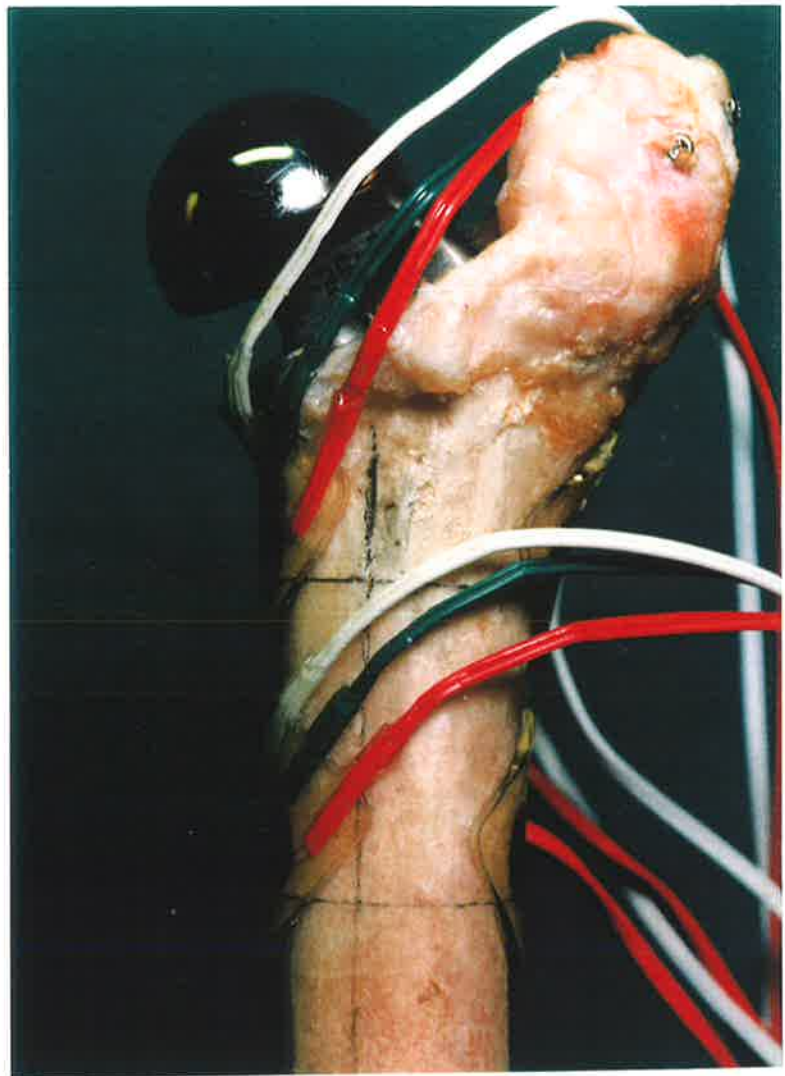
Collar Calcar Contact

In 12 of the 14 femurs with collared implants (7 study. 5 control), collar contact with underlying bone was two thirds of the collar surface or greater (Grade 1). In 2 cases (2 control 476, 487) collar calcar contact was one third to two thirds (Grade 2) and in no cases, was contact less than one third of the collar area (Grade 3).

Table 5.2 Observations on the Study Femurs Following Remodelling

Implant	ID Number	Periosteal Bone Changes	Implant Version	Collar Contact (Study)	Collar Contact (Control)
Collar	499	moderate	neutral	Grade 1	Grade 1
	491	moderate	5° retroversion	Grade 1	Grade 1
	476	moderate	5° retroversion	Grade 1	Grade 2
	475	minor	neutral	Grade 1	Grade 1
	486	minor	neutral	Grade 1	Grade 1
	487	minor	neutral	Grade 1	Grade 2
	482	moderate	5° anteversion	Grade 1	Grade 1
Polish	496	minor	neutral		
	494	minor	neutral		
	477	moderate	neutral		
	480	moderate	neutral		
	481	moderate	neutral		
	485	minor	neutral		
	493	minor	5° anteversion		
Matt	486	moderate	neutral		
	460	moderate	neutral		
	470	moderate	neutral		
	473	minor	neutral		

Fig 5.16 Periosteal New Bone
Formation at the
Proximal Femur



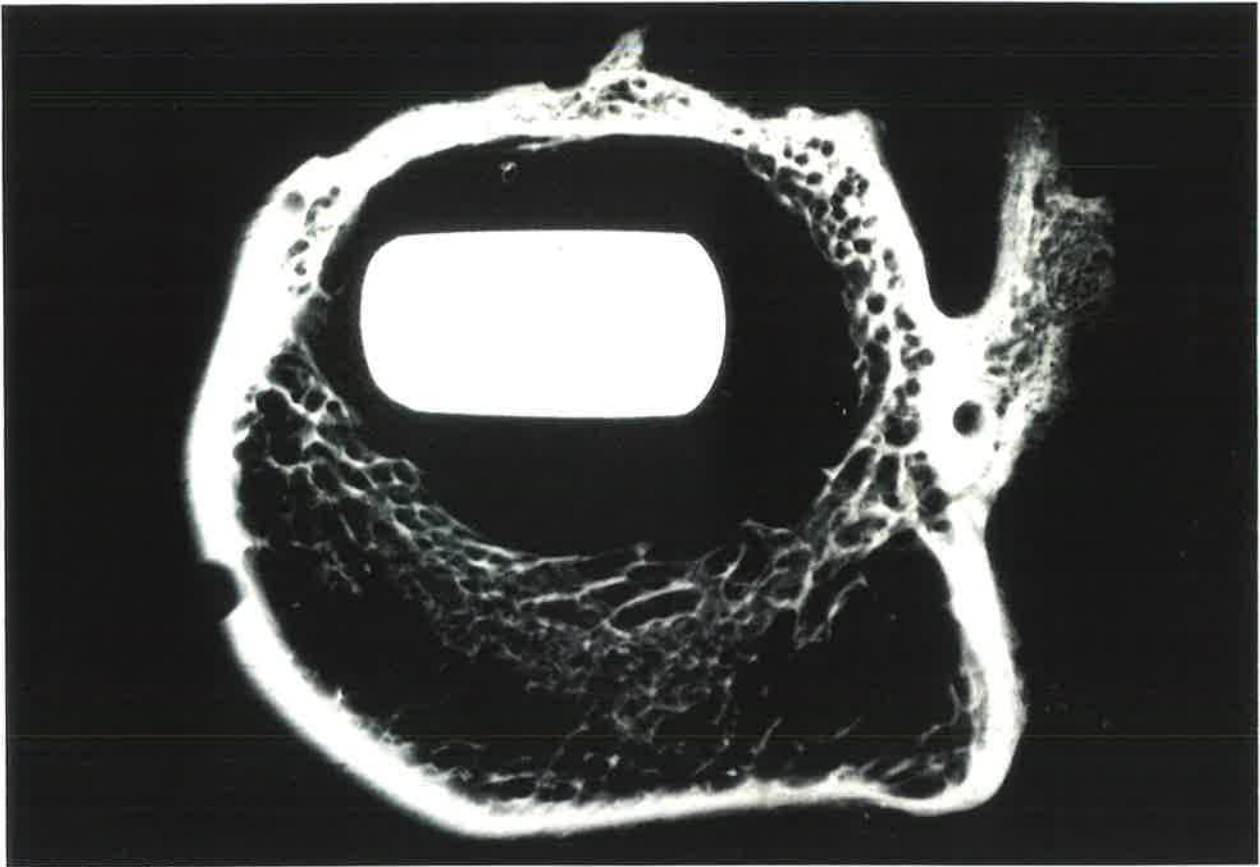


Fig 5.17 Bone Spur Formation at the Proximal Femur (Sheep 480)

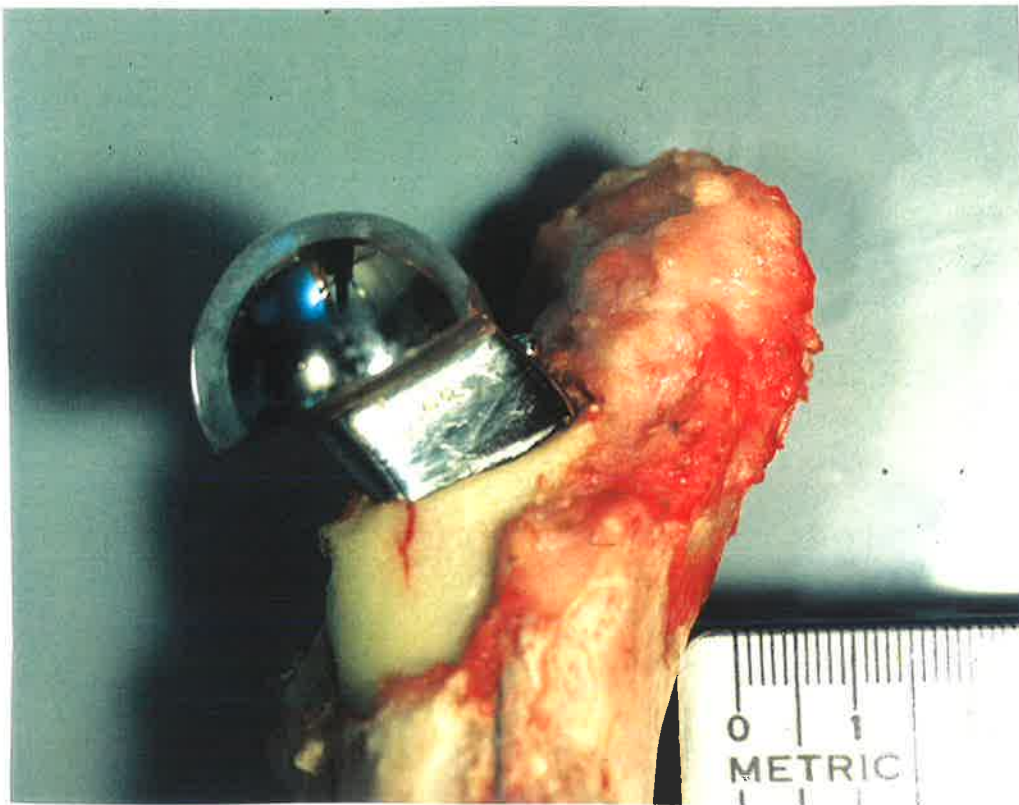


Fig 5.18 Extensive calcar resorption associated with an antero-medial cement fracture (Sheep 493 Study)

In those 2 control cases where observed bone contact was less than optimal, extruded cement was seen filling in the space between collar and bone. In no case was this interposed cement observed to be fragmented or fractured. Cement is strong in compression and this intact interposed cement would still enable load transfer from the collar to the underlying bone in the short term. Thus though collar calcar contact was incomplete in these 2 control femurs, the finding of intact interposed cement suggested the collar was not defunctioned in transferring loads to bone.

5.7.2 Cortical Strain Analysis: Study vs Control Groups

In general, cortical strain analysis of control femurs indicated a massive reduction in strain in all implant groups, compared to the intact femurs. Strain magnitudes were reduced to as little as 10-15% of the corresponding intact femur data. This indicated that the bending and torsional characteristics of the intact femur had been drastically altered by the presence of the implant.

In this section, the retrieved study femurs were compared with the control femurs and the remodelling effect on cortical strain which had occurred during 10 months of implantation were examined.

Axial Load (Table 5.3-5.5)

Following 10 months in vivo, an overall further loss of principal compressive strain occurred in the proximal rosettes of the study femurs compared to the control femurs (Table 5.3). Important losses occurred in all 3 implant groups to a magnitude of approximately 50% of the control measurements.

Notably in the collared group, PCS was not retained in the calcar of the study group. A significant loss of strain occurred ($p = 0.0094$) implying that after a period in vivo the collar's function at transferring axial load was diminished.

At the proximal lateral (rosette 2) location, important further losses in strain occurred compared to the control group with all three implant designs but particularly the collared group. Though these losses did not reach statistical significance, the power of the tests was low, indicating the potential for a type II error. Confidence Interval testing

indicated strong trends for a loss in compressive strain under axial loads after remodelling between control and study femurs.

Principal tensile strain (Table 5.4) decreased substantially following remodelling at the proximal rosette locations for polish and collared groups. The losses in strain were significant in the proximal lateral location. In the matt group PTS decreased in rosette 2 but in rosette 1, PTS was greater than the control, though with wide variation. In the small numbers tested, this was not significant.

In the distal rosette locations notably PTS of the study femurs was greater than the control indicating relatively greater preservation of strain in the polished implant group. The Confidence Intervals indicate this tendency at rosette 3 and with a strongly significant increase in PTS at rosette 4 ($p = 0.01$). For the matt group, small increases in PTS also occurred but Confidence Interval testing indicated no tendency for these relative increases to be important. The collared group showed no change in PTS between control and study groups at this location

Principal compressive strain direction (Table 5.5) tended to change with remodelling, from a longitudinal orientation, 90° - 100° to approximately 80° - 85° . This change was more pronounced at lateral locations (rosettes 2 and 4) with highly significant decreases in the strain angle for all 3 implants at rosette 4.

ML Load (Tables 5.6-5.8)

In rosette 1, both polish and matt study femurs showed relatively greater principal compressive strain compared to the control femurs. This was non significant but confidence interval testing showed a moderate tendency in this regard for the polished implants. The polished group showed a corresponding significant loss in PCS at rosette 2, reflected by a small increase in PTS at the proximal lateral rosette, a small increase in PTS at the distal medial rosette and a small increase in PCS at the distal lateral rosette. Otherwise the general pattern observed was a further reduction in PCS and PTS compared to the control femurs at the proximal and distal rosette locations.

The principal compressive angle tended to increase in all groups at the two medial rosettes from approximately 85° to approximately 100° . This was significant for the

collared group but not consistent for the matt or polished groups.

AP Load (Tables 5.9-5.11)

Reductions in principal compressive strain magnitudes were observed in all 3 study groups (Table 5.9). The reductions were most consistent and more commonly significant in the proximal locations. The collared group was a striking exception at the calcar site where PCS was no different between control and study sites ($p=0.9$). However wide standard deviations were observed and the power was very low.

Principal tensile strain (Table 5.10) has followed a similar pattern. Minor to moderate relative losses occurred in PTS compared to the control femur. The losses were more significant at the lateral locations. The matt group at rosette 2 was an exception with a small but significant increase in PTS in the study femurs compared to the control.

Principal compressive angle underwent a highly significant change for this loading mode, in all 3 implant groups and at all rosette locations (Table 5.11). The angle decreased from approximately 100° - 120° to approximately 60° - 70° .

Summary

The important findings of this section are:

1. Implantation of a metal cemented stem of any design resulted in a marked reduction in all proximal femoral cortical strains compared to the intact femur when tested under any loading mode.
2. An intra individual control vs study analysis indicated that in general cortical strain was further lost after remodelling. This occurred in the absence of radiographic loosening, so it is unlikely strain was being lost by micromotion at the implant cement or bone cement interface.
3. Strain losses after remodelling were most marked in proximal locations and losses were commonly significant especially in the proximal lateral location.

4. Notably in the collared group under axial loading, principal compressive strain was not recovered after remodelling in the calcar of the study femurs. In fact a further significant loss in calcar PCS occurred compared to the control. This indicates that the function of the collar in transferring axial load to bone was lost in vivo.
5. There is moderate support in the data for the Exeter concept of the polished stem increasing cortical hoop strain with remodelling. Under axial loads the polished stems of the study group recorded greater principal tensile strain than the control group at the distal rosette sites ie the study stems demonstrated relative preservation of PTS after 10 months in vivo, presumably from their potential to subside in vivo. However this effect was not observed at the proximal rosette locations. This effect was not observed at all with the collared stems and to a very minor degree only with the matt surfaced stems.
6. The data from M-L testing provides weak support for the Exeter concept of the polished stem tending to drift into valgus as it subsides (Fowler *et al* 1988). Compared to the collared group, the polished stems showed an increase in PCS at the calcar under a medially applied load to the femoral head. There was however only a small corresponding increase in PTS at the proximal lateral rosette; only a small increase in PTS at the distal medial rosette; and only a small increase in PCS at the distal lateral rosette. Though these changes were small and non significant, these relative principal cortical strain changes compared to the control, are all consistent with a stem tendency toward valgus inclination. Further time in vivo, allowing greater cement creep and stem subsidence may have highlighted these observed changes.

5.7.3 Intergroup Analysis

In this section, the study-control difference in each strain parameter was compared between the three implant groups. In Section 5.7.2 it was shown that the proximal femur strain pattern changes from the immediate post implantation state over the subsequent 10 months of loading. It is fundamental to this study if these changes are implant specific, ie. whether the design variables of surface finish, and collar can influence these changes in strain distribution which occur over time. This section

therefore examined the differences in time dependent effect on cortical strain between the three implant groups.

Axial Load (Appendix 4.1-4.3)

There were no significant differences between implant groups for principal compressive strain at any rosette location. In the calcar (rosette 1) the p value was 0.8002. Confidence Interval testing of difference between means confirms no tendencies toward a difference in PCS between implant types at this location.

At rosette 2, $p=0.104$ but Confidence Interval testing indicated a tendency for collared implants to have greater PCS than polished implants.

At rosette 3 and 4, p values were 0.687 and 0.552 respectively. Though subject numbers were low and statistical power was low, confidence interval testing indicated no trends for differences between implant groups.

The change in principal tensile strain was not significantly different between the 3 groups at any rosette location. Similarly the change in principal compressive angle with remodelling was no different between implant groups at any rosette location.

ML Load (Appendix 4.4-4.6)

The analysis for this loading mode revealed no statistically significant differences in any of the strain parameter changes between implant groups.

AP Load (Appendix 4.7-4.9)

At the proximal rosettes there were no differences in the change in PCS between implant groups. However at rosette 3, Confidence Interval analysis indicated a significant difference between polished and matt groups. While the polished group showed a minor increase in PCS to remodelling, the matt group lost PCS. However this difference in PCS at rosette 3 between matt and polished groups was not mirrored by a difference in PTS at the same location ($p = 0.90$). Though statistically significant, this finding is likely to be sporadic and of doubtful significance.

Analysis of differences in PTS indicated significant differences in the matt group from the other 2 groups at rosette 2. At this location the matt group demonstrated a small but significant increase in PTS with remodelling while both collared and polished groups underwent a significant fall in PTS. This difference in the change in PTS was not reflected in the PCS analysis, and is of doubtful importance. At rosette 4 no differences were observed between implant groups.

The principal compressive angle analysis showed no difference between implant groups in rosettes 1, 3 and 4. In rosette 2, however, significant differences were observed between collared and collarless groups. Both matt and polished groups behaved similarly with PCA decreasing from a mean of approximately 120° in the control to 70° in the study femur. These changes in PCA with remodelling were highly significant. The change in PCA in the collared group however was considerably less. The data suggested that the calcar collar does affect the orientation of cortical strain in rosette 2 in the immediate post implantation stage, and continued to do so in the post remodelling stage when subjected to torsional loads.

5.8 DISCUSSION

The majority of cortical strain studies in cemented Total Hip Arthroplasty have been in vitro studies. Though these studies have demonstrated the relative effectiveness of a medial collar at transmitting load to the calcar (Oh and Harris 1978, Suh *et al* 1991), these laboratory studies do not necessarily reflect the situation after a period in vivo. Hence this study was initiated to evaluate the dynamic stimulus to bone remodelling as a function of surface finish and presence of collar.

The ability to measure cortical strain precisely was demonstrated in Section 5.4. Using repeated analysis of the same implanted femur the coefficient of variation associated with repositioning the rosettes, repositioning of the femur in the testing machine, the applying of loads and instrumentation errors was approximately 10%.

This study design was based around a L-R comparison with the contralateral right femur

in each sheep serving as an internal control for the remodelling changes observed in the left femur. The left-right study (Section 5.5) showed measured L-R differences to be relatively small. Variation was most pronounced under AP loads indicating that results using these loading modes need to be interpreted with caution.

The L-R studies however were done on intact femurs. L-R variation may increase with implanted femur pairs if implant position within the femoral canal was not identical. Though all were aligned neutrally in the intramedullary canal (Ch 4), the version of the implants was different in some sheep bone pairs by up to 5°. This would have altered the neutral axis (Koeneman 1991) between tension and compression and consequently the measured principal strain magnitudes and angles. An additional factor which may have caused this axis to vary was the difference in dimension of bone secondary to subperiosteal bone formation. Both these factors would have altered relative positioning of the rosettes to the implant between left and right sides. This asymmetry in rosette placement would have introduced a further source of discrepancy between study and control data which would not solely be attributed to the remodelling response.

An increase in L-R variability would also have occurred if the cement mantles were not equivalent between sides. The femur remodelled to an implant-cement composite and in particular if the cement mantle was of varying thickness and uneven consistency with voids and microfractures, then the 1:1 coupling and conveyance of strain from implant to bone would have been lost.

The contralateral femur was implanted with the sheep alive rather than *ex vivo* in the lab. It was therefore subjected to the same potentially adverse operative conditions as the study femur, namely the limitation of exposure and blood at the bone interface, both of which may interfere with insertion and fixation of femoral stem. The contralateral femur therefore was a closer control for the study femur than a laboratory implanted specimen.

The stimulus to bone remodelling as indicated by cortical strain was analysed using cortical strain gauge rosettes. The disadvantage of strain gauge rosettes is that they can only indicate strain at discrete sites on the immediate underlying cortical surface. Relatively few rosettes were used in this study. It was possible to apply only 4 triaxial rosettes positioned at proximal and distal levels on medial and lateral locations. Strain changes anterior and posterior were not analysed and these changes may have been

important given the anterior bow of the proximal femur. A more complete description of cortical strain changes and more importantly the interpretation of significant findings would have been facilitated by the use of a larger number of rosettes. This would have required the use of smaller but non waterproofed rosettes. However cortical strain measurement required frequent wetting of the bone specimens to prevent dehydration which would have affected the strain recordings. The decision was therefore made to make accurate strain measurements from a small number of cortical sites using large but waterproof rosettes, rather than attempting to measure strain at a large number of cortical sites with small but non waterproof rosettes which may have debonded from bone.

In this study, relatively low loads were applied compared to human studies where high loads have been used (5-7 x Bodyweight) to simulate single legged stance. The loads used in this study were physiological in magnitude and calculated from previously published in vivo data of a walking sheep. They were considerably less than 1 BW when resolved into axial, ML and AP components. However though these loads were small, they were the magnitudes of load to which bone had remodelled in vivo. It was therefore thought more appropriate to examine bone response to these physiological loads rather than the high loads associated with unnatural or infrequent hip postures.

The cortical strain analysis of Section 5.7 indicated a global decrease in study femur cortical strain often to approximately 50% of the control femur, in all 3 implant groups. Many of these reductions were significant or approaching significance, and given the small number of subjects per group, this global loss in strain compared to the control femur is an important finding.

Significant strain loss was especially noted in the study femurs under AP loading which applies a torsional force to the implant. The magnitude of strain loss raises the possibility of implant loosening with micromotion and attenuation of strain transfer across the cement bone interface. In human hip arthroplasty, implant micromotion occurs especially under torsional loading which occurs in stair climbing (Burke *et al* 1988). However in the current study, radiographic analysis has shown that no implant was definitely or probably loose, making it unlikely that strain was being lost in the AP loading mode from excessive micromotion. Also as all load magnitudes employed were relatively low there was less concern for cortical strain loss from implant micromotion and friction at the interfaces.

The loss in cortical strain between cortical and study femurs was global. There was no complimentary increase in other strain parameters at the limited locations tested. For example, the loss in PCS under axial load was not compensated for by an increase in PCS at any other tested site. It was uncertain with this study if there was a compensatory increase in cortical strain at the sites not tested such as the anterior and posterior cortical surfaces. Also the study did not attempt to determine if strain increased below the tip of the stem where previous human radiographic studies have demonstrated cortical hypertrophy, indicative of strain loading.

Another limitation of this cortical strain study was that data were obtained from loads representing only one point in the gait cycle - that of midstance in a quietly walking sheep. It was assumed that midstance loads the proximal femur maximally, that bone received the most remodelling stimulus from these forces and this remodelling was reflected in cortical strain changes. However in swing phase, heel strike or toe off or any other phase of the sheep gait cycle, the loading vectors at each site of the proximal femur will change. The neutral axis (Koeneman 1991) between net tensile and compression forces will also change, and a load which for example was principally compressive at one site in midstance may have been under tension at all other phases of the gait cycle. The midstance loading vector may not have been the dominant stimulus to bone remodelling, at the particular site examined. A complete study of cortical strain changes on implantation of femoral stem would require an *in vivo* study where implanted rosettes are placed along medial-lateral and anterior-posterior cortices including levels distal to the tip of the implant, and testing continued during all phases of the gait cycle.

The observed loss of strain from control to study femurs refutes the adaptive bone remodelling theory which states that following implant insertion bone is remodelled and resorbed to return strain to normal limits. The adaptive bone remodelling, is an expression of Wolff's Law where structure adapts to function. This physiological homeostatic mechanism has not been observed in this study nor in retrieval human studies (Engh *et al* 1992, O'Connor *et al* 1993, Maloney *et al* 1990). The present cortical strain study suggests that the insertion of an implant into the femur results in such a radical and unphysiological fall in strain magnitude, to 10% of intact femur strain in some cases, that normal strain homeostatic mechanisms do not apply. The adaptive

bone remodelling principle may apply only to physiological decreases in strain magnitude. When loads are substantially less than this, the drive to strain equilibrium may not apply. Just as repetitive unphysiologically high loads results in stress fractures of bone rather than compensatory cortical hypertrophy, unphysiologically low loads due to the presence of an implant results in progressive strain loss and progressive bone resorption. Longer term studies, taken to many years rather than months post surgery, are required to demonstrate if progressive strain loss and bone loss continue or eventually stabilise.

The Explant Intergroup analysis showed that the change in cortical strain between control and study femurs post remodelling was no different between implant groups. This analysis demonstrated that the changes in PCS under axial load in the calcar for the collared group were no different from the polished or matt groups ($p=0.80$). This shows that the design strategy for calcar loading by the collar during 10 months in vivo, was no more effective at retaining PCS under axial load than either of the collarless designs. Even though visual inspection of retrieved femurs had indicated a consistently high level of collar apposition to bone, much of the interposed tissue was fibro osseous in nature. Intimate collar contact with cortical bone was lost and the mechanism for load transmission had been reduced.

The Explant intergroup analysis of PTS under axial load showed no significant difference between polished stems and the matt or collared groups at any rosette location. This study therefore cannot provide definite support for the design rationale of the polished tapered stem with its ability to subside in vivo and creating greater hoop strain than the non polished groups.

Under ML load there were no significant differences in the remodelling response, as indicated by cortical strain changes, between implant groups.

Under AP loads, sporadic significant differences in strain magnitudes were noted. These differences conformed to no specific pattern of behaviour or hypothesis. Reasons for the increased occurrence of significant differences under AP load include the relatively poor L-R symmetry in torsional characteristics (Section 5.5, 3.2) of the femur pairs. Also as these data were subjected to multiple comparisons, and with a significant level of 0.05, it could be expected that by chance, 1 statistical test in 20 will be positive without

actually indicating a significant difference.

The change in principal compressive angle with remodelling, also did not vary between implant groups at any rosette location. This was consistent with the failure to detect significant difference in PCS and PTS between groups. If the polished stem had in fact subsided to create significant hoop stresses in bone then the PC angle would have shifted toward zero, and a difference with the collared and non subsiding matt implant group would have appeared.

Power calculations were performed and the low power in the majority of tests raises the possibility of a Type II error, where a significant difference existed but study numbers were too small to have found that difference. However confidence interval testing indicated that there was no detectable trend towards statistical difference between groups.

From this analysis it is concluded that the pattern and magnitude of the generalised loss in cortical strain between study and control femurs is no different between implant groups. The null hypothesis is accepted for this animal model, which with its thin cortices and wide intramedullary canal, is an accelerated model for stress shielding. The insertion of any implant into the femur has caused such a radical and unphysiological loss in cortical strain magnitude that strain homeostasis does not occur. The effect of the implant design features examined was too small in this model to have a measurable influence on this loss of cortical strain. Specifically the collar did not cause relative preservation of longitudinal strain in the proximal femur compared to the collarless designs. Also the polished tapered stem did not significantly load the bone with increasing hoop strain any more than the matt or collared stem. There was no significant difference or trends to an important difference in the principal compressive angle between implant groups.

Essentially any cemented implant is overwhelmingly too stiff for design features such as a collar or surface finish to make a difference in how periprosthetic bone remodels to what little strain is transferred to it. The presence of a collar, or a surface finish and stem geometry which can facilitate subsidence, are ineffectual at retaining cortical strain or decreasing the relative loss of cortical strain compared to a matt collarless implant.

Table 5.3 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

AXIAL LOAD

Principal Compressive Strain (PCS)

(Bars indicate one standard deviation)

(Strain in microstrain)

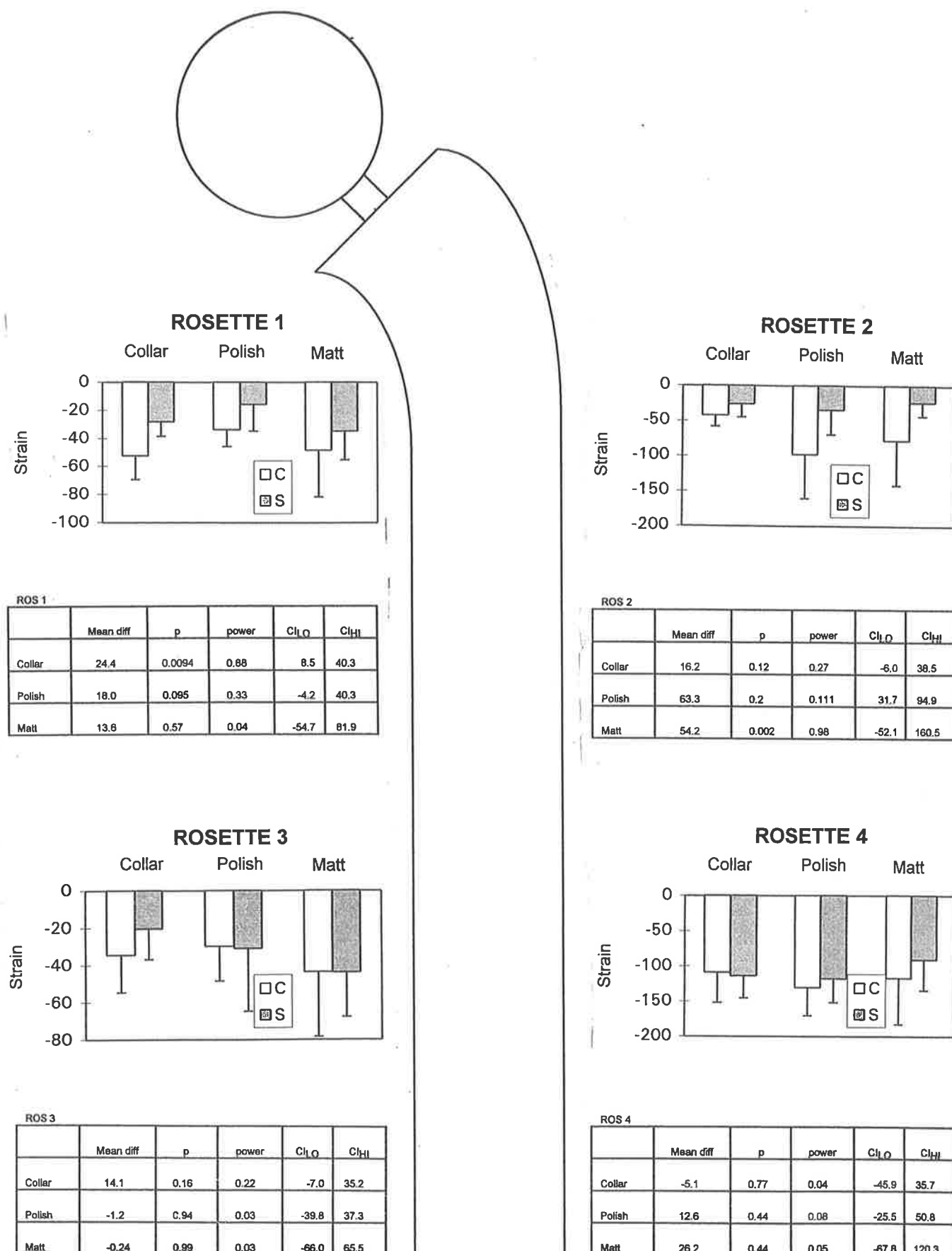


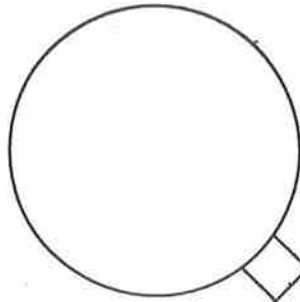
Table 5.4 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

AXIAL LOAD

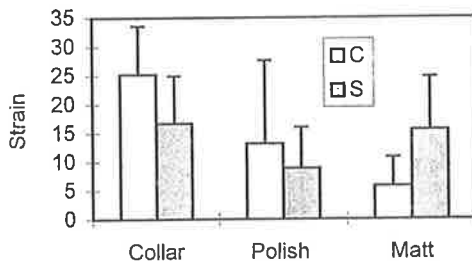
Principal Tensile Strain (PTS)

(Bars indicate one standard deviation)

(Strain in microstrain)



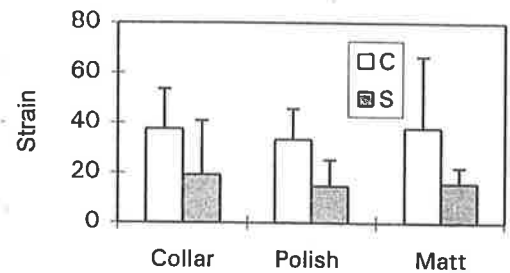
ROSETTE 1



ROS 1

	Mean diff	p	power	CI _L O	CI _H I
Collar	-8.5	0.1	0.28	-19.8	2.8
Polish	-4.2	0.2	0.14	-12.3	3.9
Matt	9.7	0.5	0.05	-33.8	53.3

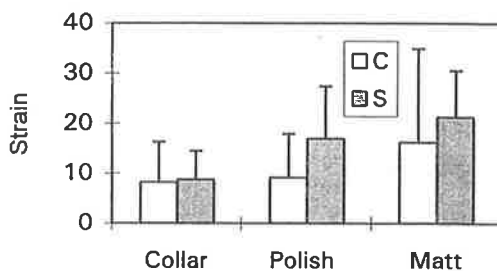
ROSETTE 2



ROS 2

	Mean diff	p	power	CI _L O	CI _H I
Collar	-18.4	0.05	0.45	-37.9	0.9
Polish	-18.6	0.02	0.65	-34.5	-2.6
Matt	-22.2	0.19	0.12	-64.1	19.6

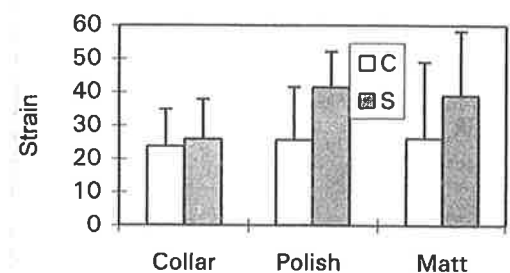
ROSETTE 3



ROS 3

	Mean diff	p	power	CI _L O	CI _H I
Collar	0.5	0.9	0.03	-10.1	11.2
Polish	7.9	0.2	0.16	-6.3	22.1
Matt	5.1	0.6	0.04	-23.4	33.7

ROSETTE 4



ROS 4

	Mean diff	p	power	CI _L O	CI _H I
Collar	2.2	0.75	0.04	-14.5	19.0
Polish	15.8	0.01	0.83	4.7	26.8
Matt	12.8	0.5	0.05	-36.8	62.6

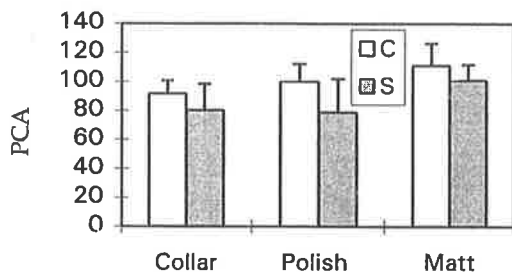
Table 5.5 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

AXIAL LOAD

Principal Compressive Angle (PCA)

(Bars indicate one standard deviation)
(PCA in degrees)

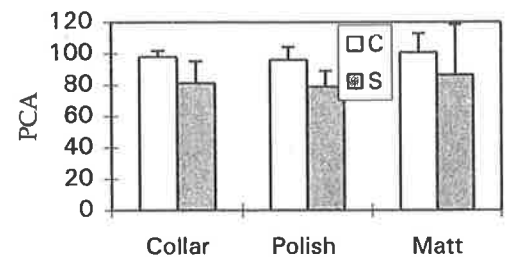
ROSETTE 1



ROS 1

	Mean diff	p	power	CI _L	CI _H
Collar	-11.3	0.23	0.13	-32.2	9.6
Polish	-21.3	0.10	0.31	-48.2	5.6
Matt	-10.1	0.19	0.11	-29.7	9.4

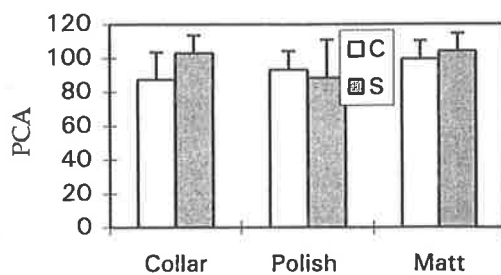
ROSETTE 2



ROS 2

	Mean diff	p	power	CI _L	CI _H
Collar	-16.6	0.03	0.6	-31.5	-1.67
Polish	-16.8	0.02	0.74	-30.1	-3.6
Matt	-14.3	0.25	0.09	-46.5	17.9

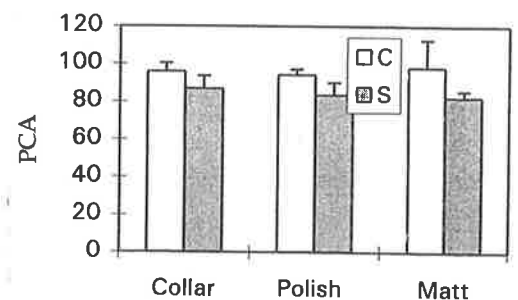
ROSETTE 3



ROS 3

	Mean diff	p	power	CI _L	CI _H
Collar	15.7	0.09	0.32	-4.06	35.5
Polish	-4.8	0.6	0.05	-26.1	16.5
Matt	4.7	0.46	0.05	-13.1	22.6

ROSETTE 4



ROS 4

	Mean diff	p	power	CI _L	CI _H
Collar	-9.08	0.007	0.91	-14.7	-3.4
Polish	-10.5	0.002	0.98	-15.8	-5.3
Matt	-15.9	0.09	0.24	-37.3	5.54

Table 5.6 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

ML LOAD

Principal Compressive Strain (PCS)

(Bars indicate one standard deviation)
(Strain in microstrain)

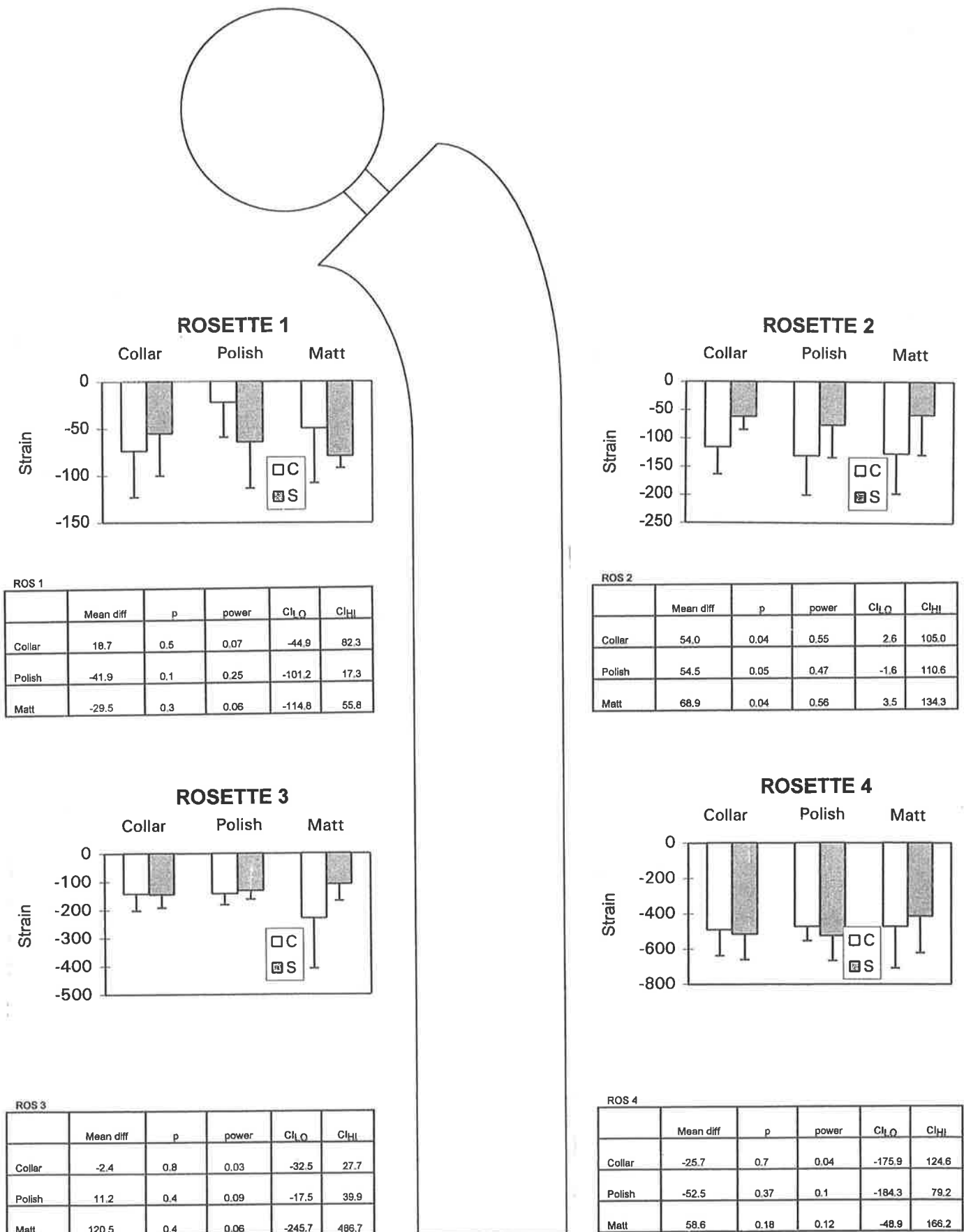


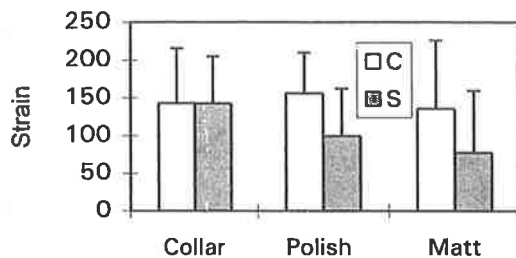
Table 5.7 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

ML LOAD

Principal Tensile Strain (PTS)

(Bars indicate one standard deviation)
(Strain in microstrain)

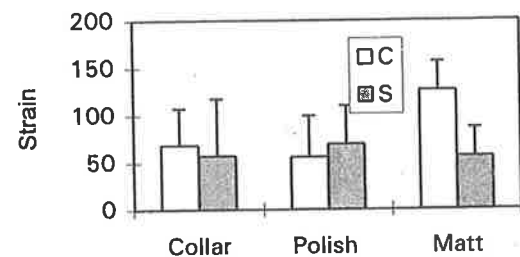
ROSETTE 1



ROS 1

	Mean diff	p	power	CI _L	CI _H
Collar	-0.3	0.99	0.03	-58.3	57.7
Polish	-56.7	0.2	0.17	-155.0	41.5
Matt	-57.8	0.01	0.96	-89.3	-26.2

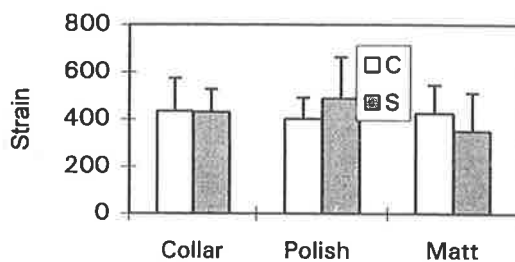
ROSETTE 2



ROS 2

	Mean diff	p	power	CI _L	CI _H
Collar	-11.4	0.7	0.04	-77.8	54.9
Polish	13.2	0.5	0.07	-33.1	59.5
Matt	-70.2	0.004	0.99	-99.4	-40.9

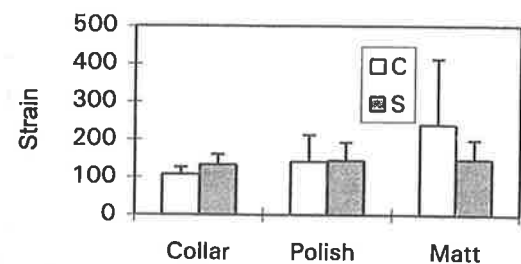
ROSETTE 3



ROS 3

	Mean diff	p	power	CI _L	CI _H
Collar	-4.0	0.9	0.03	-105.5	97.4
Polish	85.9	0.26	0.13	-86.1	258.1
Matt	-73.9	0.09	0.26	-169.7	21.8

ROSETTE 4



ROS 4

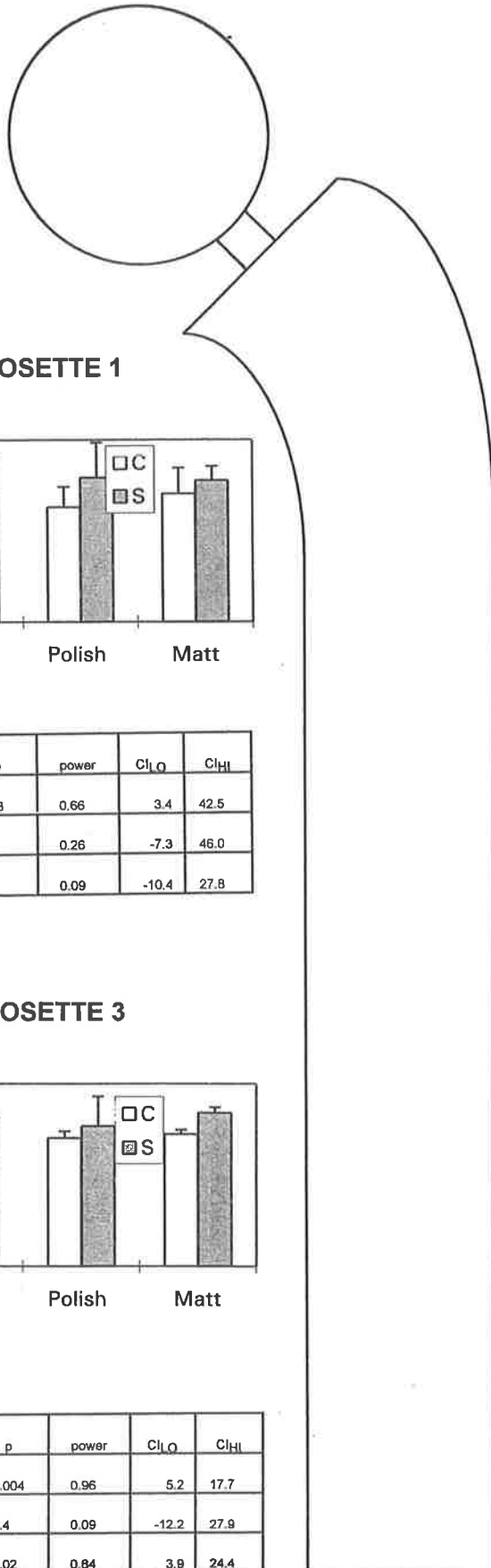
	Mean diff	p	power	CI _L	CI _H
Collar	25.6	0.12	0.27	-9.3	60.4
Polish	2.6	0.9	0.03	-54.5	59.6
Matt	-92.4	0.5	0.05	-449.4	264.5

Table 5.8 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

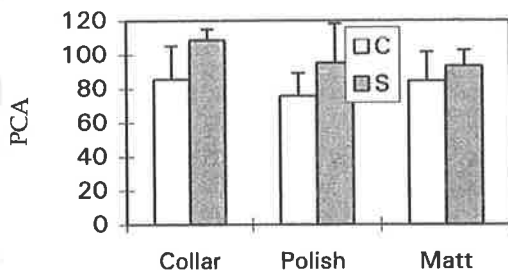
ML LOAD

Principal Compressive Angle (PCA)

(Bars indicate one standard deviation)
(PCA in degrees)



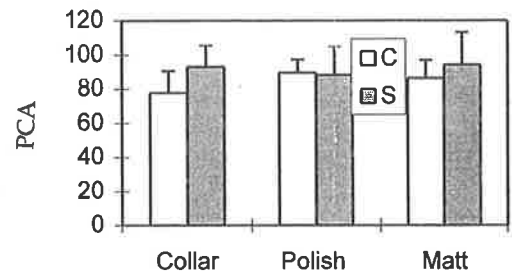
ROSETTE 1



ROS 1

	Mean diff	p	power	CI _L	CI _H
Collar	22.9	0.03	0.66	3.4	42.5
Polish	19.3	0.1	0.26	-7.3	46.0
Matt	8.7	0.2	0.09	-10.4	27.8

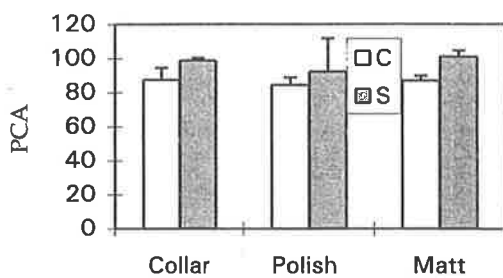
ROSETTE 2



ROS 2

	Mean diff	p	power	CI _L	CI _H
Collar	15.1	0.1	0.3	-3.9	34.2
Polish	-1.3	0.8	0.03	-15.3	12.7
Matt	7.9	0.5	0.04	-32.3	48.1

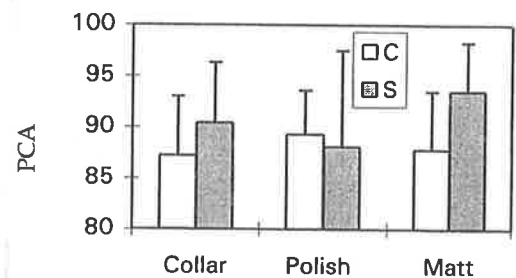
ROSETTE 3



ROS 3

	Mean diff	p	power	CI _L	CI _H
Collar	11.5	0.004	0.96	5.2	17.7
Polish	7.8	0.4	0.09	-12.2	27.9
Matt	14.1	0.02	0.84	3.9	24.4

ROSETTE 4



ROS 4

	Mean diff	p	power	CI _L	CI _H
Collar	3.2	0.3	0.1	-3.9	10.3
Polish	-1.3	0.7	0.04	-9.5	6.9
Matt	5.6	0.3	0.07	-8.6	19.9

Table 5.9 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

AP LOAD

Principal Compressive Strain (PCS)

(Bars indicate one standard deviation)

(Strain in microstrain)

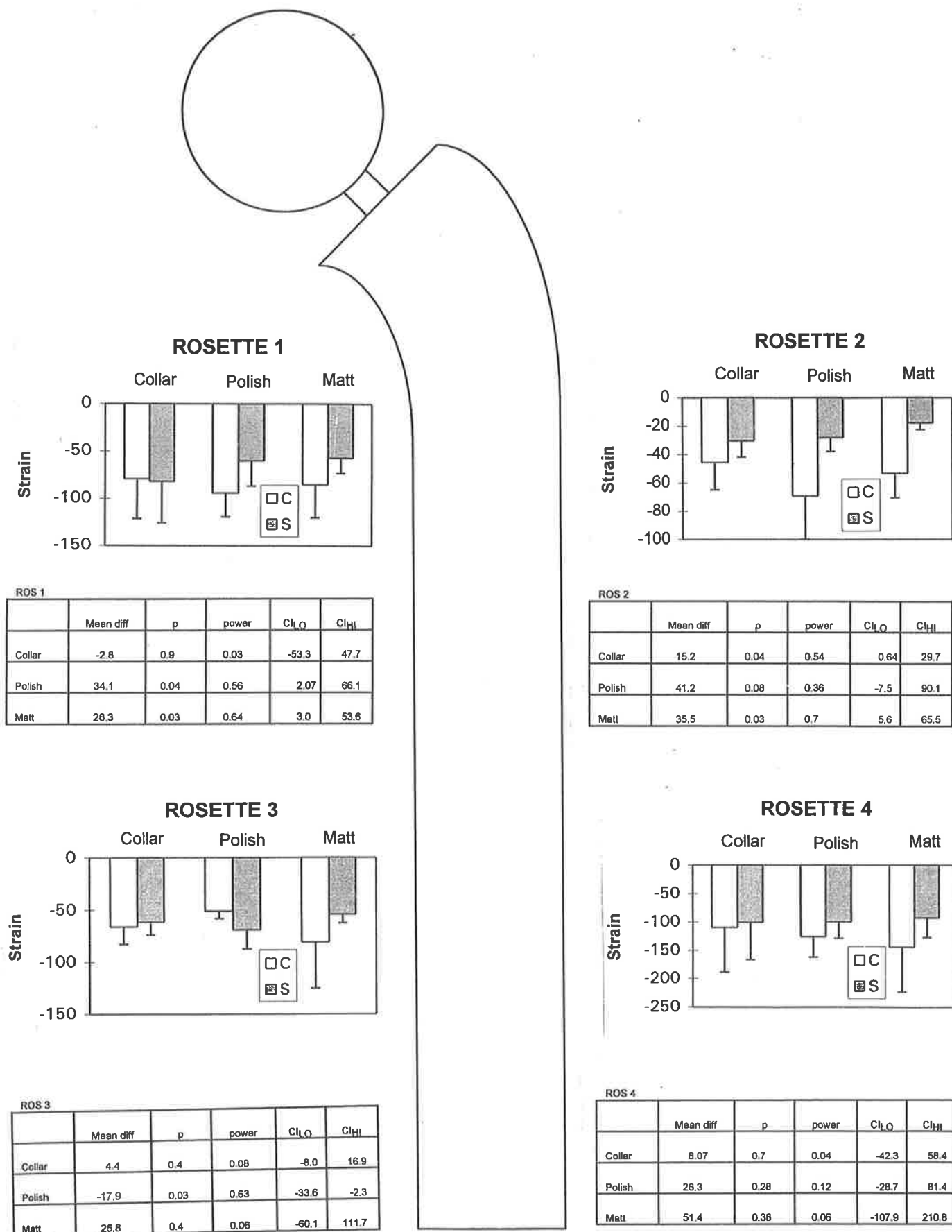


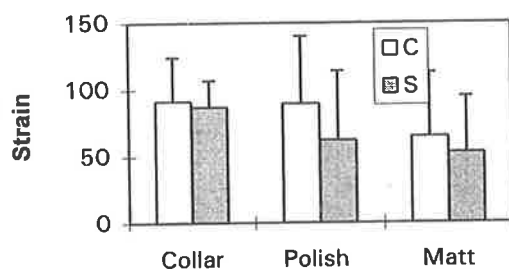
Table 5.10 Cortical Strain Following Remodelling

An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

AP LOAD**Principal Tensile Strain (PTS)**

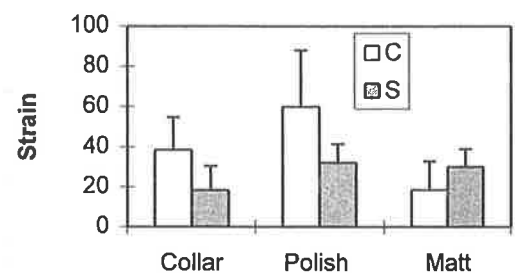
(Bars indicate one standard deviation)

(Strain in microstrain)

ROSETTE 1

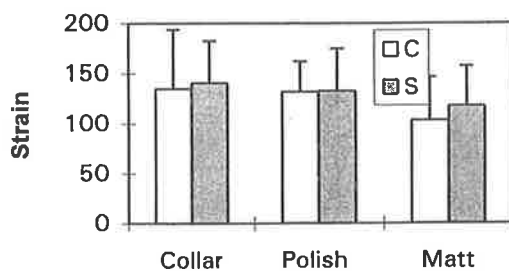
ROS 1

	Mean diff	p	power	CI _L O	CI _H I
Collar	-4.5	0.7	0.04	-39.1	30.2
Polish	-27.3	0.1	0.3	-61.8	7.2
Matt	-11.9	0.4	0.06	-49.4	25.5

ROSETTE 2

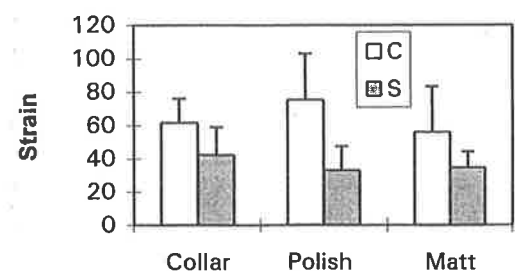
ROS 2

	Mean diff	p	power	CI _L O	CI _H I
Collar	-20.1	0.01	0.8	-34.4	-5.8
Polish	-27.7	0.05	0.4	-56.9	1.3
Matt	11.5	0.03	0.63	1.2	21.9

ROSETTE 3

ROS 3

	Mean diff	p	power	CI _L O	CI _H I
Collar	5.6	0.7	0.04	-39.1	50.4
Polish	0.8	0.96	0.03	-46.9	48.6
Matt	14.1	0.4	0.06	-33.2	61.4

ROSETTE 4

ROS 4

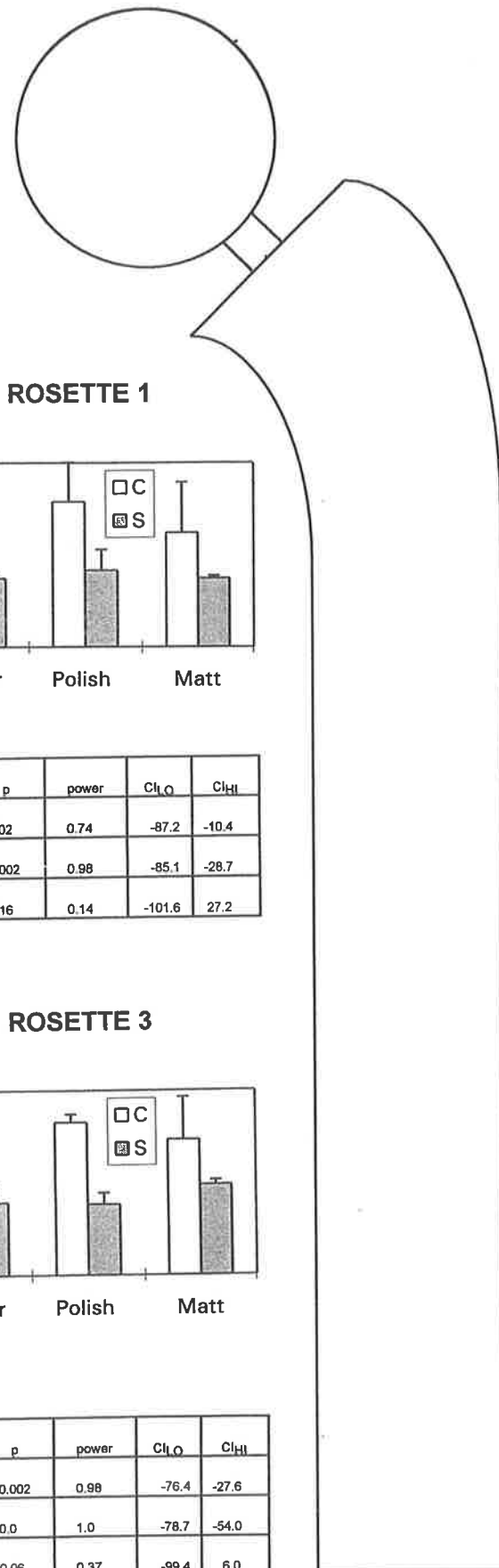
	Mean diff	p	power	CI _L O	CI _H I
Collar	-19.4	0.002	0.98	-28.6	-10.2
Polish	-42.2	0.01	0.85	-71.3	-13.2
Matt	-21.1	0.11	0.2	-51.0	8.8

Table 5.11 Cortical Strain Following Remodelling
An Analysis of Study vs Control Differences at Each of the Four Rosette Locations for Each Implant Group

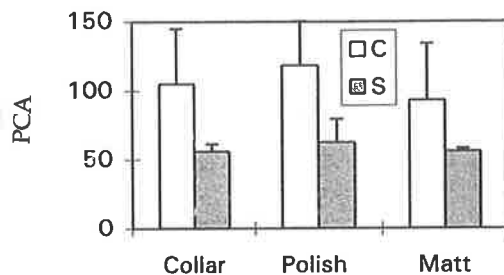
AP LOAD

Principal Compressive Angle (PCA)

(Bars indicate one standard deviation)
(PCA in degrees)



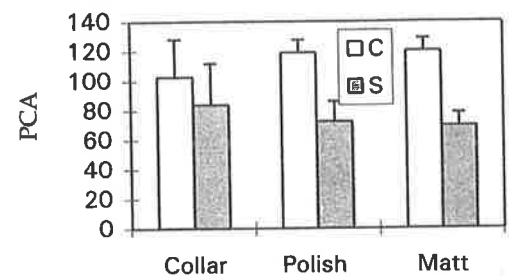
ROSETTE 1



ROS 1

	Mean diff	p	power	CI _L O	CI _H I
Collar	-48.8	0.02	0.74	-87.2	-10.4
Polish	-56.9	0.002	0.98	-85.1	-28.7
Matt	-37.2	0.16	0.14	-101.6	27.2

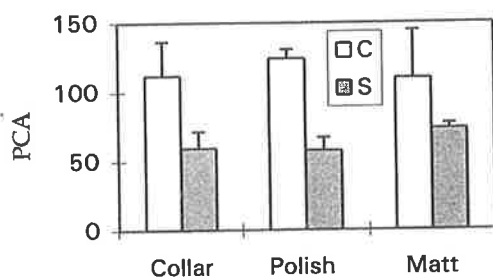
ROSETTE 2



ROS 2

	Mean diff	p	power	CI _L O	CI _H I
Collar	-18.9	0.14	0.23	-46.5	8.7
Polish	-46.9	0.0001	1.0	-60.4	-33.4
Matt	-50.5	0.008	0.97	-76.4	-24.6

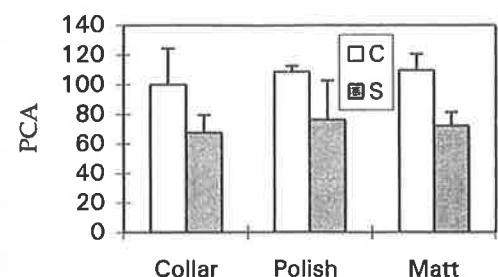
ROSETTE 3



ROS 3

	Mean diff	p	power	CI _L O	CI _H I
Collar	-52.0	0.002	0.98	-76.4	-27.6
Polish	-66.4	0.0	1.0	-78.7	-54.0
Matt	-46.7	0.06	0.37	-99.4	6.0

ROSETTE 4



ROS 4

	Mean diff	p	power	CI _L O	CI _H I
Collar	-32.5	0.01	0.79	-56.7	-8.4
Polish	-32.8	0.02	0.76	-57.8	-7.8
Matt	-47.7	0.001	1.0	-60.6	-34.7

CHAPTER 6: BONE MORPHOMETRY

6.1 INTRODUCTION

The skeletal response to well fixed cemented femoral stems has been evaluated biomechanically in Chapter 5. This chapter will now evaluate the morphometric response of femoral bone to the three implant types, after ten months of remodelling. Specifically the pattern and magnitude of bone resorption or deposition will be examined between study and control femurs, then the differences in bone remodelling changes between the three implant groups will be compared.

6.2 HYPOTHESES

1. The implanted proximal femur undergoes resorptive bone remodelling measured in comparison to the control side.
2. The magnitude and pattern of bone resorption which occurs with remodelling do not differ between implant groups

6.3 MATERIALS AND METHODS

6.3.1 Bone Sectioning Protocol

The implanted femurs were sectioned in the fresh state. To enable efficient handling the femur was sectioned with a handsaw at the 50% mark, just proximal to the level where the femur had been potted in cement for cortical strain analysis. Using an oscillating inscriber, shallow longitudinal marks were made along the anterior, and lateral cortical pencil lines marked for strain rosette placement, to aid future orientation of the cut sections. The greater trochanter, implant head, and lateral implant neck were embedded in a PMMA cement block. This cement block was clamped into the EXAKT (EXAKT, Apparatebau, Germany) bandsaw in preparation for sectioning.

Care was taken to orient each femur in the sectioning jig in an identical manner, so that

sections would be perpendicular to the long axis of the proximal femoral diaphysis. In this way no relative obliquity between matched sections could occur. The embedded proximal end of the femur was adjusted in the clamp so that the anterior longitudinal line was perpendicular to the plane of the bandsaw in the coronal plane. The femur was thus in neutral abduction-adduction. The lateral longitudinal line was oriented so that it was perpendicular to the plane of the saw blade in the sagittal plane. The femur was therefore in neutral flexion-extension. (Turner *et al* 1986, Sumner *et al* 1988, 1992) (Fig 6.1).

Sections were thus taken perpendicular to the longitudinal axis of the proximal diaphysis. However, the sections were not necessarily perpendicular to the sagittal or coronal axis of the implant. If the implant was inserted or had subsided into malalignment with respect to the diaphysis the implant would have been sectioned obliquely.

Sections were taken under constant water irrigation. Bone sections were 2mm thick. Thinner sections may have been at risk of fracture. Maloney *et al* (1996) in a human morphometric study used 5mm thick sections. In this study the blade speed of the EXAKT saw was number 6, with a force of 1.0 N acting on the specimen to draw it through the saw.

For each femur the first section was taken at the distal cut end at the 50% mark. Sectioning thus began at the same relative anatomical level for all femurs as defined by the length of the femur (Sumner *et al* 1988). The successive sections taken therefore would be from equivalent levels in the control and study femur, enabling valid comparisons of bone morphometry to be made between sides.

The section taken at the 50% mark was labelled number 1. This most distal section usually included the cement and implant centraliser. Six further sections were taken every 2mm in the distal femur. 2mm sections were then taken every 10mm until 20mm below the medial cut surface of the femoral neck. 2mm sections were then taken for the remainder of the proximal femur, thus including all the lesser trochanter.

6.3.2 High Resolution Radiography

Bone morphometric analysis was performed from contact radiographs taken of bone sections. Contact x-rays were made of each section in the Lorad MIII mammography unit (Medical Systems Incorporated, Model LBA100112, Danbury, CT, USA). This unit has a focal spot size of 0.1mm enabling images with small penumbra effect and high image resolution. In contrast the Faxitron contact radiography unit (Hewlett Packard USA) has a focal spot size of 0.5mm, and standard x-ray tubes have focal spot size of 1.0mm or more. Correspondingly greater image penumbra are formed, causing images with lower edge resolution than is possible with the mammography unit.

Single emulsion "Microvision" (Dupont, USA) film was used with the exposure set at 25kV. This high exposure enabled optimal identification of cortical porosity and cortical cancellisation.

Bone morphometric analysis was performed on bone sections from three equivalent levels in study and control femora: proximal, middle and distal. The most proximal section corresponded to Gruen zones 1 and 7 which was the level of strain rosettes 1 and 2 at the approximate midpoint of the lesser trochanter. The most distal section corresponded to the level of Gruen zones 3 and 5 which also was the location of strain rosettes 3 and 4 near the tip of the strain. The middle level corresponded to the middle of Gruen zones 2 and 6.

Bone Morphometry was performed on sections from the study femur and compared to the corresponding sections from the control side. An analysis of difference for each bone morphometry feature was performed using a two tailed student t test.

6.3.3 High Resolution Radiographic Bone Morphometry Protocol

The high resolution radiographs were analysed in the Quantimet 520 image analyser (Fig 6.2). Magnification was 5x. The software was recalibrated at the beginning of each analytical session so that 1 pixel corresponded to a linear measurement of 0.070mm. The light filter was adjusted so a constant level of illumination was used for each section. The light filter allowed maximum brightness of bone images thus enabling small cortical pores to be visible for analysis. A consistent level of subdued ambient light was used in all analytical sessions to minimise variation in selection of threshold.

The radiograph of each section was divided into quadrants by overlaying on acetate sheet with cross hairs, over the middle of the implant. For each quadrant the cortical perimeter was traced and the enclosed area (CA) calculated (Fig 6.3). The software program determined cortical length (CL) as the linear distance between the two most separated points in the cortical area. A cortical mean width of the quadrant (CW) was then calculated based on the formula $CW = CA/CL$ (Kaplan and Lewis 1971). For cortical porosity, the gray level threshold was altered to optimise the definition of cortical pores. The same gray level threshold was used for control and study sides. The software was placed in black mode while the gray scale was adjusted till the smallest visible cortical pore appeared yellow (Fig 6.4). A binary image was created whereby all pixels above the gray scale threshold were considered bone and all those below were considered non bone. The Flicker method (Parkinson and Fazzalari 1994) was employed whereby the screen image flicked between the gray level image and the coloured binary image. This was a double check to ensure all visible pores were included in the analysis.

The cursor traced around all cortical areas seen to contain pores and the enclosed cortical pore area (CPA) calculated. The cortical porosity (CP%) for that quadrant was defined as CPA/CA (%).

The trabecular bony zone of the section was then traced and trabecular area (that part of the quadrant containing trabeculae, TA); trabecular length (the linear distance between the two most separated points in TA); and mean width of the trabecular zone ($TW=TA/TL$) determined (Fig 6.5). The software was then placed in 'white' mode and the threshold adjusted until the finest trabeculae visible on the section appeared yellow

(Fig 6.6). The Flicker method was again employed to ensure all trabeculae were included in the analysis. The cursor traced around the area containing trabecular bone in a similar manner as above, and the trabecular bone area (TBA) enclosed in that area was determined. The trabecular bone density (TD) was calculated as TBA/TA .

6.3.4 Reproducibility Study of Bone Morphometry Protocol

A reproducibility study was performed to determine the random error associated with bone morphometric analysis, using a Quantimet 520 image analyser.

Method and Materials

The reproducibility of the bone morphometry protocol, was determined by repeated analysis of selected high resolution radiographs.

A high resolution radiograph of a distal section was selected (499S) and subdivided into quadrants by overlying the radiographs with a plastic sheet with cross hairs. The anterolateral quadrant was serially analysed six times, for cortical area (CA), cortical length (CL), cortical mean width ($CW = CA/CL$), cortical pore area (CPA) and cortical porosity ($CP = (CPA/CA) \times 100\%$).

A high resolution radiograph from a more proximal section containing trabecular bone was selected (496C). The posterolateral quadrant was serially analysed six times and in addition to the above cross sectional cortical parameters, the trabecular zone area (TA), trabecular zone length (TL), trabecular zone mean width ($TW = TA/TL$), trabecular bone area (TBA) and trabecular density (TD) were calculated. The gray scale threshold was selected individually for each of the six analyses.

A coefficient of variation ($CV = (SD/mean) \times 100\%$) was calculated from the six trials for each of the two analyses.

Results

The distal section analysis is shown in Table 6.1 and proximal section analysis is shown in Table 6.2.

Cortical area and cortical length were measured very reproducibly, with a coefficient of variation of 2-3% calculated over six trials. The measurement of cortical pore area (CPA) was more subjective even though random errors in identifying small pores for tracing around were minimised by a consistent light filter setting. Selection of a gray

threshold on each individual trial involved considerable subjectivity on behalf of the operator. At low gray thresholds the larger pores at the endosteal surface opened out into the cement mantle, or were seen to coalesce. The exact measurement of their area was also subjective as it was difficult to separate cortical pores from the endosteal margin of trabecular zone more proximally. At high gray thresholds small cortical pores were not identified. The calculated coefficient of variation for CAP and CP was approximately 7%.

Trabecular zone area and trabecular zone length were also measured with a high level of reproducibility ($CV < 2\%$). Trabecular bony area was only slightly more variable due to the difficulty in distinguishing the endosteal margin of cortical bone with the trabecular zone. The coefficient of variation calculated over six trials for trabecular density was approximately 5%.

Discussion

Linear measurements can be made from the high resolution radiographs with a high degree of reproducibility and a coefficient of variation of approximately 3%. Cortical porosity and trabecular bone density analysis required a greater subjective component and though the coefficient of variation was slightly higher, it was in general less than 7% for these analyses.

These coefficients of variation represent the random error of one operator in measuring bone parameters from high resolution radiographs. The principal source of error was selection of the gray scale threshold. This threshold was selected individually for each of the six trials in this substudy. The gray scale threshold determined the detection threshold for small cortical pores and the finer bone trabeculae in each trial. The error in threshold selection was reduced by employing the flicker method and by maintaining a consistent subdued level of ambient lighting which did not distort the visual perception of the features of interest, in each analytical session.

Table 6.1 High Resolution Bone Morphometry:
Reproducibility Study in a Distal Cortical Section, over six trials

499S AL Quadrant

	Trial	CA	CL	CW=CA/CL	CPA	CP=(CPA/CA)x100%
	1	65.175	18.841	3.459	8.47	13
	2	64.818	19.42	3.338	8.27	12.759
	3	62.44	19.203	3.252	8.916	14.28
	4	64.199	19.203	3.343	8.14	12.679
	5	63.716	18.841	3.382	7.829	12.287
	6	65.622	18.986	3.456	9.504	14.483
mean		64.328	19.082	3.372	8.522	13.248
SD		1.1478	0.232	0.079	0.602	0.91
CV=(SD/mean)x100 %		1.784	1.216	2.343	7.064	6.869

Table 6.2 High Resolution Bone Morphometry:
Reproducibility Study in a Proximal Bone Section, over six trials

494C PL Quadrant

	Trial	CA	CL	CW=CA/CL	CPA	CP=(CPA/CA)x100%
	1	58.407	21.377	2.732	9.074	15.536
	2	58.476	21.449	2.726	7.651	13.084
	3	55.088	22.101	2.493	7.54	13.687
	4	57.456	21.594	2.661	8.06	14.028
	5	55.577	21.232	2.618	7.808	14.049
	6	55.246	21.449	2.576	7.577	13.715
mean		56.708	21.534	2.634	7.952	14.017
SD		1.588	0.302	0.092	0.582	0.822
CV=(SD/mean)x100%		2.8	1.402	3.493	7.319	5.864

	Trial	TA	TL	TW=TA/TL	TBA	TD=(TBA/TA)x100%
	1	76.875	17.319	4.439	4.264	5.547
	2	79.201	17.246	4.592	4.059	5.125
	3	78.697	17.029	4.621	4.337	5.511
	4	76.512	17.029	4.493	4.043	5.284
	5	76.528	17.174	4.456	4.542	5.935
	6	75.924	17.391	4.366	4.343	5.72
mean		77.29	17.198	4.495	4.265	5.52
SD		1.331	0.15	0.097	0.19	0.291
CV=(SD/mean)x100%		1.722	0.872	2.158	4.455	5.27

6.4 RESULTS: STUDY VERSUS CONTROL

General Bone Remodelling Pattern

Ten months after surgery the general pattern of bone remodelling seen around all three implant groups was similar. Compared to the control femurs, the study femurs showed evidence of cortical thinning. This was especially apparent at the proximal and mid levels where endosteal cortical resorption occurred, the cortex demonstrated an increase in cortical porosity with resorption lacunae evident at the endosteal surface (485 polish Fig 6.7, 6.8). Considerable interindividual variation was seen even within the same implant group. In some femurs, cortical resorption was extensive and resembled the secondary medullary canal observed in long term implanted femurs (493 polish Fig 6.9, 6.10). When endosteal resorption was well marked, a neocortex was apparent (Fig 6.10). This comprised a narrow zone of dense cortical bone adjacent to the cement mantle and internal to the zone of cortical resorption.

More proximally the trabecular bone in the posteromedial and posterolateral quadrants showed resorption and a general loss in density. However adjacent to the cement mantle, a condensation of bone trabeculae was apparent forming a neocortex (485 polish Fig 6.11, 6.12).

Low exposure high resolution radiographs of study series of sections showed the cement mantle separate from bone. In all cases at this low exposure the cement mantle was observed in close apposition to the neocortex with no intervening radiolucencies. This confirmed the contact radiographic analysis (Chapter 4) in that after 10 months in vivo, all implants remained soundly fixed. Even in sheep 493 (polish) where gross inspection of the intact study femur had revealed 18mm of calcar lysis, low exposure radiographic analysis of transverse bone sections indicated that the cement mantle remained in close apposition to the bone (Fig 6.13). Except in the most proximal 2 sections, no cement-bone radiolucencies were observed on the transverse cut sections which would indicate implant loosening in this specimen.

6.4.1 Cortical Width (Tables 6.3 - 6.5)

There was a trend for femoral cortical width in the study femurs to decrease with

remodelling compared to the control femurs. This was clearly observed in the matt and collared groups at the proximal level. In the matt group mean cortical width decreased 15.5% and this tendency approached significance (mean difference = 0.445mm, $p = 0.076$, $CI_{Lo} = -0.98$, $CI_{Hi} = 0.089$). In the collared group, only a very weak trend was observed proximally (mean difference = 0.092mm, $p = 0.16$, $CI_{Hi} = -0.234$, $CI_{Hi} = 0.049$). At the middle and distal levels, no trends in change in cortical width were observed.

In the polish group, cortical thinning of the study group compared to the control group was not observed.

6.4.2 Cortical Porosity (Tables 6.6 - 6.8)

In the control sections no cortical porosity was detectable at any level. All study femurs showed evidence of endosteal cortical resorption with increased cortical porosity. Though high resolution radiograph bone morphometry may not be sensitive enough to detect the very small cortical pores in a 2mm bone section, the underdetection was a systematic error and could be discounted in a comparative left - right study.

The matt study femurs showed the greatest and most consistent increase in cortical porosity following remodelling when compared to its control group. This was most marked proximally (mean % difference 6.2%, $p = 0.14$, $CI_{Lo} = -3.8$, $CI_{Hi} = 16.2$) and in the mid level (mean % difference = 4.3%, $p = 0.11$, $CI_{Lo} = -1.9$, $CI_{Hi} = 10.5$) where moderate trends were observed. The polished group also displayed increases in cortical porosity most prominent at the mid level (mean % difference = 3.8%, $p = 0.056$, $CI_{Lo} = -0.14$, $CI_{Hi} = 7.71$). In the collared group study femora had increased cortical porosity but to a lesser degree than the matt and polished groups.

Even though the sheep subjects were from a similar background and the surgical technique used was consistent, there was a wide interindividual variation in cortical porosity. There was a marked variation in the bone remodelling response from individual to individual even within the same implant group. For example, in the matt group one sheep (473 matt) showed a mean cortical porosity of 13.7% at the proximal level, and in another sheep (460 matt) porosity was only 0.3% at the same level.

6.4.3 Trabecular Density (Table 6.9)

Trabecular density was recorded in the proximal sections where cancellous bone was found, principally in the posterolateral and posteromedial quadrants. In all 3 implant groups, trabecular density of the study femurs tended to decrease compared to the control femurs.

For the matt group, the study femurs had undergone significant loss of trabecular density compared to the control group (mean difference = -11.82%, SD = 2.55%, $p = 0.0026$) with up to 15.0% loss in trabecular density in subject 460.

For the polished group, the Study vs Control difference in trabecular density was not significant though trabecular bone was lost (mean difference = -4.85%, SD = 12.7%, $p = 0.35$). Wide interindividual variation was seen with five of the seven study femurs losing trabecular density and two of the seven increasing density.

For the collared group, the Study vs Control difference in trabecular bone density was also not significant (mean difference = -3.37%, SD = 9.22%, $p = 0.37$).

6.4.4 Discussion

Study vs Control

10 months after surgery, bone morphometry studies indicated that study femurs have undergone cortical and trabecular remodelling compared to the control femurs. The pattern of remodelling was similar to that reported by Sumner *et al* (1992) in a canine cementless model and Maloney *et al* in long term human autopsy retrievals (1991, 1996).

Most of these remodelling changes did not cause the study side parameters to be statistically significantly different from the control side. The number of survivors per group however were small and the power of each 2 tailed paired t test was low, in most cases the power was less than 0.3. A larger sample size per group would have increased the power and may have shown a significant Study vs Control difference in

some cases. 95% confidence intervals were calculated for each test and interpreted so that non significant findings were not mistaken for no difference between study and control sides.

95% confidence interval indicates a pattern of change in bone morphometry with remodelling. In the matt group, greater resorption remodelling was observed than with the other implant groups. This was most marked proximally where cortical width and cortical porosity showed strong trends and trabecular density loss was strongly significant compared to the control side. Both collared and polished groups showed weaker trends to resorptive remodelling. To determine if implant design had an effect in the magnitude of resorptive remodelling, the study-control differences for each implant design were compared between groups.

Table 6.3 Bone Morphometry: Cortical Width (mm):
A Study vs Control Comparison at three levels

MATT Implants

Proximal

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	3.19	2.70	3.04	2.81	2.70	1.87	2.61	2.20
AL	2.97	2.30	2.66	3.10	2.43	2.17	2.20	2.20
PL	3.06	2.21	3.57	3.42	2.98	2.46	2.50	2.56
PM	3.40	2.12	3.28	2.83	2.96	2.08	2.58	1.98
mean	3.15	2.33	3.14	3.02	2.76	2.14	2.47	2.23

$$\begin{aligned}
 p &= 0.07 \\
 CI_{Lo} &= -0.98 \\
 CI_{Hi} &= 0.08
 \end{aligned}$$

Mid

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	3.55	3.50	4.26	4.29	3.76	3.99	3.99	3.79
AL	2.76	2.51	3.66	4.07	3.07	3.07	3.09	3.23
PL	3.54	2.07	3.47	3.61	2.85	2.95	2.40	2.47
PM	3.20	2.95	4.02	3.78	3.83	3.42	3.03	2.99
mean	3.26	2.75	3.84	3.92	3.37	3.59	3.12	3.12

$$\begin{aligned}
 p &= 0.54 \\
 CI_{Lo} &= -0.28 \\
 CI_{Hi} &= 0.18
 \end{aligned}$$

Distal

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	3.70	4.10	4.64	4.51	4.40	3.95	4.01	4.10
AL	2.91	3.25	3.85	4.04	3.40	3.80	3.19	3.20
PL	2.82	2.79	3.72	3.64	3.22	3.09	2.65	2.56
PM	3.48	3.14	3.94	4.20	3.70	3.55	2.78	2.71
mean	3.23	3.32	4.03	4.09	3.68	3.59	3.15	3.14

$$\begin{aligned}
 p &= 0.75 \\
 CI_{Lo} &= -0.11 \\
 CI_{Hi} &= 0.14
 \end{aligned}$$

Table 6.4 Bone Morphometry: Cortical Width (mm):
A Study vs Control Comparison at three levels

COLLARED Implants

Proximal

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	2.47	2.10	2.54	3.00	2.95	3.09	2.76	2.50	2.67	2.50	2.84	3.04	2.50	2.16
AL	2.46	2.45	2.51	2.13	2.91	3.04	2.41	2.95	2.07	2.80	2.70	2.95	2.23	2.34
PL	2.47	2.10	2.76	2.55	2.83	2.72	2.59	2.81	1.90	2.43	2.95	2.68	1.92	1.57
PM	2.59	2.16	2.36	2.33	3.33	2.32	3.29	2.67	2.30	1.50	2.85	2.61	1.67	1.43
mean	2.49	2.20	2.54	2.50	3.00	2.79	2.76	2.73	2.23	2.30	2.83	2.82	2.08	1.87

$$\begin{aligned}
 p &= 0.16 \\
 CI_{Lo} &= -0.23 \\
 CI_{Hi} &= 0.05
 \end{aligned}$$

Mid

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	3.71	3.39	3.51	4.01	4.18	4.34	4.58	4.49	3.71	3.91	3.90	4.00	3.02	3.10
AL	3.17	2.93	3.20	3.44	3.76	3.59	4.02	3.83	3.54	3.35	4.00	3.80	3.48	3.54
PL	2.65	2.33	3.08	2.82	3.17	3.10	3.32	3.17	2.81	2.52	3.22	3.40	3.07	2.80
PM	3.82	3.20	3.60	3.35	3.58	3.60	3.73	3.55	3.13	3.48	3.40	3.44	3.27	2.99
mean	3.34	2.96	3.35	3.40	3.67	3.65	3.16	3.76	3.29	3.31	2.88	3.66	3.2	3.10

$$\begin{aligned}
 p &= 0.22 \\
 CI_{Lo} &= -0.21 \\
 CI_{Hi} &= 0.06
 \end{aligned}$$

Distal

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	3.77	3.47	4.07	3.69	4.41	4.60	4.62	4.40	4.22	3.92	4.03	4.04	3.39	3.34
AL	3.26	3.18	3.59	3.51	3.53	3.71	4.00	4.00	3.12	3.07	3.50	3.70	3.43	3.51
PL	3.03	2.76	3.05	2.96	3.61	3.86	3.20	3.28	2.77	2.86	3.60	3.50	2.77	2.62
PM	3.22	2.95	3.44	3.23	3.69	3.69	3.61	3.56	2.86	3.21	3.40	3.40	3.04	2.69
mean	3.31	3.09	3.53	3.35	3.81	3.96	3.86	3.81	3.24	3.26	3.60	3.66	3.16	3.04

$$\begin{aligned}
 p &= 0.33 \\
 CI_{Lo} &= -0.18 \\
 CI_{Hi} &= 0.07
 \end{aligned}$$

Table 6.5 Bone Morphometry: Cortical Width (mm):
A Study vs Control Comparison at three levels

POLISHED Implants

Proximal

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	4.92	2.73	2.81	3.04	3.30	2.60	2.19	2.65	2.89	2.93	2.82	2.87	3.06	3.40
AL	2.75	3.02	2.38	2.93	2.76	3.68	2.03	2.96	2.30	2.50	2.51	3.14	2.60	3.26
PL	2.61	2.89	2.87	3.47	3.58	3.57	2.75	2.50	2.79	2.01	2.75	3.43	3.26	3.47
PM	3.00	2.56	2.80	3.04	2.81	2.61	2.19	2.78	2.86	2.38	3.05	2.70	3.53	2.86
mean	3.32	2.79	2.71	3.10	3.11	3.12	2.29	2.72	2.71	2.45	2.77	3.03	3.11	3.25

$$p = 0.64$$

$$CI_{LO} = -0.26$$

$$CI_{HI} = 0.39$$

Mid

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	2.96	3.72	4.08	4.23	3.68	3.77	3.17	3.40	4.15	3.82	3.88	4.11	4.80	4.72
AL	4.25	3.31	3.36	3.97	4.14	4.16	3.91	4.09	3.09	3.38	3.36	4.04	3.84	3.80
PL	3.09	2.52	2.89	3.02	3.44	3.22	2.89	2.89	3.00	2.86	3.35	3.10	3.38	3.15
PM	2.61	2.95	3.93	4.03	2.79	4.16	2.73	2.66	3.66	3.66	4.06	3.67	3.82	3.40
mean	3.23	3.12	3.56	3.8	3.5	3.83	3.18	3.26	3.47	3.43	3.66	3.73	4.0	3.73

$$p = 0.46$$

$$CI_{LO} = -0.11$$

$$CI_{HI} = 0.22$$

Distal

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	2.88	3.84	3.95	2.98	4.09	4.02	3.41	3.78	4.46	4.75	4.18	4.53	4.65	4.63
AL	4.73	3.88	3.35	3.95	4.85	4.23	4.11	4.01	3.84	4.03	3.88	4.11	3.95	3.87
PL	3.03	2.98	3.19	4.24	3.47	3.27	2.86	2.79	3.16	3.23	3.25	3.32	3.23	3.27
PM	3.40	3.23	3.97	3.65	3.42	2.96	2.96	3.08	3.34	3.46	3.89	3.60	3.36	2.9
mean	3.50	3.48	3.61	3.70	3.96	3.64	3.30	3.41	3.71	3.86	3.80	3.89	3.79	3.66

$$p = 0.89$$

$$CI_{LO} = -0.17$$

$$CI_{HI} = 0.15$$

Table 6.6 Bone Morphometry: Cortical Porosity (%):
A Study vs Control Comparison at three levels

MATT Implants

Proximal

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	0	16.9	0	0	0	12.3	0	0
AL	0	5.5	0	0	0	39.3	0	0
PL	0	8.05	0	0	0	1.15	0	2.5
PM	0	4.8	0	1.3	0	2.3	0	4.69
mean	0	8.8	0	0.3	0	13.7	0	1.8

$$\begin{aligned}
 p &= 0.14 \\
 CI_{LO} &= -3.8 \\
 CI_{HI} &= 16.15
 \end{aligned}$$

Mid

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	0	6.63	0	0	0	18.9	0	8.87
AL	0	0.63	0	0	0	6.88	0	3.54
PL	0	1.20	0	0	0	4.60	0	2.29
PM	0	7.38	0	0	0	7.70	0	0.24
mean	0	3.96	0	0	0	9.52	0	3.37

$$\begin{aligned}
 p &= 0.11 \\
 CI_{LO} &= -1.9 \\
 CI_{HI} &= 10.5
 \end{aligned}$$

Distal

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	0	4.06	0	0	0	4.60	0	1.03
AL	0	0	0	0	0	4.44	0	1.51
PL	0	0	0	0	0	1.02	0	0
PM	0	0	0	0	0	0	0	0
mean	0	1.1	0	0	0	2.5	0	0.6

$$\begin{aligned}
 p &= 0.14 \\
 CI_{LO} &= -0.66 \\
 CI_{HI} &= 2.74
 \end{aligned}$$

Table 6.7 Bone Morphometry: Cortical Porosity (%):
A Study vs Control Comparison at three levels

COLLARED Implants

Proximal

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0	0	0.33	0	0	0	4.8	0	3.36	0	0	0	12.8
AL	0	2.46	0	0.37	0	0	0	0	0	10.7	0	0	0	8.3
PL	0	0	0	0	0	0	0	0	0	3.46	0	0	0	1.47
PM	0	0	0	0	0	0	0	0	0	8.50	0	0	0.38	4.05
mean	0	0.6	0	0.2	0	0	0	1.2	0	6.5	0	0	0.9	6.6

$$\begin{aligned}
 p &= 0.1 \\
 CI_{Lo} &= -0.64 \\
 CI_{Hi} &= 4.94
 \end{aligned}$$

Mid

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0.22	0	5.30	0	0	0	0.77	0	0	0	0	0	1.57
AL	0	0	0	1.87	0	0	0	0	0	0	0	0	0	2.20
PL	0	0	0	2.20	0	0	0	0	0	0	0	0	0	0.09
PM	0	0.39	0	1.08	0	0	0	0	0	0	0	0.01	1.17	1.36
mean	0	0.15	0	2.61	0	0	0	0.19	0	0	0	0.002	0.29	1.3

$$\begin{aligned}
 p &= 0.17 \\
 CI_{Lo} &= -0.33 \\
 CI_{Hi} &= 1.46
 \end{aligned}$$

Distal

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0.21	0	1.52	0	0	0	0.14	0	0	0	0	0	0.11
AL	0	0.56	0	2.08	0	0	0	0	0	0	0	0	0	3.37
PL	0	0	0	2.38	0	0	0	0	0	0	0	0	0	0.83
PM	0	0	0	0.38	0	0	0	0	0	0	0	0	0	1.02
mean	0	0.2	0	1.6	0	0	0	0.04	0	0	0	0	0	1.3

$$\begin{aligned}
 p &= 0.14 \\
 CI_{Lo} &= -0.19 \\
 CI_{Hi} &= 1.09
 \end{aligned}$$

Table 6.8 Bone Morphometry: Cortical Porosity (%):
A Study vs Control Comparison at three levels

POLISHED Implants

Proximal

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0.28	0	4.14	0	0	0	0	0	27.1	0	0	0	5.70
AL	0	0.14	0	1.52	0	0.05	0	0.03	0	2.47	0	0	0	1.43
PL	0	0	0	0.05	0	0.32	0	2.31	0	2.54	0	0	0	0
PM	0	0	0	0.06	0	0.55	0	0	0	7.00	0	0	0	0
mean	0	0.1	0	1.4	0	0.23	0	0.6	0	9.75	0	0	0	1.8

$$p = 0.18$$

$$CI_{LO} = -1.2$$

$$CI_{HI} = 5.2$$

Mid

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	1.14	0	22.0	0	0.24	0	8.19	0	9.20	0	0	0	0.16
AL	0	0	0	10.0	0	1.27	0	14.0	0	2.87	0	0	0	1.30
PL	0	0.54	0	5.00	0	3.99	0	3.92	0	4.00	0	0	0	0
PM	0	0	0	3.39	0	0.57	0	8.47	0	5.53	0	0.03	0	0.14
mean	0	0.42	0	10.1	0	1.5	0	8.6	0	5.4	0	0.006	0	0.4

$$p = 0.05$$

$$CI_{LO} = -0.14$$

$$CI_{HI} = 7.7$$

Distal

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0	0	3.06	0	1.08	0	2.86	0	0.07	0	0	0	0
AL	0	0	0	14.7	0	1.67	0	1.48	0	0.48	0	0	0	1.2
PL	0	0	0	17.3	0	0.34	0	0.38	0	0	0	0	0	2.9
PM	0	0	0	4.59	0	0.29	0	3.74	0	0	0	0	0	0.32
mean	0	0	0	9.9	0	0.8	0	2.11	0	0.2	0	0	0	1.1

$$p = 0.18$$

$$CI_{LO} = -1.3$$

$$CI_{HI} = 5.3$$

Table 6.9 Bone Morphometry: Trabecular Density (%):
A Study vs Control Comparison at the proximal levels

MATT Implants

Sheep no:	470		460		473		486	
Quadrant	Control	Study	Control	Study	Control	Study	Control	Study
AM	0	0	62.2	53.4	0	0	0	0
AL	0	0	60.7	25.3	0	0	0	0
PL	14.9	7.90	55.7	56.0	24.6	10.4	14.7	2.77
PM	15.4	5.07	62.2	46.4	25.8	16.3	19.4	7.60
mean	7.57	3.23	60.2	45.3	12.6	6.67	8.5	2.59

$$p = 0.0026$$

$$CI_{LO} = -15.9$$

$$CI_{HI} = -7.7$$

POLISHED Implants

Sheep no:	477		493		494		496		485		480		481	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AL	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PL	73.4	62.1	0	0	27.4	14.0	19.6	15.2	10.4	12.1	14.5	9.8	21.2	19.5
PM	39.9	53.6	34.8	55.3	36.9	22.8	41.5	9.67	30.4	12.5	26.4	19.7	52.7	34.4
mean	28.3	28.8	8.7	13.8	16.0	9.2	15.2	6.2	10.2	6.1	10.1	7.2	18.5	13.5

$$p = 0.35$$

$$CI_{LO} = -16.6$$

$$CI_{HI} = 6.9$$

COLLARED Implants

Sheep no:	476		499		482		475		491		487		468	
Quadrant	C	S	C	S	C	S	C	S	C	S	C	S	C	S
AM	0	0	52.5	0	27.3	27.2	33.1	36.4	0	0	0	0	0	0
AL	0	0	46.5	77.5	20.9	55.7	30.2	26.8	0	0	0	0	0	0
PL	23.1	9.8	55.8	44.5	39.2	37.6	19.8	10.9	9.1	6.78	22.9	24.4	11.6	6.9
PM	33.8	9.2	61.7	79.4	54.5	19.9	45.5	33.4	10.6	5.8	40.4	33.5	17.0	11.2
mean	14.1	4.9	54.1	50.3	35.5	35.1	32.1	26.8	4.9	3.1	15.3	14.5	7.1	4.5

$$p = 0.37$$

$$CI_{LO} = -11.9$$

$$CI_{HI} = 5.1$$

6.5 RESULTS: ANALYSIS OF INTERGROUP DIFFERENCES

In this section, the remodelling effect on bone morphometry parameters was analysed as a function of implant design. The null hypothesis was that the change in periprosthetic bone parameters occurring with remodelling, did not differ between implant groups.

6.5.1 Cortical Width

At the proximal level the polished group retained cortical width significantly more after remodelling, than the matt group. The difference between means (polish-matt) was 0.51mm, $p < 0.05$, $CI_{Lo} = 0.129$, $CI_{Hi} = 0.89$.

The collared group likewise had a strong trend in this regard. The difference between means (collar-matt) was 0.353mm, $CI_{Lo} = -0.028$, $CI_{Hi} = 0.734$.

At the proximal level, no difference existed between polished and collared groups. The difference between means (polish-collar) was 0.157mm, $CI_{Lo} = -0.17$, $CI_{Hi} = 0.48$.

At the mid and distal level no significant differences or trends were detected between the three implant groups.

6.5.2 Cortical Porosity

At the proximal level the matt group indicated a strong trend towards a greater increase in cortical porosity after remodelling than the other two groups. Matt-Collar: mean difference 4.02%, $CI_{Lo} = -1.4$, $CI_{Hi} = 9.4$; Matt-Polish: mean difference 4.18%, $CI_{Lo} = -1.2$; $CI_{Hi} = 9.6$. There were no differences in the cortical porosity changes between collared and polished groups.

At the mid level, a similar strong trend existed for the matt group to have a greater increase in cortical porosity than the collared group. Matt-Collar: mean difference 3.7%, $CI_{Lo} = -0.63$, $CI_{Hi} = 8.1$; but not between matt and polished groups. There was a weak trend for the polished group to have undergone greater resorptive remodelling and

cortical porosity change than the collared group. Polish-Collar: mean difference 3.2%, $CI_{Lo} = -0.50$, $CI_{Hi} = 6.9$.

At the distal level, no trends were apparent between groups on 95% confidence interval testing.

6.5.3 Trabecular Density

The matt group displayed greater resorptive remodelling of bony trabeculae than the other two groups, though statistical significance was not achieved. Matt-Collar: mean difference -8.4%, $CI_{Lo} = -21.8$, $CI_{Hi} = 4.9$; Matt-Polish: mean difference -6.9%, $CI_{Lo} = -20.3$, $CI_{Hi} = 6.4$.

There was no difference in the loss of trabecular density between collared and polished groups.

6.5.4 Discussion

Cortical area and subperiosteal area are other bone parameters which reflect remodelling. They have been studied in other quantitative studies (Torchia and Ruff 1990, Maloney *et al* 1996, Bobyn *et al* 1987). However these parameters are very sensitive to the effects of obliquity in the sectioning process. Also Turner *et al* (1986) stated that exact matching of the level of left and right sections was difficult, and that total cortical area variation by 10% was acceptable in matching sections. As this could be the magnitude of our treatment effect, we chose not to analyse cortical or subperiosteal area directly in the current study.

The matt group had undergone relatively more resorptive remodelling than the polished and collared groups. This was noted especially at the proximal level. The matt group was small and even among the four subjects, large interindividual variation was noted. Sheep 473 in particular showed marked bone resorption with a cortical porosity of 39.3% in the anterolateral quadrant of the proximal section. This far exceeded the porosity recorded in any other quadrant in any other sheep. Likewise the cortical width at the proximal level of study sheep 473 was very low, and this one sheep in the small

matt group would have skewed the overall data toward showing more bone resorption with the matt implants. There were no clear differences in remodelling between the polished and collared groups at any level. Though the polished group had undergone relatively greater cortical porosity than the collared group at the mid level, this was not reflected in cortical width changes.

This study may be criticised for the small number of subjects in each implant group. The small numbers in each group lowered the power of the statistical tests used. A significant difference may have existed in the bone morphometric changes between polished and collared implants but the study has been unable to demonstrate it. Furthermore the bone morphometry as described above is a relatively insensitive means for measuring bone remodelling response. It can measure cortical width well, but measurement of cortical porosity and trabecular density are subject to artefact from the thick sections, and from gray scale thresholding which is an operator dependent subjective process. Back scatter electron microscopy and paraffin thin section undercalcified histology are more accurate techniques to measure bone remodelling changes. However bone morphometric analysis from contact radiographs is a technique which has been used recently in arthroplasty retrieval studies (Maloney 1991, 1996) and the use of the mammography unit increased the spatial resolution and accuracy of the technique. Also any underdetection of cortical porosity or bone trabeculae was a systematic error, and in a comparative L-R study or intergroup analysis of L-R differences could be disregarded.

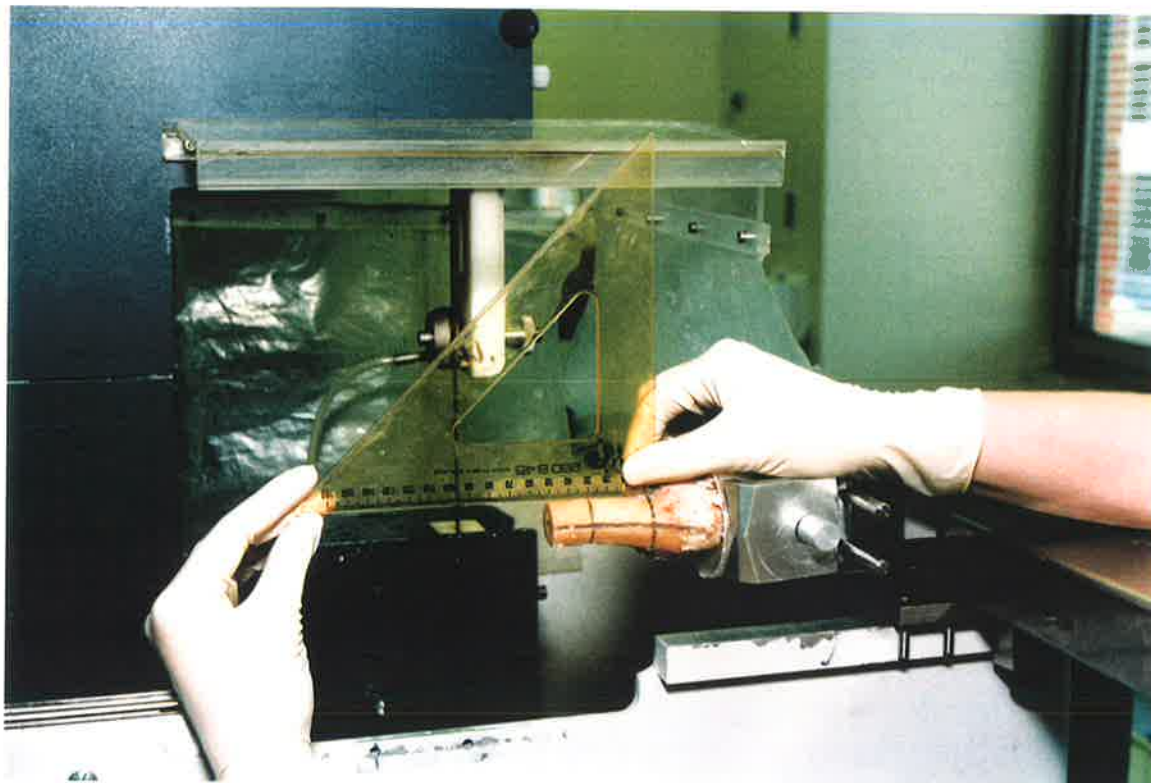


Fig 6.1 The proximal femur was aligned and fastened in the EXAKT saw such that the bandsaw blade was perpendicular to both the lateral and anterior inscribed cortical lines.



Fig 6.2 Bone Morphometry and Image Analysis Lab.



Fig 6.3 Cortical Section analysed by quadrants. The cortical perimeter was traced with a cursor and cortical area calculated.



Fig 6.4 To calculate cortical porosity, the grey scale threshold was adjusted so the smallest visible pore appeared yellow.

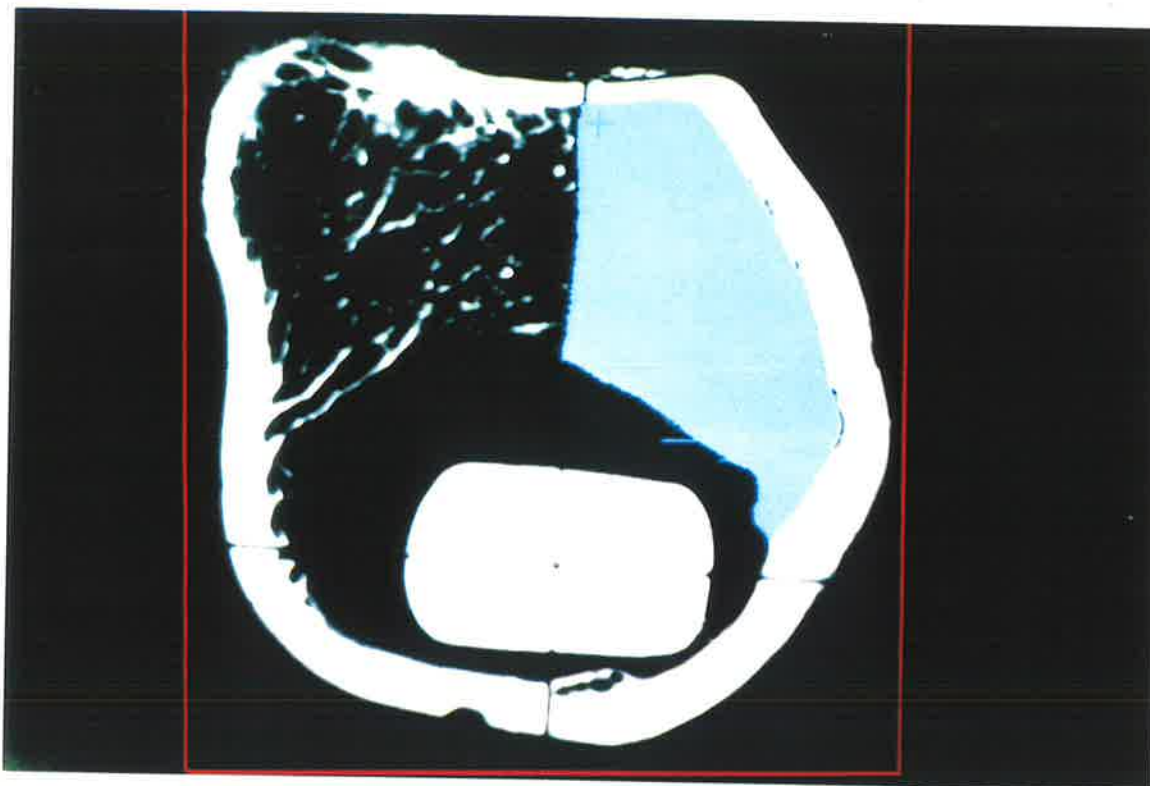


Fig 6.5 Trabecular area in the posterolateral and posteromedial quadrants of the proximal section was measured

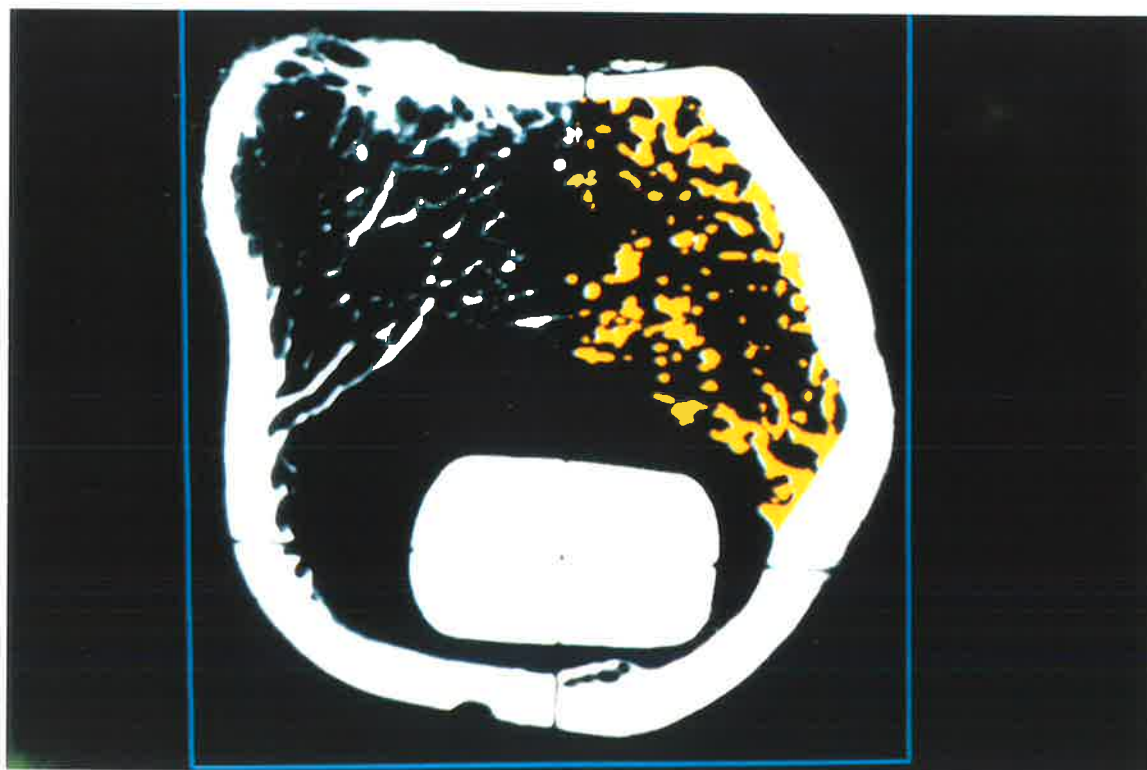


Fig 6.6 To calculate trabecular bone area in each quadrant, the grey scale threshold was adjusted so that the smallest visible trabecula appeared yellow.

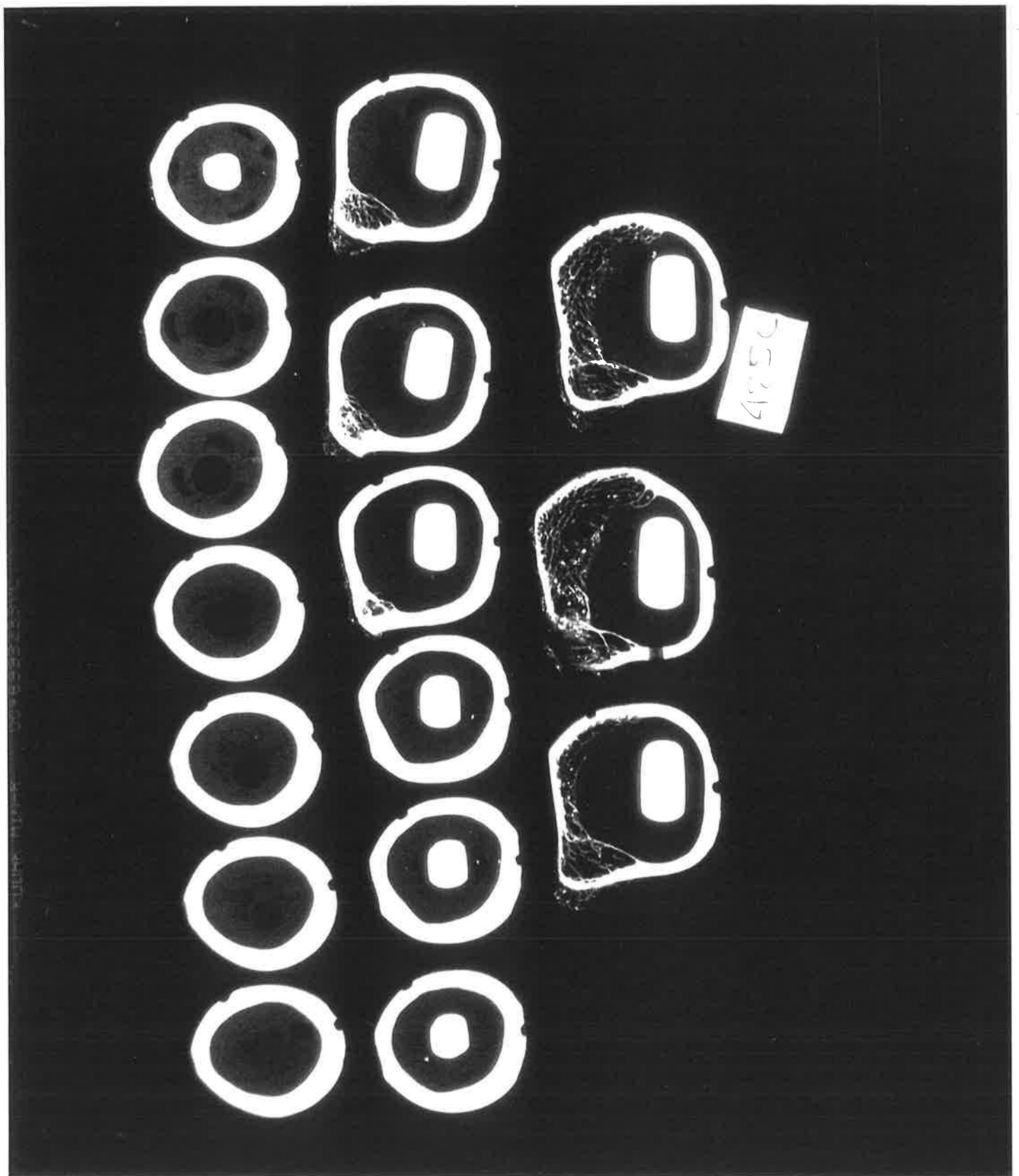


Fig 6.7 High Resolution Radiographic Series of Bone Sections
485 (polish) Control

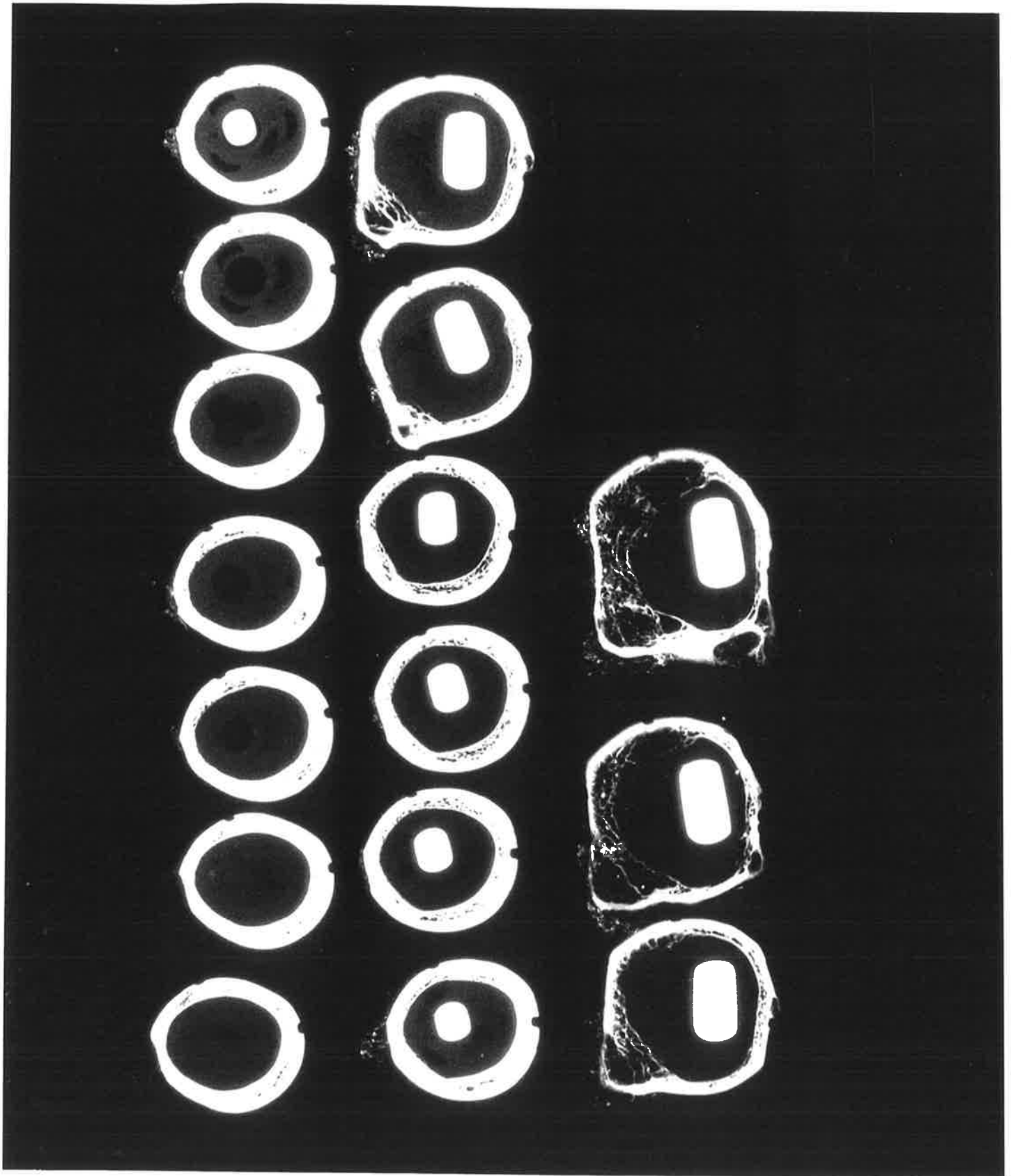


Fig 6.8 High Resolution Radiographic Series of Bone Sections
 485 (polish) Study
 Endosteal Cortical Resorption with Increase in Cortical Porosity

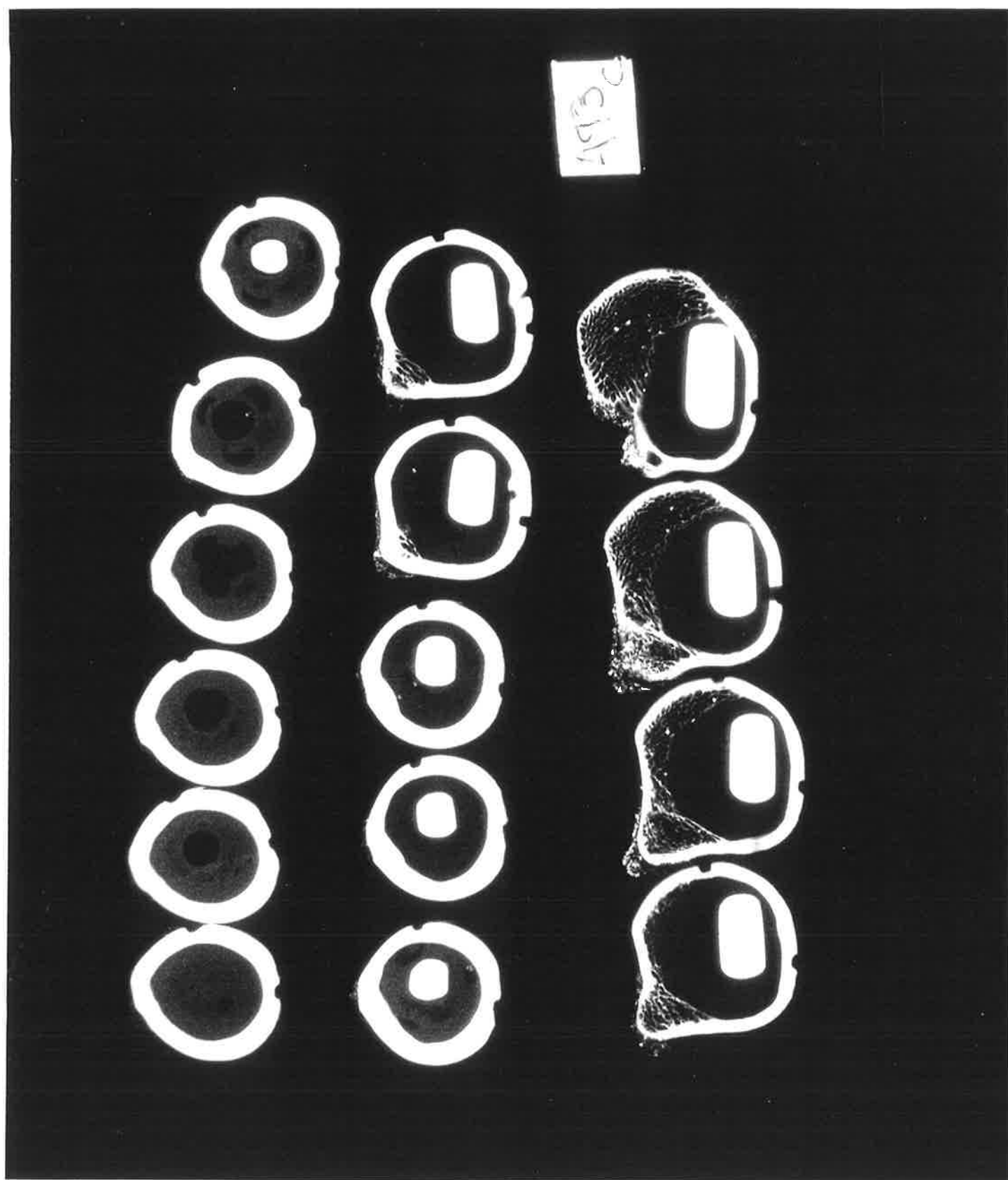


Fig 6.9 High Resolution Radiographic Series of Bone Sections
493 (polish) Control

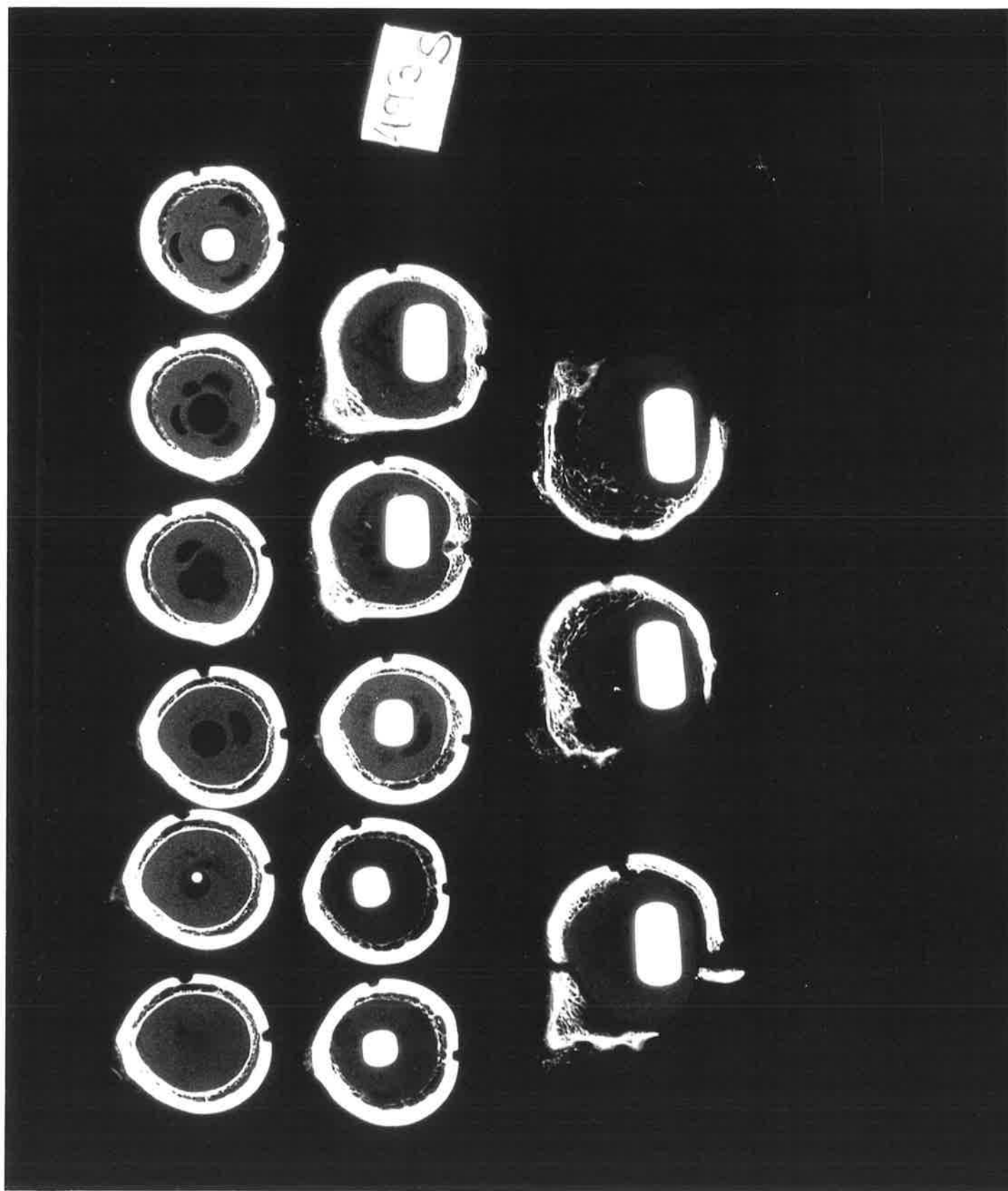


Fig 6.10 High Resolution Radiographic Series of Bone Sections

493 (polish) Study

Marked cortical resorption with secondary medullary canal and neocortex formation. Calcar lysis in proximal sections

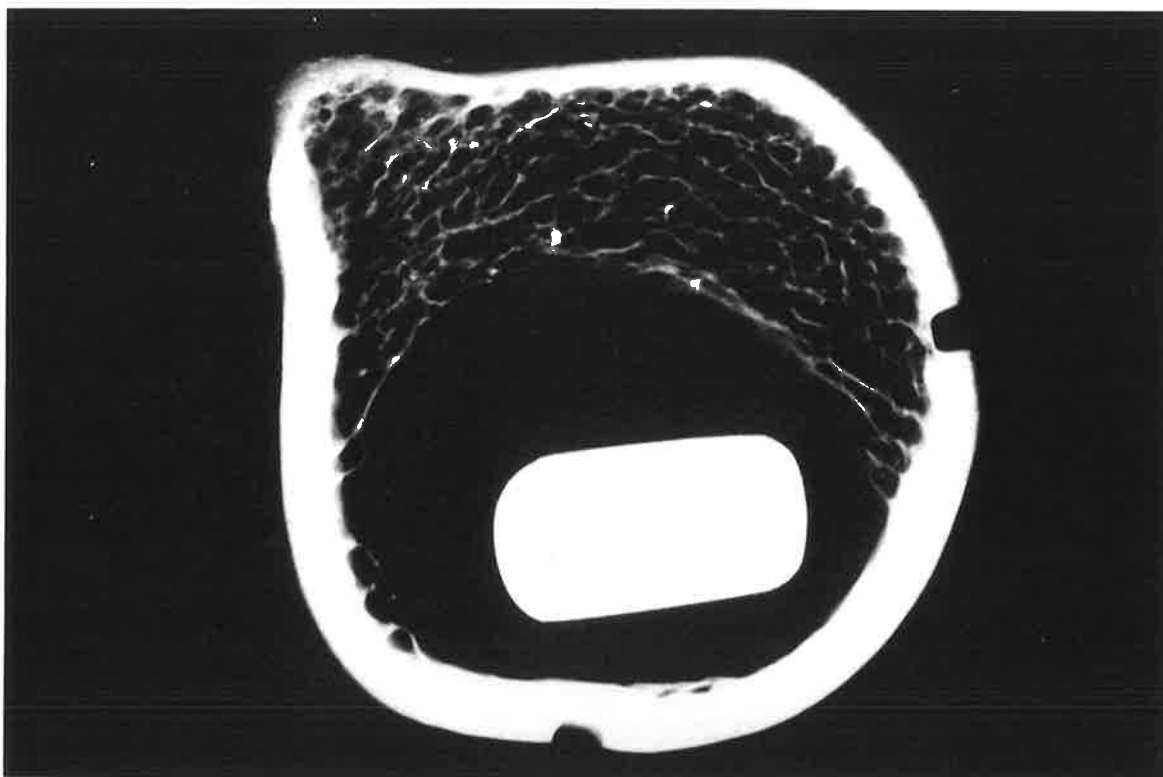
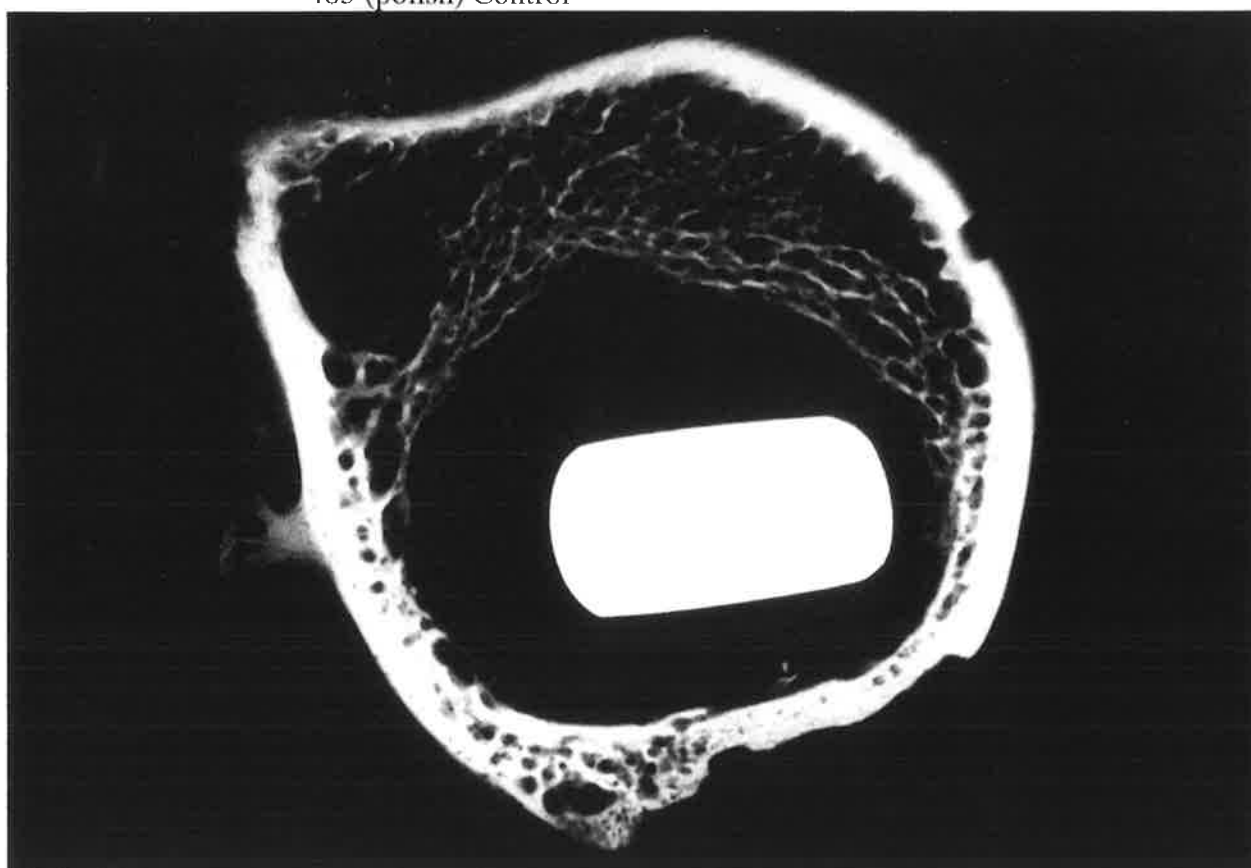


Fig 6.11 Normal Bone Trabeculae Density and Distribution
485 (polish) Control



6.12 Loss of trabecular bone density with condensation adjacent to the cement
mantle forming a neocortex
485 (polish) Study

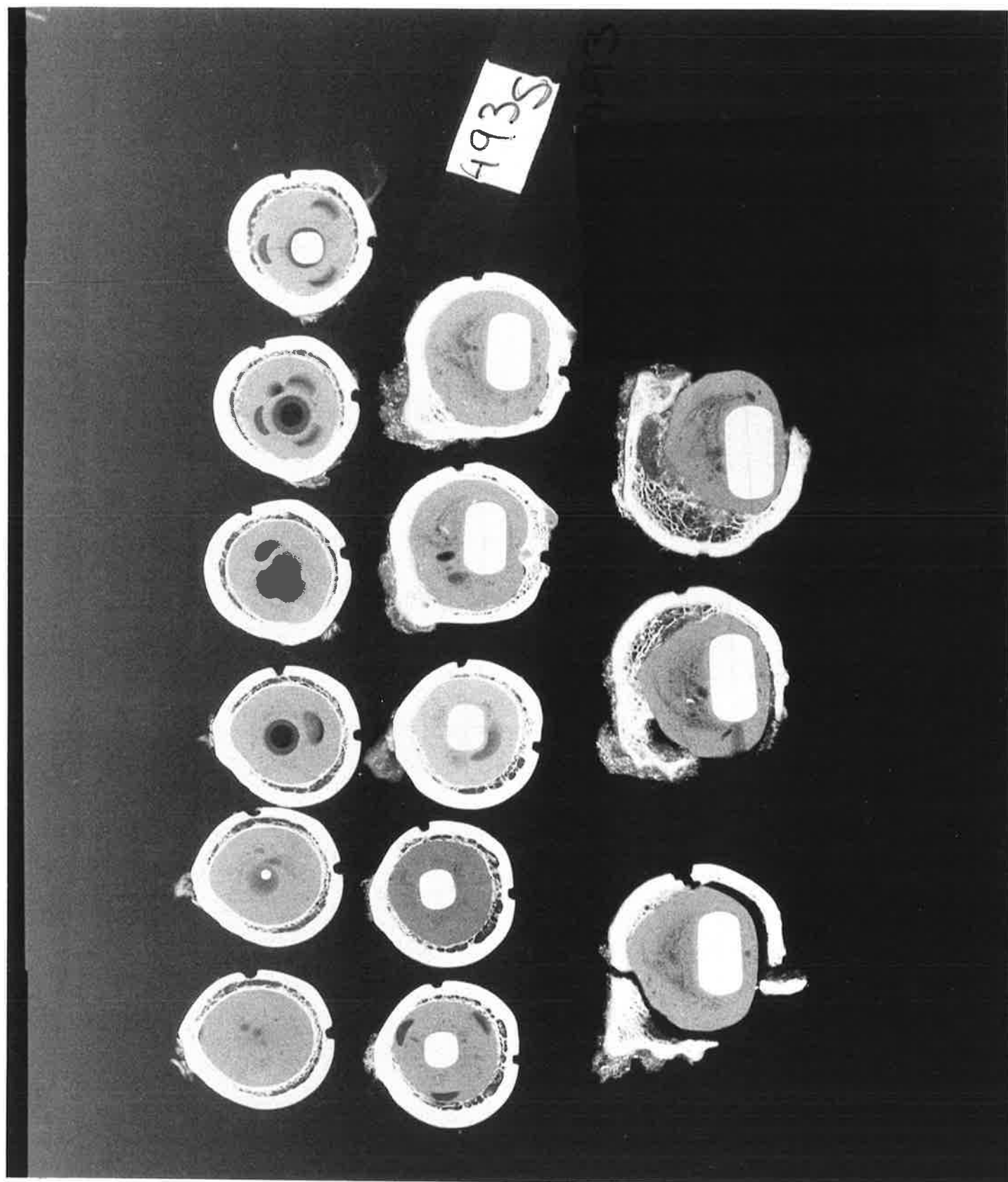


Fig 6.13 High Resolution Radiographic Series of Bone Sections

493 (polish) Study

Low exposure to show cement mantle. Despite calcar lysis in this specimen, this series shows no significant cement bone radiolucencies which would indicate loosening.

CHAPTER 7: CLINICAL LONGITUDINAL EVALUATION OF THE EXETER STEM USING DEXA

7.1 INTRODUCTION

Cortical strain and bone morphometric analysis gave no clear indication that implant design variables affect the pattern and magnitude of bone remodelling around femoral stems. Even within implant groups there was wide interindividual variation in the bone remodelling response to implantation. This has been noted previously in human autopsy retrievals of paired femora studies (Sychterz *et al* 1996, Engh *et al* 1992, Maloney *et al* 1996). These authors found that patient factors were important. There was a high inverse correlation between the bone mineral content of the contralateral control femur and the %bone mineral content loss in the remodelled femur. This finding suggested that osteoporosis could affect the magnitude of periprosthetic bone loss following THA.

The above studies were comparative L-R studies on autopsy retrieved femur pairs implanted with a variety of implant designs, and at variable postoperative intervals. The study designs were therefore not optimal and the use of the contralateral femur as a control was also not optimal for several reasons. Left-right differences occur, and pre-existing arthritis has an effect on BMD (McCarthy 1991). Furthermore gait studies (Bryan *et al* 1996) following THA indicate subtle favouring and decreased loading of the involved limb causing a further difference in BMD between sides. Finally, as proximal femoral bone loss occurs with aging (Jones *et al* 1994), the BMD of the contralateral hip at the time of analysis would not be identical to the BMD at the time of implantation. These factors limit the suitability of the contralateral femur as a control as they can not indicate the true magnitude of changes which have occurred in the implanted femur.

Longitudinal studies of bone remodelling are more useful than cross sectional or retrieval studies. The best control for bone remodelling changes subsequently occurring in a hip is the same hip studied pre-operatively or in the very early post-operative stages.

This chapter describes a 12 month longitudinal clinical study of bone remodelling after THA using a polished double tapered collarless implant. The objective was to confirm the importance of osteoporosis in the femoral bone remodelling response. The

hypothesis was that patients who were osteoporotic at the time of THA would undergo a greater rate and magnitude of proximal femoral bone loss compared to non-osteoporotic patients.

7.2 METHODS AND MATERIALS

A 12 month longitudinal study of patients who had undergone a primary polished Exeter THA for osteoarthritis was performed. All operations were performed via the posterior approach with modern cementing techniques by one of two surgeons. A highly standardised operative protocol and post-operative regime were followed. At the time of analysis all patients were fully weight bearing and all hips were functioning satisfactorily and no hips were radiographically loose. Patients were encouraged to mobilise full weight bearing on the operative side on the first postoperative day. Patients were encouraged to discard their walking aids by six weeks post-operatively.

There were 25 patients (10 male and 15 female) with a median age of 73 years (range: 48 years to 88 years). Height and weight data were recorded for each patient. Bone mineral content (BMC) of the proximal femur was measured in g/cm^2 using a LUNAR DPX-L densitometer (Madison, Wisconsin, USA). A high resolution DEXA scan of the proximal femur requires 15 minutes of scanning time and exposes the patient to 4.8mrem of radiation. The average annual per capita background exposure to radiation in the United States is 170mrem, and the maximum permissible dose for the general population is 500mrem per year (Appendix G Radiation Safety, LUNAR DPX Operators Manual 1991). Multiple high resolution DEXA scans of a hip therefore are deemed to pose no significant health risk. An AP DEXA scan was performed on the operated hip at 1 week, 3 months, and 12 months post-surgery. A foot and leg holder was used to ensure the hip was positioned reproducibly in slight flexion, neutral abduction-adduction and neutral rotation on each occasion.

Scans were analysed using high resolution software (LUNAR Orthopaedic Software versions 1.1, 1.2) (Figure 7.1). The software was limited to a scan 13 cm in length so the bone distal to the implant was excluded from analysis. Bone Mineral Content (BMC) was analysed according to Gruen zones (Gruen *et al* 1979) using the technique described and validated by Cohen and Rushton (1992). With this technique BMC was measured from the implant edge out to the bone soft tissue edge. Cement was therefore

included in the analysis of bone (Fig 7.2). However all periprosthetic bone could also be measured including the changes from the neocortex formation and endosteal cortical resorption occurring immediately adjacent to the cement mantle. Furthermore, bone changes anterior and posterior to the cement mantle could be included in the analysis with this technique. The precision error of this technique has been reported as approximately 3% (Cohen & Rushton 1992).

Bone cement contains barium and its mineral density does not change significantly over time. Therefore, using this technique, any measured changes in BMC in any given Gruen zone must solely represent changes due to bone remodelling in that zone. While the presence of cement would prevent measurement of bone mineral **density** changes, due to the unknown relative volumes of cement and bone, the presence of cement would not affect an assay of change in bone mineral **content** over time.

All subjects underwent single photon absorptiometry scanning (Molsgaard Medical, Horsholm, Denmark) of the dominant wrist. Scanning was performed one week post-surgery (Fig 7.3). Subjects were osteoporotic if their forearm BMD was less than two standard deviations of the young normal South Australian population. (Nordin *et al* 1986).

The changes in BMC from the 1 week (index) scan were analysed by zone as a function of post-operative interval. The patient group was then stratified by their forearm BMD into osteoporotic and non osteoporotic subgroups and the results reanalysed. Differences between the two subgroups were compared and tested for statistical significance using a two-tailed paired student t test.

7.3 RESULTS

Of the 25 patients, 2 died from unrelated causes and 3 declined follow-up scans. 20 patients had a 3 month and 12 month post-operative scan. Of these 20 patients, there were 13 non-osteoporotic patients (7 female, 6 male, median age = 71 years) and 7 osteoporotic patients (5 female, 2 male, median age = 83 years) as defined by the forearm BMD. The patient data is summarised in Table 7.1.

The mean percent loss in BMC for all patients at 3 months and 12 months compared to

the index scan is shown in Table 7.2. At 3 months BMC had decreased in all Gruen zones. Bone loss was maximum in the proximal zones with 14.40% (SD = 13.15) loss in zone 7. By 12 months bone loss had progressed but only to a small degree. Maximum mean BMC loss occurred in Gruen zone 7 with 17.74% (SD = 11.71) loss compared to the index scan. Loss in BMC was least in the distal periprosthetic zones (zones 3, 5).

A large inter-individual variation in BMC loss was observed in all zones causing large standard deviations. This was especially notable in the proximal zones, where some patients appeared to retain or even increase BMC but other patients underwent marked bone loss. The maximum BMC loss observed in Gruen zone 7 was 51.1% at 12 months.

To account for this variation the patients were stratified by the presence or absence of osteoporosis as defined by their forearm BMD at the time of surgery, and reanalysed. There were 13 non osteoporotic patients. The percent BMC loss for these two subgroups at 3 months is shown graphically in Figure 7.4, and at 12 months in Figure 7.5.

At 3 months a significant BMC loss from the index scan had occurred in Gruen zones 1, 2, 6 and 7 in both nonosteoporotic ($p < 0.05$) and osteoporotic groups ($p < 0.01$). In the distal zones (Gruen zone 3 and 5) periprosthetic bone was relatively well preserved with an observed bone loss of approximately 5-6%.

By 12 months, bone loss in the osteoporotic group had progressed with highly significant losses in all zones ($p < 0.01$) compared to the index scan. The mean BMC loss in Gruen zone 7 was 27.84% (SD = 14.02). The maximum loss in BMC observed in Gruen zone 7 was 51.1%.

In the non-osteoporotic group at 12 months, bone loss in each zone was noted to be relatively small with no progression of loss from the 3 month stage. In zones 1, 2, 3, and 5, mean BMC loss was approximately 5-6%. Mean BMC loss in this group was maximal in Gruen zone 7 and measured 11.85%.

At both 3 and 12 months the osteoporotic patients had lost more bone than the non-

osteoporotic patients. By 12 months this difference in magnitude of bone lost was significantly greater ($P<0.05$) in the proximal and middle zones (1, 7, 2 and 6). Although in the distal zones (3, 5) there was considerably greater loss of bone in the osteoporotic hips, this difference was not statistically significant. When adjusted for covariables of age, height, weight, and sex, the difference between the osteoporotic and non-osteoporotic groups was maintained.

Table 7.1 Osteoporotic Subjects (N=7)

Case	Sex	Age (years)	Weight (kg)	Height (cm)	Years Since Menopause
SA	F	83	59	145	-
AB	M	87	70	160	NA
CB	M	88	77	163	NA
TM	F	69	90	161	25
JN	F	72	70	172	-
RP	F	73	57	159	-
ES	F	83	64	158	27

Non Osteoporotic Subjects (N=13)

Case	Sex	Age (years)	Weight (kg)	Height (cm)	Years since Menopause
AA	M	82	67	163	NA
EA	F	74	72	168	30
JB	F	48	90	159	0
JC	M	76	63	155	NA
DC	M	75	95	183	NA
VC	M	82	100	190	NA
MD	F	70	82	169	-
EG	F	71	92	165	33
CK	M	77	73	171	NA
GR	F	57	90	173	10
VS	F	60	88	162	-
JS	F	53	76	158	0
JZ	M	69	94	170	NA

Table 7.2 Percentage Bone Mineral Content Changes at Post-operative Intervals
3 months and 12 months

	Postoperative Interval					
	3 months			12 months		
	% BMC Loss			% BMC Loss		
zone	N	mean	SD	N	mean	SD
1	20	10.59	10.45	20	10.45	10.94
2	20	9.63	6.5	20	12.77	11.15
3	20	6.76	5.26	20	9.6	11.85
5	20	6.72	4.98	20	9.15	11.76
6	20	7.11	4.71	20	12.65	13.04
7	20	14.4	13.15	20	17.74	11.71

7.4 DISCUSSION

Longitudinal studies are the optimal design for THA densitometric studies where the same hip studied perioperatively is used as a control for the subsequent bone remodelling changes which occur. This short term longitudinal study indicated a large interindividual variation in the early femoral bone remodelling response to cemented implants of the same design. Stratification of these patients by their forearm BMD revealed significant differences in the remodelling behaviour of those patients who were osteoporotic at the time of surgery. Osteoporotic patients lost significantly more bone than patients who were not osteoporotic. The magnitude of proximal femoral bone loss was large, up to 50% at 12 months post-surgery in one case, and this loss occurred in a cemented implant with reportedly favourable effects on stress shielding related bone loss (Fowler *et al* 1988). Furthermore in osteoporotic patients, bone loss occurred at a faster rate in contrast to the non osteoporotic group where bone loss in the middle and distal zones appeared to stabilize at 12 months post surgery.

This longitudinal study demonstrates that the presence of osteoporosis significantly increases the magnitude of periprosthetic bone loss in the short term following THA. This study has made no attempt to either investigate the cause for osteoporosis in the seven osteoporotic subjects or investigate the mechanism by which osteoporosis causes accelerated periprosthetic bone remodelling. However this study confirms the findings of recent autopsy retrieval studies and calls attention to the effect of osteoporosis and other biological factors on bone remodelling. These may be as important or even more important than implant design variables on periprosthetic bone remodelling..

The effect of osteoporosis may also have clinical ramifications on the choice of implant for primary or revision surgery in osteoporotic elderly patients. The use of a stiff, extensively porous coated cementless stem, which by itself has been reported to increase bone resorption, may compound the accelerated bone loss seen in these patients.

The effect of osteoporosis in patients should also be considered when interpreting and comparing quantitative bone remodelling data between clinical studies. Conclusions cannot be drawn on the relative bone resorption occurring around different implant designs when the variable of osteoporosis has not been considered. The presence of

osteoporosis may be determined by a single photon absorptiometry scan of the dominant wrist, and this analysis should be considered in future longitudinal studies of periprosthetic bone remodelling.

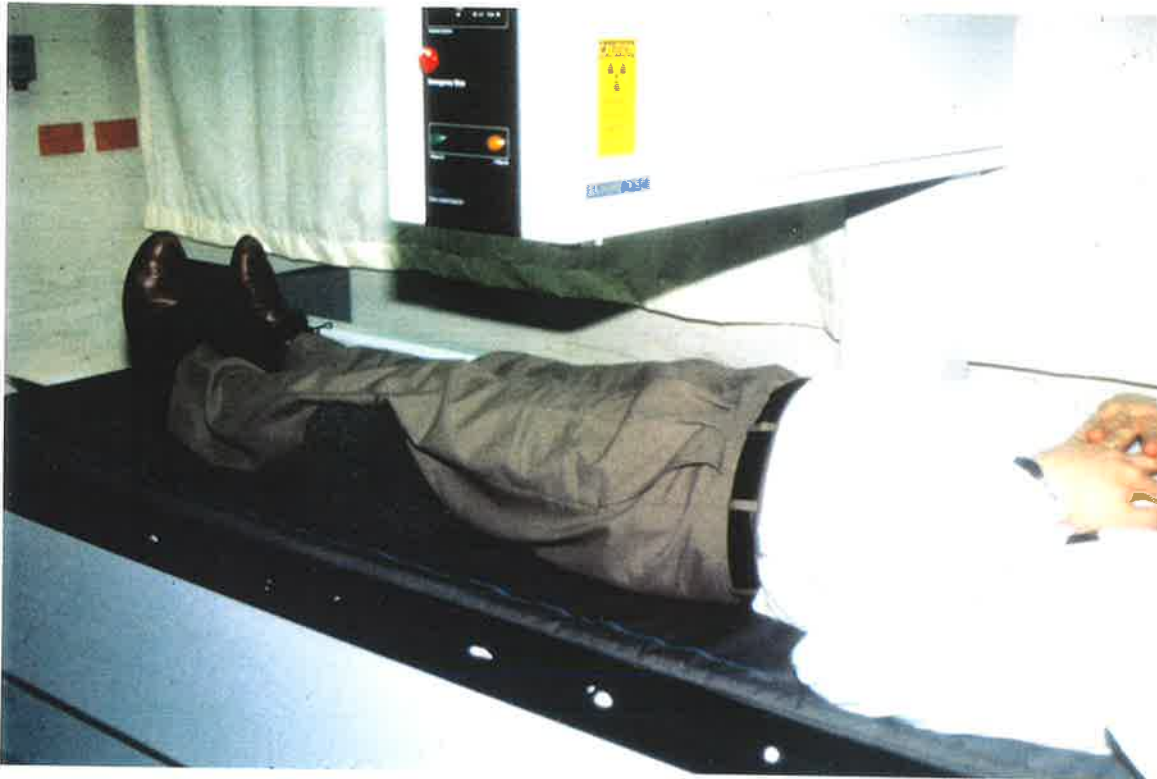


Fig 7.1 Hip scanning in the AP projection with the LUNAR DPX-L densitometer

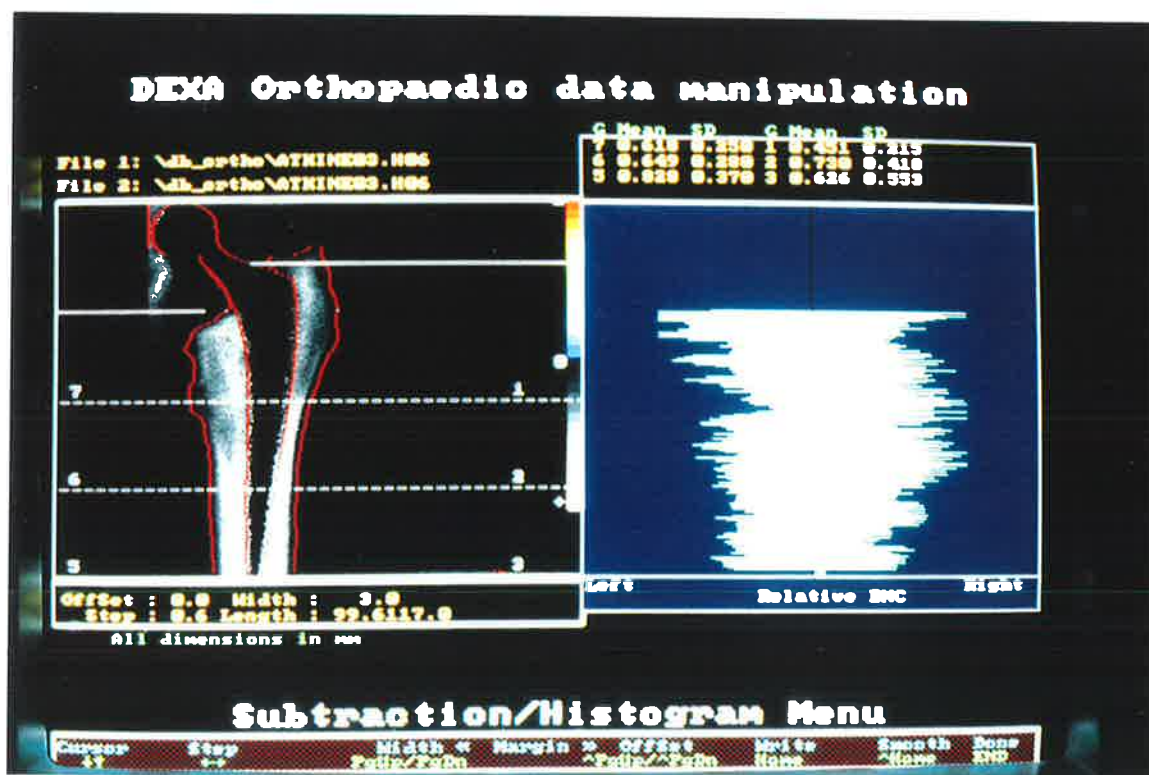


Fig 7.2 AP DEXA scan showing Gruen zone analysis of periprosthetic bone mineral content



Fig 7.3 Single Photon Absorptiometry of the dominant wrist was performed perioperatively

Fig 7.4: Graph comparing % BMC loss of osteoporotic and nonosteoporotic subjects at 3 months post surgery (with standard deviation)

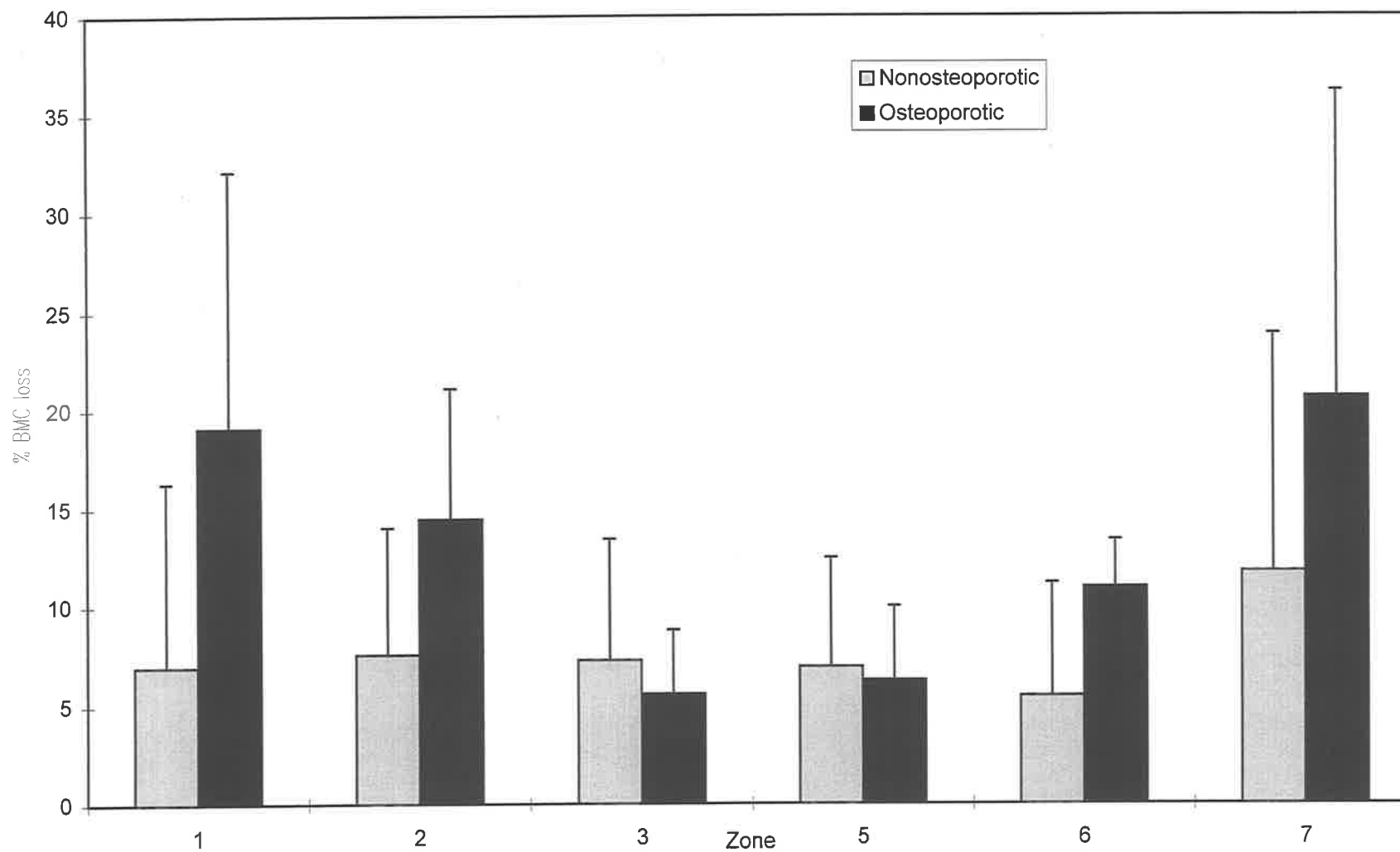
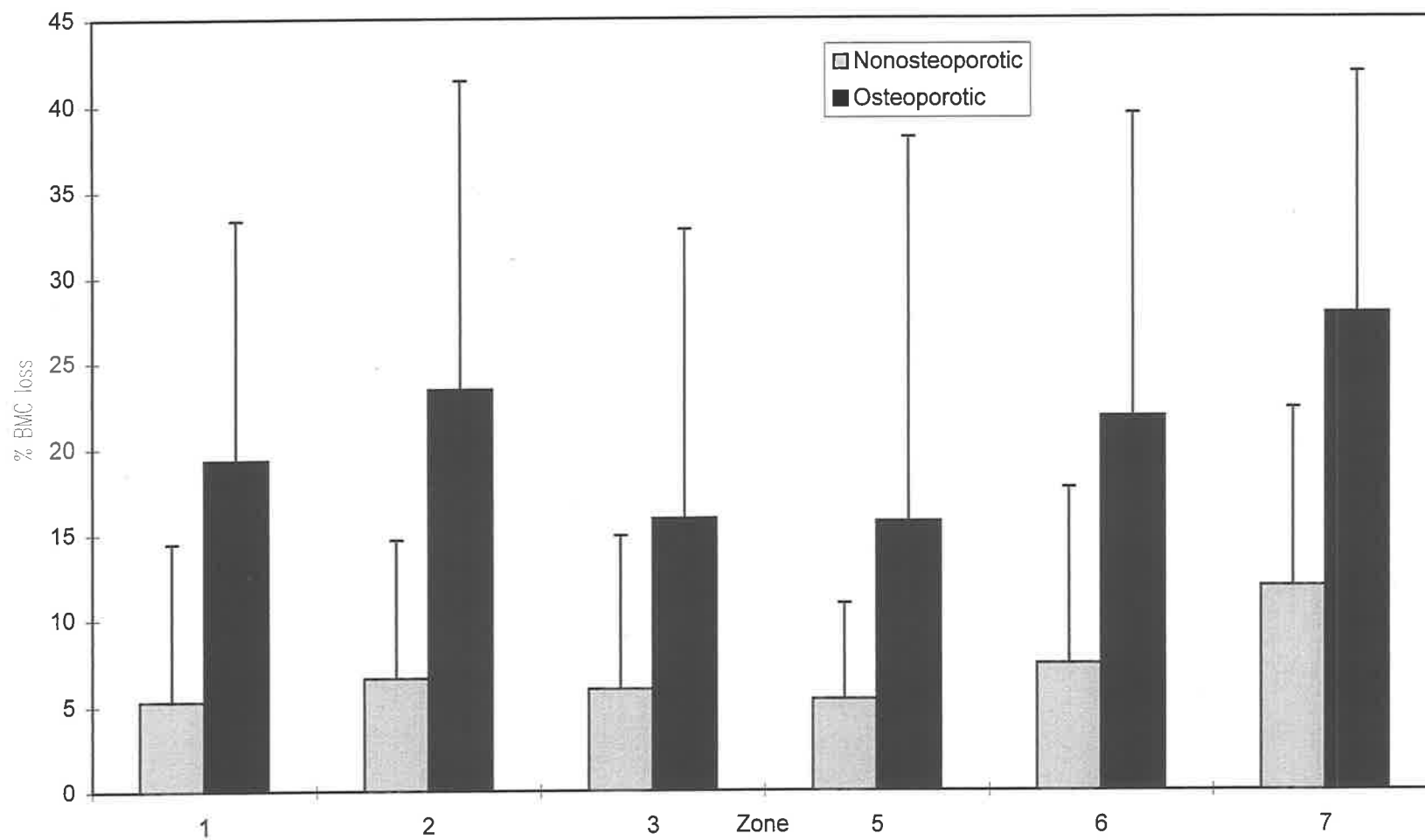


Fig 7.5: Graph comparing % BMC loss of osteoporotic and nonosteoporotic subjects at 12 months post surgery (with standard deviation)



CHAPTER 8: GENERAL DISCUSSION

In this section, the results of the experimental work will be discussed in relation to the thesis objectives and central hypothesis. The central hypothesis was that there was no important difference in the skeletal remodelling response around cemented femoral implants of a polished, matt finished or collared matt finished design. This null hypothesis was examined using an autopsy retrieved matched pair sheep arthroplasty model. The limitations of the experimental work and the impact of those limitations on the conclusions drawn will be discussed. Finally future research directions for this work and related work will be explored.

8.1 Sheep Hip Arthroplasty Model

The first section of this thesis developed the sheep model for hip arthroplasty studies. Though the dog has been more commonly employed, the sheep has a number of significant advantages including availability, genetic uniformity, and relative docility in the early postoperative stage. An anterolateral surgical approach was developed, which with the modification of gluteus tendon advancement, produced surgically good results. The rehabilitation protocol developed was well tolerated, and the sheep regained mobility and full weight bearing status quickly. We believe that the sheep is a good surgical model for hip arthroplasty studies.

The experimental chapters found no difference in the skeletal remodelling response between the three implant groups. None of the hips were clearly failing from aseptic loosening as shown by their clinical function and high resolution contact radiographs. Biomechanically and morphometrically, the femoral skeletal response to ten months of in vivo loading, showed no important difference between groups. There are three possible explanations for this:

1. the sheep was an inappropriate model to examine this particular aspect of hip arthroplasty.
2. the study design and methodology were inadequate to detect any difference which occurred.

3. The null hypothesis must be accepted.

Each of these possibilities will be discussed.

8.1.1 Was the Sheep Model Appropriate for Bone Remodelling Studies?

Though THA in sheep was surgically successful, the sheep may be an inappropriate model for specific aspects of arthroplasty research such as femoral bone remodelling studies. The anatomical and biomechanical issues were discussed in Chapter 2 and there are obvious limitations in extrapolating the proximal femoral loads which initiate bone remodelling in a quadruped, to events which occur in bipedal animals such as humans. However the sheep femur has a wide intramedullary canal with thin cortices and relatively little cancellous bone. Implantation of a large canal filling and therefore very stiff prosthesis-cement composite as was used in this study, would cause relatively greater load sparing of the proximal femoral cortex and accelerated bone adaptation, compared to a femur with thick cortices and a narrow canal which could only accommodate a small and less stiff prosthesis-cement composite. The sheep femur is therefore an accelerated model for bone remodelling. Differences between implant groups might be observed earlier in a sheep model, and before bone changes secondary to aseptic loosening occurs. The sheep model is therefore appropriate for this particular type of arthroplasty research.

Another limitation of the model to be considered, is whether the femoral implants used were appropriate for use in the sheep. The implants were custom made for the sheep femur for this study. All implants shared a double tapered geometry which in most femoral specimens allowed a 2-3mm complete mantle of cement. However the width to length ratio of the stem taper was greater than the "Exeter" (Howmedica) or "CPT" (Zimmer) stems currently in clinical use. The taper of the sheep implants may have been too broad proximally and geometrically inappropriate for the polished implants to subside and load bone with hoop stresses. Furthermore the forces which load the sheep hip in quiet walking, and certainly the forces which the explanted femurs were tested with, may have been too low to break any interface bond between the cement and polished implant surface and to initiate subsidence. In this study loads of less than one body weight were used but routinely in the human, the hip is subjected to forces of 5-7

times body weight. It may take these large forces to initiate subsidence of a polished tapered cemented stem. It may also take these large forces applied over a long time period before cement creep and subsidence occur. It is acknowledged that the design of the polished stem was probably not ideal for the purpose of this study.

The collared implants however were appropriate for the sheep model. Cortical strain analysis of the control femurs showed the collar dimensions were effective to load the calcar and that the collar was functional at least initially, even though no difference was subsequently found in remodelling behaviour compared to the collarless implants.

8.1.2 Study Design and Methodology Issues

Certainly the number of subjects in each experimental group was too small. This was a major limitation of the thesis. The statistical power of most comparisons was low. Nevertheless the subject number per group which had assumed a 70% difference in test parameters between groups, had been calculated on the best evidence available from previous studies. In addition extra subjects were used to allow for complications which might have necessitated withdrawal of subjects from the study. Had the study developed as predicted, the calculated sample size per group would have been sufficient to detect significant differences in the test parameters examined. Even though the study was underpowered, confidence interval testing was performed and this did allow detection of any trends for differences between groups.

The interval between implantation and sacrifice was relatively short compared to the clinical context where human arthroplasty studies report changes occurring over 10 to 20 years. The question is raised whether ten months was long enough for any remodelling difference between groups to become detectable. However, human studies have shown that the majority of adaptive bone remodelling occurs in the first two years after implantation and then remodelling changes plateau (Kiratli *et al* 1992). Furthermore the sheep was an accelerated model for remodelling as discussed above, and even at ten months there was one sheep (493 polish) which had developed signs of possible loosening. If the sacrifice interval had been extended, then a greater percentage would have developed loosening and confounding bone changes associated with that process would have been observed.

The methodology for both cortical strain analysis and bone morphometry was reasonably reproducible. Preliminary reproducibility studies showed minor to moderate coefficients of variation for the various outcome measures. Nevertheless the question is raised whether the analytical tests were accurate and sensitive enough to detect any changes occurring. The study design however was a comparison of left vs right differences rather than a comparison of absolute values of raw data. In a comparative analysis of differences, the sensitivity in each test is a systematic error and would have less impact on the study's findings.

8.1.3 Accept the Null Hypothesis

The alternative conclusion, if the sheep model was appropriate and the study design was adequate, is to accept the hypothesis that the three implant groups did not in fact differ significantly in their skeletal remodelling response.

A prosthesis-cement composite filling the capacious sheep intramedullary canal, may just be too stiff for subtle implant design features to have an important effect on the mechanism of load transfer from the implanted composite to bone. Specifically the polished taper with its capacity to subside in vivo does not load the bone with increased hoop strain; and the collared implant does not continue its increased axial loading of the calcar.

The Scandinavian Hip Registry has shown that both polished "Exeter" stem (Howmedica) and the "Spectron" collared matt finished stem (Smith and Nephew) have equivalent clinical performances in the medium term. The Registry also showed their performance is equivalent to the Charnley stem which conforms to neither generic design. This raises the possibility that implant design features have less effect on clinical outcome than previously thought, providing the basic principles such as rounded implant edges, neutral implant alignment, and contemporary cement techniques are adhered to.

The morphometric analysis of the matt tapered stem did demonstrate more proximal bone resorption than other groups in this study. The clinical performance of the matt "Exeter" stem is inferior to the otherwise identical polished "Exeter" stem, but there is little evidence that resorptive remodelling per se will predispose to aseptic loosening

(Engh *et al* 1992b). The matt stems have been associated with osteolysis when otherwise well fixed (Anthony *et al* 1990) indicating that their inferior performance may be related to micromotion of the rough surfaced taper against the cement mantle and producing an increased volume of particulate wear debris. This process leading to osteolysis is however distinct from the skeletal loading and bone remodelling process.

In this animal model, adaptive bone remodelling theory and Wolf's law was not observed. Following implantation and in vivo remodelling, femoral cortical strain did not return to normal but remained low and in many cases less than the control. This finding is consistent with long term human autopsy retrieval studies. It is probable that the prosthesis-cement composite was simply too stiff for the sheep femur, and that after implantation, cortical strain had fallen so far below physiological levels (in some cases to 10% of the intact femur), that normal strain homeostatic mechanisms were lost.

This animal study also demonstrated high inter-individual variation within implant groups even when the subjects were genetically quite similar. This interindividual variation was higher than anticipated when the study was conceived. Some of the variation may have been related to the size of the animal. Even though all sheep were between 55kg and 70kg in weight, the variable of height was not controlled, and this would have a bearing on the dimensions of the femurs which were implanted. Some of the interindividual variation would also have been related to inconsistencies in surgical technique. One important variable in surgical technique which was not controlled and which would affect bone remodelling, is the quality of the cement mantle. All femurs had a high resolution and low exposure radiograph taken of a series of bone sections, (eg fig 6.13). These radiographs often revealed large cement voids which would have attenuated the transfer of cortical strain from the implant to the cortical surface during testing. The cement voids also would have reduced the local stiffness of the prosthesis cement composite, and this would have reduced the local stress shielding effect which would have impacted on the changes in the adjacent bone morphometry.

However the great variability in skeletal response may be due not only to the mechanical loading environment but also to biological factors in the individual subject. These factors include the hormonal effect on bone mineral metabolism. They are outside the scope of this thesis. Clinical DEXA studies indicate that resorptive bone remodelling appears to equilibrate after 2-3 years, and the level of bone loss may reflect

a balance between mechanical and biological factors. In this thesis, the clinical longitudinal densitometric study of the “Exeter” THA has provided support for this concept. The presence of osteoporosis at the time of surgery significantly increased the magnitude and rate of periprosthetic bone loss following THA.

8.2 DIRECTIONS FOR FUTURE RESEARCH

Future arthroplasty research using the sheep model should include a modification of stem geometry. The stem would be less broad proximally allowing a wider cement mantle at the calcar. This has been correlated with lower rates of aseptic loosening in clinical studies (Charnley 1979), and calcar cement fracturing and calcar lysis as seen in sheep 493 would be less likely. This would therefore allow a longer time before sacrifice and any in vivo remodelling difference between implant groups could be highlighted without the confounding effect of implant loosening on bone resorption.

Furthermore a polished taper which was less broad proximally would be more effective in subsiding as cement creep occurred. With the longer time to sacrifice, this more effective taper would accentuate the changes in principal strain and bone morphometry which might occur.

There is scope for further clinical research into DEXA applications for measuring bone mineral content around cemented THA. Longitudinal studies can be performed to evaluate femoral bone remodelling around different cemented implant designs. These studies would be long term and ongoing to determine if a plateau in bone remodelling change occurred. The rate and magnitude of periprosthetic bone loss could be compared between implant groups with due regard to the patient specific variables which can affect bone loss, including age, sex, weight and the presence or absence of osteoporosis.

Finally DEXA could be developed and used clinically for surveillance of osteolysis or excessive stress shielding detected on plain radiographs of THA. DEXA has been established as an accurate and sensitive technique and could also be used to detect pre-radiographic lysis, and measure and monitor rapidly progressive lesions. This information would be useful to guide the clinician when to perform revision surgery on a symptomatic THA before substantial loss of bone stock made reconstruction difficult.

8.3 CONCLUDING REMARKS

This thesis has been an autopsy retrieval matched pairs study of femoral bone remodelling occurring around cemented polished, matt finished, and collared matt finished implants. Within the limitations of the animal model and methodology used, no important differences were detected between the three implant designs in either cortical strain or bone morphometric changes occurring after ten months *in vivo*. The null hypothesis is accepted.

The sheep model indicated wide interindividual variation in bone remodelling response even within the same implant group. The longitudinal densitometry study of human subjects also demonstrated wide inter-individual variation in periprosthetic bone loss in the short term when a single implant design was used. This study found that osteoporotic subjects lost significantly more periprosthetic bone than non osteoporotic subjects in the short term. Osteoporosis is clinically a major factor affecting periprosthetic bone remodelling and biological factors in the individual must be considered as well as the mechanical properties of the implant, in assessing femoral bone remodelling after THA.

Hip Arthroplasty Instrumentation: Exposure
(left to right)

Charnley Initial Incision Retractor

Modified Hohmann Bone Elevator and Weight

Mallet

Osteotome

Hohmann Retractor

Curved Periosteal Elevator

Head Sizing Template

Collared Trial Implant

Neck Osteotomy Cutting Guide

T Handle Awl

Femoral Broach



APPENDIX 2

Hip Arthroplasty Instrumentation: Implantation
(left to right)

Simplex Bone Cement

Cement Syringe and Introducer

Angled and Straight Cement Cures

1.5% Hydrogen Peroxide and Intramedullary Gauze Pack

Intramedullary Brush

Cement Pressurisers

Implant with Centraliser

Intramedullary Cement Plug and Introducer

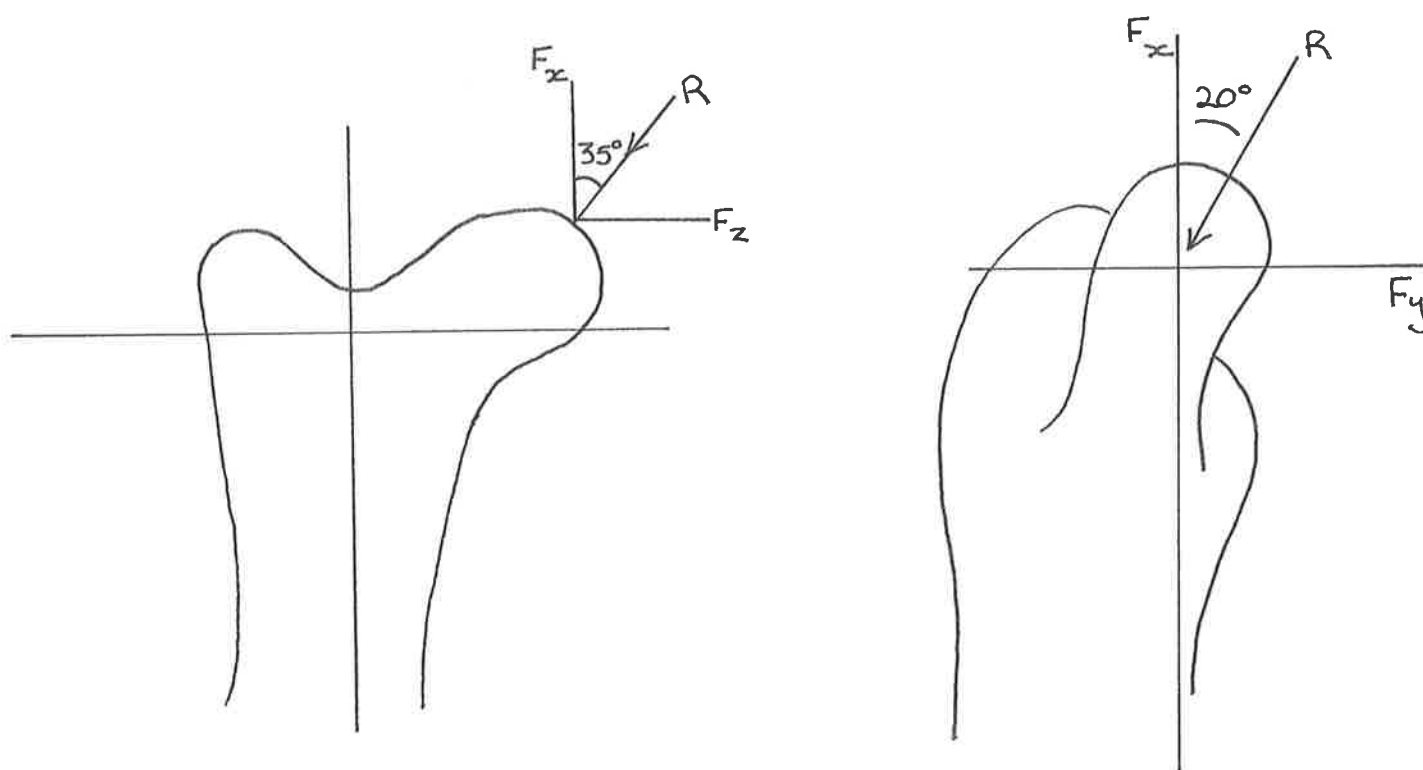
Intramedullary Vent with Sucker



APPENDIX 3 Calculation of Explanted Hip Loading Forces

A sheep hip loading protocol was designed, using physiological forces based on the data from Lanyon *et al* (1981) who measured in vivo strain in sheep femurs during normal walking.

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



R = resultant load acting on femoral head = 500N

Fx, Fy, Fz = vector loads

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.

$$R'^2 = x^2 + z^2$$

$$R''^2 = x^2 + y^2$$

$$x = R' \cos 35 \text{ and } R' = R \cos 20 \quad \text{for the x-z plane}$$

$$x = R'' \cos 20 \text{ and } R'' = R \cos 35 \quad \text{for the x-y plane}$$

Solving the above equations for x, y and z (for a 65kg sheep with R = 500N)

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

The vector loads used for testing (N) in each direction (x,y, z) are represented as multiples of body mass (kg). Hip Joint Loading for this study in each direction was then calculated based on the weight of each sheep.

$x = 5.923 \times \text{BW (kg) N}$	Axial
$y = 2.154 \times \text{BW (kg) N}$	Antero-posterior
$z = 4.415 \times \text{BW (kg) N}$	Medio-lateral

APPENDIX 4 The Intergroup Comparisons

Appendix 4.1 Between Group Comparisons: Axial Load Principal Compressive Strain

Rosette 1 $p=0.8002$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-24.14	6.40	36.94
Collared - Matt	-24.97	10.84	46.65
Polished - Collared	-36.94	-6.40	24.14
Polished - Matt	-31.37	4.44	40.25
Matt - Collared	-46.65	-10.84	24.97
Matt - Polished	-40.25	-4.44	31.37

Rosette 2 $p=0.1041$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Matt	-44.16	9.15	62.46
Polished - Collared	1.63	47.10	92.56
Matt - Polished	-62.46	-9.15	44.16
Matt - Collared	-15.36	37.95	91.26
Collared - Polished	-92.56	-47.10	-1.63
Collared - Matt	-91.26	-37.95	15.36

Rosette 3 $p=0.6866$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Matt	-32.81	14.32	61.44
Collared - Polished	-24.87	15.32	55.51
Matt - Collared	-61.44	-14.32	32.81
Matt - Polished	-46.12	1.00	48.13
Polished - Collared	-55.51	-15.32	24.87
Polished - Matt	-48.13	-1.00	46.12

Rosette 4 $p=0.5518$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Polished	-48.46	13.62	75.70
Matt - Collared	-30.73	31.34	93.42
Polished - Matt	-75.70	-13.62	48.46
Polished - Collared	-35.21	17.73	70.66
Collared - Matt	-93.42	-31.34	30.73
Collared - Polished	-70.66	-17.73	35.21

Appendix 4.2 Between Group Comparisons: Axial Load Principal Tensile Strain

Rosette 1 $p=0.1976$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Polished	-6.779	13.978	34.734
Matt - Collared	-2.480	18.276	39.033
Polished - Matt	-34.734	-13.978	6.779
Polished - Collared	-13.403	4.299	22.000
Collared - Matt	-39.033	-18.276	2.480
Collared - Polished	-22.000	-4.299	13.403

Rosette 2 $p=0.9525$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-23.609	0.149	23.906
Collared - Matt	-24.095	3.764	31.622
Polished - Collared	-23.906	-0.149	23.609
Polished - Matt	-24.243	3.615	31.473
Matt - Collared	-31.622	-3.764	24.095
Matt - Polished	-31.473	-3.615	24.243

Rosette 3 $p=0.6445$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Matt	-16.714	2.766	22.245
Polished - Collared	-9.249	7.363	23.975
Matt - Polished	-22.245	-2.766	16.714
Matt - Collared	-14.882	4.597	24.077
Collared - Polished	-23.975	-7.363	9.249
Collared - Matt	-24.077	-4.597	14.882

Rosette 4 $p=0.4299$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Matt	-23.26	2.94	29.13
Polished - Collared	-8.80	13.54	35.88
Matt - Polished	-29.13	-2.94	23.26
Matt - Collared	-15.60	10.60	36.80
Collared - Polished	-35.88	-13.54	8.80
Collared - Matt	-36.80	-10.60	15.60

Appendix 4.3 Between Group Comparisons: Axial Load Principal Compressive Angle

Rosette 1 $p=0.6743$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-30.88	1.15	33.17
Matt - Polished	-20.91	11.12	43.14
Collared - Matt	-33.17	-1.15	30.88
Collared - Polished	-17.34	9.97	37.28
Polished - Matt	-43.14	-11.12	20.91
Polished - Collared	-37.28	-9.97	17.34

Rosette 2 $p=0.9665$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-19.589	2.281	24.151
Matt - Polished	-19.330	2.540	24.409
Collared - Matt	-24.151	-2.281	19.589
Collared - Polished	-18.392	0.259	18.909
Polished - Matt	-24.409	-2.540	19.330
Polished - Collared	-18.909	-0.259	18.392

Rosette 3 $p=0.2067$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Matt	-16.42	10.96	38.35
Collared - Polished	-2.84	20.52	43.87
Matt - Collared	-38.35	-10.96	16.42
Matt - Polished	-17.84	9.55	36.94
Polished - Collared	-43.87	-20.52	2.84
Polished - Matt	-36.94	-9.55	17.84

Rosette 4 $p=0.4082$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-7.645	1.489	10.622
Collared - Matt	-3.897	6.813	17.522
Polished - Collared	-10.622	-1.489	7.645
Polished - Matt	-5.386	5.324	16.034
Matt - Collared	-17.522	-6.813	3.897
Matt - Polished	-16.034	-5.324	5.386

Appendix 4.4 Between Group Comparisons: ML Load Principal Compressive Strain

Rosette 1 $p=0.2184$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Matt	-37.44	48.20	133.85
Collared - Polished	-12.40	60.64	133.68
Matt - Collared	-133.85	-48.20	37.44
Matt - Polished	-73.21	12.44	98.09
Polished - Collared	-133.68	-60.64	12.40
Polished - Matt	-98.09	-12.44	73.21

Rosette 2 $p=0.8966$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Polished	-59.32	14.45	88.21
Matt - Collared	-58.87	14.89	88.65
Polished - Matt	-88.21	-14.45	59.32
Polished - Collared	-62.46	0.44	63.35
Collared - Matt	-88.65	-14.89	58.87
Collared - Polished	-63.35	-0.44	62.46

Rosette 3 $p=0.1889$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Polished	-33.39	109.29	251.96
Matt - Collared	-19.79	122.89	265.57
Polished - Matt	-251.96	-109.29	33.39
Polished - Collared	-108.07	13.60	135.28
Collared - Matt	-265.57	-122.89	19.79
Collared - Polished	-135.28	-13.60	108.07

Rosette 4 $p=0.4580$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-102.71	84.33	271.37
Matt - Polished	-75.84	111.20	298.25
Collared - Matt	-271.37	-84.33	102.71
Collared - Polished	-132.63	26.87	186.38
Polished - Matt	-298.25	-111.20	75.84
Polished - Collared	-186.38	-26.87	132.63

Appendix 4.5 Between Group Comparisons: ML Load Principal Tensile Strain

Rosette 1 $p=0.3524$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-33.05	56.44	145.94
Collared - Matt	-47.48	57.47	162.41
Polished - Collared	-145.94	-56.44	33.05
Polished - Matt	-103.92	1.02	105.96
Matt - Collared	-162.41	-57.47	47.48
Matt - Polished	-105.96	-1.02	103.92

Rosette 2 $p=0.0896$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Collared	-39.13	24.61	88.36
Polished - Matt	8.60	83.35	158.09
Collared - Polished	-88.36	-24.61	39.13
Collared - Matt	-16.02	58.73	133.48
Matt - Polished	-158.09	-83.35	-8.60
Matt - Collared	-133.48	-58.73	16.02

Rosette 3 $p=0.2007$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Collared	-68.65	90.01	248.68
Polished - Matt	-26.10	159.96	346.01
Collared - Polished	-248.68	-90.01	68.65
Collared - Matt	-116.11	69.94	256.00
Matt - Polished	-346.01	-159.96	26.10
Matt - Collared	-256.00	-69.94	116.11

Rosette 4 $p=0.2489$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-102.61	23.00	148.62
Collared - Matt	-29.27	118.02	265.32
Polished - Collared	-148.62	-23.00	102.61
Polished - Matt	-52.28	95.02	242.31
Matt - Collared	-265.32	-118.02	29.27
Matt - Polished	-242.31	-95.02	52.28

Appendix 4.6 Between Group Comparisons: ML Load Principal Compressive Angle

Rosette 1 $p=0.6224$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-22.89	3.64	30.17
Collared - Matt	-16.81	14.30	45.40
Polished - Collared	-30.17	-3.64	22.89
Polished - Matt	-20.45	10.66	41.76
Matt - Collared	-45.40	-14.30	16.81
Matt - Polished	-41.76	-10.66	20.45

Rosette 2 $p=0.3247$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Matt	-19.21	7.17	33.56
Collared - Polished	-6.08	16.42	38.92
Matt - Collared	-33.56	-7.17	19.21
Matt - Polished	-17.14	9.25	35.63
Polished - Collared	-38.92	-16.42	6.08
Polished - Matt	-35.63	-9.25	17.14

Rosette 3 $p=0.7796$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-16.896	2.670	22.237
Matt - Polished	-13.269	6.298	25.864
Collared - Matt	-22.237	-2.670	16.896
Collared - Polished	-13.059	3.627	20.313
Polished - Matt	-25.864	-6.298	13.269
Polished - Collared	-20.313	-3.627	13.059

Rosette 4 $p=0.4020$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-8.862	2.452	13.766
Matt - Polished	-4.376	6.938	18.252
Collared - Matt	-13.766	-2.452	8.862
Collared - Polished	-5.163	4.486	14.134
Polished - Matt	-18.252	-6.938	4.376
Polished - Collared	-14.134	-4.486	5.163

Appendix 4.7 Between Group Comparisons: AP Load Principal Compressive Strain

Rosette 1 $p=0.2496$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Matt	-49.71	5.78	61.27
Polished - Collared	-10.44	36.88	84.21
Matt - Polished	-61.27	-5.78	49.71
Matt - Collared	-24.39	31.10	86.59
Collared - Polished	-84.21	-36.88	10.44
Collared - Matt	-86.59	-31.10	24.39

Rosette 2 $p=0.3948$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Polished - Matt	-42.21	5.68	53.56
Polished - Collared	-14.79	26.05	66.88
Matt - Polished	-53.56	-5.68	42.21
Matt - Collared	-27.52	20.37	68.25
Collared - Polished	-66.88	-26.05	14.79
Collared - Matt	-68.25	-20.37	27.52

Rosette 3 $p=0.0658$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-15.72	21.35	58.42
Matt - Polished	6.68	43.75	80.82
Collared - Matt	-58.42	-21.35	15.72
Collared - Polished	-9.22	22.39	54.01
Polished - Matt	-80.82	-43.75	-6.68
Polished - Collared	-54.01	-22.39	9.22

Rosette 4 $p=0.6037$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Polished	-65.62	25.11	115.84
Matt - Collared	-47.35	43.38	134.11
Polished - Matt	-115.84	-25.11	65.62
Polished - Collared	-59.11	18.27	95.64
Collared - Matt	-134.11	-43.38	47.35
Collared - Polished	-95.64	-18.27	59.11

Appendix 4.8 Between Group Comparisons: AP Load Principal Tensile Strain

Rosette 1 $p=0.4846$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Matt	-39.43	7.46	54.35
Collared - Polished	-17.15	22.83	62.82
Matt - Collared	-54.35	-7.46	39.43
Matt - Polished	-31.51	15.37	62.26
Polished - Collared	-62.82	-22.83	17.15
Polished - Matt	-62.26	-15.37	31.51

Rosette 2 $p=0.0377$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	1.74	31.68	61.62
Matt - Polished	9.40	39.34	69.28
Collared - Matt	-61.62	-31.68	-1.74
Collared - Polished	-17.87	7.67	33.20
Polished - Matt	-69.28	-39.34	-9.40
Polished - Collared	-33.20	-7.67	17.87

Rosette 3 $p=0.9027$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-53.90	8.53	70.96
Matt - Polished	-49.13	13.30	75.73
Collared - Matt	-70.96	-8.53	53.90
Collared - Polished	-48.48	4.77	58.01
Polished - Matt	-75.73	-13.30	49.13
Polished - Collared	-58.01	-4.77	48.48

Rosette 4 $p=0.1572$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Matt	-28.33	1.69	31.71
Collared - Polished	-2.77	22.83	48.44
Matt - Collared	-31.71	-1.69	28.33
Matt - Polished	-8.88	21.14	51.16
Polished - Collared	-48.44	-22.83	2.77
Polished - Matt	-51.16	-21.14	8.88

Appendix 4.9 Between Group Comparisons: AP Load Principal Compressive Angle

Rosette 1 $p=0.7044$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-38.10	11.65	61.39
Matt - Polished	-30.01	19.73	69.48
Collared - Matt	-61.39	-11.65	38.10
Collared - Polished	-34.34	8.09	50.51
Polished - Matt	-69.48	-19.73	30.01
Polished - Collared	-50.51	-8.09	34.34

Rosette 2 $p=0.0471$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	2.75	28.08	53.42
Collared - Matt	1.98	31.68	61.39
Polished - Collared	-53.42	-28.08	-2.75
Polished - Matt	-26.11	3.60	33.31
Matt - Collared	-61.39	-31.68	-1.98
Matt - Polished	-33.31	-3.60	26.11

Rosette 3 $p=0.3705$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Matt - Collared	-26.58	5.30	37.18
Matt - Polished	-12.20	19.68	51.56
Collared - Matt	-37.18	-5.30	26.58
Collared - Polished	-12.80	14.38	41.57
Polished - Matt	-51.56	-19.68	12.20
Polished - Collared	-41.57	-14.38	12.80

Rosette 4 $p=0.5587$
Confidence Interval Analysis

Group Comparison	CI _{LO}	Difference between mean	CI _{HI}
Collared - Polished	-27.19	0.22	27.64
Collared - Matt	-17.03	15.12	47.27
Polished - Collared	-27.64	-0.22	27.19
Polished - Matt	-17.25	14.90	47.04
Matt - Collared	-47.27	-15.12	17.03
Matt - Polished	-47.04	-14.90	17.25

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