

**Displaced Intracapsular Proximal Femoral
Fractures- Studies Relating to Management,
Epidemiology and Outcome**

**Thesis submitted for the degree of MD at the University of
Leicester**

by

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“The Queen had only one way of settling all difficulties, great or small. “Off with his head”. (CS Lewis, Alice in Wonderland)

1. Background to Displaced Intracapsular Hip Fractures

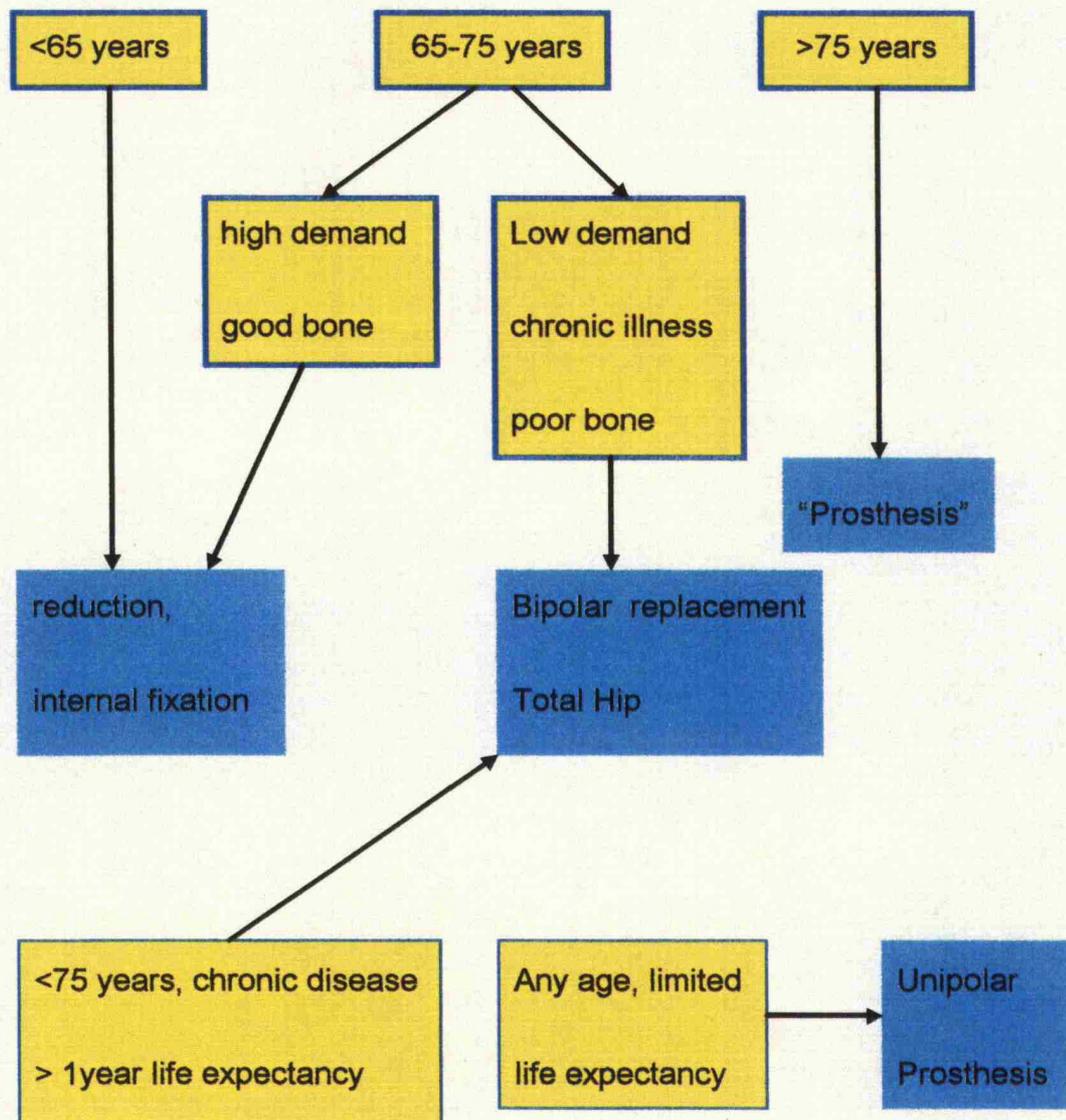
1.1 Introduction

Proximal femoral fractures in the elderly are often seen as unglamorous and mundane, but they are an increasing problem and the greatest single burden on orthopaedic trauma services. They present a continuing challenge to medical services and the community. Of the various fracture types, none is such a persistent clinical problem as the displaced intracapsular hip fracture.

Kellogg Speed described this problem of "the unsolved fracture" in 1935 (Speed 1935), but even then he referred back one hundred years to work by Astley Cooper which had recognised the difficulty in treating this fracture (Cooper 1824). The description remains apt to this day. Nicoll borrowed Speed's title for an editorial (Nicoll 1963) and said, in reference to an idea for a multicentre study that "there is no doubt that at the end of three years most of the questions about which we have been arguing for the past ten years could be answered". Yet thirty years later there is little increase in our knowledge. Although there have been vast numbers of publications on the treatment of displaced intracapsular hip fracture most are at best small or retrospective studies with inadequate follow-up to answer the most pressing questions. This deficiency has been confirmed by a recent exhaustive meta-analysis of the literature (Lu-Yao et al 1994). In addition, the few published randomised prospective studies comparing arthroplasty with fixation have not taken into account important determinants of outcome such as mental function. This does

not stop teachers of the subject prescribing treatment algorithms which may be based on a certain amount of logic, but which are far from sound in their scientific basis (Swiontkowski 1994, Kyle 1994). An example of such a treatment protocol is shown in figure 1.1; it probably reflects consensus opinion, but there is no hard evidence for most of the management pathways suggested.

Figure 1-1 Treatment Algorithm - Typical Example (Swiontkowski 1994)



Each year around 60,000 people sustain a fracture of the proximal femur in England and Wales (Audit Commission 1995) and at any one time eighteen percent of orthopaedic beds are occupied by such patients (Lewis 1981). The in-patient cost to the health service was estimated to be £160 million per year in 1987 (Wallace 1987), and such costs are likely to be much higher now, at least in the order of £250 million on acute services alone (Audit Commission 1995). The true financial cost to the country taking account of long term factors such as increased dependence on social support services due to increased disability following fracture is far greater than these figures.

As well as increasing costs, actual numbers of cases are rising constantly. The chance that a man will sustain a fracture of the proximal femur before reaching 85 years is 5%, and for a woman is 12% (Gallagher et al 1980, Jensen 1980, Hedlund et al 1987). A study done in Oxford looked at the change in incidence over a 27 year period and found the age specific rate of fracture had doubled; a change in fracture aetiology was postulated (Boyce and Vessey 1985). At least an 11.2% increase over ten years is predicted in this centre (Anderson et al 1993A). In another study the annual increase in hip fracture has been reported to be as great as 10% per year (Wallace 1983). Larsson (Larsson et al 1989) reported a 32% increase over a 10 year period.

The direct cause of the increasing fracture incidence is not clear, but recent work suggests that the age-specific incidence has not altered (Anderson et al 1993), and that the rise is due purely to the growing elderly population. This is supported by other work (Jarnlo et al 1989, Zetterberg et al 1984). There is no doubt that the problem is continuing to increase. Under current

patterns of care, the highest estimates of annual hip fracture incidence by the year 2016 (117,000 cases in the UK) would require resources equivalent to eight new district general hospitals over the next twenty years (Audit Commission 1995).

With this background we should consider the following important points:

The two main types of proximal femoral fracture, intracapsular and extracapsular, occur in approximately equal numbers. Terminology varies; proximal femoral fractures (strictly correct), are more commonly called hip fractures; this is quite acceptable. Intracapsular fractures are often called subcapital fractures, or femoral neck fractures. It is widely accepted that extracapsular and undisplaced intracapsular fractures can be effectively treated by internal fixation (Sikorski and Barrington 1981, Skinner et al 1989, Kyle et al 1979). There is no such consensus view on the treatment of displaced intracapsular hip fractures in the elderly, which seem to be treated according to local preference with no such thing as standard treatment across the country, as shown by a recent survey (Anderson et al 1990). There was a roughly equal preference for internal fixation or hemiarthroplasty of various types.

Management of displaced intracapsular hip fracture is not always a dilemma. Specific comorbidities sometimes dictate a particular line of treatment. Dementia gives a poor survival prognosis (Wood et al 1992) and therefore treatment is only aimed at short term pain free survival. Rheumatoid arthritis, Parkinson's disease and pathological fracture are other conditions which may determine treatment.

Generally accepted clinical practice in most units, *not* based on

particularly good clinical evidence, is for active patients below 60 - 65 years to be treated with internal fixation primarily.

The dilemma lies where patients are too old to be "automatic" choices for treatment by reduction and internal fixation but where they do not have any of the preexisting conditions which may dictate a specific treatment plan. The age at which this line can be drawn is arbitrary, but generally taken to be at about 65 years. This particular group of displaced intracapsular proximal femoral fractures where there is real debate about treatment made up 25% of all proximal femoral fractures in Leicestershire in 1991-1993. This is the group which remains unsolved and which needs to be addressed.

There are recognized complications of both hemiarthroplasty and internal fixation. Hemiarthroplasty may be specifically complicated by dislocation, femoral stem loosening and acetabular erosion. Internal fixation may be specifically complicated by failure of fixation ("redisplacement"), non-union or avascular necrosis; these terms however are often misused, non-union more often being due to simple mechanical failure of fixation.

Each of these complications may cause symptoms sufficient to warrant further surgery. The failure rate for internal fixation of displaced intracapsular fractures, measured by reoperation rate, has been reported at anything from 8-38% in the first three years (Skinner and Powles 1986, Sikorski and Barrington 1981) and it is generally lower than this for hemiarthroplasty in the same period (D'Arcy and Devas 1976). The justification given by those who advocate fixing these fractures primarily, is that if internal fixation is successful it restores the normal hip joint, whereas a successful hemiarthroplasty will eventually fail due

to either femoral loosening or acetabular erosion. This is not necessarily true, because a significant proportion of patients who have undergone successful fixation with union of the fracture, get persistent symptoms from the sequelae of late avascular necrosis (AVN) and segmental collapse of the femoral head. It is not possible, on work so far done, to use preoperative imaging to predict success for internal fixation (see chapter 5), therefore treatment has evolved empirically based on common sense rather than science along the lines of algorithms such as figure 1.1.

One thing is certain in the field of proximal femoral fracture management: displaced intracapsular hip fracture remains the challenge and this is where we should continue to direct our research efforts. The main aim of this thesis is to address this particular problem scientifically, and ultimately to supercede some of the confusing messages in the literature regarding this subject.

1.2 Anatomy of the hip

1.2.1 Osteology

The bones comprising the hip joint are the head of the femur and the acetabulum (fig 1.2). The acetabulum is the socket of the hip joint and is a concavity formed at the confluence of the three components of the bony pelvis: the ilium, the ischium and the pubis (fig 1.3). The ilium forms the antero-superior two fifths of the acetabulum, the ischium forms the floor and the postero-inferior two fifths and the pubis forms the antero-superior one fifth. The acetabulum is approximately hemispherical in shape and coincides with the

shape of the femoral head in the anatomical position. There is a deficiency inferiorly called the acetabular notch. The concavity of the acetabulum consists of two areas; the central acetabular fossa which is non-articular and contains a synovium covered fibrofatty pad, and the crescentic lunate surface which articulates with the head of the femur.

The proximal femur consists of the head, the neck and the greater and lesser trochanters (fig 1.2).

Figure 1-2 Simple Diagram of Bony Components of Hip Joint

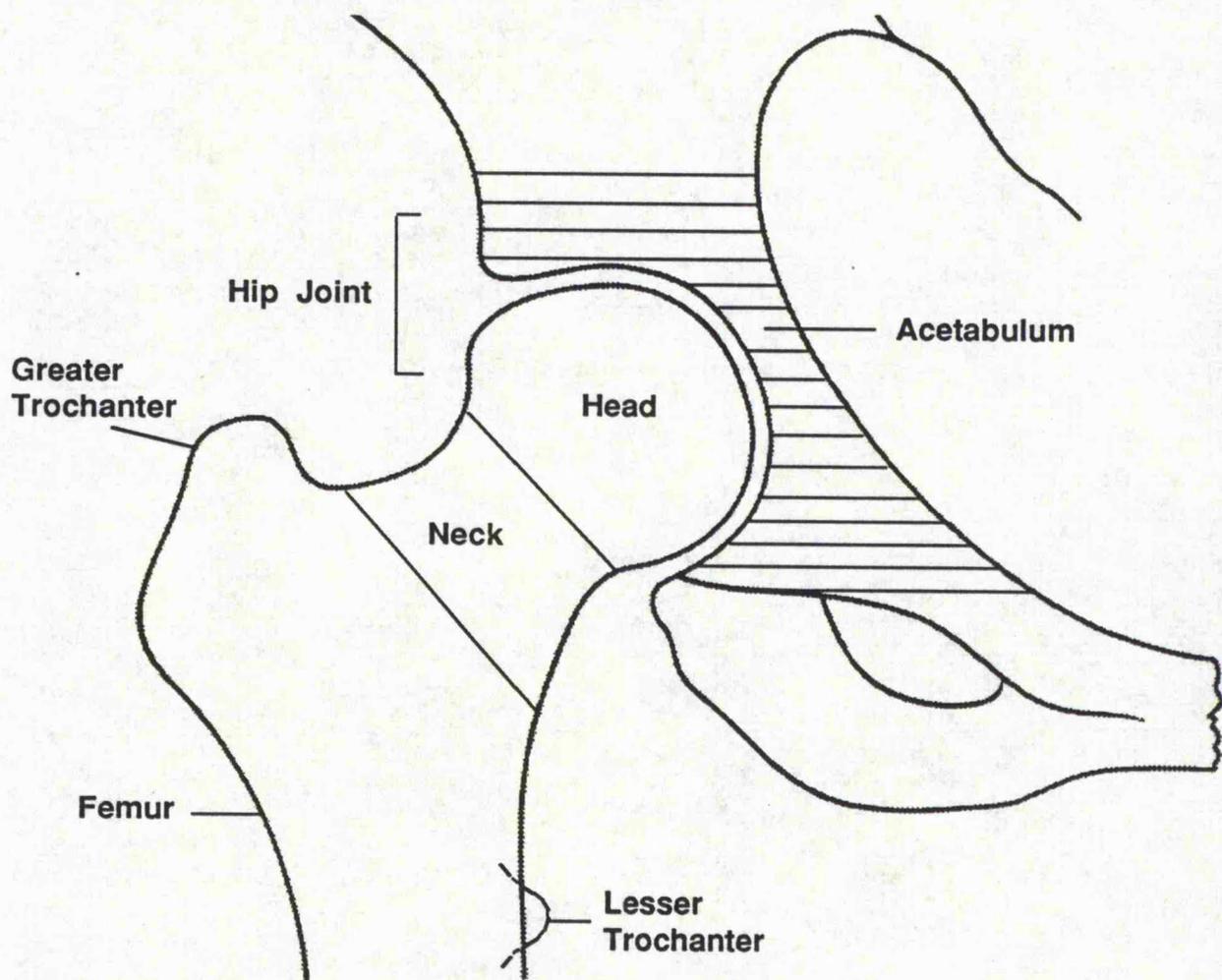
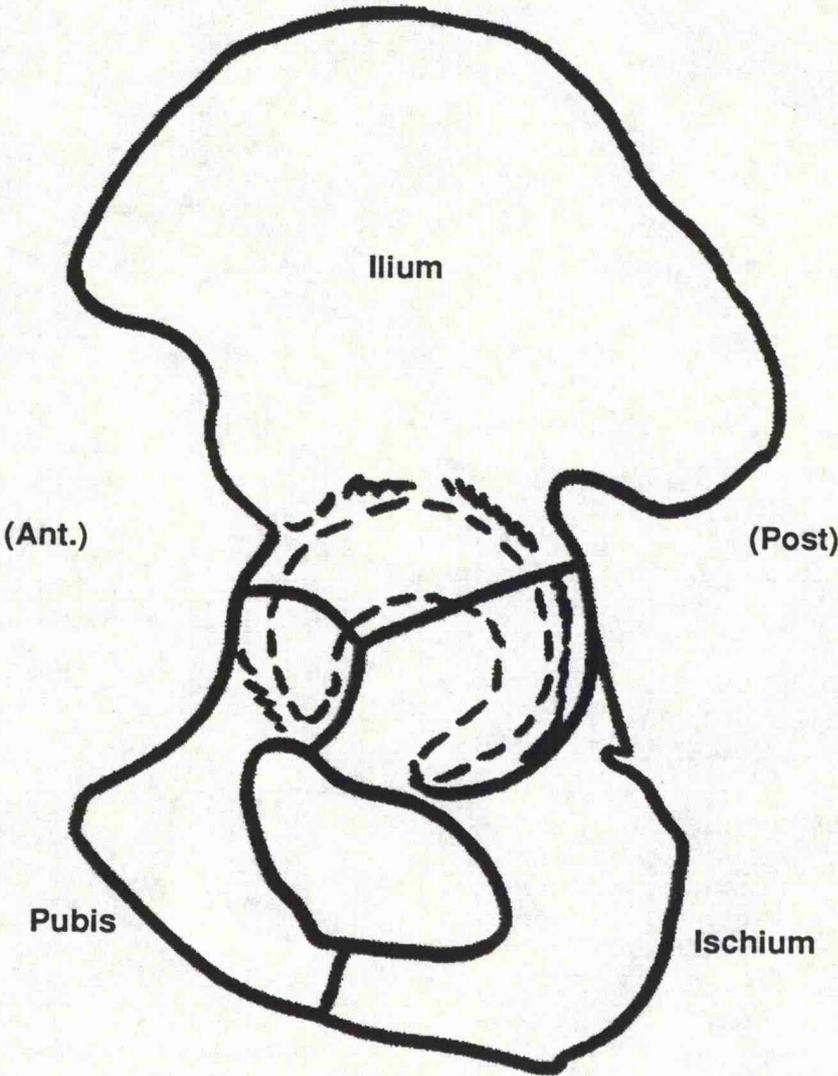


Figure 1-3 Bony Components of Hemi Pelvis Constituting the Acetabulum

Lateral view



The head of the femur forms two thirds of a sphere directed superiorly medially and anteriorly. In fact it is not exactly spherical, but "barrel-shaped" with the radius being longer by about 2mm in the direction of its axis than across it (Clarke and Amstutz 1975). The axis is normally parallel to that of the neck, but occasionally it may not be parallel due to differential epiphyseal growth.

Medial to the axis of the femoral head is the fovea centralis, a small pit where articular cartilage cover is interrupted and into which the ligamentum teres is attached. The head of the femur lies entirely within the capsule of the hip joint.

The diameter of the head varies from 40-60mm, and articular cartilage cover is thicker superiorly (4mm) than at the periphery (3mm) (Hoagland and Low 1980).

The neck of the femur is approximately cylindrical and about 5cm in length. It connects the femoral head to the shaft of the femur at an angle of approximately 130 ± 7 degrees. It is usually anteverted with respect to the femoral shaft, by 10 ± 7 degrees in normal specimens. The anterior surface of the neck is entirely within the capsule of the hip joint which is attached to the intertrochanteric line but posteriorly the capsule is inserted halfway down the neck. The intertrochanteric line joins the greater and lesser trochanters anteriorly and marks the junction of the anterior neck with the shaft.

The greater trochanter is a large postero-lateral projection of bone at the junction of the neck with the shaft. The lesser trochanter is a conical eminence that projects postero-medially from where the shaft joins the neck. Both are the

site of major muscle attachments. The intertrochanteric crest joins the trochanters posteriorly and is the junction of the posterior neck with the shaft.

The internal structure of the proximal femur consists of trabecular bone invested by thin cortical bone, except for the calcar femorale which is a dense vertical plate of bone that originates from the postero-medial portion of the femoral shaft. The medial cortex of the femoral neck is sometimes mistakenly referred to as the calcar in the literature on hip arthroplasty.

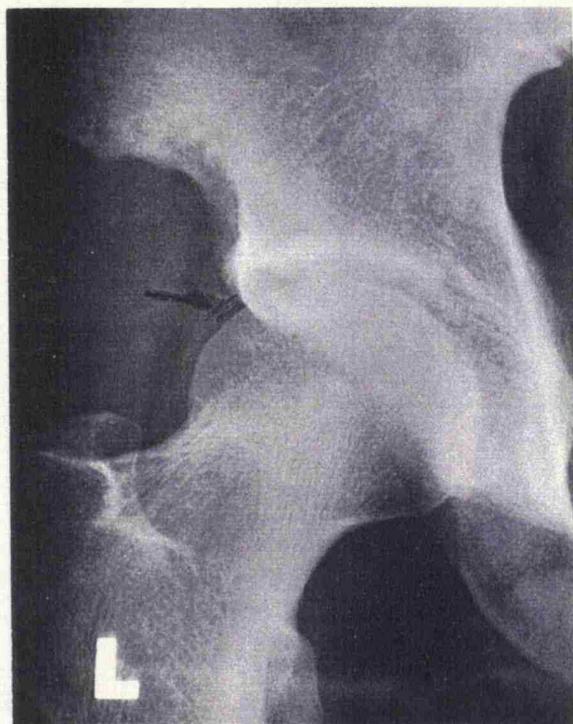
The arrangement of the bony trabeculae in the proximal femur is characteristic. They can be seen in sagittal sections of the proximal femur and on radiographs, and there are three main groups (Fig 1.4). The principal compressive (medial) group fan out from the calcar femorale to the superior aspect of the head and correspond to the principal direction of force through the femoral head during weight bearing (Garden 1961A). These are important reference points for grading the degree of fracture displacement and adequacy of fracture reduction using Gardens criteria for reduction.

The secondary compressive (lateral) group of trabeculae fan out from the calcar to the lateral shaft and greater trochanter. The principal tensile group pass from the fovea to the lateral femoral neck and then become the secondary tensile group as they pass from the neck to the femoral shaft (arcuate). With bone loss, such as occurs with osteoporosis, one or more of these trabecular groups may become radiologically indistinct, a phenomenon which has been used as an indirect measure of bone density (Singh et al 1970). Ward's triangle is an area which lies between the intersection of the trabecular groups. It is along the lines of the principal compressive trabeculae and through this triangular area that the majority of intracapsular proximal femoral fractures

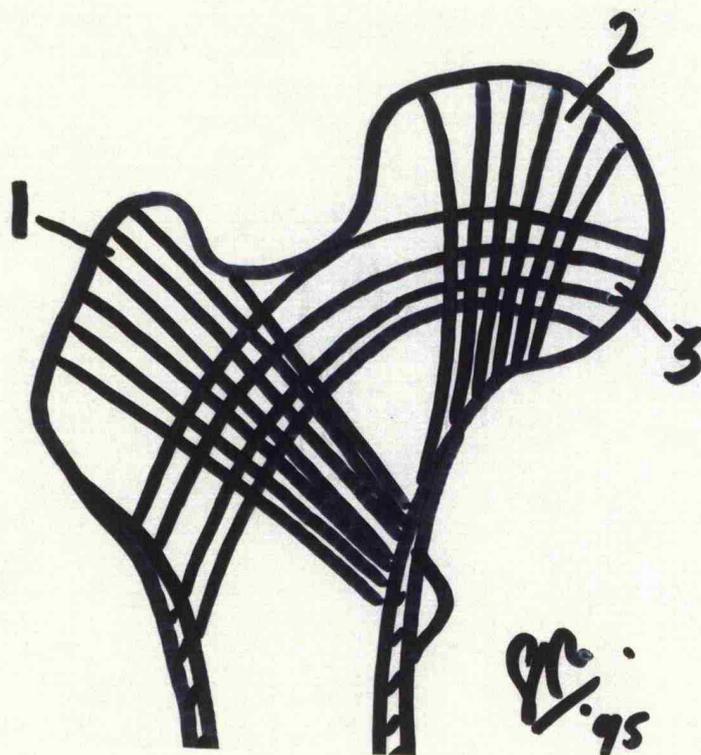
seem to occur (Klenerman and Marcuson 1970).

Figure 1-4 Bony trabeculae in the proximal femur a) radiograph b) diagram

a)



b) 1. lateral group 2. medial group 3. arcuate group



1.2.2 Arthrology

Mechanically, the hip joint is a multiaxial spheroidal joint. It is a hyaline cartilage joint which moves in all planes, and the articulation is not quite spherical.

The acetabulum is ringed by a fibrocartilaginous acetabular labrum along its rim. The capsule of the joint is attached anteriorly from the acetabular labrum to the intertrochanteric line and posteriorly it inserts 1.5cm proximal to the intertrochanteric crest. There are three ligaments which are thickenings of the capsule: The iliofemoral (ligament of Bigelow), pubofemoral and ischiofemoral ligaments (Fig 1.5).

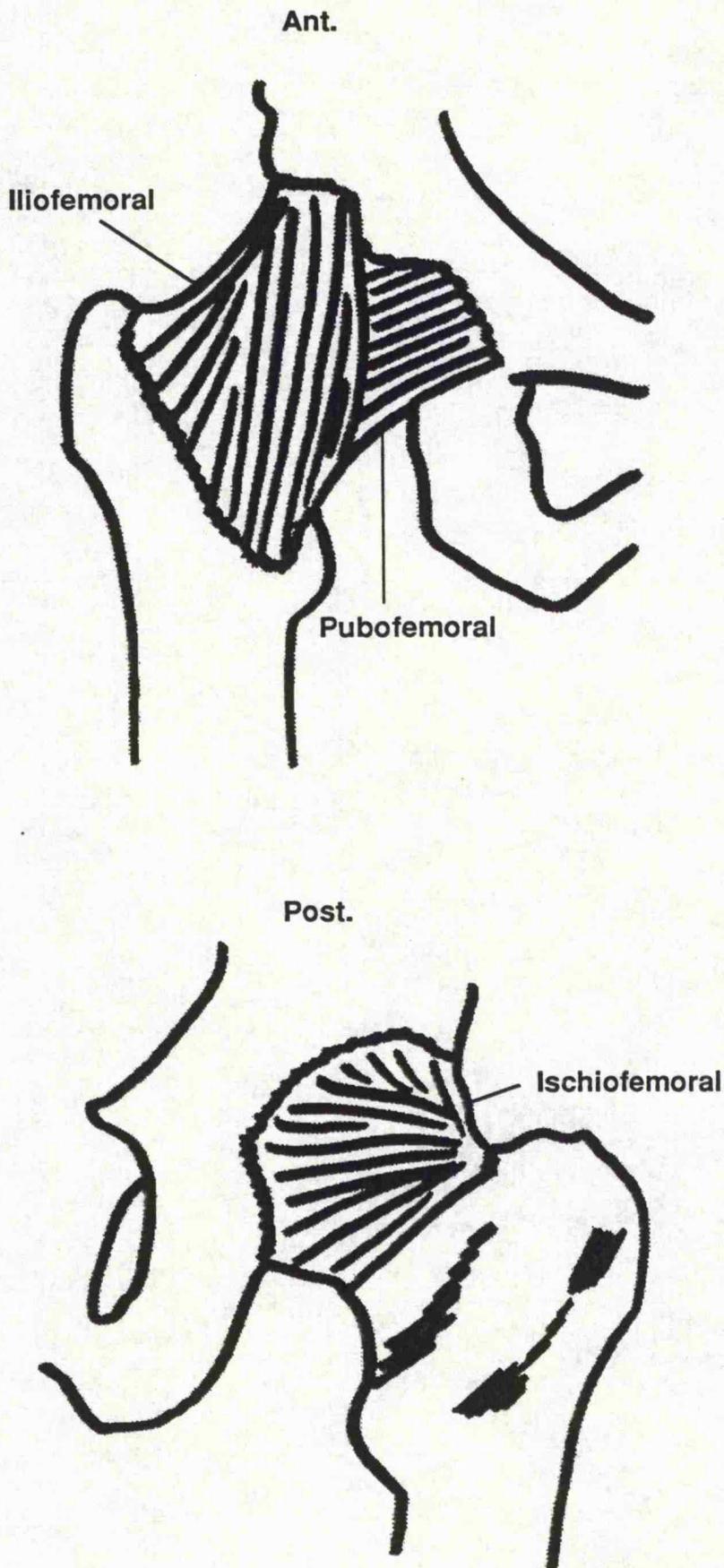
The ligamentum teres arises from the acetabular and is attached to the fovea.

1.2.3 Muscles Acting on the Hip Joint

Flexion of the hip is produced by psoas major and iliacus and to a lesser extent by sartorius, rectus femoris and pectineus. Extension is produced principally by gluteus maximus and the hamstrings. Gluteus medius and minimus produce abduction. Adduction is produced by the three adductors, longus, brevis and magnus, and gracilis.

Internal rotation is produced by psoas, tensor fascia lata and the anterior fibres of gluteus minimus and medius and external rotation by the obturators, gemelli and piriformis.

Figure 1-5 Capsular Ligaments Around the Hip Joint



1.2.4 Vascular Supply

The blood supply of the proximal femur is thought to be of major importance at the root of problem in displaced intracapsular hip fracture. The majority of studies on the vascular anatomy of the proximal femur have been done using vascular injection techniques (Howe et al 1950, Trueta and Harrison 1953), and has been well summarised by Crock (Crock 1980) as follows:

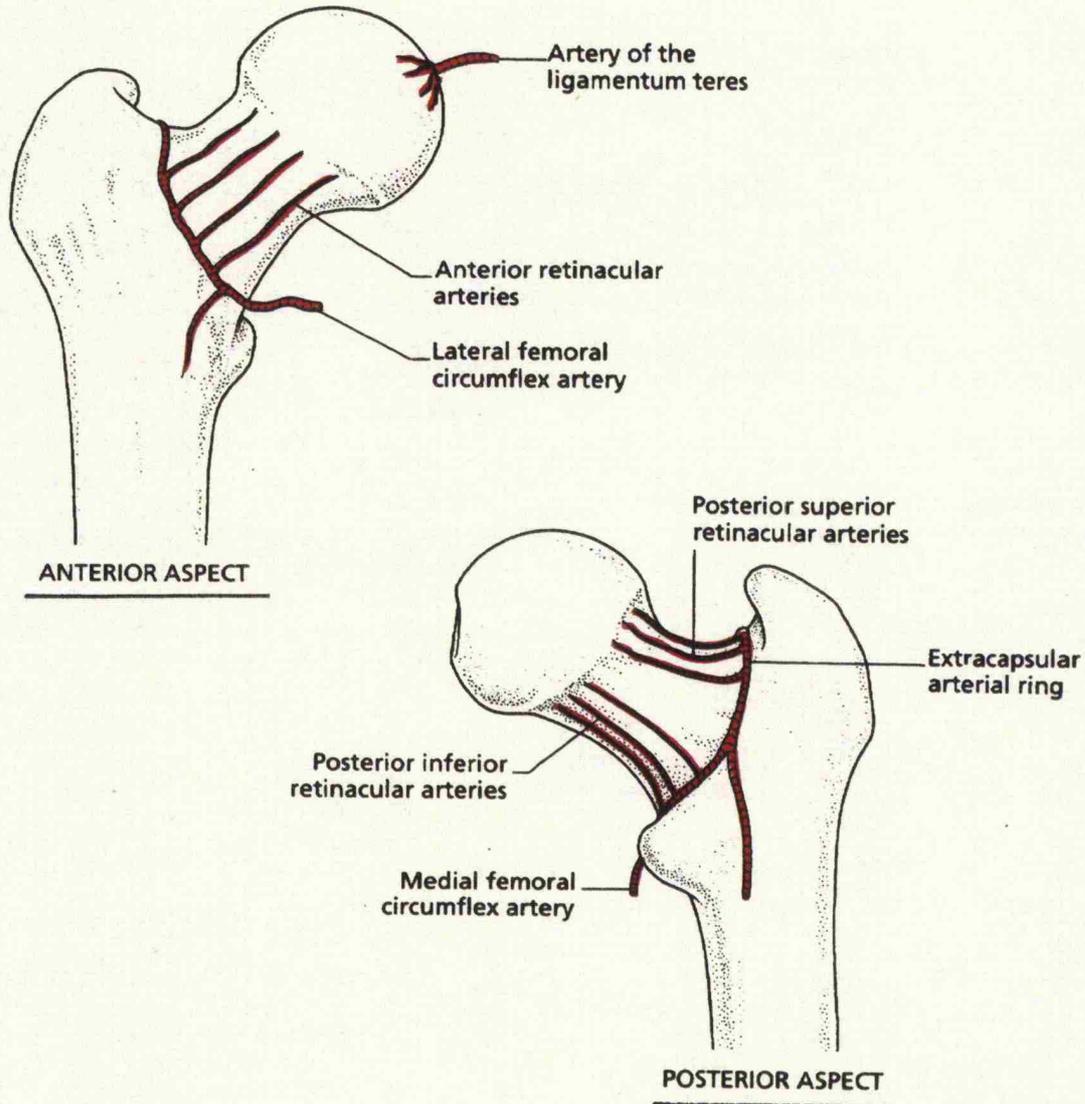
The blood supply to the proximal femur is derived from three arterial groups (fig 1.6).

- 1) The extracapsular arterial ring
- 2) Ascending cervical branches of the extracapsular ring (retinacular arteries)
- 3) The arteries of the ligamentum teres.

The extracapsular ring is formed posteriorly by a branch of the medial femoral circumflex artery, anteriorly by branches of the lateral femoral circumflex artery. Minor branches from the superior and inferior gluteal arteries. Ascending cervical vessels arise from this extracapsular ring and pass through the capsule anteriorly at the intertrochanteric line and posteriorly through orbicular fibres. They then go proximally under reflections of synovium and joint capsule to form a subsynovial anastomosis at the junction of the bony part of the neck and articular surface of the head. The vessels lie intimately related and bound down to the postero-superior aspect of the femoral neck and may therefore be easily damaged in intracapsular fractures of the proximal femur where displacement occurs.

Figure 1-6

Principal Vascular Supply to the Femoral Head (after Parker and Pryor, Hip Fracture Management 1993. Blackwell Scientific)



Once the arteries from the from the intraarticular ring enter the femoral head they are termed the epiphyseal arteries. The most important blood supply comes from the lateral epiphyseal vessels, less so from the inferior metaphyseal arteries. Trueta (Trueta and Harrison 1953) found that these supplied four fifths of the femoral head in seven subjects, two thirds in another seven, and just over half in one. This is supported by other studies (Sevitt and Thompson 1965). The area supplied includes the most important weight bearing portion, the supero-lateral segment area of the femoral head

The posterior superior retinacular vessels enter the superior aspect of the neck lateral to the articular rim. The inferior retinacular vessels enter the neck inferiorly close to the margin of the articular surface and supply the infero-medial portion of the femoral head.

The medial epiphyseal artery is the artery of the ligamentum teres and supplies a variable wedge of bone adjacent to the fovea (Catto 1965A). This artery is not always present and may be insufficient on its own to maintain viability of the femoral head but it may provide a central conduit for slow revascularisation after damage to the major vessels.

There is some confusion on the nomenclature of these small vessels in the literature; for example Crock disagrees with Trueta's assertion that the lateral epiphyseal and inferior metaphyseal vessels are distinct.

Venous drainage (Phillips 1966) is via lumino capsular veins and tortuous medullary sinusoids, which drain mainly into the obturator and femoral veins.

1.3 The aetiology of proximal femoral fractures.

1.3.1 Osteoporosis

The term osteoporosis is often used loosely, without a clear understanding of its meaning.

The definition of osteoporosis as agreed by the Department of Health (Advisory group on osteoporosis 1994) is "... a disease characterised by low bone mass, microarchitectural deterioration of bone tissue leading to enhanced bone fragility and a consequent increase in fracture risk" (WHO 1994). Riggs (Riggs 1986) defined osteoporosis as "an absolute decrease in bone density to the point at which fractures begin to occur", where the bone that remains has no change in the ratio of mineralized to non-mineralized matrix. Both of these definitions imply that there is a generally recognised association between osteoporosis and fractures.

One of the great problems in this area of study is the difficulty of measuring osteoporosis to give a repeatable quantitative result, and in defining a normal range for this measurement. The current gold standard for measuring bone mineral density (BMD) is dual emission x-ray absorptiometry (DEXA) (Cullum et al 1989). Although accurate and reliable this technique is not readily available everywhere and is costly. In addition it involves exposing the patient to ionising radiation.

A World Health Organisation (WHO) study group (WHO 1994) found that estimates of the prevalence of low bone mineral density yield a 32-fold range in the numbers affected depending on the criteria used to define osteoporosis as measured by BMD. It is usually taken as 2.5 standard deviations (SD) below the young adult reference mean. Osteopenia is defined

as being 1-2.5 SD below the normal adult mean, and normal is within 1 SD of the mean. Using this definition of more than 2.5SD less than the adult mean, it was estimated that 30% of all postmenopausal women have osteoporosis. A "fracture threshold" is referred to, which is a cut off for BMD that captures most patients with osteoporotic fractures. However the fracture risk for a given BMD is higher in the elderly due to other factors such as falls.

In 20% of cases of osteoporosis a secondary disease can be identified that is largely responsible for the osteoporosis, but in the other 80% the condition is involuntional (Riggs and Melton 1986). Two types of involuntional osteoporosis are recognised: Type I is so called postmenopausal. Type II is age-related and probably has a greater correlation with hip fracture.

However although both types of involuntional osteoporosis are more common in the elderly, the true relationship between increased risk of proximal femoral fracture and osteoporosis is unclear. Examination of the central area of the femoral neck in postmortem subjects without fracture or other coexistent disease has shown decrease in bone area with increasing age (Komatsu 1988). A direct causal relationship between hip fracture and osteoporosis has yet to be proven (Riggs and Melton 1986, Compston et al 1987, Hedlund et al 1987, Jarnlo et al 1989), but there is good circumstantial evidence, in that oestrogen therapy after the menopause prevents or slows down involuntional osteoporosis and fracture risk (Ettinger et al 1985).

The total bone mineral density (BMD) in the lower femur is lower in patients with femoral neck fractures than in controls (Hoiseth et al 1991) and the BMD as measured by DEXA has been shown to be predictive for hip

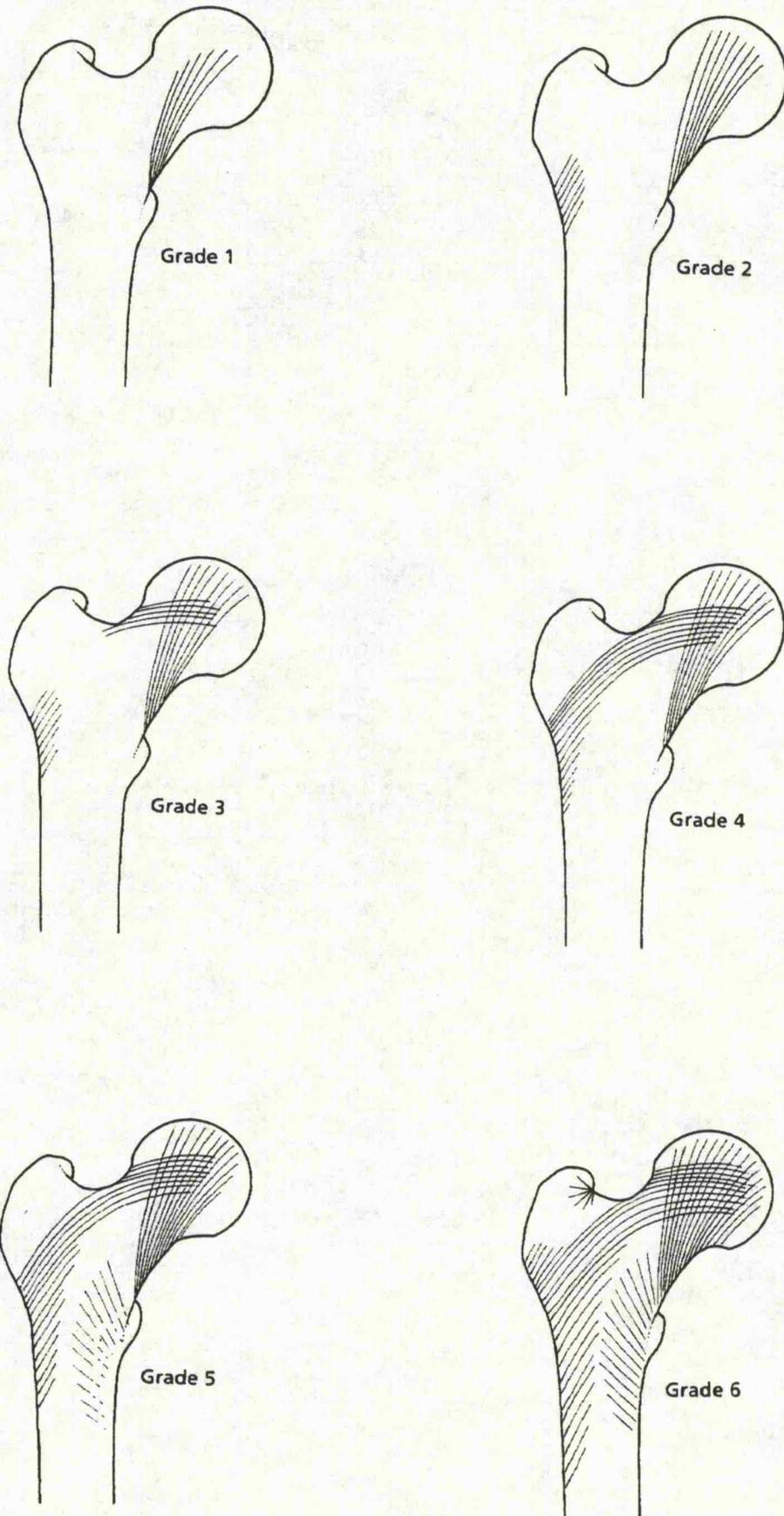
fractures in elderly women (Cummings et al 1993). Significant differences in BMD between hip fracture patients and a control population have also been found using DEXA (Stewart et al 1994).

One study has shown an increased incidence of osteoporosis in those women sustaining hip fractures (38%) as compared to the incidence of osteoporosis in the normal population (11.5%) (Makin 1987). However of those sustaining a fracture 34% had borderline osteoporosis and 28% no evidence of osteoporosis. Aitken (Aitken 1984) showed no such difference between osteoporosis in a fracture population of 200 patients and a control group.

Solomon (Solomon 1968) in an epidemiological study found that Bantu tribesmen in South Africa had a femoral neck fracture rate less than 10% that of Western Europeans and ascribed this to a lower prevalence of postmenopausal osteoporosis in the Bantu, although measurements of osteoporosis were not taken.

Singh (Singh et al 1970) has suggested that age-related bone loss can be correlated with the radiographic appearances of the trabeculae on an ordinary antero-posterior radiograph of the hip. The Singh index is divided into 6 grades, Grade VI being normal and grade I severe bone loss (fig. 1.7). However the Singh index does not always correlate with bone mass and the inter and intraobserver error when classifying these grades is high (Smith et al 1989). The Singh index is not of great practical use in screening or fracture management, and is now clinically obsolete.

Figure 1-7 Singh Index for radiographic grading of osteoporosis; diagrams showing trabeculae visible on radiographs. Grade 1= only a few medial compressive trabeculae visible, to Grade 6=all three main groups fully visible



1.3.2 Osteomalacia.

In osteomalacia there is a defective mineralisation of the organic bone matrix, due to a failure of osteoid to calcify as it is laid down in bone. This is seen histologically as an excess of osteoid. But this may also occur in hypophosphatasia and Paget's disease. Therefore it is often more useful to define osteomalacia as a disorder resulting from lack of vitamin D or an alteration in its metabolism.

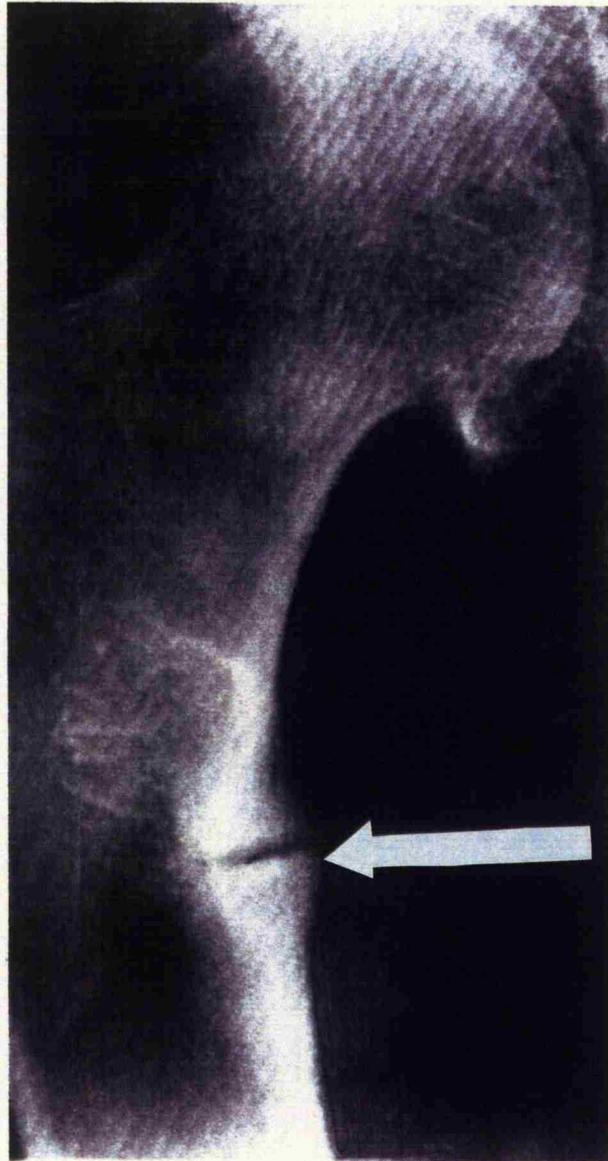
Osteomalacia is multifactorial in many patients because the aetiological factors tend to occur in particular lifestyles. Vitamin D aids calcium transport across the small intestine, therefore dietary deficiency of vitamin D is a potent cause of osteomalacia. The main dietary sources are fish, dairy products and margarine. There is also cutaneous synthesis of vitamin D precursors under the influence of sunlight. Therefore groups at risk include the elderly and Asians, in particular those with vegetarian diets, who may have dietary deficiency and low exposure to sunlight. It has been reported that in the elderly fracture population the commonest cause of osteomalacia is dietary and lack of sunlight (Hoikka et al 1982).

Vitamin D deficiency has been recognised as a problem in the United Kingdom since the 1960s (Dunnigan et al 1962), often being secondary to poor dietary intake.

Looser's zones are stress fractures surrounded by unmineralised callus and are virtually diagnostic of osteomalacia. They tend to occur on the concavity (compression side) of long bones (Fig. 1.8). It has been suggested (Dent and Stamp 1977) that Looser's zones follow trauma.

Figure 1-8

Looser's Zone (arrowed) in the Proximal Femur. Typical appearance and position-
subtrochanteric region, compression side.



Osteomalacia has been postulated as a significant factor contributing to proximal femoral fracture (Chalmers et al 1967, Jenkins et al 1973, Aaron et al 1974). However, direct examination of femoral heads following fracture (Wicks et al 1982) and of iliac crest biopsies (Wilton et al 1987A) and other work (Robinson et al 1992) has failed to confirm osteomalacia as a significant predisposing factor for hip fracture. A decrease in bone, but not serum, levels of dihydroxy vitamin D has been found in patients with subcapital proximal femoral fractures (Lidor et al 1993), suggesting that this may be a factor in the injury.

The gold standard diagnostic test for osteomalacia is accepted to be iliac crest biopsy with histological examination of osteoid seams, but this may not be conclusive because normal bone contains some osteoid and there is no set definition of the level at which to diagnose osteomalacia. Different histomorphometric criteria account for some of the variation in the reported incidence of osteomalacia and is one of the problems in assessing the literature on this subject.

Aaron (Aaron et al 1974) found an incidence of around 30% with a seasonal variation (lowest in the summer) in femoral neck fracture patients. Wilton (Wilton et al 1987B) found only a 2% prevalence, though others say it is higher (Hordon and Peacock 1990).

There is no doubt that the prevalence of osteomalacia is higher in Asians than Caucasians. Asian immigrants have low 25 (OH) Vitamin D levels (Preece et al 1973) which appear to increase in the summer spontaneously due to exposure to sunlight (Gupta et al 1974). The incidence of osteomalacia in UK Asian immigrants is probably not very different from that in their native

country (Holmes et al 1973). Asians, in particular elderly females, tend to keep out of the sun and often have a diet deficient in vitamin D. It has been suggested that the flour contained in chappati bread, part of the staple diet, counteracts the effect of dietary vitamin D in the same way as phytate (Ford et al 1972). The increased skin pigmentation of Asians or negroid races does not appear to influence cutaneous metabolism of vitamin D unduly (Stamp 1975).

The question of whether ethnic variation in vitamin D status influences hip fracture epidemiology is discussed further in chapter 6, with results of a study on variations in epidemiology and outcomes between Asians and Caucasians.

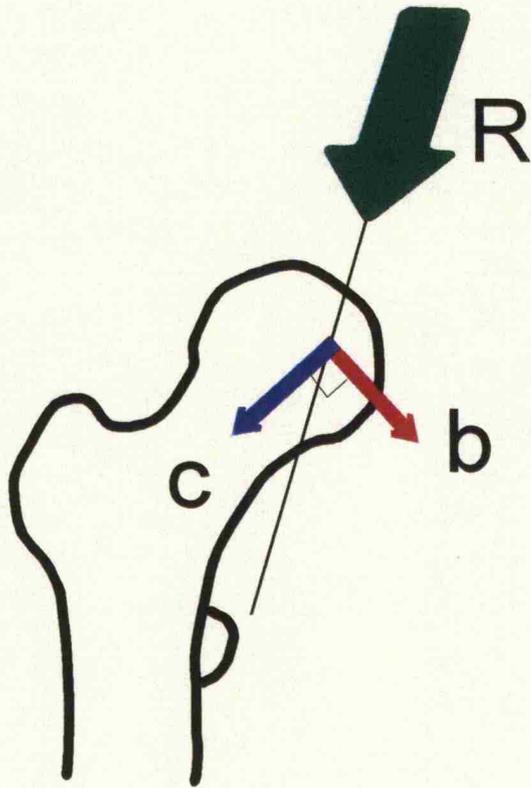
1.3.3 Biomechanical factors.

Although weight passes directly through the hip joint, the centre of gravity in man is above the hip joint and therefore muscle forces must be applied around the hip to balance the body's mass over it. To stand all day is therefore energy consuming, and the muscles acting around the hip joint are necessarily powerful. The muscles can be rested by shifting the weight from one leg to another or by leaning back on the ligaments of Bigelow (iliofemoral ligaments) to lock the hips in extension (Radin 1980).

The normal forces acting around the femoral neck can be resolved into two components; a line of force perpendicular to the femoral neck which acts as a bending component and a line of force along the axis of the femoral neck which acts as a compressive force (fig 1.9). The typical fracture pattern of an intracapsular rather than an extracapsular fracture can be produced in

cadaveric femora by increasing the compressive component in relation to the bending component (Hirsch and Frankel 1960).

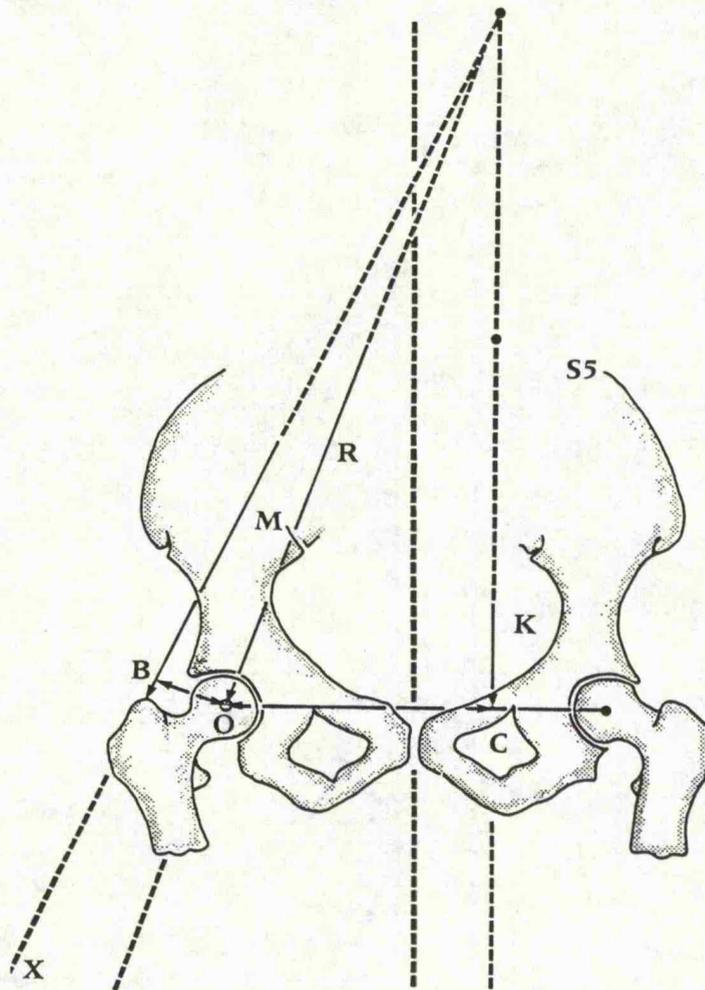
Figure 1-9 Simplified resultant forces on the proximal femur. *c*=compressive component, *b*=bending component, *R*=resultant force.



Pauwels (Pauwels 1980) produced a diagram of forces around the hip joint on weight bearing which is well known (Fig 1.10).

Figure 1-10

Pauwels Diagram of Forces Acting on Hip Joint. K = body weight vector, M =muscle balance vector, R =compressive force. OC = bodyweight lever arm from centre of hip, OB =muscle lever arm



The action of the hip abductors, which produce axial compression along the femoral neck at the time of injury, may have a significant role in fracture aetiology (Frankel 1960). This may partly explain a recent report that an increase in "hip axis length", the distance from the greater trochanter to the inner pelvic brim, is associated with an increased risk of femoral neck fracture independent of age and bone mineral density in elderly women (Faulkner et al 1993). Biomechanical studies have shown that forces as low as 256 kg can produce fractures of the femur (Compere et al 1942). During normal walking (Paul 1966), there is a cyclical load taken through the hip joint with two peaks; the first peak is at heel strike and the second just before toe off. The mean force was 3.39 times body weight and peak force was 4.46 times body weight. This is a well known study and the results have been corroborated by other workers (Crowninshield et al 1978).

A fall in an average sized adult may exceed the energy absorbing capacity of the upper femur, and it is only because of the dissipation of these considerable forces by normal muscular reaction and ligamentous restraint that the femur does not spontaneously fracture during normal walking. In the elderly these intrinsic protective mechanisms may not act quickly or efficiently enough to prevent fracture. Protective mechanisms during a fall, such as putting out ones arms is also impaired by age-related slowing of neuromuscular responses.

In addition to these soft tissue protective mechanisms, the bony components of the hip joint may deform under load, further absorbing some of the impact forces. In fact full congruity of the femoral head and acetabulum

occurs only under full load, diminishing the force per unit area and maintaining it within tolerable limits (Bullough et al 1973).

A certain level of trabecular microfracture following deformation of the femoral head is physiological, but there is a theory that repeated high levels of trabecular fracture can lead to bone remodelling and stiffening, thereby diminishing the ability of the joint to become congruent under load (Bullough et al 1973). This can lead to damage to the articular surface and subsequent osteoarthritis. Microfractures have also been demonstrated in the femoral neck of elderly subjects (Freeman et al 1974) and it is suggested that these may progress to a complete fracture. Although stress fractures of the femoral neck do occur (Devas 1965) the most common precipitating incident in a complete fracture of the femoral neck is a specific traumatic incident such as a fall.

A combination of an external rotation force with a strong abductor force tensioning the anterior femoral neck and compressing the posterior femoral neck may produce the posterior comminution of the femoral neck which is so often present in intracapsular fractures. At least 50-60% of intracapsular hip fractures demonstrate some degree of posterior comminution (Brown and Abrami 1964, Klenerman and Marcuson 1970). It is postulated that posterior comminution at the fracture site is the cause of many of the problems of early fixation failure (Scheck 1980), though there is insufficient evidence to say that the presence of posterior comminution should preclude fixation as a treatment.

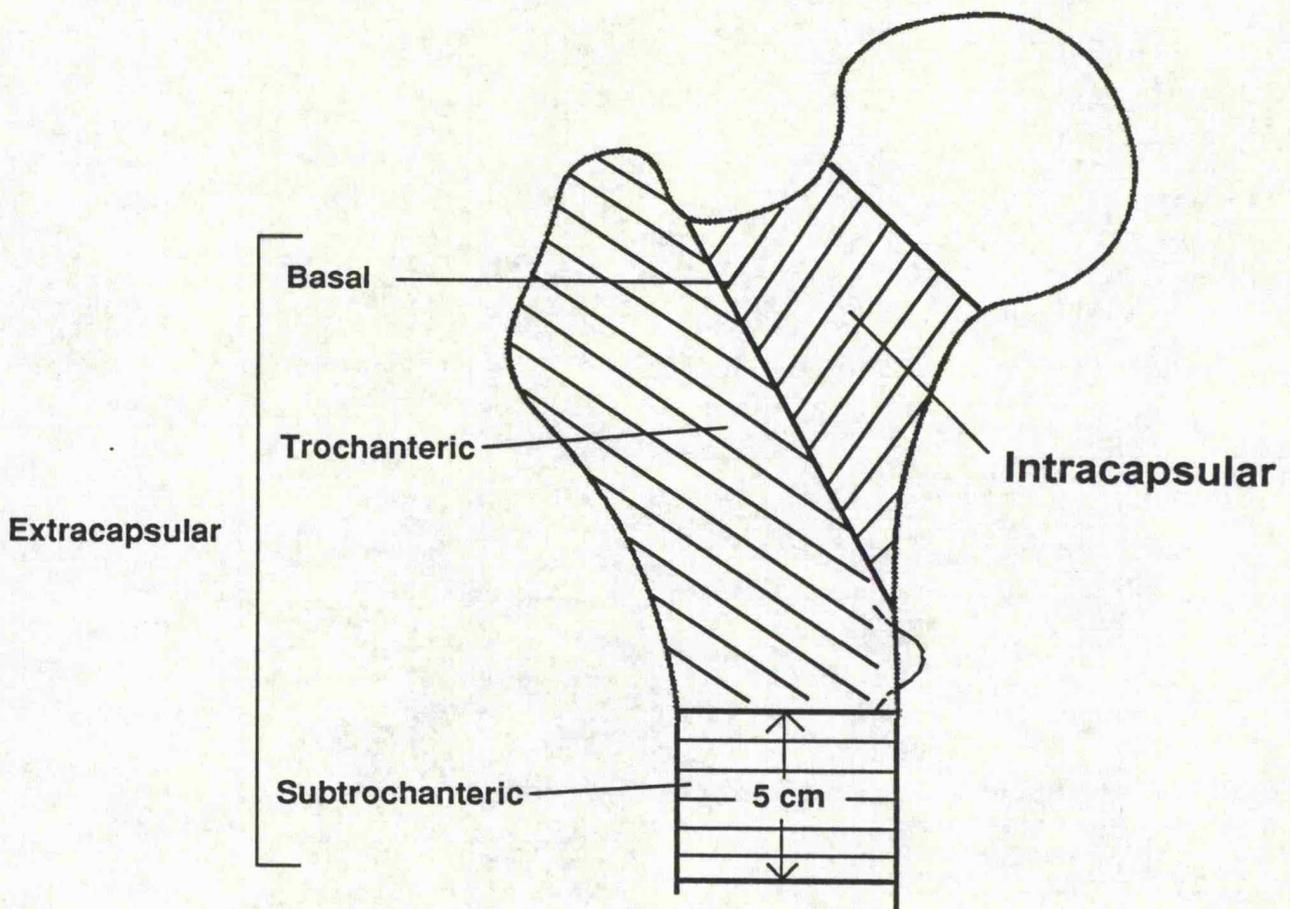
1.4 Classification of fractures of the proximal femur

Fractures of the proximal femur may be classified broadly into two anatomical groups: intracapsular and extracapsular fractures (fig 1.11),

depending on their relationship to the hip joint capsule.

Figure 1-11

General Anatomical Classification of Hip Fractures



1.4.1 Extracapsular fractures.

These are fractures that occur in the proximal femur distal to the insertion of the fibrous capsule, in the metaphysis of the femur rather than the diaphysis. Extracapsular fractures occur through an area of cancellous bone with a good blood supply and usually progress to union. The blood supply to the head of the femur is not interrupted by the fracture, and therefore it is not at risk of developing avascular necrosis. This thesis is concerned mainly with intracapsular proximal femoral fractures. Extracapsular fractures will not be discussed further.

1.4.2 Intracapsular fractures.

These occur proximal to the insertion of the joint capsule. Because of the anatomy of the blood supply (1.2.4), there is potential for damage to the blood supply to the proximal fragment. This means that non-union and avascular necrosis are common complications of this injury.

The difference in prognosis between these fractures that occur within the capsule of the hip joint and extracapsular fractures was first recognised by Astley Cooper (Cooper 1824). Any classification of these fractures, as for other fracture types, should have some relevance to the prognosis.

1.4.2.1 Pauwels Classification

The classification of Pauwels was the earliest attempt at a useful grading system for intracapsular hip fractures. It is based on the angle of inclination of the fracture line with respect to the horizontal (Pauwels 1935). The

classification divides intracapsular fractures into three types, the fracture line becoming more vertical as the grade increases (fig 1.12).

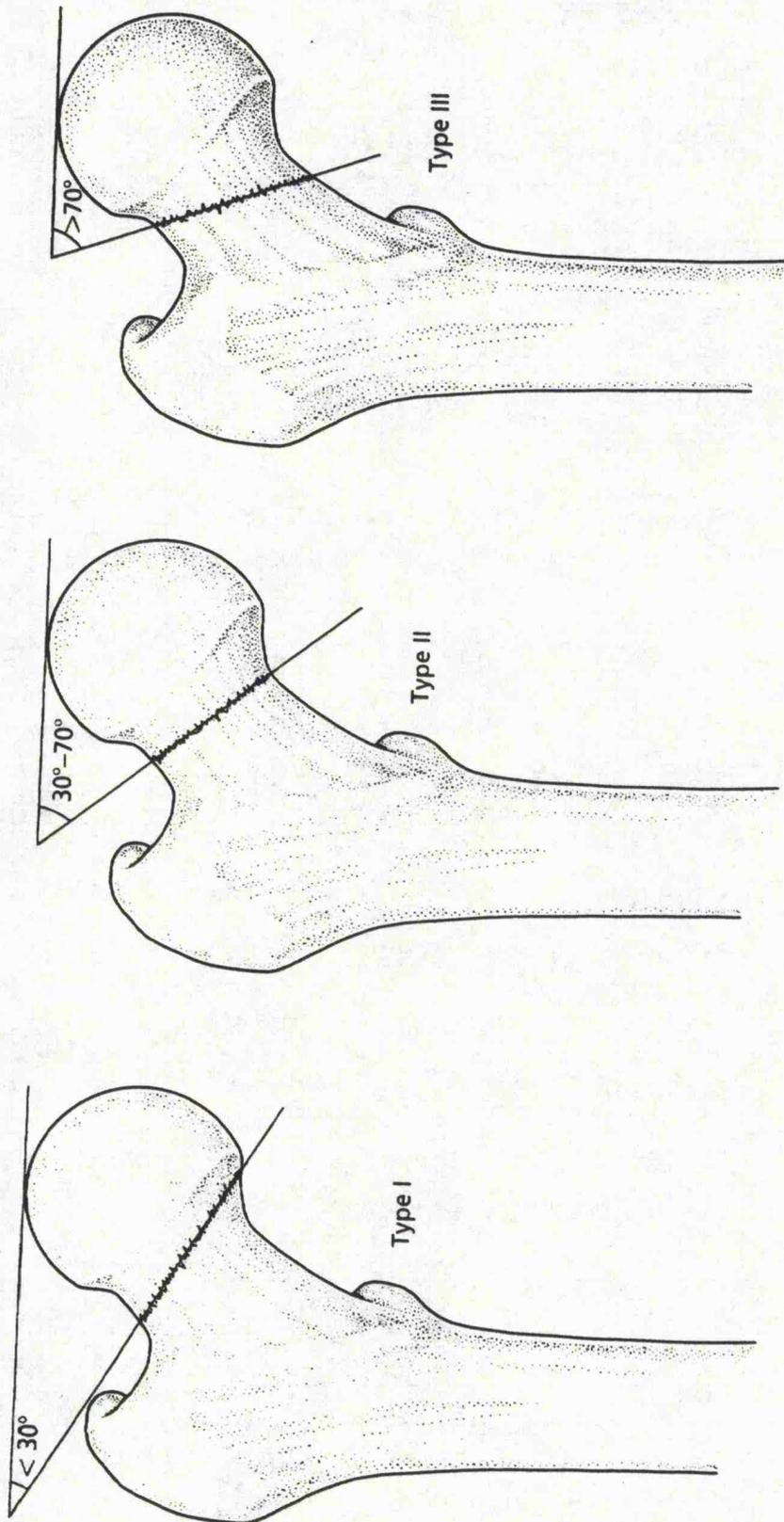
- Type I** fracture line 30 degrees from the horizontal
- Type II** fracture line 30-70 degrees from the horizontal
- Type III** fracture line > 70 degrees from the horizontal

Pauwels stated that type III fractures had an increased incidence of non-union because of the greater shearing forces across the fracture line (Pauwels 1935).

This classification is based on the radiographic appearance of the fracture on an antero-posterior projection and may not represent the angle of the fracture line itself. Because of the spiral nature of the femoral neck, rotation of the distal fragment varies the apparent obliquity of the fracture angle on radiographs (Garden 1974). Linton showed that by altering either the position of the radiograph source or the limb the apparent inclination of the femoral neck could be changed, demonstrating that the classification may be altered by radiographic variables (Linton 1944).

Apart from the questionable radiographic basis, the use of this classification has been called into doubt for clinical reasons. There does not appear to be a difference between non-union and avascular necrosis rates between Pauwels types II and III, with 12% non-union and 33% avascular necrosis rates in type II as compared to 8% non-union and 30% avascular necrosis rates in type III (Boyd and Salvatore 1964). This work has been supported by other authors (Cassebaum and Nugent 1963, Ohman et al 1969).

Figure 1-12 Pauwels Classification of Intracapsular Hip Fracture (refer to text)



Finally, Pauwels classification is based on the post reduction appearance. Therefore it is of no clinical value in terms of preoperative decision making and may be considered obsolete.

1.4.2.2 Garden Staging

The classification of Garden is the most widely used classification for intracapsular hip fracture. It is based on the displacement of the head of the femur as seen on antero-posterior radiographs of the hip prior to reduction of the fracture (Garden 1961B), using the trabecular lines as reference points.

The Garden classification is divided into four stages (Fig 1.13) which can be summarised:

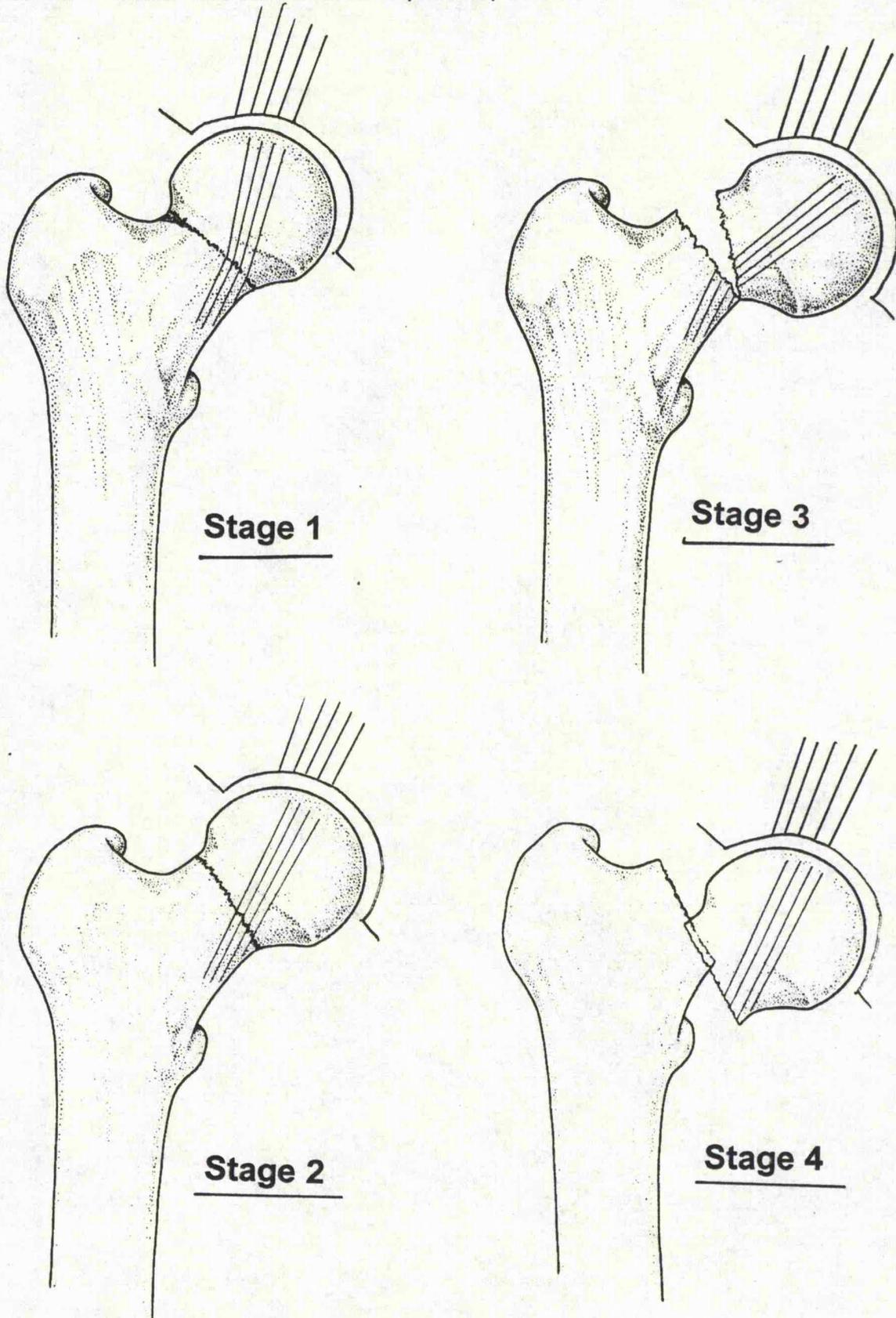
Stage 1 An incomplete or impacted fracture. The medial cortical trabeculae of the neck are intact. This group includes the abducted impaction fracture.

Stage 2 A complete but undisplaced fracture. The alignments of the trabeculae of the head, neck and acetabulum are undisturbed. These are rare fractures; only 19/1503 intracapsular fractures in one series (Barnes et al 1976).

Stage 3 **A complete but only partially displaced fracture. The trabecular pattern of the femoral head does not line up with the trabecular pattern of the acetabulum.**

Stage 4 **A complete fracture with total displacement of the fracture fragments. The trabecular pattern of the femoral head lines up with the trabecular pattern of the acetabulum.**

Figure 1-13 Garden Classification of Intracapsular Hip Fracture



It is somewhat surprising that more than thirty five years later Garden's classification is still widely used, particularly in view of the fact that in his first description it was simply put as an alternative to the postoperative basis of Pauwels system: "...the following classification...is suggested in the hope that it may prove to be of additional value" (Garden 1961B). Garden suggested that increase in stage indicated a worsening of the prognosis, particularly in a stage 4 fracture where the rotation of the head implies complete disruption of any ligamentous attachments between the head and neck and consequently a disruption of a significant proportion of the blood vessels supplying the head.

A large multicentre study of hip fractures, much quoted in the literature, seemed to confirm these views, with higher stages having a worse prognosis (Barnes et al 1976). Although there was a difference in outcome between stages 3 and 4, it was not large. Similarly the prognosis for stages 1 and 2 was similar.

The Garden classification relies on visualisation of the trabeculae in the femoral head and the acetabular roof. With increasing osteoporosis these trabeculae become less apparent (the basis of the Singh classification) making classification more difficult. In an intraobserver error study of the Garden classification of radiographs of 100 intracapsular fractures by 8 observers there was complete agreement on the Garden stage in only 22% of cases (Frandsen et al 1988). Agreement on whether a fracture was displaced or undisplaced was much greater. Division of fractures into stage 3 or 4 has not been found to have any predictive value in determining either quality of fracture reduction or incidence of non-union (Parker 1993).

In recent literature the classification of intracapsular fractures has been simplified into displaced (Garden stages III and IV) and undisplaced (Garden stages I and II). This is of value because there is little doubt that non-union and avascular necrosis are much more common in displaced than undisplaced fractures (Rehnberg and Olerud 1989, Sernbo et al 1990, Herngren et al 1992). This simple classification into displaced and undisplaced intracapsular fractures now appears to be generally accepted.

1.5 Diagnosis of intracapsular proximal femoral fractures

1.5.1 Clinical presentation

The typical patient with this fracture is an elderly female with a history of a fall, presenting with pain in the hip and difficulty or inability to weight bear on the affected limb. With displaced fractures the affected limb lies shortened and externally rotated (because of the unopposed action of the external rotators).

There may be tenderness directly over the hip. Bruising and swelling is more common in extracapsular than intracapsular fractures. There is usually pain on movement of the hip. These classic signs and symptoms are not always present and up to 9% of fractures may have a delay in diagnosis due to absence of all or some of them (Eastwood 1987).

Patients with undisplaced fractures, particularly Garden stage I, present a more difficult diagnostic problem. Symptoms and signs are more subtle and patients may continue to weight bear with only slight discomfort. Careful clinical examination usually reveals some pain and decreased range of movement

around the hip. This is important because initial failure in diagnosis may lead to an undisplaced fracture becoming displaced with the associated increased therapeutic problems (Parker 1992).

Younger patients usually present after significant trauma and other significant injuries may be present. Ipsilateral intracapsular hip fracture and femoral shaft fracture is a recognised association in these patients, with the hip fracture often being missed as treatment is focused on the more obvious shaft fracture. (Friedman and Wyman 1986, Swiontkowski 1987, Wu and Shih 1991).

1.5.2 Imaging and Examination

Standard convention is for an antero-posterior (AP) radiograph of the hip to be taken with the hip in about 10 degrees of internal rotation to allow for the normal anteversion of the femoral neck to be negated; the x-ray beam will therefore be perpendicular to the femoral neck for optimal definition of the trabeculae. In the case of most hip fracture patients the best that can be achieved is usually an AP view in the position of comfort for the patient.

The displaced hip fracture is easily seen on any standard antero-posterior radiograph of the hip or pelvis. A lateral view of the affected hip should also be obtained because significant angulation may not be apparent on the antero-posterior view.

The most commonly missed fracture appears to be the 'undisplaced' abducted-impacted intracapsular type (Garden Stage I) (Parker and Prior 1992), which may become obvious only when it displaces after the patient has

been allowed to weight bear (Bentley 1968). In one study 43 out of 693 patients with suspected hip fractures had normal initial radiographs. Thirteen of these 43 subsequently developed a radiographically apparent fracture (Fairclough et al 1987). Some authors have suggested that patients may present with a normal initial radiograph but later progress to a definite fracture (Eastwood 1987). The incidence of apparently normal radiographs at presentation ranges from 0.4% to 2.5% (Parker 1992, O'Dwyer et al 1991), while up to 8.1% of cases have been found to have either normal or equivocal radiographs at presentation (Lewis et al 1991).

The problem of missed fractures, particularly those progressing to displaced intracapsular hip fracture, have led some authors to conclude that patients with hip pain following trauma should have technetium bone scintigraphy (Prather et al 1977, Fairclough et al 1987). There are inaccuracies in this technique; in one series a 3.8% false positive and a 0.9% false negative rate (Lewis et al 1991). Osteoarthritis is a common cause of false positive bone scans. The timing of the scan does not appear to affect the specificity (Holder et al 1990).

Computerised tomography (CT) scans have been used for diagnosis of clinically suspected intracapsular fracture, by the detection of a lipohaemarthrosis. In one series of 40 there was 1 false negative and 1 false positive (Egund et al 1990). Ultrasound to confirm the joint effusion, though not specific for fracture haemarthrosis, has been used (Wilson et al 1984). Magnetic Resonance Imaging (MRI) has also been employed, with reports of the fracture being diagnosed correctly in all cases (Deutsch et al 1989). For the

time being an isotope bone scan remains the standard clinical investigation in cases where fracture is suspected but not apparent on plain radiographs, though MRI may increasingly take over this role as it becomes more accessible.

1.6 Treatment of displaced intracapsular hip fractures

1.6.1 Non-operative Treatment

With increasing age and decreasing mental function the results of internal fixation and of patient survival deteriorate (Ions and Stevens 1987).

For immobile demented patients, Lyon (Lyon and Nevins 1984) compared operative and non-operative treatment in a small non-randomised study. Twelve patients were treated medically with intensive nursing care but with neglect of the fracture, and 14 were treated operatively. There were no early deaths or major complications and all patients developed a pain free hip when treated non-operatively, although only one (8%) returned to walking. In the operatively treated group there was a 43% major complication rate, but 44% walked again.

Poor outcome following surgical treatment of these patients must be balanced against other complications of non-operative treatment. Winter (Winter 1987) reported that three out of four cases treated non-operatively moved from minimal ambulation to a bed/chair existence and the fourth patient died after one month still in pain.

With non-operative treatment the nursing burden is considerably increased, hospital stay may be longer, and any slim chance of regaining

mobility is removed resulting in the certainty of a long term burden on the community.

There has been no published randomised prospective trial comparing the results of operative versus non-operative treatment in the management of displaced intracapsular proximal femoral fractures. In this centre such a trial had to be abandoned due to unacceptable nursing problems in the non-operated group (Harper 1995). With modern anaesthesia and surgical procedures only a small handful of demented immobile patients warrant conservative treatment.

1.6.2 Reduction/internal fixation

1.6.2.1 The timing of internal fixation.

i) General effects of delay in surgery

Whether delay between time of operative fixation influences morbidity or mortality remains controversial. There are no randomised prospective studies on this subject for reasons of ethics and patient consent to a voluntary delay in surgery.

Many of the studies which report on the matter do not take into account delays due to medical condition. Patients who enter hospital in a poor medical condition which could be improved prior to anaesthesia are inevitably the group expected to have more postoperative complications.

Studies which show some benefit to the patient of delaying surgery include one which attempts to exclude the confounding factor of poor medical condition being the cause of delay (Kenzora et al 1984). Those operated on

within 24 hours had a higher inpatient and one year mortality than those operated on between 1 and five days (1 year mortality for operation within 24 hours of injury 28%, compared to 4% for 2-5 days delay).

A more recent study (Zuckerman et al 1995) found that in patients over 65 with a good mental test score and living independently, an operative delay of more than 2 days doubled the 1 year mortality rate. This data was analysed controlling differences in age, sex and number of pre-existing medical conditions. There was no effect on hospital complications.

Most other studies which have found a difference also demonstrate a detrimental effect of delay on mortality and morbidity (Davie et al 1970, Villar et al 1986). However the weight of studies do not find any association between mortality and timing of surgery (Davis et al 1988, Dolk 1990, Wood et al 1992, Parker and Prior 1992).

ii) Specific effects of delay in surgery on the fracture

When treating displaced intracapsular hip fractures the effect of surgical delay on the incidence of non-union and avascular necrosis must also be considered in addition to the effect on general medical outcome.

In a multicentre study on displaced intracapsular hip fractures treated by internal fixation (Barnes et al 1976), no difference was found in rates of failure if operation was delayed by up to six days, but non-union increased dramatically if the delay was longer. Another study has shown a greatly increased incidence of non-union and AVN after 7 days surgical delay (Holmberg et al 1987).

Manninger (Manninger et al 1989) looked at the benefits of very early surgery, defined as less than 6 hour delay. The incidence of non-union or AVN was considerably lower in patients operated on very early. Those patients who had surgery within 6 hours had a non-union rate of 1.5% and late segmental collapse secondary to avascular necrosis of 10.5% at one year, compared to 11.1% non-union and 40% late segmental collapse for later surgery. Kinking of small blood vessels (Woodhouse 1964) or intracapsular haematoma producing small vessel tamponade (Stromquist et al 1985) for more than six hours causes irreversible ischaemic damage which is preventable by early reduction and fixation, and this may explain the findings of this study. However, Manninger's results, though often quoted, should be interpreted with some caution because the study was retrospective and non-randomised.

Even if evidence in favour of urgent surgery was conclusive, the practicalities of trauma surgery in most units would impede such an approach and the standard practice of performing internal fixation at the next most opportune moment, preferably within 3 days and certainly within the week, is a reasonable management strategy which is supported by the weight of the literature.

1.6.2.2 Reduction of the fracture

A satisfactory reduction is a prerequisite to a successful outcome for internal fixation of displaced intracapsular proximal femoral fractures, and inadequate reduction results in an increased incidence of non-union and avascular necrosis (Barnes et al 1976, Kofoed and Alberts 1980, Parker 1991,

Unger and Schuster 1986). Accuracy of reduction is best assessed on antero-posterior and lateral plain radiographs taken at the time of surgery.

In order to describe the accuracy of reduction a practical index needs to be employed. Gross malreduction can be described in terms of extreme tilting of the head on the neck in any direction, displacement of the fracture; wedging, widening or narrowing of the hip joint space; undue prominence of the fovea; loss of the circular outline of the articular margin; or disturbance of Shenton's line (Garden 1971).

A more quantitative way of assessing reduction in common use is the alignment index described by Garden (Garden 1961, 1971) (Figure 1.14).

The normal angle between the fan shaped medial group of trabeculae in the femoral head and the medial cortex of the femoral shaft on anteroposterior radiographs is 160 degrees and in the lateral view the central axis of the femoral head and the central axis of the femoral neck lie in a straight line, by convention 180 degrees. This alignment index is expressed as 160/180 and is the best possible 'anatomical' alignment. According to Garden this position "is achieved largely by chance, for no consistently dependable method of reduction has yet been described".

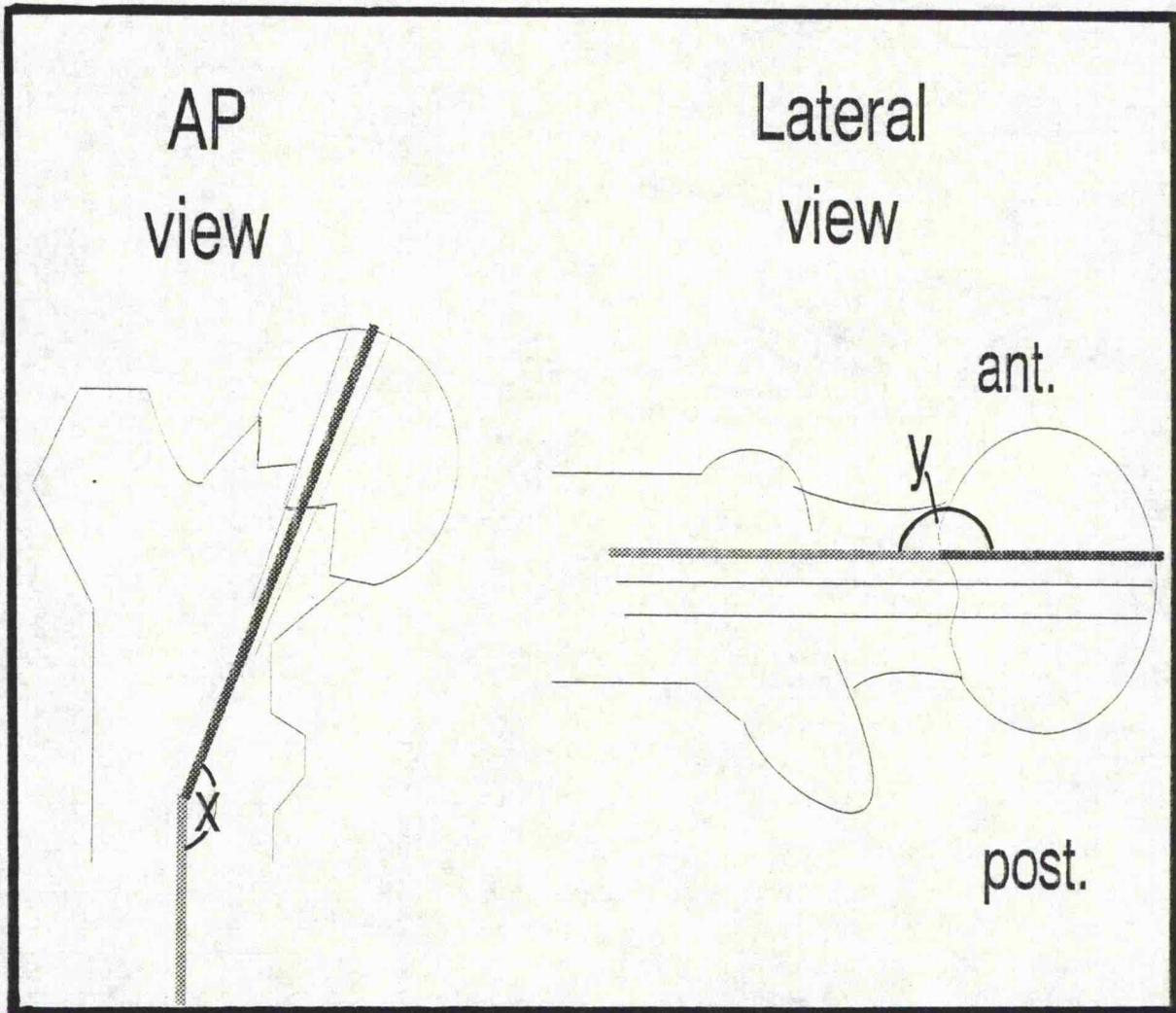
Acceptable ranges for the alignment index are not clear-cut. An alignment angle in the range of 155-180 degrees in either the antero-posterior or the lateral view was considered to be acceptable by Garden (Garden 1971). Localised collapse of the femoral head occurred in every case with an alignment less than 150 or greater than 185 degrees on the AP view regardless of the lateral alignment. Outside the 155-180 degree range, the lateral index

seemed to determine the likely outcome of the fixation fore than the AP index.

Other definitions of a good reduction based on retrospective analyses are 155-165/175-185 (Nordkild and Sonnehlm 1984) and 155-185/160-200 (Wood et al 1991). There is no doubt that it is better to stray into valgus than varus if an anatomical reduction cannot be obtained.

Figure 1-14

The Garden Alignment Index. Acceptable range of x on the anteroposterior view (AP) view is 155-180 degrees. Accepted range of y on the lateral view is 160 - 200 degrees. Angles are measured between the line of the femoral shaft and the medial compressive trabeculae in the femoral head. ant.=anterior, post.=posterior



1.6.2.3 Closed reduction methods

Closed reduction is more commonly performed than open reduction, on the premise that remaining vessels to the femoral head are put at less risk than in open reduction.

The ease of closed reduction depends on soft tissue attachments remaining between the head and the neck. If there are none the femoral head will lie free in the acetabulum, attached only by the ligamentum teres. Therefore the aim of any reduction manoeuvre is to appose the neck to the head because movement of the neck will not influence the head position. When there are soft tissue attachments remaining between the head and the neck they can be utilised in achieving a reduction. The spiral nature of the fibres of the posterior joint capsule increase stability of the reduction when the hip is internally rotated and extended, the so called "close packed" position of the capsule fibres.

Various methods of reduction have been described. It is important to note that the majority of these techniques were devised before image intensification gave the possibility of dynamic viewing of the fracture. Brueckmann (Brueckmann 1990) summarized most of the techniques but no comparison was made between the efficacies of the different methods.

The following methods of reduction, are the best known eponymous descriptions:

1) Whitman Manoeuvre

The reduction is performed on a traction table. The affected limb is flexed and then, with traction applied along the longitudinal axis of the leg, is

fully extended and abducted and brought to meet the unaffected side.
(Whitman 1920)

2) Leadbetter manoeuvre

The fractured limb is flexed to 90 degrees at the hip. Traction is applied along the axis of the thigh and combined with adduction. The affected leg is then circumducted into abduction with the leg in internal rotation. The heel palm test is applied once the leg is brought down to the level of the unaffected leg. If the fracture is reduced when the heel is placed on the palm of the hand it slowly rotates into external rotation, if the fracture is not reduced the foot rapidly springs into external rotation. (Leadbetter 1938)

3) King manoeuvre

Longitudinal traction is combined with posterior pressure on the upper thigh and internal rotation of the leg. (King 1939)

4) Smith manoeuvre

The thigh is abducted and externally rotated. In full abduction the leg is internally rotated and then adducted (Smith 1953).

5) McElvenney manoeuvre

The affected leg is internally rotated and 16-45 Kg of traction applied to medially displace the shaft. With the leg abducted pressure is applied downwards and medially over the greater trochanter. The leg is then adducted

into neutral and traction released. (McElvenney 1945)

6) Wellemerling technique

Traction is applied on the affected leg so that it is 0.25 inch longer than the other. Pressure is applied proximally over the thigh near the groin and distally under the thigh near the popliteal fossa. The leg is internally rotated and traction released. (Wellemerling 1944)

7) Flynn manoeuvre

This is a more recently described method (Flynn 1974) and is a modification of the Leadbetter technique. The hip is flexed and abducted slightly to relax the capsule and ligaments, traction is applied in the long axis of the neck to disimpact the fracture. Extension and internal rotation complete the reduction. It has been reported to be better than the Whitman and Leadbetter techniques (Compton et al 1977).

Reduction of these fractures, by whichever technique or combination of techniques requires precision and a gentle touch. Good quality image intensification, preferably biplanar, and plain radiographs are essential aids.

1.6.2.4 Open Reduction Methods

Open reduction may be indicated for failed closed reduction as defined by an alignment index, if arthroplasty is considered inappropriate (Keller and Laros 1980). It is rarely required in the elderly and will not be discussed further.

1.6.3 Internal Fixation methods

A variety of methods for fixing intracapsular fractures have been described over the years

1.6.3.1 *single flanged nails*

These nailing devices, the best known being the Smith-Petersen trifin nail (Smith-Petersen 1931) are inserted by hammering a cannulated nail over a guide wire which crosses the fracture site. A four flanged nail was introduced by Hey Groves (Hey Groves 1916) and Rydell (Rydell 1964) described a similar device.

These nails were relatively easy to insert percutaneously over a guide wire. Although some control over rotation was conferred by the flanging, the fracture stability depended mainly on contact of the bony fragments at the fracture site which could be unreliable. One solution to the problem of instability was to drive the nail through the head and into the acetabulum (Jarry 1964). This conferred increased stability but the unsurprising result was loss of hip movement.

The other disadvantage of single nails was the tendency to disimpact or distract the fracture fragments as the nail was driven across the fracture (Bentley 1968).

When compared with other devices in a large multicentre series of hip fractures single nails performed the worst of all fixation devices (Barnes et al 1976). They have been found to be inferior to fixed nail-plates (Frangakis 1966) and sliding nail plates (Fielding et al 1974). Garden himself designed a spring-loaded mechanism on a single screw to apply compression, but the device was

not extensively used (Fig. 1.15).

Figure 1-15

Garden's design for a spring loaded compression screw (positioned for a left hip looking from the front)



1.6.3.2 Internal fixation with nail plates.

Side plates were added to single nails in order to stabilise the nail onto the femoral shaft and therefore improve rotational stability.

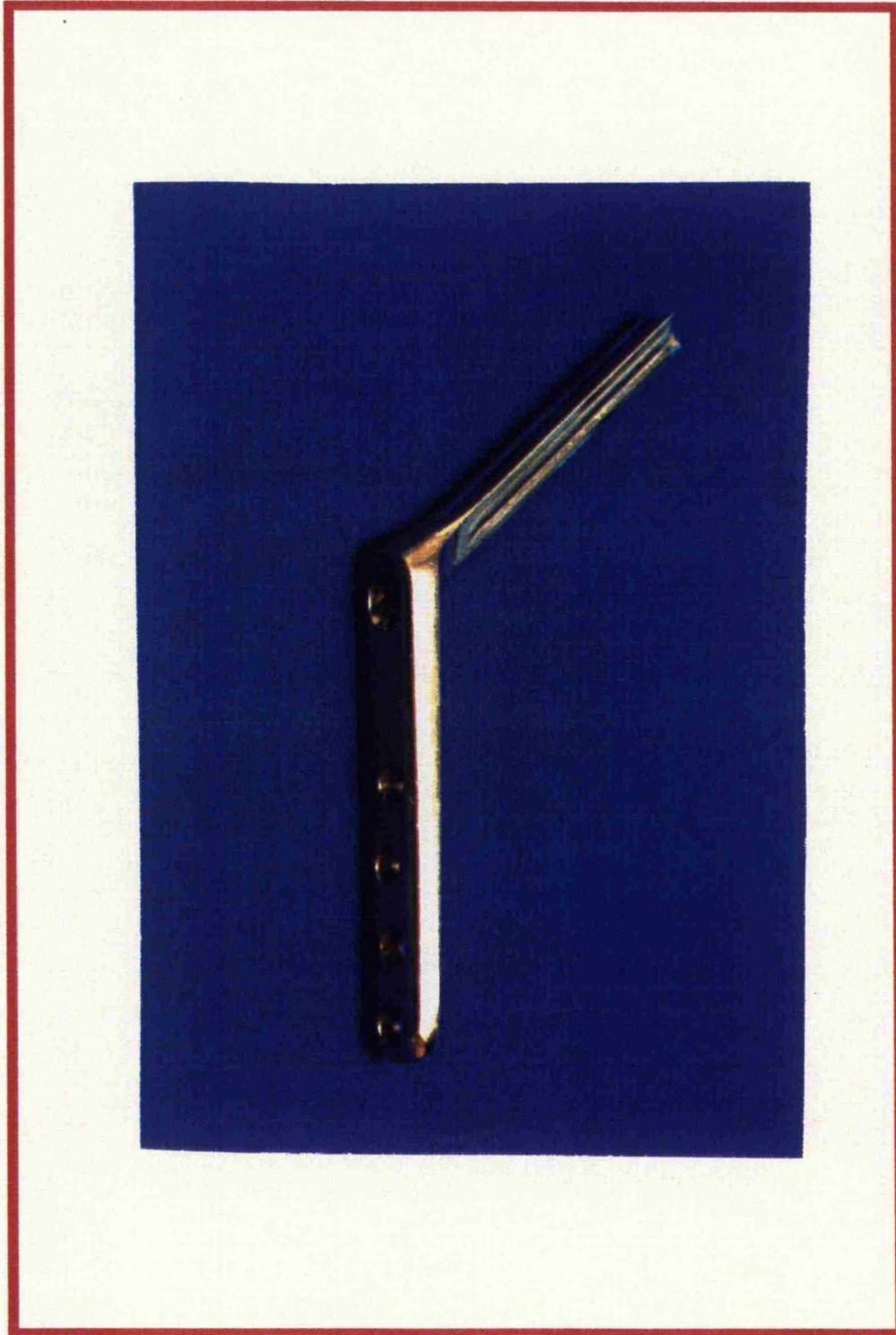
Static nail plates such as the Thornton, Jewett (Figure 1.16) and McLaughlin devices consist of a three or four flanged nail with a side plate attached. They are no longer in wide use and have been shown to be inferior to sliding screw plates (*viz*) (Svenningsen et al 1984), producing combined complication rates for both avascular necrosis and non-union of around 50%. Distraction of the fracture during implant insertion can occur with these devices, and as the fracture collapses down on weight bearing the nail can protrude through the femoral head causing damage to the acetabulum.

Sliding nail plates such as the Pugh (Pugh 1955) and Massie nails overcame this particular problem to some extent (Fielding et al 1974). Brown (Brown and Court-Brown 1979) in a retrospective study, found a 21% failure at 3 months using a sliding nail plate and did not find any relationship between the angle of the nail and the incidence of non-union, but backing out of the nail before union was a common cause of failure. In a randomised study comparing nail plates and sliding screw plate, the screw plate was found to be superior (Nordkild et al 1985).

Single nail fixation devices, with or without a side plate, and regardless of any sliding capacity, should be regarded as obsolete in the presence of more modern threaded devices such as cannulated screws and sliding screw plates.

Figure 1-16

Jewett Nail Plate



1.6.3.3 Multiple Pins.

The use of multiple pins to fix displaced intracapsular hip fractures has been extensively described (Green and Gay 1958, Kofoed and Alberts 1980). The pins can be either smooth or threaded. The disadvantage of smooth pins such as the Moore variety (Moore 1937) is that they tend to penetrate into the acetabulum rather than back out when there is collapse at the fracture site. Therefore threaded pins have been generally preferred.

The best known of the variety of threaded pins are Knowles pins (Arnold 1974), which may be inserted percutaneously.

Deyerle (Deyerle 1980) described a method of fixation using a minimum of 9 and up to 12 pins inserted parallel to each other with the aid of a side plate. This side plate acts as a lateral support to the fixation as well as a guide to parallel insertion. Deyerle stressed the importance of a slight valgus over-reduction. He reported only a 1.8% non-union rate and a 9% AVN rate at 2-13 years follow-up. Others have found Deyerle pins less successful. One study of the Deyerle technique showed complications such as joint penetration and pin breakage in up to 28% (Baker and Barrick 1978). Another study, with only 50% follow-up at 1-2 years, had a 43% AVN rate and 23% non-union rate and it was suggested the method be abandoned (Chapman et al 1975).

The correct number and placement of pins has been debated over the years with no universal consensus. Peripheral placement of the pins in the femoral head is recommended in the shape of either a parallelogram with four pins (Moore 1937) or a triangle with three pins (Arnold et al 1974), whereas Deyerle's minimum of nine pins have their positions dictated by the guiding

plate. Convergence or divergence of the pins is associated with higher rates of failure of fixation (Moore 1935), as might be expected because of the prevention of sliding compression at the fracture site. It is generally recommended that the pins are placed up to subchondral bone for a stronger hold (Arnold et al 1974).

1.6.3.4 Multiple Screws

Screws have the advantage over smooth or finely threaded pins that they can hold better in the femoral head and therefore can impart some lag/sliding effect across the fracture site.

Garden devised a two crossed screw system (Garden 1961B). One is inserted inferiorly resting on the calcar and one is inserted superiorly crossing the inferior screw. The crossed-screw configuration does not allow the screws to back out as the fracture site collapses, which may result in failure of compression or penetration of the femoral head. The use of Garden screws in a parallel mode has been shown to be superior to crossed screws, with a lower rate of non-union and avascular necrosis at two years (Parker et al 1991).

Other large diameter screws used in pairs are the Uppsala and von Bahr screws (Bahr et al 1974, Rehnberg and Olerud 1989). Von Bahr screws are not cannulated and therefore are quite difficult to insert, and have been shown to be inferior to Uppsala screws (Olerud et al 1991).

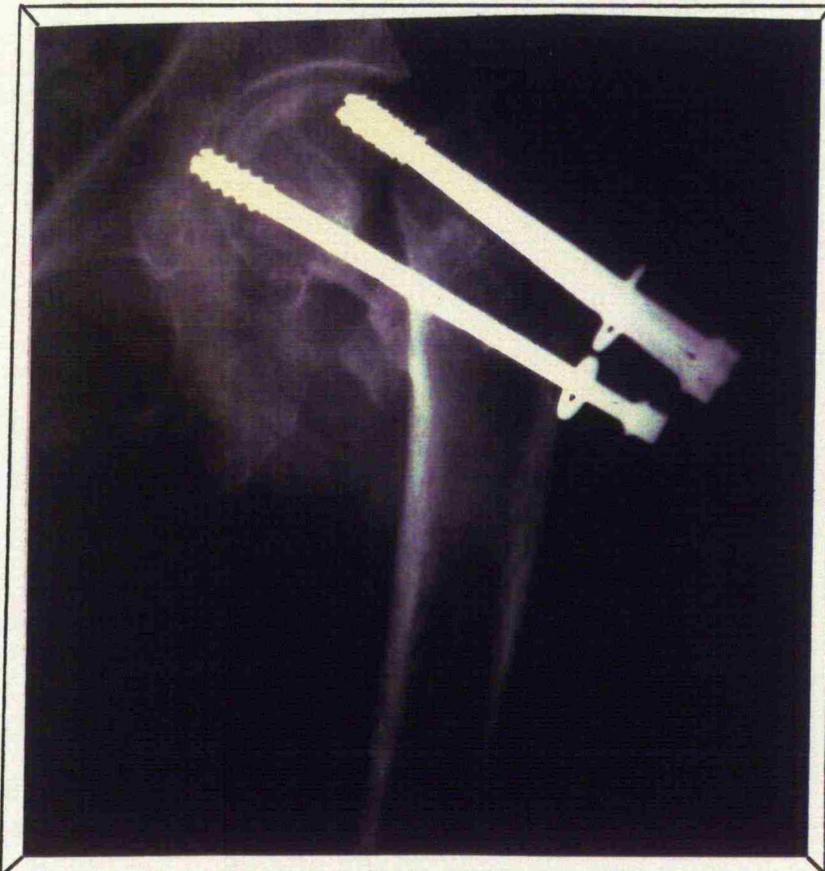
The use of three or four parallel screws (Figure 1.17) is probably the commonest fixation technique currently employed (Anderson et al 1990). These screws are often cannulated to facilitate parallel insertion over guide wires - hence they are known as cannulated hip screws (CHS).

Figure 1-17

a) three standard cannulated screws



b) radiograph of cannulated screws in situ, with washers; a failed fixation due to mechanical cutting through soft bone



The complication of subtrochanteric fracture through the point of screw insertion in the lateral cortex is recognised (Andrew and Thorogood 1984, Neuman 1990), and this tends to occur more often if the insertion site is below the lower border of the lesser trochanter (Neuman 1990). It is not a common problem though.

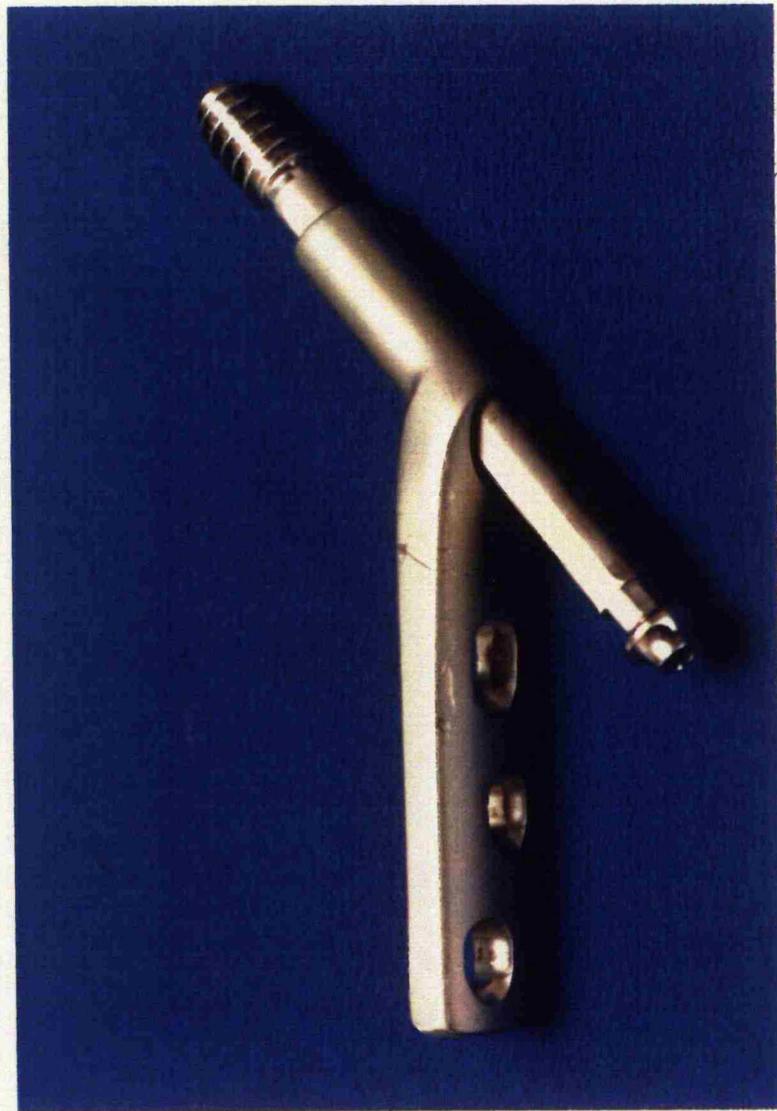
1.6.3.5 Sliding Screw Plates.

In theory the sliding screw plate (SSP) should combine the advantages of screws over pins and the benefit of a side plate (Fig. 1.18). A potential disadvantage of the sliding screw plate system is the possibility of the femoral head fragment rotating either during insertion of the lag screw or postoperatively, causing further damage to the retinacular and ligamentum teres vessels (Smith 1959). Rotation may also cause incongruity between the femoral head and the acetabulum giving rise to an increased risk of degenerative joint disease (Garden 1974).

To overcome this peroperative problem, one or two temporary guide wires can be used to stabilise the head fragment during lag screw insertion. To overcome postoperative rotation one or two supplementary screws or pins may be inserted above the main lag screw. These should be parallel so as not to impair the sliding effect of the screw plate. Ort (Ort and Lamont 1984) showed good results of the sliding screw plate with 2 Knowles pins; no non-unions, and an AVN rate of 24%. However the average age was only 65 years and the patients were selected.

Figure 1-18

Sliding Screw Plate Device with a Three-Hole Plate. A Two-Hole Plate is the Best Option for Intracapsular Fracture. A 2-Hole Screw Plate in situ is shown in Chapter 2, figure 2.14.



Rau (Rau et al 1982) reported unsatisfactory results (successful results being union with no sign of AVN) in 58% of displaced intracapsular fractures using a sliding screw plate. Mean age was 62 years, and mean follow-up was 22 months. However there was almost 50% loss to follow-up not taken account of and there were only 19 patients reported. Failures were put down largely to technical error rather than the implant itself. In addition protected weight bearing was employed for the first 3-4 months; this seems to lose one of the main potential advantages of the sliding screw plate, namely smooth compression at the fracture site.

The need for a supplementary screw or wire has not been shown conclusively (Frandsen et al 1984, Quinby et al 1986).

The lag screw can also be used to correct residual rotational deformity of the femoral head at the time of surgery before subsequently inserting a derotation screw (Muirhead and Walsh 1989). Care must be taken in this technique because of the risk of tearing any intact blood vessels within the retinaculum.

A compression screw can be inserted into a thread in the shank of the large screw through the barrel of the plate in order to apply compression across the fracture at the time of surgery. This must be used carefully in osteoporotic bone because of the risk of simply pulling the lag screw out of the femoral head, and a prospective comparison has not shown any advantage in its use (Frandsen et al 1984). One of the series with poorest results (Rau et al 1982) used a compression screw.

The careful use of the sliding screw plate has produced failure rates of

approximately 20-25% (Skinner and Powles 1986, Groof et al 1988), which is comparable to other devices. Nordkild (Nordkild and Sonnehalm 1984) recommended sliding screw plate fixation after reporting a non-union rate of only 12/92, but these included an undisclosed number of basal cervical fractures and therefore cannot be used to comment on fixation of displaced intracapsular hip fractures. In a young group of patients at 2.5 to 7 year follow-up, mean age 55 years, 14 out of 18 (78%) had no pain and were satisfied, but half of these had radiological evidence of avascular necrosis (Peterhans et al 1990).

1.6.3.6 Hook pins

This system consists of two smooth 6mm diameter pins with hooks at the end which are extended into the femoral head after percutaneous insertion of the pin.

They are used particularly in Scandinavia (Stromquist et al 1987, Nilsson et al 1989) but have not gained wide favour in the United Kingdom. Bone scans have shown better isotope uptake by the femoral head following hook pin fixation than Rydell nail fixation (Stromquist et al 1983) and a lower rate of non-union (Stromquist et al 1984A), but this is probably due to the less traumatic insertion technique of the hook pin.

Two year results show 25% avascular necrosis and failure rates for all fractures (Stromquist et al 1987). Overall results are not significantly better than those achieved with multiple cannulated screws (Wood et al 1991) or sliding screw plates (Skinner and Powles 1986). Comparison of hook pins with parallel screws showed better results with the screws (Olerud et al 1991).

1.6.3.7 Prong plates

The prong plate (Yamano 1989) is a device consisting of a side plate and two 40mm prongs attached at 60 degrees to the plate. The fracture is reduced openly, the prongs are inserted into the femoral head and the side plate is secured to the neck and greater trochanter. The only report of this device in the English literature is of a small series of 32 patients with a mean age of only 48.5 yrs (Yamano 1989). The rate of non-union was 9.3% and the avascular necrosis rate was 13.8%. However with this limited series it is not possible to make any recommendations on its use.

1.6.4 Comparisons of Parallel Screws and Sliding Screw Plate

On the evidence we have there are advantages of 1. screws over pins and 2. large screws over flanged nails. Any device with a side plate, such as the sliding screw plate, cannot be inserted percutaneously, unlike parallel screws, but the wound is rarely more than 8 cm long and this is the least important factor when considering fixation devices.

Clark (Clark et al 1990) showed no mechanical differences in fixation between a sliding screw plate and 3 cannulated hip screws in cadavers.

However Madsen (Madsen et al 1987), in a prospective randomised trial of SSP (with a superior derotation screw) versus four cannulated screws, showed a 2 year cumulative union of 64% for the SSP and 84% for cannulated screws, and Linde (Linde et al 1986) showed more scintimetric evidence of avascularity at 2-3 months following SSP than CHS.

Against this there is the recognised risk, as discussed, of subtrochanteric

fracture following cannulated screw fixation because of the lack of a side plate. There is also a poorer sliding capacity of 3 or 4 screws which are unlikely ever to be absolutely parallel compared to the simple sliding of the lag screw in the screw-plate system.

Work from this centre (Harper 1995) has shown no difference in failure rates between SSP and CHS in a randomised prospective study. However, in the CHS group there were 2 subtrochanteric fractures.

A randomised prospective study of SSP versus crossed 'Divergent' double pins (Christie et al 1988) found the incidence of non-union to be higher in the SSP group (40% versus 23%) - but they also concluded that in all of these patients mobility was extremely poor post operatively, except in those under 65 and active.

With this sparse comparative literature the parallel screw system is generally preferred over the sliding screw plate, though without convincing clinical evidence supporting either. The proper reduction and fixation in an acceptable position probably remains more important than the actual device used. In this centre the results of a randomised prospective study have persuaded us to use a sliding screw plate with careful insertion technique rather than parallel screws.

1.6.5 Treatment of displaced intracapsular fractures by hemiarthroplasty

The problems of failure sometimes encountered following internal fixation may be avoided by replacement of the femoral head rather than preservation of it. This is done either by hemiarthroplasty, where the natural

acetabulum and articular cartilage are retained, or by total hip replacement (THR).

There are several variables which should be taken into account when the results of treatment with hemiarthroplasty are considered: the prosthesis stem design, the use of cement to fix the stem in the femoral canal, the neck length of the prosthesis which determines the saw cut level, the unipolar or bipolar design of the prosthetic head. These variables make conclusive analysis of the literature difficult.

Specific complications used as outcome measures are dislocation, acetabular erosion and femoral loosening (see 1.7.2).

1.6.5.1 fixation of the femoral stem component

In the extensive literature on the subject of hip hemiarthroplasty, the distinction between the use of cemented and uncemented prostheses must always be borne in mind when analysing results. A loose stem in the femoral canal classically causes thigh pain, and the reduction of pain in the postoperative period by using cement has been well demonstrated in retrospective reviews (Follacci and Charnley 1969, Gingras et al 1980) and in randomised studies of uncemented versus cemented prostheses (Sonne-Holm et al 1982, Emery et al 1991).

Less pain and better residual function was found with cemented Thompson than uncemented Moore prostheses (Wrighton and Woodyard 1971) and Yamagata (Yamagata et al 1987) in a retrospective review of over 1000 hemiarthroplasties found that cement fixation of the femoral component lead to

a higher prosthesis survival rate.

It has been suggested that although acetabular erosion appears to be associated with loosening, the pain is primarily due to the erosion (Soreide et al 1980). Figure 1.19 shows a radiograph of erosion with associated stem loosening.

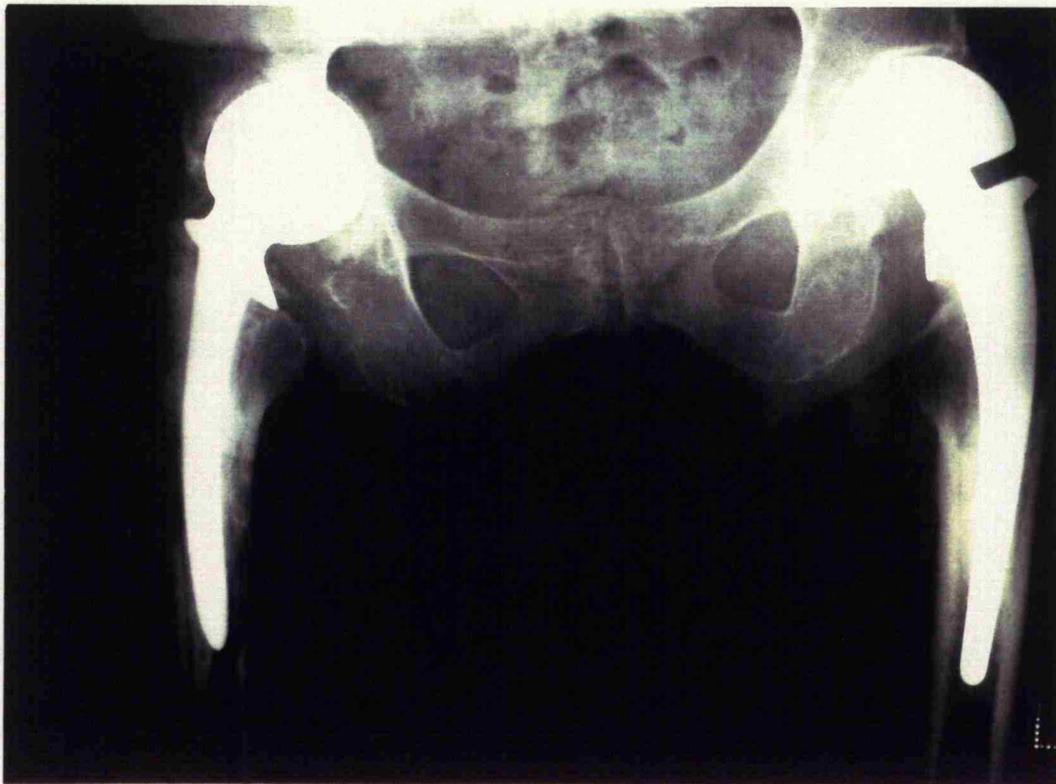
One of the main disadvantages of cement is the systemic effect on the patient during cement insertion. Sevitt (Sevitt 1972) reported a 7% fat embolism rate in cemented Thompsons compared to none in an uncemented group. However Sikorski (Sikorski and Millar 1977) found no differences in mortality.

Increased acetabular wear has been reported with cemented prostheses (Follacci and Charnley 1969), supposedly because of the loss of sharing impact load with movement in the femoral shaft. Other work has found no difference (Browett 1981). Revision of a cemented prostheses for any reason is inevitably more difficult because cement has to be carefully removed from bone which is already thin and porotic and fracture or perforation may readily occur.

The balance of the quality literature suggests less pain, better mobility and reduced revision rate for loosening; therefore the use of a cemented prosthesis is preferable in mobile elderly patients, though uncemented hemiarthroplasty is still a commonly performed procedure. (Anderson et al 1991).

Figure 1-19

Acetabular erosion and stem loosening of a unipolar prosthesis in the right femur. On the left side is a bipolar (Monk) prosthesis.



1.6.5.2 Unipolar Hemiarthroplasty

In probably the earliest reported hip hemiarthroplasty Hey-Groves used an ivory endoprosthesis to treat a femoral neck fracture in the early 1920s (Hey-Groves 1927), and an acrylic prosthesis with a short stem was later described by the Judet brothers (Judet and Judet 1950) (figure 1.20).

The Moore and Thompson prostheses are the commonest of the simple unipolar prostheses, constructed of one solid piece of metal, a monoblock, with a spherical prosthetic femoral head.

The Thompson prosthesis (Figure 1.21) was described in 1952 (Thompson 1952). The stem is curved and it was originally designed to be used without cement. More recently surgeons have used it with polymethylmethacrylate cement (D'Arcy and Devas 1976, Gingras et al 1980, Sikorski and Barrington 1981) and this is now accepted practice.

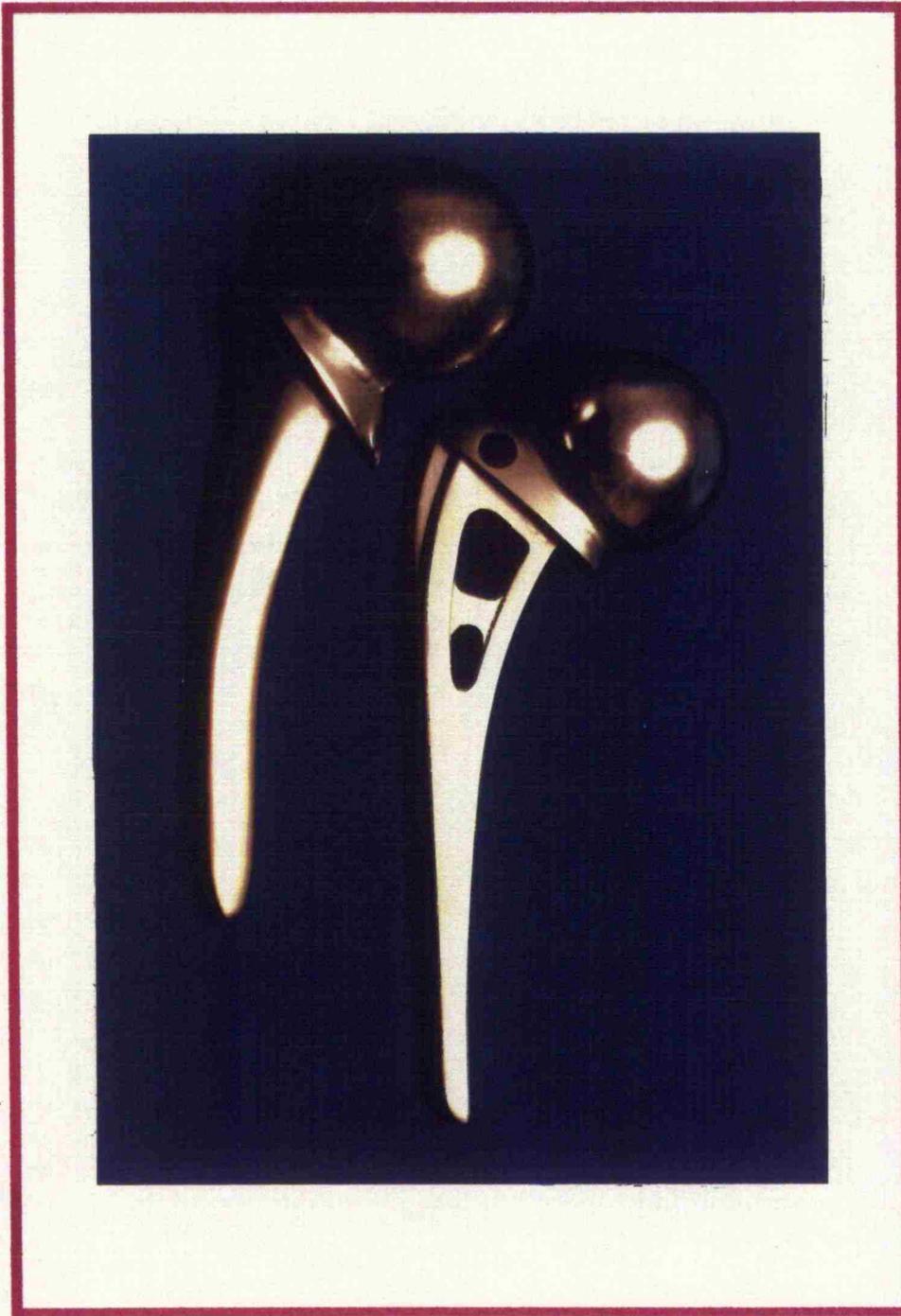
Figure 1-20

Judet hemiarthroplasty



Figure 1-21

The two most commonly used unipolar hip prostheses: Thompson (left), Moore (right).



The Moore prosthesis (Figure 1.21) is a straight stemmed prosthesis with fenestrations which were originally designed to allow ingrowth of bone in order to stabilise the stem, bone cement was not used at this time. It was designed to be calcar bearing, with the proximal femur being sectioned 1/2 - 3/4" above the lesser trochanter. It was designed by Moore (Moore 1957) as the "self-locking" metal hip prosthesis. He referred to the Judet hip in this article as his prototype but felt that the short stem on the Judet prosthesis was inadequate and this is where he concentrated on his design modification. Results with the Moore prosthesis have been widely reported in the literature, mostly in the form of retrospective series (Moore 1957, Hinchey and Day 1964, Kofoed and Kofod 1983). In a later study at a mean follow-up of almost seven years 42% of patients experienced hip or thigh pain, but only half of these had pain significant enough to limit walking distance (Pun et al 1988). Despite disappointing results such as these, and other studies showing similar poor functional outcomes, the Moore endoprosthesis has become widely accepted in the treatment of displaced intracapsular proximal femoral fractures in the elderly and is still commonly used- perhaps a reflection of the low priority this group of patients is given.

The Thompson prosthesis has been equally widely reported. Hunter (Hunter 1980) asked the question "should we abandon primary prosthetic replacement for fresh displaced fractures of the neck of the femur" given up to 50% poor results with an uncemented Thompson prosthesis- but this was a retrospective study on a mixture of patients with vague outcome criteria. In a considerably better but still retrospective study, D'Arcy and Devas (D'Arcy and

Devas 1976) reported an 18.9 % failure rate with cemented Thompson prostheses at 3 years.

Unipolar hemiarthroplasty carries a definite risk of acetabular erosion, the degree of which correlates with length of follow up (Soreide et al 1980). Rates of acetabular erosion are difficult to compare between studies because of variable definitions and means of measurement. The measurement of femoral head migration on an AP radiograph of the pelvis is notoriously inaccurate, and therefore gross radiographic protrusion is often used as an endpoint for defining erosion.

One study (D'Arcy and Devas 1976) found an 11% rate of acetabular erosion at 3 years for cemented Thompson prostheses, it being more common in younger people. Phillips (Phillips 1989) found a 47% rate at 92 months, whereas Pun (Pun et al 1988) found only 14% protrusion at 7 years with Moore prosthesis, of which only half had pain.

If the risk of acetabular erosion could be removed, hemiarthroplasty would be a more attractive option.

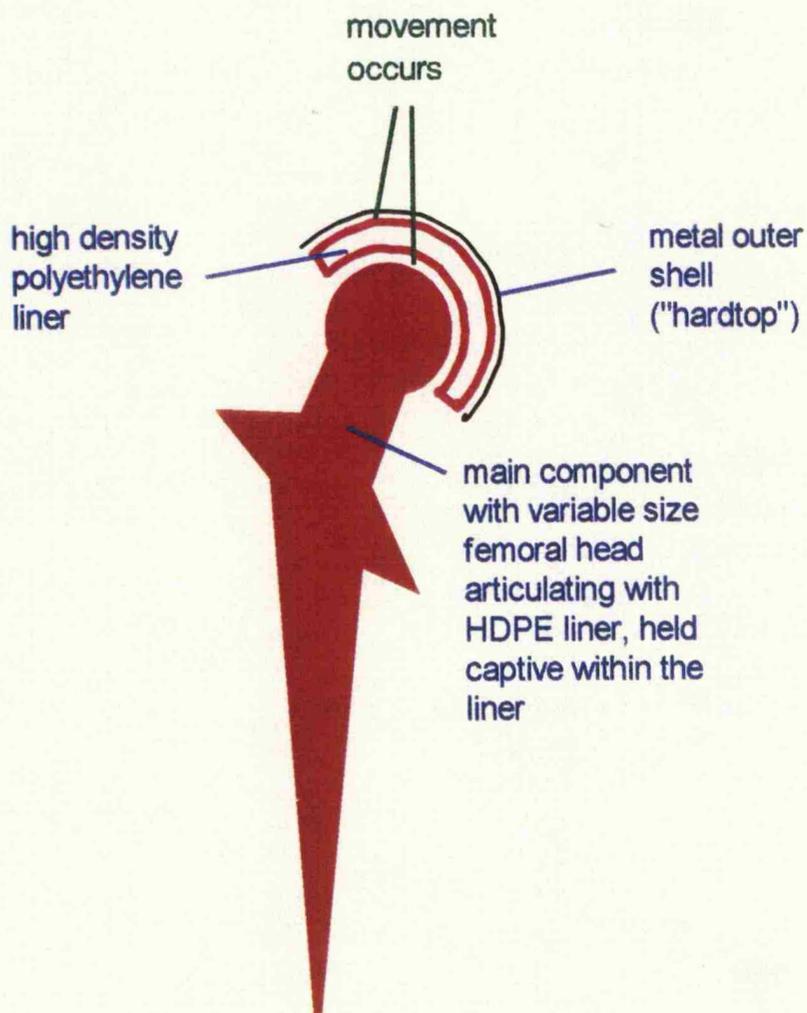
1.6.5.3 Bipolar Replacement.

A bipolar prosthesis generally consists of a metal head which articulates with the acetabulum and an intraprosthetic articulation of metal-High Density polyethylene (Figure 1.22). Bipolar prostheses were developed in an attempt to overcome the problem of acetabular erosion caused by unipolar prostheses - this initial assumption was based on the theory that there would be less wear (by shearing force) on the articular cartilage of the acetabulum

because some of the movement occurs within the components of the prosthesis i.e. intraprosthetic movement. There are other potential theoretical advantages over the unipolar prosthesis: decreased pain secondary to reduced acetabular erosion, reduced loosening of the stem by providing a plastic layer to cushion impact on heel strike and with some designs the facility for converting to a total hip replacement without the need for changing the femoral component.

Figure 1-22

Cross Section Diagram of a Bipolar Prosthesis



Based on the original design rationale the limit of intraprosthetic motion would be reached when the neck came into contact with the acetabular component at which point torque would be transmitted to the prosthesis/acetabulum articulation. Therefore the overall range of motion for the bipolar would be greater than the unipolar, also possibly improving stability.

The Monk endoprosthesis was introduced in 1970 and the Bateman bipolar prosthesis shortly afterwards (Bateman 1974). The original Monk prosthesis was a "soft top", without any metal cap on the outer polyethylene articulating surface of the prosthesis. This prosthesis has been reported as giving better pain and function than the Moore (Suman 1979), but problems with osteolysis around the acetabular cup due to polyethylene debris (Hansen and Rechnagel 1977, Webb et al 1980) prompted a change for the polyethylene cup to be covered with a cap of stainless steel- the Monk hardtop, incorporating a 25mm diameter inner femoral head (Figure 1.23).

A three year follow-up of uncemented Monk hardtops (Hoy et al 1990), in a group with median age 80 years, had a 6.6% dislocation rate postoperatively (10/152), and 8% erosion. Of survivors, the clinical result at 3 years was 'good' using the D'Aubigne score. A subsequent update this study (Hoy et al 1995), with a four year mean follow-up, showed an overall failure rate (revised cases, poor or fair outcomes) of 19%; however loss to follow-up was high, and at least a third of the failures were due to loosening of the uncemented Moore stem which would not have occurred with a cemented stem.

Another bipolar prosthesis commonly used in the UK is the Charnley-Hastings prosthesis which has a 22.5mm inner femoral head diameter-

facilitating the conversion to a Charnley THR in the event of symptomatic acetabular erosion. The Giliberty prosthesis (Giliberty 1974) is another of the early designs.

There has been some debate on whether the bipolar prosthesis continues to work in the clinical situation as it was designed; that is, how much of the intraprosthesis movement is retained following insertion.

Drinker (Drinker 1979) found that most implants still had intraprosthesis movement at 4 years in the Bateman prosthesis (22mm head). Brueton (Brueton 1993) found that after 3 years a 22mm head had a greater intraprosthesis movement than a 32 mm head and therefore the smaller intraprosthesis articulation was preferable. Phillips (Phillips 1987) however found intraprosthesis movement in only 25% of cases at 4 years. Mess (Mess and Barmarda 1989) carried out a radiological evaluation of the Bateman in weight bearing and non-weight bearing positions. Extraprosthesis movement accounted for 50% and intraprosthesis for 50% of total movement when non-weight bearing, and with weight bearing the ratio between inner and outer movement was 3:1.

Reduction of the intraprosthesis movement, if it does occur, appears to happen before three months (Verberne 1983).

Although intraprosthesis movement is probably retained at least to some degree, there is no doubt that acetabular erosion can and does occur with the bipolar prosthesis. Leyshon (Leyshon and Mathews 1984) found 5% erosion at mean 2 years review with the Monk hardtop, all with significant symptoms which started any time after 18 months- however, only patients with symptoms

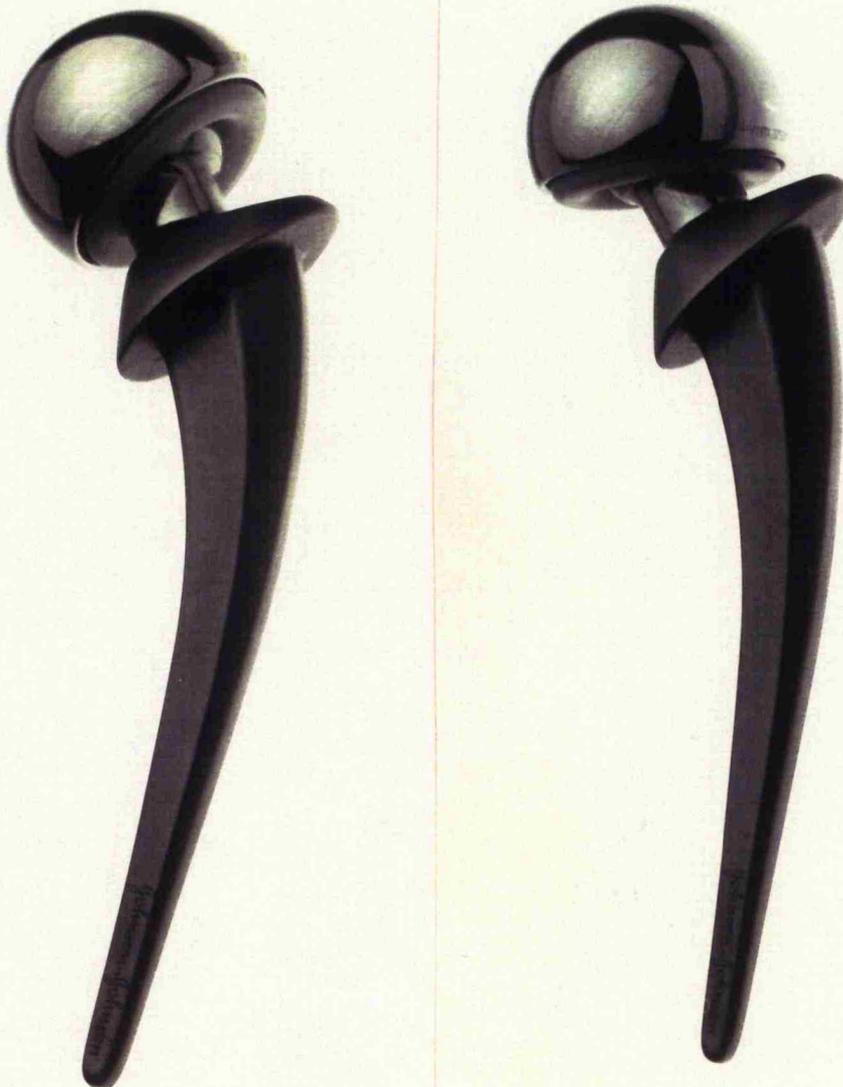
were reviewed radiologically and therefore this may be an underestimate.

Figure 1-23

Monk Hemiarthroplasty, showing extremes of intraprosthetic varus and valgus

varus

valgus



Wetherell (Wetherell and Hinves 1990), using the Hastings prosthesis found 95% with no pain at a mean 4 years 10 months. Acetabular erosion was 5.6%, though none had been revised for this reason. Bochner (Bochner et al 1988), with mean 38 month follow up of the Bateman, found measurable erosion in 21% but 90% had no significant pain. Lausten (Lausten et al 1987) found a 4% rate at 4 years.

Some series have found no acetabular erosion at over 7 years (Labelle et al 1990) and at around 3 years (Gallinaro et al 1990) with the Bateman prosthesis.

Other designs of bipolar, for example based on the Bateman, have reported encouraging results (Franklin and Gallanaugh 1983). At between 6 and 24 months postoperatively 70% of survivors were pain free.

Table 1.1 summarises some of the figures on acetabular erosion. Limited information can be gleaned because of the variation in means of measuring and defining erosion.

A unique complication of biarticular prostheses is intraprosthetic dislocation, where the 2 components actually separate. The rate of intraprosthetic dislocation when reported varies between 0.4 - 1 % (Stewart and Papagiannopoulos 1986, Bochner et al 1988, Wetherell and Hinves 1990), it may occur during reduction of a dislocated prosthesis. (Anderson and Milgram 1978). Although representing a small proportion of complications it is serious because it always requires open reduction. Improvements in manufacture have largely negated this problem.

**Table 1.1 A selection of erosion rates for unipolar and bipolar prostheses
in a selection of papers**

Author/year	prosthesis	follow up (months)	nos.	cement?	% erosion
D'Arcy, Devas 1976	Thompson	36	160	yes	11
Browett 1981	Thompson	38	83	no	35
Jensen 1975	Moore	59	60	no	17
Pun 1988	Moore	83	57	no	14
Lausten 1987	Monk	51	77	mixed	4
Labelle 1990	Bateman	89	49	yes	0
Wetherell 1990	Hastings	29	243	yes	6
Yamagata 1987	mixed unipolar	48	190	mixed	38
	mixed bipolar	44	211	mixed	34

1.6.6 The treatment of displaced intracapsular fractures by total hip replacement (THR)

It has been suggested that THR should be used to treat displaced intracapsular hip fracture as a way of avoiding failed union and acetabular erosion. It is a more complex, time consuming and traumatic operation than either hemiarthroplasty or closed reduction and internal fixation and therefore we would need convincing evidence of superior results for its use to become universal which to date is not available.

Skinner (Skinner et al 1989) in a randomised prospective trial did not show any difference in mortality between THR, internal fixation and hemiarthroplasty. Early complication rates from published papers (Sim and Stauffer 1980, Taine and Armour 1985, Delamarter and Moreland 1987, Greenough and Jones 1988) are comparable with those of total hip replacement for OA, apart from the dislocation rate which is much higher and ranges from 8-18% (Coates and Armour 1979, Dorr et al 1986). Pun (Pun et al 1987), in a young population (mean 63.5 years) showed 95% good or excellent results at 3 years although the dislocation rate was high at 8.7%.

The reason for this higher dislocation rate is thought to be the greater range of movement postoperatively compared to the OA group which has periarticular fibrosis and joint contractures (Gregory et al 1991). The mental status of fracture patients also means they are less likely to comply with postoperative instruction for THR.

Following total hip replacement up to 37% of patients do not regain their pre-fracture mobility levels at one year post fracture (Sim and Stauffer 1980),

which is comparable to the proportion from other series of different methods of treating proximal femoral fractures.

The main argument of those who propose total hip replacement is the supposed reduced need for revision surgery, but Greenough (Greenough and Jones 1988) at 56 months follow up found 49% of patients had undergone or were awaiting revision surgery, and a further 11% of patients had evidence of radiological loosening. These disappointing results were in patients under 70 years of age who would be expected to benefit most from total joint replacement rather than hemiarthroplasty. These poor results are striking, but other series have reported revision rates of 12% at 3 years (Taine and Armour 1985). However Gebhart (Gebhart et al 1992) found only a 2.2% revision at 56 months, albeit in an older age group (mean 75.2 years), and Delamarter reported no revisions at mean 3.8 years (Delamarter and Moreland 1987).

There is no convincing evidence in support of THR for fresh displaced intracapsular hip fracture. Its suggested role in young patients where acetabular erosion is likely to be a problem with hemiarthroplasty is, in practice, taken by primary internal fixation. THR may then be used as a secondary procedure if fixation fails. The economic implications of treating all intracapsular proximal femoral fractures with total hip replacements are vast. Total hip replacements cost more than fixation devices or hemiarthroplasties, they take longer to perform and require better operating theatre facilities. The practicalities in a busy trauma unit would be daunting. As a result total hip replacement for intracapsular hip fractures should be reserved for special cases such as rheumatoid arthritis, preexisting osteoarthritis, Pagets disease affecting the

acetabulum or some pathological fractures through tumour.

1.6.7 COMPARATIVE STUDIES

1.6.7.1 Studies comparing different types of unipolar prostheses

There are no good randomised prospective studies comparing the classic Moore to the classic Thompson prosthesis, especially in which both are either cemented or uncemented. In one comparative non-randomised study an uncemented Moore prosthesis had 72% good or excellent results at 40 months, compared to 66% for uncemented Thompsons (Anderson et al 1964). Wrighton (Wrighton and Woodyard 1971) noted less pain and better function in cemented Thompson compared to Moore in a retrospective study. Neither of these studies were sufficiently controlled to give sound conclusions. Most of the standard teaching about the merits of the two prostheses has by necessity to come from comparing individual series with insufficient numbers in each.

Emery (Emery et al 1991) compared cemented Thompson stems with uncemented Moore stems in a good randomised prospective study, but the comparison was only between the stems as all implants had the Monk bipolar hardtop head. Those with the cemented Thompson stem had less residual pain.

1.6.7.2 Studies comparing Bipolar and Unipolar Hemiarthroplasty

We have seen that the complications recognised in unipolar hemiarthroplasty also occur with bipolar prostheses. It is important to compare

the two directly to justify the use of the bipolar prosthesis, because the cost is approximately four times that of a simple unipolar device (1994 prices, UK: Thompson unipolar £65-70, Monk bipolar £260-280). Criteria by which they should be compared are objectively by acetabular erosion, dislocation and loosening, and clinical outcome in terms of pain, function, mobility and patient satisfaction.

Paucity of good studies in the literature is again a problem. Much of the literature (which is by and large not randomised or prospective) reports better clinical results with bipolar because patients have been selected for this procedure by virtue of their better physical condition and younger age. Patient selection is a problem for most of these studies, therefore care must be taken in comparing data from different series on a superficial level, and the case for the bipolar prosthesis remains theoretical until an adequate randomised prospective trial is reported.

The only randomised prospective study evident to date compared Bateman to Moore prosthesis and did not find any differences in Harris scores, loosening or acetabular erosion at three years (Thiel et al 1988). Even this study was only published as an abstract and therefore detailed critical analysis is not possible.

In a retrospective study comparing uncemented Moore with uncemented Monk hardtop prostheses, with 1-5 year follow-up, there was no significant difference in erosion or pain (29/317 Moore, 18/224 Monk) (Kaltsas 1986). Unfortunately there was only about a 30% follow-up rate.

There are a number of retrospective comparisons which disagree with

these. Yamagata (Yamagata et al 1987) found more erosion with unipolar prostheses in a series of 1001 hemiarthroplasties. This study has large numbers but in fact they were taken over a period of 13 years, and there were 3 different unipolar and two different bipolar implants. Follow up varied from 2 to 10 years and was generally assessed from clinical records and most recent radiographs. Of the total numbers, in fact only 401 cases (40%) had radiographs of suitable quality to measure medial erosion by reference to the Kohler line (a line from medial aspect of ilium to ischium), where a change of >1mm was considered to be erosion, and migration beyond the line or the inner wall of the pelvis defined protrusio. This study is a good example of a large retrospective series in which a valid attempt at objective analysis has been made but ultimately fails because it is not a prospective comparison.

Wetherell (Wetherell and Hinves 1990) found a 5.6% erosion rate compared to 11% for cemented Thompsons in a study from the same centre. The bipolar series was studied prospectively but the comparison was with historical unipolar controls as reported from the same centre by D'Arcy (D'Arcy and Devas 1976). Erosion was measured as superior migration on an AP film from a line joining the lateral acetabular lips- a change of 3mm or more was considered to be true erosion.

Drinker (Drinker 1979) did not find any difference in dislocation rates, though closed reduction when needed was more difficult with the bipolar. Other dislocation rates in various series are summarised in table 1.2

Table 1.2 Table of dislocation rates for hip hemiarthroplasty

Author/year	uni/bipolar	% dislocation
Hunter 1980	uni	7
Chan and Hoskinson 1975	uni (ant. approach)	0.9
	uni (post. approach)	14
D'Arcy and Devas 1976	uni	1.9
Sikorski and Barrington 1981	uni	1.9
Skinner et al 1989	uni	11
Jalovaara and Virkkunen 1991	uni	6.5
Wetherell and Hinves 1990	bi	3
Giliberty 1974	bi	2
Lausten et al 1987	bi	3
Lestrange 1990	bi	2
Unwin and Thomas 1994	bi (post.)	9
	bi (lat.)	3.3

1.6.7.3 Comparative trials between replacement and fixation

The single most important and controversial question is whether to fix or replace the femoral head in such fractures: knobs or screws? (Riley 1978). This should be answered by well designed randomised clinical trials, of which there are remarkably few published in the literature to date.

There are only four truly randomised prospective studies in the literature which compare internal fixation with replacement of the femoral head for displaced intracapsular hip fracture (Riley 1978, Soreide et al 1979, Sikorski and Barrington 1981, Skinner et al 1989), and this apparent lack of scientific quality in papers on the subject was confirmed by a meta-analysis of the literature (Lu Yao et al 1994).

Riley (Riley 1978) reported on 151 patients properly randomised to crossed Garden screws or Thompson or Austin Moore prosthesis, and operated by a large number of different surgeons. It is unclear whether the prostheses were cemented. Follow up was short, just over one year.

Soreide (Soreide et al 1979) randomised 104 patients to von Bahr screws or Christiansen prosthesis, and again follow up was only one year.

Sikorski (Sikorski and Barrington 1981) randomised patients to crossed garden screws or Thompson hemiarthroplasty by either the anterior or anterior or posterior approach (a three arm trial).

Skinner (Skinner et al 1989) compared sliding screw plate fixation with Moore hemiarthroplasty and THR. Many different surgeons were involved in all of these studies which are included in table 1.3.

Table 1.3 Table of randomised prospective comparative studies of Internal fixation versus arthroplasty

Author/yr	procedures compared	Average age (yrs)	nos.	follow up (years)	% satisfact ory	preferred treatment
Riley 1978	Crossed Garden	--	66	1	63	prosthesis
	Thomp/Moore		85	1	83	
Soreide 1979	von Bahr screws	78	51	1	55	prosthesis
	Chistiansen prosthesis		53	1	79	
Sikorski 1981	Crossed Garden screws	80	76	2	70	fixation
	Thomp (ant approach)		57		63	
	Thomp(Post Approach)		57		85	
Skinner 1989	DHS (sliding screw plate)	80	98	1	88	fixation
	Moore	81	100		71	
	THR	82	80		100	

Patient follow up in these four randomised prospective trials was one or two years. This is too short for complications such as erosion and late AVN to develop. In addition crossed Garden screws, used in two of the studies, are an outmoded method of fixation, and the use of uncemented Moore prosthesis is not the optimum arthroplasty method (sic).

Vugt (Vugt et al 1993) reported a good study which was randomised and prospective, comparing SSP fixation with cemented bipolar hemiarthroplasty,

but numbers were small with only 43 patients altogether. It was concluded that at 3 years internal fixation was justifiable as primary treatment in the 71-80 year age group though numbers alive were only 16 (SSP) and 15 (hemiarthroplasty) and statistically there was no difference. Failure rate of fixation requiring revision was 28.6%.

Some papers which purport to be randomised comparisons are not: Bray (Bray et al 1987) subtitled his paper "results of a prospective, randomised comparison", when treatment was decided on by "the philosophy of the admitting physician"- not an accepted means of randomisation. Numbers were small again- only 34 patients, in this comparison between Knowles pins (n=19) and cemented bipolar hemiarthroplasty (n=15). Failure rate of fixation was 42% at up to two years and functional results were better with a prosthesis.

Others which have been categorised with true randomised studies by the meta- analysis of Lu-Yao (Lu-Yao et al 1994) also fail to satisfy the criteria of a randomised study (Broos et al 1987, Rodriguez et al 1987).

Broos (Broos et al 1987) compared prospectively 238 patients over 70 years old with a 1 year follow-up. However the fixation group (n=81) was a mixture of Smith Petersen nails, nail plates and multiple screws over a four year period, and the prosthesis group (n=157) was a mixture of THR, cemented Thompson, and uncemented Muller hemiarthroplasty over the subsequent 4 years. The conclusion was that prosthetic replacement should be first choice treatment, but any such conclusion from such a study is invalid.

Rodriguez (Rodriguez et al 1987) looked retrospectively at 301 hip fractures treated by 3 AO screws (n=104) or cemented Thompson

hemiarthroplasty (n=104). Treatment depended on the surgical team of the day. Age was mean 79-80 for both groups. At almost 2 years reoperation for failure of fixation was 25.3%, and 16% for the hemiarthroplasty group (mainly for infection in this group). Fixation was recommended on the basis of lower postoperative mortality and lower infection rate, but more important outcome measures such as pain and function were not assessed.

Other comparative studies have also looked at now obsolete surgical procedures: Raine (Raine 1973) found that a triffin nail gave a better result in terms of morbidity and mortality than various prostheses, but the younger fitter patients were selected for the fixation group and so, like many of these studies, there is a major confounding factor of selection bias in the analysis. Stewart (Stewart 1984) compared Pugh's nail with the Thompson prosthesis retrospectively and found a higher failure rate requiring revision at one year with the nail..

Despite the flaws in these studies the findings of these series are important given the limited amount of material from which to draw conclusions. Clearly the question has not been satisfactorily answered with adequate follow up in the appropriate group of patients.

1.7 Complications of intracapsular proximal femoral fractures

Discussion in section 1.7.1 refers to patients with extracapsular as well as intracapsular fracture of the proximal femur.

1.7.1 Factors Associated with Mortality and Rehabilitation

Mortality is a definitive endpoint, and there is a strong association between proximal femoral fractures and death. However the true mortality is unknown because in an elderly population medical problems, rather than fracture sequelae, may often be the primary cause of death. Mortality is best expressed for a fixed period, either 6 months or 1 year. Inpatient mortality varies according to the length of stay and disposal methods of the individual hospital, and therefore is not a useful index for comparing different studies. A true mortality rate must be over a fixed time period to give a useful figure, e.g. 6 months, 1 year.

Overall mortality rates for patients with intracapsular proximal femoral fracture at 6 months vary between 11% (Soreide et al 1979) and 18% (Alffram 1964) with the highest increase in mortality over the non-fracture population being in the first 3 months following fracture (Bauer 1990). One year mortality for unselected groups of proximal femoral fractures ranges from 13% (Kenzora et al 1984) where the expected non fracture group mortality was 9%, 20% (Ceder et al 1987), to 26% (Skinner et al 1989). Longer term mortality for all types of proximal femoral fracture has been reported at 43% at 3 years and 56% at 5 years (Jensen et al 1979). Ten year mortality is quoted at 64% (Borgquist et al 1990A) to 80% (Jonsson et al 1990). These figures reflect non selected groups, and there are some factors which predispose to a much higher mortality.

By approximately 1 year the mortality rate appears to be the same as for the non fracture population (Jensen 1984, White et al 1987, Parker and Anand

1991). Jalovaara (Jalovaara and Virkkunen 1991) found that 5 year mortality was the same for a control group as for a group of patients following hemiarthroplasty, at around 60%.

Mental function appears to be the most important factor associated with mortality after proximal femoral fracture. Blessed (Blessed et al 1968) used dementia scales which remain the basis of a variety of mental test scores (MTS); it should be noted though that a MTS does not distinguish between dementia and delirium (acute confusion). A MTS using a maximum 13 point scoring system showed a significant difference in mortality between patients with MTS greater than 11 and those patients with a MTS less than 3 (Evans et al 1979). These results have been confirmed in a multivariate analysis of factors predicting survival using the same mental function score, where patients older than 85 years with a low mental test score had a 75% mortality at 6 months (Wood et al 1992). Dementia is therefore the primary influence on early mortality following proximal femoral fracture.

Abbreviated mental test scores have been developed by evaluation of longer scores, for example a score out of 10 developed from a 26 question system, proving just as useful (Hodkinson 1972).

Gustafson (Gustafson et al 1991) noted that on the whole mental status is very poorly documented in most proximal femoral fracture patients, and that where MTS is used, it was suggested that it is not an accurate assessment of mental status on admission to hospital because of acute confusional states related to the injury and dehydration which are thought to be underdiagnosed but Evans (Evans et al 1979) found that amongst survivors MTS at six months

was the same as on admission- suggesting that low MTS on admission is probably a reflection of dementia rather than acute confusion.

The place where the injury was sustained, in particular whether the fracture was sustained inside the home or out in the community, also contributes to prognosis, with those patients injuring themselves at home being more likely to die than those sustaining the injury away from home (Evans et al 1979, Wood 1992). This is probably due to the fact that the frailer population is less likely to venture from the home in the first place, and those who fall outside of the home are by definition a group who are probably more mobile to start off with. This can only be speculated upon, but it is important when comparing two groups in a prospective study to exclude this as a confounding factor in mortality data.

Pre-injury social dependence was found by Jensen (Jensen 1984) to be the most important factor associated with mortality. But critically in this study MTS was not assessed, and if it had been their findings may have been different.

There does not appear to be evidence in the literature of any statistically significant difference in mortality between extracapsular and intracapsular proximal femoral fractures. Foubister (Foubister and Hughes 1989) in a prospective study found mortality to be independent of fracture type or operative procedure, findings reflected by other work (Sluijs and Walenkamp 1991), but poor preoperative mobility was associated with a higher mortality (Foubister and Hughes 1989). Kenzora (Kenzora et al 1984) found at 1 year a 13% mortality for intracapsular fractures and 15% for extracapsular.

Most of the factors associated with high mortality after proximal femoral fracture are those which are associated with being old and frail; dementia, social dependence, confinement to home, and general medical ill health. In a study of 209 patients, 6 month mortality was 19% in patients aged between 65-69 years of age and 63% in patients over 85 years of age (Evans et al 1979). This should not be surprising though, as all other adverse factors are also positively correlated with age. Many of the factors coexist in the proximal femoral fracture population and it is perhaps not surprising that they are common prognostic indicators. Sluijs (Sluijs and Walenkamp 1991) was able to predict successful return home based on such social and medical criteria in 90% of cases.

Having survived the post injury period and surgery, the principal goal for the elderly patient with a proximal femoral fracture is to return to where they came from with the same degree of social independence.

As part of a study on an early rehabilitation programme, Ceder (Ceder et al 1980) looked at factors affecting early return home and successful rehabilitation as distinct from those affecting mortality. There was no difference between the sexes. Greater age as expected reduced the rate of returning home, as did worsening medical condition. Patients already living with somebody else returned home earlier than those living alone, and those who managed dressing, personal hygiene and other ADL within two weeks of surgery almost always returned home. After 4 months there was no further recovery in mobility and activities of daily living (ADL). Borgquist (Borgquist et al 1990A), in the same centre (Lund, Sweden) looked at the same cohort of

patients ten years later and found that these prognostic indicators remained valid in the 5 and 10 year perspective.

1.7.1.1 *Timing of Surgery Related to Mortality*

(see section 1.6.2.1)

It is interesting that Kenzora (Kenzora et al 1984) found that mortality rate for patients undergoing surgery for proximal femoral fracture was significantly higher in those who had surgery on day 1 than those who had a delay of two to five days. One explanation was that the trauma may affect certain physiological mechanisms, and particularly if the patient is dehydrated from lying on the floor for a considerable period the additional trauma of surgery may overwhelm the patient; those who waited longer were better resuscitated and prepared for the anaesthetic.

The cause of death in the majority of studies is not known accurately because of the lack of post mortem data.

Thromboembolic disease may account for up to 10% of early mortality following emergency hip surgery (Hull and Raskob 1986) and deep venous thrombosis may occur in 40-50% of patients who do not receive thromboprophylaxis (Stevens et al 1968, Hamilton et al 1970).

1.7.1.2 *Pressure sores*

Pressure sores are a serious general complication of proximal femoral

fracture. They may result in an increase in length of hospital stay, nearly doubling the stay of patients in one study (Jensen and Juncker 1987), as well as being a significant medical and social problem in terms of treatment following hospital discharge.

The most common sites for pressure sores are the sacrum and buttock area (55%) and the heel region (29%) (Jensen and Juncker 1987). The same study reported the incidences nearly 30% of patients sustaining a hip fracture.

It is important to take into account the grade of sore: **grade 1** =erythema which will blanch under light pressure, **grade 2**= erythema which does not blanch under light pressure (indicating some microcirculatory disruption) +/- superficial blistering or ulceration, **grade 3**= ulceration to subcutaneous tissue, **grade 4**= ulceration extending into subcutaneous fat and fascia, **grade 5**= ulceration involving destruction of muscle tissue. Anderson (Anderson et al 1993) found that all patients had at least a grade one pressure sore during admission following proximal femoral fracture. If these were discounted, it was found that around 5-6% of patients developed a pressure sore of grade 2 or more.

The factor with the clearest correlation in developing sores is the age of the patient, with most sores developing in patients over 80 years old (Versluisen 1985). This is likely to be related to the reduced mobility and poor medical condition associated with old age.

1.7.1.3 Infection

Deep infection can be a serious complication following surgery in the

elderly and a selection of reported infection rates are shown in table 1.4. In some cases in the literature there is little distinction made between true deep wound infection and superficial wound infection, so that such summary tables need to be considered with some reservation (see section 1.7.2.1).

Table 1.4 Table of (deep) infection rates for various treatment methods.

hemi= hemiarthroplasty

Author/year	implant	% deep infection
Hinchey 1964	hemi	2
Hunter 1980	hemi	9
Chan 1976	hemi	3
D'Arcy 1976	hemi	4.7
Wetherell 1990	hemi	1
Jalovaara 1991	hemi	4
Pun 1987	THR	0
Greenough 1988	THR	3
Skinner 1989	THR	1
Stromquist 1987	fixation	0
Nilsson 1989	fixation	1
Wood 1989	fixation	0

1.7.2 Complications following Hemiarthroplasty

The major complications may be early or late. Early complications include infection and dislocation. Late complications include infection (either a latent primary infection or a secondary deep infection), acetabular erosion and femoral stem loosening which may be septic or aseptic. Femoral shaft fracture may occur at the time of prosthesis insertion or later, usually at the prosthesis tip.

1.7.2.1 Infection

Infection rates following hemiarthroplasty for proximal femoral fractures are reported with a figure of around 3% (Chan and Hoskinson 1975) up to 9% (Hunter 1980) compared to 1-2% (Charnley and Eftekhari 1969) for primary elective THR. Table 1.4 shows other studies.

A particular difficulty in analysing infection rates from the literature is the loose definition of deep infection. In some cases wound erythema with a light discharge is included, in others only frank pus with wound breakdown is included. For this reason direct comparison of infection rates between different studies should be approached with caution. Nevertheless the infection rate for hemiarthroplasty is certainly higher than for THR. This may be because of less advanced theatre facilities available for trauma cases, but is more likely due to the general medical condition of the proximal femoral fracture population. In the elderly frail patient infection may be associated with an increased mortality (Hunter 1980).

1.7.2.2 Acetabular Erosion

This has also been discussed in Section 1.6.5 + Table 1.1

The late complication which is of most concern in younger patients is acetabular erosion, which can result in the need for difficult revision surgery. The bipolar prosthesis is designed to reduce the incidence of acetabular wear, but until the results of adequate randomised prospective trials are available this remains unproven. The only published randomised study does not show any difference up to three years follow up (van Thiel et al 1988).

1.7.2.3 Dislocation (See Table 1.2)

Dislocation is a potentially serious complication and has been reported to be associated with an increase in post-operative mortality of up to 50% (Paton and Hirst 1989). The dislocation rate following primary prosthetic replacement varies widely between reported series, from 0.3% (Hinchey and Day 1964) to 11% (Skinner et al 1989).

There is a higher dislocation rate associated with posterior approaches to the hip joint (Chan et al 1975, Keene and Parker 1993). Specific pre-existing conditions that increase the dislocation rate are Parkinson's disease and stroke, probably due to abnormal muscle tone and contractures. The reported rates for Parkinson's disease confirm a higher dislocation rate than for the normal population from 11% (Turcotte et al 1990) to 37% (Coughlin and Templeton 1980), though Staeheli (Staeheli et al 1988) had only one dislocation out of fifty cases (2%). These rates are difficult to compare because the severity of the disease is not indicated and some patients had tenotomies in an attempt to

reduce the dislocation rate.

Coughlin (Coughlin and Templeton 1980) found a 37% dislocation rate in a selection of Parkinson's patients with disease of varying severity, and all of the dislocated cases died within 6 months. Seventy five percent of hemiarthroplasty patients died within six months overall, and internal fixation was recommended.

Staehele (Staehele et al 1988) found a 20% 6 month mortality but only a 2% dislocation rate, suggesting that hemiarthroplasty was a satisfactory treatment - they recommended an adductor tenotomy as an adjunct to surgery.

In summary, in those patients without adverse risk factors, the dislocation rate is acceptable, and there is no good evidence that dislocation rates between unipolar and bipolar prostheses differ.

1.7.2.4 femoral stem loosening

Femoral stem loosening as a late complication may cause thigh pain, and this has been found in several studies (Lindholm 1976, Soreide et al 1980). However, compared to other complications it only seems to account for a relatively small proportion of problems. Jalovaara (Jalovaara and Virkkunen 1991) had only 1 revision for loosening out of 185 cases. It does appear that cemented prostheses do cause less postoperative pain as has been discussed in section 1.6.5.1. In uncemented hemiarthroplasty, for example with the Moore prosthesis, the stem is loose to some degree from the moment it is put in because it is not a true interference fit, therefore it is difficult to comment on the effects of so called "late" loosening in such cases, especially radiographically.

Other complications which are recognised but less common are fractures or perforation of the femoral shaft at the time of surgery by the stem of the implant. Late fractures at the stem tip do occur and may be difficult to manage with high rates of non-union (Harrington et al 1978, Cooke and Neuman 1984).

1.7.3 Complications following internal fixation.

Failure of internal fixation seems to occur by three modes. Failure within the very early postoperative period, up to about 6 weeks, occurs simply by failure of the fixation device to be secured within the porous bone of the femoral head leading to the fixation device cutting out of the bone- in other words, early redisplacement of the fracture. True non-union may occur as a result of poor vascularity at the fracture site, and later on avascular necrosis may lead to late segmental collapse (LSC). Mechanical failure, non-union and avascular necrosis would therefore ideally be approached separately but in practice they are grouped together as failure of fixation. Late segmental collapse is the phenomenon associated with bony collapse of an avascular segment leading to secondary degenerative osteoarthritis and pain. Avascular necrosis theoretically relates to changes at the cellular level, but in clinical practice the terms AVN and late segmental collapse are often used (wrongly) as alternatives. In fact probably only a small number with AVN develop LSC.

Union is said to have occurred when there is radiological evidence of trabeculae crossing the fracture line, but this diagnosis is sometimes difficult. The trouble in reviewing much of the literature is that the distinction between early redisplacement and true non-union is rarely made and it is therefore

difficult to directly compare results of different reported series.

The incidence of non-union is increased by poor reduction and inadequate fixation (Garden 1961B, Arnoldi and Lemperg 1977, Kofoed and Alberts 1980, Holmberg et al 1987A,B). Adequate fixation may produce union even in the presence of a diminished blood supply (Stromquist et al 1983), whereas inadequate fixation by inexperienced surgeons increases the rate of non-union (Holmberg et al 1987B).

Avascular necrosis following intracapsular proximal femoral fracture is probably the result of a combination of damage at the time of fracture and compression of the intracapsular vessels left supplying the neck by intracapsular haematoma (Stromquist 1983, Stromquist et al 1985, Wingstrand et al 1986).

The true incidence of avascular necrosis following fracture is not known, because it may be asymptomatic and in most clinical series cases were only picked up when symptomatic patients presented with problems .

Arteriographic examination has found evidence of partial or total necrosis in 84% of 25 femoral heads studied (Sevitt 1964). These results have been supported by other work (Catto 1965 A,B). Often the retinacular vessels were torn or damaged and the femoral head relied on supply from the ligamentum teres artery which was intact in 90% of cases. The process of revascularisation may lead to a revascularisation front between dead and living bone and it is through this area that subchondral fracture and late segmental collapse may occur.

Table 1.5 shows a selection of reported incidences of non-union and

AVN. The wide variation may be accounted for by differences in follow-up rates and definitions of non-union/AVN.

Table 1.5 Rates of failure of fixation, various studies

Study	Operation	Non-Union (%)	AVN (%) where stated
Christie 1988	SSP (SSP) + pins (Divergent)	27.6	15.7
Skinner 1989	SSP	25.0	-
Parker 1991	Garden Screws	21	-
Stromquist 1987	hook pins	30.8	6.5
Frandsen 1984	SSP	18.6	7.3
Hogh 1982	AO Screw	24.5	14.3
Holmberg 1987A	various	23.3	11.9
Kuokkanen 1990	SSP	5.6	8.3
Ceder 1980	Rydell Nail	31 total	

1.8 Aims of Experiments

The aim of the studies subsequently presented is to address aspects of the numerous questions raised about the management of intracapsular fractures of the proximal femur.

Chapters 2 and 3 are based on intermediate term clinical results of a large randomised prospective trial; in terms of numbers of patients formally randomised it this will be the largest study to date in the literature of this nature by a considerable margin. Chapter 2 looks at purely clinical results in two age groups (65-79, 80 years and over) randomised for treatment of displaced intracapsular hip fracture ; an area which in the literature is clearly deficient. Chapter 3 looks at the same study population to try and assess the use of a subjective health indicator in such a group it is clear that no consensus on the most appropriate outcome measures for this sort of frail population has been reached, and subjective health indicators should be considered more fully.

Chapters 4 and 5 each contain a study related to the complication of failure of internal fixation and avascular necrosis of the femoral head. In one, a way of avoiding heat damage at the time of surgery is addressed. In the other, a new method of diagnosing pre-operative femoral head avascularity is assessed - single position emission computed tomography (SPECT). These two studies respectively aim to reduce the number of futile internal fixations, and reduce the risk of bone necrosis and implant cut-out following fixation.

Chapter 6 is an epidemiological study which takes advantage of the uniquely high ethnic population of the study centre to look at differences in the incidence of hip fracture between two groups. This type of study aims to

produce information with implications for resource allocation, and speculation as to the underlying reasons for different fracture distributions between populations.

2. A randomised prospective trial of treatment of displaced intracapsular hip fractures

2.1 Introduction

The treatment of displaced intracapsular proximal femoral fractures is still unsolved, but it is clear from chapter one that there are specific groups of patients in whom we should have a particular interest. The lack of consensus as to the best treatment for displaced intracapsular hip fracture in the over 65s is due to a dearth of good randomised prospective comparing treatment with reduction and internal fixation of the femoral head with replacement of the femoral head. Those randomised prospective trials which are in the literature have only short follow up of at most two years (see section 1.6.7.2). This is important because the group of patients who we are most concerned about are those who continue to have an active life for a reasonable postoperative period; 5 years minimum being an acceptable figure. The few reports with long term follow up of at least 5 years (e.g. Kuokkanen et al 1990) are not randomised nor are they prospective studies.

Most of the comparative literature to date does not use adequate rigidly defined exclusion criteria in clinical studies. These exclusion criteria serve two purposes; one is to identify those patients who should not really be randomised on ethical grounds because their condition dictates a specific line of treatment. These include patients with Parkinson's disease or rheumatoid arthritis, young patients. The second is to identify patients such as the elderly demented whose

likely mortality is such that long term survival of the surgical implant takes on diminishing importance.

The high mortality following hip fracture requires that large numbers are needed in a randomised prospective study to give an adequate number of survivors at five years for sufficient statistical power.

The aim of the clinical trial described in this chapter was to assess any outcome differences between unipolar and bipolar hemiarthroplasty and internal fixation as treatment for displaced intracapsular hip fracture; at the same time fulfilling the stated criteria for trial entry, and providing adequate numbers for a statistically powerful study at the end of five years.

Of particular interest will be the use of a subjective health profile, the Nottingham Health Profile (NHP), to assess early results (Chapter 3) because outcome measures for proximal femoral fracture are not universally agreed upon. It is clear though that in a group of patients with limited life expectancy and low functional expectations, subjective criteria activities of daily living are at least as important as the more commonly used objective assessments.

2.2 Materials and Methods

Leicestershire Health Authority coincides with the county boundary, and all trauma patients are treated at one hospital, the Leicester Royal Infirmary. This means that trial recruitment can be tightly controlled because all hip fracture patients within the region end up on one of four adjacent wards and are logged onto the same hospital Patient Administration System (PAS).

Leicestershire has a large and increasing number of admissions for

proximal femoral fracture (Anderson et al 1993A) providing adequate numbers of patients for a prospective study.

Patients with displaced intracapsular hip fracture, (Garden stages 3 and 4), aged over 65 years old were the source of the study group. "Aged over 65 years " includes patients from their 65th birthday onwards.

2.2.1 Exclusion criteria

The most important design aim of this study was to try and identify those patients who were likely to survive at least 5 years from the injury. To that end patients were excluded if they were known from previous evidence to be less of a management dilemma because of high mortality or specific comorbidity dictating the method of treatment. Exclusion criteria used in this study were as follows:

1. Dementia: dementia has been shown to predispose to a high mortality in these patients (section 1.7.1.). The ultimate aim of the study was to achieve a 5 year follow up and therefore this group of patients could not usefully be recruited. Mental status was measured using an abbreviated mental test score (MTS), with a maximum of thirteen points (see Figure 2.1). Although not strictly a measure of dementia, this MTS is well validated and a level of <5/13 was used as the exclusion watershed.

Figure 2-1 Mental Test Score as used

age	1 point
time	1
address to recall at end of test e.g. 42 West Street	2 (1 for each part)
year	1
name of hospital	1
recognise two persons e.g. doctor/nurse	1
date of birth	1 for day, 1 for month, 1 for year
year of 1st world war	1
name of present monarch	1
count backwards from 10	1
total	13

2. Uncontrolled Parkinson's disease. Parkinson's Disease has specific problems associated with displaced intracapsular hip fracture. There is a high dislocation rate (section 1.7.2.2) for hemiarthroplasty which has an associated high morbidity and mortality. Therefore internal fixation is often felt to be the treatment of choice. Well controlled Parkinson's disease was not a reason for exclusion from the study.

3. Disseminated malignancy . In these patients life expectancy is short and long term outcome of surgery is usually irrelevant.

4. Pathological fracture. Life expectancy may be short as for disseminated malignancy, and in addition specific surgical treatment may be indicated, for example total hip replacement if there is acetabular involvement, or a long stem femoral component if there is extensive bone lysis below the fracture site.

5. Paget's disease. Paget's disease involving the proximal femur on the side of the fracture, or the ipsilateral acetabulum, was excluded for the same reasons as pathological fractures. These fractures do not usually follow the normal pattern and treatment by hemiarthroplasty is often inappropriate.

6. Rheumatoid arthritis (RA). There is good evidence that total hip replacement (THR) should be the treatment of choice in these patients. This is largely because of the high rates of non-union reported in displaced intracapsular hip fracture. Stromquist (Stromquist 1984) found a 75% non-union rate in 12 patients. Bogoch (Bogoch et al 1991) found a 45% non-union rate; THR has been suggested to be preferable (Bogoch et al 1991, Stromquist et al 1988), though it would be reasonable in older patients to perform hemiarthroplasty if the hip joint itself is not affected by rheumatoid arthritis. Certainly hemiarthroplasty appears to be better than internal fixation (Stephen 1981), with fewer failures requiring revision.

7. Long term steroid therapy: elderly patients may be on long term steroids for respiratory problems in particular, or RA which is itself an exclusion criterion, and the reasons are the same as for RA; that the failure rate of fixation is unacceptably high.

2.2.2 Treatment groups

Patients were divided into two groups by age. Patients over 65 years and under 80 years made up Group 1. Patients aged over 80 years (i.e. from the 80th birthday) made up Group 2. These are shown more clearly in Figure 2.2.

Group 1/Trial 1: (65-79 years) This group of patients was randomised into a three arm study:

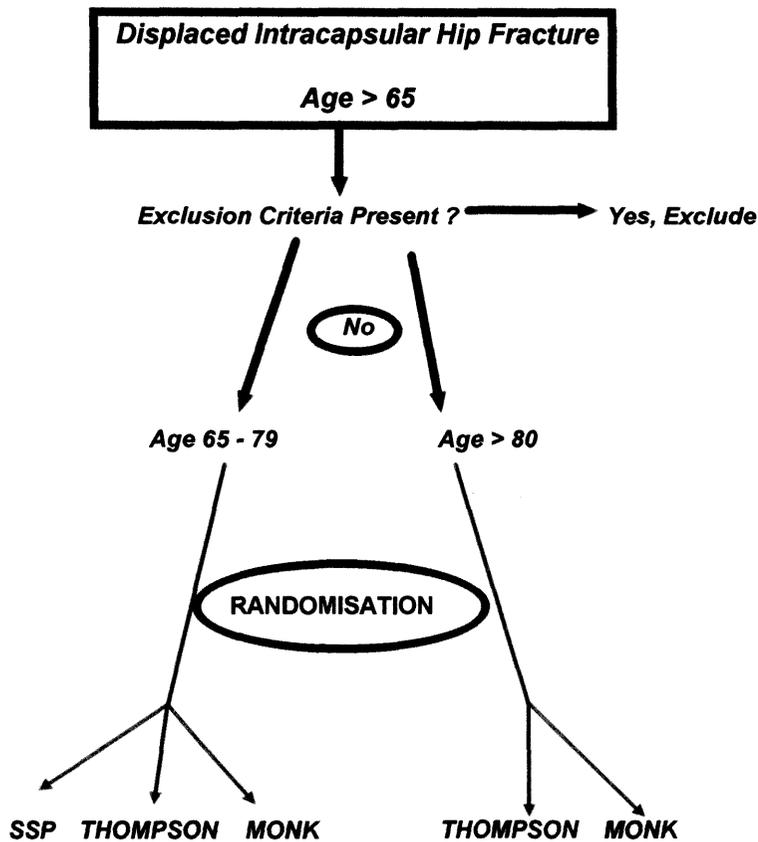
1. Reduction and internal fixation using a sliding screw plate
2. Unipolar hemiarthroplasty using a Thompson prosthesis
3. Bipolar hemiarthroplasty using a Monk prosthesis

Group 2/Trial 2: (80+ years) This group was randomised into a two arm study:

1. Unipolar hemiarthroplasty using a Thompson prosthesis
2. Bipolar hemiarthroplasty using a Monk prosthesis

The background to the rationale behind this trial design has been discussed in depth (Chapter 1). Group 2 were not treated with internal fixation because it is widely accepted that failure rate of internal fixation in patients over 80 years is very high and the short life expectancy means that acetabular erosion rarely becomes a mode of failure of hemiarthroplasty in this age group (D'Arcy and Devas 1976).

Figure 2-2 Outline Trial Protocol



2.2.3 Power calculations and statistics

Planning was made for trial entry to last 4 years, and for final follow up to be at 5 years postoperatively.

Using figures from the first year of the study and OPCS (office of population censuses and surveys) mortality figures for the two age groups, trial 1 was expected to have approximately seventy patients in each treatment group and trial 2 eighty four patients in each group after five years follow up.

On this basis, with a fixation failure rate of 25% Group 1 would have a 75% power of detecting a difference in failure rates if the hemiarthroplasty failure rate was 15%, and 90% if the hemiarthroplasty failure rate was 5% at five years. The figures of 5 and 15% used in our power calculations were rounded estimates from series starting failure rates by various means - usually painful loosening or severe acetabular erosion in the case of hemiarthroplasty. The small sample of series shown in table 1.1 show a mean of about 18% acetabular erosion at follow-up 29-89 months, but not all of these 'fail' as they may not be revised. In one series (D'Arcy and Devas 1976) 6% had been revised or were awaiting revision for failure at three years; two years less than our planned follow up.

Group 2 would have a 50% power to conclude that a difference of 8% or less would signify equivalence of the two groups with a significance level of 10%

Standard non-parametric techniques would be used to compare the secondary endpoints and ADL (activities of daily living) assessment, which can be expressed numerically, between the randomised treatment groups.

The statistical software package SPSS was used for the data analysis.

2.2.4 Endpoints

The primary clinical endpoint is death or failure requiring revision surgery up to the planned five year follow up. Secondary endpoints are acetabular erosion for hemiarthroplasty and late avascular necrosis (AVN) for the fixation group. For the purposes of this results presentation, acetabular erosion has only been recorded as a complication if it is gross radiological erosion, whereby the component is seen to break the contour of the pelvic wall medial to the acetabulum. At full five year follow-up, with a full radiographic series available, measurement of erosion will be made according to a described method (Wetherell et al 1989) which gives an acceptable accuracy on antero-posterior pelvic radiographs.

2.2.5 Outcome measures

In an elderly group of patients, functional and subjective outcome measures may be considered equally as important as more conventional objective scores.

Objective measures used in this study were the Harris hip score (Harris 1969), and plain radiographs. Plain radiographs were used to detect acetabular erosion and component loosening for the prostheses, and non union and AVN for the fixation group.

Subjective measures used were The Nottingham Health Profile (to be discussed in Chapter 3) and an ADL score to be measured in the patients

home environment. It is likely that patients perform worse at home in the long term than previously thought, because to date there has been very little feedback to the hospital regarding functional status after discharge. It may be that one treatment group will remain at their attained level of independence for longer than another because of differences in sub-clinical failure of the surgical procedure; for example, as acetabular erosion occurs slowly, loss of independence due to reduced mobility and increasing pain may be the first sign that there is a problem with the prosthesis. This aspect was developed as a separate arm of the study later on, as a modification of the ADL measure of Barthel and will not be reported in this thesis. In addition, the patients pre-injury mobility and independence status are recorded to be compared with place of discharge and other "soft" but important measures.

Patient subjective measures in the form of answers to questions about satisfaction, and the subjective feeling of return to pre-injury state were also used.

2.2.6 Method

The initial assessment of patients was carried out to assess suitability for entry into the trial, according to the exclusion criteria. A purpose designed admission form was used to ensure that all details were obtained by the admitting medical staff. These include details on home circumstances, mobility, walking aids, general health, previous fractures, drugs therapy as well as demographic data.

Informed signed consent trial was given by each patient prior to randomisation by computerised random number generation. Consent prior to randomisation was important as a method of avoiding bias in selection.

Surgery throughout the study has been performed by two surgeons only; Mr. GH Anderson (1991-2) and the author (1993-4). Surgery was performed at the first available opportunity. Anaesthesia was decided on by the anaesthetist and the method, whether general anaesthetic or spinal anaesthetic, was recorded. The same operating theatre was used for all cases. This was a conventional theatre with no laminar flow clean air facility.

2.2.6.1 Surgical Technique of internal fixation

For internal fixation, closed reduction of the fracture with radiographic screening (using an image intensifier) was performed. Antero-posterior and lateral radiographs were taken prior to fixation to record the accuracy of reduction. Reduction criteria used were those according to Garden (Garden 1961) and patients were excluded if satisfactory reduction according to these criteria were not achieved.

The reduction technique was not recorded as a matter of course because most reductions vary in some way. The usual method was gentle traction in extension followed by internal rotation.

Fixation was carried out with a sliding screw plate (SSP) device (Ambi Hip Screw, (AHS) Richards, see figure 1.18), with the patient on a standard fracture table. The main operative steps are illustrated in Figure 2.3. Of particular note when using a sliding screw plate for this fracture is the insertion of one or two temporary anchoring guide wires superiorly to control rotation while the lag screw is being inserted.

Postoperative radiographs were always taken in the operating theatre before the patient was woken up, in order to be sure of the adequacy of reduction and screw placement. If the reduction had slipped, and the fixation in situ was no longer within Gardens reduction criteria, this was noted as a failure of surgical technique.

2.2.6.2 Surgical Technique for hemiarthroplasty

The hemiarthroplasties used in this study were the Thompson unipolar and the Monk hardtop Bipolar (Duopleet, Johnson and Johnson Orthopaedic)-see figure 2.4. They had almost identical curved stems, so that the only variation between them was the articulation.

The Hardinge 'Direct Lateral' approach to the hip (Hardinge 1982) was used in every case. Both of the prostheses used are designed with a collar to sit on the calcar of the proximal femur, so the femoral neck was cut to the level of the superior limit of the lesser trochanter. Figure 2.5 shows a Thompson prosthesis with an inadequate resection of femoral neck.

The prostheses were cemented into the femur with standard viscosity cement inserted orthograde with a cement syringe, using a vent tube to reduce the risk of emboli. No cement restrictor was used. This technique was standard for all cases. Antibiotic prophylaxis was given as follows in all cases: Cephadrine 1 gram with induction, and a further two doses of 500 mg at 8 and 16 hours postoperatively. No chemical or mechanical thromboprophylaxis was used routinely.

Figure 2-3 Operative Steps for Sliding Screw Plate (SSP) Fixation. The fracture [1] is reduced and held with 2 guide wires [2]. The superior wire is to prevent rotation. The lower wire, placed in the middle third on both the AP and lateral radiographs, is over-drilled with the triple reamer [3]. The cannulated lag screw is then inserted over the guide wire [4]. The sliding plate is applied over the screw [5], and is then screwed on and the derotation wire removed [6].

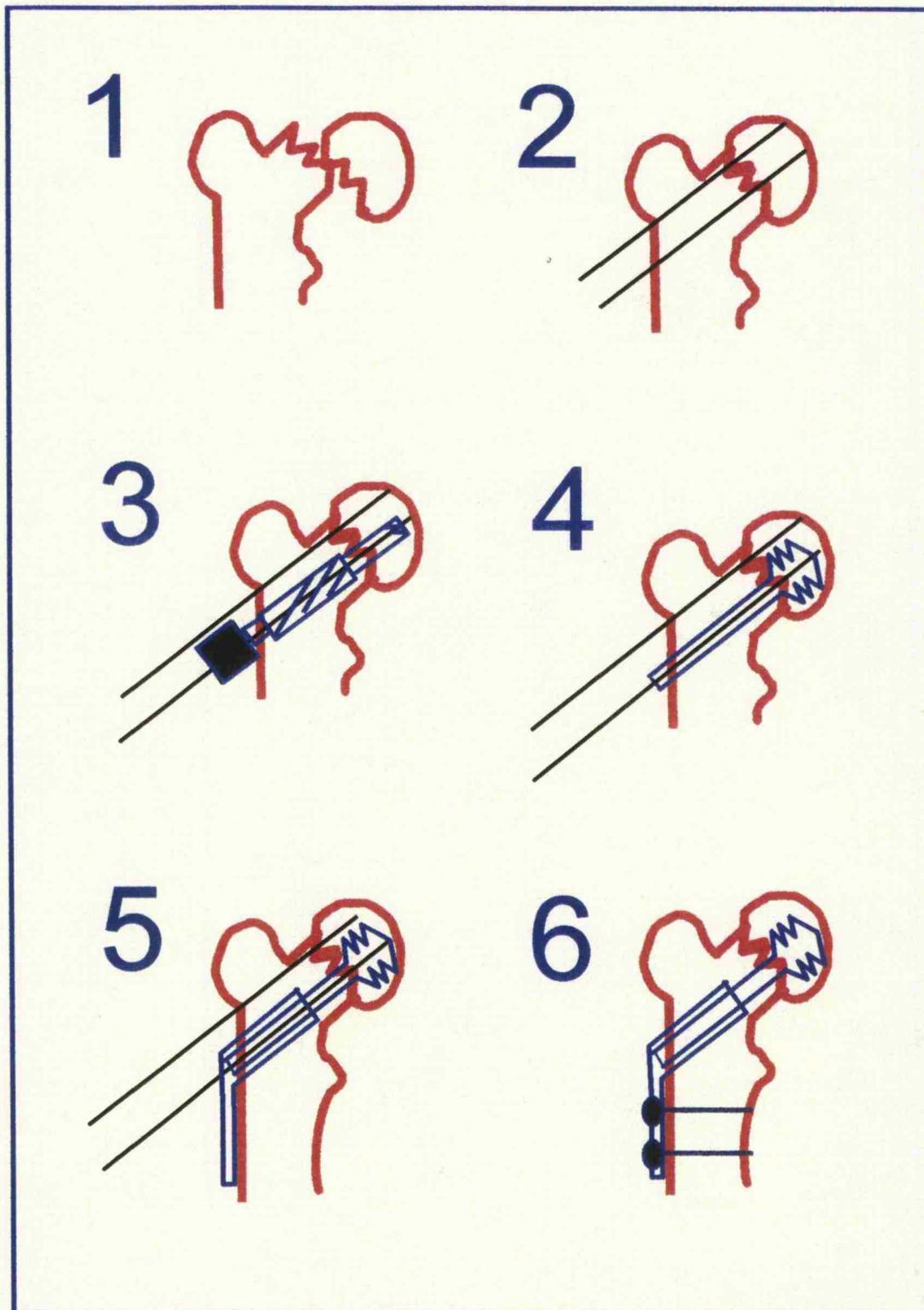


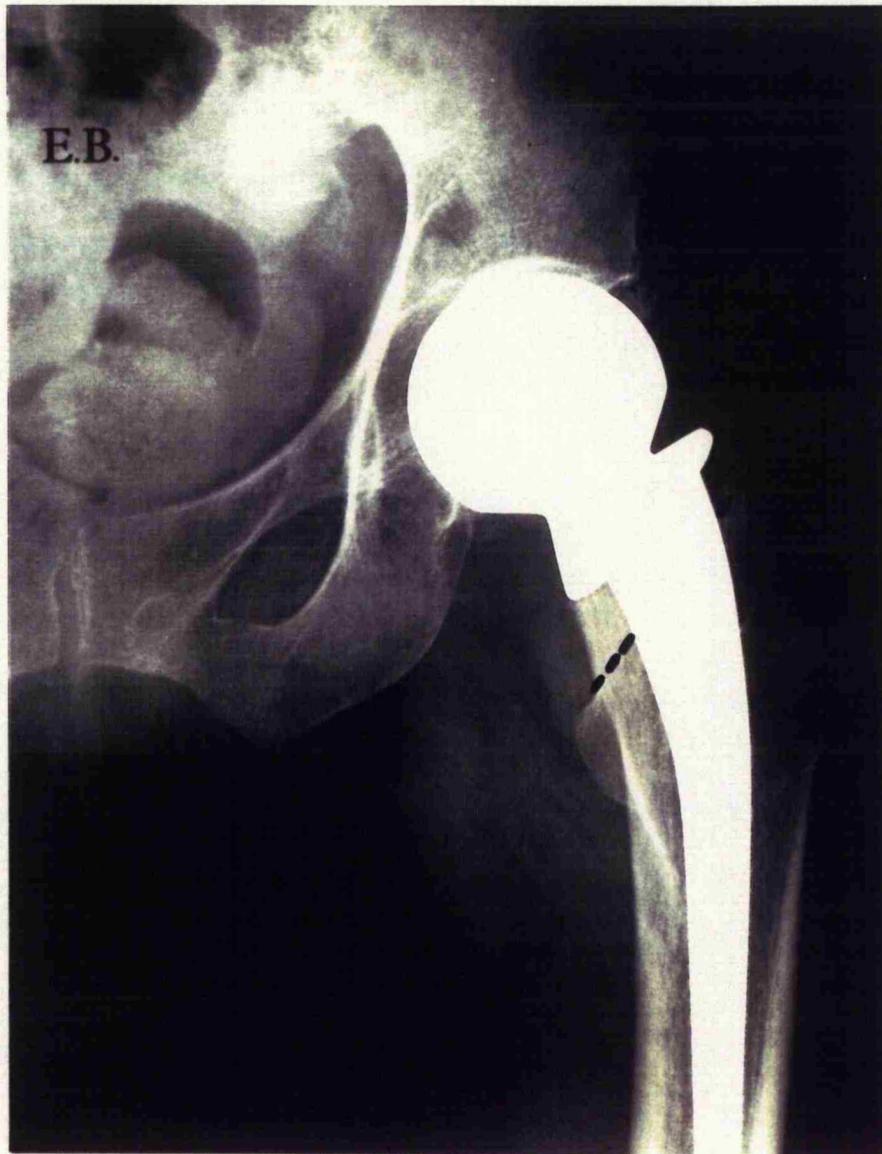
Figure 2-4

The two prostheses used in the study. Monk bipolar [left], Thompson unipolar [right].



Figure 2-5

A cemented Thompson prostheses in situ. The femoral neck cut is too high. The correct level is shown as a dotted line, just above the lesser trochanter.



2.2.7 Postoperative Regime

Postoperatively all patients were mobilized fully weight bearing with physiotherapy supervision at 24-48 hours, the same routine being used for each operative group. They were reviewed on the ward on a regular basis by the same research fellow and any complications were noted. In particular the wound was inspected to give an accurate record of wound healing and early infections. The date of discharge from the orthopaedic ward; and discharge destination were recorded.

2.2.8 Outpatient Follow-up

The first outpatient assessment for all cases was carried out by the research registrar at 6-8 weeks postoperatively. This was a routine check at which general progress was assessed and recorded, and the wound was checked for signs of infection.

Following hemiarthroplasty a plain anteroposterior standing radiograph of the pelvis centred on the pubic symphysis was taken. This would be the future baseline for measuring acetabular erosion.

Following internal fixation, anteroposterior and lateral films of the hip were taken.

In the case of uncomplicated hemiarthroplasty the next review was arranged for one year post operatively, and annually following that.

In the internal fixation group, early follow up was more frequent, every 2-3 months, until union or failure of fixation. Late follow up was the same as for hemiarthroplasty.

In addition to radiographs, at each annual review patients were formally scored using the Harris hip score, which is based largely on pain and functional indicators. Questions of subjective assessment of the procedure were also included: are you satisfied with your operation? Is your hip back to how it was before you broke it?

Patients were also assessed using a subjective health indicator, the Nottingham Health Profile, at six months (and five years) postoperatively. This will be discussed in Chapter 3.

2.3 Results

Patient entry into the study commenced 1st January 1991. Results presented here are by definition preliminary results because the study will not be formally completed until the end of 1999, that being 5 year follow up for the last patients entered into the study. The results for Trial 1, for group 1 patients aged 65-79, and Trial 2, for group 2 patients aged 80 years and over, are presented as separate studies:

2.3.1 Results of Trial 1

2.3.1.1 baseline and demographic data

Results for patients entered during the first three years of the study will be presented. Data was analysed at the end of four years, which means that all of these patients were at least one year post injury. At three years there had been entered into the study 56 AHS, 62 Monk, and 53 Thompson.

Baseline demographic variables and pre-injury levels of dependency and disability are shown in table 2.1, and graphically in the subsequent figures 2.6 - 2.10. There were no significant differences at the five percent level in any of these criteria, using statistical tests as shown.

Table 2-1

Baseline data for group 1 [age 65-79]

	AHS [n=56]	Monk [n=62]	Thompson [n=53]	P value
% female [n]	71 [40]	69 [43]	81 [43]	NS ¹
median age years [IQ range]	72 [70-76]	75 [70-78]	74 [70-77]	NS ²
median MTS [IQ range]	13 [13-13]	13 [12-13]	13 [12-13]	NS ²
% going out alone [n]	80 [45]	79 [49]	70 [37]	NS ¹
% prev. wrist or hip # [n]	14 [8]	21 [13]	15 [8]	NS ¹
% resident in the community [n]	96 [54]	94 [58]	94 [50]	NS ¹
% independent of aids or one stick only [n]	96 [54]	97 [62]	87 [46]	NS ¹
% completely independent of carers [n]	75 [42]	68 [42]	66 [35]	NS ¹

IQ = interquartile range NS = not statistically significant at the 5% level

n = no. of cases ¹ Chi square ² Mann Whitney U-test

Some of these figures are displayed graphically in figures 2.6-2.10

Figure 2-6 % female in trial 1

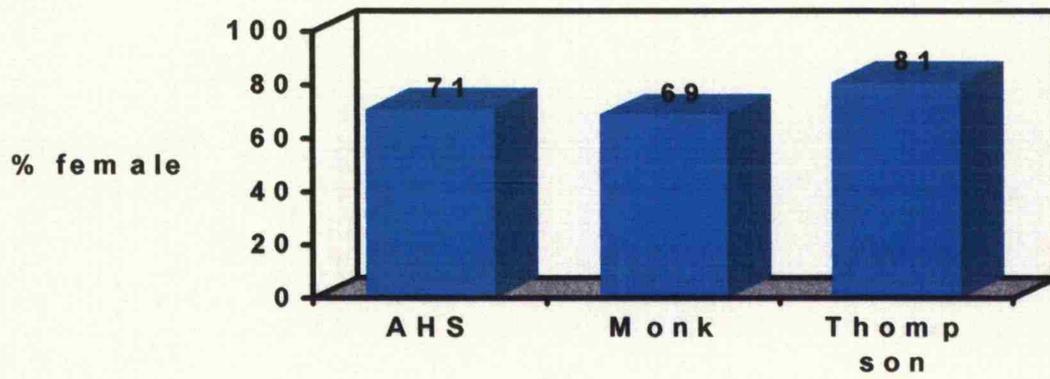


Figure 2-7 median age in years trial 1

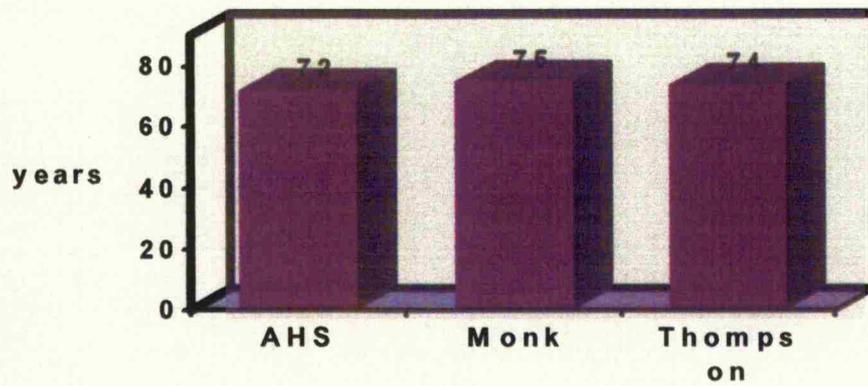


Figure 2-8 median MTS trial 1

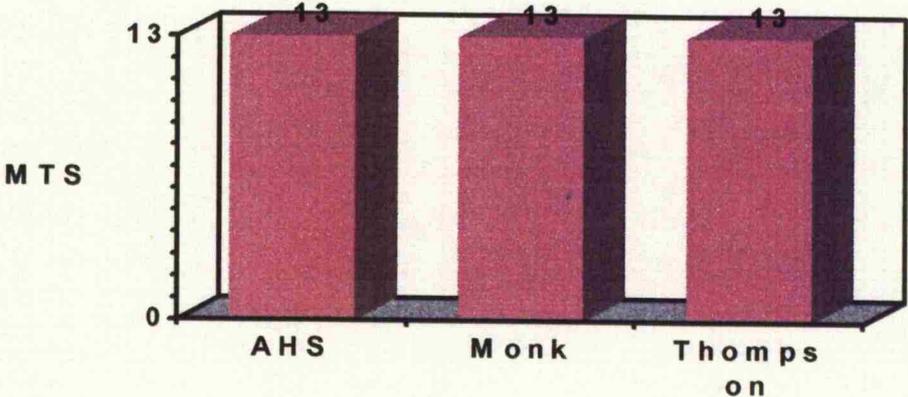


Figure 2-9 % going out alone, % resident in the community pre-injury trial 1

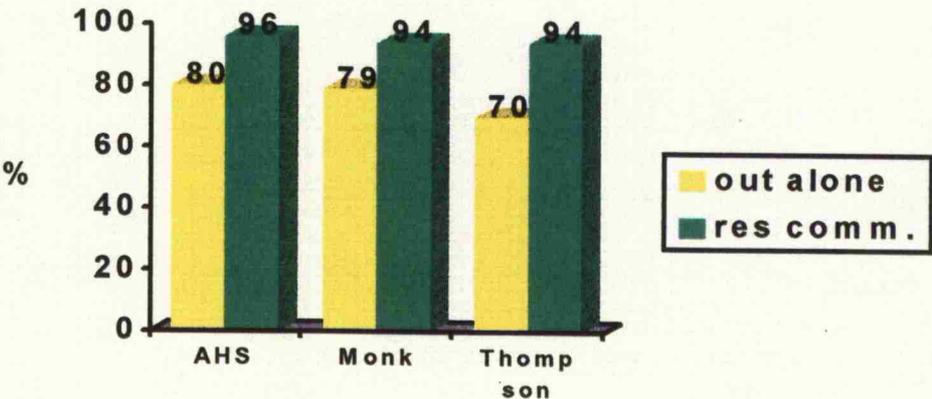
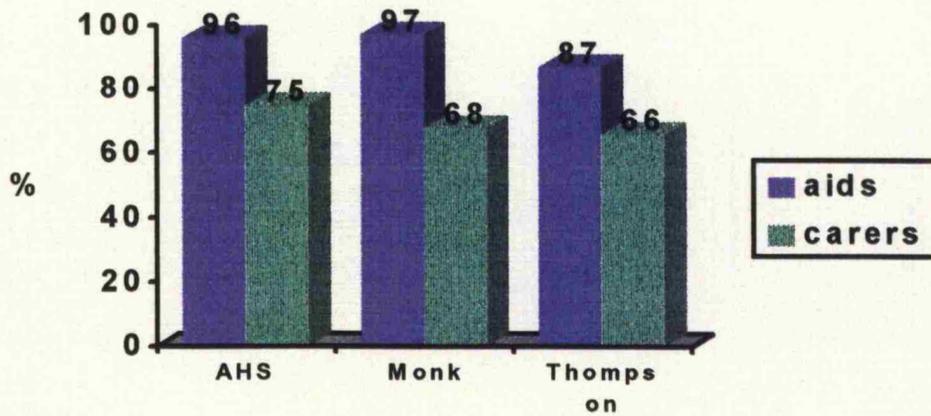


Figure 2-10 % independent of walking aid/one stick only, % independent of carers pre-injury trial 1



2.3.1.2 outcomes and follow up

The immediate hospital outcomes, in terms of length of stay on the acute orthopaedic ward, placement home, and inpatient deaths are shown in table 2.2. Length of stay specifically excludes time spent on geriatric rehabilitation units and other such hospital based care. Placement home means return to the original place of residence; for example a patient from a residential home who returns there is considered to have returned home. There were no significant differences at the five percent level in these outcomes, although it is notable that there were no deaths in the fixation group; this might support the theory that hemiarthroplasty has a greater immediate danger.

Table 2-2 Immediate hospital outcome of group 1 patients

	AHS [n=56]	Monk [n=62]	Thompson [n=53]	p value
median stay days [IQ range]	14 [10-21]	15 [13-19]	14 [11-21]	NS ¹
% returned home from acute ward [n]	64 [36]	61 [38]	66 [35]	NS ²
% died in hospital [n]	0 [0]	5 [3]	2 [1]	NS ²

¹ Mann Whitney U-test

²Chi square

Mortality in the first year is shown as a survivorship table and chart (table 2.3 and attached figure). For all treatment arms mortality at one year was in the order of 11-15%, the lowest being in the AHS group but no significant differences were noted.

Table 2.4 shows data for follow up on this group of patients. Follow up was completed, at a minimum of one year, on 44 AHS , 47 Monk and 40 Thompson. If the patients who died before the one year follow up are excluded, there is a loss to follow up of 5/49 (10%) for AHS, 6/53 (11%) for Monk, and

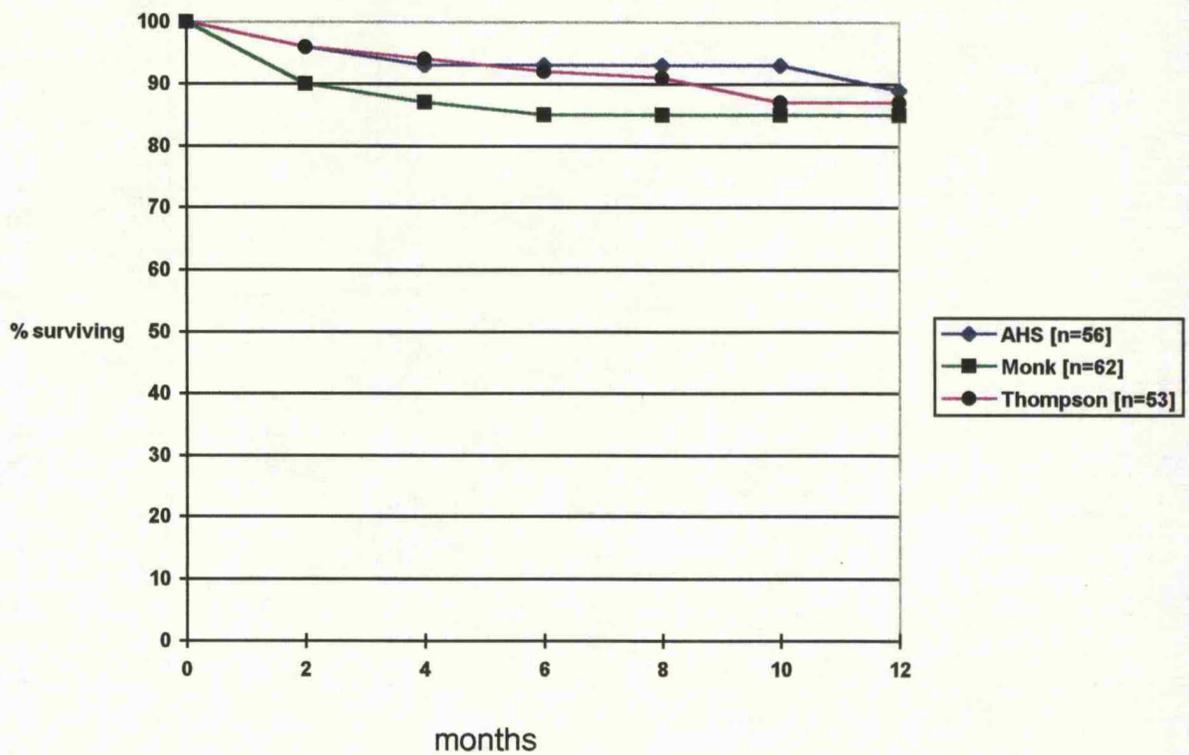
6/46 (13%) for Thompson; this is a consistent problem with all studies in this group of patients, and these figures are lower than most series. There is no significant difference between the groups for these figures. Results are shown graphically in Figures 2.11 - 2.12

Median follow up time was less in the Monk group but not significantly so, and the ages were similar. The median Harris scores were ten points lower for the AHS than the Monk (68 versus 78), $p=0.07$. The percentage of patients only using one or no sticks to walk was significantly greater in the Monk group compared to AHS- even though preoperatively the groups were the same for this measure. There was also significantly less satisfaction with the operation in the AHS group compared to both hemiarthroplasties. There was no difference in any of the other outcome measures.

Table 2-3 Proportion of patients surviving to various times from operation in the first year; %

months post op	AHS [n=56]	Monk [n=62]	Thompson [n=53]
0	100	100	100
2	96	90	96
4	93	87	94
6	93	85	92
8	93	85	91
10	93	85	87
12	89	85	87

mortality in first year, group 1



DIFFERENCES NOT SIGNIFICANT

Table 2-4 follow up assessments group 1

	AHS [n=44]	Monk [n=47]	Thompson [n=40]	p value
median follow up time days [IQ range]	685 [379-868]	505 [370-793]	706 [377-995]	NS ¹
median age [IQ range]	72 [70-76]	75 [70-78]	75 [70-78]	NS ¹
median Harris score [IQ range]	68 [62-81]	78 [68-83]	71 [64-81]	NS ¹ (0.07)
% resident home [n]	86 [38]	83 [39]	88 [35]	NS ²
% using no stick or one stick only [n]	75 [33]	91 [43]	78 [31]	NS ² Monk/Thompson 0.04 Monk/AHS
% independent of carers [n]	50 [22]	60 [28]	48 [19]	NS ²
% returned to pre-injury state [n]	32 [14]	49 [23]	43 [17]	NS ²
% none or mild pain [n]	82 [36]	94 [44]	88 [35]	NS ²
% satisfied with operation [n]	64 [28]	85 [42]	83 [33]	<=0.05 AHS/Thompson and Monk ²

¹ Mann Whitney

² Chi square

some of these data are illustrated in figures 2.11-2.12

Figure 2-11 follow up assessment trial 1. % resident at home, using one stick at most, independent of carers. Measures of independence

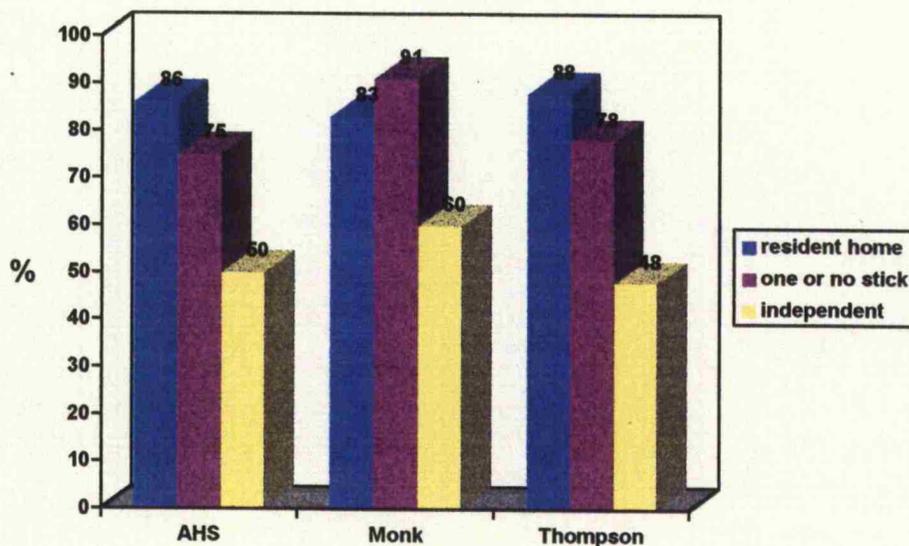
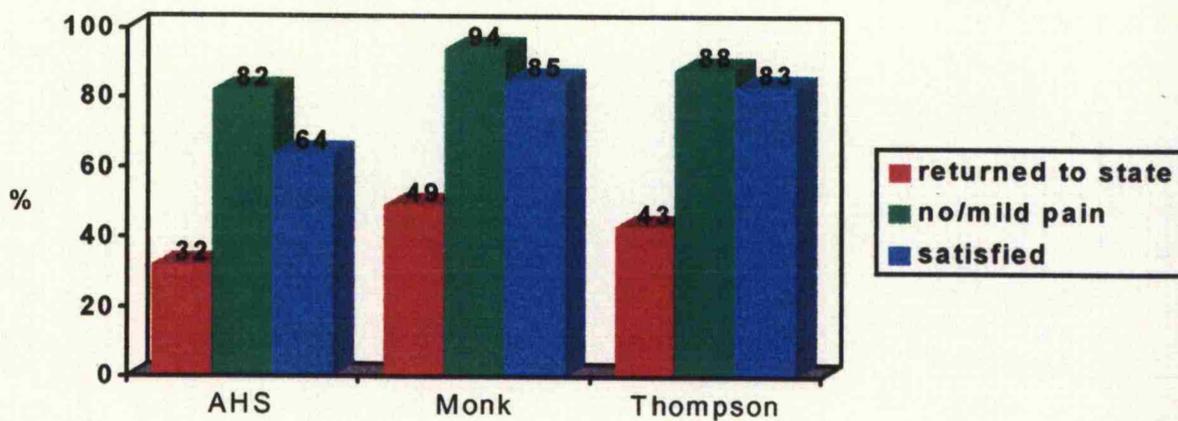


Figure 2-12 follow up trial 1. % returned to pre injury status, none or mild pain, satisfied with operation. Subjective measures



2.3.1.3 Complications

There were 14 [25%] cases of internal fixation which required revision due to failure of fixation within the first six months postoperatively. By one year a total of 15 [27%] had failed, and by two years 18 cases [33%] had required or were awaiting revision to THR. These are shown in figure 2.13. A further two cases had avascular necrosis with collapse of the femoral head but did not require revision due to other medical factors. Thus a total of 20 cases [36%] failed by two years. The majority of failures, occurring in the first six months, were due to mechanical cut out of the lag screw from the femoral head, presumably secondary to delayed or non-union in some cases, but purely a mechanical phenomenon of the implant cutting out of soft bone in cases where it occurred within the first month or two. In addition to these 20 cases requiring revision, there were two cases of AVN collapse which were not revised. Of the 20 cases revised 16 were revised to THR and 4 were revised to Monk Hemiarthroplasty where the acetabulum was felt to be undamaged. A series of films from a successful fixation with no pain at one year is shown in figure 2.14.

The Thompson group had one case of gross acetabular erosion requiring revision to THR after only 6 months. There was no identifiable reason for this; and one case of significant persistent groin pain requiring a bone scan; but no clear explanation was found, and the pain settled. There were no dislocations in the Thompson group, but there was one fracture of the femoral shaft at the tip of the stem, in the early postoperative period, which did not occur with the Monks.

In the Monk group, there was one case of post-operative dislocation, which was reduced by closed manipulation and was subsequently stable. However there was a significant degree of heterotopic ossification by three months (fig. 2.15), probably secondary to the dislocation because it was not seen in any of the other cases; functionally though there was minimal disability.

There were no cases of gross radiological acetabular erosion.

There were no significant differences in deep infection rates: AHS 0/56, Monk 0/62, Thompson 1/53.

Figure 2-13 Failure of fixation in the first 2 years. Implant survivorship.

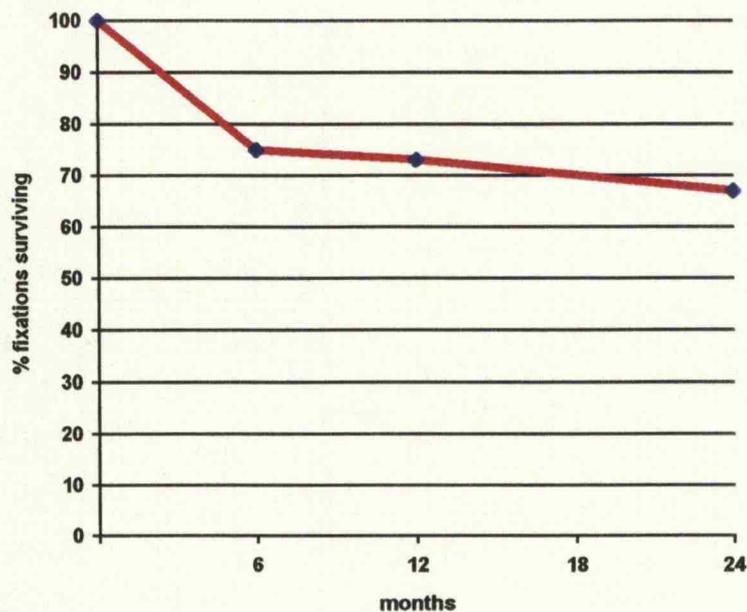


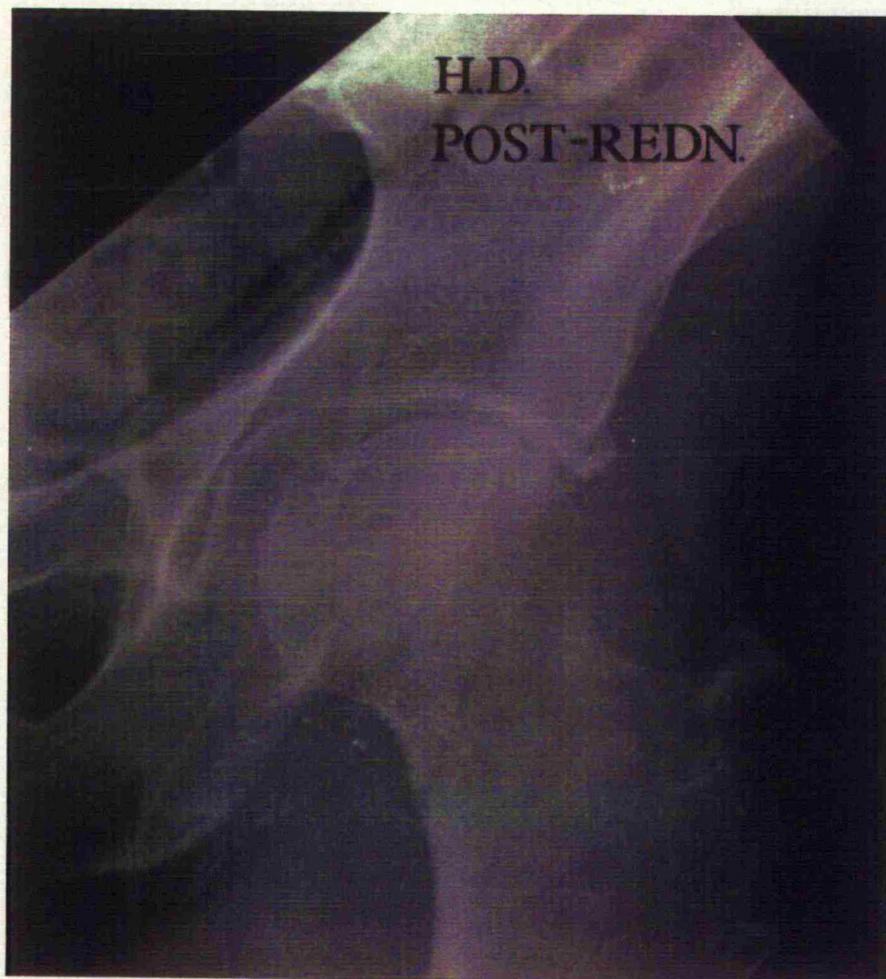
Figure 2-14 series of films following successful fixation, with no pain at one year. a) injury b) reduction, AP film c) reduction lateral film d) six weeks e) 7 months f) 1 year AP and lateral
Note that a compression screw was used in this case and by 7 months had fallen out

a)



[fig 2.14 cont.]

b)



c)



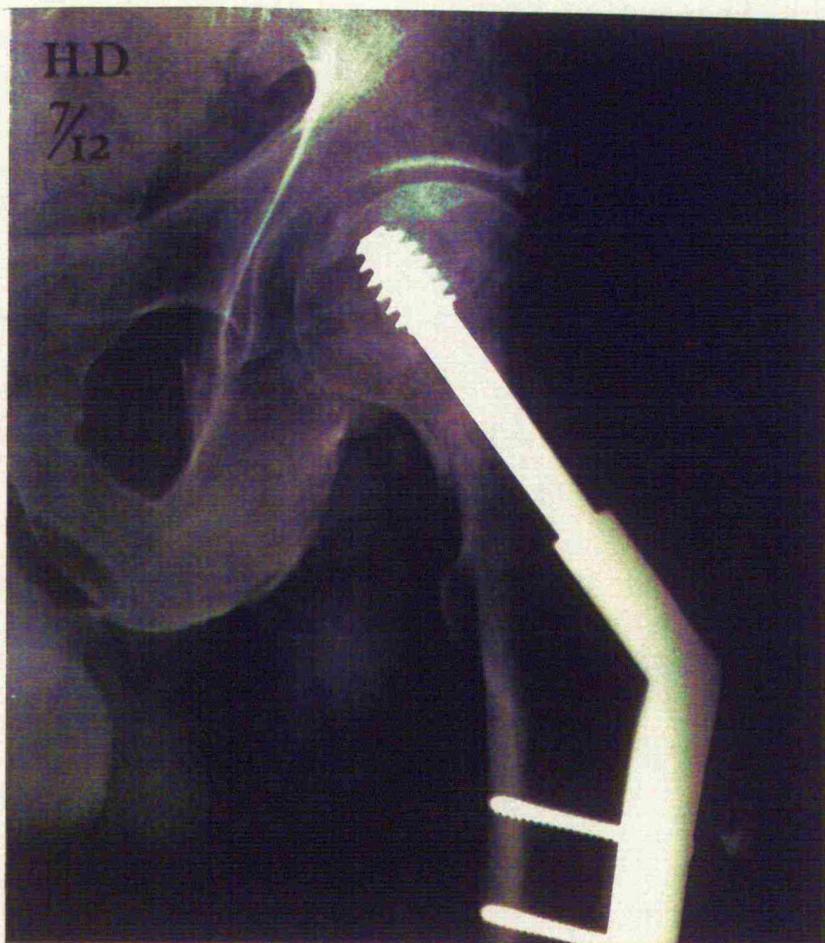
[fig 2.14 cont.]

d)



[fig 2.14 cont.]

e)



f)

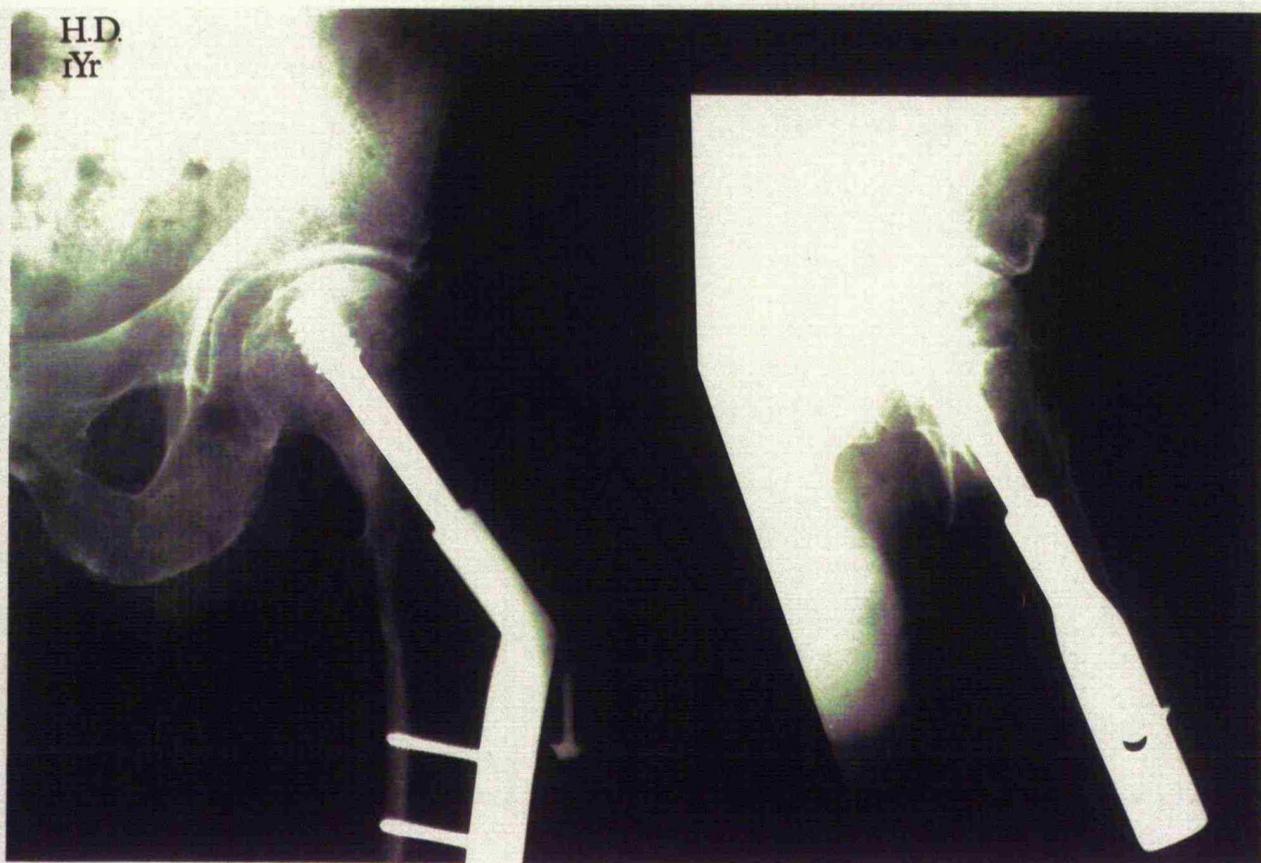
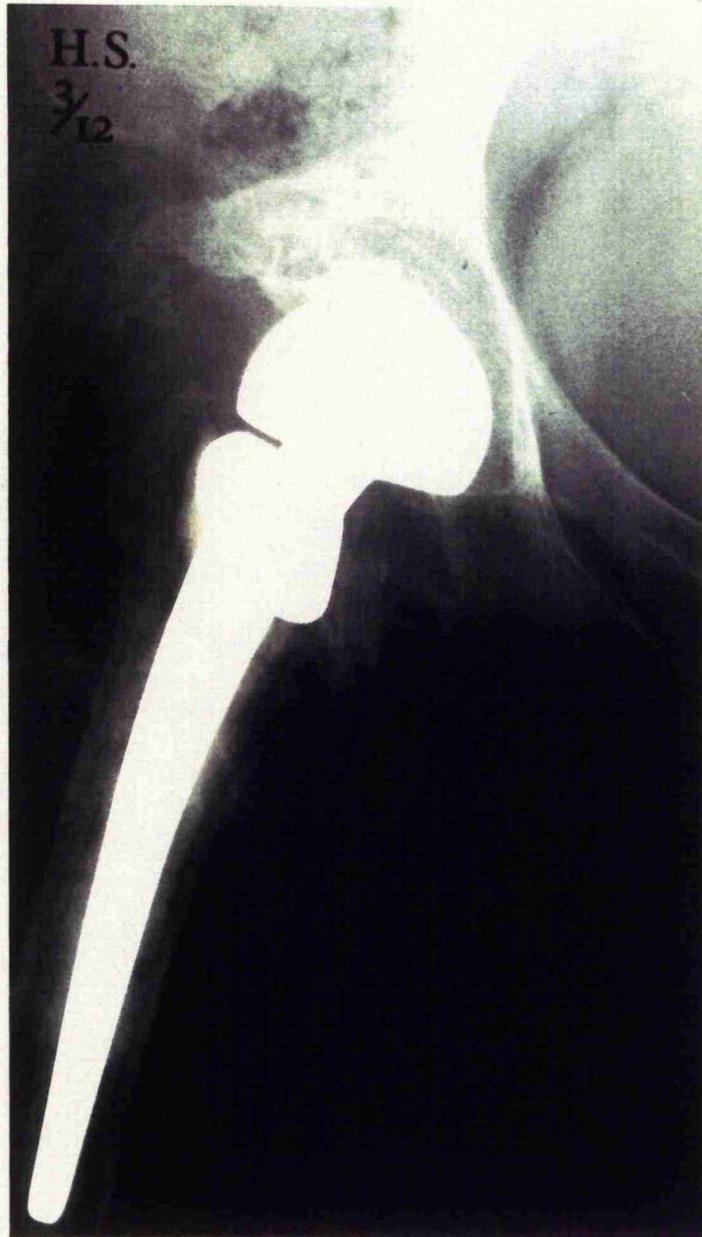


Figure 2-15 Monk prosthesis with heterotopic ossification (Brooker grade 3) secondary to dislocation



2.3.2 Results of Trial 2

For this group, because numbers were larger in each treatment arm than in trial 1, and follow up was more complete, data analysis has been carried out in a slightly different manner. This is because these results are considered to be definitive, the power of the study being made greater by the larger populations.

A total of 250 patients aged 80 years and over were randomised and followed up prospectively, 118 Monk and 132 Thompson prostheses. Differences between the groups in age, sex, pre-injury residence (community versus institutional care) and pre-operative levels of social dependency (carer versus self care) and use of walking aids (no stick or one stick only versus other) were slight and were not statistically significant at the 5% level (Table 2.5. Figures 2.16 - 2.17).

Table 2-5: Baseline demographic variables and pre-operative dependency and disability levels by type of prosthesis (Monk or Thompson).

	Monk (N=118)*	Thompson (N=132)*	p-value
% female (N)	85.6 (101)	86.4 (114)	0.86 ¹
% resident in the community (N)	84.8 (100)	79.4 (104)	0.27 ¹
% independent or one stick only (N)	75.2 (85)	79.5 (97)	0.43 ¹
% going out alone (N)	47.8 (55)	44.2 (57)	0.57 ¹
% independent of carers (N)	27.1 (26)	21.8 (24)	0.38 ¹
Median age (IQ range)	85 (82-88)	85 (82-88)	0.82 ²
Median MTS score (IQ range)	13 (11-13)	12 (10-13)	0.33 ²

*percentage are of non-missing responses

¹Chi-squared test

²Mann-Whitney U test

n = number of cases

IQ = interquartile range

some of these data are shown graphically below in figures 2.16 - 2.17

Figure 2-16 sex distribution trial 2

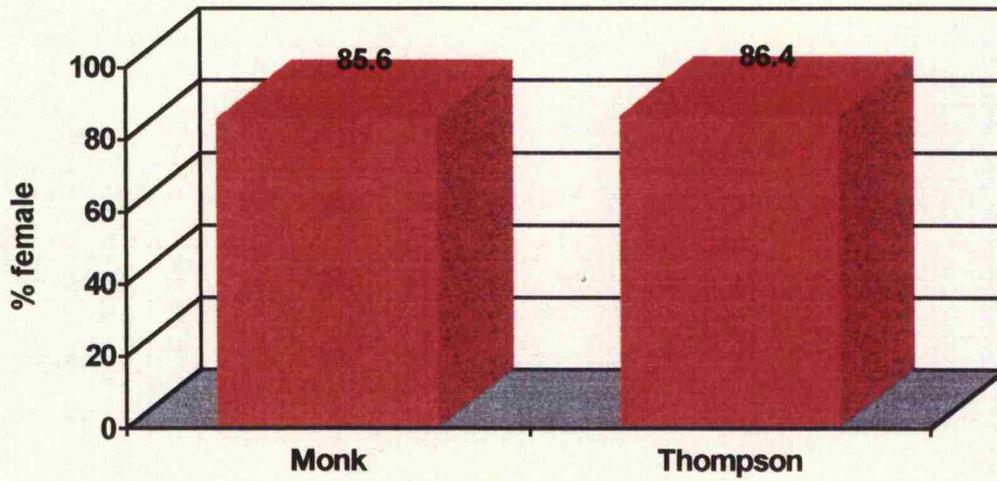
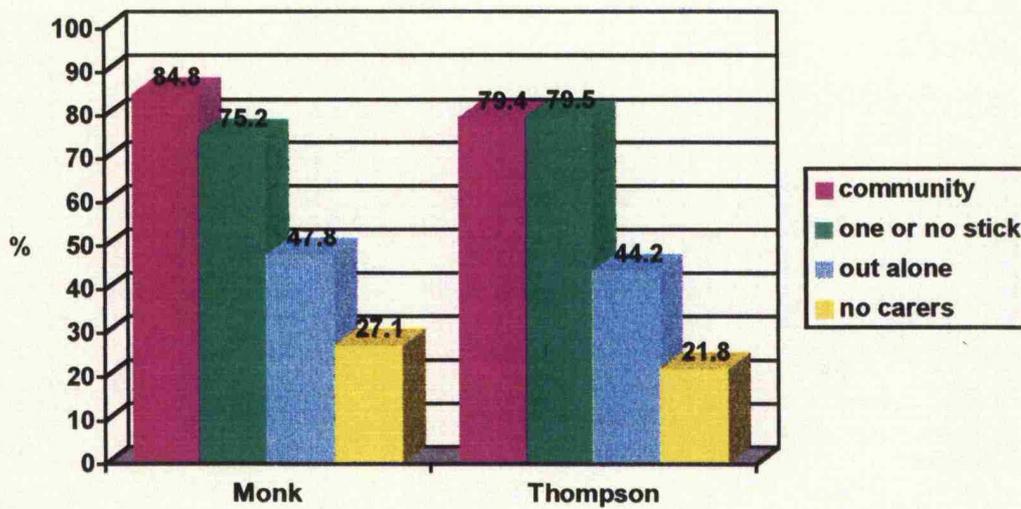


Figure 2-17 pre injury disability levels trial 2. % resident in the community, using one stick at most, going out alone, independent of carers.



Length of hospital stay was not significantly different for the two groups (Mann-Whitney U test, $p=0.40$) with the Monk prostheses spending a median of 17 days in hospital (interquartile range 13 days - 22 days) whilst the Thompsons spent a median time of 18 days (interquartile range 13 days - 23 days).

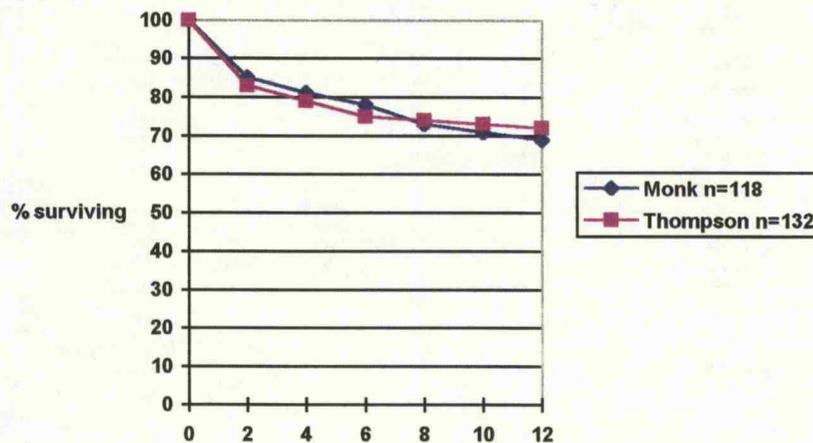
Slightly fewer of the Monk group died while an inpatient, 6.1% (7) compared to 10.8% (14) of the Thompsons (Chi-squared=1.65, $df=2$, $p=0.20$). 42.1% (48) of the Monk group returned to their pre-operative place of residence ("home") compared to 43.1% (56) of the Thompsons group (Chi-squared=0.02, $df=1$, $p=0.88$).

No significant difference was found between the two groups in survival time to one year from operation (Log rank test, $p=0.79$). Table 2.6 shows the proportion surviving to various times from the date of operation for the Monk and Thompson groups.

Table 2-6 Proportion (%) surviving to various times from operation in months by type of prosthesis (Monk or Thompson).

Months post op	Monk n=118	Thompson n=132
0	100	100
2	85	83
4	81	79
6	78	75
8	73	74
10	71	73
12	69	72

mortality over the first year, group 2



Follow-up data at approximately two years was available on 141 patients, 67 Monk and 74 Thompsons. Follow-up assessments were undertaken mainly in the outpatients clinic though a small number were reviewed by telephone (7) or at home (1). This was after exhaustive efforts to

trace non-attenders; elderly patients following this type of injury are notoriously difficult to track down because they tend to move between institutions if not living at home, or move out of the area to be near family. The median follow-up time for the Monk group was slightly longer than for the Thompsons (Table 2.7).

Data analysis (Table 2.8) was performed on an "intention to treat" basis. This is a statistical method which goes some way towards adjusting for any differential loss to follow-up between the two treatment groups. In principle, unless loss to follow up for any reason is either very small or exactly the same for all groups, we need to be sure that we still have two comparable groups differentiated by treatment. The outcomes of return to pre-injury state, limp, pain, and satisfaction with the operation were in two categories (yes or no); those dying prior to follow-up or otherwise lost were included in the "no" group. Using this intention-to-treat method of analysis, the Monk group appeared to have higher levels of post-operative functioning though differences were not statistically significant. Harris scores on those followed up did not differ significantly.

Table 2.7 shows figures and statistics performed on follow up patients only. Table 2.8 shows data of results using the intention to treat basis of analysis. Absolute values of functional outcomes are lower in table 2.8 because those lost to follow up or dead are considered to have a poor result. For example, 97% of patients with a Monk prosthesis who were followed up had no pain or mild pain only, but only 55% of this same group had no or mild pain if lost patients were presumed to have "failed " for this outcome. However, the statistical (p value) results of tables 2.7 and 2.8 are not affected except in the

'returned to pre-injury state' category where a p value of 0.03 in fact becomes insignificant at the 5% level ($p = 0.07$). This lack of difference between the two methods of analysis suggests that using the intention to treat analysis in this case may be superfluous because losses to follow up were similar for both groups.

To explore whether differences in the results shown in table 2.8 were masked by the differences in 1.follow-up time between the groups and 2. differences, albeit small, in pre-injury functional status (as shown in Table 2.5), logistic regressions were performed, to adjust for these potential confounding factors. For those who had died, follow up time was calculated as survival time from operation whilst for those alive but lost to follow-up, follow-up time was calculated as the length of stay in hospital because this was the only definite data about survival time available for these patients. Other potential confounders included in the statistical models were differences in age at operation, sex, pre-injury , MTS, and pre-injury walking independence.

After adjustment for all of these potential confounding factors there were still no significant differences between the Monk and Thompson groups for pain, limp, "satisfaction " or Harris score. However there was a significantly greater return to pre-injury state for the Thompson group (Wald chi-square=4.18, $df=1$, $p=0.041$). [The Wald chi-square is a non-parametric method which determines whether two samples come from the same population, and is sensitive to any type of difference between these indices for the 2 groups e.g. variability, skewness].

For the Thompson group, the odds of return to pre-injury state compared to Monk were 1.94 (95% confidence interval 1.03 to 3.67).

There were no significant differences at the 5% level in deep infection rate (Monk 4/118, Thompson 5/132), dislocation rate (1/118, 2/132), or gross (radiological) acetabular erosion (0/118, 3/132), using chi square analysis.

Table 2-7 Follow-up assessments by type of prosthesis (Monk or Thompson). Data calculated on followed up patients only. See table 2.8

	Monk n=67	Thompson n=74	p value
% returned to pre-injury state (N)	70.2 (47)	52.6 (41)	0.03 ¹
% with no limp (N)	37.3 (25)	32.1 (25)	0.29 ² NS
% with no or mild pain (N)	97.0 (65)	93.6 (73)	0.66 ² NS
% satisfied with operation (N)	94.0 (63)	91.0 (71)	0.51 ² NS
Median follow-up time in days (IQ range)	694 (390-864)	574 (380-783)	0.50 ² NS
Median Harris score (IQ range)	72.0 (67.0-79.0)	70.5 (65.0-77.0)	0.29 ² NS

¹Chi-squared test

²Mann-Whitney U test

Table 2-8 Follow-up assessments by type of prosthesis (Monk or Thompson). This uses the results as for table 2.7, but calculations are on an "intention to treat" basis, to include loss to follow up by death or otherwise. P values are prior to corrections for confounding factors (see text)

	Monk (N=118)	Thompson (N=132)	p-value
% returned to pre-injury state-subjective (N)	39.8 (47)	28.8 (38)	0.07 ¹
% with no limp - subjective (N)	21.2 (25)	17.4 (23)	0.45 ¹
% with no or mild pain (N)	55.1(65)	53.0 (70)	0.75 ¹
% satisfied with operation (N)	53.4(63)	50.8(67)	0.68 ¹
Median follow-up time in days (IQ range) ²	694 (390-864)	594 (380-790)	0.58 ³
Median Harris score (IQ range) ²	72.0 (67.0-79.0)	70.0 (65.0-77.0)	0.23 ³

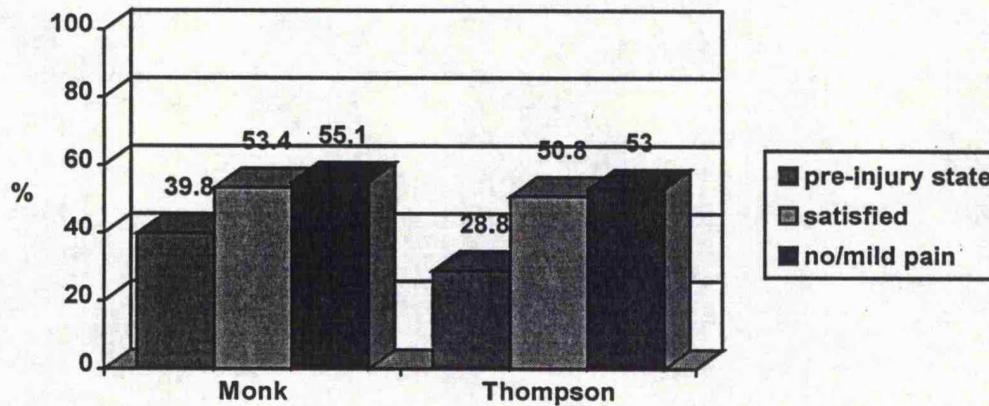
¹Chi-squared test

² These figures are only for survivors followed up, not those dying before 1 year

³ Mann-Whitney U test

some of these data are illustrated graphically in figure 2.18

Figure 2-18 Results trial 2. subjective outcome measures , after allowing for deaths and losses to follow up using the intention to treat basis



2.4 Discussion of results trial 1

Group 1 patients are considered to be the clinically most important in this study because of their younger age. The whole study was designed around the premise that five year results were paramount for the younger age group, and this was the figure upon which initial power calculations were made. These follow up results are therefore preliminary; nevertheless there are some interesting points raised.

The potential effects of non-blindness at follow-up altering the outcome of assessment should be noted, although efforts were made to avoid any influence. The reviewer made a clinical assessment of the patient and asked the follow-up questions prior to looking at the radiographs and therefore the chance of being aware of the type of implant during assessment was minimised, thereby minimising the influence of bias in practice. This is also true of the assessment of group two patients.

We can see that most of the patients, in the order of 95 %, were resident in the community prior to injury, and in economic terms it is better to aim to return these patients to their original state of independence than patients who are already dependent on some degree of residential care.

At first sight it seems that the Monk and AHS groups start off from a better baseline than the Thompson group who definitely seem to have lower levels of pre-injury ability to go out alone and walking aid requirements, though for each of these criteria there were no statistically significant differences. At five years these will all be taken into account, but differences are small and unlikely to have any influence on results. Given that patients were allocated to treatment groups at random, any such differences would not be expected as long as sufficient numbers were studied.

The most striking feature of results in this group at almost two years was the low level of satisfaction with treatment in the AHS group; this is not something which would be influenced by variations in preinjury state between the operation groups. It seems likely that this dissatisfaction is a function of the high failure rate of fixation early on. In addition, and something which is not clearly expressed in these results, most patients following hemiarthroplasty were pain free by the time of the first follow up appointment at six weeks; in contrast to that, patients undergoing fixation were usually still in pain at six months even if the fracture went on to unite successfully.

Results for the AHS group included patients who had been revised to total hip replacement following failure of fixation, on the "intention to treat" basis, rather than breaking them down into two subgroups of 1.AHS in situ and 2. THR in situ.

With this in mind the greater pain levels in the AHS group at follow up, though not statistically significant, suggest that if the THR patients were removed, the patients with fixation still in situ would fare even worse.

Numbers for this group need to be larger, and follow up needs to be longer. But it is clear at this stage that by five years there will need to be a rapid increase in the numbers of hemiarthroplasties failing by acetabular erosion, with a concurrent stabilisation of the failure rate of fixation, for fixation to be justified.

2.5 Discussion of results trial 2

In these patients over 80 years old, even after excluding those patients with high mortality indicators such as dementia, the one year mortality was still in the region of 30%. Early subjective outcomes in an elderly population should be considered paramount whatever the survival time, but perhaps moreso with such a high mortality, and the optimum realistic outcome should be return to the pre-injury levels of functioning. It could be strongly argued that subjective outcome measures may be more important in this group than conventional scores such as the Harris score (which is largely based on pain and functional ability anyhow) and radiographic findings, especially in the short term.

Acetabular erosion following hip hemiarthroplasty is generally considered to be a longer term problem in younger patients. The difference in the incidence of gross acetabular protrusion that we noted, with three cases in the unipolar group and none in the bipolar group was of interest because this is the theoretical benefit of the bipolar appearing to be demonstrated. However, these numbers were not statistically significantly different, and although the

reported cases had radiological protrusion, there were no symptoms requiring revision surgery, mobility being limited by other medical factors.

In the initial planning stages the power of the study was calculated from an assumed reoperation rate of 5% at five years, in which case there would be over 80% power to detect as significant (at the 5% level) a difference of 15% and over 95% power of detecting a difference of 20% between the two groups. However the current death rate of around 30% in the year after operation is somewhat higher than was assumed from the first year of the trial and considerably higher than the 12% annual death rate for this age group nationally (OPCS, 1990). This elevated mortality rate within the first year may have a multifactorial aetiology; it may be a reflection of the hypothesis that hip fracture in the very elderly is an expression of generally poor medical condition (especially if the cause of the fall is collapse or faint), and the treatment itself may be responsible by subjecting these patients to an anaesthetic, surgery and subsequent poor mobility during the recovery period. Future studies on this population should take these surprisingly high mortality figures into account when being planned.

The results on post-injury functioning reported here suggest that a unipolar prosthesis may give better short term results for octogenarians in terms of a return to pre-injury state. Whether this is sustained in the long term or offset by a higher revision rate will become clear in the future. At present though the theoretical advantages of the bipolar do not appear to manifest themselves in this group; it may be that in younger patients with a greater

baseline mobility the theoretical benefit from the bipolar may be more readily conferred.

There is no justification in the light of our current findings for the use of expensive bipolar instead of unipolar hip prostheses in patients over 80 years old, regardless of mental state or mobility.

It should be stressed that for both trial 1 and trial 2 these are interim reports of studies which will be completed at full five year follow-up for every patient.

2.6 Further work in this study

Numbers in both age groups need to be bigger, to enable the power of the study as originally calculated to be achieved; in particular, the numbers in the three arm study of group one should be bigger. Recruitment to the study has continued. By the end of the fourth year of trial entry, there were approximately 75 patients entered in each group of trial one, and 180 entered into each group in trial two; this is considerably larger than any of the other published randomised studies on this subject.

All patients will be visited in their home environment for assessment of ADL. This is the only truly accurate way of determining how social support resources should be allocated in the community. This will form an important part of the long term assessment and will be carried out by a research occupational therapist annually. This length of home follow-up assessment has not previously been carried out for such a prospective trial. At each visit there will be recorded the patients current home circumstances, social support input, actual required level of support (home helps, MOW, district nurse) and a formal ADL assessment. These can be

compared to previous measures and progress can therefore be charted. MTS will also be reassessed; this is because elderly patients tend to behave differently in hospital and the score recorded on admission assessment may be erroneously low.

3. The use of a subjective health indicator in a randomised trial of treatment of displaced intracapsular hip fractures.

3.1 Introduction

For many situations subjective outcome is considerably more important than objective measures. In particular this applies to elderly patients with limited goals and life expectancy, such as those which make up the majority of patients with hip fracture. Measuring health status of a population can be a complex process. Mortality rates are the oldest form of measurement of this type, but as longevity increases in affluent countries, mortality rates become less meaningful in terms of specific disease and so are losing favour. Also, mortality rates emphasise quantity rather than quality of life, and a decreasing mortality rate may not reflect an improved health status and quality of life of the survivors. Measures of morbidity are more appropriate.

These measures come in various forms; refined indices, disability indices and symptom/function indices.

Refined indices are quantitative measurements of disease prevalence and incidence.

Disability indices reflect the degree to which any form of impairment affects the functioning of an individual. One of the best known is the Activities of Daily Living (ADL) index (Katz et al 1963). Other forms have also been described. ADLs in general assess ability to manage daily activities such as bathing, toileting, dressing and feeding. Scores are assessed by observers. The Barthel

index (Mahoney and Barthel 1965) is probably the current gold standard ADL assessment.

Symptom/function indices overlap with disability indices, but tend to give a broader picture by including psychological aspects as well as physical abilities, including the patients perception of their own status. An example of this type of tool is the Sickness Impact Profile (SIP) (Bergner et al 1976), which may be self or interviewer administered. It has a disadvantage in that it can only be used with people who are regarded by themselves or others as being ill. It cannot assess patients who may be disabled in some way but are not actually seen to be ill.

For many aspects of care the patients perspective is invaluable. e.g. general attitudes to the patient, processes surrounding admission and discharge. In addition, patients views can be seen as an outcome measure in terms of the perceived benefits of treatment.

Desirable properties in patient satisfaction instruments include:

- 1 **Reliability**, with little change on test-retest studies (where an instrument produces the same results on two separate administrations where the object of measurement has not changed) and internal reliability (where similar questions should get similar responses).

- 2 **Validity**, which can be looked at by content validity, criteria validity or construct validity.

- 3 **Variability**. Respondents tend to be reluctant to express criticism of their health care, so that unless questions are chosen carefully results tend to be positively skewed (in favour of the 'good' result). Questions producing low variability should be eliminated. Disease specific instruments, such as AIMS

(Arthritis Impact Measurement Scales, Meenan 1980) have been used, but generic instruments are increasingly used because of their application to a wide range of diseases.

The MACL (Mood Adjective Check List) (Sjoberg et al 1979) is a Swedish questionnaire which assesses subjective changes in mood, and has been compared with the Nottingham Health Profile (NHP) directly (Borgquist et al 1992) (See section 3.2.3).

QALY's (Quality Adjusted Life Years) attempt to apply a single global measure to health, particularly for helping to decide on resource allocation. A well known example of such a measure is a study by Rosser & Kind (Rosser and Kind 1978), where conditions are allocated scores combining degrees of distress and disability. A similar design method was used to develop the Quantity of Well-being Scale (Kaplan et al 1989).

3.2 The Nottingham Health Profile

The Nottingham Health Profile (NHP) is a two part instrument which was developed over six years to measure perceived health problems and the extent to which such problems affect normal activities (Hunt and McEwen 1980A). It was designed to overcome some of the problems of existing subjective measures, and to be appropriate for use in the following ways:

1. For evaluation of medical/social interventions, in pre-test, post-test designs.
2. As an outcome measure for group comparisons
3. As a survey tool with specified groups such as the elderly and the chronically ill

4. As an adjunct to clinical interviews

The effects of ill health encompassing social, psychological, behavioural and physical functioning were addressed during development of the NHP. Statements were identified which were positive, easily understood, and answerable by 'yes' or 'no'.

The NHP has been validated by its designers (Hunt et al 1980, 1981) using several groups of patients from a general practice population. For example: 1. Elderly (>65 years) very fit patients, elderly fit, elderly patients with minor health/social problems and the elderly chronically ill were compared. The NHP distinguished well between the groups.

2. Significant differences were noted between frequent GP attenders and rare attenders for all indices in that study.

Reliability of the NHP i.e. consistency over time, was also established by the designers using the test/re-test technique over an eight week gap (Hunt et al 1981). Correlation for both part I and part II was highly significant for all indices in that study.

Age and sex norms for a general practice population for all NHP indices have been published by the designers, but these should be considered mainly of interest in showing differences between scores in different age and sex groups rather than be used as baselines for studies on other populations.

It was accepted by the designers that the NHP did have limitations which should be acknowledged in any study purporting to use it as an outcome measure. These were summarised in the NHP manual;

1. Items on part I are 'severe' situations, to avoid picking up too many false positives. As a result, patients feeling slightly 'under the weather' may not score.
2. In patients with few 'yes' answers it may be difficult to demonstrate change.
3. 'Zero' scorers cannot demonstrate any improvement on subsequent testing even though they may feel better.
4. Not all possible disabilities are covered by the NHP.
5. Part II answers should not refer to areas affected in the *absence* of a health problem.
6. Statistical analysis could be cumbersome with six scores from part I plus a possible seven scores from part II, especially if other variables need to be taken into account.
7. The NHP measures health by its absence i.e. all the statements describe problems

3.2.1 NHP Part I

The NHP consists of two parts; part I and Part II. Six parameters are

used in part I :

pain

physical mobility

sleep

energy

social function

emotion.

There are 38 statements in part I (see appendix 1). Each statement is answered with 'yes' or 'no', from which scores for each of these six indices are calculated. There is not a single index score. Each question contributes to the final score for one of the six parameters, for example the pain score index is composed of eight questions. The score for each parameter is out of one hundred. The lower the score the better is the performance for that index- not to be confused with the commoner protocol for a higher score being better e.g. as in the Harris hip score. The 'healthiest' score for each parameter is therefore zero, the worst is 100.

Statements for part I are presented in random order on the NHP. Each question is weighted in value for scoring purposes (see appendix 2, weighted scores for 'yes' responses on part I). Because of the random order of questions and weighting of the scores it is difficult for patients to bias the scoring although any subjective score is potentially prone to such problems, and some consider that weighting is not always as scientific as it could be (Jenkinson 1991).

There are significant sex differences in normal control groups (Hunt et al 1985), therefore all data analysed to compare two or more population groups must be standardised for differences in the sex profiles of each group.

3.2.2 NHP Part II

Part II consists of seven particular areas of daily life which may be affected by health. These are expressed simply as yes/no to each question and are scored as "1" for 'yes' and "0" for 'no' (appendix 1). The seven statements described in

the original work were not all utilised in this study- the five most relevant areas were chosen. These are:

1. Looking after the home
2. Social life
3. Home life
4. Interests and hobbies
5. Holidays

3.2.3 The NHP In Orthopaedics

The NHP has been used previously in orthopaedic surgery in a limited fashion, but not as a measure in a randomised prospective study. Wiklund (Wiklund and Romanus 1991) used it to assess quality of life before and after total hip replacement for total hip replacement in 56 patients. They concluded that quality of life after total hip replacement was similar to a healthy reference group, and that both parts of the NHP were valuable in the evaluation of the result of as well as the indications for total hip replacement.

Borgquist (Borgquist et al 1992) used the NHP in hip fracture patients. The NHP and MACL (Mood Adjective Checklist) (Sjoberg et al 1979) were completed by 100 patients at 6 and 12 months following surgery for proximal femoral fracture, and the results of these were compared with functional status as measured by ADL assessment at 4 months. The patients were all capable of completing the questionnaires because only those if admitted from and discharged to their own homes were selected to take part. In the NHP assessment it was pain and physical mobility that was most affected by the

fracture, but these were in accordance with the assessment of the physiotherapy evaluation; that is, it was felt that no more information was gained from the NHP than from the objective outcome.

The use of a subjective health profile such as the NHP in this randomised prospective study into the treatment of displaced intracapsular proximal femoral fracture is an important step for three main reasons:

1. subjective assessment of well-being is paramount in an elderly population,
2. the clinical results of the study itself can be assessed using the subjective criteria, and
3. the viability of using such a profile in conjunction with or instead of more usual objective measures can be assessed.

3.3 *Patients and Methods*

The study population were patients in the randomised study described in chapter two.

Exclusion criteria were as discussed in chapter 2, and included a mental test score (MTS) of less than 5/13. The main aim of this was to exclude patients known to have a high mortality following hip fracture (Wood et al 1992). A secondary benefit of this exclusion is that demented patients are not suitable candidates to complete a subjective health profile, albeit a fairly simple one requiring only yes or no responses.

3.3.1 Questionnaire Method

All patients in the study were reviewed clinically at six weeks, and then annually with Harris hip score assessment and radiographs. Patients in the internal fixation group were seen more frequently, until union or early failure requiring revision. In addition to these conventional measures, at six months postoperatively all patients were sent the NHP to complete and return. Hospital Patient Administration System (PAS) data was checked for the correct address and to ensure that patients were still alive, prior to sending the NHP with a pre-paid return envelope and covering letter (appendix 3).

With these thorough preliminary backup checks, only one letter and NHP was sent out to each patient. Non-responders were not chased up.

Data was entered onto a customised database which automatically calculated the weighted scores for each of the questions .

3.3.2 Statistical methods

Differences in baseline variables (table 3.1) between responders and non-responders were assessed by log linear models with adjustment for age. Differences in the NHP Part I indices between operation types were assessed in each age group (65-79 years, >80 years) by the Cochran-Mantel-Haenszel [CMH] statistic with strata defined by sex. The CMH method is a means of deriving the pooled odds ratio from a table, and is equivalent to a sex adjusted Kruskal Wallace test. The adjustment for sex differences was undertaken since there was some imbalance in the sex ratios between the operation types and the NHP scores are sex specific as has been noted. Some of the data, where appropriate, was analysed with the Kruskal-Wallace H test, a non-parametric alternative to one way

analysis of variance; essentially, it tests whether several samples could come from the same population.

The statistical software package SPSS was used for data analysis.

3.4 Results

3.4.1 response rates

At the time of data analysis, 432 patients who had been randomised were at least 6 months post surgery. Of these, 79 patients (18.3%) had died before the time the NHP was due to be sent i.e. 18.3% died within the first six months. Therefore 353 profiles were sent out.

258 completed replies were received (73.1% crude response rate), with 238 being correctly completed (67.4% usable response rate)- these were termed 'responders'. The 20 spoiled replies had usually been completed by a family member on behalf of a confused relative, though in one case the NHP was completed on behalf of a deceased patient.

95 (26.9%) were not returned at all- these were termed 'non-responders'. These were not pursued further except to recheck that the correct address had been used and that the patient was still alive at the time of sending. In all cases they had been.

Responders had a mean age of 80.2 years (non-responders 82.7) and mean MTS of 12.2/13 (non responders 11.4/13). Group 1 patients (age 65-79) gave a 74.3% usable response rate (110/148); group 2 patients (age >80 years) gave 62.4% (128/205) usable response rate. *Baseline variables for responders in both groups 1 and 2 are shown in table 3.1*

The statistical analysis for differences between all indices has been done standardising for differences of sex distribution between the two groups.

Table 3-1 Baseline characteristics of responders to the NHP by age group and operation type (A=AHS, M=Monk, T=Thompson).

	Group 1 65-79 yrs			Group 2 80+ yrs	
	A (N=37)	M (N=39)	T (N=34)	M (N=56)	T (N=72)
Age (yrs)					
Mean	73.4	74.5	74.4	85.8	85.0
SD	4.3	3.9	4.4	4.9	3.5
Follow-up (days)					
Mean	177.7	175.3	169.4	175.5	161.1
SD	45.0	42.9	46.8	43.9	41.2
Sex					
% Female	70.3	66.7	88.2	85.7	88.9
(N)	(26)	(26)	(30)	(48)	(64)
Aids					
% independent	74.3	75.7	63.6	35.7	36.9
(N)	(26)	(28)	(21)	(20)	(24)
Mobility					
% independent	89.2	89.7	82.3	58.2	57.1
(N)	(33)	(35)	(28)	(32)	(40)

3.4.2 Results for NHP Part I

3.4.2.1 Group 1, ages 65-79 years [table 3.2]

There were replies from 37 AHS patients (mean age 72.9 years, range 65-78, SD +/-4; mean follow-up 178 days, SD +/-44.7), 39 Monk (74 years, range 66-79, SD +/-4; follow up 175, SD 42.9) and 34 Thompson (73.9 years, range 65-78, SD 4.4; follow up 169, SD 46.8). There was no significant differences in age or follow-up by Kruskal Wallace analysis at the 5% level..

There were significantly better scores for physical mobility and sleep in the Monk group than Thompson or AHS groups. The Monk prosthesis was also better for the other indices, but not significantly using Kruskal Wallace analysis. The AHS scored badly for pain compared to the two prostheses.

3.4.2.2 Group 2, ages 80+ years [table 3.2]

There were replies from 56 Monk (mean age 85.8 years, range 80.2-99.5, SD +/-4.8; mean follow-up 176 days, SD +/- 43.5) and 72 Thompson patients (85 years, range 80.1-95.3, SD 3.5; follow up 163, SD 43.5). No significant differences using Kruskal Wallace analysis were noted.

The Monk scored better in every index apart from sleep, though not significantly at the 5% level using Kruskal Wallace analysis.

3.4.2.3 both age groups combined

For a comparison of Monk Versus Thompson between larger numbers, both age groups were combined and patients having internal fixation were excluded. There were 95 Monk (mean age 80.7 years, range 66-99, SD +/-7.2; mean follow-up 175 days, SD +/-43) and 106 Thompson (81.1, 65-95, 6.3; 165, 44.4). There were no significant differences using Kruskal Wallace analysis at the 5% level.

Again the Monk was better or equal for every index, though not significantly at the 5% level.

Table 3-2 Median levels of indices by age-group and sex for operation type (A=AHS, M=Monk, T=Thompson), for Part I of the NHP. Statistical analyses to look for differences between treatments were performed standardising for sex differences even though they are shown separately here.

	Group 1			Group 2	
	65-79 years			80+ years	
	A	M	T	M	T
Males					
Pain	18.5	10.6	5.8	0.0	10.0
Physical	44.0	23.4	44.3	46.1	46.2
Sleep	28.7	0.0	25.5	25.5	28.7
Energy	60.8	24.0	24.0	30.4	50.0
Social	9.7	0.0	0.0	0.0	0.0
Emotion	7.2	0.0	3.5	7.2	9.3
Females					
Pain	22.9	0.0	26.0	38.8	11.4
Physical	12.7	12.7	67.0	66.6	61.5
Sleep	12.6	0.0	66.8	34.6	20.6
Energy	0.0	24.0	68.4	48.8	80.4
Social	0.0	0.0	19.7	22.5	22.5
Emotion	7.1	0.0	38.4	15.6	25.0

3.4.3 Results for NHP Part II

The results of the 5 sections used in this part of the NHP are shown in table 3.3. A 'Yes' or 'No' answer was given to the questions, 'Does your health interfere with:

- 1 **Looking after the home**
- 2 **Social Life**
- 3 **Home Life**
- 4 **Interests and hobbies**
- 5 **Holidays**

In group 1 patients, those with a bipolar prosthesis had significantly less trouble in looking after the home and in going on holiday than the fixation group. For these two indices there were no differences between the unipolar and internal fixation groups. For the other 3 indices (social life, home life, interests/hobbies) there were no significant differences between any of the treatment groups. There were no differences in the other measures.

In group 2 patients, there were no differences between the unipolar and bipolar for any of the five indices. Figures 3.1 and 3.2 display these results graphically.

Table 3-3 Data for NHP Part 2, for group 1 (age 65-79) and group 2 (age >80) of the study

Does Health Interfere with looking after the home, social life, home life, interests/hobbies, holidays? Yes(%)

	AHS Gp 1 (n=37)	Thompson Gp 1 (n=34)	Monk Gp 1 (n=39)	p value	Thomp Gp 2 (n=72)	Monk Gp 2 (n=56)	p value
Looking after the home	24 (65)	20 (59)	15 (38)	NS	49 (68)	38 (68)	NS
Social Life	12 (32)	13 (38)	12 (31)	NS	39 (54)	33 (59)	NS
Home Life	6 (16)	5 (15)	4 (10)	NS	12 (17)	8 (14)	NS
Interests/Hobbies	15 (41)	10 (29)	8 (21)	NS	35 (49)	25 (45)	NS
Holidays	19 (51)	15 (44)	6 (15)	P0.003	38 (53)	25 (45)	NS

Figure 3-1

NHP Part 2 Results Gp 1 (Age 65-79)

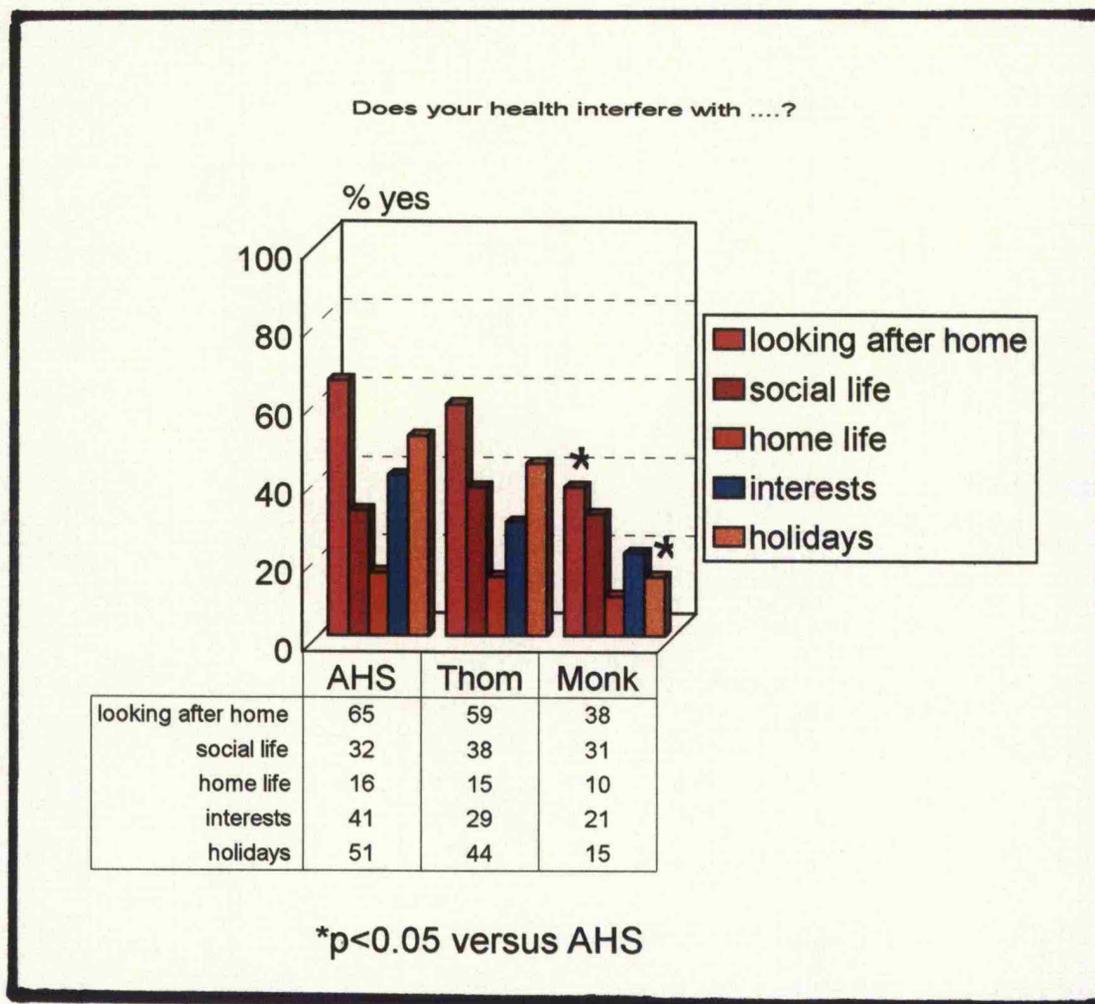
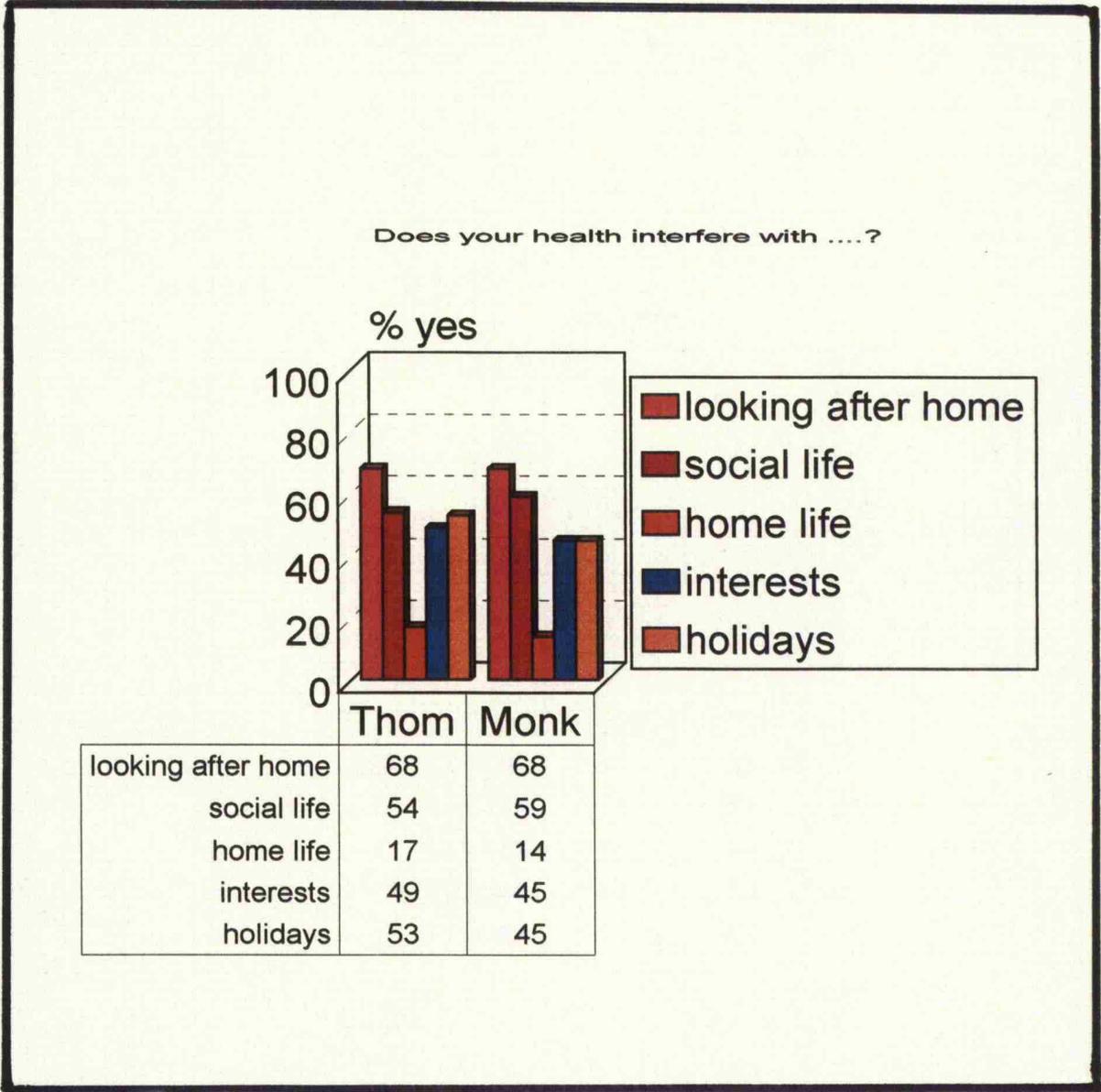


Figure 3-2

NHP Part 2 Results Gp 2 (Age >=80)



3.5 Discussion

There are certain practical points which became evident in using the NHP. A computerised database is required because of the fairly complicated weighted scoring system and because the six indices in part I are expressed separately, which means there are a large number of figures to analyse. In normal historical controls there were differences between the sexes for all indices, therefore standardisation for sex (and age) had to be undertaken before statistical analysis could be performed (Hunt 1986).

The 67.4% usable response rate compares well to the response rate of 68% which was received from a control population aged 20 years and over by the developers of the NHP (Hunt 1986).

There is no doubt that response rate is one of the limitations in the use of postal questionnaires for subjective health assessment. Considering the age of the subject population this response rate for a single approach is acceptable. In another study using NHP in hip fracture patients (Borgquist et al 1992), all 100 patients assessed agreed beforehand to complete the NHP; at six months the response rate was 98%. This is clearly not directly comparable to our study. At one year in the same study a repeat send with reminder only had 83% response even in this prepared group.

The fact that the AHS scored badly on the pain index compared to the prostheses is probably a reflection of the low union rate for this injury at six months both in our series and others (Barnes et al 1976).

The six month mortality of 18.3%, even after excluding from the trial those patients who were anticipated to die early (namely those with MTS < 5/13), supports further the rationale for taking the results of early assessment as an outcome measure seriously because in a group with limited life expectancy it is reasonable to say that optimum subjective outcome should be reached quickly rather than aiming for a long term satisfactory result; although this is relevant mainly to the older age group.

There is an impression that the bipolar prosthesis may be providing a better subjective outcome at six months, particularly in the younger patients, although the statistics are not conclusive. It may be that younger patients seem to benefit more because a minimum baseline mobility is necessary before the bipolar can confer any benefit.

Harris Scores were not assessed at this six month point so no direct comparison can be made though the trend of Harris Scores at one year support our impression. At the five year follow-up, all patients randomised into the study are going to be assessed clinically with the Harris score, radiologically, and subjectively with the NHP. Thus a correlation will be possible between the two assessment methods at that stage.

In practical terms it has been shown that a postal health questionnaire received a good response rate in an elderly population and characteristics of likely responders have been identified. After a single send patients aged 65-79 years gave a 74% usable response rate, compared to 62% for the over eighties, and responders had a higher MTS as might be expected. It seems that the use

of a questionnaire like this in patients over 80 years old may not get an adequate response rate.

In clinical terms, with appropriate statistical methods to standardise for sex ratios within groups, a validated outcome measure for group comparison is available.

With these conclusions in mind, the NHP will be used as one of the key outcome measures in the final report of the major clinical study (chapter 2).

There is an important role for the NHP as an additional intermediate assessment or complement to standard hospital review. The use of subjective health indicators in general should be encouraged in orthopaedic practice and research.

4. Temperature generation within the femoral head from using the triple reamer during internal fixation of proximal femoral fractures

4.1 Introduction

The vascularity of the femoral head is vulnerable to injury, particularly following displaced intracapsular hip fracture, as has been discussed in chapter 1. When the treatment is by reduction and internal fixation it is important to consider every step of the treatment process and to reduce the potential for further damage to the blood supply at each step.

Heat generated by the drill during reaming for insertion of the internal fixation implant, is something which should be under the control of the surgeon and is therefore avoidable or at least controllable.

Thermal damage to the femoral head at the time of surgery may cause problems in two ways. Firstly, bone necrosis in the narrow zone around the thread of the implanted screw may compromise the stability of the screw-bone fixation. This in turn may lead to delay in union of the fracture, and therefore an increased risk of mechanical failure. Secondly, damage to the microvasculature in the zone around the screw may potentially exacerbate the problems of avascular necrosis and segmental collapse of the femoral head which can occur later.

Temperatures as low as 44-47 degrees centigrade ($^{\circ}\text{C}$) have been reported to cause damage to bone in rabbits (Eriksson 1984). These figures were obtained from an extensive in vivo study using an titanium optical thermal

chamber. To start off with, recognition of bone necrosis was evaluated histologically and histochemically; histochemical analysis was found to be more sensitive. Typical reactions of bone to heat of 53 °C for one minute was acute increase in blood flow followed by cessation of blood flow in almost all small blood vessels, which returned after about one hour. At two days, there was no active blood flow seen, and at one week the vessels had disappeared with new ones beginning to form (Eriksson 1984), being fully formed by about 5 weeks. Fat cells were damaged in a similar pattern. Bone resorption was a delayed but more long-lasting phenomenon, starting about 3 weeks after the thermal damage, and becoming the dominant microscopic feature at 6-8 weeks.

Threshold temperatures for bone injury were also studied. 50°C for one minute gave a consistent bone injury, as did 47°C for 5 minutes. In 40% of cases, heating to 47°C for 1 minute caused bone resorption by 3 weeks, though the damage was less than that caused by 50°C. Bone regeneration capacity was completely extinguished by 50°C for one minute, partially reduced by 47°C for one minute, and not reduced at all by 44°C for one minute. Therefore at somewhere between 44°C and 47°C it is presumed that identifiable bone necrosis can occur. Following intracapsular fracture the human femoral head is probably less resilient than rabbit bone because of its tenuous vascularity, and therefore these threshold temperature levels may safely be considered applicable to the clinical situation.

High speed power tools such as drills and reamers are known to cause high temperatures, especially in cortical bone where temperatures in the region

of 90-100°C are not uncommon (Matthews and Hirsch 1972, Eriksson et al 1984, Calder and Harper unpublished data this centre).

Factors which affect the temperature rise in bone cutting and drilling are numerous. A lower drill speed is generally recommended to reduce thermal damage (Matthews and Hirsch 1972, Lavelle and Wedgewood 1980). In the absence of cooling (e.g. by saline irrigation), speeds in the region of 750-1250 revs/min have been recommended (Saha et al 1982). Although drill speed is important, one of these studies (Matthews and Hirsch 1972) found that the force applied to the drill was more important than drill speed as a factor in both the magnitude and duration of cortical bone temperature elevation; increased applied force was associated with *decrease* in the maximum temperatures.

Drill diameter may be important, in that drills of larger diameter may cause higher temperatures (Tetsch 1974). The triple reamer for the SSP is certainly a larger diameter than most drills used in orthopaedic surgery (*viz.*).

Worn drills cause greater temperature rises than sharp drills (Matthews and Hirsch 1972, Lavelle and Wedgewood 1980), and this is can certainly be a persistent problem in financially constrained trauma units.

Where fixation is by the SSP device, a triple reamer is used for the preparatory reaming. This triple reamer (figure 4.1) is a convenient tool for reaming the proximal femur and femoral head when using a sliding screw and plate device. This is because it has three reaming components of different diameter, each serving a different purpose. A narrow central first stage to ream for the thread of the large lag screw; a broader tapered second stage to open

up the lateral cortex so that the barrel of the plate will fit in place; and a third stage which can bevel the lateral cortex to allow the plate to lie flush with the bone.

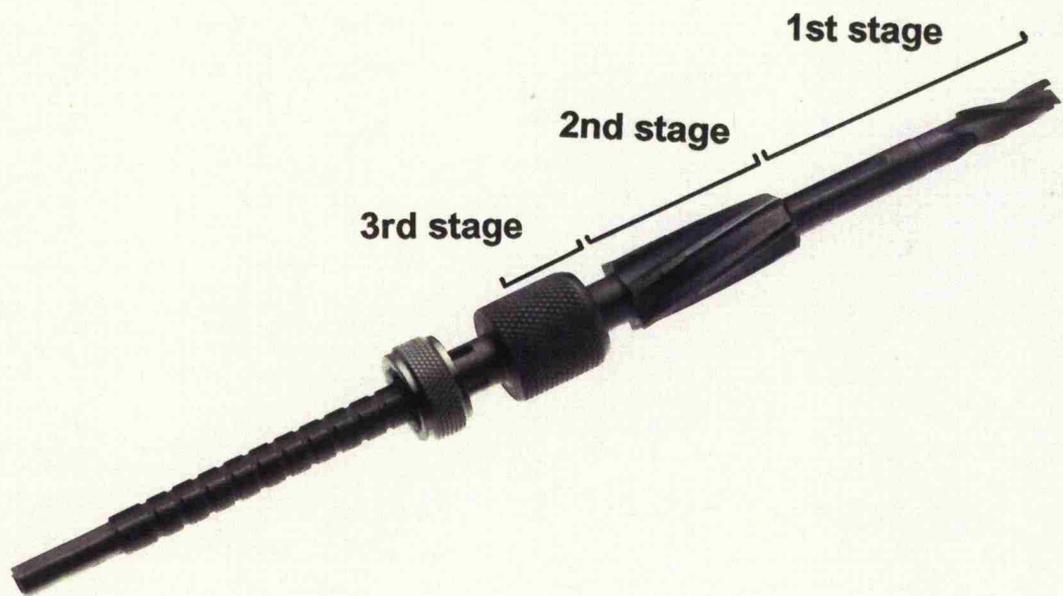
Standard technique is for the guide wire to be measured after insertion across the fracture site to give the screw length. Reamer length is then set to allow the tip of the reamer to be within 5-10mm of the articular surface of the femoral head once fully inserted.

The hardest bone, and therefore that which requires most work to ream, is that in the lateral cortex. Linde (Linde et al 1986) observed qualitatively that the reamer got particularly warm during reaming of the barrel hole in the lateral cortex, although temperatures were not measured; it was hypothesised that the tip of the small diameter first stage of the drill would by then be in the femoral head to which heat may have been transmitted.

Figure 4-1

The Triple Reamer shown a) intact b) dismantled

a)



b)



Svenningsen (Svenningsen et al 1984), who has some of the best results using the sliding screw plate, used separate reamers for the lateral cortex and the femoral neck and head. This variation in technique may be a contributory factor to the good results.

As a result of the design of the triple reamer it is possible that thermal damage is produced in the femoral head while the lateral cortex is being reamed. If so, it is just within this zone of the femoral head that the blood supply and vitality of the cancellous bone is most vulnerable following displaced intracapsular hip fracture and superadded thermal damage may not be tolerated.

An alternative reaming technique that reduces thermal damage within the femoral head may lessen the risk of failure of fixation due to both early mechanical and late vascular complications.

4.2 Patients and Methods

A model proximal femur was split in the coronal plane of the neck and a triple reamer was inserted at the measurement which would have been used in the clinical situation i.e. the distance from lateral cortex to 5mm within the articular cartilage. It can be seen that the tip of the reamer would spin within the femoral head while work is being expended in reaming the lateral cortex (Figure 4.2). The use of the triple reamer may be modified by setting the reamer to its shortest length during reaming of the lateral cortex. By doing this, the drill tip will not be in the femoral head during this phase, and therefore may not cause thermal damage (Figure 4.3).

Figure 4-2

The 2nd stage of the triple reamer reaming the lateral cortex while the 1st stage is spinning within the femoral head

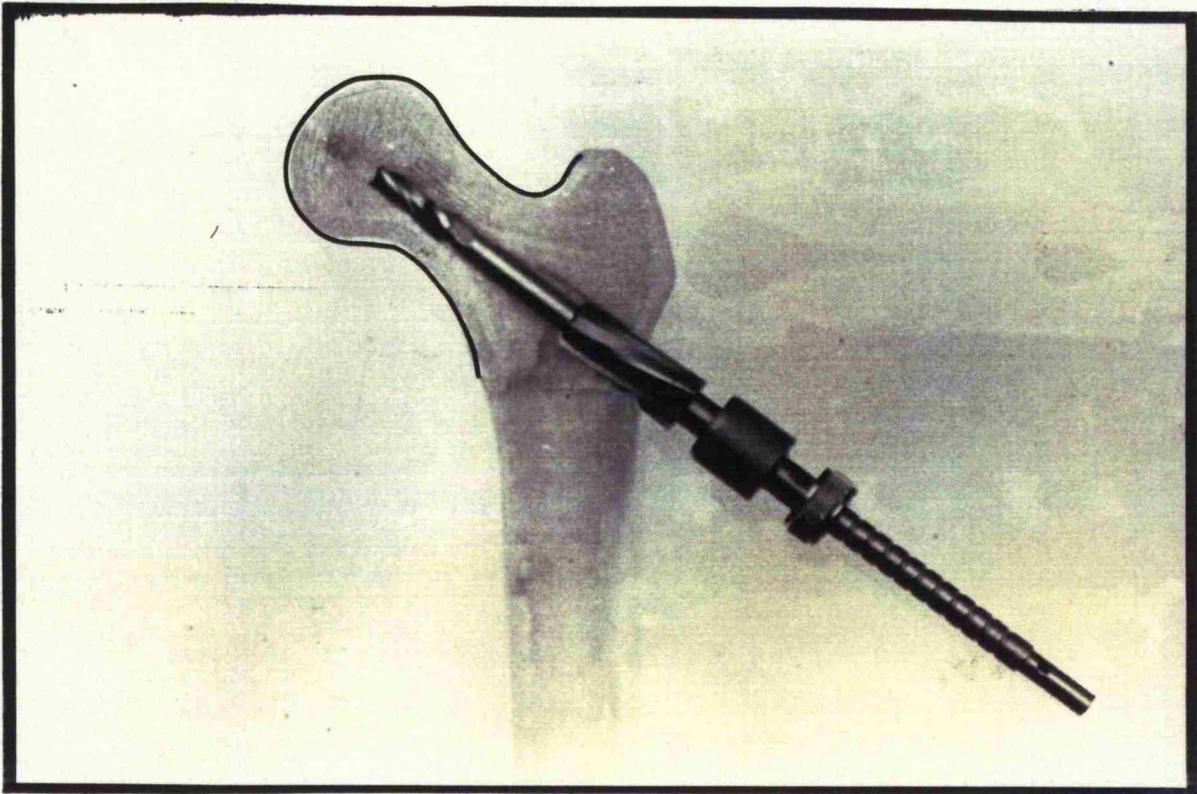
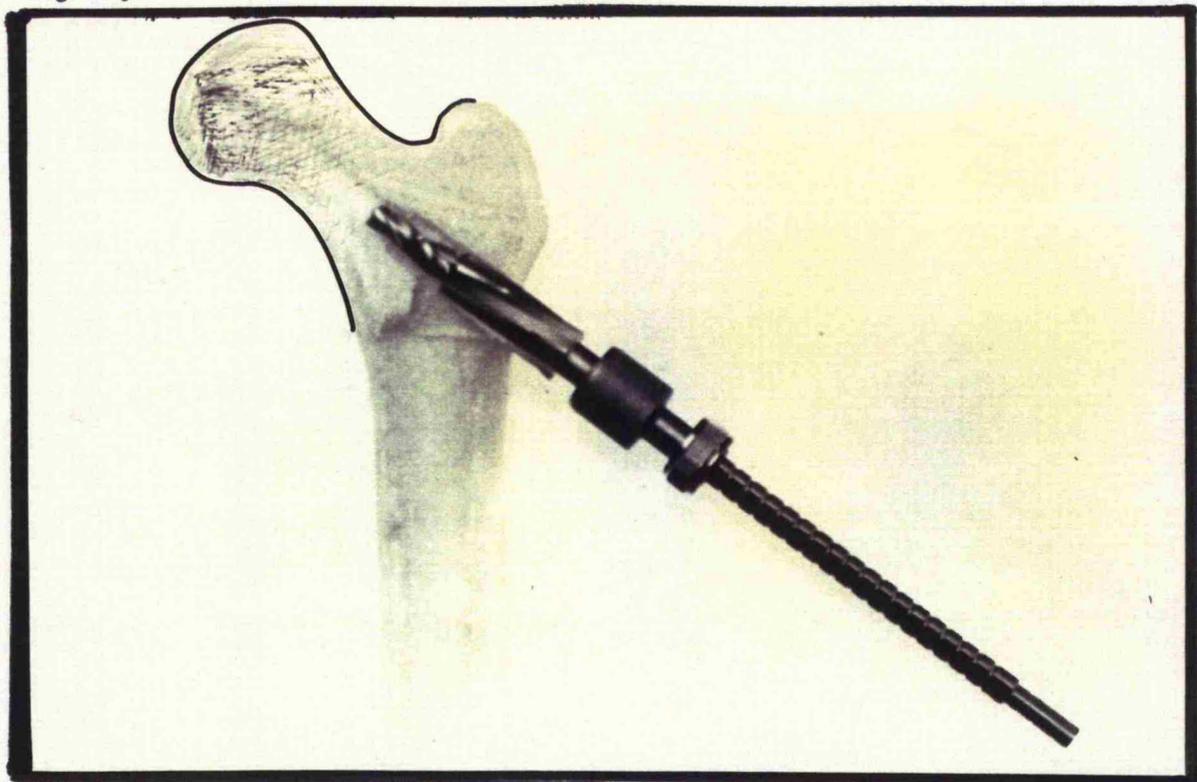


Figure 4-3 The 1st stage is not within the femoral head using a modified technique. [CF Fig. 4.2]



To try and avoid this, a modified reaming technique was employed. The steps in the process of modified reaming were:

1. Setting the triple reamer to its minimum length (60mm with the instrumentation used) to ream the lateral cortex (Figure 4.4)
2. Resetting to the measured length of the lag screw (lateral cortex to about 5mm from articular cartilage), to complete the reaming of the femoral head as a separate procedure (Figure 4.5).

Patients included were female, aged over 60 years, with proximal femoral fracture with an intact lateral cortex, requiring treatment by a sliding screw plate. Nineteen patients were randomised to either standard or modified reaming as described. The same surgeon performed all cases using the same instrumentation each time. Reamers were of the same age and condition, new at the start of the study. The same air drill was used for all cases, powered at the same pressure each time, with a free running speed of 350 revolutions/second. Reaming pressure applied by the surgeon was standardised as far as possible.

Temperatures within the femoral head were measured by insertion of a thermocouple probe into the femoral head immediately after reaming. The probe used was a type K thermocouple, made from stainless steel, with dimensions of 100mm by 3.2mm with a ground, chiselled tip. The response time of the probe was 0.9 seconds for 0-60°C. The probe was installed and sealed into a 5 ml syringe body to make it sterilisable and reusable for the purposes of this study.

The peak temperature reached and the length of time at which temperature was above 44°C was recorded for each case with a handheld digital thermometer (accuracy +/- 0.2°C, resolution 0.1°C) and a chart recorder

readout. Figure 4.6 shows the probe and the handheld recorder. Figure 4.7 shows the probe in our model, with the tip at the measurement point.

In preliminary tests simultaneous temperature recording and reaming was attempted but was not found to be practically feasible, because of the difficulties in measuring drill tip-probe distances on biplanar radiographs (Andersen and Bruun 1989), and because temperature changes outside 2-3mm from the drill track were negligible.

Analysis of data was with 'epi-info' software, using the Kruskal Wallace H test which is one of the non-parametric alternatives to a one way analysis of variance (ANOVA); this was required because no assumptions about the underlying distributions of the temperatures could be made.

Figure 4-4 triple reamer set to minimum length

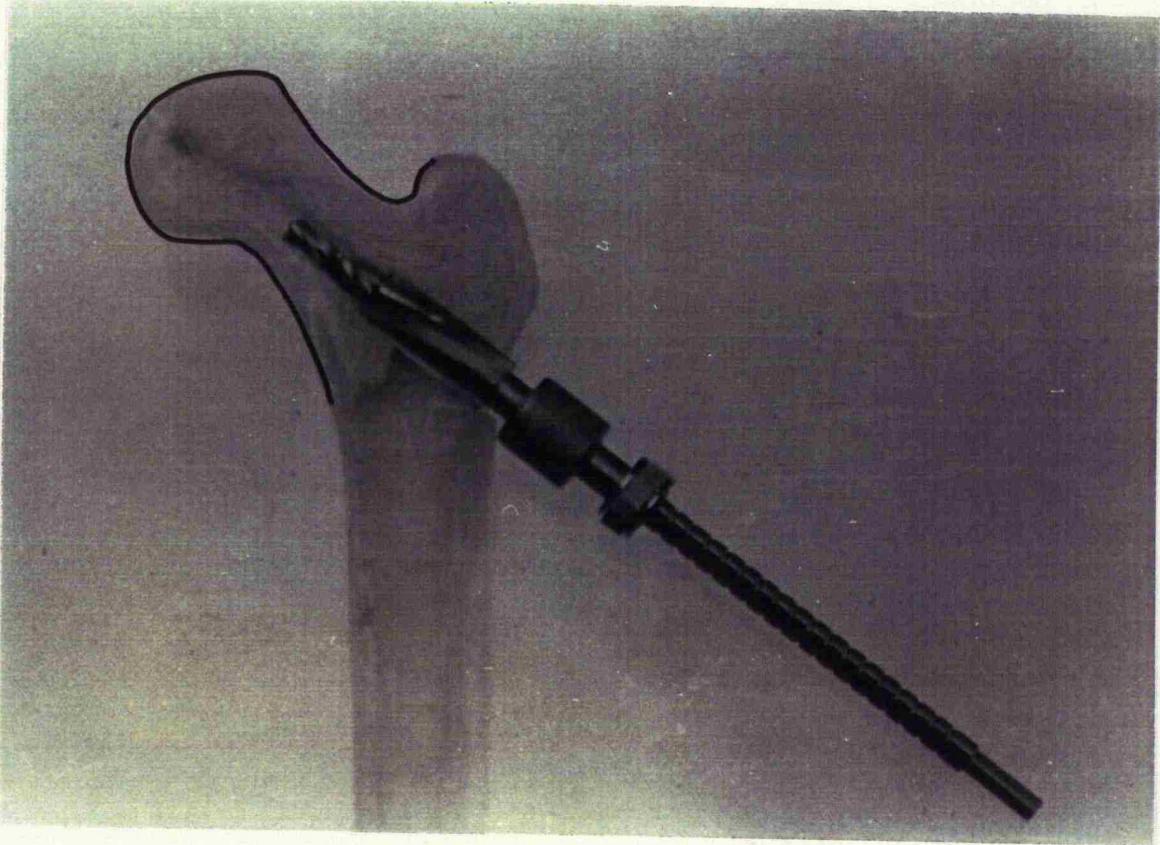


Figure 4-5 triple reamer set to measured length

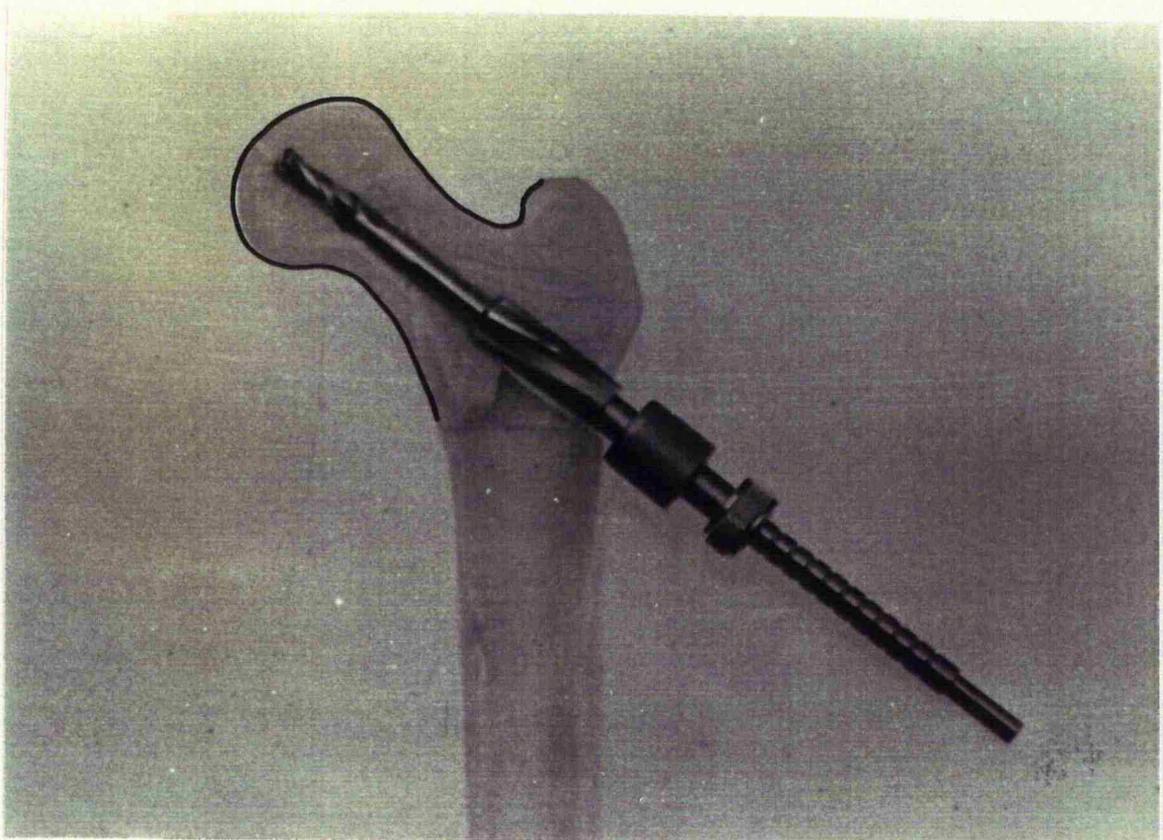
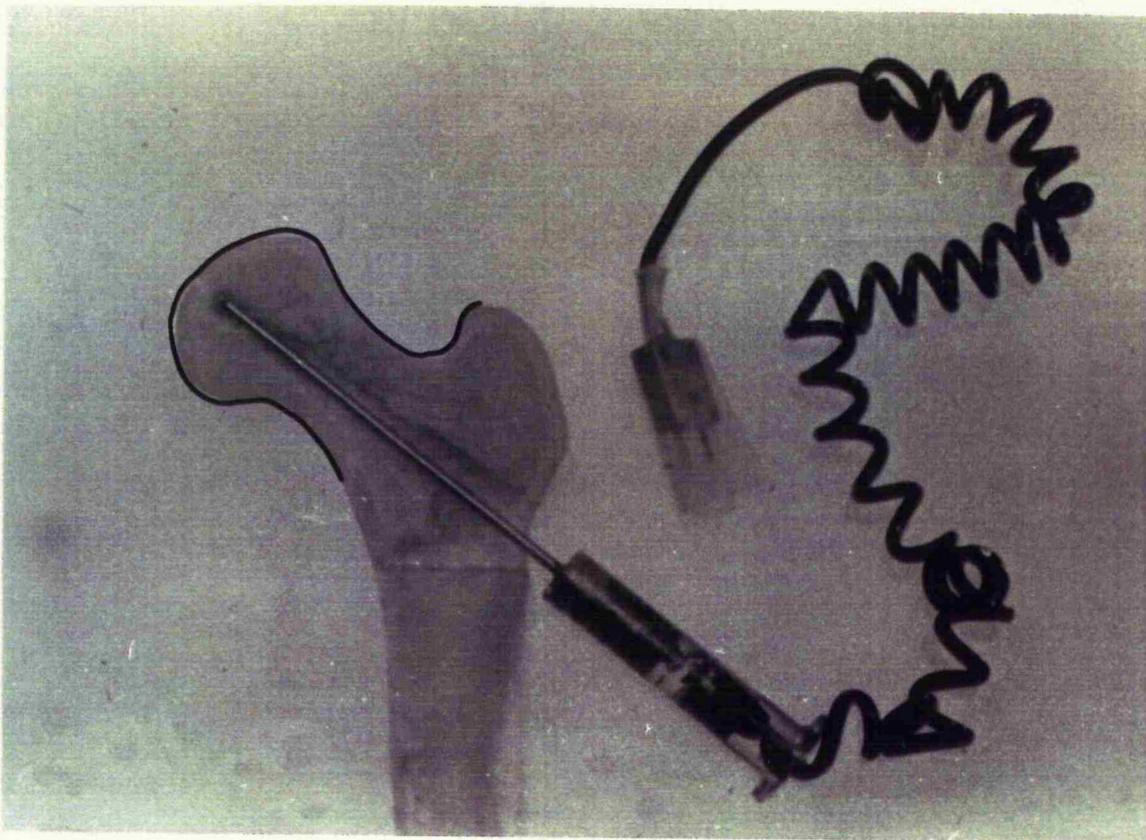


Figure 4-6 temperature probe with handheld recorder



Figure 4-7 temperature probe in measurement position



4.3 Results

Results are shown in tables 4.1 - 3 and Figure 4.8.

The exchange of drill with probe took on average 2 seconds and the peak temperature was extrapolated backwards on the chart readout (figure 4.9-diagram). The average rate of cooling in those cases where the temperature went above 44°C was 0.44°C/second and the average peak temperature in this group was 50.7°C, therefore the error in our extrapolation to account for the reamer-thermocouple exchange time was less than 0.9 percent/second.

The temperature was higher in the standard reaming group. There was a difference of 5.6°C in mean peak temperature ($p=0.1$). The length of time spent over 44°C was significantly longer ($p<0.05$) in the standard group. The Kruskal Wallace method of data analysis was used.

The numbers of patients in each group where the peak temperature was over 50°C, which is the definite damage threshold according to Eriksson (Eriksson 1984) was significantly greater in the standard group (5/9 standard reaming, 1/10 modified reaming, $p=0.05$, Fishers exact test, 1 tailed p value).

Table 4-1 results data

Patient	reaming method st=standard, mod=modified	peak temperature °C	extrapolated peak temperature °C	duration >44°C (seconds)
1	st	60.2	64	48
2	st	40	42	0
3	st	44.6	45	15
4	st	45	46.5	14
5	mod	41.8	43.8	0
6	mod	45.6	47	9.5
7	mod	48.4	52	19
8	st	47.9	50	16.5
9	mod	39	40	0
10	st	44	50	6
11	mod	46	49.5	7
12	st	46.4	48	14
13	mod	42.5	43.5	0
14	st	58	66	24
15	mod	45	47	9
16	mod	43.5	46	4
17	mod	43	46	3.5
18	mod	44	48	5
19	st	51	56	19

Table 4-2 *temperatures in the two groups*

reaming method	n	mean age years (SD)	mean temperature °C (SD)	peak temperature (SD)	temperature range °C
standard	9	83.2 (9.4)	51.9 (8.4)		42-46
modified	10	80.9 (12.0)	46.3 (3.3)		40-52
p value	-	NS	NS (0.1)		-

Table 4-3 *Duration of potentially damaging temperatures*

reaming method	mean duration >44°C, seconds (SD, median)	% cases with peak temperature >50°C
standard	17.4 (13.4, 15)	55
modified	5.7 (5.9, 4.5)	10
p value	<0.05	0.05 (Fishers exact test)

Figure 4-8 Maximum Peak Temperatures by Reaming Method

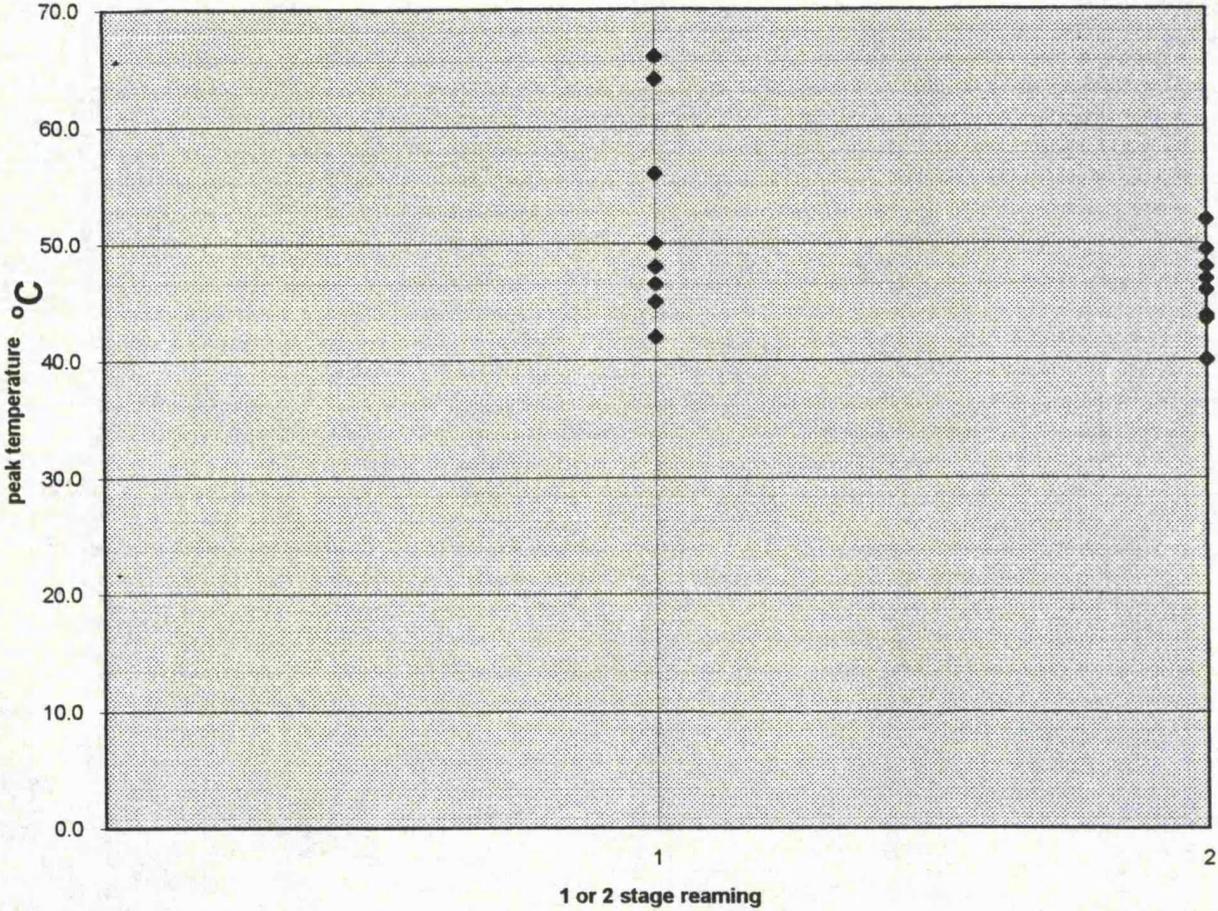
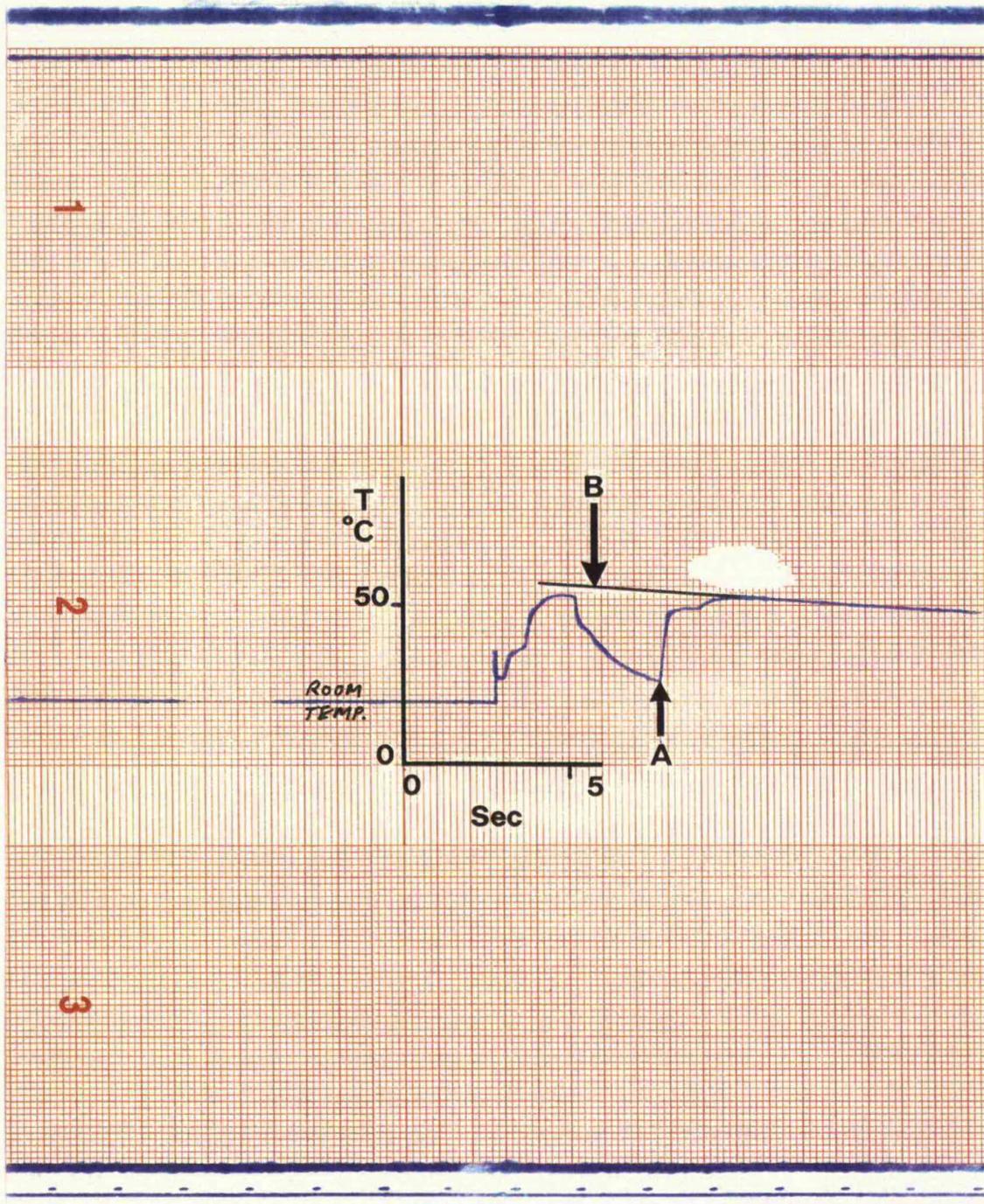


Figure 4-9 Typical Chart Recorder Readout Showing Extrapolation for True Peak Temperature. A=temperature probe insertion, B= extrapolated peak temperature. Trace before point A is artifact. Room temp. = 20°C, Body temp. = 37°C



4.4 Discussion

These results suggest that even in the porous bone of this elderly group of patients, with the benefit of sharp new drills, potentially damaging temperatures are generated during reaming of the femoral head with the triple reamer. Higher peak temperatures (70-90°C) were measured in men and younger women as compared to the elderly using the same techniques. (Calder, unpublished data) This is perhaps predictable in hard bone.

Work has suggested that the vascularity of the femoral head may not be globally affected by thermal injury from reaming, due to cooling in the zone immediately around the reamer (Andersen and Bruun 1989). That work entailed the measuring of temperatures at distances of 1-5mm from the periphery of the femoral head reamer, the distance being calculated from radiographs at right angles to each other. The accuracy of measurements to within 1mm using that technique must be questioned.

During preliminary investigations in this study it was noted that temperature changes outside 2-3 mm from the drill track were negligible. This begs the question: are these temperature rises of any clinical relevance? The degree of femoral head avascular necrosis due to thermal damage cannot be directly assessed from this study, but even the very local thermal damage measured here is probably of clinical significance. This is because a lucent area, possibly of zonal necrosis, is often seen around the thread of the lag screw on radiographs. This may be caused by local thermal damage and may

compromise the rigid hold of the screw thread within the femoral head, thereby causing delayed or failed union (Eriksson 1984, Christie 1981).

Internal liquid cooling of oscillating saws has been found to reduce temperatures in cortical bone significantly. Toksvig-Larsen (Toksvig-Larsen et al 1991) used an oscillating saw blade with internal channels for the passage of irrigating saline at 80ml/minute. Reduction of temperatures was significantly greater than with simple saline irrigation from a syringe. However this is not an easy practical solution for a spinning device.

Wykman (Wykman 1992) evaluated the effect of fluid cooling on cement bone interface temperatures during insertion of the acetabular component of a Charnley THR, and found that the use of irrigation did reduce the median temperature by about 8°C.

A simpler way of reducing generated temperatures than by fluid irrigation is important in this type of fixation. Cutting out of the screw from the bone is still a problem, particularly for intracapsular hip fractures in which femoral head viability may be already tenuous.

The method described is a simple modification of standard reaming technique which seems to reduce potentially damaging temperatures within the femoral head during this type of reaming. Reaming becomes a two stage procedure but the extra time involved is negligible- perhaps 30 seconds added on to the operating time.

A potential bias in this study is that the surgeon may theoretically produce variable temperatures by simply altering the pressure on the drill

during reaming. This aspect was standardised qualitatively as far as possible. Ideally, a pressure transducer could have been utilised to keep the pressure constant. The numbers in the study were smaller than ideal, and to confirm the findings irrefutably a larger study with the use of a pressure transducer would be needed.

This study population was of elderly females, who are known to have a greater degree of osteopenia than other groups, and therefore it may be postulated that reaming temperatures are not going to be raised particularly dramatically in this group because there is little bone resistance to reaming. Younger patients, in whom treatment by internal fixation following displaced intracapsular hip fracture is the treatment of choice, have denser bone and temperature elevations would be considerably higher. It is here where this technique would be of particular use.

5. The use of SPECT* compared with planar bone scan to assess vascularity of the femoral head.

*Single Positron Emission Computed Tomography

5.1 Introduction

The failure rate of internal fixation has been reported as between 8% and 38% (Sikorski and Barrington 1981, Skinner et al 1989), the most widely quoted rate being around 25%. (See section 1.7.3) Early failure of fixation, within the first few days or weeks, may be due to poor operative technique exacerbating the problems of poor mechanical strength of the bone ; inadequate reduction of the fracture according to Gardens criteria; poor positioning of the screw; or fixation which fails due to poor mechanical strength of the bone despite a good surgical technique. In these cases the device cuts out of the bone of the femoral head; i.e. "fracture redisplacement" occurs.

Late failure by AVN is a well recognised long term complication requiring revision surgery in many cases. Both non-union and late AVN are largely due to damage of an already tenuous blood supply. Section 1.7.3 discusses the distinction between non-union and AVN.

A method of identifying preoperatively those femoral heads which are viable and which therefore have a greater chance of successful healing is needed. This would enable us to rationalise our treatment protocol for the use of internal fixation in displaced intracapsular hip fracture. Various imaging techniques are available.

Speer (Speer et al 1990) had disappointing results using pre-operative magnetic resonance imaging (MRI) to predict fixation outcome for displaced intracapsular hip fracture. Isotope bone scans have been studied more extensively and have been more promising.

5.1.1 Planar isotope bone scans

Holmberg (Holmberg and Thorngren 1984) used relative uptake ratios of radioisotope by the femoral head on the fractured side compared to the normal side and found that with a head to head ratio of <0.9 , 45/46 displaced intracapsular hip fractures had a subsequent healing complication (non-union or AVN), compared to 3/42 if the ratio was >0.9 .

Lausten (Lausten et al 1992) looked at pre-operative and one week post-operative scans in 49 cases (though in fact only 18 had both scans), and concluded that pre-operative scintigraphy is useful for predicting non-union and AVN in elderly patients.

Alberts (Alberts et al 1987) used postoperative planar scintimetry at fixed intervals, using head to head uptake ratios (HHR) of the fractured side compared to the normal side. Planar scintimetry at one and six weeks was a good predictor of union. Those that healed without complication had peak uptake at 6 weeks, followed by a gradual decline. Fractures going on to non-union or late segmental collapse (LSC), defined as deformity of the weight bearing portion of the femoral head after fracture healing, showed a lower initial uptake and a more gradual increase. Preoperative scans were not performed

however, and although these findings were of interest they did not help initial management. A very low radionuclide uptake according to visual assessment from 6 weeks after fracture was felt to be indicative of a future non union. The methodologic error of HHR was 10%.

In a comparison of pre- and postoperative (7-10 days) scintimetry in 40 displaced intracapsular hip fractures treated by closed reduction and internal fixation (Alberts 1990), assessed by HHR and head to neck ratios (HNR), pre-operative HNR gave a better prediction of union than post-operative, but this was still not felt to be very satisfactory because there was no distinction between healing complications with mild symptoms and very severe symptoms. Post-operative scintimetry was thought to be a potential help in the selection of the most effective form of treatment. This would appear debatable.

The finding that postoperative, as opposed to preoperative, scans do correlate with outcome of fixation to some extent were also reported by Stromquist (Stromquist et al 1984B). It was found that a planar bone scan performed 1-3 weeks after internal fixation which showed deficient femoral head uptake was a good predictor of healing complications. This is of little use in the clinical situation where a preoperative predictor is required.

Imaging techniques such as planar isotope bone scans and magnetic resonance imaging (MRI) have been generally disappointing in the pre-operative prediction of failure of fixation, but isotope scans have been the most promising. The problem may lie in the limitations of the imaging technique. Stromquist (Stromquist et al 1984B) suggested that for planar bone scanning of the normal hip *"less than half of the emission ascribed to the femoral head is*

derived from the femoral head itself". This contamination of the image by overlying structures may be why planar isotope scans have been of little clinical use.

5.1.2 Single Positron Emission Computed Tomography (SPECT)

SPECT produces a slice of tomographic image of an isotope scan in much the same way as a CT scan image is based on x-rays. It has been used extensively to assess cerebral and myocardial vascularity (Holman and Tumei 1990). Its use in quantitative bone scanning has been less extensive but work appears to confirm it as reliable and reproducible for Tc-99m Methyl Diphosphonate (MDP) uptake by bone (Front et al 1989).

SPECT is potentially more reliable than planar isotope bone scanning because although the same basic technology is employed as in planar Tc-99m MDP bone scanning (i.e. gamma camera detection of radioisotope emissions), enhanced contrast is achieved by the removal of gamma counts from overlying structures. There is improved contrast resolution achieved by considerable grey-scale expansion as the tomographic effect reduces background activity.

SPECT has been reported as being more sensitive for bone imaging than planar scans. One study (Collier et al 1984, 1985) used SPECT and planar scans on 21 clinically suspected cases of avascular necrosis of the femoral head. SPECT was found to be more accurate in picking up photopaenic defects suggesting avascular areas. This has been supported by other work (Bellah et al 1991).

Problems imaging femoral heads due to artifacts from the bladder were initially troublesome, but have been overcome with image data processing. Gillen (Gillen et al 1991) reproduced the significant count losses which had been observed in the clinical situation using models and concluded that a combination of both a high count density region and a high attenuation structure caused the losses. Other techniques such as oblique angle reorientation of the data, to account for the femoral neck anteversion, have also improved image quality in looking at avascular necrosis (Kraznow et al 1989).

Bunker (Bunker et al 1990) applied simple image processing techniques to the problems of hot-spot bladder pixel overflows (i.e. image artifacts) and reduced the technical inadequacy rate from 19% to 2%. O'Connor (O'Connor and Kelly 1990) confirmed that image processing techniques significantly improved the procedure but did not fully recover the true activity within the femoral head, particularly the medial aspect, and therefore caution should still be exercised.

SPECT may offer a refinement in determining preoperatively the vascularity of the femoral head and therefore the relative risk of developing vascular related healing complications after fixation.

5.1.3 Tetracycline as a vital label

Tetracycline can be used as a vital marker for bone because it is taken up by vascularised bone and fluoresces under ultraviolet light. This can be used to assess blood supply of the femoral head (Stromquist 1983). Uptake has previously been assessed microscopically, but we have found that macroscopic

assessment shows the uptake distribution well. Labelling of bone in this manner is a well recognised method of vital analysis of bone.

Stromquist (Stromquist 1983) used a method of administering tetracycline either preoperatively or peroperatively, followed by intraoperative core biopsy from the femoral head at the time of internal fixation. The specimens were examined by fluorescence microscopy under ultraviolet light. They were estimated for degree of distribution and intensity of fluorescence, and a mean value of fluorescence was calculated by this method. Ratios of femoral head to greater trochanter fluorescence were also calculated. A single core biopsy is only a very small sample of the femoral head taken at one point in time and may not have reflected the global picture of uptake in the femoral head.

Measurement of tetracycline uptake is difficult to perform quantitatively. Unlike Stromquist, some studies using tetracycline labelling have used only presence or absence of fluorescence (Rokkanen and Slatis 1974, Lucie et al 1981). Measuring tetracycline uptake in this way it has concluded that ischaemic change occurs to some degree in every femoral head after displaced intracapsular hip fracture. (Rokkanen and Slatis 1974),

In order to assess the role of SPECT as a useful tool in looking at femoral head vascularity, it was important to correlate SPECT findings with planar bone scan findings as used and reported upon in the clinical situation, because a planar bone scan is the current standard in most hospitals for assessing avascularity (with the general lack of easy access to an MRI

scanner). If there were no differences in reported results of SPECT and planar scans, the method would have little advantage.

5.2 *Patients and methods*

5.2.1 outline

Ten patients with displaced intracapsular hip fracture, in whom hemiarthroplasty was to be performed, underwent a standard planar isotope bone scan and SPECT of the femoral heads within 48 hours of admission to hospital. Informed consent was obtained. The findings of both scans were compared with tetracycline uptake by the bone within the femoral heads.

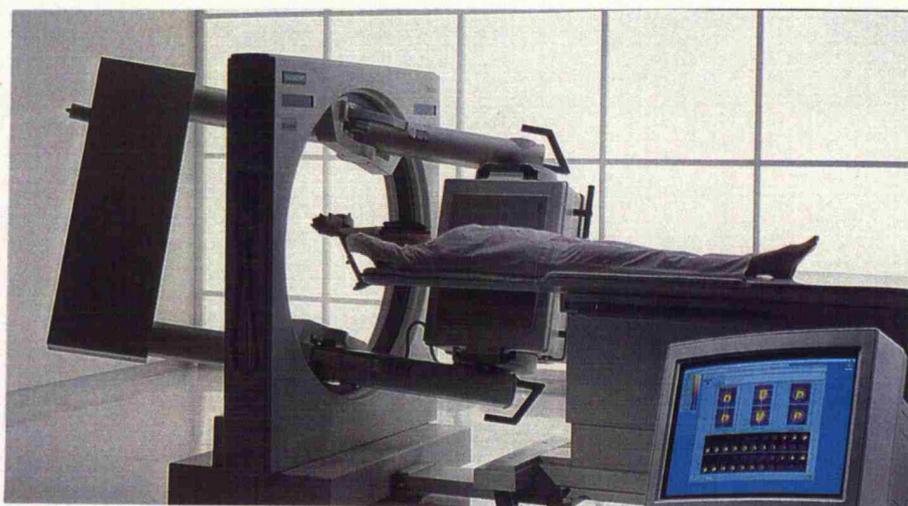
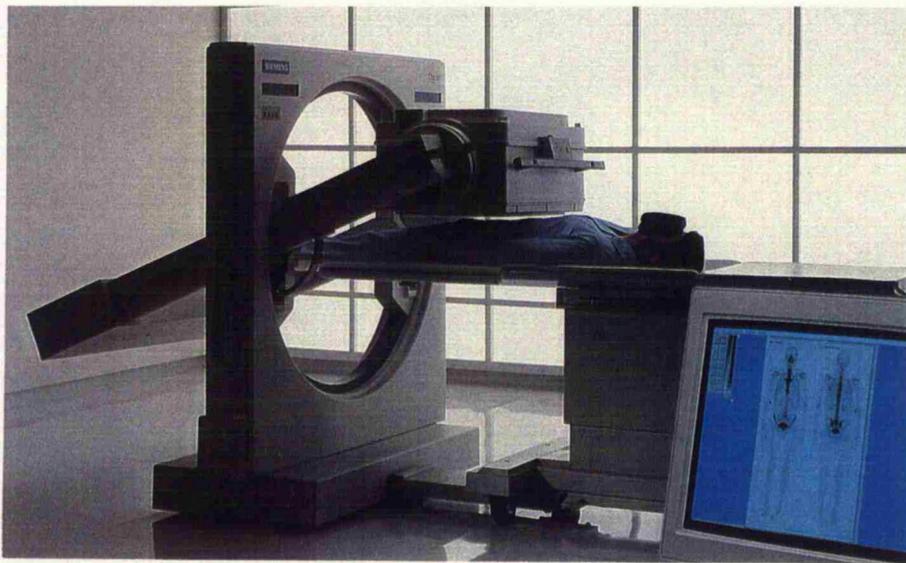
5.2.2 SPECT protocol

For the planar and SPECT isotope scans, patients were given 600MBq of intravenous technetium-99m methyldiphosphonate (Tc-99m MDP) 3 hours pre-imaging. Scanning was performed using a "Siemens Diacam" (Fig. 5.1) which can operate in either planar or SPECT mode. Pre-processing of the digital data was required in order to eliminate scatter from bladder uptake. 5mm section reconstruction was used for SPECT image production; i.e. each image produced was 5mm from the previous scan slice.

5.2.3 Tetracycline protocol

Tetracycline 1g intravenously was given 12-24 hours prior to surgery. Informed consent was given by the patient for both the isotope scans and tetracycline labelling.

Figure 5-1 The SPECT camera



5.2.4 Material Processing

Following hemiarthroplasty the femoral head was retained and stored in 99% alcohol solution to fix the labelled specimen.

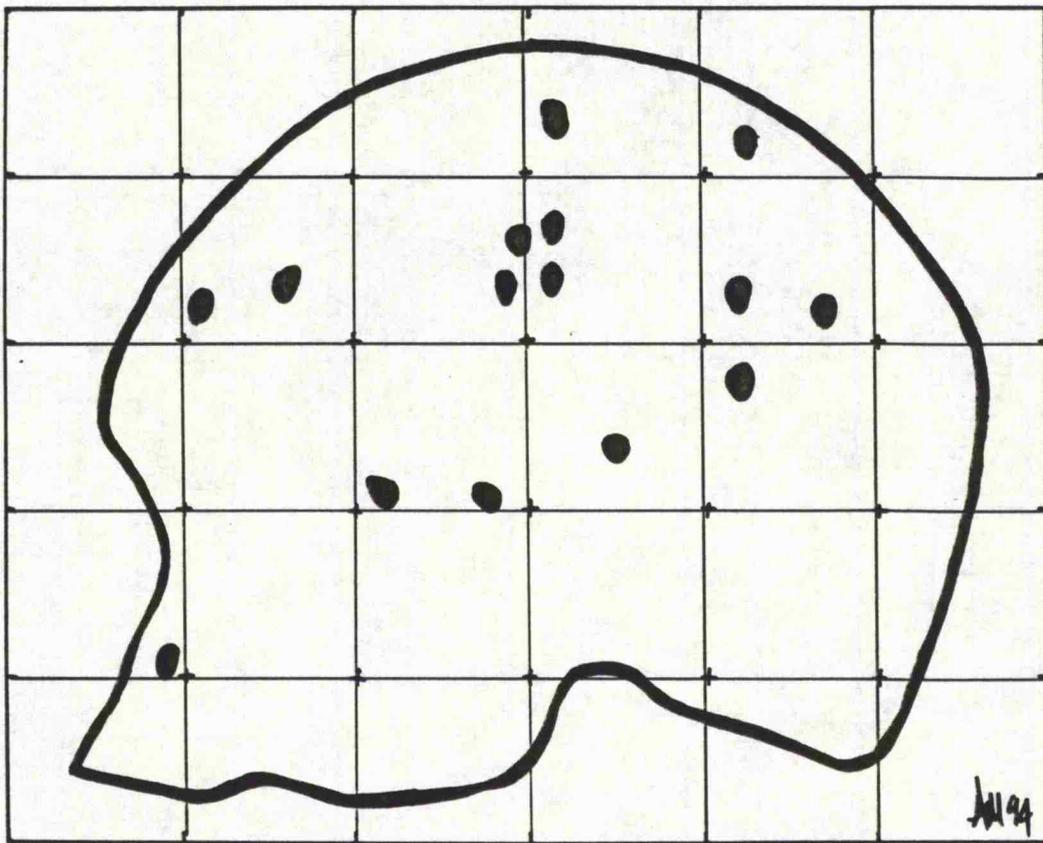
Each femoral head was mounted on a methylmethacrylate cement cylinder to allow firm vice fixation. This was achieved by creating multiple holes in the posterior part of the femoral head and fixing a cylindrical cement handle to this by use of a cylindrical mould. Each femoral head was bisected in the coronal plane using an "Exakt" water-cooled band saw with a 0.2mm cutting band. Two 2mm sections were cut in the same plane from each specimen. One case had only one section cut due to technical difficulties. Two control femoral heads, which had not been scanned or tetracycline labelled, were also sectioned as controls for tetracycline uptake measurements.

Each of the 23 sections was placed in a transparent petri dish lid, with the dish base placed on top to provide a transparent surface to trace the outline of the section. This was examined macroscopically under an ultraviolet light source. For each section areas of fluorescence corresponding to areas of tetracycline uptake were plotted by the author and another observer blinded to the details onto the petri dish base using an indelible marker pen. Following plotting of tetracycline fluorescence, these tracings were photocopied to give a permanent image.

Tetracycline uptake distribution was not measured in absolute quantitative terms. The measurement of the area of small zones of fluorescence was not practically accurate enough. A more appropriate method to allow comparison of the sections was to use a grid of 1cm squares and count

the proportion of squares containing areas of fluorescence (figure 5.2). Distribution of the fluorescent zones within the section was felt to be more relevant than absolute quantity.

Figure 5-2 Diagram showing the use of a grid to measure distribution of tetracycline uptake on a femoral head section. Heavy black shading = fluorescence



Using this method of grid measurement, each plotting trace was then examined by two blinded observers and the tetracycline uptake distribution (TUD) measured. This meant that for each section there were 4 measurements.

The SPECT and planar isotope images were reported by an experienced independent observer (an orthopaedic radiologist). Comparative visual estimates of radionuclide uptake were considered to be the most applicable to the clinical situation, where in most hospitals subjective reports are generated by a radiologist. Lausten (Lausten et al 1992) used simple visual estimation of planar bone scans, where uptake was reported as normal or reduced. Alberts (Alberts 1990) also found visual assessment a reliable method of reporting uptake in some cases, at the same time noting that even quantitative estimation using pixel counts in areas of interest had at least a 10% methodological error.

In this study both SPECT and planar scans were graded visually as positive, equivocal or negative by the observer blinded to the findings of the tetracycline measurements, using absolute criteria and by comparison of isotope uptake with the non-fracture side. *By convention, A scan indicating avascularity of the femoral head was considered to be positive and a scan indicating a normal femoral head was considered to be negative.*

5.3 Results

By convention, terminology used to describe the measurement stages was as follows:

Each femoral head had 2 sagittal sections cut, termed section 'a' and section 'b'. Fluorescence for each section was plotted onto an outline of the femoral head by two different observers ('plotters', p1 and p2). Each plot of fluorescence was measured and expressed as TUD by two more observers ('measurers', m1 and m2). As shown in table 1 there were 4 final readings of TUD for each section (and therefore 8 readings of TUD for each femoral head). TUDs were calculated for each section from each of the 4 readings for that section, try and reduce confounding factors from interobserver measurement error.

5.3.1 isotope scans

The reported SPECT/planar scan findings for each case are shown in table 1.

Table 1 SPECT and Planar bone scan findings for each case.

+ =Positive, - =negative, C= control.

Case	SPECT	Planar Scan
1	+	-
2	+	+
3	-	-
4	+	-
5	-	-
6	+	+
7	+	+
8	+	+
9	C	C
10	-	-
11	-	-
12	C	C

Note that no scan was reported as equivocal.

The figures show an example of :

1. negative findings on planar scan and SPECT (Fig. 5.3, 5.4) ,
2. negative findings on planar scan and positive SPECT (Fig. 5.5, 5.6)
3. one where both the planar and the SPECT scans are positive (Fig. 5.7, 5.8).

It should be remembered that the SPECT images consist of multiple sections which can all be visually assessed on the computer screen or hard copy films. A single view such as the examples shown is not as clear as the overall picture from the collated images.

Table 2 Data Table of TUDs for all femoral head sections

case	m1/p1a	m1/p1b	m1/p2a	m1/p2b	m2/p1a	m2/p1b	m2/p2a	m2/p2b	mean all	mean section a	mean section b	mean m1	mean m2
1	0.32	0.29	0.14	0.13	0.35	0.50	0.05	0.08	0.25	0.21	0.25	0.22	0.24
2	0.42	0.29	0.16	0.21	0.30	0.24	0.17	0.24	0.25	0.26	0.25	0.27	0.24
3	0.65	0.70	0.45	0.64	0.60	0.60	0.38	0.67	0.57	0.52	0.65	0.61	0.56
4	0.35	0.35	0.30	0.47	0.30	0.35	0.25	0.35	0.34	0.30	0.38	0.37	0.31
5	0.48	0.39	0.48	0.57	0.30	0.39	0.35	0.43	0.42	0.40	0.45	0.48	0.37
6	0.13	0.04	0.00	0.00	0.13	0.04	0.00	0.00	0.05	0.07	0.02	0.04	0.04
7	0.19	0.04	0.00	0.12	0.15	0.07	0.00	0.10	0.08	0.09	0.08	0.09	0.08
8	0.17	-	0.20	-	0.13	-	0.19	-	0.17	0.17	-	0.19	0.16
9	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
10	0.35	0.39	0.43	0.56	0.30	0.35	0.35	0.48	0.39	0.36	0.44	0.43	0.37
11	0.38	0.40	0.50	0.68	0.21	0.38	0.46	0.56	0.43	0.39	0.50	0.49	0.40
12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

key to table

m1=TUD (tetracycline uptake distribution) measurements by 1st measurer
m2=TUD measurements by 2nd measurer
p1= 1st plotter
p2= 2nd plotter
a= section a
b= section b

eg. column m1/p1a = TUD measurements of section "a" by 1st measurer with fluorescence plotted by 1st plotter. Also refer to main text section 5.3

5.3.2 Tetracycline labeling

Examples of labelled sections under ultraviolet light are shown in Figures 5.9 - 5.11. These photos were all taken under the same conditions and exposure times. Note the artefact made by the 'corkscrew' used to remove the femoral head at the time of surgery in fig. 5.11.

The mean TUD measurement for each case by each measurer (m1 and m2), using the grid method, are shown in figure 5.12. Differences in uptake measurements between the two observers did not alter the rank order and were considered to be insignificant .

The measurement of TUD for each section (a and b), and the mean value of these, is shown in figure 5.13.

Both of the control femoral heads were reported negative for tetracycline uptake by both observers. Therefore we can be confident that interobserver and specimen variation affects are minimal, and that our method is specific enough for tetracycline fluorescence for the purposes of this study.

The means from figure 5.13 are plotted in groups according to bone scan findings, and ranked according to these findings, in figure 5.14. It can be seen that there is a good subjective correlation of TUD with scan findings. For example the four cases with normal SPECT and planar scans had the highest TUD.

In two out of the ten non-control cases (patients 1 and 4), the planar scan was negative but the SPECT was positive (suggesting avascularity). Tetracycline uptake distribution for these was in the mid-range.

Figure 5-3 Planar Scan Showing Normal Left Femoral Head

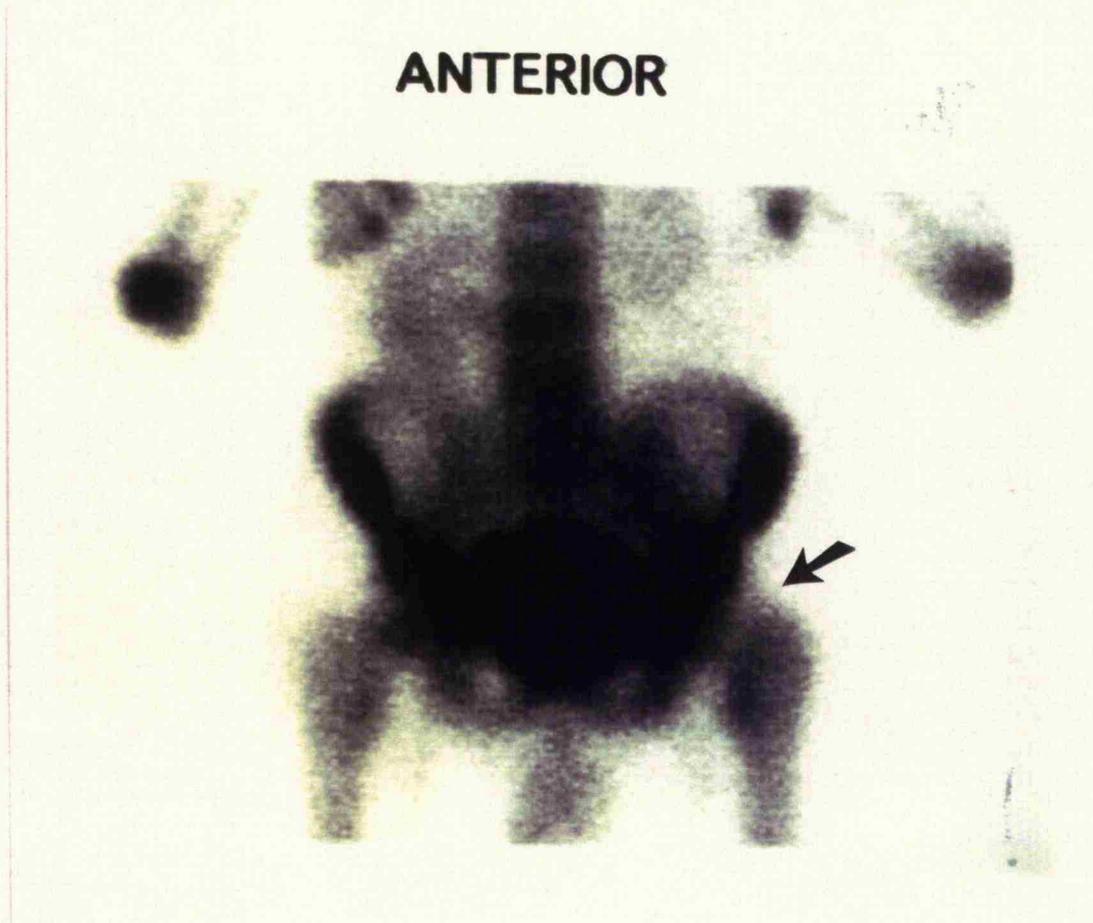


Figure 5-4 SPECT Showing Normal Left Femoral Head, Same Case as Figure 5.3

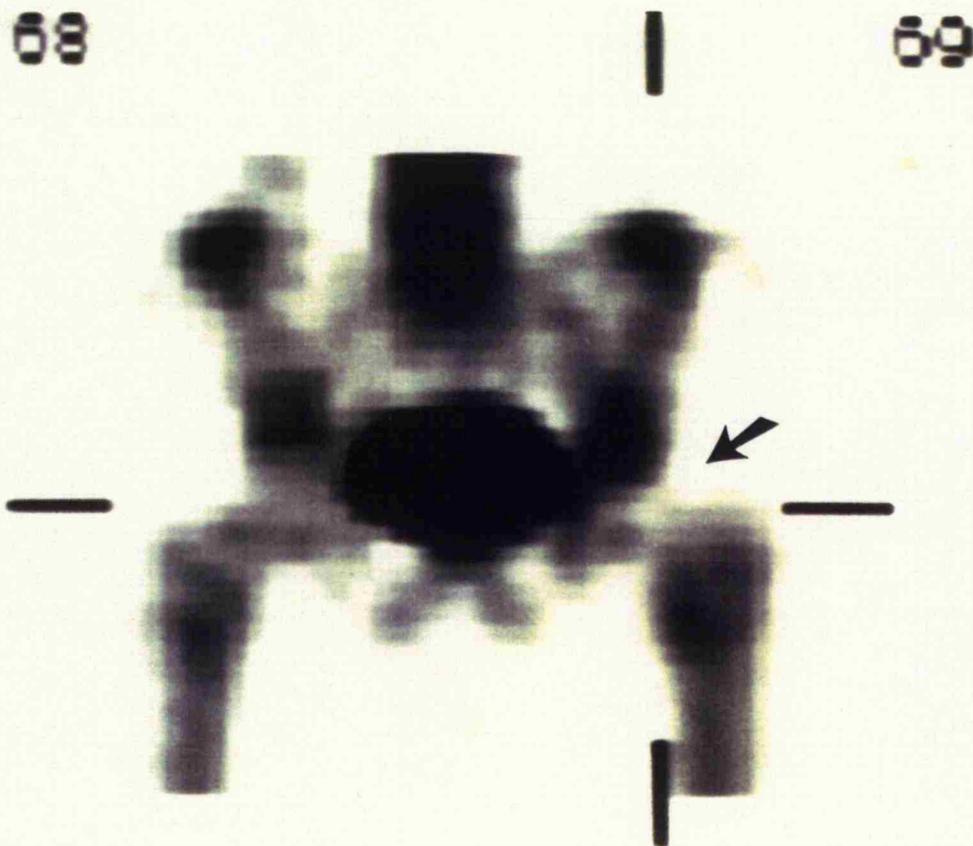


Figure 5-5 Planar Scan Showing Normal Uptake Right Femoral Head

ANTERIOR

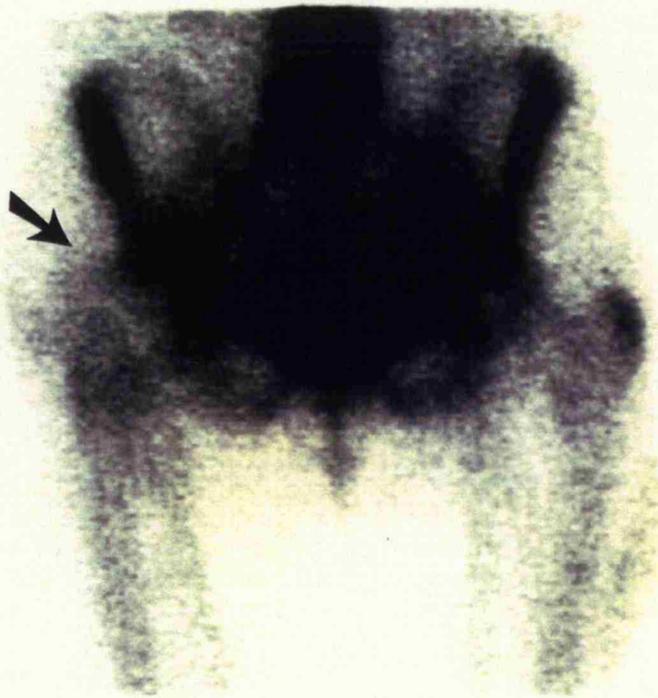


Figure 5-6 SPECT Showing Diminished Uptake Right Femoral Head, Same Case as Figure 5.5

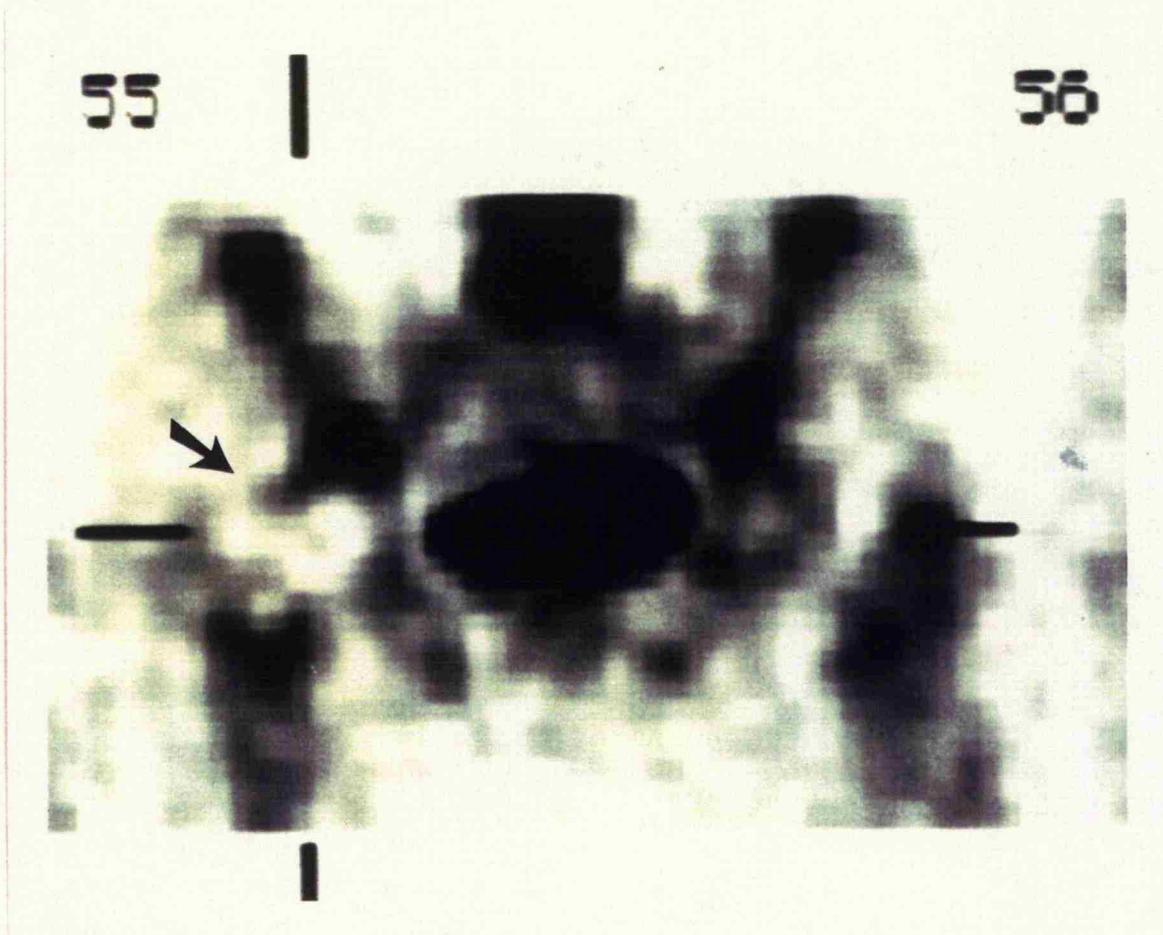


Figure 5-7 Planar Scan Showing Slightly Diminished Uptake Left Femoral Head

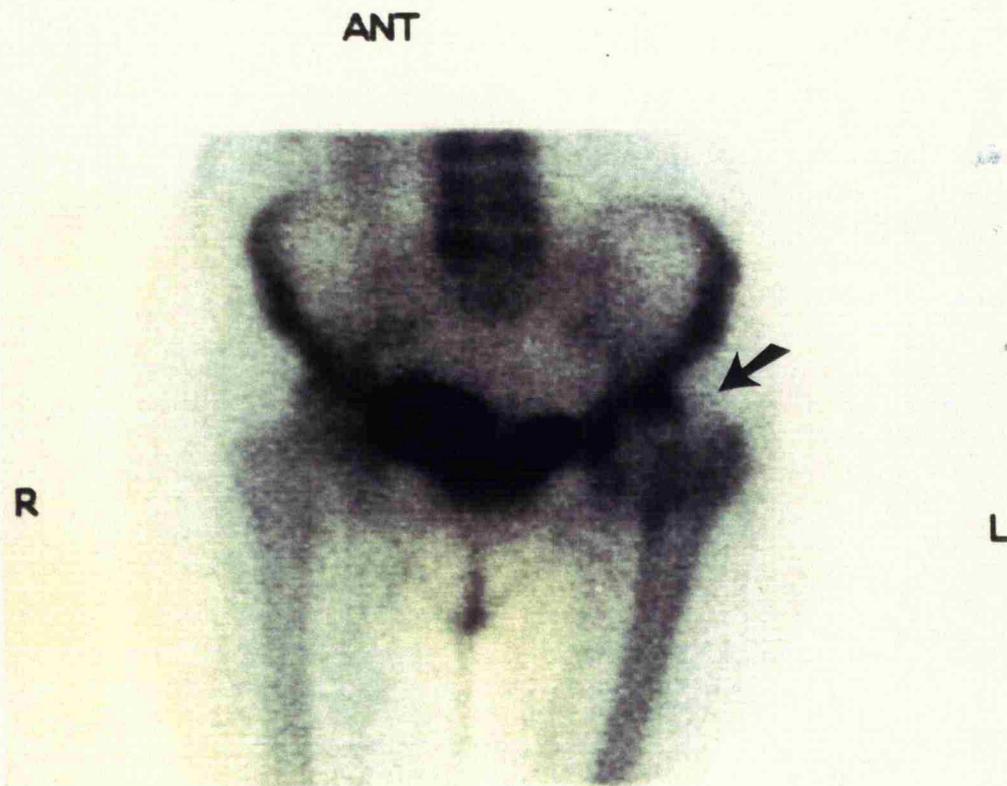


Figure 5-8 SPECT, Same Case as Figure 5.7, Showing Diminished Uptake Left Femoral Head
Much More Clearly



Figure 5-9

Control - No Fluorescence (Case 9)

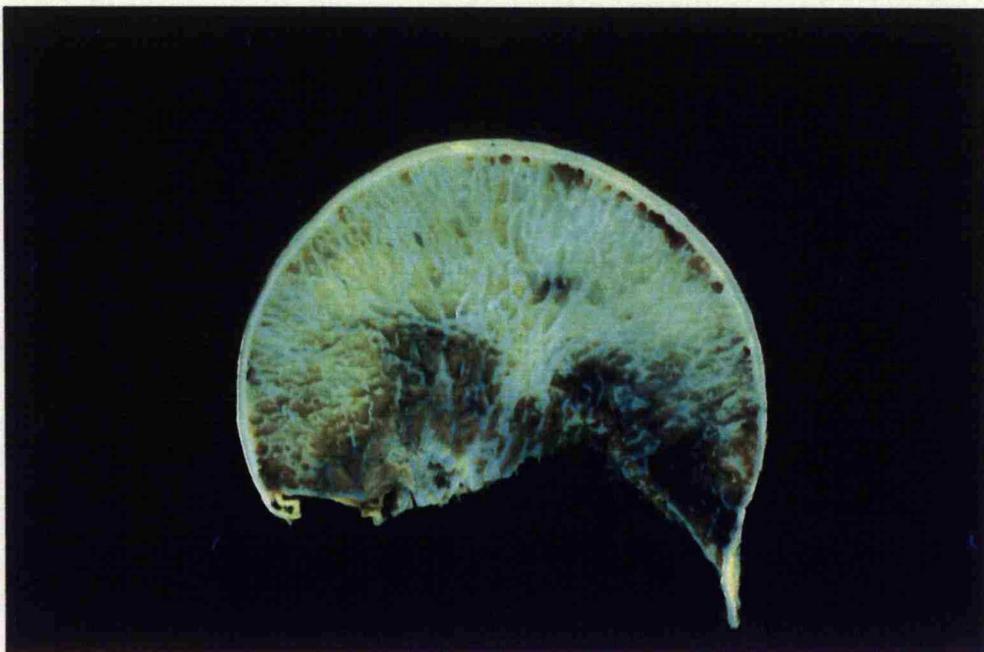


Figure 5-10 Bright Fluorescence and High TUD (Case 3)

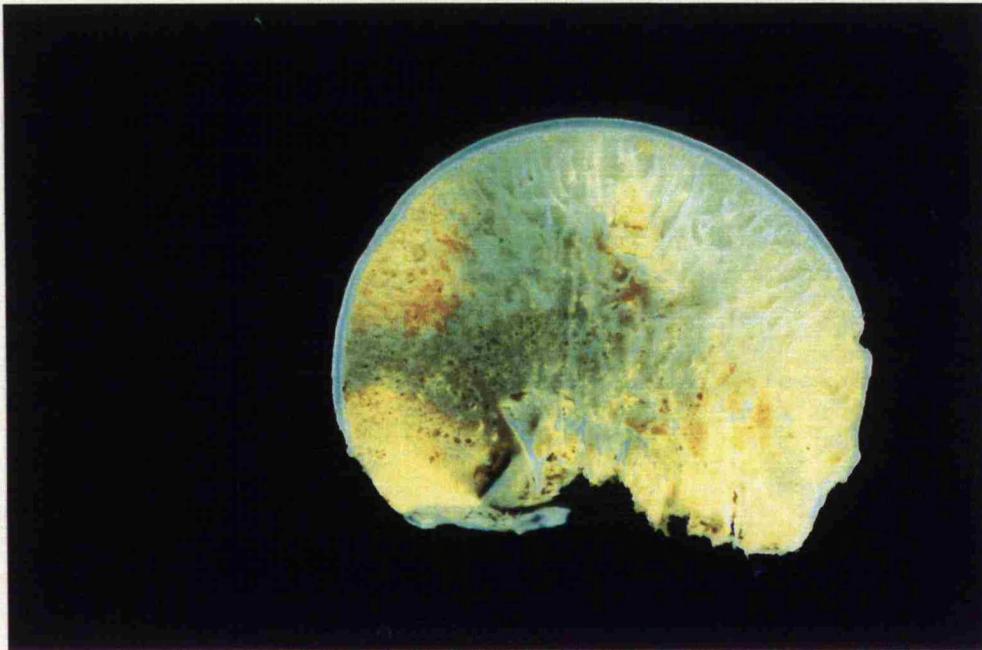


Figure 5-11 Moderate Fluorescence (Case 10)



Figure 5-12 TUD for each femoral head by measurer (m1 and m2), showing little interobserver variation

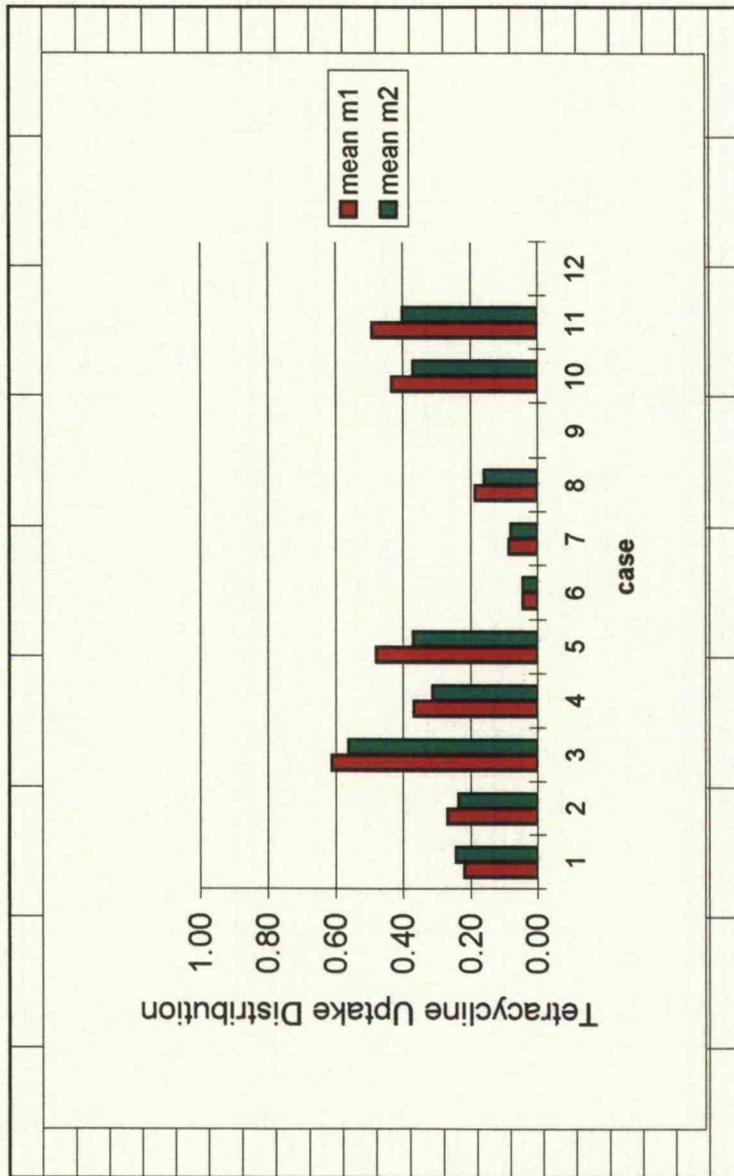


Figure 5-13 TUD for each femoral head section (a and b), and mean.

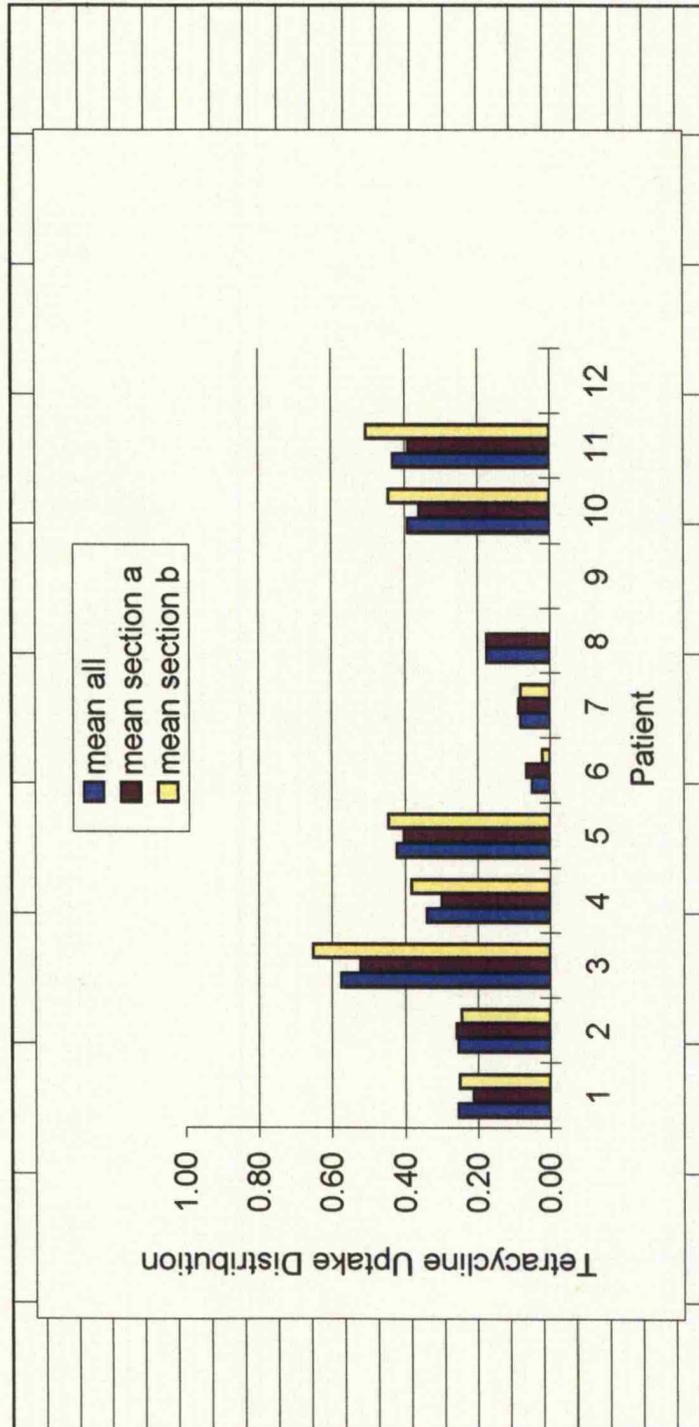
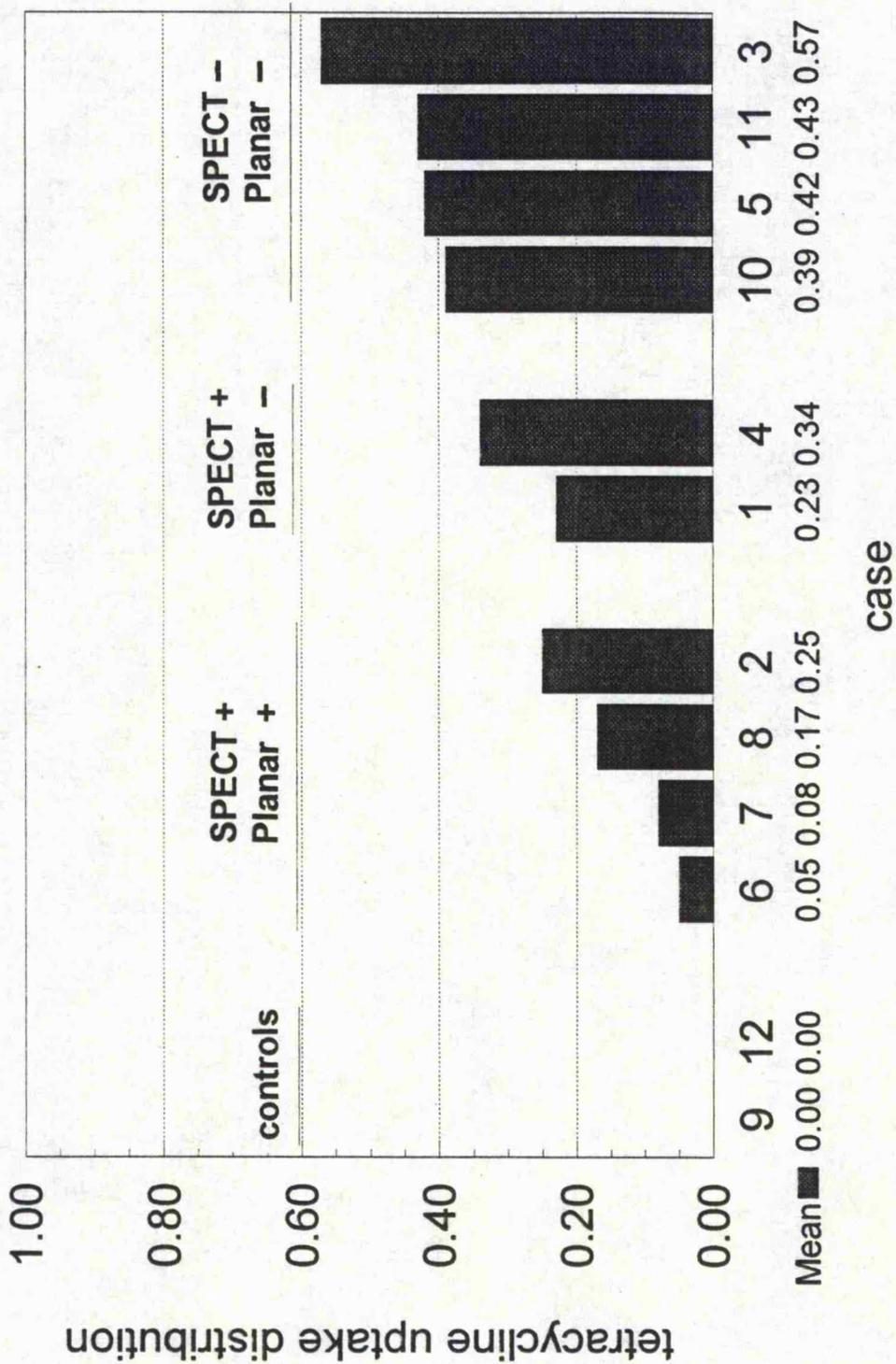


Figure 5-14 Mean TUD for each femoral head, ranked and grouped according to SPECT/planar scan findings.



5.4 Discussion

It appears that SPECT may have advantages over planar scans in examining the femoral head following displaced intracapsular hip fracture. Quality of SPECT images has been improved following removal of bladder artifacts by data pre-processing techniques (Gillen et al 1991, Bunker et al 1990).

A single reproduced SPECT image is often more coarse than the planar scan image as can be seen in figures 5.4 - 5.6. However because several sections through the femoral head can be viewed on screen, the data reflected is a more accurate representation of the underlying situation.

Of particular interest in these results are those cases (1 and 4) where there is a discrepancy between the reported findings of the planar isotope scan and the SPECT. Because of the inherent greater accuracy of the SPECT scan, these cases may be considered as false negative planar bone scans.

The likely reason for the apparent false negative rate of planar bone scan imaging is that a planar image consists of summated counts due to overlying and adjacent bone, particularly in displaced fractures where the proximal femur may overlap the femoral head. SPECT can take a section image to remove these unwanted counts. Coronal and sagittal image sections were more useful quantitatively than transverse ones for analysis of vascularity, although no quantitative could be obtained to support this, work is currently going on to quantify bone SPECT images accurately, but at present qualitative reporting is still the norm.

The particular method of tetracycline uptake measurement used has not been previously described, but follows the principles of that well used by Stromquist (Stromquist et al 1984). Although the assessment is performed macroscopically rather than microscopically as was in that case, it was interesting that there was a good crude visual correlation with the SPECT findings, and it may be that macroscopic assessment of the whole section may give a better overview of the true situation than simply looking at a small core from one part of the femoral head.

In summary of this preliminary study, isotope bone scans are a commonly used diagnostic tool in orthopaedic surgery and orthopaedic surgeons and radiologists should be aware that planar isotope bone scans for assessing femoral head avascularity may have a false negative rate, and SPECT should be used in its place where it is available.

5.5 Further work

A prospective study of preoperative SPECT on all patients undergoing internal fixation of intracapsular femoral neck fractures may realise the potential for more accurate prediction of late failure. Any intracapsular hip fracture, whether displaced or undisplaced that is going to be treated by internal fixation will have a preoperative SPECT.

Informed consent will be obtained. As soon as possible after admission, and before operation, a SPECT scan will be performed of the femoral head of the fractured hip. Surgery will then be carried out as for normal clinical practice in this unit. A SPECT will be repeated 6-8 weeks post operatively. The end

point will be development of a healing complication (failure of fixation, non-union or late segmental collapse). End point assessment will be at six months, twelve months and twenty four months post fracture.

If it becomes evident that there is a definite place for internal fixation in the treatment of displaced intracapsular hip fracture, the preliminary work reported here will require further validation. In particular, the reading of the SPECT images was undertaken by only one (experienced) observer, and this aspect would need to be validated further by a study on intra- and interobserver variation.

6. Ethnic variation in the epidemiology and rehabilitation of hip fracture patients

6.1 Introduction

The city of Leicester has a population which is 9.3% of Asian origin and the majority of this Asian group (90%) originate from the Indian subcontinent (OPCS 1992). In Leicestershire the county boundary coincides with the health district boundary, and all trauma is treated at one hospital within the district. All hip fractures taken from this population are treated in the same unit and details are entered onto a prospective database.

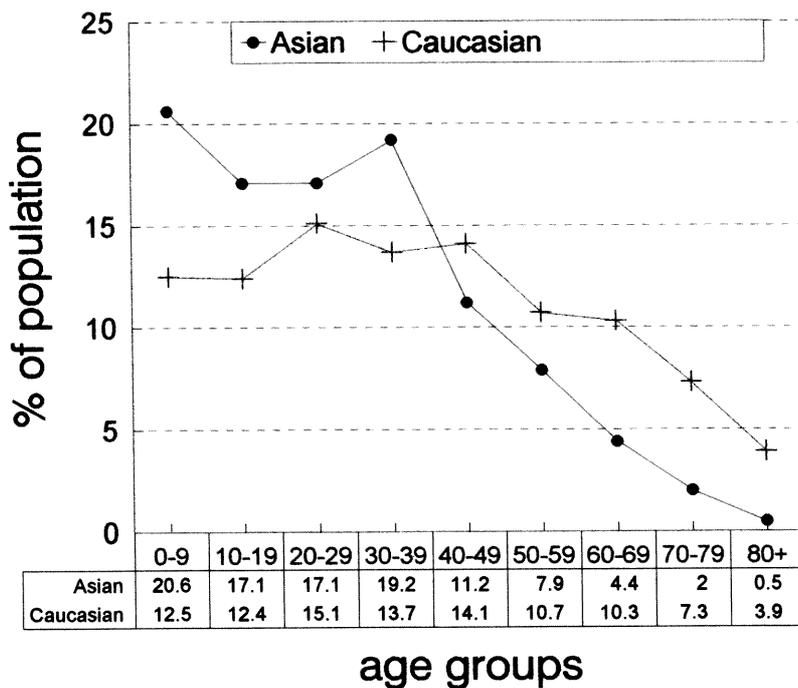
At present the Asian population is a relatively young group of patients, compared to the Caucasian population (Fig. 6.1). As a result, because hip fracture is largely a disease of the elderly, it may be expected that the crude incidence within the total Asian population would be lower than the crude incidence within the total Caucasian population.

In the past a high incidence of osteomalacia has been reported in patients with femoral neck fracture (Aaron et al 1974). More recently there has been good evidence to suggest that osteomalacia is not a significant predisposing factor for hip fracture (Wilton et al 1987B, Robinson et al 1992). Therefore although the prevalence of osteomalacia in Asians is higher than in Caucasians (Stephens et al 1982), we should not necessarily expect a difference in the incidence of hip fracture between these groups, and studies in

areas with smaller ethnic populations have confirmed this (Parker and Prior 1992).

Does a higher prevalence of osteomalacia predispose to differences in the incidence and pattern of hip fracture, and how do cultural differences influence postoperative rehabilitation following this injury?

Figure 6-1 Population Age Distribution for Two Ethnic Groups



Vitamin D deficiency has been recognised in the United Kingdom since the 1960s (Dunnigan et al 1962), though currently the exact level of the problem is unknown. Osteomalacia seems to have declined in the general population to around 2% prevalence (Wilton et al 1987A). In the Asian immigrant population there has been a slow reduction in Vitamin D deficiency in children but not in the adult population (Stephens et al 1982). There is a high proportion of vegetarians in the Leicestershire Asian community which is largely Hindu (Gujurati) vegetarian (OPCS 1992)- a diet which increases the risk of osteomalacia due to vitamin D deficiency. The great majority of vitamin D deficient subjects have been found in this cultural group. Of those suspected clinically, over 50% actually have abnormally low vitamin D levels (Iqbal et al 1993).

The older citizens are more likely than subsequent generations to abide by their traditional diets and cultural habits, thereby perpetuating the problem of vitamin D deficiency, and therefore osteomalacia, amongst first generation Asian immigrants (Stephens et al 1982). Certainly most patients presenting to orthopaedic departments with symptomatic osteomalacia are of Asian origin (Stamp et al 1980).

Evidence of interracial differences in hip fracture epidemiology is stronger when other groups are compared. Solomon (Solomon 1968) in an epidemiological study found that Bantu tribesmen in South Africa had a femoral neck fracture rate less than 10% that of Western Europeans and ascribed this to a lower prevalence of postmenopausal osteoporosis in the Bantu. Although this was a reasonable hypothesis, measurements of osteoporosis were not

taken (and it would not have been possible to do so), and it is unclear if any other non-racial factors were responsible.

6.2 Aim of study

The aim of this study was to determine whether or not the real incidence of hip fracture in Leicester's large Asian population differed from that of the indigenous Caucasian population, and whether there was any difference between the two groups in type of fracture sustained. In addition the cost of treating such fractures in terms of length of hospital stay and placement following discharge from the acute orthopaedic ward was compared.

Any differences have important logistical and financial implications for future health care, as the age distribution of Asians comes to match that of the indigenous population. The findings may be applicable to other similar multiracial communities.

6.3 Materials and methods

6.3.1 Patients

Data was collected prospectively over two years (1991-1992) on all patients with proximal femoral fracture in the county of Leicestershire.

Details recorded were baseline demographic data, fracture type (intracapsular, extracapsular, subtrochanteric), treatment method, length of hospital stay and discharge destination.

Ethnic origin was recorded as Caucasian, Asian or other for the purposes of this study.

Data collection was performed by a single surgeon to reduce the variation in the interpretation of collected data and diagnoses. Ethnic origin was ascribed both by patient questioning and confirmed in cases of doubt, by name origin which is very specific for this population group.

Population census data broken down by age and ethnic origin was obtained from official sources (OPCS 1992) (Table 6.1).

Table 6-1 demographic data and hip annual fracture incidence

ethnic origin	sex	age <65 years	age >65 years	hip fracture <65 years	hip fracture >65 years	annual incidence hip fracture <65 years. %	annual incidence hip fracture >65 years. %
Caucasian	m	325206	51749	15	189	0.002	0.18
	f	320524	73692	76	951	0.01	0.64
Asian	m	38365	1770	2	16	0.003	0.45
	f	39201	1754	4	19	0.05	0.54

6.3.2 Statistical Analysis

Patients were divided into age groups of less than 65 years and over 65 years. This was an acceptable division for standardising the two populations because the vast majority of patients with proximal femoral fracture are over the age of 65 years.

Using this breakdown, the figures for incidence of fracture and fracture type were age-sex standardised for the two main ethnic groups.

The statistical software package used was SPSS.

6.4 Results

The number of proximal femoral fractures in Leicestershire was 641 cases in 1991 and 633 cases in 1992- a total of 1274 over our study period. It is predicted that by the year 2000 there will be 713 cases per annum; an increase over ten years of 11.2% (Anderson et al 1993A).

Summary population and fracture incidence data for two age groups are shown in Table 6.1. It is important to note that the Asian population is younger than the Caucasian. The Asian age distribution curve is to the left of the Caucasian group as shown in figure 6.1. This is because the Asian group is a young immigrant community, with a relatively small number of older dependant family members most of whom have been brought over to this country in their old age. It will take some years before the age distribution curve shown in figure 6.1 shifts to the right to match the shape of the indigenous population curve.

The average age for hip fracture initially appeared to be significantly lower in the Asian population when crude figures were assessed (table 6.2).

Table 6-2 Crude figures for hip fractures in the two ethnic groups

ethnic origin	mean age (sd)	age range	
Asian	76 (11.9)	42-92	p<0.05 Students T test
Caucasian	80.2 (10.3)	18-104	

However these crude figures need to be standardised for age and sex differences between the two groups, because the difference may be due to the younger mean age of the Asian population compared to the Caucasian and the different sex distributions of the two groups. The younger age distribution in Asians also explains Table 6.3, which shows that Asians make up 9.3% of the total population, but only 3.2% of hip fractures. However, over the age of 65 years, these two percentages are very similar (2.7% and 3.0%).

Table 6-3 Proportion of population sustaining hip fracture in two age groups

ethnic group	all ages %	all hip fractures %	age >65 years %	hip fracture >65 years %
Caucasian	88.9	96.7	96.9	97
Asian	9.3	3.2	2.7	3
Other	1.8	<0.1	0.4	<0.1
total	100	100	100	100
actual number this study	867521	1274	129483	1175

The overall annual incidence of proximal femoral fracture in Caucasians was 0.079%. The age-sex standardised rates in Asians was 0.103% (Standard Error 0.017, range 0.0703-0.136 at 95% confidence levels). The standardised incidence ratio Asian:Caucasian is therefore 1.32 .

At 95% confidence levels the range of this ratio is 0.94-1.79, therefore there is no significant difference in the age-sex standardised rate of proximal

femoral fracture between the two ethnic groups at the 5% level. However the standardised incidence ratio of 1.32:1 is a striking difference and may become statistically significant as total numbers increase the statistical power.

The risk of fracture in males over 65 years was significantly higher in Asians: risk ratio = 2.5 [annual incidence 0.45% cf 0.18%] ($p < 0.05$ using chi square). There were no other significant sex differences (see Table 6.1).

The incidence of subtrochanteric fractures was significantly higher in Asians (4/41) than Caucasians (17/1232) (Fishers Exact Test, $p < 0.05$). This is shown in figure 6.2 which illustrates the relative proportions of fracture types in each ethnic group.

Figure 6.3 illustrates the postoperative stay in days, and place of discharge destination- whether or not the patient returned home to pre-injury residence, or to other accommodation. These are both good indirect indicators of speed and level of postoperative recovery and rehabilitation.

Hospital stay was significantly longer in the Asian group: median 21 days (mean 25.5, Interquartile Range 15-91) compared to 15 days (mean 17.6, IQR 11-123) ($p < 0.05$ using Kruskal Wallace test).

The percentage of patients returning directly to the pre-injury residence was less in the Asian group, 22% (9/41) compared to 27% (337/1232), but this was not a significant difference at the 5% level (chi square analysis).

Figure 6-2 Ethnic variation in classification of proximal femoral fractures.

Intra=intracapsular, extra=extracapsular, subtroch=subtrochanteric

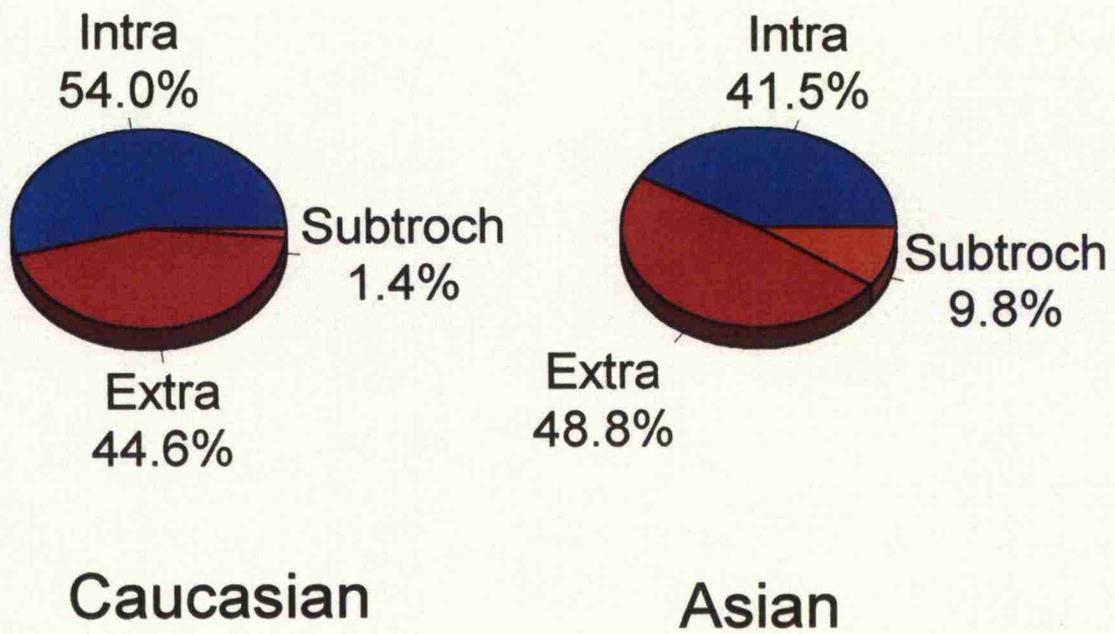
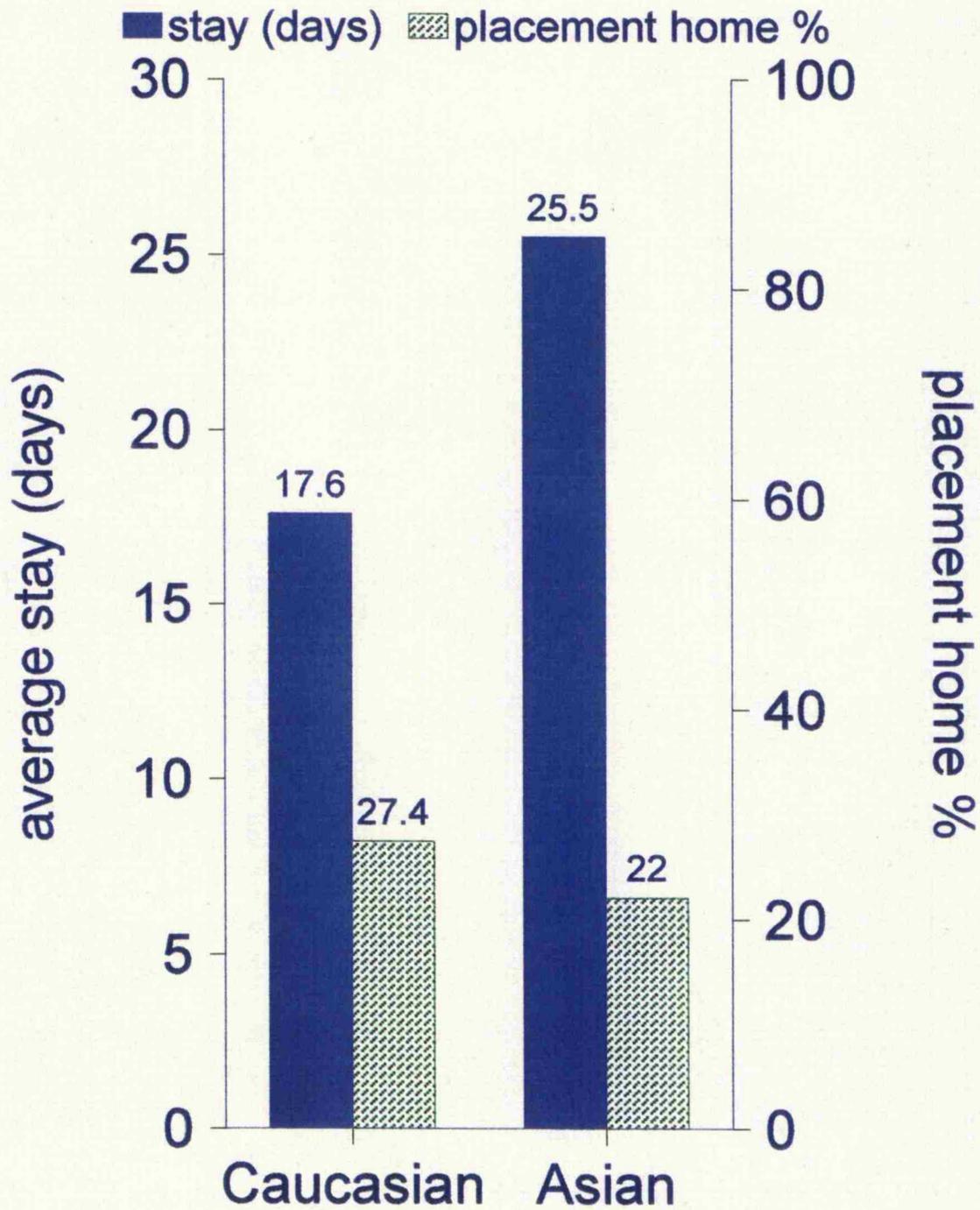


Figure 6-3 Hospital length of stay and placement after discharge in two ethnic groups



6.5 Discussion

This data suggests that there is not a statistically significant increased risk of hip fracture in Asians aged 65 years and over compared to Caucasians in the same age group, despite the standardised incidence ratio of 1.32:1. This agrees with the findings of Parker (Parker et al 1992) when a smaller number of patients was looked at.

There is a higher incidence of subtrochanteric fractures, which are more often associated with pathological aetiology in this age group than are other proximal femoral fractures, and there is a lower age at which the injury is sustained in Asians. These differences suggest that there may be different factors within the two groups. Osteomalacia is the most likely cause of this different epidemiological pattern. One explanation would be that Loosers zones typically occur in the subtrochanteric region on the medial aspect of the femoral cortex (figure 1.8) and may explain the higher incidence of subtrochanteric fractures. However, more proximal extracapsular fractures related to osteomalacia certainly do occur as shown in figure 6.4.

Hospital stay on the acute orthopaedic ward is significantly longer, and direct return to pre-injury residence from the acute ward is less frequent in the Asian group. These differences between the two groups in social outcome may be explained by underlying cultural differences. Family home care arrangements and customs of caring for elderly family members affect the timing and place of discharge. Language communication problems (older generation immigrants often do not speak the native language) on the hospital

wards with doctors, nursing staff, physiotherapists and occupational therapists all contribute to delays in post operative recovery and rehabilitation.

Patients not returning directly to pre-injury residence went either to permanent higher dependency accommodation, or to temporary rehabilitation or convalescence units (either private or NHS). In any case, this was a sign of slower recovery of pre-injury functional status. Both of these findings have financial implications. In Leicester an average of 20.5 hip fractures in Asian patients are treated each year, each staying 7.9 days longer than a Caucasian patient. On this basis the extra annual cost is approximately £40,000, or £2000/patient.

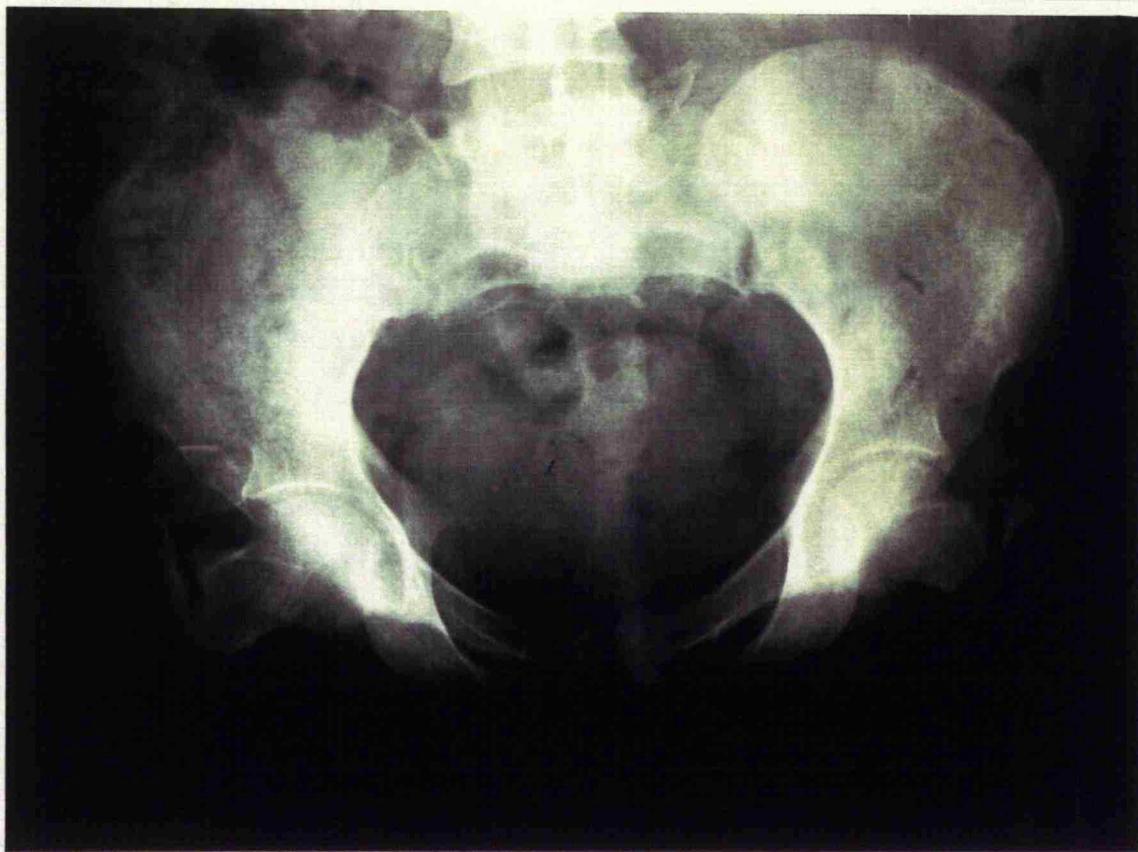
The reasons for this longer hospital stay may be that the language barrier is still a difficult problem to overcome. Many Asian patients in the vulnerable age group do not speak good English. Post-operative mobilisation and nursing care are likely to be hindered by this, as communication from carer to patient is of the utmost importance. Cultural differences in the way that families become involved in after-care may also play a part in the findings of delay in discharge.

There are both pathophysiological (fracture types) and cultural (social outcomes) differences, albeit interlinked, contributing to the identified differences. Cultural problems may be tackled by improved communication with and education of families as well as patients, perhaps with easier access to an interpreter on the wards. Pathophysiological differences, possibly accounting for the different fracture types in the two groups, such as vitamin D deficiency

might tend to become less of an influence as the Asian population ages and blends culturally with the indigenous group.

Now that differences have been identified it would be financially and clinically prudent to address both the rehabilitation needs and pathophysiological differences between the two ethnic groups. As a result of the skew age distribution seen in figure 6.1 the vulnerable population will increase disproportionately within the Asian group. Therefore in the meantime, provision will have to be made for the increasing health care burden of the Asian group of patients over the coming years, as it ages relatively more quickly than the Caucasian group.

Figure 6-4 bilateral extracapsular femoral neck fractures through Loosers Zones in a sixty year old Asian woman



7. Summary Discussion

It has long been recognised that proximal femoral fractures are going to be a continuing and ever increasing burden on the healthcare systems of the western world, and since at least 1935 (Speed 1935) displaced intracapsular hip fractures have been considered the particular challenge in this field. Technically, comminuted extracapsular hip fractures may be more demanding to treat, but there are nothing like the plethora of treatment options to tax the surgeon as there are with the displaced intracapsular fractures.

Over thirty years ago it was said that: "there is no doubt that at the end of three years most of the questions about (displaced intracapsular hip fracture) which we have been arguing for the past ten years could be answered" (Nicoll 1963). The literature review in chapter 1 makes it clear that we have failed dismally to take up this rhetorical challenge.

At the heart of the general failure of clinical studies to date has been the lack of a scientific approach. Randomised prospective clinical studies to compare treatments are rare (Lu-Yao et al 1994), and those which have been produced (table 1.3) are laudable but disappointing in size (given the frequency of the injury) and length of follow up.

Recently in the United Kingdom the Audit Commission produced a national report (Audit Commission 1995), entitled "United They Stand- Coordinating Care for Elderly Patients with Hip Fracture". This study was carried out at nine hospitals across the country. It did not specifically

concentrate on intracapsular fractures, but the conclusions are pertinent to our work. Amongst the findings and guidelines, it was noted that although more than 95% of hip fractures are treated surgically (Parker et al 1992), in many cases (over 60% in one hospital) surgery and anaesthesia are performed by relatively inexperienced senior house officers. This was stated in the context that early mobilisation and rehabilitation is more likely to be achieved following a technically sound surgical procedure. In addition the importance of regular operating lists to avoid the common problem of delays in surgical treatment were stressed. Given the existence of regular hip fracture operating lists and a single experienced surgeon in our centre, neither of these specific problems applied to the study presented in chapter 2. It could be argued that this goes some way towards explaining, for example, the extremely low dislocation rate in our trial thereby making these results unobtainable in everyday practice.

The rationale of operative treatment to most cases has been supported by other measurements. Parker (Parker et al 1992) assessed the "cost per QALY" (quality adjusted life year) for different methods of treatment. At one year post injury, when life expectancy for hip fracture patients is the same as that for the general population, conservative treatment for displaced intracapsular hip fracture had cost 14 times as much per QALY than operative treatment. To accept that health service resources are finite demands a system for their allocation, and QALYs may have an increasing role in this respect. In the same way, the Nottingham Health profile as reported in chapter 3 appears to be a viable outcome measure which warrants increasing use in orthopaedic practice. ADL scores such as that planned as an additional outcome measure

in the fixation versus hemiarthroplasty trial (Appendix 4) also warrants greater consideration.

The Audit Commission report also concluded that speed of return to pre-injury residence was expedited when there was some degree of formal liaison between the orthopaedic and geriatric medicine units. This again is an aspect which was facilitated by the existence of our clinical trial; orthogeriatric liaison was regular though not rigidly structured- patients were seen once a week by a geriatric rehabilitation team if it was deemed necessary, but not pre-operatively as in some centres. More recent studies continue to stress the desirability of combined care between orthopaedic surgeons, geriatricians and backup services (Kreibich et al 1995).

The importance of pre-injury dependence indicators (e.g. residence and mobility) as used in chapter 2 has been reiterated recently for predicting mortality, mobility and housing requirements at one year in hip fracture patients (Hubble et al 1995).

The acceptability of a 33% failure rate for internal fixation by two years is open to debate. This figure is high but is comparable to those from other studies (table 1.5). These patients are usually in some degree of pain up until the failed fixation is revised to a prosthesis. Even those patients undergoing successful reduction and internal fixation often take at least six months to painfree fracture union (only 14.5% united by six months in Barnes et al 1976). There is undoubtedly a group whose fractures unite but have persistent pain because of AVN which may only develop radiological signs at a later date.

This raises an ethical question: should a third of elderly patients with

displaced intracapsular hip fracture be subjected to pain for a considerable length of time when a cemented hemiarthroplasty appears to give almost complete pain relief in the short term? Arguably the failure rate of hemiarthroplasty due to acetabular erosion and loosening at later follow up will have to be comparable to the fixation failure rate after same period for there to be a strong argument in favour of fixation.

We know from mortality data that an 80 year old woman who survives to one year from injury has a mean life expectancy of seven years. The argument of ideal length of follow up is difficult; clearly the longer the better, but this has to be offset against a diminishing statistical power of the study as surviving numbers diminish. Recruitment to the prospective randomised trial described in chapters 2 and 3 has been extended for a further year to increase the power of the study, making a planned total of five years trial recruitment with five years follow-up. For the fixation versus unipolar or bipolar hemiarthroplasty argument, five year completed follow up on this large randomised group is anticipated to go along way towards answering the dilemma.

If reduction and internal fixation is carried out, every effort should be made to select those patients likely to have a successful outcome. The study of SPECT reported here (chapter 5) promises a more accurate means of preoperative femoral head vascularity assessment to help in patient selection.

Having selected patients for fixation, meticulous operative technique to reduce the iatrogenic damage to the fracture biology must be employed. The work on reducing temperatures generated at the time of surgery by modifying the use of the triple reamer (chapter 4) will realistically only be of significance

in patients younger than our study group (i.e. less than 65 years) because bone in the elderly is soft to the point that reaming may not generate adequate heat to cause damage.

This thesis has addressed aspects of management of displaced intracapsular hip fracture at each clinical stage; pre-operative assessment of femoral head viability, surgical treatment methods, specific surgical technique in reaming, outcome measures using a subjective health profile, and local demography and epidemiology with all of its resource implications.

Unfortunately most clinical data is “soft” compared to the hard measurements available in non-clinical research, and one has to be circumspect in interpretation of the statistical analysis of any such study. There will always be room for criticism even of well designed clinical studies.

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“The truth is rarely pure, and never simple”- Oscar Wilde



SJ Calder Thesis. Appendix 1. Nottingham Health Profile

1

Listed below are some problems people may have in their daily life.

Look down the list and put a tick in the box under **YES** for any problem you have at the moment.

Tick the box under **NO** for any problem you do not have.

Please answer every question. If you are not sure whether to say yes or no, tick whichever answer you think is more true at the moment.

	YES	NO
I'm tired all the time		
I have pain at night		
Things are getting me down		

	YES	NO
I have unbearable pain		
I take tablets to help me sleep		
I've forgotten what it's like to enjoy myself		

	YES	NO
I'm feeling on edge		
I find it painful to change position		
I feel lonely		

	YES	NO
I can only walk about indoors		
I find it hard to bend		
Everything is an effort		

SJ Calder Thesis. Appendix 1. Nottingham Health Profile

2

	YES	NO
I'm waking up in the early hours of the morning		
I'm unable to walk at all		
I'm finding it hard to make contact with people		

	YES	NO
The days seem to drag		
I have trouble getting up and down stairs or steps		
I find it hard to reach for things		

Remember if you are not sure whether to answer yes or no to a problem, tick whichever answer you think is more true at the moment.

	YES	NO
I'm in pain when I walk		
I lose my temper easily these days		
I feel there is nobody I'm close to		

	YES	NO
I lie awake for most of the night		
I feel as if I'm losing control		
I'm in pain when I'm standing		

SJ Calder Thesis. Appendix 1. Nottingham Health Profile

3

	YES	NO
I find it hard to dress myself		
I soon run out of energy		
I find it hard to stand for long (eg at the kitchen sink, waiting for a bus.)		

	YES	NO
I'm in constant pain		
It takes me a long time to go to sleep		
I feel I am a burden to people		

	YES	NO
Worry is keeping me awake at night		
I feel that life is not worth living		
I sleep badly at night		

	YES	NO
I'm finding it hard to get on with people		
I need help to walk about outside (eg a walking aid or someone to support me)		
I'm in pain when going up and down stairs or steps		

	YES	NO
I wake up feeling depressed		
I'm in pain when I'm sitting		

Now we would like you to think about the activities in your life which may be affected by health problems

In the list below, tick YES for each activity in your life which is being affected by your state of health. Tick NO which is not being affected, OR WHICH DOES NOT APPLY TO YOU.

Is your present state of health causing problems with ...

	YES	NO
Looking after the home (Examples: cleaning and cooking, repairs, odd Jobs around the home etc)		

	YES	NO
Social life (Examples: going out, seeing friends, going to the pub etc)		

	YES	NO
Home life (That is: relationships with other people in your home)		

	YES	NO
Interests and hobbies (Examples: sports, arts and crafts, do-it-yourself etc)		

	YES	NO
Holidays (Examples: summer or winter holidays, weekends away etc)		

SJ Calder Thesis. Appendix 2. Weighted Scores for Nottingham Health Profile

STATEMENT	WEIGHT	CODE
I'm tired all the time	39.20	EN1
I have pain at night	12.91	P1
Things are getting me down	10.47	EM1
I have unbearable pain	19.74	P2
I take tablets to help me sleep	22.37	SL1
I've forgotten what it's like to enjoy myself	9.31	EM2
I'm feeling on edge	7.22	EM3
I find it painful to change position	9.99	P3
I feel lonely	22.01	SO1
I can only walk about indoors	11.54	PM1
I find it hard to bend	10.57	PM2
Everything is an effort	36.80	EN2
I'm waking up in the early hours of the morning	12.57	SL2
I'm unable to walk at all	21.30	PM3
I'm finding it hard to make contact with people	19.36	SO3
The days seem to drag	7.08	EM4
I have trouble getting up and down stairs or steps	10.79	PM4
I find it hard to reach for things	9.30	PM5
I'm in pain when I walk	11.22	P4
I lose my temper easily these days	9.76	EM5
I feel there is nobody I am close to	20.13	SO3
I lie awake for most of the night	27.26	SL3
I feel as if I'm losing control	13.99	EM6
I'm in pain when I'm standing	8.96	P5
I find it hard to dress myself	12.61	PM6
I soon run out of energy	24.00	EN3
I find it hard to stand for long (eg at the kitchen sink, waiting for a bus)	11.20	PM7
I'm in constant pain	20.86	P6
It takes me a long time to get to sleep	16.10	SL4
I feel I am a burden to people	22.53	SO4
Worry is keeping me awake at night	13.95	EM7
I feel that life is not worth living	16.21	EM8
I sleep badly at night	21.70	SL5
I'm finding it hard to get on with people	15.97	SO5
I need help to walk about outside (eg a walking aid or someone to support me)	12.69	PM8
I'm in pain when going up and down stairs or steps	5.83	P7
I wake up feeling depressed	12.01	EM9
I'm in pain when I'm sitting	10.49	P8

6 May 1988

Ref:0238920L

Dear

My records show that you have recently suffered a fracture of your hip which was treated at the Leicester Royal Infirmary. I am very anxious to discover how people get on following their discharge from hospital after such an injury and would be grateful if you could complete the enclosed questionnaire and return it to me in the envelope provided.

The information will be treated with full confidentiality and will greatly help us to treat people who suffer such injuries in the future. If you have any difficulty with the form send me a note in the envelope and I will try to help.

Many thanks for your assistance,

Yours sincerely,

S J Calder

Registrar in Orthopaedic Surgery.

HIP FRACTURE PROJECT

Code _____ Name _____ Date _____ Follow up 1 2 3 4 5

INSTRUMENTAL A.D.L INDEX

Function	Description	Score	Comments
Cooking	<u>Gets to the kitchen, prepares the food, manages stove.</u>		
Independent	Performs the activity when necessary	2	
Partly dependent	Does not prepare meals or only heats up prepared food	1	
Dependent	Does not perform the activity	0	
Cleaning	<u>Performs house cleaning, vacuuming, washing floors.</u>		
Independent	Performs the activity when necessary	2	
Partly dependent	Has assistance seldomly	1	
Dependent	Does not perform the activity or has assistance regularly	0	
Transportation	<u>Gets to the stop for public transport, gets on & goes by bus, train</u>		
Independent	Performs the activity when necessary	2	
Partly dependent	Performs the activity together with another person	1	
Dependent	Does not perform the activity	0	
Shopping	<u>Gets to the shop, manages stairs or other obstacles, selects groceries, pays for them & carries them home</u>		
Independent	Performs the activity when necessary	2	
Partly dependent	Performs the activity together with another person	1	
Dependent	Does not perform the activity or needs assistance with some part of the activity	0	
Laundry	<u>Uses washing machine/hand washes, hangs clothes to dry or operates drier, irons & puts away</u>		
Independent	Performs the activity when necessary	2	
Partly dependent	Performs the activity together with another person	1	
Dependent	Does not perform the activity	0	
		Score	

M.T.S	SCORE
Age to nearest year	0 1
Time to nearest hour	0 1
Address to recall at end of test - 42, West St	0 1 2
Date	0 1 2 3
Day of week	0 1
Place of residence	0 1
Date of birth	0 1
Year of first World War	0 1
Name of present monarch	0 1
Count backwards from 1-10	0 1
Score	(max . 13)

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"In research the horizon recedes as we advance, and is no nearer at sixty than it was at twenty. As the power of endurance weakens with age, the urgency of the pursuit grows more intense....and research is always incomplete"

M Pattison 1875
