Proximal Humerus Fracture Rehabilitation

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A thesis submitted in partial fulfilment of the requirements of Sheffield Hallam University for the degree of Doctor of Philosophy

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I. Declaration

I hereby declare that, to my best knowledge and belief, it contains no material previously published or written by another person nor material which to a substantial extent has been accepted for the award of any other degree or diploma of the university or other institution of higher learning, except where due acknowledgement has been made in the text.

Steve Hodgson

1 August 2006

II. Acknowledgements

The idea for the study originated from a discussion with David Stanley who willingly gave up his time to consider the proposal and to give advice. His support, allowing his patients to enter the study, reading papers and passing comment, has been invaluable in the whole process.

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Thank you.

III. Dedication

This is dedicated to my children, Jenna and Helena, for asking why I still had to do homework at my age and to my parents for their constant support and encouragement. I would also thank Karen for helping keep my sanity during the final draft.

IV. Figures & Tables

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V. Abbreviations

ADL	Activities of Daily Living
AO	Arbeitsgemeinschaft fur Osteosynthesefragen
BMC	Bone Mineral Content
BMI	Body Mass Index
BMD	Bone Mineral Density
P	Bodily pain (SF-36)
CSDQ	Croft Shoulder Disability Questionnaire
CSS	Constant Shoulder Score
CT	Computerised Tomography
CVA	Cardiovascular Accident
DoH	Department of Health
EQ	EuroQoL
GP	General Practitioner/ General Practice
ICC	Intraclass correlation coefficient
LLI	Long term limiting illness
M	Million
MS	Musculoskeletal
N	Newtons (force)
NHS	National Health System
OA	Osteoarthritis
PF	Physical function (SF-36)
PH	Proximal Humerus
POP	Plaster of Paris
RCT	Randomised Controlled Trial
RLP	Role limitation-physical (SF-36)
ROM	Range of Movement
RR	Relative Risk
SES	Socioeconomic status
SD	Standard Deviation
SDQ-NL	Dutch Shoulder Disability Questionnaire
SF-36	Short Form 36 Health Survey
SPADI	Shoulder Pain and Disability Index
STHFT	Sheffield Teaching Hospitals Foundation Trust
SRQ	Shoulder Rating Questionnaire
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

VI. Abstract

Background

The western world faces an explosion in the number of patients who will fracture their proximal humerus (PH) as a result of the rapidly changing demographics and the increase in osteoporosis. In 1998 there were 110 000 PH fractures in the United Kingdom (UK) and epidemiological studies indicate that the PH fracture incidence is increasing. Scant evidence exists to the optimum management and rehabilitation of these fractures and the aims of the study were to investigate the effect of an accelerated rehabilitation programme on patients' recovery.

Method

A Randomised Controlled Trial (RCT) comparing two rehabilitation programmes (n=86) with patients who sustained two-part fractures of the proximal humerus was performed. Patients were randomised to receive immediate physiotherapy within one week (Group A) or delayed physiotherapy (Group B) after 3 weeks immobilisation. Assessment was at 8, 16 and 52 weeks with the Constant Shoulder Score (CSS), Short form generic health survey (SF-36) and Croft Shoulder Disability Questionnaire (CSDQ). Additional reassessment was undertaken at two years. Regression analysis modelling was conducted to identify the risk factors for developed long-term shoulder disability.

Results

At the primary outcome point (16 weeks) Group A experienced less pain ($p<0.01$) and had greater shoulder function ($p<0.001$) compared to Group B. At 52 weeks the differences between the Groups had reduced. Overall, Group A experienced less pain as measured with the SF-36 (mean difference 486 CI 83 to 889, $p<0.01$) and improved

shoulder function (mean difference in AUC 6.4 [95% CI: 2.5 to 10.5], $p < 0.002$). At one year, shoulder disability (CSDQ) was 42.8% in Group A and 72.5% in Group B ($p<0.01$). By two years, shoulder disability in Group A remained unchanged (43.2%), but had reduced in Group B (59.5%).

Discussion

Immediate physiotherapy following a proximal humerus fracture results in faster recovery with maximal functional benefit being achieved at one year and requires fewer treatment sessions (9 versus 14 treatments, Group-A and B respectively). Delayed rehabilitation by three weeks shoulder immobilisation produces a slower recovery. The belief that patients make an excellent recovery after one year is questionable as 25 patients (33.5%) still reported considerable shoulder disability after two years of their injury. Gender (female), age and high levels of social deprivation were identified as risk factors for continued shoulder problems at two years after the fracture.

Conclusions and recommendations

This work suggests that patients who fracture their PH should not be immobilised before referral for physiotherapy as immediate referral to physiotherapy (within 1 week) results in faster recovery and less reported pain. Physiotherapy should be targeted towards those patients who are identified as having a greater risk of developing long-standing problems. Currently, a wide variation in PH fracture management exists in UK hospitals and implementing clinical care pathways will help target finite resources.

Contents

CHAPTER 1: INTRODUCTION

Please note: Within the text any reference to the 'author's research', 'author's work' or 'proposed research', refers to the research undertaken as part of the PhD thesis by myself, Stephen Hodgson.

1.1 An ageing population: implications for the proposed research

Society will experience an explosion in the elderly population in the future and this will have considerable implications for many aspects of health and social care. The increases are not evenly distributed across each age group, but are concentrated in the older categories and are further inflated by the decline in younger age groups. In 2002 there were 19.8 million people aged 50 years and over in the UK, an increase of 24 % from 1961 (16 million), but by 2031 the population projection is 27 million (Statistics 2005). This represents a 37% increase in people aged 50 and over in only three decades and this trend shows no sign of diminishing.

There are many implications of an ageing population, but the rise in osteoporosis and the related increase in fractures caused as a direct result of this bone loss, causes the greatest concern. The so called 'osteoporotic fractures' (e.g. hip, proximal humerus, wrist) are placing an ever increasing burden on health and social services' budgets as they struggle to balance both the requirements of managing an acute injury and the long-term impact of disability to the person and their carers. Proximal humerus (PH) fractures are the third most common osteoporotic fracture after the wrist and hip (Melton III 1988). Furthermore, as well as the obvious implications to the person who fractures their PH, the rise in number of PH fractures places increasing pressures on carers and this does not always diminish with age. As a recent population census (Statistics 2005) in the UK indicates, 4000 people aged 90 and over provide more than 50 hours per week as unpaid carers. The size of the problem in the UK (and other western countries) is incalculable. This thesis addresses the long-term problems of PH fractures by investigating how they are managed and rehabilitated. The findings from the proposed research will help to reduce the burden faced by the person who fractures their PH, their carer and a society that must deal with the consequences of this increasingly common injury by improving the effectiveness of management and treatment.

The research covers PH fractures, but recent research suggests that 'osteoporotic fractures' share many similar characteristics and should be viewed as part of a continuum. For example, sustaining a wrist fracture increases the risk of having a PH fracture (Lauritzen et al. 1993) in the future and this subsequently increases a person's chance of having a hip fracture. 'Osteoporotic fractures' must not be viewed in isolation as a single episode, but as part of a larger picture that requires early intervention to prevent further injury. However, this approach is not adopted by the current trauma services that deal with the acute injury and rarely orders further investigations or starts preventative programmes. The author examines the links between these fractures as the findings from this research have implications for many other types of fractures. If patients are developing long-term disability from a PH fracture, this will increase their future risk of other 'osteoporotic fractures' as they are more likely to fall if their neuromuscular function (ability to balance and compensate in response to changes in centre of gravity) is compromised (Kelsey et al. 1992). This research has established an optimum rehabilitation programme which will potentially maximise recovery and thus reduce the person's risk of further fractures.

Conventional rehabilitation to date has been based along traditional lines and practice varies between and within hospitals, compounded by the poor evidence base from which to inform clinicians (Gibson et al. 2001). The new approach to fracture management presented in this thesis represents another original aspect to the thesis.

PH fractures (fig. 1), as seen in the literature review, are increasing exponentially and this trend shows no sign of declining (Buhr and Cooke 1959; Kannus et al. 1996; Kannus et al. 2000). Additionally, the number of falls that result in an injury are increasing and the greatest changes are in the older adult category (Kannus et al. 1999) with fractures forming the largest group of fall-induced injuries. However, research in the field of PH fractures is generally of a poor standard and in several key areas is almost absent. In any thesis it is important to highlight the 'gaps' in the evidence base and this research addresses fundamental issues around PH fractures. To allow discussion of the problems facing the clinical management of PH fractures, this thesis incorporates evidence from other areas of fracture management and shoulder rehabilitation to develop ideas and to recommend future research.

1.2 Justification for this Research Study

The desire to conduct research within this field stems from personal observations when working as a physiotherapist in a fracture clinic. The traditional approach to modern PH fracture management and rehabilitation, combined with the lack of good quality evidence, limited the efficacy of clinical practice and this resulted in patients receiving unacceptable treatment. The patriarchal structure of orthopaedics in which innovation is stifled and barriers are constantly erected that prevents change has resulted in PH fracture management remaining unaltered for over one hundred years.

This research challenges some entrenched views about PH management and proposes a radical new approach to rehabilitation. Thus, potentially limiting some of the long-term problems facing the person who fractures their PH and the burden faced by their carers.

Figure 1: Proximal humerus fracture

1.3 Originality in the Proposed Research

The author's research is original as it:

- Investigates the effects of immediate rehabilitation *before* a period of immobilisation (current practice immobilises before rehabilitation).

- Includes an *active* rehabilitation programme based on best available evidence that selects treatments for their proven clinical efficacy.

- Incorporates long-term, prospective evaluation (two year) of patients' status following a PH fracture to investigate, for the first time, the long-term impact of a PH fracture on a vulnerable population.

- Evaluates shoulder disability and general health status in combination with impairment measures (e.g. ROM, strength, pain) to fully assess the wider health implications of a PH fracture. Previous research in this area has relied mainly on impairment measures to judge outcome, thus missing crucial information from which to base conclusions and recommendations.

- Recognises the importance of patient risk factors in predicting long-term recovery and challenging current practice (characterised by over-reliance on radiographic appearance).

- Compares socioeconomic status to patient outcome to establish if a link exists between general health status and PH fracture recovery. Research in other 'osteoporotic fractures' confirms the influence on general health status after fracture, but these wider issues have not been addressed in previous research.

- Challenges perceived wisdom that states that patients make excellent recovery following this injury and opens new avenues of research.

- Includes data from the first national survey in the UK establishing current PH fractures management from which to base future recommendations and guidelines.

Each point is covered in greater detail within the relevant section, but the research is innovative in that it is the first to challenge the belief that fractures require a period of immobilisation before rehabilitation starts. The proposed rehabilitation programme is a radical departure from current thinking and will challenge many to consider their practice. Rehabilitation in many upper limb conditions, and especially PH fractures, has virtually no reliable evidence on which to base clinical decisions.

Many surgeons believe that PH fractures require immobilisation for healing to occur and early movement results in non-union (fractures failing to heal) or at the very least, exacerbation of pain. The research evidence from the few studies that exist does not support this view and the findings from the proposed study will help clarify whether immobilisation is necessary for bone healing and if early movement leads to non-union (failure of the normal fracture repair process).

1.4 Immobilisation in Current Health Care

Following an extensive search, no previous research has been found that has investigated the effects of immediate rehabilitation on patient function following a PH fracture. Two key issues arise from the extensive literature review. First, little evidence exists to support current clinical practice and second, bone (as with all forms of connective tissue) actually requires movement to stimulate repair and remodelling

(Carter 1984; Buckwalter 1996). This concept is reinforced in other areas of healthcare, for example, after cardiac surgery the myocardium continues to heal without immobilisation or following a hernia repair the patient often walks out of the operating theatre, stressing the incision, but with little ill effect and minimising post-surgical complications. Increasingly, more operations are being undertaken as day cases with people walking out of operating theatres and encouraged to resume their normal function. This tendency to avoid prolonged hospitalisation could be explained by financial restraints and the increase in hospital infections, but it is also a response to the benefits of early return of function. Damaged structures require *controlled* stress from movement to maximise recovery and the seminal work linking 'form and function' was made by Woolf as far back as 1892 (Woolf 1892). The quantity of evidence supporting this concept is so overwhelming that it is inconceivable why current fracture management remains so intransigent to change, although most of this research is on animals or lower limb fractures.

1.5 Historical Perspective

The dichotomy between the 'movers' and 'resters' in the history of orthopaedic surgery remains an ongoing controversy (Salter 1982). The 'father' of British orthopaedics, Hugh Owen Thomas, was a strong advocate of rest and stated that:

"... rest or immobilisation must be complete, prolonged and uninterrupted."

Hugh Owen Thomas (cited in the Presidential address by Salter) (Salter 1982)

This assertion from the latter part of the nineteenth century continues to resonate today and immobilisation remains largely unchallenged in fracture management. For example, modern PH fracture management immobilises the patient for three weeks before starting rehabilitation, although as can be seen from the only UK survey conducted as part of this research (see results section for further detail) it is not uncommon to immobilise patients for up to eight weeks. The wide variation in the period of immobilisation reinforces the belief that surgeons are not basing their decisions on firm evidence, but continue along a time-honoured approach.

The aim of the author's research was to question the basis for this practice and test the efficacy of immobilisation versus immediate rehabilitation; allowing surgeons and physiotherapists to make informed decisions and about PH fracture management and rehabilitation. This new approach was found to be effective and it will reduce long-term disability and improve the patient's quality of life after a PH fracture.

The next part reviews the literature base underpinning the author's research and considers the size of the problem facing society with an increasing older population. The associated rise in PH fractures is discussed and the current evidence base to both management and rehabilitation is critically evaluated. From this the justification to conduct this research is made and the aims of the study are outlined.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction to Literature Review

Before reviewing the literature relevant to this study, it is important to define two key terms in the study: the orthopaedic management of the PH fractures (proximal humerus) and the subsequent rehabilitation of the patient following the fracture. PH fracture management is undertaken by an orthopaedic surgeon and includes decisions on the type of approach, for example 'conservative' or surgical. Additionally, the surgeon will monitor progress and recognise possible complications resulting from the fracture (mal-union, non-union, nerve/vascular damage). This study does not include patients undergoing surgery and only includes those managed by conservative means.

Rehabilitation is defined as:

"...restoration (to the maximum degree possible) either of function (physical or mental) or of role (within the family, social network or workforce)."

Nocon & Baldwin 1998 (Nocon and Baldwin 1998)

Rehabilitation is usually undertaken by the physiotherapist, but the decision when this process starts is made by the referring surgeon. The physiotherapist's role is to return the patient to their previous functional state, or as close as reasonably possible using education, passive movement and a graded home exercise programme. Both the surgeon and physiotherapist must liaise closely together to optimise patient recovery.

This study investigates both the management and rehabilitation of the PH fracture and the results have far ranging implications for both these aspects of care, but the findings also have relevance to all fracture treatment.

A PH fracture is not always the result of a chance event, but is often the final consequence of a series of risk factors (risk factors are specific patient characteristics that individually or collectively increase a person's chance of having a fracture e.g. gender, age, activity level). The probability of long-term functional loss is the interaction between risk and mediating factors. Mediating factors prevent the person with specific risk factors developing long-term shoulder disability e.g. two people with the same risk factors but with different levels of social deprivation; the one with the higher level of deprivation is more likely to develop shoulder disability. The reporting of musculoskeletal problems and illness is higher in areas with high levels of socioeconomic deprivation (Davies et al. 1994; Saul 1995; Paul et al. 1998). No previous research has investigated the effects of socioeconomic status (SES) on shoulder function, but evidence for joint pain, low back pain (Walsh et al. 1992; Urwin et al. 1998), neck pain (Webb et al. 2003)knee pain (Webb et al. 2004) and disability levels (McEntegart et al. 1997; Melzer et al. 2000; Bajekal 2005; Rautio et al. 2005) has consistently demonstrated that people living in areas of high social deprivation have more problems compared to those living in areas of low deprivation.

The factors linking pain to social deprivation remain to be elucidated (Aggarwal et al. 2003), but possible explanations are divided between behavioural and materialistic differences (Feinstein 1993). The 'behavioural' explanation suggests that lower social deprivation is associated with activities that compromise health. For example, smoking is associated with higher rates of low back and shoulder pain (Adamson et al. 2006) and the authors suggest that habitual flexed postures and repetitive arm movements could explain this observation. Additionally, less social contact and low levels of physical activity (Stuck et al. 1999) are risk factors in predicting functional decline and both these factors are seen in areas of high deprivation (Guralnik and Kaplan 1989; Verbrugge 1989; Vita et al. 1998).

There is increasing evidence that smoking has an deleterious effect on bone healing in various fractures including the scaphoid (Little et al. 2006), calcaneus (Folk et al. 1999) and tibia (Schmitz et al. 1999; Harvey et al. 2002; Dahl and Toksvig-Larsen 2004; Castillo et al. 2005). These studies measured the time for clinical bone union to occur between groups of smokers and non-smokers and the increased risk of delayed union for smokers varied between a relative risk (RR) of 1.2 (Folk et al. 1999) and 2.5 (Dahl and Toksvig-Larsen 2004). Furthermore, a study by Glassman et al. (Glassman et al. 2000) who reviewed patients following a spinal fusion (n=357), found that non-union rates were 14.2% and 26.5% for non-smokers and smokers respectively. The researchers also identified a group of patients who quit smoking following the surgery and their risk of developing non-union reduced to a value similar to that of the non-smokers (17.1%). This led the author to suggest that smoking cessation helps reverse the impact of smoking and implies that its effects are transitory. However, the effects of cigarettes are hard to isolate in clinical studies as possible co-founders exist that might also influence bone healing. Nevertheless, animal experiments found delays in spinal fusion in mean extension stiffness (32%)

with rabbits who were given intermittent smoking for six weeks compared with controls (Lee et al. 2005). Bone lengthening in rabbits (Ueng et al. 1997) grouped into smoking (n=19) or non-smoking (n=19) demonstrated lower levels of maximal torque (22%) across the fracture site at eight weeks in the smoke inhalation group. Although, animal studies must be viewed with some caution, short periods of smoking do appear to delay bone healing. Many smokers who sustain a fracture have probably had the habit for many years and this would probably further delay fracture healing.

Factors that possibly explain the differences between levels of social deprivation in the materialistic category include education (Leveille et al. 1992) and income (Jette and Branch 1985; Leveille et al. 1992; Maddox and Clark 1992). Lower educational attainment is associated with higher rates of functional decline (Maddox and Clark 1992; Maddox et al. 1994) and there is convincing evidence that people living in areas of high deprivation do less well in healthcare systems (Feinstein 1993). An example of this is the work by Criswell and Katz (Criswell and Katz 1994) who reported that patients with Rheumatoid arthritis and who had high educational attainment received better healthcare than patients with lower education. The reason given for this difference was that higher education allowed the person to negotiate for treatment. Furthermore, low income (associated with low educational attainment) predicts the decline in physical function (Leveille et al. 1992; Koster et al. 2005) and physical disability (Jette and Branch 1985). Low income might limit access to healthcare and cause the person to work in environments that could harm their health.

The association between certain psychological profiles (e.g. high deprivation causes increased stress on the individual) and high levels of social deprivation have also been given as reasons for increased levels of morbidity (Urwin et al. 1998). However, when this hypothesis is tested, the results are unclear with some authors reporting that psychological factors did predict functional decline (Kempton et al. 1999; Martikainen et al. 1999), and others finding only weak links between psychological factors and functional decline.

Overall, an explanation for the links between social deprivation and morbidity remain equivocal and further research is needed to test the complex relationship between the many different factors. The work has started in the area of functional decline and disability, but little work exists in the field of specific musculoskeletal conditions. For this reason PH fracture risk factors, functional loss and mediating factors are included in the literature review to allow the author to explore those characteristics that clinicians managing PH fractures must consider. Additionally, this allows exploration of potential problems for recovery and ongoing disability.

With any review of the literature, it is important to highlight the 'gaps' in current knowledge and how this research adds to the body of evidence. However, in the field of management of proximal humerus fractures what little evidence that exists is weak and making informed decisions based on current research is impossible. The Cochrane review of PH fracture management (Gibson et al. 2001) came to similar conclusions and stated that only tentative recommendations could be made with the available evidence. Furthermore, upper limb fracture rehabilitation is probably even less well researched as most programmes are based on empirical evidence alone. So, for both management of PH fractures and rehabilitation, the evidence is not available or often of a low standard.

This research aims to investigate both management and rehabilitation approaches and proposes a new approach to fracture management that is previously untested and could potentially revolutionise modern fracture management. Furthermore, current rehabilitation is reviewed to formulate the best programme for PH fractures, but with the lack of evidence base within this field, other shoulder conditions are included to justify the programme. The research is original in two key aspects: first, initially investigating the effects of immobilisation on recovery by comparing three weeks immobilisation with immediate restoration of function is something that previous research has ignored. Secondly, by recognising the limitations of basing fracture management solely on radiographic appearance and incorporating wider patient characteristics and socioeconomic variables in formulating a truer representation of an individual's risk of long-term shoulder disability. Both these approaches are new and, as such, the literature review is far ranging in its scope to reflect these aims.

The literature review covers four main areas: epidemiology, aetiology, medical management and finally, rehabilitation. Overall, epidemiology has the strongest evidence base and this clearly delineates the current problems in fracture management with an exponential growth in PH fractures. The epidemiology highlights the problems facing health providers as they attempt to manage this common injury with finite resources. This research is essential for many reasons and future demographic changes only serve to highlight its importance as management and rehabilitation of these fractures must be optimised to cope with the predicted future demands. Without the development of 'clinical pathways' (as routinely seen in stroke and falls management) to take the patient from injury to functional independence many patients may receive inadequate treatment and develop long-term problems, thus impacting on their quality of life and placing an additional burden on health and social services. This study helps provide the evidence base on which to form these clinical decisions.

The inclusion of risk factors in developing shoulder pain and dysfunction within the epidemiology section is paramount to the later exploration of the results that highlight the factors that mediate long-term shoulder disability. These seemingly disparate factors are increasingly acknowledged among practitioners as key characteristics in the development of many major health problems, ranging from cancer and cardiovascular disease to arthritis. Likewise, recovery from a shoulder fracture is influenced by these factors and must be considered when planning treatment and is therefore included in the review. Current practice makes little or no consideration of these factors and including them will challenge the conventional management of both PH fractures and other fractures in an older population.

Most PH fractures in an older population are as a consequence of a fall, but only in approximately 5% of falls does a fracture occur (Oakley et al. 1996). Falling is relatively common, but the relationship between the force of the fall and injury mechanism is complex and recent research suggests that the type of the upper limb fracture produced has a characteristic pattern that distinguishes it from other fractures

(Palvenen et al. 2000). For example, falls resulting in a PH fracture are usually sideways and the person fails to extend their arm, whereas the fall resulting in a wrist fracture is usually forward and the arm is broken as the patient's arm is extended. Identifying fall patterns that result in a PH fracture will allow incorporation of preventative measures in rehabilitation programmes for older adults.

Mechanism of injury resulting in a PH fracture is discussed in Aetiology (page 72) and is important to consider for a number of reasons: a component of fracture rehabilitation is prevention of further injuries and knowledge of injury mechanics allows the tailoring of exercise programmes to diminish the harmful effects of the fall, thus limiting future fractures.

Medical management of PH fractures is based mainly on radiographic appearance with little, or no, importance given to the patient or their personal circumstances. For example, their level of physical activity or previous shoulder pain before the fracture could influence their rate of recovery and management should consider these factors. Many PH fractures are complex with considerable fragmentation of bone and displacement. In an attempt to help standardise radiographic interpretation the Neer classification scheme (Neer 1970; Neer 1970) was developed to classify each fracture into certain groups (the largest group, and the one that is included in this research, is the 'minimally displaced' or type one fracture) and it measures displacement and angulation of each fracture segment. Interpretation of a three-dimensional fracture from a two-dimensional image is fraught with difficulties and research has repeatedly questioned its reliability and clinical utility. Thus, management is based on a system that is unreliable, and even if it were reliable, would fail to consider other important factors in deciding on management. The system is reviewed as it allows comparisons to be made in the discussion between current practice and the author's results, therefore allowing recommendations to be made regarding future management.

As previously stated, management is based on a radiographic system with questionable reliability, but current clinical practice remains unswerving in its commitment to this system. In the case of 'minimally displaced fractures', rehabilitation commences after a variable period of immobilisation and challenging the necessity for immobilisation is a central theme in this thesis. The review considers evidence that casts doubt on the necessity to immobilise fractures with both laboratory and clinical research indicating that tissue responds to *movement* and immobilisation only produces secondary damage.

This research aims to establish if PH fracture healing requires a period of immobilisation for optimum repair. The first task is to review evidence for immobilisation in fracture healing. This is widened to include lower as well as upper limb fractures and the results are extrapolated to PH fractures. The case for immobilisation is discussed and balanced against current evidence and, from this key research, questions are based.

Following the review, the main problems surrounding the medical management of PH fractures are identified and this links to the study's proposed aims. The main goal of the study was to investigate if immediate rehabilitation, without immobilisation, results in better shoulder function and enhanced general health gains. The literature review first considers existing management before comparing it with this new approach.

There is a growing evidence base for the physiotherapy treatment efficacy in several shoulder conditions, for example shoulder instability (laxity of capsule and supporting ligaments/muscles) and impingement (catching of tendons against the coracoacromial arch). Current evidence would support an active approach to rehabilitation using education, exercise programmes and an accelerated return to function, therefore, avoiding the use of electrotherapy modalities and other passive interventions that demonstrate poor clinical value.

These differing approaches to rehabilitation are reviewed to justify the programme used in the author's research and to highlight trends in rehabilitation that this work builds on. The research is generally of a low standard with weaknesses in sample size, flawed designs and unreliable outcome measures and is compounded by the retrospective nature of most fracture research (variable review dates and unreliable outcome measures). This contributes to the uncertainty around fracture rehabilitation, but does allow the author to highlight the necessity for this and future research. This research also challenges modern fracture management and rehabilitation, something that has remained unchanged for decades, and proposes a novel approach to PH rehabilitation. Any new system that questions conventional practice is certain to face opposition from certain quarters. This research is no different and it raises ethical issues concerning the possibility of increasing fracture complications (failure of the fracture to heal or to develop a mal alignment). The importance that some surgeons attribute to rest in fracture repair is strong and concerns that early movement across a fracture site results in more pain and an increase in fracture complications is not uncommon. The review discusses the evidence base of these concerns and questions their credibility by comparing the results in other areas of fracture repair that have avoided immobilisation. Furthermore, as part of the ethical considerations for the study it was important to justify early movement and give a reasoned argument for its inclusion to present to the ethics committee.

In summary, robust epidemiological evidence points to an increasing problem facing health care providers coping with an explosion in PH fracture rates. The evidence base to management and rehabilitation of these fractures is weak and treatment is mainly based along traditional lines. Evaluation is incomplete with no measure of disability or consideration of generic health status. This review considers these key aspects to justify the proposed research and to highlight why this research is original in several fundamental areas. Immediate rehabilitation, avoidance of immobilisation, active patient-centred rehabilitation and realistic outcome measures all challenge current practice and represent a new approach in the field of fracture treatment.

2.1.1 Search Strategy

Electronic searches were performed in the following databases:

a. **MEDLINE (Silverplatter) 1980-2004**

b. **EMBASE 1980-2004**

c. **CINAHL 1980-2004**

d. **The Cochrane Library** (http://www.update-software.com) 2004 Issue 1

e. **National Register of Research Trials 2003**

f. **PeDRO database** Physiotherapy database based at Sydney University *http://ptwww.cchs.usyd.edu.au/pedro/ (October 2004)*

g. **Other searches:** References from key papers were checked for new research areas and key authors were identified. Additionally, colleagues working in specialist areas were contacted for their views on current research areas and authors were suggested.

Search terms included the following:

HUMERUS: injuries/ fractures/ epidemiology/ physiotherapy/ physical therapy/ rehabilitation/ orthopaedic/ aetiology

PROXIMAL HUMERUS: Injuries/ fractures/ epidemiology/ physiotherapy/ physical therapy/ rehabilitation/ orthopaedic/ aetiology

SHOULDER FRACTURES: Injuries/ fractures/ epidemiology/ physiotherapy/ rehabilitation/ orthopaedic/ aetiology/ upper limb/ immobilisation.

HIP FRACTURE: epidemiology/ immobilisation/ co-morbidity

WRIST FRACTURE: epidemiology/ immobilisation/ co-morbidity

UPPER LIMB FRACTURE: epidemiology/ immobilisation/ co-morbidity

2.2: Epidemiology: Proximal Humerus Fractures

2.2.1 Introduction

In order to establish the extent of the problem facing society, the author first needs to consider the epidemiology of PH fractures and their close association with the rise of osteoporosis. Quantifying the number of patients who fracture their proximal humerus each year within the United Kingdom is difficult for several reasons: the problems of fracture classification, case ascertainment, (providing a specific reference code that accurately identifies each condition) and incomplete records ensure that any data must be viewed with some caution. This is further complicated when trying to predict future levels of shoulder fractures when secular trends and an increasingly ageing population are put into the equation. Initially, the Epidemiology section will cover those trials conducted within the last 30 years in the UK in which a specified population was sampled. The inclusion of International studies helps to highlight some of the deficiencies of the UK data and allows a full exploration of the demographic variables.

Increasingly, it is recognised that people who fracture, or have an increased risk of fracturing, their proximal humerus (PH) share certain characteristics that identify them from other types of osteoporotic fractures, for example, wrist fracture. Patients who fracture their wrist or PH are often osteoporotic, but the fall mechanism that results in each fracture is different. The fall resulting in a wrist fracture is usually forwards (Palveneṅ et al. 2000) and the patient attempts to break the fall by using the arm: the fall resulting in a PH fracture is usually sideways and the patient is unable to break their fall (Nevitt and Cummings 1993). The fall producing a PH is usually sideways and the force of the fall is directly onto the shoulder; thus resulting in a fracture. The patient is unable to 'break' the fall with their arm and this inability to save themselves is an indication of their poor neuromuscular control mechanism (Kelsey et al. 1992). Identification of these specific risk factors is fundamental in planning prevention strategies and is important to the author's work as these factors are investigated in the later analyses. Furthermore, identifying the risk factors that predict those patients that will continue to have long-term problems is a departure from present fracture management that fails to consider why some patients make excellent recovery whilst others continue to experience ongoing problems.

As Baron stated:

"...individual fractures have distinct epidemiological patterns, there may be discreet etiologic factors that require separate preventative efforts."

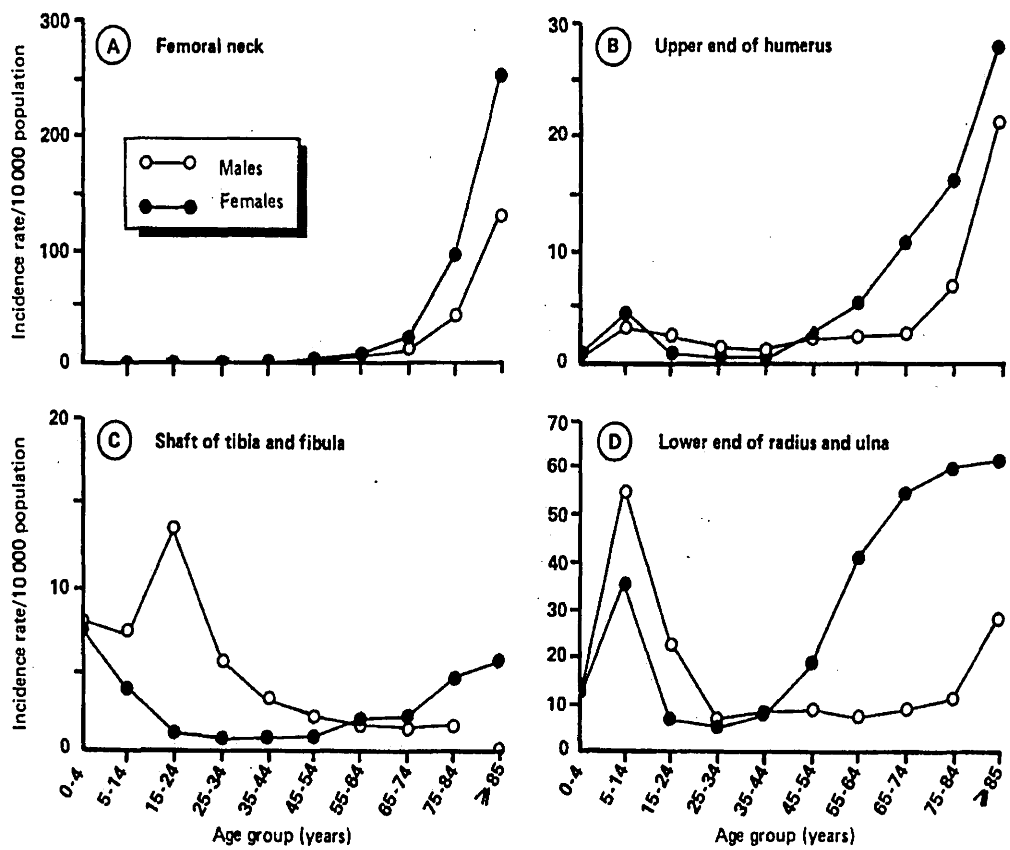
Baron et al. 1996 (Baron et al. 1996)

Finally, the prevalence of shoulder dysfunction in a population not actively seeking medical interventions is considered as this has implications for the proposed research. The natural history of many shoulder problems is unknown and this is important because rehabilitation would be unnecessary if all patients recovered spontaneously following a fracture. The best evidence is considered to help answer this question.

2.2.3 Osteoporotic Fractures

In 1988, 1.3 million people sustained 'osteoporotic fractures' (Melton III 1988) in the USA with estimated costs running to $18 billion. The cost to a UK hospital (1993/4) for any closed upper limb fracture is estimated at £1200 (CHKS 1995) and for women reaching the age of 50 years, 40 out of 100 will have one or more fractures (Lips 1997). Worryingly, these figures continue to increase exponentially. Osteoporotic fractures (e.g. hip, PH, wrist, rib, spine) are characterised by increasing incidence with increasing age compared with non-osteoporotic fractures (fig. 2).

Figure 2: Fracture incidence by type of fracture in UK (Donaldson et al. 1990).



The database for hip fractures is the most reliable and figures are closely monitored as small changes in fracture incidence have significant economic implications for health providers. In an attempt to quantify worldwide projections for hip fractures, Gullberg et al. (Gullberg et al. 1997) estimated that 1.26M hip fractures occurred in 1990, with this rising to 2.6M by the year 2025 and an estimated 4.5M in 2050. Caution must be taken with any estimate of future fracture rates as the unknown factors such as demographic changes and secular trends can not be included in the final calculations. Older people sustaining 'osteoporotic fractures' will continue to take an even greater proportion of the health and social funds in the future, thus the proposed study has clear fiscal implications for health providers faced with a finite budget.

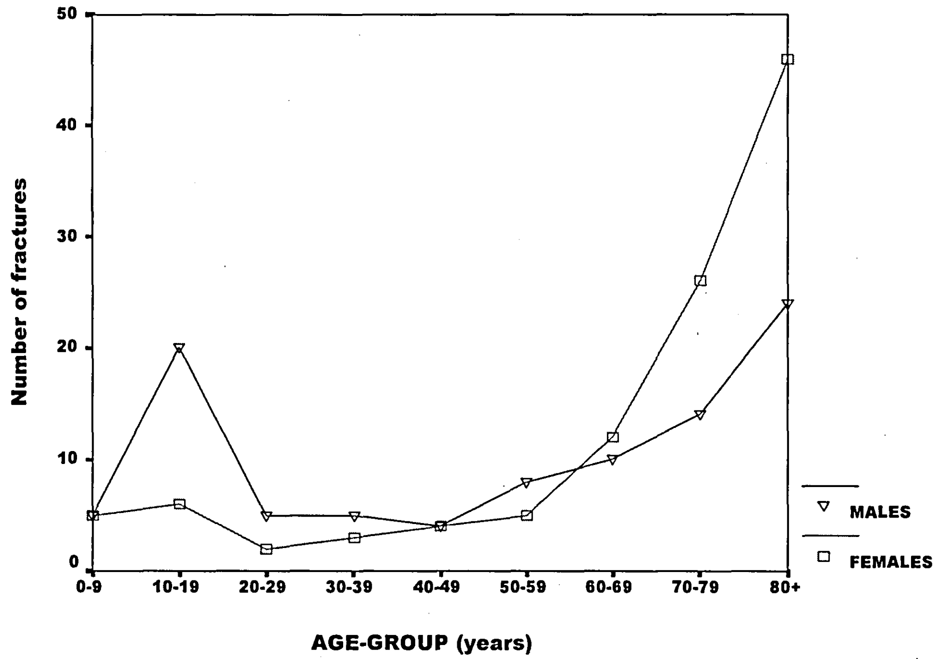
In the last 40 years, five major epidemiological studies have investigated fracture incidence in the United Kingdom. Consistently, their results show that the incidences of fractures increase with age and more women sustain fractures than men. In the largest, and probably the most reliable study (n=5M), Van Staa et al. (Van Staa et al. 2001) demonstrated that women aged 55 years and over were more than twice as likely to sustain any fracture than men. Similar results were seen with Donaldson et al. (Donaldson et al. 1990), however great variation exists between other studies and absolute figures are inconsistent. Studies based in large cities (Singer et al. 1998) (Johansen et al. 1997) give higher fracture incidence figures and this could be explained by demographic variations and coding errors within the sample. Both these studies used populations of just over 15 000 people, a relatively small population compared with the sample used by Van Staa et al. (2001). These studies consistently show that osteoporotic fracture rates are rising and exponentially. Future projections are high and the trend does not appear to be reversing, or even slowing down.

2.2.4 Proximal Humerus Fractures

No study has exclusively examined the rate of PH fractures in the UK and most published studies have grouped all fractures together. The lack of clear and specific data within this field reduces the accuracy of future projects and reflects the low priority given to PH fracture research. Only one epidemiological study has presented results that have included national data (Kannus et al. 2000) (based in Finland) and many only provide extrapolations from smaller samples. These must be viewed with some caution as it is known that PH fracture incidence varies with geographic and demographic features (Karagas et al. 1996; Lauderdale et al. 1998; Ismail et al. 2002).

In 1959, Buhr and Cooke (Buhr and Cooke 1959) published the results of a five year survey on the 'common fractures' occurring in Oxford, UK. They described the shape of the fracture incidence pattern (fig. 3) in the upper humerus as 'J-shaped' (gradual increase followed by a sudden rise in incidence) with its increasing gradient over 50 years of age. The male fracture pattern clearly shows a bimodal distribution (Melton III 1988) with a higher male incidence in early years due to contact sport and road traffic accidents (Donaldson et al. 1990) and then a rising in later years as a consequence of falling. This apparent increase in the older population, Buhr and Cook (Buhr and Cooke 1959) attributed to the 'bones becoming thin and brittle'. Many studies since have reported similar patterns, the only difference being the absolute figures of those people who sustain fractures.

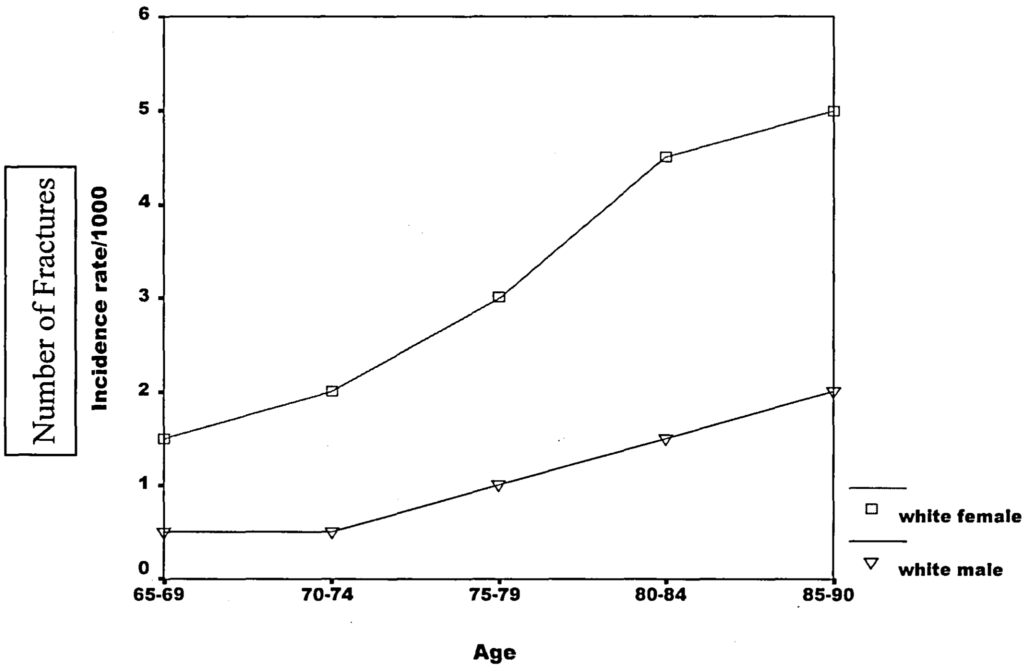
Figure 3: Incidence of Proximal Humeral Fractures describing the 'J' shaped exponential growth in fracture incidence with increasing age (adapted from Burh & Cook, 1959).



Absolute fracture rates vary as several factors (fig.4) are thought to influence fracture incidence: gender (Baron et al. 1996b) geographic (Karagas et al. 1996; Ismail et al. 2002), seasonal (Lauritzen et al. 1993), demographic (Turner et al. 1998) and ethnicity (Baron et al. 1994). Compounding these difficulties are variations in data collection and small sample sizes, although in the only National survey (Kannus et al. 1996) conducted in Finland over a 23 year period, the results showed a 13% increase in proximal humerus fractures each year between 1970 to 1993. Additionally, the mean age of the fracture incidence also increased from 72.1 to 76.2 years over the 23 year period, thus reinforcing the idea that the consequences of PH fractures are mainly on older adults in society.

Figure 4: Incidence of Proximal Humeral Fractures by Gender

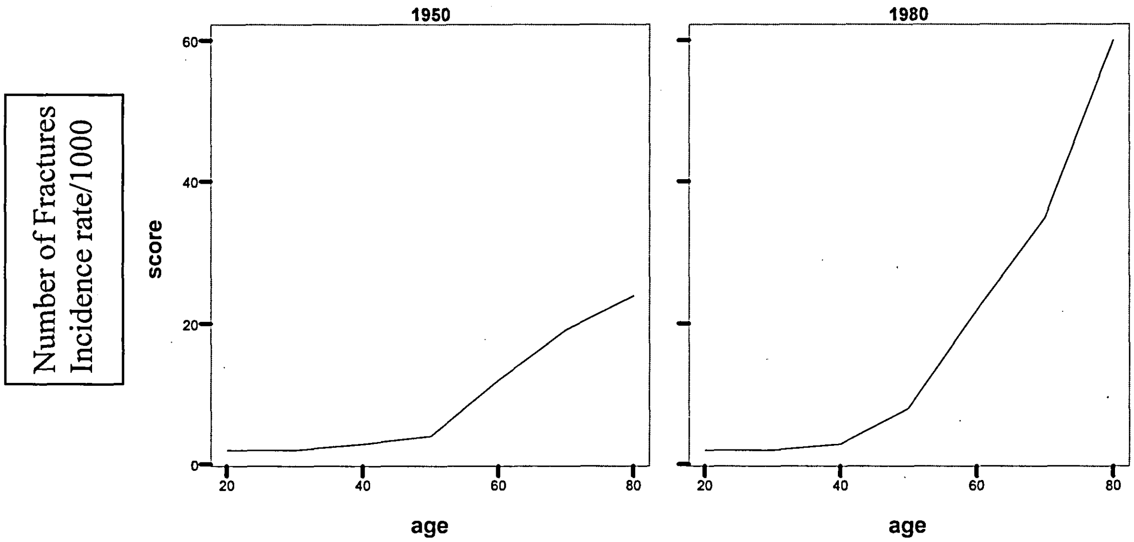
(Adapted from Baron et al. 1996-USA)



Bengner (Bengner et al. 1988) reported similar findings as Kannus and based their 30 year (1950-81) review of PH fractures around Malmo, Sweden. The same precautions as those expressed in the Kannus study are applied to this study i.e. higher fracture rates in Scandinavian countries, nevertheless their results clearly show an increase in the PH fracture incidence from 1950 to 1980 (fig.5). In Tottori, Japan (Hagino et al. 1999), the fracture incidence rate increased over a period of nine years in a population over the age of 35 years, however Asian populations have lower fracture rates (Ho et al. 1989; Rowe et al. 1993).

The reason for the difference in fracture incidence between Asian and Caucasian populations is not clear and it is thought that fracture risk is a complex interaction between genetic and environmental factors (Nguyen et al. 2004). No published work exists that has specifically investigated PH fractures between different ethnic groups, but hip fracture incidence is lower in African (Solomon 1979) and Asian (Xu et al. 1996; Yan et al. 1999) populations compared with Caucasians. The explanation for the difference in fracture incidence is not simply related to BMD as studies have demonstrated that Asian populations have lower or equal bone density compared with Caucasians. Yan and colleagues (Yan et al. 2004) compared the BMD (upper femoral shaft) of Chinese and Caucasian populations and the Chinese had lower bone density, but still had lower incidence of hip fractures. The authors noted that the Chinese population were significantly shorter and lighter than their Caucasian controls and suggested that better neuromuscular function was in some way protective in the Chinese subjects. To highlight the importance of neuromuscular status in fracture prevention, work by Suriwongpaisal et al. (Suriwongpaisal et al. 2001) demonstrated that higher levels of activity were associated with a reduced risk of hip fracture in a Thai population. Interestingly, the incidence of hip fracture is not consistently lower in all Asian countries when compared to Caucasian populations. Hong Kong and Singapore have a similar incidence of hip fracture compared with Caucasians (Lau et al. 2001), but Malaysia and Thailand are approximately 50% lower. This difference between Asian countries is thought to reflect the increasing economic changes and urbanisation of Southeast Asia (Lau et al. 2001).

Figure 5: Age-specific annual incidence of Proximal Humerus fractures between 1950 and 1980 (From Bengner et al. 1988).



Only one study has not shown an increase in PH fracture rates over time (Horak and Nilson 1975). However, the results, as previously mentioned, are unreliable when taken in isolation. The work of Kannus et al. (Kannus et al. 1996) and Hagino et al. (Hagino et al. 1999) is probably a more accurate representation of the fracture rate as they measured the same population over different time periods. If it is accepted and the results are extrapolated to the UK, what are the implications? Proximal humerus fractures constitute approximately 7.4% (Doherty et al. 2001) to 10% (Baron et al. 1996b) of all fractures. Population figures based on 1994 (Johansen et al. 1997) estimated that 1.1 million fractures occurred in the UK. If 10% of these people (Baron et al. 1996b) fractured their PH, this would represent an annual rate of 110 000 fractures. When considering risk of fracture, Barrett et al. (Barrett et al. 1999) calculated that 5% of women aged 65 would experience a fracture if they reached the age of 90. Forty-two per cent (Doherty et al. 2001) of women aged 50 years or over will have at least one fracture and of these, 50% will have multiple fractures.

As previously discussed, this has important implications for the author's research as PH fractures are increasingly seen as part of a continuum with people who fracture their PH more likely to sustain a hip fracture in the future (Lauritzen et al. 1993). Therefore, the proposed research, with its aim to determine the optimum rehabilitation following a PH fracture, may prevent future fractures and, thus, directly influence morbidity and long-term disability. With the recently published results of the 2001 population census (Statistics 2001) showing a five-fold increase in the population over 85 years since the 1950s, PH fracture rates (Baron et al. 1996) (Barrett et al. 1999) are probably underestimating the impact of an ageing population.

2.2.5 Prevalence of Shoulder Disability in the Population

Several studies suggest that much of the population live with shoulder symptoms and associated disability. The exact figures vary, but range from 21% (Chard et al. 1991) to 34% (Chakravarty and Webley 1993). All studies sample people over the age of 50 and some evidence exists that the older population have higher levels of shoulder dysfunction (Badley and Tennant 1992), but other studies refute this claim (Van der Windt et al. 1995). However, Van der Windt et al. (1995) only included General Practitioner (GP) patients and many elderly people who are symptomatic stop seeking further medical help. Two recent studies by Badcock et al. (Badcock et al. 2002) and Pope et al. (Pope et al. 1997) that surveyed a younger population (aged 18 to 75 years old) found that reported shoulder pain reduced to 11.7% and 20%, respectively. Pope et al. stresses the importance of defining case definition and its possible influence on the final result.

What is not in doubt is that many people in the community have some level of shoulder dysfunction, many of whom do not seek help. This has relevance to planning research trials and long-term monitoring of shoulder problems. For example, in North America a third of all acute injuries involve the upper limb (Kelsey et al. 1992) and many of these probably have *pre-existing* shoulder dysfunction. This pre-existing morbidity may probably influence their rate of recovery and possibly change the disablement process.

This has important implications for PH fracture patients, especially if older adults already have high levels of shoulder dysfunction before their fracture. Pre-existing shoulder morbidity may influence recovery and eventual functional status. No previous research has considered this fact as all assume, incorrectly, that the person had good shoulder function pre-fracture and attribute any resulting dysfunction to the injury. This complicates the interpretation of the results, but does give a realistic representation of fracture recovery and is another reason why the proposed research questions current thinking. Thus, pre-fracture shoulder status must be considered when interpreting the outcome of interventions that aim to return patients to 'normal' function. Many people have reduced shoulder function before the fracture and this may influence the recovery process. Thus, an important reason to record shoulder dysfunction and balance this across groups using RCT designs.

2.2.6 Summary

The evidence suggests that the rate of osteoporotic fractures is increasing and the rate of change appears to be accelerating. Humerus fractures, as a common osteoporotic fracture, are also increasing, but the lack of large epidemiological studies makes confirmation of these trends difficult. Osteoporotic fractures will continue to be a major problem for a large section of the ageing population and limit their quality of life (Wildner et al. 2002) whilst placing additional fiscal strain on the health and social services (Torgerson and Dolan 2000). Thus, the proposed research is timely and important in view of the problems facing society. The next part of the literature review considers the risk factors, for example, gender, age, osteoporosis, neuro-muscular status, that predispose a certain person to having a PH fracture as this may have significant implications to the findings of this study.

Following a PH fracture, it is often stated that full function is regained within one year or less (Mills and Horne 1985; Young and Wallace 1985) of the initial injury, but serious methodological limitations and poor outcome measures of the research casts doubt on this view. These studies reported 'excellent' or 'very good' results in terms of shoulder function in over 90% of cases by 6 or 12 months, but reassessed the patients with the Neer outcome measure (Neer 1970) which has not been validated and no reliability data exists.

In fact, evidence suggests that patients have ongoing shoulder problems for many years after an upper limb fracture (Wildner et al. 2002). Furthermore, an older population (aged 65 years and older) is likely to complain of shoulder pain for other common shoulder problems many years after the initial presentation (Vecchio et al. 1995). Most orthopaedic research evaluates PH fractures after one year of the initial injury and states that most make a full recovery (Clifford 1980; Mills and Horne 1985; Kristiansen and Christensen 1987). Many might, but, especially in older adults, patients never fully recover and they are forced to adapt to limited shoulder function. Previous PH fracture research in this area has tended to use outcome measures that have not undergone rigorous evaluation and this has possibly over estimated patient recovery. This is the first study to evaluate patients using a battery of outcome measures that will accurately assess recovery after a PH fracture.

2.3 Epidemiology: Risk Factors for Proximal Humerus Fractures

2.3.1 Introduction

Risk factors are highly relevant to this research as they identify those patients who will fracture their PH and this has important implications for rehabilitation and the prevention of future fractures (or other injuries). Identifying those patients at greater risk of developing complications or ongoing problems after a PH fracture will allow health staff to target resources on maximising shoulder function.

Gender and age are discussed next in relation to PH fracture incidence as they both influence fracture rate. Currently, PH fractures and their consequences affect women, but the rate of osteoporosis is increasing in men and this may be linked to a possible reduction in co-ordination and strength with more sedentary work (an association exists between heavy manual labour and a reduction in fracture rates (Herala et al. 2002)), they too will probably experience similar problems. This is important to this study as gender is later shown to influence recovery and long-term levels of shoulder disability.

Additionally, PH fracture incidence increases with age and this has future implications for older adults as they are the fastest growing group within the UK. It is important to consider the trends and the magnitude of the problem faced in the future as they emphasise the importance of the proposed study and permit the author to suggest other areas of potential research. The second part of this section reviews the contribution of bone mineral density (BMD) as a predictor of future fracture risk-specifically to the upper limb, but with some discussion on the global impact of reduced BMD. Measurement of BMD is not included, as this is a huge area that falls outside the remit of the literature review.

2.3.2 Gender and Age

Seminal work by Knowelden (Knowelden et al. 1964) reported an increase in the PH fracture incidence in both men and women with increasing age, but higher in women. Several authors report similar results with all 'osteoporotic fractures' (Singer et al. 1998; Van Staa et al. 2001; Ismail et al. 2002) and more specifically with the proximal humerus (Kristiansen et al. 1987; Kannus et al. 1996; Johansen et al. 1997). The fracture ratio between men and women varies: 1:3 (Baron et al. 1996b); 1:2.3 (Singer et al. 1998) and 1:2 (Horak and Nilson 1975). Certainly, women over the age of 60 years have more fractures and specifically more fractures to the proximal humerus. This trend is set to increase (Kannus et al. 2000) as a recent national survey in Finland suggested a three-fold increase in PH fractures by the year 2030. The investigator gives no possible explanation for this rise, but fall-induced injuries are increasing (Kannus et al. 2000) and this suggests that neuromuscular status is increasingly compromised in a large section of the older population.

The increasing sedentary nature of work and leisure pursuits with older adults (aged 65 and over) in the UK spending on average 3.75 hours watching television per day (Statistics 2005) could explain why muscle strength and co-ordination, leading to more falls, is declining. This is compounded by increasing social isolation and the rise in obesity with clinical obesity reaching 300 million worldwide (Brundtland 2002). Thus, fall-induced injuries show no sign of reducing in the future. Obesity is associated with higher levels of disability (Webb et al. 2003), spinal (Webb et al. 2003) and knee pain (Webb et al. 2004). However, low BMI is a risk factor for hip fracture (Nevitt and Cummings 1993), but not PH fractures (Lee et al. 2002). The exact reason why lower BMI increases hip fracture risk is unknown, but less soft tissue around the upper femur during the fall could increase the force applied to the bone resulting in a fracture. Another possible explanation, is that obesity produces increased bone stress and this results in higher levels of BMD, thus reducing fracture risk. These factor are not as relevant to PH fractures as less fat is laid down around the shoulder girdle, but BMI was recorded in the present study to measure any possible influence on recovery.

Allowing for the higher fracture incidences in Scandinavian countries (Ismail et al. 2000), PH fracture incidence continues to rise and with the recently published Population Census in the UK (Statistics 2001) indicating that the percentage of the population over 60 years is greater than that under 16 years (21% versus 20%, respectively), the three-fold increase in fracture incidence by the year 2030 might actually be a conservative estimate. If the increase in the older population continues, and there is no reason to suggest that it will not, then humerus fractures are likely to have an even greater impact in the future. The cost to the health service, specifically to PH fractures, is unknown, but Dolan and Torgerson (Dolan and Torgerson 1998) estimated that the NHS and social services spent £942 million on fractures in women aged 50 and over in 1998. The actual cost is higher as this does not include men, the 'hidden' costs of care or additional visits by healthcare workers. Hip fractures accounted for the largest part of the NHS budget (87%) and research from the USA supports this with seven billion dollars been spent on hip fractures in 1988. The exponential growth in PH (and hip fractures), unlike many other common non-osteoporotic fractures, incur considerable ongoing care costs. The proposed research will potentially have significant cost benefits to the NHS if early rehabilitation results in less long-term disability and faster return to *independent* function for the patient. Furthermore, if restoration of function improves balance and physical activity levels, then this may prevent future fractures.

2.3.3 Osteoporosis

Osteoporosis is defined as a bone mineral density (BMD) level more than 2.5 standard deviations (SD) below the young normal mean (WHO 1994) and low bone mass (or osteopenia) is a BMD below 1 SD, but less than 2.5 SD. Increasingly, more people are being diagnosed as 'osteoporotic' and Melton III (Melton III 1995) estimated that 70% of the women in North America aged over 80 years are osteoporotic, a total population prevalence among women of approximately 30%. Figures vary, but by the age of 50 years the chance of a woman having an osteoporotic fracture in her remaining life is 30-42% (Delmas 1995; Doherty et al. 2001). More worryingly, the report by Doherty (Doherty et al. 2001) states that more than 50% of the women sustaining a fracture, will have multiple fractures. Multiple fractures with increasing impairment (Lauritzen et al. 1993; Lee et al. 2002) are a major cause of disability and functional limitations are the main driving force behind the downward spiral in the disablement process (Lawrence and Jette 1996).

Medication is the primary intervention for the treatment of osteoporosis after the diagnosis is made following bone mineral density (BMD) measurements. However, the relationship between low BMD and fracture risk is complex and several confounding variables exist. Several researchers have reported lower BMD in fracture populations, both in upper (Nguyen et al. 2001) and lower limb fractures (Nevitt and Cummings 1993), compared with non-fracture groups. Low BMD is consistently identified as an independent variable in those people who have several common fractures: wrist (Ingle and Eastell 2001), hip (Nevitt and Cummings 1993), rib (Seeley et al. 1991) and humerus (Lee et al. 2002). Although the detection rate (or sensitivity) of BMD to identify those people who will have a fracture is poor (Kanis 2002) as 96% of such fractures would arise in women without osteoporosis. After the age of 70 years the relationship between BMD and fracture risk changes (Gardsell et al. 1989) and it is suggested that neuromuscular control mechanisms below the age of 70 years act to protect the skeleton by limiting the effects of the impact or preventing a fall (Cummings and Nevitt 1989).

2.3.4 Other Factors

Several other factors seem to contribute to fracture risk; the greatest of these being a propensity to fall. Geusens (Geusens et al. 2002) clearly demonstrated in a large cohort study (n=2649) that people diagnosed with osteoporosis, who reported no falls in the previous year, had a 2.8 fold relative risk (RR) of having a fracture compared with a RR of 24.8 in those who reported more than one fall in the previous year. This nine-fold difference in the risk of fracture highlights the importance of fall prevention programmes and the multifaceted nature of fracture prevention. Other independent risk factors include: maternal hip fracture (Cummings et al. 1995), weight at the age of 30 (Lee et al. 2002), poor functional status (Kelsey et al. 1992), and hemiplegia (Gallagher et al. 1980). These factors could possibly reflect neuro-muscular function and in the case of maternal hip fractures, the increased risk could be related to inherited lower BMD or associated factors such as activity level that has been shown to increase the incidence of osteoporotic fractures (Joakimsen et al. 1998; Turner et al. 1998).

This has important implications to the author's thesis, as the current practice in prevention of fractures is primarily by medication, aimed at improving, or maintaining, BMD. In a large (n=15098) longitudinal study over 25 years, investigating the levels of osteoporosis on fracture incidence in twins (Kannus et al. 1999), the authors challenged this approach. The study demonstrated only a 10% concordance rate i.e. a small incidence of both twins having an osteoporotic fracture if osteoporosis was the primary cause of fractures. In conclusion, he recommended that treatment should be directed towards fall prevention and the protection of vulnerable anatomical sites, thus limiting the over reliance on medication to increase bone density. The author's research compliments this approach as maintaining, and improving, physical function is central to the rehabilitation process. Therefore, reducing future fractures whilst maintaining function and preventing the person's descent into disability.

PH fracture rates vary both geographically and seasonally, with studies in the UK reporting greater fracture incidence during periods of ice and snow (Ralis 1981; Ralis 1986) with a 4% and 12% increase in fracture incidence in women and men, respectively (Levy et al. 1998). This might explain the higher fracture rates in countries of Northern Europe with their colder climates, but Lofthus (Lofthus et al. 2001) found no such seasonal variation in a study based in Norway.

In North America, variations in the incidence of hip fracture exist (Karagas et al. 1996; Lauderdale et al. 1998), with higher rates in the south compared with the north of the country. In proximal humerus fractures, the difference is in an east-west direction, with the lower incidence in the west (a similar pattern is seen in distal wrist fractures). No definite explanations for these variations are given, but the different aetiology for lower and upper limb fractures (see Aetiology of Falls) could help explain the differences. More people live below the poverty line in the south of the country compared with the north and studies link socioeconomic factors to increased morbidity (Davies et al. 1994; Paul et al. 1998) and mortality (Kitagawa and Hauser 1973). High levels of co-morbidity are predictive of functional decline (Stuck et al. 1999) and falls and associated fractures are just concomitants of deterioration in general health. Thus, PH fracture incidence is influenced by many known, and unknown, factors that are not considered in modern fracture management.

If the fracture rate is higher in winter, this will place an increased burden on the health service as it also struggles to manage the influx of acute respiratory disease at the same time. Furthermore, if PH fracture incidence varies across the UK, as seen with other fractures across Europe and USA, then some regions might experience even higher demands. This hypothesis remains speculative as no national epidemiological study exists for the UK.

2.3.5 Summary

Gender is still a risk factor for sustaining a PH fracture with women more likely to have a fracture compared with men although this trend is lessening. The reasons for this are complex and it is too simplistic to attribute this solely to increases in osteoporosis. Changes in lifestyle as a result of increasingly sedentary occupations and leisure pursuits are influencing BMD and declines in neuromuscular status (i.e. balance, strength) are increasing a person's propensity to falling and sustaining a PH fracture. Furthermore, the influence of seasonal variations and geographic factors on fracture incidence suggests that the burden of PH fractures is not equally distributed within the UK, therefore producing unequal stresses on healthcare providers. Previous PH fracture research commonly ignores these issues and fails to incorporate them within the study design or evaluates their impact on the patient. The author's research does, for the first time, include these factors in detailed analysis to explore the reality of fracture recovery. This has obvious implications to PH fractures, but the findings could equally be applied to other similar fractures and warrants further research.

The next section reviews the factors that affect shoulder function in a population and considers the impact of these factors on the upper limb. At face value, these factors might appear disparate, however the author's research substantiates their relevance to shoulder recovery and patterns start to emerge that allow reinterpretation of commonly held beliefs.

2.4 Epidemiology: Factors Affecting Shoulder Function

2.4.1 Introduction

Within any population, evidence suggests that many people experience chronic shoulder dysfunction or a loss of normal function (MacFarlane et al. 1998). Shoulder dysfunction is not a time-limited condition and many people continue to experience pain and loss of function many months after consulting their general practitioner (GP) (Chard et al. 1991; Croft et al. 1996). The definition of 'dysfunction' is "an impairment or abnormal functioning of the body part or organ" (Gay et al. 1984) and shoulder dysfunction is a limitation on normal shoulder use due to pain or stiffness. This is distinguished from shoulder disability, and there are many definitions of disability, but within the context of this study it is defined as:

"Limitation or inability in performing tasks, activities and roles to levels expected within physical and social contexts"

Jette, 1994 (Jette 1994).

This distinction is important to the author's research as shoulder disability incorporates the social impact to the patient and therefore considers the wider impact of shoulder fractures. Once again, this approach is new in the field of fracture rehabilitation and, consequently, failure to measure the social component post-PH fracture, results in under-reporting of the problem. Current orthopaedic research rarely considers the social impact of PH fractures (or any other fracture) and compounds this by only evaluating impairment (ROM, strength) in most trials.

Pain is included in this section, strictly speaking not a disability, but as a strong mediator of disability and its inclusion is needed to fully explore the problems of upper limb function. Delineating the full impact of shoulder pain and disability is further complicated by the identification of what constitutes the shoulder, neck or upper back. These are, obviously, not discreet anatomical areas, such as the knee or ankle, and considerable overlap exists. For example, is the pain on the medial border of the scapula part of the shoulder, neck or upper back? This confusion does influence the general applicability of the results and this is highlighted in the review. For example, following a PH fracture, some studies do not consider pain on the posterior aspect of the shoulder as a consequence of the fracture, others do, and this can lead to problems when comparing results.

As previously discussed (page 49), risk factors exist that predisposes a person to having a PH fracture. Likewise, recovery from shoulder fractures (or other shoulder conditions) does not proceed in a uniform manner, but is probably influenced by many factors and most of these remain unknown. The following section considers other factors that are important to the author's research for two reasons: first, to fully understand why recovery rates vary, it is important to measure all possible risk factors at the start of the proposed study. Secondly, as part of the data analysis, the factors are included in the regression analysis modelling to help identify the factor, or more probably; the combination of factors, that predict those people with a PH fracture who will develop long-term shoulder dysfunction.

The World Health Organisation defines risk as:

"...a probability of an adverse outcome, or a factor that raises this probability."

WHO, 2002 (WHO 2002)

Some researchers have investigated risk factors in developing shoulder impairment and disability, but most of the available evidence concerns general musculoskeletal disability and no research has considered risk factors in PH fractures with the possible exception of age. Current practice in PH fracture management relies almost totally on radiographic appearance to make the prognosis. The proposed research is certainly the first in the UK (and probably in all Europe and North America) to consider a range of factors and evaluate their individual and collective influence on recovery. This is important to clinical practice as identification of risk factors allows health workers to distinguish those patients who require additional rehabilitation and longer follow-up care. Thus, targeting the most needy population and make use of a finite resource.

The major risks of gender, co-morbidity and other socioeconomic factors are discussed and related to the upper limb. These are later included in the author's research as part of the regression analysis when identifying factors that predict long-term disability.

2.4.2 Shoulder Pain

In a recent survey (Picavet and Schouten 2003) conducted in the Netherlands, investigating the prevalence of musculoskeletal pain in a population aged 25 years and over, the authors identified shoulder pain as the second most common area of musculoskeletal pain (20.9%) after low back pain (26.9%). Overall, 53.9% of the sample reported some musculoskeletal pain at the time of the survey (point prevalence) and 44% experienced pain for longer than three months. The survey was large (n=3664), but its relatively low response rate (47%) questions the reliability of the result. However, shoulder pain is a common problem in the population and symptoms continue to persist even with some form of medical or physiotherapy intervention. This does raise the question of treatment efficacy and if the high recurrence rate is due to inappropriate treatment or a natural history that continues over many years (this is discussed in section 2.7.3 on Shoulder Rehabilitation).

The recalcitrant nature of shoulder pain is reinforced by another study (Croft et al. 1996) based in primary care investigating patients over an 18 month period with shoulder pain. Only 49% made a complete recovery despite treatment, and the investigators question the efficacy of injection therapy. Similarly, Vecchio and co-workers (Vecchio et al. 1995), found that having treatment made no difference to long-term prognosis. Vecchio reassessed patients with identified shoulder problems over a three year period (n=136) and 60% had received some form of treatment (injection 41%, physiotherapy 17%, non-steroidal anti-inflammatory medication 2%). After three years, 74% still had persistent shoulder signs, however details about treatment received was not included and treatment success was not evaluated by a recognised outcome measure.

Commonly, treatments of injection therapy and medication have no evidence base from which to suggest they change the progression of shoulder pain and disability. This questions the efficacy of current approaches to the most common shoulder problems and justifies the author's research in this area.

Persistent shoulder pain and associated disability are not uncommon after disease or injury and this is similar to many other conditions with a pattern of recurrence and exacerbation. Shoulder problems are not self limiting and many people continue to report ongoing problems many years after the initial onset, especially in older adults. Additionally, a significant percentage of those people with shoulder problems do not actively seek medical help or additional treatment. They adapt to the functional limitation and conceivably, this could lead to an underestimation of shoulder problems in the population. Currently, commonly used treatment strategies have little evidence of efficacy with longitudinal studies showing no difference in recovery rates between those having treatment or not (Vecchio et al. 1995; Croft et al. 1996). However, large, well designed, prospective studies investigating treatment efficacy do not exist for physiotherapy interventions, but the proposed research will add to the available literature on treatment effectiveness in the area of shoulder fractures.

If common shoulder problems are resistant to treatment and many people continue to experience pain for many months, as research indicates, then the implications to the author's research are important for two reasons. First, if relatively minor shoulder soft tissue problems are slow to recover and recurrence is common, then PH fractures with both bony and soft tissue damage are more likely to produce even greater long-term shoulder dysfunction. Trauma to the shoulder that results in a fracture is also likely to produce associated soft tissue damage (Codman 1934). Additionally, work by Visser (Visser et al. 1999) found evidence of nerve damage in 68% of patients who had sustained a PH fracture, thus, reinforcing the belief that soft tissue damage is also associated with shoulder fractures.

Secondly, in the studies cited, the mean ages of the populations studied are approximately 45 years (Vecchio et al. 1995; Croft et al. 1996; Picavet and Schouten 2003) and mean age for PH fractures is closer to 70 years or older (Kannus et al. 1996; Court-Brown et al. 2002). Ageing tissues are slower to respond to injury and disease with histological and biomechanical studies demonstrating age-related changes in tendons, ligaments and capsular structures (Laurencin and Gelberman 1993) that will delay, or prevent, repair. An older population will, in all probability experience, continuing problems after injury that could last for several years and some evidence in the area of fracture rehabilitation would support this view (Madhok and Bhopal 1992; Wildner et al. 2002). Also, this runs counter to the belief that recovery after a PH fracture is complete within one year of the injury (Clifford 1980; Young and Wallace 1985). Investigating wether patients have ongoing problems after a year of their initial injury is one of the aims of the proposed study and comparing recovery with previous research will help to give a clear indication of patient status at one and even two years post-fracture. To date, no other research has investigated long-term shoulder dysfunction following a PH fracture and this study proposes to fill this gap.

2.4.3 Gender

Gender, as well as a major risk factor in sustaining a fracture or developing general disability, is associated with increased utilisation of health care (Verbrugge et al. 1989). Considerable evidence supports the premise that female gender is an independent risk factor in developing shoulder disability. Only one paper (Lundgren-Lindquist and Sperling 1983) reports no difference between gender in people over the age of 79 years, when reporting upper limb dysfunction. The others consistently report women having higher levels of shoulder dysfunction and pain (Cunningham and Kelsey 1984; Gotoh et al. 1998; Picavet and Schouten 2003). The prevalence of shoulder disability in Holland in people aged 18 years and older (Van der Windt et al. 1995) for example, is 11.1 versus 8.4 (1000/years) for women and men, respectively. Even when the neck is included in the assessment (Ektor-Anderson et al. 1999; Croft et al. 2001), women still show higher levels of disability.

Why do women show higher levels of disability? It is suggested that gender differences in social learning models could explain the phenomena (Keefe et al. 2000). Women with osteoarthritis (OA) of the knee show pain behaviours such as guarded movement, rubbing and keeping the joint rigid. This maladaptive coping strategy (an abnormal reaction to a problem that maintains symptoms) could explain increases in disability as Cunningham and Kelsey (Cunningham and Kelsey 1984) observed higher self-reported disability in women, but in the performance tests no gender differences occurred. At a physiological level, variations in female responses to noxious stimuli (Fillingim and Maixner 1995) compared with males, is another possible explanation for higher rates of reported pain and disability. The answer is probably a combination of physiology, psychology and socioeconomic factors. Some of these components are reviewed in the next two sections as all these factors potentially have an impact on the author's research and the complex relationship they form has never been considered in upper limb fracture research to date.

The implications of this research to the proposed study are that more PH fractures are in women and this is reflected in the population sample. Furthermore, women, for whatever reason, experience more long-term disability following joint impairment compared with men (Dunlop et al. 1998; Keefe et al. 2000; Jinks et al. 2002; Wildner et al. 2002). This evidence suggests that gender influences recovery from a range of musculoskeletal impairments and women are at greater risk of developing long-term problems. However, in all the papers reviewed by the author on PH fractures, no paper considered women to have a greater risk of developing shoulder disability as a consequence of this fracture. This is the first study to re-interpret the literature base and suggest a possible link.

2.4.4 Co-morbidity

Evidence connecting co-morbidity to the development of shoulder impairment or disability is limited and further research is needed in this field. To explore possible relationships between co-morbidity and shoulder disability, work on healthy ageing and osteoarthritis are included. Many people who fracture their PH have other problems that reduce their quality of life (Sartoretti et al. 1997) and these will influence recovery. No research has specifically investigated the effects of co-morbidities on PH fractures recovery, but in a large study conducted in USA (Verbrugge et al. 1991) on arthritis, the authors concluded that arthritis had a propelling effect on disability. The high level of co-morbidities in people who sustain a PH fracture (Sartoretti et al. 1997) could possibly indicate a similar effect as that seen in arthritis. i.e. recovery mediated by the presence of co-morbidities. Previous PH fracture research has failed to consider this when evaluating the outcome.

Absence of co-morbidity, or several chronic conditions, is recognised as an independent predictor of healthy living and continued good physical health (Guralnik and Kaplan 1989; Harris et al. 1989). Consequently, the lack of other diseases allows the person to remain active, thus avoiding further risk factors, for example raised body mass index (BMI) (Stuck et al. 1999; Jinks et al. 2002), low levels of exercise (Strawbridge et al. 1993) and functional limitations that influence disability (Lawrence and Jette 1996).

Increasing age is associated with a number of conditions (Dunlop et al. 1998), but this is not a chronological progression and huge variations exist in each age group (this is discussed in the socioeconomic factors, page 65). Similarly, the National Health Interview Survey (NHIS) (Verbrugge et al. 1989) reported that health problems are the main driving force in the disablement process and, that as the number of chronic problems increases, so the level of disability rises rapidly. This was a large survey (n=16 148) and sampled non-institutionalised adults aged 55 years and over, therefore its results are reliable. According to these figures, arthritis was the most common chronic condition (43.7%) followed by high blood pressure (40.3%) and other studies support these findings (Badley et al. 1984; Verbrugge et al. 1991). People with arthritis also had significantly higher levels of chronic conditions compared with those without arthritis (2.8 versus 1.8 chronic problems).

Many people with PH fractures experience poor general health and part of this is related to associated co-morbidities (Sartoretti et al. 1997). This is important to understand, as it is the complex interaction between different diseases that dictate their functional status. The fracture may just be the last in a series of events that push the patient toward increasing disability and the loss of independence.

In addition to co-morbidity, pain will influence a person's general health perception as pain in one area of the body increases the likelihood of experiencing pain in another region (Ektor-Anderson et al. 1999). Croft was the first to coin the phrase: 'the more pain you have: the more you get' (Croft 1996) and this holds true in the shoulder. Many patients with shoulder conditions experience ongoing pain (MacFarlane et al. 1998) and this will be compounded by co-morbidities.

In a study comparing a person's 'quality of life' with five common shoulder conditions (Gartsman et al. 1998) and against a range of other medical conditions, found that quality-of-life was reduced by a similar margin in both groups (see appendix XIV, tables 1 & 2 for full results of Gartman et al.'s study). The impact on ‘quality of life’ with shoulder conditions was as great as diabetes, heart failure and myocardial infarction. For example, patients with shoulder arthritis had SF-36 lower scores than patients having a myocardial infarction (Physical Function: 57.5 & 69.7; Pain: 36.6 & 72.8, Role limitation physical 41.0 & 51.8; Shoulder arthritis and Myocardial infarction respectively). These results would suggest that the effects of shoulder problems are not just stiffness and occasional episodes of pain, but they are part of a more complex global impact on the patient and contribute to pain experienced in areas of the body remote from the original problem (Rekola et al. 1997).

The proposed study will investigate whether PH fractures have a similar effect on the patients’ general health and ‘quality of life’. The proposed research addresses these limitations and the decision to use a generic health measure as part of the outcome measures (discussed in Chapter 3) are based on the problem of associated co-morbidities. So far, no previous research study has used a generic health measure to evaluate PH fracture outcome.

2.4.5 Socioeconomic Factors

Socioeconomic status is one of the most persistent and ubiquitous risk factors known for many common health conditions. The term ‘socioeconomic’ refers to demographic, social and personal circumstances such as education level, income, housing, ethnicity, unemployment and living status. A plethora of factors exist and some studies specifically measure a given selection or rely on global assessment of deprivation such as the Townsend deprivation index (Townsend et al. 1988).

The Townsend index uses four dimensions to produce a measure of deprivation:

- Percentage economically active residents aged 16 to retirement age
- Percentage private households who do not own their own car
- Percentage households who do not own their own home
- Percentage private households with more than one person per room.

Wilson, 2000 (Wilson 2000)

From this, a Z-score (an index formed from normative data for a given population-allowing comparisons to be made between different groups or individuals) is used to produce a single index of deprivation. Usually the electoral wards are used to assess the deprivation within a specific region. Some problems exist with only using four dimensions of deprivation and no account is given to other factors, for example education, ethnicity and income, however it does provide a reasonable measure of deprivation, previous data exists on a range of populations and it easy to use.

Seminal work based on death certificate information from the 1960s (Kitagawa and Hauser 1973) links socioeconomic factors to mortality. Since then, several other reports (McDonough et al. 1999; Melzer et al. 2000) identify socioeconomic factors as a main driving force in the inequality of health with the socioeconomically disadvantaged experiencing the greatest burden of morbidity. This section reviews the influence of socioeconomic factors in the mediation of disability, specifically related to the upper limb.

Research exists on general disability and socioeconomic influences, but few report on any possible relationship between musculoskeletal dysfunction and the impact of socioeconomic factors. A survey based in Sheffield (Paul et al. 1998), that sent questionnaires to all wards found that 27.5% of responders reported a health problem that limited their activity. They defined this as long-term limiting illness (LLI) and it progressively increased with age and was higher in men than women in all age groups except for the 85 to 94 year age band. The incidence of reported musculoskeletal disorders increased rapidly with age and showed wide variations within different areas of Sheffield. This correlated closely with levels of social deprivation (as defined by the Townsend index) with the highest levels of musculoskeletal problems in areas of high social deprivation. Differences between the least (Broomhill: 44.5%) and highest deprived area (Brightside 56.9%) in Sheffield, were significant with a 1:3 relative risk of developing musculoskeletal problems in areas of high deprivation. People in all areas reported similar levels of joint impairment, but different disability levels as these are mediated by other factors, for example, level of education, income and housing status (Cunningham and Kelsey 1984; Eachus et al. 1999).

2.4.6 Summary

Pain is a major determinant of shoulder function, although the belief that shoulder pain is a self-limiting condition is shown to be wrong, judging by the population studies. Also, treatment does not seem to affect the long-term outcome, however the results must be viewed with some caution as the evidence for treatment efficacy is largely retrospective and lacks consistency in outcome measures and, more importantly, type of treatment given. After a PH fracture, pain is the main symptom and it is closely associated with loss of shoulder function.

Gender, advancing age and co-morbidities are linked to higher levels of shoulder problems and continuing long-term dysfunction. The wider impact of quality of life issues is highly relevant to PH fracture patients who are commonly in poor general health and shoulder pain will have a disproportionate effect on their every day functioning.

Additionally, socioeconomic variables have powerful influences on disease prevalence and its progression. When evaluating outcome, few studies include measures of socioeconomic status, especially in the area of orthopaedics. The studies that exist on the effects of socioeconomic factors on musculoskeletal disease suggest that recovery and progression of musculoskeletal disability is, in part, mediated by factors such as education, income and employment status.

The population forming the author's research includes areas of high deprivation and research indicates that this will influence the eventual outcome. Socioeconomic parameters are used in the regression analysis to examine whether levels of socioeconomic deprivation affect recovery from PH fractures.

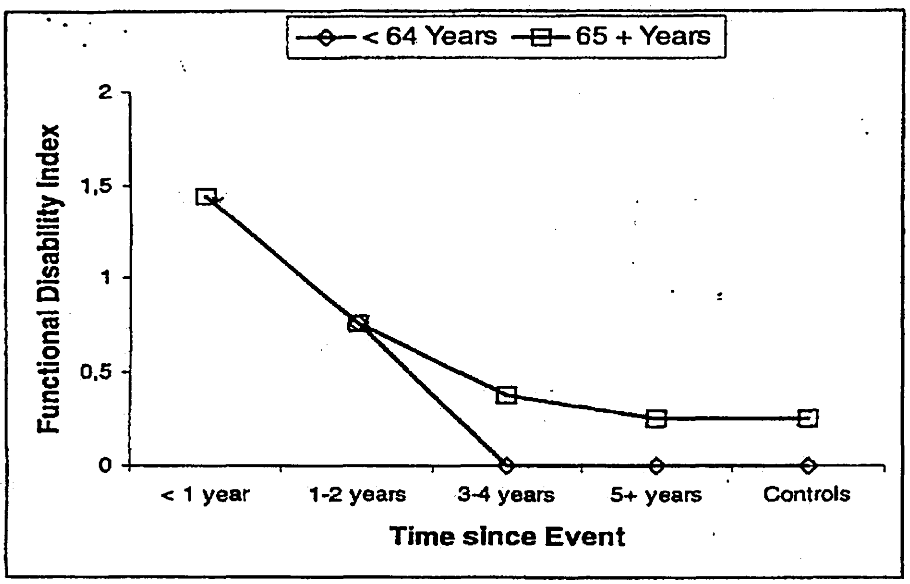
2.5: Aetiology

2.5.1 Introduction

Before discussing upper limb fractures and its aetiology, it is necessary to define 'falls' and the risk factors that predispose a person to falling. Most PH fractures are as a result of moderate trauma such as a fall from standing height. Most research covers general falls and interventions; very few studies exist specifically related to upper limb fractures and work on hip fractures is included to develop ideas and themes related to upper limb fractures.

It is essential to review the mechanism of falling and peoples' predisposition to falling, and preventing it, is an important aim of rehabilitation (Skelton 2001). Preventing future falls, and the associated fracture, is not the key aim in the author's research, but it is important to consider the reduction in neuromuscular status (i.e. loss of balance) when planning rehabilitation. Research suggests that following an upper limb fracture, people are more likely to fall again and sustain another fracture (Gallagher et al. 1980; Cummings et al. 1995). Furthermore, this increased risk of falling is probably higher in the proceeding years after the fracture as recent research (Wildner et al. 2002) indicates that functional activity is reduced in the two years immediately following the fracture and only approaches 'normal' levels after four years (fig.6). This continuing reduction in functional levels questions the belief that patients make excellent recovery after PH fractures, but also, loss of function is related to increased risk of falling and hence further fractures. Rehabilitation should maximise function to reduce the risk of further fractures and central to this is improving neuromuscular status, therefore linking falling to the proposed study.

Figure 6: Level of disability after a fracture grouped by age (<64 years & 65 years +) (Wildner et al. 2002) People below the age of 64 and sustained are controls and are represented along the horizontal axis.



A complex pattern emerges on fall mechanisms, similar to that of epidemiology with many people falling, but only a relatively small percentage sustaining a fracture. The factors that determine if a person is likely to have an upper limb fracture are discussed as these have direct relevance to the author's research with many patients sharing common characteristics. Identifying these characteristics will improve rehabilitation programmes by accelerating recovery and preventing patients from having further fractures.

2.5.2 Falls and Trauma

Defining what actually constitutes a 'fall' may seem straightforward, but several definitions exist:

"An event which results in a person coming to rest unintentionally on the ground or other lower level, not as a result of a major hazard."

Tinetti, 1988 (Tinetti et al. 1988)

" A fall is an unexpected event where a person falls to the ground from an upper level or the same level".

WHO, 1977 (WHO 1977)

This is more than a case of semantics, as researchers use different definitions for falls and once other terms are included, for example, 'trips' and 'slips' (Steinberg et al. 2000) the actual assessment of falls prevalence becomes uncertain. At what point does a 'slip' or 'trip' become a 'fall' and is it relevant to the definition if an injury has occurred? Patients are often required to record falls in a diary and, understandably, some form of self-reporting is necessary, but inaccuracies in data collection will occur with recall and definition, especially since many people at risk of falling have some form of cognitive impairment (Tinetti et al. 1988). Work monitoring the fall direction with patients who fracture their hip by Greenspan and colleagues (Greenspan et al. 1998) found that 40% could not indicate the direction they fell. This must be considered when reviewing the body of evidence in this area.

This highlights some of the problems that the proposed research must consider when evaluating older adults, especially ones that have poor health and possibly memory problems. Potential inaccuracies in recall with some of the study population and failure to comply with rehabilitation protocols might influence the results. Therefore, the results presented can only be an estimation of the size of the problem and further research is necessary, but the findings have great relevance to PH fractures.

Approximately 30% of people aged over 65 years fall each year (Campbell et al. 1981; Prudham and G 1981) and falls are a major cause of increased morbidity and mortality (Perry 1982). Furthermore, falls lead to disability and this is recognised in the National Service Framework for older people (DoH 2000) with its aim to reduce the number of serious injuries as a consequence of falls.

With over 30% of the older population falling, what is surprising, is the low incidence of fractures as a result of the fall (5-8%) (Perry 1982; Nevitt et al. 1989). However, other investigators report (Tinetti et al. 1988) a higher serious injury rate (24%), but this includes non-fractures, but what constitutes a 'serious injury' is dependent upon the individual and how it is classified-causing further data inaccuracies.

Allowing for this higher figure, most falls do not result in a serious injury and protective mechanisms exist that mediate the force of the fall. Undoubtedly, falling increases morbidity especially if the result is a PH fracture and mortality is increased following a hip fracture. Mortality rates within one year of a hip fracture vary between 11% (Beals 1972) and 71% (Pitto 1994). Also levels of morbidity in those who survive a hip fracture are high and in one study (Pandi et al. 2005) only 36% (17/47) could walk independently a year after the fracture. Research on mortality rates following PH fracture do not exist, but the increased risk of having a hip fracture following a PH fracture (Lauritzen et al. 1993) would possibly indicate that a PH fracture would inceases mortality, but not at the rate seen after a hip fracture.

A PH fracture constitutes a serious threat to a person's general health and quality of life, further emphasising the relevance of the proposed research. Although, few studies exist that explain the association between PH fractures (or any other fracture) and increased risk of falling, understanding the neuromuscular responses to a fall will allow the implementation of preventative strategies. This is further discussed, specifically relating to the upper limb, after the section on risk factors for falling.

2.5.3 Risk Factors for Falling

Many people fall, but only in a relatively small proportion does a fracture or a serious soft tissue injury occur. In the case of fractures, the existence of osteoporosis is deemed to be the deciding factor (Nevitt and Cummings 1993) for a fracture following a fall. Work by Lotz et al. (Lotz and Hayes 1990) casts doubt on this idea as they found that only one-twentieth of the kinetic energy that can be generated from a typical fall is required to cause a fracture. Therefore, most falls have the energy to fracture the bone and Lotz et al. suggest that the absorption of this energy, or not, by the bone is the crucial factor in determining a fracture. Reducing the energy of the fall by use of the arm is crucial to preventing fractures (Kelsey et al. 1992) and this is associated with neuromuscular status. Rehabilitation should restore shoulder function, but with PH fractures it is imperative that total trunk control is also re-established to prevent fracture recurrence. Neuromuscular balance mechanisms are thought to protect the skeleton from fractures (Cooper et al. 1987), but this rarely considered in rehabilitation of PH fractures. By incorporating balance training within rehabilitation programmes it might be possible to reduce the incidence of future falls and fractures.

Some groups of people with specific medical conditions have an obvious increased risk of falling, for example, after a cerebro-vascular accident (CVA) (Langhorne et al. 2000). Identifying risk factors in the general population is less precise as falls occur as a result of intrinsic and extrinsic factors (Downton 1993) and the combined effects of each are difficult to isolate. Outside the home, weather makes a difference to fall rates and therefore, fractures. With higher rates of fractures during icy or snowy periods (Levy et al. 1998) to such an extent that the term 'epidemic' (Ralis 1986) is used with more than 70% of fractures occurring during the winter months. The implication for the author's research being that recruitment to the study will be concentrated in the winter months and will coincide with icy weather.

Within the home, environmental hazards increase the risk of falling, and programmes aimed at reducing this risk by supplying home safety information and an assessment reduce the risk of falling by 30% (Steinberg et al. 2000). These programmes reduce the risk of falling, but not necessarily the risk of sustaining a major injury and studies are needed that aim at reducing the injury rate.

The intrinsic factors for falling are many and varied. The common ones include: cognitive impairment (Tinetti et al. 1988; Nevitt et al. 1989), functional disabilities (Herala et al. 2002), the number of risk factors (Tinetti et al. 1988), osteo-arthritis (Nevitt et al. 1989; Campbell et al. 1990) and reduced strength (Tinetti et al. 1988; HealthEducationAuthority 1999). Additionally, gender is a risk factor with women falling more than men (Campbell et al. 1990; Herala et al. 2002), but some authors found no such association (Nevitt et al. 1989). This lack of association in Nevitt et al.'s work is surprising considering many risk factors mentioned already (OA, reduction in ADL's and disability) are higher in women (see earlier section on disability and gender) as likewise are fracture rates. The weight of evidence would suggest women do fall more frequently than men.

The importance of maintaining strength and activity, not for reducing falling risk; but for reducing fractures, is reinforced by a study reporting an association between heavy functional activities and fracture prevalence (Herala et al. 2002). With the incidence of soft tissue injuries remaining constant with functional decline, it would imply that people maintaining high functional capacity still fall, but their ability to limit the force; and therefore prevent a fracture, is enhanced. The ability of the person to use their 'explosive power' (Skelton 2001) to prevent a fall is considered in the next section. The author's study monitors activity following a PH fracture to investigate if a link exists between repeat falls and the decline in functional tasks.

The causative factors in fractures are reviewed in the next section. The complex interaction between the falling mechanism and the ability of bone to absorb the stress dictates whether a fracture occurs or not. The current reliance on bone density alone fails to consider the 'absolute risk' to fractures when history of falls, age and propensity to fall are included (Masud and Francis 2000). Prevention of fracture is realistically only achievable by regular exercise (Kannus 1999) and maintaining activity levels following a PH fracture is a central tenet to the author's research.

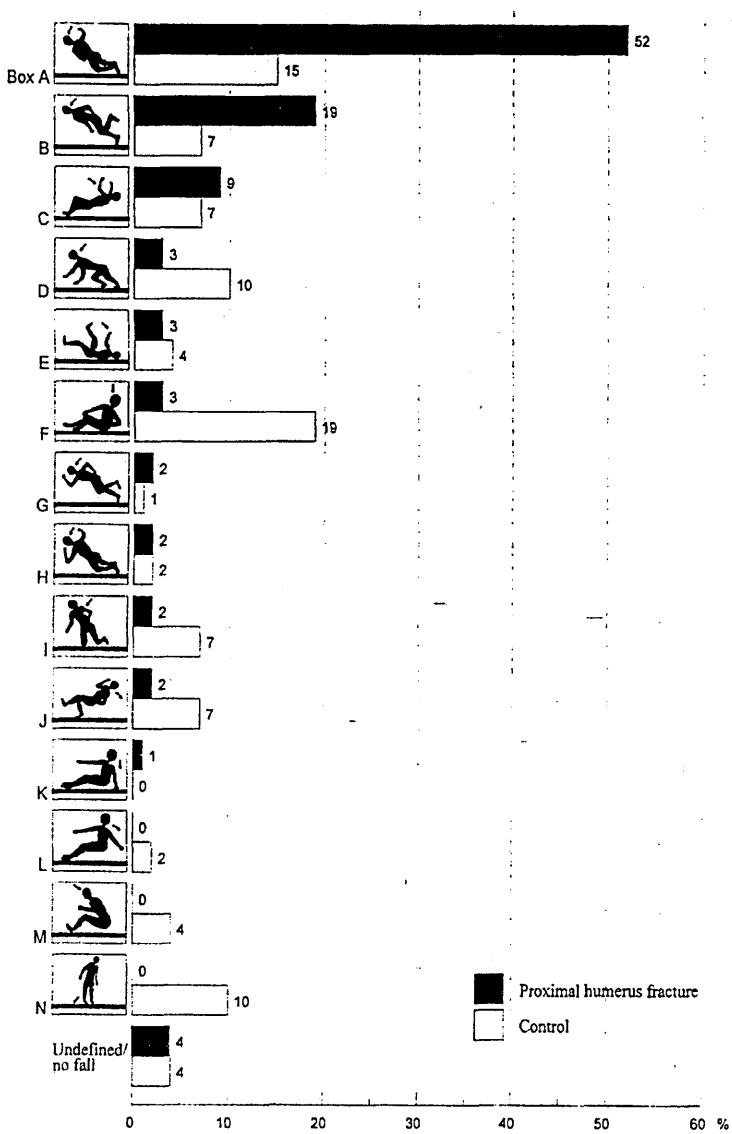
2.5.4 Upper Limb Trauma

As previously discussed, not all falls result in a fracture. The forces applied to the bone and the internal structure of the bone, added to the person's neuromuscular saving responses, all produce a complex series of events and conditions that, *sometimes*, produce a fracture. The two most common upper limb 'osteoporotic fractures', namely the proximal humerus and distal radius (wrist) fractures are compared and contrasted to highlight differences in aetiology. Currently, little evidence exists in this area and occasionally the review includes hip fractures to develop themes and ideas. Most studies concentrate on mechanisms that produce fractures; a more useful strategy might be to investigate the circumstances and conditions in which *no fracture* is sustained. Knowledge of this would allow clinicians to develop individualised, fracture-prevention strategies for high risk groups.

The application of a force results in the biomechanical loading to bone (Lundon 2000) and the magnitude and direction of this force will dictate the type of injury that occurs. Little is known about the forces and energies transmitted to the upper limb during a fall (Chiu and Robinovitch 1998), but Palvenen et al. (Palvenen et al. 2000) gives vital information about the actual fall mechanism in the proximal humerus, elbow and wrist fracture (fig. 7). The study by Palvenen et al. interviewed patients within 24 hours of their injury and records direction and mechanism of the fall and personal details to develop risk factors. Consideration must be given to two potential weaknesses in the study. First, interviewing older people within 24 hours of a major fracture, often when they are still in shock, questions the reliability of the information. Second, the paper states that the sub-cutaneous haematoma on the shoulder indicates a direct impact on the shoulder, but fractures to the proximal humerus produce considerable bleeding within the bone. Thus, determining the mechanism of the haematoma may not be fully clear.

However, allowing for these limitations, the results indicate that patients who fracture their proximal humerus (PH) fall forwards and onto the shoulder, compared with controls (22%). Furthermore, only 7% of the PH patients broke their fall, compared with 48% of the patients who fractured their wrist. What are the implications of this? Research suggests that patients with PH fractures have poor neuromuscular status compared with other fractures (Kelsey et al. 1992) and other authors propose neuromuscular control mechanisms for differences in fracture rates (Cooper et al. 1987; Donaldson et al. 1990). The upper limb minimises the impact of a fall, but a high level of neuromuscular control is necessary. Patients with PH fractures probably need their upper limb to balance and the dissociation needed between their trunk and upper limb is lacking. Thus, the fracture is caused by a direct impact in which the upper limb is fixed by the side of the trunk and not able to 'break' the fall or adopt any other saving reaction. A fracture to the proximal extremity may represent a more fundamental problem with the person's trunk control and gait. Indeed, research recognises poor gait and reduced physical capacity as risk factors in hip and PH fractures (Nevitt and Cummings 1993; Cummings et al. 1995).

Figure 7. Fall Direction with a Proximal Humerus fracture (from Palvenen et al. 2000).



In contrast, patients who fracture their hip (Greenspan et al. 1998) fall to the side and fewer patients who fracture their hip 'break' their fall compared with the fallers who do not incur a fracture (33% versus 45%). Falls are the major cause of disability in adults aged over 75 years (Health Education Authority 1999) and the decline in physical activity, reaction times (Herala et al. 2002) and balance (Tinetti et al. 1988) increase the risk of falling. Once again, a reduced ability to 'break' the fall, possibly because of reduced neuro-muscular mechanisms as seen in PH fractures (Kelsey et al. 1992), and a tendency to fall sideways onto the hip, represents a decline in functional status. A fall that results in a direct impact to either the humerus (Palvenen et al. 2000) or the hip (Cummings and Nevitt 1994) is more likely to result in a fracture. Most falls produce a force that is 20 times greater than that needed to fracture a long bone (Lotz and Hayes 1990) so protection of the skeleton that reduces this impact is fundamental in preventing fractures.

Hip fractures have the highest associated mortality and morbidity rates (DoH 2000) and this reflects the poor functional capacity in this group, even more than the PH patients. Even if the fall does not result in a fracture or serious soft tissue injury, approximately one third of all fallers develop a fear of falling and this is associated with an increased risk of falling. The decline in function is highlighted by the fact that less people fracture their hip outside the home (20% versus 60%) compared with a PH fracture (Sartoretti et al. 1997). Additionally, PH or wrist fractures are a risk factor for sustaining a hip fracture (Gallagher et al. 1980; Lauritzen et al. 1993) and these three fractures are probably all part of a continuum with initial fractures of the wrist, then humerus and, later, following further functional decline, the hip. The hip fracture can be considered as a symptom of a greater physical decline and a loss of compensatory strategy, although all too often these fractures are only viewed as an isolated incident and their full significance is not appreciated.

2.5.5 Summary

The problems of agreeing on a common definition for 'falls' and the recall bias of patients after they have fallen, makes research in this field difficult. Over a third of people over 65 years fall, but only a small percentage sustains a serious injury as people manage to avoid injury by neuromuscular control. This is often missing in adults with a PH fracture and they are at risk of further falls and associated fractures. This must be considered when planning rehabilitation and any programme that maximises recovery and, within the shortest possible time, will have many benefits to the patient.

Falls resulting in an 'osteoporotic fracture' have different characteristics, but they exist along the same continuum with a progression from the wrist to proximal humerus and hip fractures; different fractures and mechanisms of injury, but sharing an underlying decline in physical function and osteoporosis. A fall resulting in a PH fracture is obliquely forward and impacts directly onto the shoulder. This inability to utilise the normal saving reactions may indicate a level of postural control in which the upper limb is used to maintain balance, thus preventing it from helping to 'break' the fall. These people remain vulnerable to further falls and subsequent injury, thus accelerating their decline into increasing disability and dependence.

Regarding the author's research, if avoiding immobilisation and starting physiotherapy immediately after the fall results in rapid restoration of function compared with conventional treatment, then the patient will return to functional independence faster and have less pain. Furthermore, the patient may be less vulnerable to further falls that lead to a fracture as their neuromuscular balance mechanisms will protect them. This component to fracture rehabilitation is rarely considered in other research as each fracture is viewed as an isolated incident and there is a failure to consider the future risk of fractures to the patient. This proposed research represents a new approach to managing a vulnerable group within society.

The next part covers fracture management by surgeons from the point where the person attends fracture clinic and treatment is decided. Most PH management (and many other fractures) is largely untested and based on a long tradition that advocates rest and immobilisation for fracture repair. The evidence base for fracture repair does not support this view and relevant evidence is critically reviewed to justify the proposed change in management to both the ethics committee and surgeons.

2.6 Proximal Humerus Fractures Medical Management

2.6.1 Introduction

This section reviews proximal humerus fracture management by orthopaedic surgeons. Orthopaedic surgeons assess the patient at fracture clinic (usually the day after the injury) and decide on the type of treatment depending on the fracture. The decision is usually made from a radiograph and fracture classification is made using the Neer scheme (appendix 1). The Neer classification system groups the fracture by the number of fracture segments and the degree of angulation of each segment. The most commonly classified PH fracture is the 'minimally displaced' fracture (or type one) and this is the only type of fracture included in the author's research (the type one fracture is also known as a two part fracture, as in appendix 1, but with minimal or no displacement to the fracture parts). The minimally displaced fractures are managed conservatively (does not require surgery) and the most complex fractures are often surgically repaired, although the evidence base for any of the management strategies is poor. Furthermore, the Neer system by which fractures are classified has serious limitations and these are considered in the next section.

Firstly, the classification systems are poorly researched and authors (Burstein 1993; Sidor et al. 1993; Siebenrock and Gerber 1993) have expressed doubts about their usefulness, especially those used for proximal humerus fractures. This is explored further in the proceeding section. Secondly, measures to evaluate treatment outcome are generally poor with no or limited evaluation before clinical implementation. Many researchers use their own outcome measures or, even worse, modify an existing instrument, thus making comparisons and accurate measurement impossible. As stated in the Cochrane report on management of PH fractures (Gibson et al. 2001) insufficient evidence from randomised trials exist from which to determine the most appropriate intervention for management. The Cochrane report is formed after systematically reviewing all available evidence on the management and rehabilitation of PH fractures. Their recommendations and conclusions are made on the best available evidence and are probably the best indication of current practice.

Discussing the classification system is important to the proposed research as this is the main method by which PH fractures are categorised and management decisions are made. This narrow approach to fracture management whereby the patient's individual characteristics (e.g. gender, co-morbidities and level of physical activity) are largely ignored, contrasts with the research evidence that suggests a range of other factors might better predict eventual functional outcome and they should be included in the management assessment. Additionally the individual's response to pain, the biological responses to bone healing and ageing, all contribute to this process. Furthermore, the omnipresent influence of socioeconomic factors, as they do in so many health related problems, may influence the restoration of function. No previous PH fracture research has identified which factors are most relevant and this forms part of the author's research.

2.6.2 Proximal Humerus Fracture Classification

The first attempt to classify fractures of the proximal humerus in 1896 by Kocher (Kocher 1896), met with little success and it was not until Codman (Codman 1934) defined four patho-anatomical sections (anatomical head, the greater tuberosity, lesser tuberosity and the shaft) that a system generally accepted (Bigliani et al. 1996). Building on this work, Neer (Neer 1970) developed a classification system that used the four segment suggested by Codman, but based the classification, not on the number of fracture lines, but on the degree of rotation and displacement of each segment (appendix I). The Neer type one PH fracture (or minimally displaced fracture) is defined as 'no segment been displaced more than one cm or angled greater than 45 degrees'.

The type one fracture is the most common fracture to the proximal humerus, but its exact incidence (expressed as a percentage of all PH fractures) varies between authors: 85% (Neer 1970), 70% (Bengner et al. 1988), 52% (Rose et al. 1982) and 50% (Court-Brown et al. 2000). The wide variation reflects the reliability problems of the Neer classification scheme with discrepancies between observers when identifying fracture segments (Sidor et al. 1993; Siebenrock and Gerber 1993; Bernstein et al. 1996; Sallay et al. 1997). The AO (Arbeitsgemeinschaft fur Osteosynthesefragen) classification system is the second most commonly used system, but this too has not undergone reliability studies. Furthermore, at least one author has found its ability to predict outcome is inferior to the Neer system (Court-Brown et al. 2000).

The Neer system is the most commonly used classification system (Bigliani et al. 1996) and it wasn't until its universal acceptance, that its reliability and reproducibility has been challenged. An editorial by Burstein (Burstein 1993) in the American Journal of Bone and Joint Surgery said the Neer system is a 'poor tool' and sparked vituperative correspondence from supporting surgeons. The two studies, on which Burstein based his comments (Sidor et al. 1993; Siebenrock and Gerber 1993), found low reliability and reproducibility with the Neer system. The Siebenrock and Gerber study examined 95 patients with PH fractures and each radiograph was assessed by five orthopaedic surgeons who classified the fracture using the Neer classification system (into a group between one and four). The radiographs were re-assessed by the same assessors eight weeks later and 'inter' and 'intra' observer reliability was calculated using kappa coefficients (a score of 0.75 is considered good or excellent reliability). The observers only agreed on 25 fractures (26%) and, in instances of disagreement, at least three different Neer classes were assigned to 27 (39%) fractures. The inter-observer reliability was low with a mean kappa score of 0.40 (range 0.25 to 0.51) and intra-observer score of 0.60 (range 0.46 to 0.71). Siebenrock and Gerber concludes that the Neer system does not allow "meaningful comparisons of similarly classified fractures in different studies" and even when they used more experienced observes, the reliability did not improve. Therefore, two independent observers are unlikely to place a PH fracture into the same group.

Sidor et al. (1993) reported a slightly better inter-observer kappa reliability coefficient mean score of 0.48 (range 0.43 to 0.58) with 50 PH fractures. Five observers assessed the radiographs (three shoulder specialists and two interns), but the specialist's reliability was only marginally better than the interns (0.52 compared with 0.48). This suggests that increased experience when using the Neer system does not confer any additional benefit as reliability remains moderate.

Another study (Kristiansen et al. 1988) asked four observers to classify 100 PH fractures using the Neer classification system. The intra-observer reliability ranged from 0.03 to 0.47 with all PH fractures, but the agreement did increase with the type one fractures (59% agreement with type one fracture across four observers). Siebenrock's observers were more experienced than those in the Kristiansen study and they also had three radiographs of each fracture, although this made little difference to the overall score. Both these studies questioned the usefulness of the system for PH fractures, although the reliability when used with the type one (minimally displaced) fracture was marginally better. These findings and those of Siebenrock et al. and Kristiansen et al. suggest that the Neer classification system has moderate to low reliability in all PH fractures, with the possible exception of the type one fracture.

In its defence, other authors (Bernstein 1994; Cuomo 1994; Rockwood 1994) claim that the system is an excellent means of communication and its reliability might be improved with better imaging technology. This assumption is wrong on two counts. First, the system is routinely used as a basis for judging and comparing clinical trials and not only as a means of communication. Second, work with Computerised Tomography (CT) scanning by Castagno et al. (Castagno et al. 1987) shows that more fractures are visualised by CT, but this did not improve the reliability of the system when the observers have both CT and radiographs to make their decision (Sallay et al. 1997). Sallay et al. used two observers to assess CT scans and radiographs of PH fractures (n=12) and found low interobserver reliability when both radiographs and CT scans showed an average intraclass correlation coefficient (ICC) of 0.34 and 0.37 respectively. Similarly, another study using CT (Bernstein et al. 1996) to investigate reliability of the Neer classification scheme, found that two observers could not agree on the number of fractures in over half the cases.

In a letter to the Journal of Bone and joint surgery, Neer (Neer 1994) defended his system and claimed that the problem lies with the inappropriate use of the tool, but does not give further clarification. These are small studies, but their results would tend to support the comments by Burnstein that the tool is not reliable and further systems must be developed. Consistent with this perspective, Zyto (Zyto 1998), investigating recovery following complex proximal humerus fractures, found no correlation between radiographic appearance and functional recovery. Likewise, Young and Wallace (Young and Wallace 1985) retrospectively assessing fracture-dislocations found no correlation between displacement and the outcome.

The balance of evidence suggests that the system has considerable limitations and its reliability is probably better with less complex fractures (Kristiansen et al. 1988) or 'minimally displaced fractures', but reliability issues persist. Even if surgeons could accurately identify fracture lines and reliably classify the PH fracture, it still fails to consider the range of factors that might influence recovery e.g. age, general health, level of physical activity, gender, previous shoulder dysfunction. These factors are not considered in the management of PH fracture and they might have a greater influence on prognosis than a classification system that relies on x-ray appearance, however unreliable it may be in practice. This is an area for future research, but my work will prove useful in assessing the possible influence of these other factors (age, gender, general health, level of physical activity) on recovery from a PH fracture.

The factors that influence recovery are relevant to the author's thesis as this work proposes to identify other risk factors that identify the person who fractures their PH and has a greater risk of developing long-term problems. This approach is innovative in any type of fracture management, but in the field of PH fractures, it is unknown. Certainly, work linking high levels of deprivation to Saul (1995) increased disability (Melzer et al. 2000), depression (Miech and Shanahan 2000), chronic illness (Paul et al. 1998) (Saul 1995) and reduced mortality (Kitagawa and Hauser 1973; Haan et al. 1987; Davies et al. 1994; Phillimore et al. 1994) are well documented. However, this is new in the field of fracture repair and potentially represents a change in direction for fracture management. Furthermore, this would partially negate the problems with PH classification systems if other factors are more important than radiographic appearance. The orthopaedic treatment of these fractures is covered in the next section and further discussion is included under rehabilitation. This allows the author to critically evaluate current management strategies against best available evidence and to highlight the importance of the proposed research.

2.6.3 Fracture Management

Treatment of proximal humerus fractures is by surgery or conservative management. This review will mainly concern the conservatively treated fractures, although treatment by surgery is mentioned to highlight some of the difficulties in this field. Neer (Neer 1970) advocates that the more complex fractures (type three and four) need surgical intervention and that the more common type one (minimally displaced) fracture is best managed conservatively. However, in two studies (Court-Brown et al.

2000; Court-Brown et al. 2001) the author could find no difference in outcome between those patients managed conservatively or surgically. Court-Brown and colleagues (2000) reviewed 1027 PH fractures (49.9% type one fractures) over one year by blinded assessment and found no difference between those managed surgically or conservatively. Age remained predictive of outcome with older groups, but the older group still returned to 'normal activity' despite having a lower shoulder score than younger patients. The main limitation of this study is the lack of any reliability data for the shoulder outcome measure (Neer shoulder score) and the number of patients who refused follow up is not recorded. The review (n=126) by Court-Brown (2001), who re-evaluated only two-part PH fractures (mean age 72) managed either conservatively and those managed surgically over five years, has the same limitation (no reliability data for the shoulder outcome measure) as previously mentioned, but found that surgery did not improve recovery. Once again, age was a better predictor of long-term outcome than the treatment received, but the retrospective nature of the results that did not have standardised re-assessment points must be viewed with some caution.

Likewise, in a retrospective RCT, Zyto et al. (Zyto et al. 1997) reported no difference between patients randomised to receive either conservative management or surgical intervention. Moreover, six of the eight patients reporting complications had surgery. Surgery is more expensive than conservative management, and if the higher rates of complications with surgery are to be believed, then this casts strong doubts on the efficacy of surgery in all PH fractures.

Further evidence is needed to fully explore this issue, but it remains unproven that surgery is the best option for more complex fractures. The author's research only includes the less complex PH fractures (minimally displaced, or type one) for ethical and logistical reasons, but there is no reason to suppose that the more complex fractures would not also benefit from immediate rehabilitation. Surgery, in the complex fractures, is no better than conservative treatment; but has significant cost implications and is associated with increased complications (Zyto et al. 1997). This is an area for future research.

Conservative management is universally accepted as the optimum treatment for type one PH fractures (Neer 1970; Crawford-Adams 1983; Apley and Solomon 1993). What is not so clear is whether these fractures require immobilisation before starting active exercise and rehabilitation. Answering this question is fundamental to this thesis as confusion exists as to the optimum period of immobilisation, and more importantly, do PH fractures require immobilisation for optimum fracture repair? The proposed research challenges the necessity of immobilisation and is counter to current ideas regarding fracture repair with most authors recommending some period of immobilisation after the fracture ((four days (Brostrom 1943), 7-10 days (Skinner 1995) (Bigliani et al. 1996), three to four weeks (Mills and Horne 1985)). All of these recommendations are based on clinical experience and no study has investigated the optimum time of immobilisation, assuming it is necessary. The justification for immobilisation is mainly pain relief (Adams and Hamblelen 1992; Bigliani et al. 1996) before beginning active rehabilitation.

The Cochrane review concludes that:

" Some evidence that short periods of immobilisation are acceptable... "

Gibson & Handoll, 2001 (Gibson et al. 2001).

Although 'acceptable' is not the same as 'necessary', the question still remains, do these patients benefit from immobilisation? This remains unknown. The next section presents the best available evidence for the effects of movement on tissue healing and specifically to fractures.

2.6.4 Immobilisation and Bone Repair

This is discussed in two parts. The first part considers the biological effects of immobilisation on bone healing and fracture repair, but does not include the effects on soft tissues. Although, the effects on soft tissue repair are important, they are not included within this review as it falls outside the scope of the thesis. Although, the comments made about the deleterious effects of immobilisation on bone apply equally to other connective tissues and this is further considered in the discussion section. The second part considers the clinical implications, both in the upper limb and in other common fractures, of immobilisation and uses available evidence to explore the relevant issues.

- **Experimental Evidence**

The following evidence is mainly based on animal models for the effects of immobilisation, and movement, on bone morphology. Inherently, problems exist using animal models with the assumption often made that the results can be directly applied to humans. Additionally, the problems of comparisons between animals (and birds), variations in time and magnitude of the applied force applied, surgical intervention and often large 'drop-out' rates, make absolute values of bone remodelling unreliable. However, the studies seem to consistently support the statement that:

"...changes in a bone's mechanical environment are a powerful determinant of its remodelling behaviours."

Lanyon, 1984 (Lanyon 1984)

Galileo (Galileo 1638), in 1638, was the first person to recognise the relationship between the load applied to a bone and its morphology and not until the late nineteenth century did Woolf (Woolf 1892) propose the link between form and function (Wolf's law). Just like plants responding to gravity or light (helio or photo-tropism), bone responds to applied pressure, or lack of it, and this is known as piezo-tropism (Treharne 1981). The term 'functional adaptation' (Roux 1895) probably best describes this effect as bone is maintained by a combination of hormones, moderated by stresses, matrix damage and cell death (Lanyon 1984). When stresses are removed from the body, for example, during weightlessness in space travel, significant bone loss is a result (Vico et al. 2000) (Miyamoto et al. 1998). Thus, reinforcing the importance of controlled loading of the body for optimal function. The absolute magnitude of the stimulus required to maintain bone architecture is unknown, but it will vary with gender, ethnicity and degree of trauma to bone i.e. type and extent of fracture. Furthermore, bone remodelling and adaptation to repeated loading reduces with increasing age (Carter 1984; Buckwalter 1985) and possible explanations for this are the age related decline in cell function (Campisi-unpublished data). The reduction in bones' response to remodelling with age is highly relevant to the author's research considering the age of the study population and the high incidence of osteoporosis. Clearly, the effects of bone loss and reduction in remodelling are further reinforced in ageing tissue and will further limit fracture repair.

Of all the connective tissues; bone and muscle are the most responsive to activity (Buckwalter 1996). Immobilisation of a limb results in bone loss and the pattern of bone demineralisation varies over time. Within the first few weeks of immobilisation (two to four weeks) the bone loss is rapid and reaches a plateau at six weeks (Uhthoff and Jaworski 1978). At the same time a longer, slower bone loss occurs over 24 to 32 weeks; this secondary bone loss is also slower to re-mineralise once motion is restored. With movement, cyclical loading of bone appears to be the best method of stimulating bone remodelling, however the optimum load necessary to achieve this is unclear (the optimum load being one that maximises bone formation without causing tissue break down). Work by Langdon (Lanyon et al. 1977) suggested a force of 200 Newtons (N) is needed for bone remodelling, but Panjabi and colleagues (Panjabi et al. 1979) produced the same result with only 50 N force. Recently, work stimulating bone formation (in sheep hind legs) using low magnitudes and high frequency ' bursts' of daily activity (Rubin et al. 2001), questions the need for high loads. Bone density increased 34.2% compared with the controls and caused the author to suggest that extremely small strains, for example those arising from muscle contraction, are strong determinates of bone morphology. Postural muscle control and reduced activity levels, combined with increasingly sedentary occupations, will contribute to the general increase in osteoporosis in the population.

The low levels of activity needed to stimulate bone turnover and the effect of activity on bone repair have important implications for the author's research. If early movement of a fracture produces greater stimulation of bone repair (and other connective tissues surrounding the fracture) compared with immobilisation, as this evidence suggests, this will accelerate fracture repair and therefore increase function. The low levels of activity required for bone remodelling as highlighted by Rubin's work, questions the idea that high-force impacts are needed for this effect. Low levels of stimulation, similar to those produced by muscle activity, should be sufficient to influence bone repair. All of these effects are negated by traditional management programmes that incorrectly include immobilisation to influence bone repair and this thesis challenges this approach.

Some of the earliest work on the effect of stress on bone morphology by Hert (Hert et al. 1971a; Hert 1971b) clearly demonstrated that applied stress, via pneumatic compressors, to intact rabbit long bones, produced bone remodelling. Using a bird model, Rubin (Rubin and Layton 1987) reports that bone mineral content (BMC) reduces by 88% in the non-mechanically stimulated group, although the lack of consistency with the force questions the reliability of this figure. Investigating the effect of exercise on bone modelling following immobilisation (Maeda et al. 1993; Inman et al. 1999), both authors found that exercise, both during and after the period of immobilisation, reduced the rate of bone loss or increased the rate of bone recovery. Both used rats as the study group and Maeda found that after six weeks exercise, following six weeks immobilisation, the bone mass only recovered 60% of the baseline values.

The rats' limbs were immobilised (not fractured) and, more importantly, we assume that they were not experiencing pain. When a person is immobilised, it is usually as a result of a fracture which is different from normal bone remodelling. Furthermore, pain experienced during the fracture, and for a substantial period after the injury, will influence the person's willingness to use the limb. If bone mass does not completely recover after the period of immobilisation in healthy rats, then the older person, who has an fracture as a result of osteoporosis and experiences pain with the loss of muscle strength, is likely to have even greater problems.

Pain experienced following a fracture is an important factor in the author's work as willingness to move the arm is dictated mainly by pain levels (Badcock et al. 2002) and more precisely, 'fear of pain' (Vlaeyen and Linton 2000). If early movement of the shoulder fracture exacerbates pain, then the person will be unwilling to move and this will influence bone repair. However, evidence with other musculoskeletal problems (Malmivaara et al. 1995; Wilkinson 1995) suggests reduction in pain levels with early movement. There is no reason to doubt a similar effect occurs with fractures. As yet this remains unknown, and this thesis aims to investigate this hypothesis and test whether patients do experience more pain when encouraged to move the limb immediately. Pain levels are judged over two years to give a complete picture of the pain experience after the injury.

- **Clinical Evidence**

The evidence for the harmful effects of immobilisation on bone healing at a biological level are compelling, however in the clinical arena few studies have compared different periods of immobilisation. Even fewer have investigated proximal humerus fractures, so all studies examining the effects of immobilisation on fracture management are included in the review. The few studies that exist are often small, use untested outcome measures and have serious design faults.

Two studies have investigated the effects of immediate mobilisation on ankle fractures, one using immobilisation and bracing (Egol et al. 2000) and the other comparing plaster of Paris (POP) with immediate mobilisation using bandaging (Port et al. 1997). Both report superior functional results and less treatment with immediate movement, but the differences reduced over the follow-up period. This trend, reporting a difference in the initial follow-up point, is repeated in several studies. The immobilised group taking longer to recover, but they continue to improve and at long-term evaluation, the differences reduce. In the case of ankle trauma without an associated fracture, evidence (Brooks et al. 1981) suggests that early rehabilitation produces superior results compared with immobilisation. Immediate movement reduces joint stiffness and encourages restoration of function back to a pre-injury level; with the immobilised subjects requiring longer to recover. In the younger person, a period of immobilisation will probably not prevent the return to pre-injury status, although in the older person, with reduced bone strength, problems may continue. This cannot be answered with the available literature and further work is needed.

In the upper limb, recovery following minimally displaced wrist fractures (distal radius and ulna) is faster and is accompanied by less swelling using crepe bandaging and immediate mobilisation (Dias et al. 1988). Likewise, a study investigating the effects of immobilisation following excision of the trapezium for osteoarthritis of the thumb, concluded that:

"...prolonged splintage confers no extra benefit..."

Horlock & Belcher, 2002 (Horlock and Belcher 2002)

The authors question the benefit of immobilisation as it only adds to joint stiffness. Furthermore, the most dramatic example of the unnecessary use of immobilisation is seen in the rehabilitation following the surgical repair of the anterior cruciate ligament (ACL). After years of prolonged use of immobilisation following surgery, the latest evidence supports an accelerated programme without a period of immobilisation (Pinczewski and Clingeleffer 1996). Already a large body of evidence demonstrates the harmful effects of immobilisation on articular cartilage (Akeson et al. 1973; Noyes et al. 1974; Noyes 1977; Akeson et al. 1984) thus, reinforcing the need to restore activity.

In studies using surgically induced fractures (Panjabi et al. 1979; Goodship and Kenwright 1985), the authors found that fracture site characteristics (tortional stress and fracture load) were improved by cyclical loading, compared with fixation or compression alone. Additionally, and of high clinical relevance, Panjabi et al. (Panjabi et al. 1979) noted that in the stimulated group, the time taken for complete fracture healing was reduced by 27% compared with the control. Interestingly, the compressed group had greater fracture stiffness initially and they suggested that the preservation of microvascular structures improved the initial callus formation.

This highlights the dichotomy between fracture management between those who advocate 'movement' and others who advocate, 'rest'. This has its origins as far back as antiquity with Hippocrates using braces to immobilise fractures and Aristotle (Salter 1982) recognising the importance of movement for life ('movement is life'). At the end of the nineteenth century Lucas-Championniere, a distinguished French surgeon stated that:

"...controlled early resumption of activity can promote restoration of function."

Buckwalter et al. 1985 (Buckwalter 1985)

However, he clashed with the British surgeon, Owen-Thomas, who promoted enforced rest for fracture healing. Owen Thomas's legacy is still influencing British orthopaedic thinking today as, despite convincing scientific evidence vindicating Lucas-Championniere, prolonged periods of immobilisation remains a central tenet in the management of many fractures.

An extensive literature search failed to find any clinical evidence to suggest that early mobilisation of fractures was associated with an inferior outcome, but the dangers of 'insufficient immobilisation' are cited as a cause of non-union (Bigliani et al. 1996). Clearly, this is based on empirical evidence and is not supported by the literature presented. The trend in rehabilitation is toward early intervention and this needs to be evidence based (Nocon and Baldwin 1998). The next section covers physiotherapy and the evidence available for PH fracture rehabilitation.

2.6.5 Summary

The Neer scheme is universally used to classify PH fractures and to dictate treatment. Several problems exist with the scheme's reliability as intra and inter-reliability of complex fracture patterns using a two-dimensional image is prone to problems of interpretation. This has serious implications for fracture management and selecting specific types of PH fractures for research. However, for the more common type one (minimally displaced) PH fracture as used in the author's research, the reliability is better than with the complex fractures.

Conservative management is recommended for the type one fractures and, following a period of immobilisation, some form of rehabilitation. The scientific evidence for immobilisation, and especially prolonged immobilisation, is for early restoration of function with controlled stresses applied through the fracture. This maximises both the fracture characteristics and reduces the time of clinical union. The balance of evidence would support movement to stimulate fracture repair, but traditional views still advocate rest based on empirical observations. Fracture management is slow to change in the UK with an institution that favours conservatism and stifles innovation. The author's research questions these long-held views and if the results indicate that immobilisation confers no additional benefit, then this represents an important change in the PH fracture management.

The next section covers rehabilitation and the evidence base for current practice. This underpins the proposed study, but the available research is generally poor it is impossible to make firm recommendations. This further supports the need for PH fracture rehabilitation research to help guide clinical decisions.

2.7: Proximal Humerus Fracture Rehabilitation

2.7.1 Introduction

This part of the literature review examines the physiotherapy interventions in the rehabilitation of the proximal humerus. In previous sections the quality of the studies, or lack of evidence, has been mentioned and the comments of the Cochrane (Proximal Humerus Review) reviewers are pertinent:

"...there is insufficient evidence from randomised trials to determine which interventions are most appropriate..."

Gibson, 2001 (Gibson et al. 2001)

Randomised controlled trials are not the only acceptable forms of evidence when deciding interventions and the present thesis incorporates a range of studies that may be small and have no control group, but give valuable insight into treatment. Jull's seminal (Jull 1979) work on passive movement and its influence on rate of recovery following a PH fracture is one such example. Randomised controlled trials will help by comparing two or more treatments and give a definitive answer, but other studies will highlight *which* treatments to test.

The paucity of rigorous studies ensures that findings made must be viewed with caution regarding the type of rehabilitation necessary after a PH fracture. This assumes rehabilitation given by physiotherapists is necessary and at least one author (Lundberg et al. 1979) has questioned its efficacy. The main questions discussed in this section include the following:

1. Is physiotherapy necessary following a PH fracture?
2. If it is necessary, what is the optimum treatment?
3. At what point should physiotherapy commence after the initial injury?
4. What are the effects on shoulder function and bone healing of immediate physiotherapy?

In the author's proposed research all patients were given physiotherapy as part of a pragmatic trial. This aimed to test conventional treatment and no clear conclusions toward the efficacy of physiotherapy are given from the best available evidence. Points two to four are tested within the study and the findings are extensively covered in the discussion section.

2.7.2 Rehabilitation

Some authors consider physiotherapy unnecessary (Lundberg et al. 1979; Solem-Bertoft et al. 1984) following a PH fracture and claim that patients have excellent recovery within one year of the initial injury without physiotherapy. In small studies Lundberg et al. (n=42) and Solem-Bertoft et al. (n=20), compared independent exercises ('no physiotherapy group') with physiotherapy (active and passive exercises under the direct guidance of the physiotherapist). This highlights the problem of what constitutes 'physiotherapy' as both groups received physiotherapy contact (three versus nine treatment sessions). The authors do not define physiotherapy, but physiotherapy in both studies was the application of some form of modality (heat, electrotherapy, exercise) and ignores the importance of giving patients information

(Dayo and Diehl 1986; Fitzpatrick et al. 1987) in order to reduce their fears and encourage return to normal function.

Education is one of the most important aspects of physiotherapy and as both groups receive this, it is not surprising that no differences were found at the follow-up. Additionally, no validated or reliable outcome measure was used to assess outcome and shoulder function was only measured at one year. Subsequently, the authors' conclusions that independent exercises are no better than 'conventional' physiotherapy are not supported by this evidence and further research is required. It does, however, suggest that home exercises and advice are fundamental components of the rehabilitation programme.

There is no evidence for the efficacy of heat or electrotherapy in the available literature, but it often, perhaps incorrectly, forms the central part of 'physiotherapy' programmes. Evidence suggests that the efficacy for electrotherapy is poor for shoulder fractures (Liversley et al. 1992) and for many general problems (Van der Heijden 1999; Van der Windt et al. 1999). The conclusion drawn from a meta-analysis (Gam and Johnnsen 1995) of all available studies on ultrasound was that it had an "unimportant analgesic effect across a variety of disorders." It is for these reasons that electrotherapy should not be a central component to shoulder rehabilitation (if used at all) and more active coping strategies that aim to restore function should be employed (Brox 2003)

It may be for this reason that 'physiotherapy' (studies using electrotherapy alone) is seen to be ineffective with certain conditions and studies based on exercise, mobilisation and advice are uncommon. The studies that are available indicate that programmes featuring these three components are more effective and it is for this reason that the author's research incorporates these key elements in the programme.

No research has compared the effects of physiotherapy against a control group in shoulder fractures, but work investigating the influence of physiotherapy on wrist fractures (Watt and Taylor 2000) found that the patients receiving physiotherapy had faster improvement in both wrist extension and grip strength. Oskarsson et al. (Oskarsson and Hjall 1997) repeated the above study and found no differences in outcome between the control group and these that received physiotherapy. However, their study did not randomise group allocation and patients self-selected to have physiotherapy if they experienced wrist 'stiffness'. Therefore, the most symptomatic patients had physiotherapy at 10 weeks after the fracture (delayed), thus invalidating the results. In a comparative study between physiotherapy and self-training following sub-acromial decompression (Anderson and Sojbjerg 1999), the authors found no difference between the groups. The average age was 46 years and the self-instruction group had greater health staff contact, but these results suggest that patients gained no benefit from physiotherapy.

If physiotherapy is not required following a PH fracture, it implies that patients make excellent recovery without any form of rehabilitation. Literature from large retrospective studies suggests that patients make 'excellent' or 'satisfactory' recovery

(Mills and Horne 1985; Young and Wallace 1985; Kristiansen et al. 1989), although what constitutes a 'satisfactory' recovery is not stated and this judgement is not made by the patient, but the physician.

The reliance on impairment measures (for example, range of movement, strength and radiographic appearance) fails to recognise the importance of patient self-evaluation on the result. The majority of patients over the age of 60 years (the most common age group to fracture their humerus) are unlikely to have excellent recovery after a fracture with epidemiological studies consistently showing limited shoulder function in a 'normal' population (Chakravarty and Webley 1990; Chakravarty and Webley 1993) and shoulder dysfunction is unlikely to recovery spontaneously (MacFarlane et al. 1998). Several patients probably have reduced shoulder function *before* their injury and this is unlikely to improve following the fracture. Moreover, no study has evaluated levels of shoulder function after one year of a PH fracture and the natural history of this condition remains unknown.

Jull's research (Jull, 1979) demonstrated that PH fractures could be safely and effectively moved without a period of immobilisation. Following a PH fracture, patients (n=14); 11 female) were divided into 'younger' (five patients aged between 13 to 17 years) or 'older' (nine patients aged between 58 to 80 years) groups. Treatment in the form of passive exercise and joint mobilisation (in combination with a home programme consisting of pendular shoulder exercises) achieved 90 degrees shoulder flexion within 14 days of the injury. No complications were reported and the older group achieved full shoulder function by one month and the mean discharge time was 7.5 weeks. Even though this study was conducted 26 years ago and has design limitations (no control group, no recognised shoulder outcome measure and small sample size) it was the first to challenge the belief that patients need weeks of immobilisation (Adams and Hamblelen 1992) before starting rehabilitation and that early movement increases the number of complications (Bigliani et al. 1996).

Conversely, other work (Kristiansen et al. 1989) found no differences in shoulder function when patients were randomised into one or three week periods of immobilisation before starting physiotherapy. In larger retrospective studies, three papers report that the time spent in a sling correlated with the speed of recovery and restoration of function (Clifford 1980; Young and Wallace 1985; Koval et al. 1997). Although, Mills and Horne (Mills and Horne 1985) found no difference in outcome, but maximum improvement did occur earlier in those patients immobilised for less than three weeks. The retrospective nature of these studies and lack of standard outcome points are key issues when interpreting these results and they must be viewed with some caution. Other limitations of the studies cited includes the work by Clifford (1980) who reviewed PH fractures (n=80), but did not classify the fractures into specific groups and, more importantly, 96 (55%) patients were lost to follow up. Furthermore, Young and Wallace (1985) evaluated PH fractures (n=72) over only six months, and stated judged treatment to be successful if sixty degrees shoulder abduction was achieved i.e. 30% recovery of normal range. The selection of thirty degrees abduction, an indicator of successful functional outcome, is not discussed in the paper. The limitations in both these studies (Clifford 1980, Young & Wallace

1985) must be considered when interpreting their results, but their findings provide some insight into the possible relationship between immobilisation and recovery rate.

No study has investigated the effects of *immediate* physiotherapy on the rehabilitation of PH fractures and the author's research study is the first to test the hypothesis that immediate physiotherapy optimises shoulder recovery, but evidence from other shoulder research on bone remodelling would support its efficacy. Three papers have demonstrated that following a rotator cuff tear (Kannus et al. 1995), hemilplegia (Jorgsen and Jacobsen 2001) or frozen shoulder (Leppala et al. 1998), the bone density in the proximal humerus is reduced. Bone density recovered over the proceeding year, but full recovery was not achieved and differences between the control and affected arm were dependent upon the level of shoulder function regained i.e. poor upper limb recovery is associated with reduced bone re-mineralisation.

One possible flaw with the research by Kannus et al. (1994) is the baseline measurements (see above): patients with rotator cuff pathology probably have reduced shoulder function *before* the operation (to repair the rotator cuff tear) and this is likely to reduce their baseline bone density. The BMD was only measured after the operation and was still reduced, but, without baseline measures, bone loss, might be underestimated in relation to normative values. Restoration of shoulder function, with no or minimal immobilisation, is most likely to minimise bone loss after any shoulder problem. This effect is likely to be higher in an older population with osteoporosis and other co-morbidities. Therefore, if bone is to be preserved, activity must start immediately and this is tested in the author's research.

2.7.3 Shoulder Rehabilitation

"It is important to recognise the functional interdependence of joints and soft tissues in the upper quadrant when treating dysfunction of the shoulder."

Bang and Deyle, 2000 (Bang and Deyle 2000)

2.7.4 Systematic Reviews

The following section reviews the best available evidence for the rehabilitation of common shoulder disorders and is important as its findings underpin shoulder fracture rehabilitation.

The findings from systematic reviews (Van der Heijden et al. 1997; Green et al. 1998) on the efficacy of shoulder interventions are consistent in several key areas: a general lack of quality evidence can neither support nor refute the efficacy of common shoulder interventions for shoulder pain. The studies reviewed usually involve small samples (less than 25 patients in each arm of the trial), poor outcome measures and high drop-out rates. This is further compounded by inconsistency in defining 'physiotherapy' and identifying what actually constitutes a 'shoulder disorder'. Many structures refer pain to the shoulder region (e.g. cervical, thoracic spine) and problems exist with diagnostic categories as:

"...aetiology and pathogenesis of shoulder disorders tend to remain enigmatic."

Van der Windt, 1995 (Van der Windt et al. 1995)

Furthermore, when interventions are compared with control groups (Green et al. 1998), the effect sizes (defined as the impact made by the independent variable (Munro 1997)) are small (range –1.4 to 3.0). After reviewing 58 studies (31 studies met the inclusion criteria), the only conclusion that Green makes is that sub-acromial injection is better than placebo in improving shoulder abduction.

Most interventions for shoulder pain are limited to electrotherapy and injection therapy and only recently has research investigated the effects of exercise and mobilisation (passive movement) in shoulder treatment. Additionally, electrotherapy is seen to be the main component of 'physiotherapy' and fails to recognise the fundamental basis to physiotherapy as being exercise and movement (passive or active). In a review of interventions for sub-acromial impingement (Michener et al. 2004) the authors concluded that exercise and joint mobilisations are efficacious. Recent evidence in other areas of rehabilitation, would suggest that education, exercise and mobilisation of stiff joints are effective in a range of common musculoskeletal disorders (O'Sullivan et al. 1997; Crossley et al. 2002; Jull and Trott 2002). Interestingly, in these studies, the improvements were maintained at follow-up times ranging from 6 to 30 months, despite treatment finishing within an average of six weeks. Maintaining improvement over this period of time suggests that patients continue with some form of exercise or maintain their functional gains.

This section discusses the available evidence for modalities (e.g. electrotherapy and hydrotherapy), exercise and mobilisation. Current shoulder research is emerging that clearly points toward an active programme based on exercise and advice. This work is included to develop an approach for PH fractures rehabilitation.

2.7.5 Electrotherapy

No evidence exists for the inclusion of electrotherapy in rehabilitation programmes, specifically for PH fractures (Liversley et al. 1992), other shoulder conditions (Van der Heijden et al. 1997) (Van der Heijden 1999) (Vecchio et al. 1993) or pain relief (Gam and Johnnsen 1995). The passive nature of electrotherapy might actually retard recovery when a more active, engaging approach is required (Brox 2003). Patients with rotator cuff disease, receiving an exercise-based approach improved considerably despite having a failed 'physiotherapy' programme that included electrotherapy (Brox et al. 1999). Patients only entered the Brox et al. study if they had symptoms for at least three months and outpatient physiotherapy had failed. However, they only received electrotherapy, thus, supporting the view that electrotherapy has a limited role in shoulder rehabilitation. The use of hydrotherapy (Revay et al. 1992) in PH fracture rehabilitation produced no improvement in shoulder function, but more research is needed to test the efficacy of hydrotherapy. Several studies have failed to support the use of electrotherapy in a range of shoulder problems and its value in PH fracture management is questionable. It is for this reason that neither electrotherapy nor hydrotherapy are included in the author's treatment protocols.

The next section reviews the available evidence for exercise and joint mobilisation in the shoulder region. The evidence base is not large, but several well conducted papers are starting to demonstrate moderate treatment efficacy, however more work is needed and specifically with shoulder fractures before this approach can be fully accepted.

2.7.6 Exercise

Therapeutic exercise and joint mobilisation are axiomatic to physiotherapy practice, but evidence for its efficacy in shoulder rehabilitation is sparse and research is hindered by the limited knowledge of the natural history of many common shoulder disorders (Geert and Van der Heijden 1999). Current research is split between those who set wide-inclusion criteria and define shoulder pain as 'any symptom within the shoulder girdle complex' with no attempt at using diagnostic categories, and others who select patients by specific shoulder disorders, confirmed by diagnostic tests. Both approaches are reasonable with wide-inclusion criteria evaluating current practice in a pragmatic trial. However, by incorporating all shoulder problems together it fails to recognise the importance of specific therapeutic exercises directed toward a clear diagnostic category (Gibson et al. 2004).

In two systematic reviews of interventions for shoulder pain (Van der Heijden et al. 1997; Green et al. 1998), only six studies that included exercise or mobilisation met the inclusion criteria out of a possible 51 trials. Exercise is not used exclusively in research programmes, but is combined with education, advice and a graded home exercise programme and there is evidence to support this approach (Brox et al. 1999) (Malone et al. 2004) (Gibson et al. 2004) . A systematic review (Michener et al. 2004) on interventions for sub-acromial impingement syndrome, concluded both exercise and joint mobilisation to be 'efficacious' in this condition compared with control groups.

When exercise was compared with surgery in the treatment of rotator cuff disease (Brox et al. 1999), the results in both groups were superior to the placebo group. The exercise programme aimed at normalising neuromuscular patterns by using a graded increase in resistance to the rotator cuff and scapular stabilising muscles. Exercise was equally effective as surgery and at the two-and-a-half year follow up, more people in the exercise group remained at work (80% versus 59%), and the authors suggested that the improvements were as a result of patients maintaining their exercise programme. Although, they did not keep an exercise diary to substantiate these claims. Similarly, patients given a supervised exercise programme for shoulder pain (Hay et al. 2003) had better improvement at six months compared with injection and had few re-consultations with their GP. Giving patients an exercise programme that specifically addresses their shoulder problems and requires them to continue with it for a period of time makes the patient a more active recipient of treatment. This avoids the passive nature of injection therapy which, through its application, does not require their active participation in the resolution of symptoms and is against the view that patients should be encouraged to adopt an active coping strategy to aid recovery from shoulder problems (Brox 2003). This could possibly reinforce the view that home exercise programmes give the patient greater control of their condition and promote independence; therefore, producing better long-term outcomes in shoulder function.

Evidence is starting to emerge that exercise aimed at restoring neuromuscular function (Gibson et al. 2004) is effective in the management of shoulder instability and rotator cuff tendinopathies (Humphreys et al. 2004). Following a PH fracture, changes in the neuromuscular patterning of the shoulder are common as stiffness in the glenohumeral joint results in compensatory movement in the shoulder girdle. Early restoration of normal neuromuscular shoulder control (correction of scapulo-humeral rhythm and prevention of excessive shoulder girdle elevation or 'shrugging') is paramount in preventing secondary problems by patient education and exercise. Furthermore, the exercise programme should address the contribution of the entire body to the control of the shoulder (Gibson 2004) as part of the kinetic chain model (McMullen and Uhl 2000).

The episodic nature of shoulder symptoms is highlighted by many studies (Croft et al. 1996) (MacFarlane et al. 1998) who state that shoulder dysfunction is not self-limiting and the natural history is characterised by further exacerbations. Meaningful evaluation of patients must include functional assessment based against the natural history of the condition. A good example of the benefits of this research is seen in the treatment of lateral elbow pain by injection or physiotherapy (Smidt et al. 2002). Patients who received injection therapy did better than the physiotherapy group at six weeks (92% compared with 47%). However, at 52 weeks the physiotherapy group were better than those having an injection (91% compared with 69%). The injection group continued to have more symptoms than the 'wait and see' group (69% compared with 83%) and would suggest an injection gives fast initial improvement, but at one year is worse than the 'wait and see' group. The problems of the episodic nature of shoulder problems are considerable as the author's research evaluates the patient's functional status over time. Furthermore, a certain proportion of patients will probably have shoulder problems before their shoulder fracture. Previously discussed work has suggested levels of shoulder problems in a 'normal' older population to be approximately 20 to 25 percent (Chakravarty and Webley 1990; Chard et al. 1991; Chakravarty and Webley 1993) and this could influence the result. This is further considered in the methods section.

2.7.7 Joint Mobilisation

Only one small study (Jull 1979) has specifically investigated the effects of joint mobilisation on PH fractures, but evidence for its efficacy in other shoulder conditions is starting to emerge. When joint mobilisation was used to accelerate shoulder movement following PH fractures (Jull 1979), 11 out of 14 patients achieved 90 degrees shoulder abduction within the first treatment session (rehabilitation started within 14 days post-injury). All patients had full active flexion by 27 days and Jull suggested that mobilisation limits the effects of shoulder stiffness. Not all PH fractures require joint mobilisation, but certain patients might benefit from this approach. No study has evaluated the addition of joint mobilisation within PH fracture programme, but a study (Bang and Deyle 2000) investigating the efficacy of treatment for sub-acromial impingement, both groups had an exercise programme, but one also received joint mobilisation. The combined group showed improvements in pain and strength at follow-up compared with the exercise group. Likewise, in shoulder impingement syndrome (Conroy and Hayes 1998) improvements were reported in pain and range of movement with the addition of joint mobilisation. With rotator cuff tendinopathy (Humphreys et al. 2004), both exercise and joint mobilisation groups improved their pain and disability scores when compared with the placebo group. The combining of exercise and mobilisation produced further improvement.

The additional effect of joint mobilisation can only be established by comparing three groups: exercise, joint mobilisation and a combined group of both exercise and mobilisation. This study does not exist in shoulder rehabilitation, but work by Jull et al. (Jull and Trott 2002) in treatment of cervicogenic headaches compared three such groups. With a similar result to Bang et al. (Bang and Deyle 2000), both exercise and mobilisation groups improved, but the combined group had further improvement, albeit small (10%). Research evidence supports the central role of exercise in rehabilitation (Feine and Lund 1997), but addressing joint limitation could give additional improvement.

2.7.8 Immobilisation

The standard immobilisation period before starting physiotherapy is three weeks (Clifford 1980; Mills and Horne 1985; Kristiansen et al. 1989) although this is based on empirical evidence and only one study has actually compared different periods of immobilisation. Kristiansen and associates (Kristiansen et al. 1989) compared one and three weeks immobilisation before starting rehabilitation and reported no differences between groups. This is an important study as it is similar to the proposed research; however it has several limitations in three key areas: first, the use of an outcome measures with no evidence of a validation process that classifies treatment success into 'poor', 'good', or 'unsatisfactory' without any justification. Second, high attrition rates (50% lost by two years) and third, the fractures were not selected by classification and complex fractures are known to recover slower (Court-Brown et al. 2000). Additionally, patients did not have physiotherapy and fractures were either reduced by open or closed manipulation despite no evidence to support this treatment (Neer 1970; Gibson et al. 2001; Court-Brown and McQueen 2002). This is against current opinion and prevents comparison with other studies (extensive searches could not find another study where manipulation of the fracture was used prior to rehabilitation). Furthermore, no measures of general health status or shoulder disability were included, thus failing to detect subtle limitations in functional status. These limitations are long lasting, especially in an older population (Nankhonya et al. 1991; Madhok and Bhopal 1992) and must be considered when selecting appropriate outcome measures.

The problems of high drop-out rates and reliability of selected outcome measures are consistent throughout PH fracture research. For this reason, it is hard to compare results and little consideration of shoulder function, resulting disability or generic health status (to evaluate the overall impact of a given condition on a person's health) is made. Not including these important components of health tends to produce an over optimistic view of recovery from PH fracture repair leading to claims of excellent recovery within one year of the injury. The author's research intends to avoid these pitfalls and includes a battery of outcome measures to fully evaluate the overall impact of a PH fracture. Thus, obtaining a more accurate and comprehensive evaluation of recovery (or lack of it) following the fracture from which to base management decisions.

The lack of consensus on a recommended period of immobilisation is reflected in the Cochrane review (Gibson et al. 2001) that comments on the lack of reliable evidence on which to base much of proximal humerus fracture management. Some authors (Crawford-Adams 1983; Mills and Horne 1985) suggest three weeks immobilisation before starting passive movement, but defer active movement for six weeks (no rationale is given). Others suggest shorter periods (7-10 days) of rest (Skinner 1995; Bigliani et al. 1996) and Apley (Apley and Solomon 1993) states that movement can begin after pain subsides, but he provides no evidence for this assertion other than clinical experience.

No consistent period of immobilisation is given in any literature and this probably reflects current clinical practice that shows wide variation in periods of immobilisation within hospitals (see UK survey in Results Chapter). The proposed research aims to test the efficacy of using immobilisation in PH fracture management and whether pain experience is reduced by having this delay before starting physiotherapy. However, in other areas of research the evidence would suggest that immobilisation only delays recovery and increases pain. For example, bed-rest for lower back pain (Malmivaara et al. 1995; Wilkinson 1995), repair of knee ligaments (Goldstein and Barmada 1984; Woo et al. 1987), acute ankle sprain (Kerkhoff et al. 2002), and acute neck sprain (Mealy et al. 1986).

Rest has traditionally been the most common treatment advised by physicians (Waddell 1998) and is thought to originate from Hunter as far back as the eighteenth century (Hunter 1794) who advocated rest for wounds and inflammatory conditions. This erroneous link between tissue healing and rest continues to resonate in modern medicine and, only relatively recently, with clinical research by Salter (Salter 1982) on the beneficial effects of immediate movement of tissue repair and animal experimentation (Akeson et al. 1973; Buckwalter 1985), has the issue of immobilisation been re-evaluated. The author has experienced this resistance to change with the adoption of accelerated programmes that have proposed no immobilisation before starting physiotherapy. Some orthopaedic surgeons remain staunch advocates of rest in fracture healing, without supportive evidence, and are unwilling, or unable, to change their views. The main concern with early movement appears to focus on the increased risk of complication (e.g. failure of the fracture to heal or delayed healing, mal-union or vascular damage) that might arise as a result of increased stresses placed across a recent fracture. The evidence for this hypothesis is unfounded, but hard, clinical research in PH fractures is limited and the next part of the literature reviews the available evidence.

2.7.9 Complications and Accelerated Rehabilitation

Immediate physiotherapy, without a period of immobilisation, raises a number of issues regarding possible complications such as non, or delayed union of the fracture. The potential harmful effects of early movement on proximal humerus fracture are characterised by the comment made by Bigliani and associates (Bigliani et al. 1996) who state that non-union is caused by 'insufficient immobilisation'. No evidence for this statement is presented, but other authors have made similar claims regarding movement at the fracture site (Crawford-Adams 1983).

Exact figures for how many proximal humerus fractures develop non-union do not exist, but over a 10 year period in Western Ontario, Canada, Najak et al. (Najak et al. 1995) reported that 17 patients required surgical intervention for non-union. No actual figures are given for the total number of fractures that did not develop a non-union, but this figure probably represents a very small proportion of the total number of fractures. Interestingly, when discussing possible causes of the non-union, the authors state that early movement appears not to be a factor because all were immobilised for six weeks. This can be interpreted in one of two ways: immobilisation for six weeks could produce more non-unions (if patients are normally mobilised sooner) or if patients were moved earlier, the non-union rates might increase. Lack of detailed figures in the paper does not allow further interpretation. Furthermore, if Bigliani's comments are correct, and complications are caused by insufficient immobilisation; six weeks immobilisation should result in no complications as this is an extensive period of rest. Clearly, this is not the case and casts further doubt on this theory.

A possible clue in the development of non-union is given by Zyto and co-workers (Zyto et al. 1997) who randomised patients (n=40) with complex PH fractures to receive either surgery or conservative management. The complex PH fractures are more likely to experience healing problems, and indeed this is the case with eight patients going on to develop a non-union fracture. Crucially, six out of these patients had surgery compared with the group beginning active exercise within seven to ten days. Surgery might increase the non-union incidence, but other studies are not available to fully explore this proposition.

Complication rates might actually increase with immobilisation; an idea that is counter to current orthopaedic thinking. The rise in complications with the more complex PH fractures could be a direct result of removing the stimulus to bone repair: namely movement. PH fractures might heal *despite* immobilisation, but at a cost of reduced function and increased dependence on carers. The author's research turns conventional wisdom on PH fracture management on its head by proposing that immobilisation, and not movement, reduces fracture healing and probably results in more complications. In evolutionary terms, humans have evolved to maximise function and part of this includes a repair process that has movement as a central driving factor in tissue healing. The heart is not immobilised following open heart surgery and tissue repair is completed in an environment of constant movement. There is no reason to suggest that bone, as a specialised connective tissue, will not respond in a similar way.

In three studies that began active shoulder movement within seven days of the injury (Jull 1979; Liversley et al. 1992; Revay et al. 1992) there were no reports of complications. Kristiansen (Kristiansen et al. 1989) reported one complication in the group that moved within one week of the injury (the same as the group immobilised for three weeks). Clinical data does not appear to support the increased incidence on non-union in early movement, but, as in many other areas of PH research, the evidence is neither extensive nor of a sufficiently high standard to draw firm conclusions.

Similarly, in management of other common fractures such as the wrist (Dias et al. 1988) and ankle (Port et al. 1997; Dogra and Rangan 1999), early movement results in faster restoration of function without any increase in complications. Port and associates compared immediate mobilisation with cast immobilisation for four weeks for stable distal fibular fractures. There were no complications in the 'mobilisation' group, but the 'immobilised' group had one case of radiographic non-union at six months. This is further evidence that complications could be reduced with immediate movement.

Equally, soft tissue injury responds to accelerated rehabilitation, for example, Achilles tendon (Mortensen et al. 1999) and knee ligament ruptures (Pinczewski and Clingeleffer 1996). The atrophic effects of immobilisation on muscle are significant within one week (Kannus et al. 1992) as studies immobilising the wrist for only nine days demonstrated (Miles et al. 1994) modest reductions in cross sectional area of the forearm muscles (4.1%), but greater changes in muscle extensor (32.5%) and flexor (29.3%) strength. This represents significant reductions in strength, especially as the subjects were healthy, young female students with no injury or experience of pain. Arguably, when these findings are applied to an older population who already has compromised tissue quality and pain after a fracture, the effects of immobilisation will probably be greater.

The weight of evidence in fractures (excluding shoulder fractures) would support the theory that early movement, without a period of immobilisation, would accelerate bone healing in PH fractures. Additionally, this approach does not necessarily increase complication rates and might actually reduce the incidence. This proposition tested in the author's research as shoulder function, and more importantly, complication rates are monitored over two years following the fracture.

Bone remodelling is both sensitive to alterations in magnitude and distribution (Rubin 1984) and fracture healing is accelerated by the addition of movement (Panjabi et al. 1979; Kenwright et al. 1991). No clinical research investigating the efficacy of treatment programmes exists that indicates, or even suggests, that early movement contributes to the development of complications. The only caveat to this statement is the poor quality of most trials as highlighted in the Cochrane review. The efficacy of different rehabilitation programmes is weakened by poor trial design for common orthopaedic conditions: proximal radius fracture (Handoll et al. 2002), hip surgery (Handoll et al. 2003), and proximal humerus fractures (Gibson et al. 2001). Their conclusions assert that lack of evidence makes evaluation of the relative effectiveness of different interventions impossible. Of all the fractures, the hip and wrist have undergone the most extensive research and if this is the conclusion, then it is fair to assume that this is the case for all other fractures.

2.7.10 Summary

The evidence base for most interventions in shoulder disorders is limited, but recent research is starting to address some of the methodological issues, specifically outcome measures and definitions of 'physiotherapy' and diagnostic categories. The available evidence is generally weak, but suggests that a structured exercise programme, aimed at stretching and strengthening shoulder muscles, with the addition of joint mobilisation produces beneficial results for most common shoulder problems.

Exercise and mobilisation (and following a home exercise programme) is paramount to restoration of shoulder function following a PH fracture. The evidence base for this type of approach is good for many common shoulder problems but not, unfortunately, for PH fracture. However, it is reasonable to assume that an exercise based regime would be equally effective with fractures. The reluctance to mobilise fractured shoulders probably stems from the traditional view that fracture repair is enhanced with rest. The evidence does not support this assertion and early restoration of activity by exercise, education and, if necessary, joint mobilisation, is paramount.

The case for starting physiotherapy after a period of immobilisation is not supported by the current literature. The best evidence would suggest that patients will probably benefit from immediate physiotherapy by maximising shoulder function and additionally reduce the demands on health providers. The long-term outcome for this common fracture is unknown and certainly the detailed evaluation of shoulder function that is required to make management decisions is absent. The evidence for early movement producing an increase in complications is mainly anecdotal and, ironically, some evidence suggests that early movement in fracture repair limits complication rates. This area still remains contentious and is an area for future research. The paucity of evidence for physiotherapy ensures that any programme given is mainly based on best practice and general consensus.

The proposed research is important for many reasons; not least because, few reliable studies have been published in this area, therefore making objective clinical decisions impossible. The research fills an important gap and builds on experimental research that supports early restoration of function to provide the stimulus to bone repair and to minimise complication rates. This is essential to all fractures, but in the case of PH fractures the high incidence of osteoporosis gives it added importance. Accelerating fracture repair and simultaneously minimising bone loss is vital to prevent future fractures and maintain shoulder function. The author's research addresses the key questions set against an ageing population with concomitant rises in osteoporosis and falls-related injuries.

2.8 Study Aims & Hypotheses

2.8.1 Study Aims

- To investigate the effects of an accelerated physiotherapy programme on proximal humerus fractures.
- To examine the long-term effects of a PH fracture using shoulder specific outcome measures and a generic health questionnaire.
- To identify risk factors in the study population that predicts reduced shoulder function following a PH fracture.
- To conduct a National UK survey of Trauma services to assess the current management and rehabilitation of PH fractures.

2.8.2 Hypotheses

The hypotheses tested were:

Hypothesis 1 (H1)

A difference exists in shoulder function following immediate physiotherapy compared with delayed physiotherapy after a PH fracture.

Null Hypothesis

No difference exists in shoulder function after immediate physiotherapy compared with delayed physiotherapy following a PH fracture.

Hypothesis 2 (H2)

A difference exists in generic health status after immediate physiotherapy compared with delayed physiotherapy following a PH fracture.

Null Hypothesis

No difference exists in generic health status after immediate physiotherapy compared with delayed physiotherapy following a PH fracture.

Hypothesis 3 (H3)

A difference exists in long-term (two years) shoulder function after immediate physiotherapy compared with delayed physiotherapy following a PH fracture.

Null Hypothesis

No difference exists in long-term (two years) shoulder function after immediate physiotherapy compared with delayed physiotherapy following a PH fracture.

Hypothesis 4 (H4)

Socioeconomic risk factors will predict recovery following a PH fracture

Null Hypothesis

Socioeconomic risk factors will not predict recovery following a PH fracture

Hypothesis 5 (H5)

No standardised management and treatment strategy exists for the provision of PH fractures in the UK.

Null Hypothesis

A standardised management and treatment strategies exists for the provision of PH fractures in the UK.

CHAPTER 3: METHOD

3.1 Introduction

The method is in two parts. The first part describes the National UK survey that reviewed the current management and rehabilitation of patients who fractured their PH. The second part and main part of the thesis investigated the effects of an accelerated physiotherapy programme on shoulder function and generic health status after a PH fracture. Additionally, within this section, risk factors that predict long-term shoulder disability were calculated.

3.2 National UK Survey

After the start of the main study, it was soon realised that no previous research had ascertained details of the actual management and physiotherapy procedures used for PH fractures in the UK (or any other country). This was an omission from the Literature review and it was felt that specific information was needed to answer questions raised from the findings. This was highlighted by discussions with Orthopaedic surgeons who stated that their management was consistent and standardised, but no National guidelines existed and evidence from local physiotherapists treating PH fractures showed that treatment varied between consultants and hospitals. Thus, it was decided to conduct the first ever national survey of trauma centres in the UK to determine what the current management and physiotherapy treatment there was for PH fractures. Although, the survey was conducted after the main study and, in retrospect, it would have been preferable to do it earlier, however, its findings proved most helpful in explaining the results and making further recommendations.

In October 2001, a postal questionnaire was sent to senior physiotherapists involved in shoulder fracture rehabilitation working in all the Trauma centres in the UK. A supporting letter was also sent to the physiotherapy manager in the department asking them to give the questionnaire to the most senior physiotherapist, who treated patients with upper limb trauma. It was decided not to send the letter to the orthopaedic consultants within the trauma centre (see below) as the aim of the survey was to investigate the range of physiotherapy treatments and to determine the medical management of patients who fractured their PH. The questionnaire was designed after consultation with a senior physiotherapist with 20 years experience working in Trauma and Orthopaedics (Doncaster Royal Infirmary). From this initial discussion, it was decided not to send the questionnaire to Consultant Orthopaedic surgeons as most trauma centres have at least four teams (many have more) and this would necessitate sending out over 500 questionnaires, probably reducing the return rate.

The question of consistency of PH fracture management within consultants was also discussed and indicated that, from clinician's experiences that, the medical management was varied both within and between hospitals. One of the aims of the questionnaire was to determine the range of medical managements used, hence the decision to send the questionnaire to the physiotherapist who treated PH fractures. It was thought that this approach would maximise information about the range of medical management strategies, but could possibly overlook patients who were not referred for physiotherapy. Only including patients who were referred for physiotherapy was a possible limitation of the survey, but it was thought that maximising response rate was more important, especially since no previous survey had ascertained the treatment or management of PH fractures in the UK.

The questionnaire aimed to investigate the following questions:

- How many patients are routinely referred for physiotherapy following a PH fracture?
- What is the initial management of these patients? (e.g. period of immobilisation, method of immobilisation)
- What physiotherapeutic modalities (electrotherapy, mobilisation, exercise etc) are used?
- Do management guidelines exist within the hospital?

The physiotherapy manager in each Hospital was sent the forms and asked to give the questionnaire to the most senior physiotherapist who treated upper limb fractures. It was thought that this approach would be quicker than contacting each hospital by telephone to determine the most relevant physiotherapist to whom the questionnaire should be sent. Also, the Manager would be more likely to give the questionnaire to the most senior physiotherapist and this approach might actually increase the response rate.

The questionnaire was piloted by sending it (on the 1st September 2001) to senior orthopaedic physiotherapists in four hospitals (Central Sheffield University Hospital, Rotherham District Hospital, Bassetlaw Hospital and Chesterfield Royal Hospital).

After a period of two weeks, each senior physiotherapist was contacted and their comments noted. The main comments were favourable and no major structural change was needed to the questionnaire as it was mainly trying to gain information and did not seek opinions.

Changes made:

- A box with 'sometimes' was added to Question 1 as physiotherapists indicated that the practice of immobilisation varies considerably within each hospital (none of the four hospitals had a standardised approach to PH fracture management and considerable variation existed between consultants).

- 'Neer type one' classification was added to the questionnaire (line one) as it was thought that this would ensure all physiotherapists would help identify the type of PH fracture.

The physiotherapists in three hospitals stated that consultants referred all PH fractures for physiotherapy and they were confident that their comments represented all patients who entered their hospital. The one remaining hospital stated that one consultant did not routinely refer all patients to, but she estimated that over 90% were routinely referred, if not for treatment, then for advice. This would support the view that the senior physiotherapist would answer the questionnaire with knowledge from at least 90% of the PH fractures in each hospital. This was thought acceptable considering the questionnaire only sought to give an overall impression of the management and treatment strategy for each hospital and did not ask for specific numbers of PH fractures.

Randomisation

A sample of 70% of all trauma centres within each region in the UK were selected by random number tables (Swinscow and Campbell 1997). Two hundred trauma centres were identified using the Regional Directories (2000/01) of the eight regional NHS centres in England (Wales, Northern Ireland and Scotland excluded). A total of 139 questionnaires were sent to all the regions on the 1st October 2001 and a reminder letter (appendix XI) was sent to 16 hospitals four weeks later (1st November 2001).

3.3 Randomised Controlled Trial

This was a pragmatic Randomised trial (RCT) as defined by Rowland (Rowland 1998) as it measured effectiveness, or the benefit a treatment produces in routine clinical practice. Furthermore, pragmatic trials allow evaluation of a new treatment against current treatment and do not usually involve the use of a 'placebo'. Furthermore, conclusions from these types of trials can, if accepted, be adopted directly into clinical practice (Fayers and Hand 1997). The study started in October 1998 based at the Accident & Emergency Department at Sheffield Teaching Hospitals Foundation Trust (STHFT). After giving informed consent, patients sustaining a proximal humerus fracture (PH) were recruited into the study. All patients were recruited within a week of their fracture (most within two days).

This chapter reviews and justifies the method for the study and covers the following main areas: study design, population & sampling, assessment & follow-up, physiotherapy protocol, treatment providers, outcome measures, statistical analysis, pilot study and ethical considerations.

3.4 Pilot Study

The study design and outcome measures were evaluated prior to the main study. The study design was modified in response to these findings and the following changes to the proposed study were made.

- Fracture clinic staff were not highlighting the patients with PH fractures and they were not being considered for the study. Therefore, a large sticker was placed on all the x-rays and notes of patients eligible for the trial to ensure the surgeon considered the patient for the trial.
- Patients sustaining a fracture over the weekend were referred to Mr Stanley's Monday afternoon fracture clinic so they were not lost in the system over the week-end.
- Consent forms were originally given to the surgeon at fracture clinic, but this lead to problems with incomplete data. The forms were completed by the physiotherapist in orthopaedic clinic.
- A 10% sample of the randomised assessment forms were checked by a Senior Lecturer.
- Some confusion over the wording (Questions 4-9) of the SF-36 health survey for the initial assessment lead to a change of the phrase: "During the last

week…" to "Since your fracture…". Some patients interpreted the former wording to indicate their health status before the fracture and not their required health status *since the fracture*. This was only included for the initial baseline scores for the SF-36.

- To improve recruitment to the study, the principal researcher had weekly meetings with the clinic staff to highlight the aims of the trial and to ensure all PH patients were considered for the research.
- Patients were referred to the two clinics each week by a Consultant surgeon specialising in upper limb trauma to maximise recruitment and to ensure consistency with classification of fractures.
- Strength testing of shoulder abduction (part of the CSS) was initially in standing to ensure consistency in posture, however poor balance in some of the patients produced a measurement error. This was modified to take the measurement in sitting. Postural alignment was maintained with a towel in the lumbar spine to sustain the lordosis.
- The Balance assessment (Berg Balance test) was stopped after ten patients as it produced unnecessary stress with some patients.
- The eight week follow-up was planned to coincide with the patient's next fracture clinic appointment, but this proved impossible with pressures on clinic staff and booking ambulances. The eight week appointments were conducted at the patient's home.
- Some patients were unwell and could not attend the hospital out-patients and had their treatment by the community physiotherapy services in Sheffield.

This only included three patients out of a total of 68 and clear guidance was given to the physiotherapists and the hospital protocol was followed.

- To facilitate economic evaluation of the study, data was collected on the number of clinic visits, x-rays taken and secondary referrals. This data was included in the regression analysis modelling to identify trends in recovery and any ongoing health requirement (specific economic evaluation was not undertaken following advice from the statistician as insufficient data existed for cost-effectiveness/benefit to be calculated).

3.5 Study Design

3.5.1 Randomised Controlled Trial (RCT)

A pragmatic RCT design was selected to test the hypotheses and the reporting of the study complies with the revised CONSORT statement (Moher et al. 2001) made in 2001 by Moher and colleagues. The control group was the 'conventional' treatment group (Group B) that consisted of three weeks immobilisation with a collar and cuff before starting physiotherapy. Strictly speaking, this is not a 'control' group within the sense of the Randomised Controlled Trial, but it would be unethical to withhold usual treatment to any patient. This compromise is within the meaning of the 'pragmatic' trial (Rowland 1998) and is commonly employed in research that aims to make informed choices between treatments.

Treatment was divided between one of two groups (fig.8). Conventional treatment consisting of immobilisation with collar and cuff for three weeks (then physiotherapy) compared with an accelerated rehabilitation programme (no period of immobilisation) and immediate physiotherapy. Thus, comparing conventional treatment with a new intervention.

3.5.2 Recruitment Procedure

After attending Accident and Emergency following a fall, the patient was examined and x-rays were taken. If the upper humerus was fractured, the patient was referred to fracture clinic the next day (up to two days if the injury was over a weekend). The orthopaedic surgeon assessed the PH fracture and classified it by the use of the Neer Classification system (Neer 1970). The Neer classification scheme was selected for the study after discussions with Mr David Stanley (Consultant Orthopaedic Surgeon at the Northern General Hospital Trauma Unit at Sheffield). He suggested that the Neer classification scheme should be used as it was universally accepted within Sheffield and throughout the UK. Additionally, the scheme was used in most previous PH fracture research and its inclusion in this study would allow comparisons between results. He recognised its weaknesses regarding reliability, but thought that for minimally displaced fractures (Neer type one) it would be the most appropriate classification system.

All patients with minimally displaced fractures (or type one fractures) were eligible to be considered for the study and were given the research protocol information (appendix XIII) and asked to consider entering the study. All the surgeons at fracture clinic were either at Consultant or Specialist registrar level with a minimum of five years experience in orthopaedics.

Following the informed consent (appendix XII) procedure conducted by the clinic physiotherapist, the patient's baseline assessment details were recorded (appendix II).

General information recorded:

- Personal details and social history
- Fracture characteristics and past medical history

Baseline outcome measures include:

- Constant Shoulder Score (CSS)
- SF-36 generic health questionnaire (SF-36)
- Balance assessment score using Berg Balance Scale (Berg et al. 1989).

If the patient fulfilled the entry criteria, they were asked to enter the study by the referring orthopaedic surgeon in fracture clinic. The information sheet was given to the patient by the referring surgeon and any questions that the patient might have were answered. Following this, the clinic physiotherapist (working in fracture clinic) formally consented the patient and explained the nature of the research and what was expected of the patient. The baseline assessment forms and outcome measures (CSS, Berg balance score and SF-36) were recorded by the clinic physiotherapist. The patient completed the forms and outcome measures and help was given by the physiotherapist if they experienced any specific problems relating to the questions. This help was kept to a minimum and most patients completed the forms unaided. Follow-up assessments (2, 8, 12 and 24 months) were conducted by the author (SH) who was blinded to group allocation.

From the patient's post code, the level of deprivation was calculated using the Health Profile of Sheffield's Electoral wards (Davies et al. 1994). The work by Davies el al. classified all Sheffield by electoral wards (29) into a league table of level of social deprivation (highest to lowest areas). They used the Townsend Deprivation index to achieve this goal. The league table of deprivation was later used in the regression analysis to classify all the subjects into 'low' (top half of the table) or 'high' levels of social deprivation.

Townsend Deprivation Index determines the level of deprivation on the following criteria:

- Percentage economically active residents aged 16 to retirement age
- Percentage private households who do not own car
- Percentage households who do not own their own home
- Percentage private households with more than one person per room

Townsend, 1988 (Townsend et al. 1988)

The research was based in the Sheffield Teaching Hospitals Foundation Trust (NGH) in Sheffield (Trauma and Orthopaedic Unit) and patients were recruited from the hospital's Accident and Emergency Department (fig. 8). The physiotherapy was undertaken at the Sheffield Teaching Hospitals Foundation Trust (NGH or the Royal Hallamshire hospital).

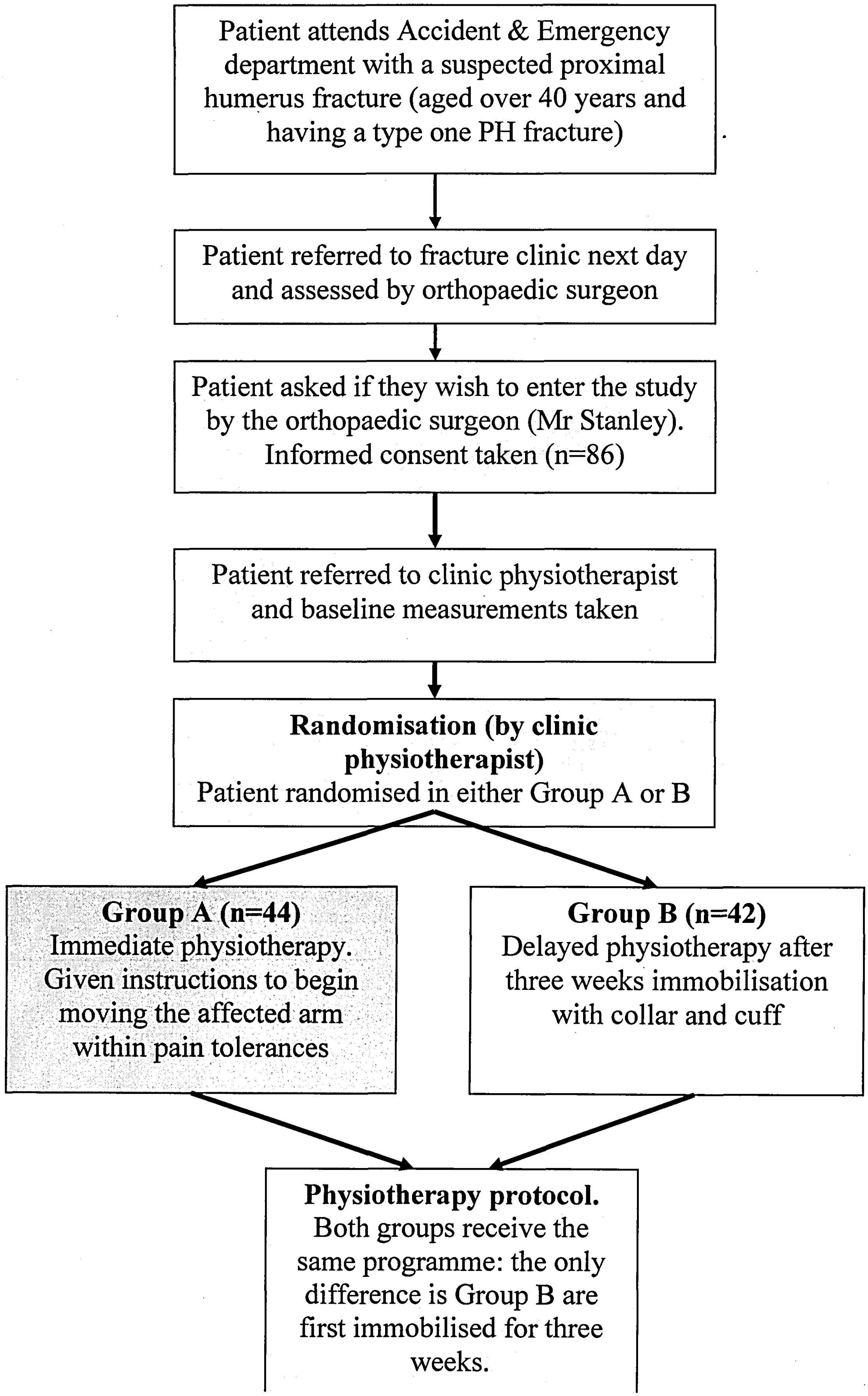
Work by several authors has indicated that a moderate body mass index is predictive of health status (Guralnik and Kaplan 1989; Harris et al. 1989). Body mass was calculated by multiplying weight (in kilograms) by the square of the height in metres (Bird et al. 1998). The patient's height (standing ruler) and weight (scales) were measured by the clinic physiotherapist after the baseline measurements were completed.

Patients were asked if they were able to use public transport as some research uses this as a measure of activity (Sartoretti et al. 1997) as the ability to use a bus implies a certain level of neuromuscular co-ordination and functional independence. A person's ability to use public transport has been used as an outcome measure for general disability (Branch and Jette 1981) and following hip fractures (Sartoretti et al. 1997). Its inclusion in this study was used to evaluate the wider impact of PH fracture on the patient. Work by Kelsey et al. (Kelsey et al. 1992) has suggested that PH fractures are associated with poor neuro-muscular control mechanisms and an ability to use public transport was a measure of a person's balance and willingness to go outside.

Side of fracture and handedness was recorded to investigate for a possible relationship, but Koval (Koval et al. 1997) found no difference between handedness and side of fracture in a large retrospective study. Although, both Hagino et al. (Hagino et al. 1999) reported a higher fracture incidence in the left arm (55%, n=579 and 57%, n=5586 respectively).

At discharge, the physiotherapist recorded the number and type of treatments, date of discharge and possible complications or unusual problems during rehabilitation.

Figure 8: Flow-chart showing the route the patient takes from admission to entering the study.



3.5.3 Randomisation Process

A person independent to the study conducted the randomisation process by using random number tables (Swinscow and Campbell 1997). Group allocation was by sealed, opaque envelopes that were attached to the sequentially numbered assessment forms. Patients were randomly allocated to Group A (immediate) or Group B (delayed). Group A attended physiotherapy within seven days of the injury for advice by the clinic physiotherapist, the same person who completed the baseline assessments. The session included education about the fracture, advice on pain relief and to take the arm out of the sling and move it four to six times each day. Use of a 'collar and cuff' was permitted, but they were instructed to remove their arm from the sling and begin active, controlled exercise. Group B were given a 'collar and cuff' and immobilised for three weeks and an appointment was made for them to attend physiotherapy in three weeks. The physiotherapist was aware of the group allocation, a pre-requisite of the local ethics committee (see ethics section). Both groups received the same physiotherapy protocol, the only difference being that the start date for physiotherapy was delayed by three weeks in Group B.

3.6 Population & Sampling

3.6.1 Study Population

The population was defined as people living within the catchment area of the Trauma and Orthopaedic Centre, based at the STHFT. Seventy-six thousand patients (NHS 2005) attend the trauma centre every year and approximately 643 (Kempton 2000) sustain a PH fracture.

3.6.2 Study Inclusion/Exclusion Criteria

Most fractures to the PH are in an older population with osteoporosis (OP) and the incidence rates increase exponentially in both genders at around the age of 45 years (refer to epidemiology section in literature review). The trial criteria are purposely wide to include a representative sample of the study population, thus not limiting the trial's external validity (Bailey 1997).

Inclusion Criteria

- Male/female aged over 40 years
- PH fracture (Neer type one or minimally displaced)
- Consent to enter the study
- Understanding of written and verbal information

Exclusion Criteria

- Multiple or pathological fractures
- Requiring surgery
- A poor level of general health, which would prevent regular hospital attendance for physiotherapy. Patients with a poor level of health would not be automatically excluded from the study, provided they were mobile, as these patients often fracture their proximal humerus (Kelsey et al. 1992).

Selecting the Neer type one fracture for the study had several potential advantages:

- It is the most common PH fracture (Neer 1970; Bengner et al. 1988; Court-Brown et al. 2000), despite the variation in its reported incidence.

- Conservative management is universally recommended (Neer 1970; Gibson et al. 2001), whereas surgery is often advocated for the more complicated fractures (Neer 1970). However, even with the more complicated fractures its benefit is equivocal with several authors failing to show a difference between conservatively or surgically managed fractures (Zyto et al. 1995; Zyto et al. 1997; Court-Brown et al. 2001).

Any potential complications with immediate physiotherapy would have been minimised by investigating the more stable fracture type, as concerns exist about early movement of fracture fragments before clinical union is attained (Neer 1970; Crawford-Adams 1983; Bigliani et al. 1996).

3.7 Assessment & Follow-Up

3.7.1 Assessment

`This was a single 'blind' study with the physiotherapists providing treatment being aware of group allocation (see Literature Review: Ethics section), but the assessor (author, SH) was 'blinded' to group allocation. The concealment of group allocation was made by sealed, opaque envelopes that were opened by the clinic physiotherapist only after baseline measurements. The initial re-assessments (8 weeks) were completed at the patients next fracture clinic appointment. This limited the additional journey times to the hospital for the patients and was another recommendation of the ethics committee.

The physiotherapists providing treatment were not blinded to group allocation for two reasons. First, a PH fracture produces considerable tissue trauma and the physiotherapist would know by the haematoma formation the likely time scale of the injury. Secondly, the physiotherapist must know if the fracture occurred yesterday or a week ago as this would influence initial treatment. Treatment in the 'immediate' group must consider the implications of over vigorous movement of the fracture if the therapist was 'blinded' to group allocation. Potentially this could increase the complication rates to those patients in the 'immediate' group and was a concern of the ethics committee. Thus, the decision was made to not blind the therapist, although, this could introduce bias into the results and the implications of this decision are discussed in the findings. However, this condition was a pre-requisite of the ethics committee granting approval.

3.7.2 Follow-up

Problems with lack of trial homogeneity (Handoll and Madhok 2002) and different assessment points (Court-Brown et al. 2000) are cited as reasons for making valid comparisons between studies difficult. To address this issue, follow-up times of 8, 16 and 52 weeks were selected which corresponded with other PH fracture research and also considered the key recovery times for this type of fracture.

Primary Outcome Point

Sixteen weeks was the primary outcome point as most recovery following PH fractures occurs within this time after initial injury (Solem-Bertoft et al. 1984; Mills and Horne 1985; Liversley et al. 1992). Furthermore, patients were commonly discharged from fracture clinic at this time and so, basing power calculations and trial results at this time would appear justified.

Secondary Outcome Points

- Early (eight weeks)

Most PH studies include an assessment within four to eight weeks (Lundberg et al. 1979; Kristiansen et al. 1989) as part of the evaluation of initial progress and to detect trends in recovery that might be masked at 16 weeks. By eight weeks the patient should regain some level of function with range of movement (ROM) returning (Jull 1979; Solem-Bertoft et al. 1984).

- Long-term Outcome Points (one and two years)

Long-term evaluation usually occurs at one year (Lundberg et al. 1979; Solem-Bertoft et al. 1984; Zyto et al. 1997), but other authors have a final follow-up at six months (Liversley et al. 1992). They claim that older patients stop improving between three to six months, but this contrasts with another study that measured improvement up to one year (Solem-Bertoft et al. 1984). The recommendation for PH fractures is for longer and more in depth evaluation (Koval et al. 1997), that includes multiple outcome measures and re-assessment for several years after the fracture (Wildner et al. 2002). The complex nature of recovery and ongoing problems following an upper limb fracture are only just beginning to be understood. Including one and two year follow-up points acknowledges the ongoing nature of shoulder problems that often remain problematic for several years, especially in older adults after the initial injury

(Madhok and Bhopal 1992; MacFarlane et al. 1998; Wildner et al. 2002). This study is the first to use a prospective two year evaluation of PH fractures and the results will test the hypothesis that these fractures produce long-term shoulder disability and do not recover by one year.

3.7.3 Summary

Follow up evaluation was initially at 8 and 16 weeks and long-term at one and two years. At 8, 16 and 52 weeks an assessor blinded to group allocation evaluated the patient. The two year evaluation was via postal questionnaire to prevent patients, many of whom were elderly and had general mobility problems, having additional journeys to hospital. Additionally, the use of home visits and postal questionnaires (discussed in the outcome measurement) for assessment, in an older group, probably limited the drop-out rate from the study. It was decided to do home visits for evaluation (2, 4, & 12 months) as problems were encountered with the provision of ambulances and it was thought that patients would not want to spend several hours waiting for an ambulance to bring them into hospital. Home visits minimised the inconvenience to the patient as many were rather frail and found ambulance journeys difficult.

3.8 Physiotherapy Protocol

The physiotherapy programme (appendix VII) was in three distinct phases as suggested by Hughes and Neer (Hughes and Neer 1975): Early (first two weeks of physiotherapy), Intermediate (2 to 4 weeks) and Late (4 to 12 weeks). The programme was not prescriptive and recognised the varying approaches of the physiotherapists and the range of patients' functional loss with an upper limb fracture.

Accepting some variation in treatment (within strict guidelines) was part of the pragmatic trial approach (Rowland 1998) that aimed to assess the impact of the treatment any patient would receive in a similar situation.

The main aim of the programme was to maximise shoulder function (Ginn et al. 1997) in the shortest possible time and within the pain tolerances of the patient. The role of therapeutic exercises was central to the programme with their established efficacy in regaining symptom-free movement and function (Kisner and Colby 1996). The exercises were based on the concept of strength, flexibility and neuromuscular training proposed by Hertling and Kessler (Hertling and Kessler 1996) that minimise the effects of immobilisation and encourage restoration of function.

3.8.1 Early Phase (first two weeks)

Patients were educated about their injury to reduce anxiety and prevent the development of fear-avoidance strategies (Vlaeyen and Linton 2000). They were encouraged to remove their arm from the sling every hour and begin gentle active/assisted movements. A home exercise programme was completed (three to five times/day for approximately 10 minutes), based on the programme of Solem-Bertoft (Solem-Bertoft et al. 1984) and Revay (Revay et al. 1992).

Pain management was by education and ice or heat in the initial stages and no form of electrotherapy was used. The evidence for the efficacy of ultrasound therapy is poor with both a meta-analysis (Gam and Johnnsen 1995) and systematic review (Geert and Van der Heijden 1999) questioning its use in musculoskeletal disorders.

Furthermore, in one of the few studies to compare an electrotherapy modality (pulsed electromagnetic high frequency energy) to a sham treatment (Liversley et al. 1992) in PH fractures, found no difference between groups.

Mobilisation was included within this period as there is some evidence that it reduces pain and restores movement (Jull 1979). However, this particular research had no control group so caution must be taken when interpreting this result. Postural advice was given aimed at restoring symmetry of the shoulder (Raine and Twomey 1996) and preventing the patient from using 'shoulder shrugging' (or excessive elevation of the scapula) in response to shoulder stiffness or pain (Babyar 1996). The excessive elevation of the scapula is common following trauma to the PH as the person attempts to recruit the shoulder girdle to elevate the arm. This abnormal shoulder pattern is reinforced with functional activity and contributes to long-term problems.

3.8.2 Intermediate Phase (two to four weeks)

The level of functional, task-specific, exercise was increased with the patient expected to perform light, assisted movements. Incorporating strengthening within the functional demands of the patient maximises the concept of the muscle specificity of the exercise (Lieber 2002). Patients must practise those tasks that they use daily to minimise disability levels and reduce any fears they might have about moving their shoulder. Written information was given to patients to enhance compliance and demonstrate correct performance of the exercises as Schoo and colleagues (Schoo et al. 2004) reported high levels of compliance (79-91%) in older adults with arthritis in the knee and hip. Although other authors have reported lower levels of compliance with lower back pain (about 40%) (Deyo 1982), this involved a younger age group and the PH patients in the author's study are closer to the population age in Schoo's research. Maximising compliance is important as Jan and co-workers (Jan et al. 2004) reported patients (following unilateral total hip replacement) in high compliance exercise groups showed significant increases ($p<0.05$) in hip strength and function compared with low compliance and control groups. Patients with lower back pain have lower compliance to exercise programmes, even with the addition of a motivational course (Friedrich et al. 1997), but no research has explored the compliance of PH fracture patients to home exercise programmes.

3.8.3 Late Phase (four to eight weeks) & Discharge

With increasing stability of the scar tissue and the clinical union of the fracture (Crawford-Adams 1983), exercises were progressed against gravity and lengthening techniques were introduced. Discharge occurred when both the patient and physiotherapist were satisfied with the level of shoulder function and the patient was independent in activities of daily living (ADL). Most patients were discharged within 12 weeks of starting physiotherapy (Solem-Bertoft et al. 1984). Patients were not given a specific number of treatments (e.g. one treatment session over 12 weeks) as PH fractures are known to vary in their requirements following this type of injury (Koval et al. 1997; Wildner et al. 2002). For ethical reasons it was thought that limiting patients to a specific number of treatments, after which time they would be discharged, even if they required further intervention, was not acceptable. For these reasons the number of treatment sessions varied, but probably reflected what happens in clinical practice.

3.8.4 Treatment Providers

Treatment was provided by 15 physiotherapists working at Sheffield Teaching Hospitals Foundation Trust (FTHFT). No staff had specialist skills in shoulder rehabilitation, but all had experience of rehabilitating patients with PH fractures. No specific training was given to the physiotherapists other than instruction in the treatment protocols and to avoid using electrotherapy. Physiotherapists followed the treatment protocol (appendix VII) that was agreed with staff before the trial started. The agreement was made following two discussions with all the physiotherapists who were involved in treatment provision on the trial. There was general agreement about the protocol, but one physiotherapist wanted to include acupuncture as part of the treatment. However, when this was discussed and the author (SH) requested that treatment was based on the 'core skills' of a qualifying physiotherapist, the group consensus was to not include acupuncture in the study.

The aim was to maximize recovery within the shortest possible time, but without causing the patient undue distress. Additionally, the protocol selected reflected the core skills of a physiotherapist and avoided the use of electrotherapy as its efficacy is poor in these types of fractures (Liversley et al. 1992).

As part of a 'pragmatic' trial, the study assessed real clinical practice (Rowland 1998) and recognised that treatment provision is not identical and patients are not rehabilitated in 'ideal' situations. For the results to maintain their external validity (Bailey 1997) and to remain relevant to all the UK, treatment was based on current practice within Sheffield and the Trent region.

Treatment was stopped when the physiotherapist, in agreement with the patient, thought that independent shoulder function had been achieved and the patient could continue their home exercise programme without supervision. Maintaining point of discharge at the discretion of the patient and physiotherapist reflects current clinical practice and avoids ethical problems if patients recover slower.

3.9 Outcome Measures

The outcome measures were selected that allowed comprehensive evaluation of the potential health gains from a new approach in PH fracture management and rehabilitation. This approach is recommended by Rowland (Rowland 1998) as it allows evaluation of different health gains, but with measures that are acceptable to an older population and allow comparisons with similar studies.

The study was evaluated using the following outcome measures:

- Constant Shoulder Score (CSS)(Constant and Murley 1987)
- Short Form 36 General Health Survey (SF-36)(Ware and Selbourne 1992)
- Croft Shoulder Disability Questionnaire (CSDQ) (Croft et al. 1994)

The CSS was the primary outcome measure and both the SF-36 and CSDQ were secondary measures. The CSS measures shoulder function and impairment and is the most relevant judge of PH fracture recovery. SF-36 measures the wider impact on general health, but will not be as responsive as the CSS to clinical change. CSDQ is an overall measure of shoulder disability and is less dependent on impairment than the CSS (please see table 1 for outcome variables).

The CSS is a measure of shoulder impairment (i.e. level of pain and limitation of ROM or strength) and gives a score between 0 (maximum shoulder impairment) to 100 points (no shoulder impairment). The CSDQ measures limitations in shoulder function as recorded (yes/no) by the patient for 22 questions (a score of 0 represented full shoulder function and 22 represents maximum shoulder disability). The SF-36 measures general health status using eight dimensions of health and a score of 100 points represents normal health status and zero represents maximum limitation in health status for the given health dimension e.g. role limitation-physical dimension.

Table 1: Outcome variables

Variable	**Explanation**
Constant shoulder score (CSS)	Shoulder impairment (0 to 100 points)
Short form 36 health survey (SF-36)	General health status (0 to100 points)
Croft shoulder disability questionnaire (CSDQ)	Shoulder function and limitations (0 to 22).
Gender	Male/female
Body mass index (BMI)	Kgs/m (squared)
Number of fall	In previous year
Dominant arm	Right/left
Side of fracture	Right/left
Living status	Alone, with partner, lives with others
Help required at home	Yes/no
Occupation	Present or previous
Previous fractures	Fractures in last year
Previous shoulder/arm problems	In previous year
Berg Balance measure	Later removed
Number of treatment sessions	Physiotherapy
Number of clinic visits	Post fracture visits to fracture clinic
Number of x-rays	Post fracture radiographic examination.
Secondary referral (number).	Referral required to other professional.

3.9.1 Constant Shoulder Score (CSS)

This is a measure of shoulder impairment and function (appendix III) developed by Constant and Murley (Constant and Murley 1987) and has gained acceptance in Europe, USA and Japan (Constant 1997). The score incorporates measures of pain, functional limitations, ROM and strength to give both a subjective (35 points) and objective (65 points) measure. Pain reported on functional tasks comprises 15% of the score. A score of 100 represents maximum shoulder function and a score of zero indicates no upper shoulder function.

When Constant (Constant and Murley 1987) described the test, they reported that repeated assessment of 100 shoulder patients (various conditions) by three examiners produced an observer error of 3% (range 0 to 8%). The full reliability study was not recorded and only the aggregate scores out of 100 were given, and the specific scores for the components were omitted.

- **Limitations**

Possible limitations are raised in one of the few independent evaluations of the score's reliability (Conboy et al. 1996). Twenty-five patients, with three different conditions ('dislocation', 'arthritis' and 'impingement'), were assessed by three independent assessors. The conclusions state the overall "reliability of the score was low" (95% confidence limit between 15 to 20 points for a single observation on one patient). The reliability was not consistently low across all conditions: most 'dislocations' with full ROM and intermittent pain consistently scored maximum marks (100 points) despite having problems with their shoulder and were seeking medical help (intermittent symptoms with good ROM are notoriously difficult to assess with any shoulder measure). The 'arthritis' (general shoulder restriction) group showed higher reliability, probably because the restricted ROM was related to symptoms. The CSS scores highly for ROM limitation and pain, therefore shoulder restriction with 'arthritis' or post shoulder fracture are well suited to this outcome measure. Also, the 'arthritis' group did not show the 'ceiling' effects (the tendency for subjects to score maximum marks with an outcome measure) as seen in the 'dislocation' group. Indeed, this assertion is supported by a reliability study of the CSS using only PH fractures (Langdown et al. 1997). In contrast to Conboy's result, Langdown et al. (1997) found that a two-way analysis of variance showed no differences between groups and concluded that the CSS was a reliable outcome measure for shoulder fractures.

Authors defend the score as a valid method for shoulder evaluation (Rockwood 1994; Constant 1997) but, recognise the problems of assessing the shoulder with varying symptoms relative to ROM and recommend the score for degenerative (or osteoarthritic) conditions (Carr 1997). No author quoted research data to support their assertions, but work by Ring (Ring et al. 1999) found a high correlation ($r2=0.869$, $p<0.001$) between the CSS and the Disability and Shoulder, Hand Questionnaire (DASH). Furthermore, Zyto (Zyto et al. 1995) reported that the CSS agreed with the patients own opinion of their shoulder function (no data reported in the paper to support this statement).

Others have identified the importance of pain experienced during a given activity in determining the level of impairment measures (Solem-Bertoft et al. 1996). Pain experienced correlates highly with impairment and it is more predictive of functional level than time of recovery from injury. Pain contributes 15% to the CSS, but this does not recognise the large impact of pain on functional shoulder activity. PH fractures produce considerable pain and will influence the overall score; however the weighting of 15% for the CSS is low. Although, pain was also measured with the bodily pain dimension in the SF-36 health survey and allows comparisons between the two measures.

Measurement of shoulder strength in the CSS is by isometric testing of abduction at 90 degrees from the trunk. Measuring isometric strength using a hand-held dynamometer is reliable when compared with expensive isokinetic measurement instruments (Magnusson and Gliem 1990) (Interclass correlation coefficient ranging from 0.82 to 0.99). Also, spring dynamometry is as accurate as dynamometry when measuring shoulder elevation (ICC 0.96 & 0.92 in spring dynamometry and dynamometry respectively) but its reliability is lower in external rotation (Hayes et al. 2002).

Shoulder abduction (90 degrees) strength was measured with a hand held digital balance (Salter Weight-Tronix) and the reading was taken after a sustained hold of five seconds (Bankes et al. 1998). The procedure was initially piloted on two patients (not on the trial) and the following changes were made:

- Shoulder abduction was tested in seated position (standing recommended), but the patient's poor balance prevented this position been used.
- The hand-held digital balance was fixed to the floor for the measurements using a weight.
- For strength testing, the patient was asked to sustain their maximum abduction force for five seconds and this was then repeated three times and the average score recorded.

To test the reproducibility (test/re-test) of the CSS, ten patients were re-assessed within one week of their 16 week assessments (appendix X, table 11). The results produced a standard deviation for the CSS of 6.7 and a coefficient of variation of 13% for repeated measurements. This was considered acceptable for evaluating shoulder function.

An inability to abduct the arm to 90 degrees produced a score of zero and the average of three attempts was calculated as recommended by Magnusson (Magnusson and Gliem 1990).

The CSS has its limitations when assessing intermittent shoulder problems. However, in assessing stiff or osteoarthritic shoulders, similar to PH fractures, the result is reliable and reflects the patient's opinion of their shoulder condition. More importantly, it is easy to administer and has low system error (Conboy et al. 1996).

3.9.2 Short Form 36 General Health Survey (SF-36)

A generic health measure was included in the study to evaluate the high levels of co-morbidity and the poor general health that is reported following PH fractures (Kelsey et al. 1992; Hawker et al. 1995; Rekola et al. 1997; Sartoretti et al. 1997). Additionally, the high levels of osteoporosis associated with these fractures (Nguyen et al. 2001) and the minimal force required to precipitate the injury (usually a fall from standing height) (Kristiansen et al. 1987), suggests that patients will also have associated health problems. Furthermore, the effects of this injury continue for many years (Van der Windt et al. 1995; MacFarlane et al. 1998) and the SF-36 will evaluate the patient's 'quality of life' and the full impact of this injury. This approach is recommended in the evaluation of many orthopaedic disorders (Fletcher et al. 1992; Dawson et al. 1996; Fernandez et al. 1997). The SF-36 comprises of eight dimensions (appendix V) that are transformed into a 100 point scale (zero representing poor health and 100, perfect health).

The SF-36 (Ware and Selbourne 1992; Ware et al. 1993) is the most commonly used generic measure and has under gone extensive testing that suggests that it is a reliable measure of patients' general health, it is also easy to score and administer (Garratt et al. 1993; Jenkinson et al. 1993). However, some authors have questioned its reliability with older adults (Brazier et al. 1992; Mallinson 1998) and some concerns exist towards its sensitivity to clinical change (Mawson 1995). Although, work by Ruta (Ruta et al. 1999), comparing the SF-36 with a patient generated index, reported the pain dimension to be the most responsive to clinical change in lower back pain patients. However, the patient generated index was more responsive in all the other dimensions.

Similarly, research determining the responsiveness of the SF-36 to severity of arthritis (Kosinski et al. 1999) following treatment, also found the pain dimension to be most responsive (with role limitation and physical functioning dimensions). Furthermore, Wolinsky and colleagues (Wolinsky et al. 1998) raised issues of ceiling and/or floor effects (limitations in the scaling within the dimensions that inappropriately groups people together with different health status) with the SF-36 in adults aged between 55 and 99 years and in poor general health. This led him to question the ability of the SF-36 discriminate intra-individual comparisons, but stated that its sensitivity could detect changes between groups.

In studies comparing responsiveness of the SF-36 with a disease specific measure (Hawker et al. 1995; Amadio et al. 1996; Martin et al. 1997; Wright and Young 1997) all found the SF-36 to be less responsive to clinical change. Although, in contrast to this result Meenan and co-workers (Meenan et al. 1984) state that it could detect clinical change in their study. However, they evaluated patients with Rheumatoid arthritis, a disease with a large global impact, and the SF-36 would detect the wider range of improvements.

This would suggest that certain dimensions of the SF-36 have clinical value, and in the case of PH fractures, those dimensions that measure physical health (pain, physical functioning, role limitation and social limitation) could provide valuable general health information. The author's trial compares the changes in the SF-36 between groups, so limitations of responsiveness of the measure are reduced. Furthermore, the SF-36 is a secondary measure that allows exploration of the findings to direct future work and its inclusion is further justified on these grounds.

Despite good psychometric properties, Brazier (Brazier et al. 1992) cautioned the use of the SF-36 with the elderly (the study was based in Sheffield and had an overall 83% return rate), but this is refuted by Lyons and colleagues (Lyons et al. 1994) who specifically investigated its use with the elderly. Lyon's sample had a mean age of 74 years and demonstrated high internal consistency (Cronbach's alpha 0.82 and above for each parameter) and 98.8% of data complete. The main difference between the work of Brazier and Lyons was the method of administration: postal and interview respectively. Also, Mallison (Mallinson 1998) reported that only 34 of 56 responders (60.7%) completed all the items on the SF-36 when administered by post, thus supporting the idea that this method of administration has serious limitations. Twenty one patients of 45 (47%) had some problems completing the questionnaire and 11 of 45 (24%) reported they found all the questions difficult. The higher rate of completed questionnaires with an interview is not unexpected as older patients might be confused by the length of the form and complexity of the questions (at least one question uses a double negative).

Later qualitative work by Mallinson (Mallinson 2002) identified the problems that patients (n=56; aged 65 to 98 years) had when completing the SF-36 questionnaire and considered the vagueness of some questions (e.g. 'Can you walk a mile?'

Response: 'How far is a mile') or the problem of double questions. For example, to the question: 'Can you bend, stoop or kneel?' Response: 'I can bend, but can't kneel'. Patients were unsure how to answer this question and often averaged their answer to select the middle option. Clearly, the interpretation of some of the SF-36 questions, especially in an older population, limits the usefulness of the questionnaire and this must be taken into account when considering the results.

In the author's study the SF-36 was completed by interview due to concerns given by Brazier. The assessor's experiences of administering the SF-36 to patients who fracture their PH would support the concerns of Brazier and question the measures reliability as a postal questionnaire in older adults. The decision to include the SF-36 in the author's research was based on the lack of other creditable alternatives to measure generic health status. The issue of sensitivity to change is partially negated in the case of PH fracture patients as they will naturally recover from the fracture and the aim is to measure the rate of this change. Additionally, repeat measures of any outcome measure will increase its sensitivity to change.

Is the SF-36 the best generic measure of health status for use with PH patients? The ubiquitous nature of the questionnaire and the readily available normative data to both a general population (Brazier et al. 1992; Jenkinson et al. 1993) and shoulder specific disorders (Gartsman et al. 1998) will permit useful comparisons. Furthermore, when comparing different generic health measures (Beaton et al. 1997) in musculoskeletal disorders, the SF-36 was the most responsive with moderate to large effect sizes

(0.55-0.97). The SF-36 does have a role in evaluating shoulder fractures, but only as part of an assessment package and it was not the primary outcome measure.

The study population is likely to have co-morbidities and associated general health problems. The SF-36 will detect these global changes, allowing regression analysis to identify factors that might lead to long-term shoulder disability. Comparing the SF-36 domains with factors such as levels of social deprivation, age, and gender which are not routinely assessed when considering management of the PH fracture. Thus, developing new management strategies and informing future research. As Brown-Court commented:

"There is virtually no information available about social and financial consequences of these fractures (Hagino et al. 1999)."

Court-Brown, 2002 (Court-Brown and McQueen 2002)

The SF-36, used in conjunction with a disease specific measure, will begin to address these issues.

The SF-36 was assessed at baseline, 8, 16 and 52 weeks in a face-to-face interview situation. All dimensions were calculated and tested (appendix V), but the Physical functioning, Bodily pain, Social functioning and the Role limitations (physical problems) dimensions are most relevant to the nature of the condition (Amadio et al. 1996; Beaton and Richards 1996) and are commonly used in orthopaedic research (Martin et al. 1997).

3.9.3 Croft Shoulder Disability Questionnaire (CSDQ)

The CSDQ (appendix VI) is a simple and easy to score measure (Croft et al. 1994; Paul et al. 2004) and work by Pope (Pope et al. 1997) in a large epidemiological study in a population (range 18 to 75 years) found high acceptance of the score. Combined with the advantages of extensive normative data-based in a geographic area similar to Sheffield, and high response rates via postal questionnaire, would support its use in this type of study. This is a self-completing questionnaire that asks the patient to self-report their shoulder function with 22 upper limb functions (e.g. washing, carrying shopping, and writing) and produces a dichotomous result that is summed. A score of five or more represents significant shoulder disability (Croft et al. 1994), but only a score of 'zero' represents full shoulder function.

The CSDQ was constructed by selecting questions from the Functional Limitations Profile (FLP), a British version of the extensively tested American Sickness Impact Profile (Bergner et al. 1981). Further questions relating to shoulder limitations were selected after consultation with physiotherapists, occupational therapists and shoulder patients. The CSDQ was validated by sending it to two different groups: one group were identified as having shoulder pain (n=71) from a randomised sample of adults aged 18 years on an age-gender register. The second group (n=54) were patients who had attended their GP, complaining of shoulder pain. Both groups completed the CSDQ and were examined, shoulder ROM (active and passive abduction, internal and internal rotation) and strength (resisted abduction using a spring balance) were recorded (table 2). From the answers given to the CSDQ (22 questions) about shoulder function, the rank-order of these disabilities was analysed for both study groups (Spearman's rank correlation coefficient) and this was compared with the measures from the clinical examination. The association between shoulder ROM, strength and disability score (CSDQ) was investigated by stratifying the disability score into (i) those reporting no pain, (ii) those reporting one to four items (iii), those reporting five or more items.

Table 2: Association between disability score and shoulder restriction measures in 56 subjects from the community (adapted from Croft et al. 1994).

Movement	Median	CSDQ score 0 OR	CSDQ Score 1-4 OR	CSDQ Score > 5 OR	Trend analysis Chi-square	p-value
Abd (degrees)	168	1.0	1.7	6.6	13.5	0.000
IR (degrees)	61	1.0	1.8	3.2	4.6	0.031
ER (degrees)	74	1.0	4.6	4.0	3.1	0.079
HBB (cms)	32	1.0	1.7	5.7	10.1	0.002
Strength (Kg)	5.4	1.0	3.5	7.0	2.0	0.153

Key:	
CSDQ	Croft Shoulder Disability Questionnaire
OR	Odds ratio
Abd	Abduction
IR	Internal rotation
ER	External rotation
HBB	Hand behind back

The results indicated that as the disability score increased, the range of movement (abd, IR, HBB) reduced and was statistically significant, but ER did not achieve statistical significance (p=0.079). The measurement of strength correlated to the disability score, but proved less helpful and was only completed by 28 subjects. Croft et al. used these results to confirm that the CSDQ was a valid measure of shoulder disability and recognised that testing repeatability is harder to achieve when subject are liable to considerable change over time.

In a later validity and reliability study (Paul et al. 2004) of the CSDQ against three other self-completed shoulder questionnaires (Shoulder Pain and Disability Index [SPADI], Shoulder Rating Questionnaire [SRQ], Dutch Shoulder Disability Questionnaire [SDQ-NL]) the CSDQ demonstrated high content and face validity compared with the other outcome measures (correlation: SDQ-NL 0.55, SPADI 0.57, SRQ 0.72) with a statistical significance of $p<0.01$. The correlation scores for the CSDQ against shoulder ROM was low (flexion -0.341, $p<0.01$, abduction -0.342, $p<0.01$ and external rotation -0.020, not significant). However, this result is not unexpected as many people with shoulder problems have pain, but often have full shoulder movement (this is not a problem with a PH fracture population as pain and shoulder limitation are more likely to correlate). The responsiveness (patients completed the questionnaire twice within six weeks) for the CSDQ (responsiveness ratio of 1.39) was lowest of all the questionnaires (SPADI 1.67, SDQ-NL 1.73 and SRQ 2.76). This result questions the usefulness of the CSDQ to measure change over time (in the present study change over time was measured with the CSS), although the questionnaire did have the largest correlation ($r= -0.680$, $p<0.01$) with the Euroqol (EQ) that measures perceived health status. The work of Paul et al. (2004) suggests the CSDQ has good validity, can be completed within five minutes (mean time to complete three minutes), but, in the words of the authors, has 'moderate' responsiveness.

The research by MacFarlane (MacFarlane et al. 1998) and Pope (Pope et al. 1996) in which a population was surveyed by postal questionnaire would support its reliability by this method of administration. Several orthopaedic studies have demonstrated the benefits of postal evaluation and self-administered questionnaires (Johanson et al. 1992; Dawson et al. 2000; Jinks et al. 2002). These studies assessed patients following hip and knee surgery and achieved good response rates from a similar population to that of the author's research. With the financial restrictions on the study, and the general immobility of the study population, the adoption of the CSDQ postal questionnaire provides the best measure of patient reported disability. Thus, allowing a two year evaluation, and possibly even longer follow-up.

3.9.4 Summary

The primary outcome measure was the disease specific measure (CSS) that measures both shoulder impairment and functional limitations. The SF-36 quantifies the wider impact on the patients' general health and associated co-morbidities. Additionally, the SF-36 data are included as part of the regression analysis when identifying the risk factors in the development of shoulder dysfunction. Long-term follow-up (one & two years) is with the CSDQ, a self-reporting measure of shoulder function that is easily completed by the patient. Further evaluation at five or ten years is anticipated to give a complete picture of the impact of PH fractures on an older population.

3.10 Statistical Analysis

3.10.1 Power Calculation

The sample size was based on the Constant shoulder score (CSS) and this was the primary outcome measure. Basing the power calculation on a disease specific measure is supported in the literature as it targets musculoskeletal disorders and improves sensitivity (MacFarlane and Brookes 1997). For the purposes of sample size calculation we assumed a mean difference between the two groups of ten points in the Constant shoulder scores at 16 weeks to be of practical importance. Also assuming a standard deviation of 15 points in Constant shoulder score indicated that to have an 80% power of detecting a mean difference of 10 or more points as statistically significant at the α level of 5% (two-sided), 36 subjects were required for each group. Assuming a dropout rate of 20%, 43 patients were recruited to both groups. Any data from patients leaving the trial was included in the final analysis unless they were incorrectly recruited into the study (for example they went on to have surgery). If they withdrew from the study for personal reasons, death or changed groups their data was included in the final analysis.

3.10.2 Analysis

The Statistical Package for the Social Sciences (SPSS) for windows was used for all the statistical analyses (version 10.0). All data was inputted into SPSS by Julie Harris, an experienced research co-ordinator with over 10 years' experience, by double entry method. Additionally, a 10% random sample of the database was checked for accuracy and an error rate of less than one percent was found. All analyses were completed on an intention-to-treat basis. Demographic and clinical data were compared between the two groups. The SF-36 scores were assumed to be continuous data. Mean Constant Scores and SF-36 dimension scores at 16 weeks follow-up were compared between Group A and B by two independent sample t-tests. Ninety-five percent confidence intervals for the mean differences were also calculated. The Constant score and the SF-36 summary measure were analysed by calculating the area-under-the-curve (AUC) in which all follow up points are included e.g. 8, 16 and

52 weeks, as suggested by Matthew et al. (Matthews JNS et al. 1990) for serial measurements.

The score for each shoulder with the CSS was calculated using the standardised scoring system (appendix IV). The maximum score is 100 and this represents normal shoulder function (for a person aged 25 years). A score of zero represents no shoulder function. The CSS was calculated and expressed as a ratio between the fractured and unaffected shoulder. If the patient was experiencing acute shoulder pain in the unaffected side at the baseline measurement (in practice this rarely happened), their shoulder was re-assessed at the later follow up point and the best score was recorded.

Thus, a score of one represents full return of shoulder function and zero, no functional return; in the fractured shoulder compared with the unaffected shoulder.

For the two year follow-up data analysis, the analysis of the Croft Shoulder Disability Questionnaire (CSDQ) data utilised the Mann-Whitney test (statistical significance set at 5%) to assess the relation between the groups.

3.10.3 Regression Analysis

Binary logistic regression was calculated for dichotomous data, whilst continuous data was included in the General linear repeated measures modelling.

Two-way contingency table analysis was used to initially explore differences between the immediate (group A) and delayed (group B) treatment groups across demographic, social background and health-related, healthcare, disability and impairment characteristics. Chi-squared tests of independence were performed to assess the statistical significance of possible associations. Health-related quality of life and impairment profiles were graphically investigated using error bar plots and simple differences between study groups were tested using non-parametric approaches.

Main effects binary logistic modelling was employed to investigate the explanatory power of such factors as treatment group, demographic and other background characteristics with respect to disability and impairment outcomes and use of healthcare. This approach models a transformed binary outcome, such as a Croft disability score (CSDS) at one year (a score of one or more indicated 'disabled' and a score of zero indicated 'no disability'), on a linear function of one or more explanatory variables. The power of such explanatory factors was expressed as an odds ratio.

Finally, the quality of life and impairment progress of the subjects over the first 12 months were modelled using general linear repeated measures approaches.

3.11 Reliability

The reliability of the Constant shoulder score was measured using a sample of ten patients. Consecutive patients were selected and repeat measures were taken over one week (mean time six days). The measures were taken after six months of the fracture as recovery rate would be reducing and shoulder function stabilising. All measures were taken at the patients' home. Standard deviation, mean differences and within coefficient of variation (Bland 1995) were calculated and expressed as a percentage difference between the two scores (standard deviation divided by the mean and multiplied by 100 to give a percentage).

3.12 Ethical Considerations

The study was approved by the North Sheffield Local Ethics Committee on 8th July 1998, after minor modifications to the original design (the use of hospital letter headings and stopping the research if more than five patients experienced complications as a result of immediate rehabilitation). Data collection started in October 1998 and, after the two year follow-up, finished in March 2002.

The ethical considerations centred on the possible increase in complications (non or delayed fracture union) within the intervention group with immediate physiotherapy. No evidence exists for this assertion within the literature, however it was agreed to monitor any complications in the intervention group and if the rates exceeded 5% more than the conventional group, the research would be stopped.

The committee also raised concerns about any additional visits to the Hospital (above the normal orthopaedic clinic appointments) that the patient would be expected to make. In response to this, patients were evaluated at home at 16 weeks (unless still attending hospital) and at one year. The CSDQ was administered by postal questionnaire at two years.

The treating physiotherapists were not 'blinded' to group allocation as they needed to carefully monitor the patients' progress in case complications developed. Blinding to group allocation could severely compromise this task and potentially limit the patient's care. Additionally, the level of post fracture bruising would soon indicate to the physiotherapist the time since injury. This could not be masked and might be a possible source of 'bias' in the study.

3.13 Summary

The method is in two parts: Part 1 comprises a National UK survey determining the current management and rehabilitation of PH fractures. Part 2 consists of a pragmatic RCT investigating the effect of immediate physiotherapy on the rehabilitation of PH fractures started in October 1998. Patients were recruited from the Trauma centre at STHFT and were randomly allocated to either immediate (within one week) or delayed (immobilisation for three weeks) physiotherapy. Evaluation was at 8, 16 and 52 weeks using the CSS, CSDQ and SF-36. Long-term evaluation (two years) was by postal questionnaire (CSDQ). Regression analysis used baseline characteristics and SF-36 data to identify risk factors in the development of shoulder dysfunction.

Chapter 4: Results

4.1 Introduction

This chapter initially presents the results of the UK survey on management of type one PH fractures) and the results of the RCT at years one and two. Additionally, the regression analyses data are presented for the risk factors in the development of shoulder dysfunction.

4.2 National UK Survey

Response Rates

Table 3: Response rate

Questionnaires sent	139
Returned	127
Response rate	91%
Adjusted response rate *	94%

*The adjusted response rate does not include the four questionnaires sent to hospitals not having trauma services.

Individual Questions

Question 1. Are patients who fracture their PH routinely immobilised?

Yes	73 (58%)
No	26 (20%)
Sometimes	28 (22%)

Question 2. If they are immobilised, how long is this period?

1 week	3 (3%)
2 weeks	21 (21%)
3 weeks	56 (55%)
4 weeks	17 (17%)
5-7 weeks	4 (4%)

Question 3. Are patients routinely referred for physiotherapy?

Yes	103 (81%)
No	0
Sometimes	24 (19%)

Question 4. How long after the injury, do patients have first contact with a physiotherapist?

1 week	43 (36%)
2 weeks	32 (27%)
3 weeks	30 (25%)
4 weeks	13 (10%)
6 weeks	2 (2%)

(seven physiotherapists were unable to answer this question)

4.3 Randomised Controlled Trial

4.3.1. RCT Results (One Year)

Baseline Characteristics

The group variables were comparable (table 4) after statistical analysis and only number of treatment sessions per group were statistically significant (fig.10) at $p<0.002$. Patients were not given a specific number of treatment sessions, but were discharged when functional independence was achieved. Thus, Group B required additional treatment sessions to achieve independent shoulder function.

The number of males in each group is different (Group A-11, Group B-5) with a statistical significance of $p<0.20$. To test any possible influence of gender allocation on the study, it was included as a co-variate in regression analysis (fig.12). Its inclusion did not influence the shoulder function results at 16 weeks. This further analysis suggests that gender did not influence the final result, but the relatively few numbers of males in each group is a limitation to the study.

Table 4: Subjects' baseline characteristics

Factor	Group A (immediate)	Group B (delayed)	Mean difference (95% CI)	P value for difference
Number of subjects (Baron et al. 1996)	44(33/44) (Allison et al. 2002)	42 (37/42) (Dunlop et al. 1998)		0.20#
Side of fractured limb (left:right)	25:19	24:18		0.85#
Dominant hand (left:right)	5:39	6:36		0.93#
Mean body mass index (SD)	26.8 (5.4)	25.4 (4.7)	1.4 (-0.8 to 3.5)	0.21
Mean Age (SD)	70.7(12.5)	69.6(11.6)	1.1 (-4.04 to 6.31)	0.66
Mean number of treatment sessions (SD)	9(6)	14(9)	-5 (-7.8 to 0.46)	0.002*
Deprivation Level				
Low	29(66%)	31(74%)	0.636	0.287#
High	15(34%)	11(26)		
CSS (unaffected shoulder)	72.6(17.2)	74.8(12.2)	2.2	0.78
SF-36 Dimension				
Physical function	34.7 (25.4)	45.4 (24.0)	-10.7 (-21.5 to 0.11)	0.05
Social functioning	46.2 (29.7)	49.1 (34.3)	-3.0 (-16.8 to 10.7)	0.66
Role limitation (physical)	8.0 (19.3)	3.0 (8.2)	5.0 (-1.4 to 11.4)	0.13
Role limitation (emotional)	46.2 (46.2)	35.7 (45.6)	10.5 (-9.2 to 30.2)	0.29
Pain	30.5 (23.7)	23.1 (20.1)	7.4 (–2.1 to 16.8)	0.12
Mental health	63.1 (27.3)	56.6 (28.5)	6.5 (-5.4 to 18.5)	0.28
Vitality	38.3 (26.2)	38.2 (25.1)	0.08 (–10.9 to 11.1)	0.98
General health perception	65.7 (22.3)	73.1 (22.3)	-7.4 (–17.0 to 2.2)	0.13

P-values from two-independent samples t-test, except # chi-squared test (* denotes statistically significant).

The SF-36 dimensions between the two groups show greater variability (table 4) and the wider standard deviations (range 8.2 to 46.2) could explain this observation. Some patients completed the SF-36 within hours of their injury and this might have influenced their ability to answer the questions based on the experiences over the last week (as required in the acute version of then SF-36). This will be discussed further in the limitations of the study. The wide standard deviation of the SF-36 scores is similar to other larger studies (Jenkinson et al. 1993; Ruta et al. 1994; Jenkinson et al. 1999) and this would suggest that these results are within normal limits.

The left shoulder was more commonly fractured in the subjects (49: 27, left and right respectively) and this is equally balanced in the two groups even though the right limb is the dominant limb (11:75 left and right respectively). Handedness was balanced between both groups with ratio of left to right of 5:39 and 6:36 in groups A and B respectively. Additionally, both age (70.7:69.6 Group A and B respectively) and BMI (26.8:25.4 Group A and B respectively) were similar and no statistical differences existed between the groups. This suggests that the randomisation process was successful.

4.3.2 Attrition

One Year Assessment

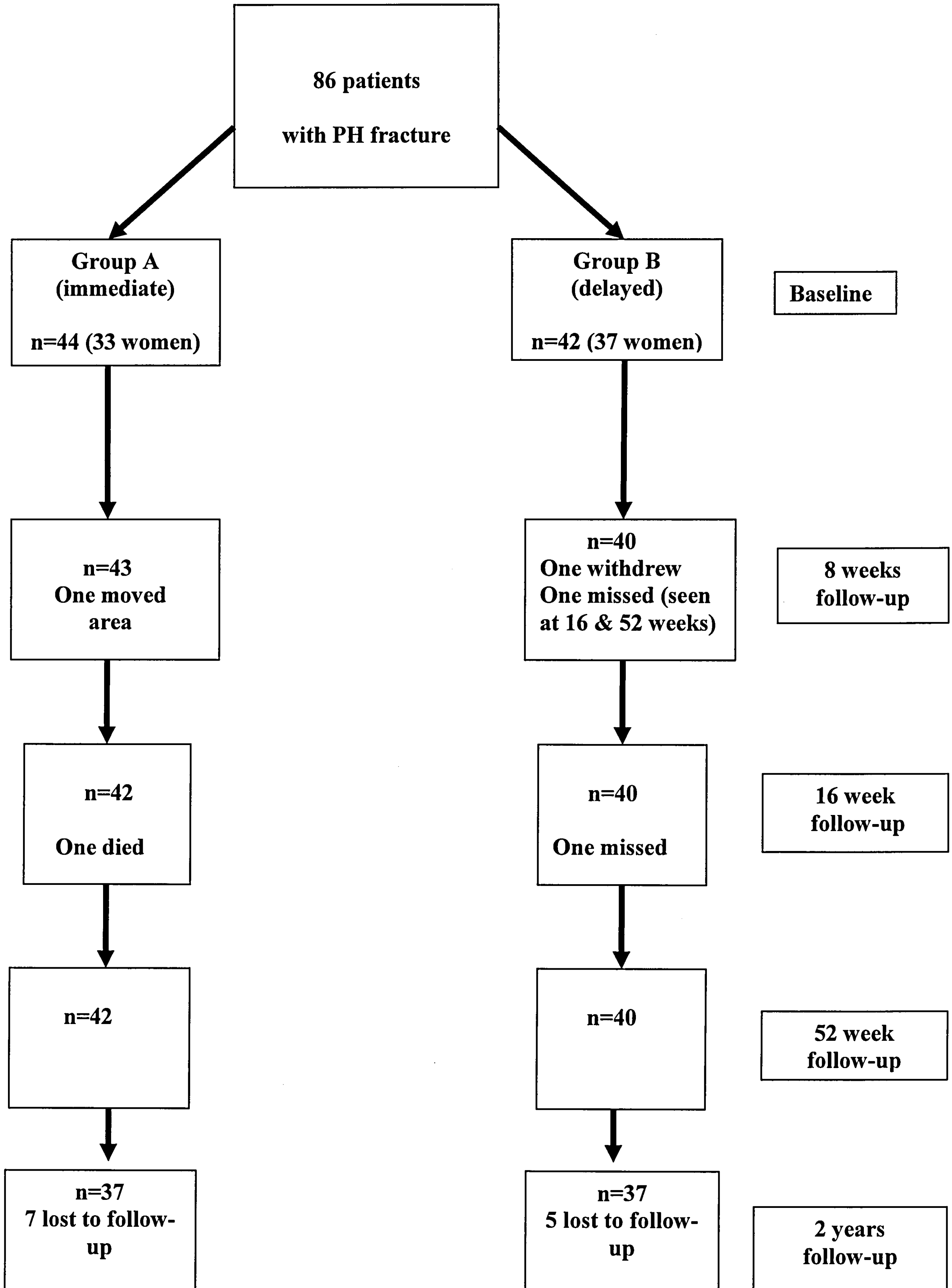
Eighty-two patients (fig.9) remained in the study (Group-A, n=42, Group-B, n=40). Both groups lost two patients at the one year follow up assessment and this represents an attrition rate of 5% or less. This is an acceptable attrition rate for this type of study. Every effort was made to follow up patients who had moved area and one patient who had moved several hundred miles away was sent the SF-36 and shoulder disability questionnaire, but the SCC was not completed.

Two Year Assessment

From the 86 patients that started the study at the one year follow-up point, 74 remained at the two year review (14% attrition). Group A (immediate) lost seven patients and group B (delayed) lost five patients to follow-up, leaving 37 patients for assessment in both groups. Three patients died during the follow-up period, two had moved area and seven failed to complete the Croft shoulder disability questionnaire for personal reasons.

Two patients in Group B did not follow the instruction to maintain their fractured limb and continued to remove their arm from the sling at every opportunity. They both received the normal physiotherapy programme and their data was analysed within their original group allocation. Both patients (subjects 013 & 045) made rapid progress and had recovered 90% of their shoulder function by 16 weeks as measured by the CSS.

Figure 9: Patient flowchart at follow-up points

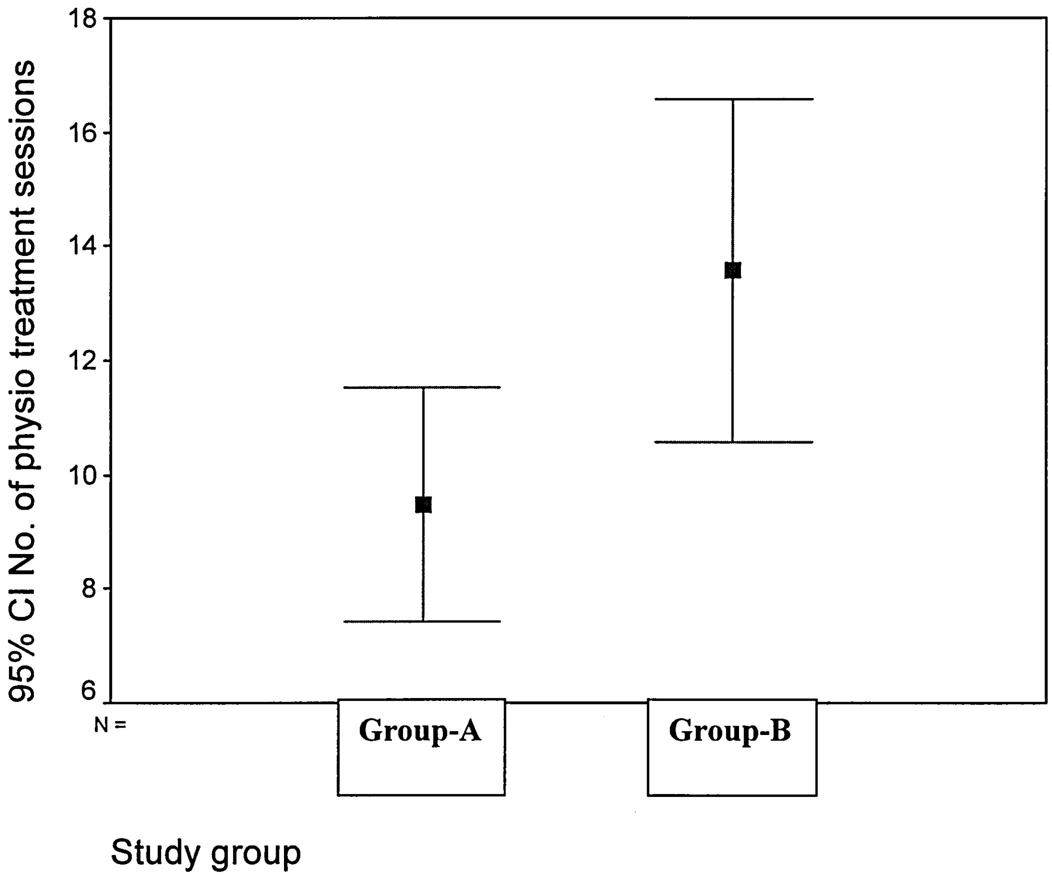


4.3.3 Treatment

The only other difference between the groups after they had completed the physiotherapy protocol was the number of treatments given. The number of treatments given was not pre-set as patients were discharged when they had achieved independent shoulder function. The difference in treatments (fig. 10) was statistically significant ($p<0.01$) with Group A having 9 (SD 6) and Group B, 14 (SD 9) treatments. The standard deviation is higher in Group B with higher variance in number of sessions needed to achieve acceptable shoulder function. This is an important finding as Group A consistently required less treatment to reach the same stage as Group-B. This represents a substantial saving in both time and money and is revisited in the discussion.

Patients were treated once per week over the first six weeks of the treatment. After this, the interval between treatments was increased at the discretion of the physiotherapist if rehabilitation was progressing at an acceptable rate. It could be argued that more intensive treatment would benefit the patient (no research has investigated the frequency of treatment provision), but this is not common practice and would currently be prohibitive due to staffing levels and pressures on the ambulance service who are needed to transport many of the patients. The initial discussions with the physiotherapists who provided the treatment suggests that once a week treatment is the usual practice and the study wanted to maintain this as part of the pragmatic approach.

Figure 10: Treatment sessions by group allocation (95% error bars)



4.3.4 Complications Reported (over 36 months)

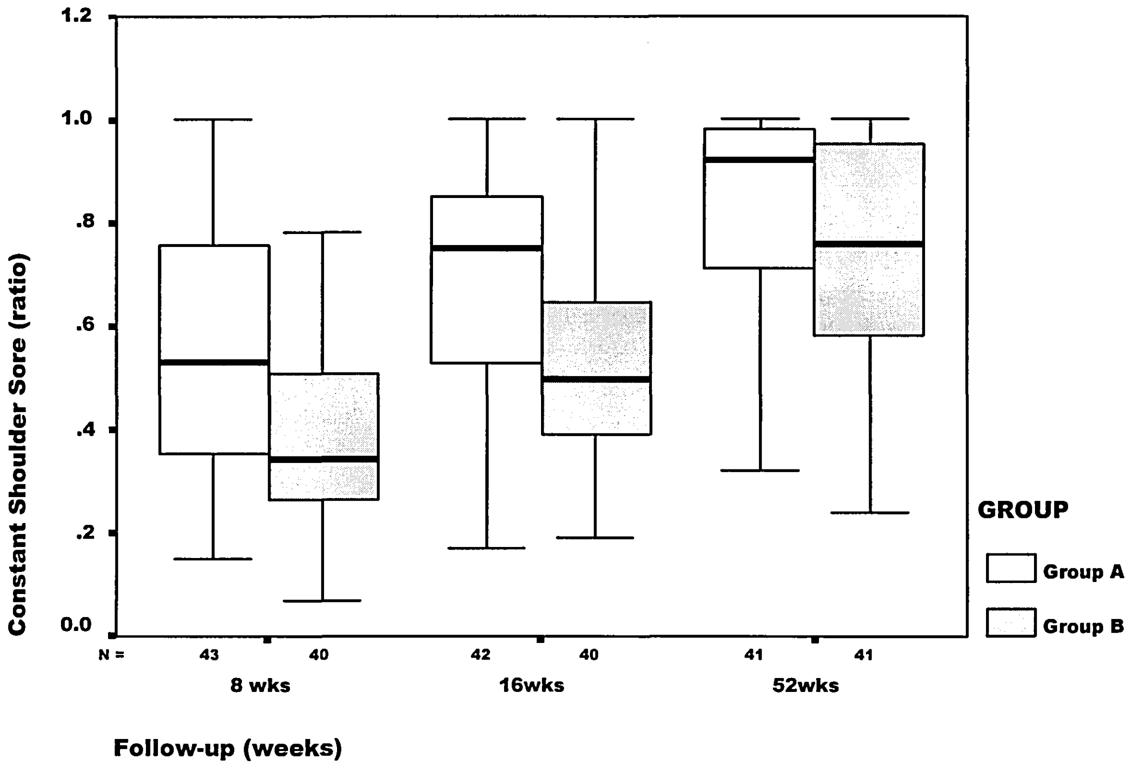
Within Group A, three complications occurred (table 5) over 36 months following their initial shoulder fracture. They had no specific shoulder complications with only one fracture to the hip (at one month), wrist (36 months) and rib (at two months).

Group B had twice as many patients with complications (six) compared with Group A, but only one related to the humerus (PH re-fracture at two months). The others had a range of fractures, all except one (foot), are classified as 'osteoporotic' fractures. These are small numbers, but the results suggest that the neuro-muscular status remains compromised for longer in Group B compared with Group A. With both groups being equal there should be similar numbers of complications and this is discussed later.

Table 5: Complication (fractures) reported over three years

Group Allocation	*Complication*	*Time since injury (months)*
Group A		
04	Hip	1
064	Wrist	36
069	Ribs	2
Group B		
02	PH	2
033	Hip	18
034	Foot	14
039	Hip	30
083	Thoracic spine	15
088 (×3)	Hip	16
	Radius	24
	Clavicle	30

Figure 11: Constant shoulder score for both groups at 8, 16 & 52 weeks (A ratio of 1.0 implies the patient had equal function in both the fractured and unaffected shoulder).



4.4 Constant Shoulder Score Results

At the primary outcome point (16 weeks), the difference between the mean CSS was highly significant in Group A (p<0.001), with a 0.16 mean difference between the groups (95% CI 0.68 to 0.25). Similar differences (fig. 11 & table 7) were seen at 16 weeks (p<0.001), but at one year (appendix X, table 5) the differences reduced and the groups were not statistically significant (p<0.15). When sensitivity analysis (applying different statistical tests to the data to assess its robustness under different conditions) was applied to the data and a non-parametric test was calculated (table 6 & appendix X, table 6) the significance dropped to just above the 5 percent level ($p<0.06$).

Table 6: Constant Shoulder Score difference between groups at 52 weeks. (Non-parametric analysis)

Mean rank differences

Ranks

	GP	N	Mean Rank	Sum of Ranks
CONDIF52	early	41	46.33	1899.50
	late	41	36.67	1503.50
	Total	82		

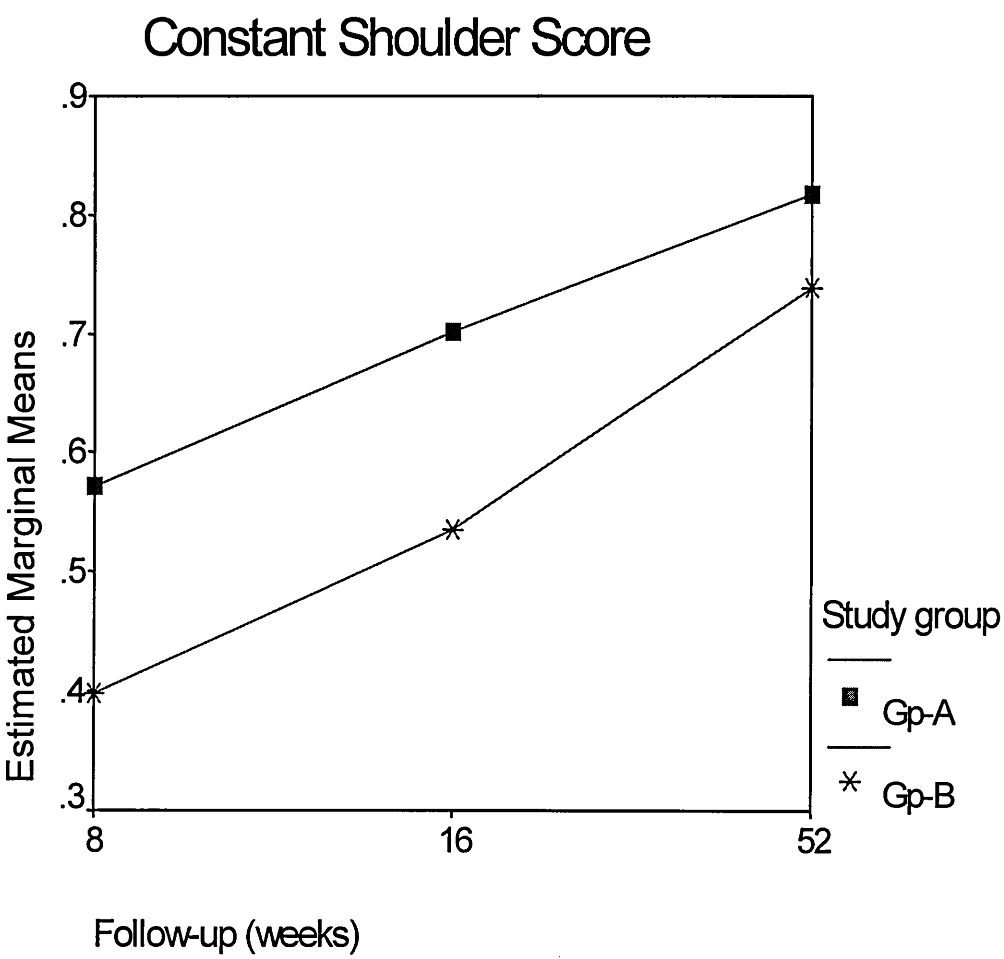
When the total 'area-under-the-curve' was calculated (all three outcome points were used to calculate the differences between the groups), Group A scored higher over 52 weeks (table 7) with a mean difference of 6.4 ($p<0.002$) i.e. Group A were consistently scoring higher on their CSS following their injury over the first year. At all three outcome follow-up points Group A scored higher on the CSS compared with Group B, but the difference narrows at one year as both groups continued to improve with time.

4.4.1 Regression Analysis (Constant Shoulder Score)

The regression analysis modelling with the shoulder impairment score (CSS) used group allocation, level of deprivation and gender as the co-variates. Table 2 (appendix X) demonstrates that only group allocation (Group A) remained significant at 8 weeks ($p<0.01$) and 16 weeks ($p<0.01$). By 52 weeks, the difference narrowed (Fig.12) and group allocation was not significant ($p<0.17$), but a difference remained between groups that might have clinical implications. This reinforces the view that

Group A progressed faster and, when age was controlled, the difference between groups was greater. This trend is seen in the SF-36 results later.

Figure 12: Regression Modelling Analysis of Constant Shoulder Score (covariates group allocation, level of deprivation and gender).



Mean Constant scores represent the ratio between the fractured and the unaffected side i.e. a score of 1.0 represents full function.

	Follow-up 8 weeks		Follow-up 16 weeks				Follow-up 52 weeks					
	Mean (SD)		Mean (SD)		Mean difference (95% CI)	p-value for difference	Mean (SD)		Total area under curve (SD)		Mean Difference (Total area) (95%CI)	p-value for difference
Group A (< 1 week)	n=43	0.57 (0.26)	n=42	0.70 (0.2)	0.16 (0.68 to 0.25)	0.001	n=41	0.82 (0.2)	n=41	34.6 (9.5)	6.4 (2.5 to 10.5)	0.002
Group B (at 3 weeks)	n=40	0.39 (0.19)	n=40	0.54 (0.2)			n=41	0.75 (0.2)	n=41	28.2 (8.6)		

4.5 SF-36 Results

All the domains for the SF-36 were calculated (table 8), but the main analysis concentrates on the domains most relevant to the study population i.e. Physical function (PF), Role limitation-physical (RLP), Social function (SF) and Bodily pain (P).

4.5.1 Skewness

When the SF-36 is examined for central symmetry, the scores for the four most relevant dimensions (PF, RLP, P & SF) the skewness at 16 weeks (appendix X, table 9) is acceptable for RP, SF and P as the scores are within 0.2 (Hildebrand 1986). Only the PF scores are outside this acceptable range (skewness - 0.81). Additionally, the skewness for the three dimensions is less than twice the standard error. For the SF-36 at 52 weeks (appendix X, table 10), the skewness is greater for all dimensions and all are outside the cut off value of 0.2. However, the Pain and Role limitation (physical) dimensions are less than twice the standard error. The distribution is acceptable for the primary outcome points at 16 weeks, but the SF-36 scores at 52 weeks must be viewed with some caution.

At the primary outcome point (16 weeks) the mean differences were greater in Group A in all domains except for vitality. In both Role limitation (physical) and Bodily pain the difference was statistically significant ($p<0.02$ and $p<0.01$ respectively). Social and Physical functioning were not statistically different at this point ($p=0.86$ and $p=0.90$ respectively).

At eight weeks, Group A reported better health in five out of eight dimensions (PF, SF, RLP, RLE, P) and the differences were statistically significant. Group A experienced less pain even at eight weeks and this trend continued over the 16 and 52 week assessments. By 16 weeks only the two dimensions of Pain and Role limitation (physical) remain statistically different as the effects of immobilisation in Group B are reduced with time.

At 52 weeks, the pain and Role limitation (physical) continued to show a trend that favours Group A (appendix X, table 4) but is not statistically significant. The general convergence of SF-36 scores at 52 weeks is seen in all dimensions except that of RLE. The difference between groups at 16 weeks with RLE was 6.7 (table 8), whereas at 52 weeks this was nearly double (12.5).

This might suggest that Group-B had increasing long-term emotional problems that limited their function, possibly as a result of their ongoing pain. This could help explain the reduction in shoulder function seen at two years in Group B. This is covered in more depth in the discussion section

4.5.2 Regression Analysis Modelling (SF-36)

The repeated measures regression analysis model incorporated age as the only covariate. This was the only significant variable when all factors were considered (appendix X, table 1). The modelling confirmed the early improvements in PF, RLP, and P, with significant improvements at 8 and 16 weeks, but a gradual narrowing of the differences (fig. 13-15) at 52 weeks. Throughout this period Group

Table 8: Short form (SF-36) health survey

SF-36	8 week follow-up Gp A n=43 Gp B n=40	16 week follow-up Gp A n=42 Gp B n=39			52 week follow-up Gp A n=40 Gp B n=40			
Dimension	Mean (SD)	Mean (SD)	Mean difference (95% CI)	p-value for difference	Mean (SD)	Total area under curve (SD)	Mean (AUC) Difference: (95% CI)	p-value for difference
Physical functioning								
Group A	64.5 (25.3)	69.9 (25.1)	0.65 (–10.15 to 11.45)	0.90	65.4 (31.3)	3370 (1271)	-10 (-575 to 553)	0.97
Group B	59.4 (23.5)	69.2 (23.6)			68.4 (30.2)	3381 (1229)		
Social functioning								
Group A	82.5 (25.4)	83.0 (26.7)	0.95 (-10.12 to 12.01)	0.86	78.6 (26.6)	4093 (1135)	37 (-466 to 540)	0.88
Group B	78.6 (28.9)	82.1 (23.0)			80.0 (27.2)	4056 (1095)		
Role limitation (physical)								
Group A	48.8 (43.3)	61.9 (43.6)	22.2 (3.4 to 40.9)	0.02*	60.0 (44.1)	2872 (1874)	727 (-71 to 1526)	0.07
Group B	25.6 (33.2)	39.7 (40.8)			54.4 (44.2)	2144 (1655)		
Role limitation (emotional)								
Group A	89.1 (27.0)	78.6 (38.9)	6.7 (-10.9 to 24.4)	0.45	80.8 (35.3)	3966 (1320)	579 (–62 to 1222)	0.07
Group B	68.3 (39.2)	71.8 (40.9)			68.3 (42.7)	3386 (1526)		
Pain								
Group A	65.8 (19.0)	72.0 (20.6)	12.2 (3.2 to 21.2)	<0.01*	69.2 (27.2)	3475 (949)	486 (83 to 889)	0.01*
Group B	50.5 (18.6)	59.9 (20.0)			65.6 (26.6)	2989 (830)		
Mental health								
Group A	72.9 (19.7)	74.0 (17.3)	2.8 (-5.7 to 11.3)	0.51	69.0 (22.1)	3722 (904)	80 (–327 to 488)	0.69
Group B	69.1 (19.9)	71.2 (21.1)			70.7 (18.7)	3641 (904)		
Vitality								
Group A	54.8 (22.9)	54.8 (23.3)	-1.39 (-11.5 to 8.7)	0.78	55.4 (26.9)	2796 (1127)	-19 (-504 to 464)	0.93
Group B	52.7 (23.0)	56.1 (22.4)			56.2 (26.0)	2816 (1013)		
General health perception								
Group A	67.3 (19.2)	64.6 (16.7)	-0.94 (-9.7 to 7.8)	0.83	63.0 (19.2)	3377 (857)	-198 (–629 to 232)	0.36
Group B	67.1 (23.3)	65.5 (22.7)			69.3 (22.0)	3576 (1049)		

A demonstrated higher scores for each of the three dimensions, with pain (fig. 15) and RLP (fig.13) showing the greatest differences up to 52 weeks.

Physical function (fig. 14) was the only graph that showed a large difference (Physical function score at baseline: 34.7 and 45.4 for Group A and B respectively) from the baseline score, with Group B having better physical health after their injury, but this reduced after eight weeks. The difference in baseline score was probably related to some patients interpreting their physical function in time since the fracture and others before the fracture. This was discussed as part of the changes to the SF-36 questionnaire when the problem was observed. Group A's Physical function increased rapidly from this low level and by the first outcome assessment it was greater (table 8) than that of Group B (Physical function score at eight weeks: 64.5 and 59.4 for Group A and B respectively). This rapid improvement suggests that patients in Group A returned to general activities faster than Group B. The Physical function score comprises activities that are dominated by upper limb function (e.g. walking, climbing stairs, bending and stooping) and the improvement in Group A suggests a wider benefit to an accelerated rehabilitation programme that both maximises upper and lower limb function. The lower score at baseline in Group A could falsely magnify this effect, as the mean difference was not statistically significant at eight weeks ($p< 0.9$), but is an interesting finding.

Group A (fig.15) experienced less pain (a score of 100 indicates no pain) compared with Group B. Once again, the difference between the groups narrowed at 52 weeks, but a strong trend existed in favour of immediate physiotherapy.

Figure 13: Regression Analysis Modelling SF-36 (Role Limitation Physical) Year One

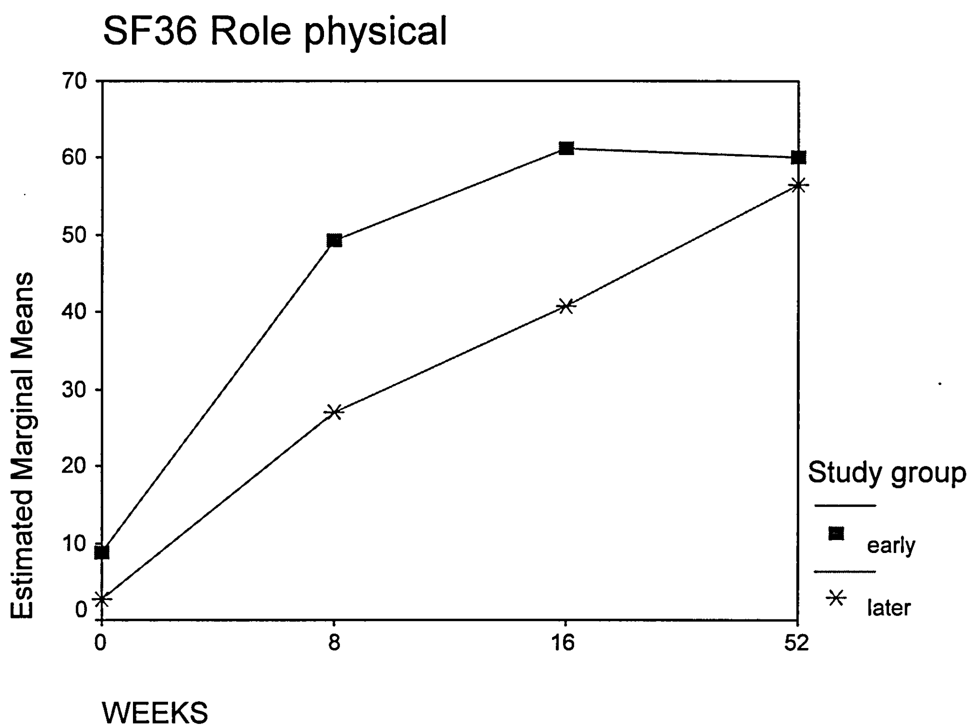


Figure 14: Regression Analysis Modelling SF-36 (Physical Function) Year One

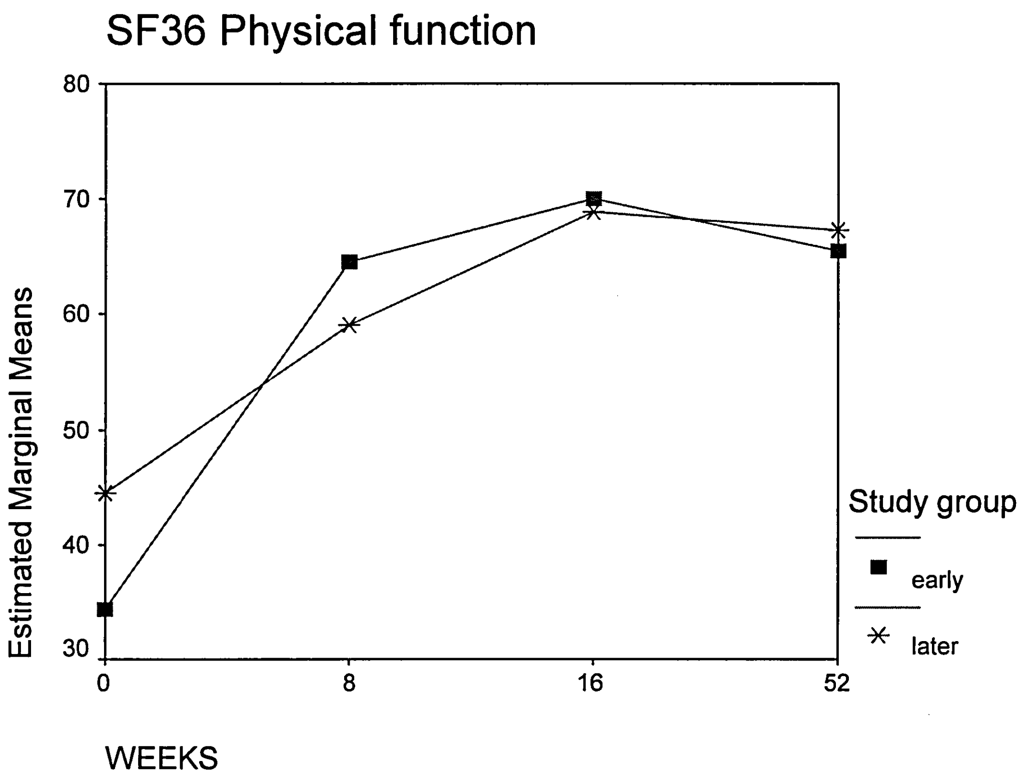
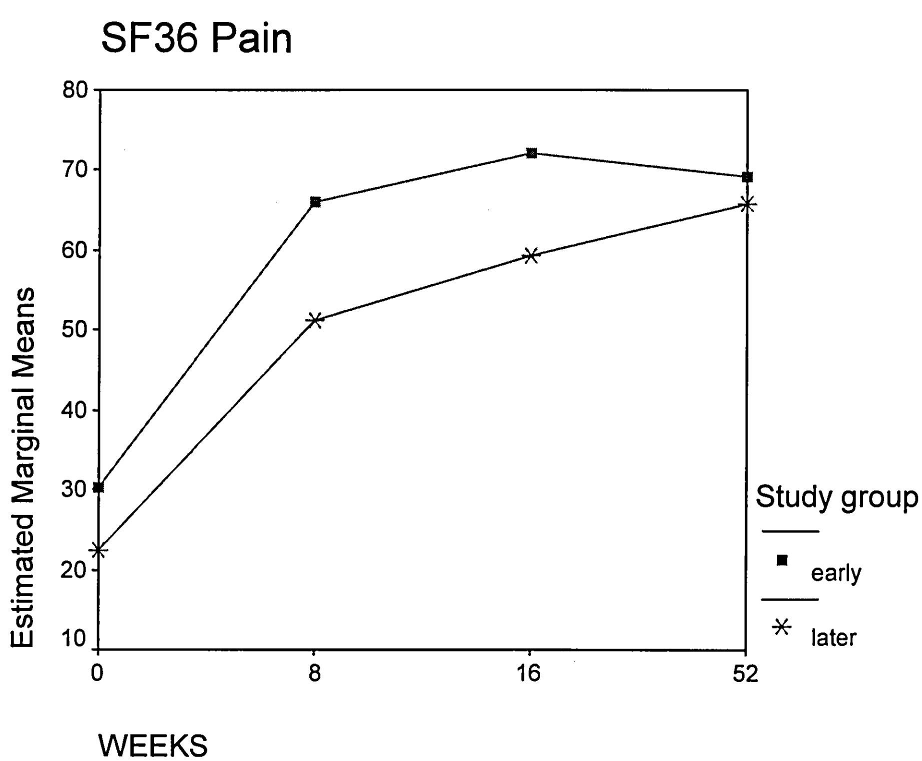


Figure 15: Regression Analysis Modelling SF-36 (Bodily Pain Score) Year One



4.6 RCT Long-Term Results (Two Years)

4.6.1 Response rate

As part of the long-term evaluation, patients completed a postal shoulder disability questionnaire (CSDQ) at two years after their initial injury. They also completed the CSDQ at one year to allow comparisons between shoulder disability at one and two years. From the original 86 patients who entered the study, 74 remained at the two year review (table 9).

Table 9: Follow-up at one & two years

Follow-up point	Group A (immediate)	Group B (delayed)	Follow-up rate (%)
1 Year	42	40	82 (95)
2 Year	37	37	74 (86)

This represented a response rate of 86%, but is an acceptable level for this type of population. Brazier (Brazier et al. 1992) reported a similar response rate of 83% with an older population based in Sheffield for the SF-36 questionnaire. Group A (immediate) lost seven patients and Group B (delayed) lost five patients to follow-up, leaving 37 patients for assessment in both groups. Three patients died during the follow-up period, two had moved area and seven failed to complete the questionnaire. The characteristics of the remaining subjects (table 10) were comparable and no statistical difference existed for any variable.

Table 10: Patient Characteristics at Two Years

Follow-up	**Two Years**	
Factor	**Group A (immediate)**	**Group B (delayed)**
Number of subjects (male: female)	37 (8:29)	37 (5:32)
Mean Age (SD)	68.6 (12.2)	68.2 (11.4)
Mean body mass index (SD)	27.2 (5.5)	25.2 (4.9)
Side of fractured limb (left: right)	21:16	20:17
Lost to follow-up (male: female)	7 (2:5)	5 (0:5)

4.6.2 Shoulder Disability

At two years, the total number of patients with some level of shoulder disability in Group A was 16 (43.2%) and 22 (59.5%) in Group B (table 11). At one year, Group A had 18 (42.8%) patients reporting shoulder disability compared with 29 (72.5%) in Group B ($p<0.01$). By year two, shoulder disability in Group A remained constant at 43.2% (16 patients) whereas in Group B disability had reduced to 59.5% (22 patients). At two years the number of subjects scoring five or more (i.e. a high level of shoulder disability) on the disability questionnaire was 12 (32.4%) and 13 (35.2%) in Group A and B, respectively.

The difference at two years was not statistically significant, but represented an important clinical difference between the groups. Clearly, many patients who fracture their PH continued to experience some level of shoulder disability, despite which treatment programme they followed. When combined together, 51% of patients continued to have problems with their fractured shoulder up to two years after their initial injury.

Table 11: Shoulder disability (CSDQ) by group allocation

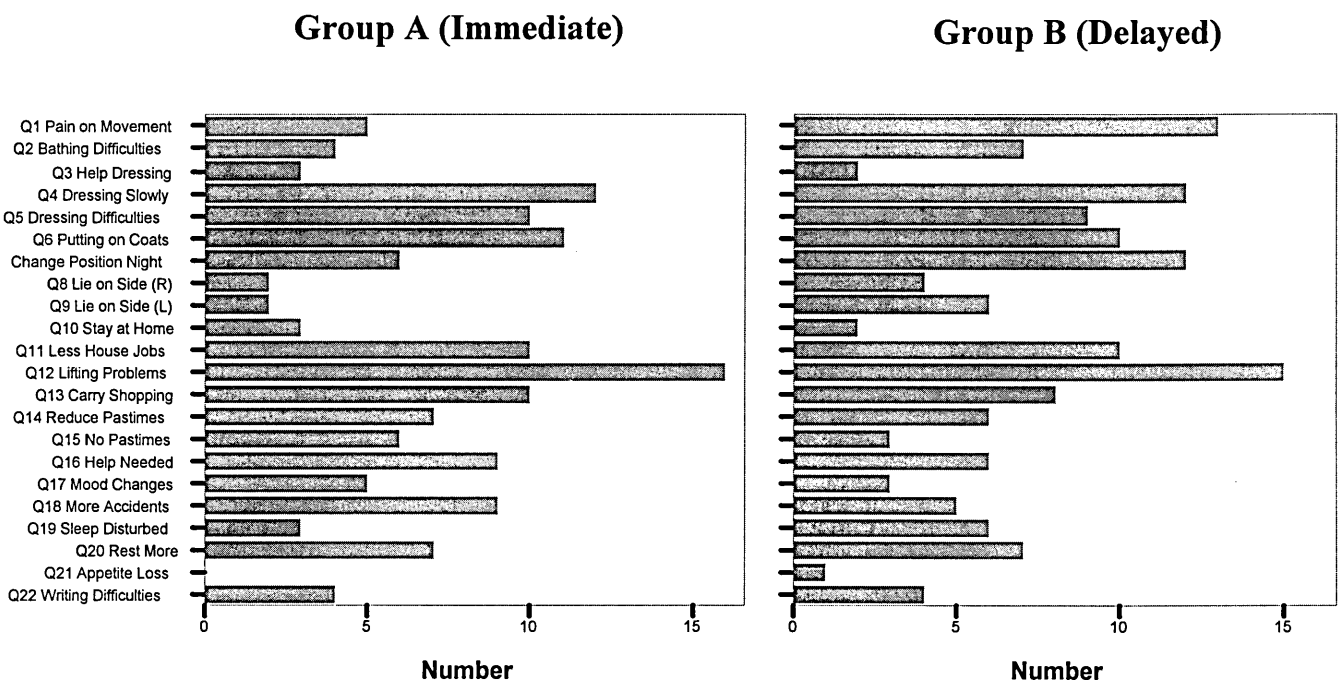
Follow-up point	**Croft Shoulder Disability Score**		
	Score	**Group A (immediate)**	**Group B (delayed)**
1 Year	Nil	24 (57.2%)	11 (27.5%)
	1to 4	5 (11.9%)	12 (30.0%)
	5 or more	13 (30.9%)	17 (42.5%)
	Total Disability	**18 (42.8%)**	**29 (72.5%)** *
2 Year	Nil	21(56.8%)	15 (40.5%)
	1to 4	4 (10.8%)	9 (24.3%)
	5 or more	12 (32.4%)	13 (35.2%)
	Total disability	**16 (43.2%)**	**22 (59.5%)**

* denotes statistically significant at p<0.01

When the CSDQ was analysed by individual items (there are 22 questions) out of the 74 patients assessed at two years, 42.0 % (31 patients) reported continued problems with heavy lifting and 32.4% (24 patients) experienced dressing difficulties (fig.16). When the individual scores were evaluated, patients in Group B reported nearly three times more pain on movement, twice as many problems at night with changing position and disturbances in sleep compared with Group A. This further reinforces the SF-36 pain results showing that Group A reported less pain at one year.

Figure 16: Croft Shoulder Disability Questionnaire (CSDQ)

scores for each question at two year follow-up.



4.7 Binary Logistic Modelling

The modelling used shoulder disability as the dependent variable with a score of zero being 'not disabled' and a score greater than 0 as 'disabled' (For the categorical variables coding see appendix X, table 8). The level of shoulder disability (CSDQ) at 52 weeks in both groups was used in the modelling.

Gender and Group allocation were the independent variables. Both were significant ($p<0.04$ & $p<0.004$ respectively), but group allocation (Table 12) had the greater odds ratio (Exp B) with a score of 4.30 (odds ratio is e [the base of the natural logarithm, 2.718] raised to the power of weighted-B). This result suggests that a person in Group B was more than four times (4.3) more likely to report shoulder disability (at one year) compared with Group A. When women are compared with men, they are four times more likely to experience shoulder disability at one year (odds ratio 0.25). Fewer men were recruited than women, but the males who did enter the study clearly experienced less levels of shoulder disability at 52 weeks. Previously, gender has never been considered as a risk factor for fracture recovery. The magnitude of the difference (factor of four) would merit further research in the role of gender in fracture repair.

Table 12: Model Output (Binary Logistic Modelling)

Variables in equation

	S.E	**df**	**Sig.**	**B**	**95% CI for Exp(B)**	
					Lower	**Upper**
Step Gender	0.68	1	0.04	**0.25**	0.06	0.94
Group (1)	0.49	1	0.004	**4.26**	1.61	11.23
Constant	0.34	1	0.69	0.88		

Key:

Stepwise regression analysis- independent variables removed (Step)
Beta (B)
Standard error (S.E.)
Degrees of Freedom (D.F.)
Significance (Sig.)
Exp(B)
Confidence interval (CI)

4.8. Repeat Regression Modelling

The regression modelling was based on the SF-36 scores at 52 week follow-up (appendix X, table 12). The main explanatory variates investigated include: study group (early, later treatment); age; gender; deprivation category (Townsend) of ward of residence (low, high deprivation); previous falls; previous shoulder problems; fracture side; dominant arm and body mass index (BMI). Variables were selected by the step wise (see comments made in 'limitations' section) method to select variables for the regression modelling. The independent variables that significantly predict the SF-36 Pain dimension (dependent variable) were gender, deprivation and group allocation.

Patients in Group A (table 13) reported less pain at 8 and 16 weeks and this was statistically significant at both these points ($p<0.001$ and 0.009 respectively). However, the pain score at 52 weeks by group allocation reduced and the difference was not statistically significant ($p<0.79$). Thus, Group A had less pain until week 16 and then the scores narrowed to 52 weeks.

Conversely, gender did not influence pain scores at eight weeks ($p<0.52$), but did at 16 weeks ($p<0.006$) and again at 52 weeks ($p<0.001$). Acute pain in the first eight weeks of the fracture was not related to gender, but as pain continued and became chronic (16 week onwards), the influence of gender grew to be more important. This was opposite from the pattern seen with group allocation. Interestingly, the pain score did not narrow at 52 weeks, but actually widened (fig. 17) as chronic pain became increasingly related to gender. The same trend was observed in the physical function score (fig.18), but at 52 weeks it actually declined in females (score 60) compared to men who reached a plateau with a mean score of 75 (15% higher).

Table 13: Regression modelling of SF-36 (Pain) with independent variables (group allocation, level of deprivation & gender).

Parameter Estimates

Dependent Variable	Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
SF36 Pain 0 weeks	Intercept	26.094	8.376	3.115	.003	9.405	42.784
	[GROUP=1]	7.381	5.174	1.427	.158	-2.927	17.690
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1	3.352	5.626	.596	.553	-7.858	14.562
	[DEPUPLOW=2	0[a]	.	.	.	.	.
	[GENDER=0]	-6.954	7.155	-.972	.334	-21.212	7.303
	[GENDER=1]	0[a]	.	.	.	.	.
SF36 Pain 8 weeks	Intercept	53.470	6.939	7.706	.000	39.643	67.297
	[GROUP=1]	14.623	4.286	3.412	.001	6.082	23.163
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1	1.422	4.661	.305	.761	-7.865	10.709
	[DEPUPLOW=2	0[a]	.	.	.	.	.
	[GENDER=0]	-3.785	5.928	-.638	.525	-15.597	8.027
	[GENDER=1]	0[a]	.	.	.	.	.
SF36 Pain 16 week:	Intercept	66.433	7.093	9.366	.000	52.301	80.566
	[GROUP=1]	11.730	4.381	2.677	.009	3.001	20.460
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1	11.120	4.764	2.334	.022	1.627	20.612
	[DEPUPLOW=2	0[a]	.	.	.	.	.
	[GENDER=0]	-17.024	6.059	-2.810	.006	-29.098	-4.951
	[GENDER=1]	0[a]	.	.	.	.	.
SF36 Pain 52 week:	Intercept	81.470	9.278	8.781	.000	62.984	99.957
	[GROUP=1]	1.516	5.731	.264	.792	-9.903	12.935
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1	12.391	6.232	1.988	.050	-2.558E-02	24.808
	[DEPUPLOW=2	0[a]	.	.	.	.	.
	[GENDER=0]	-27.730	7.926	-3.499	.001	-43.523	-11.937
	[GENDER=1]	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Key

Beta (B)
Standard Error (Std. error)
t-test (t)
Significance (Sig.)
Group A (Group=1)
Group B (Group=2)
Low deprivation level (DEPULOW)
Female Gender (Gender=0)
Male Gender (Gender=1)

Figure 17: SF-36 Score (Pain) by Gender

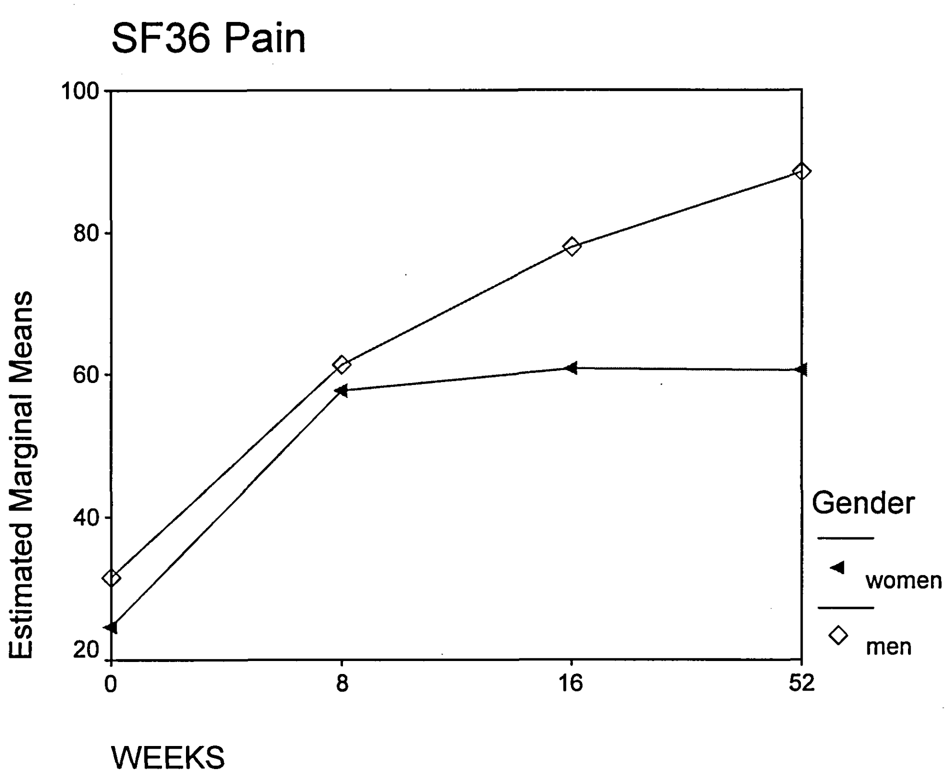
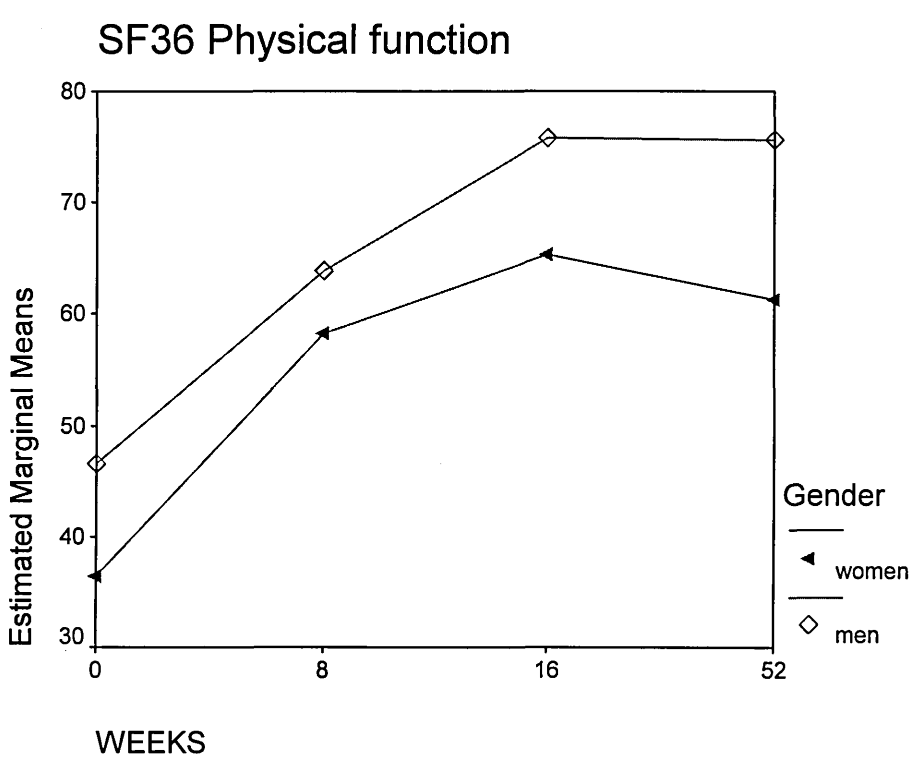
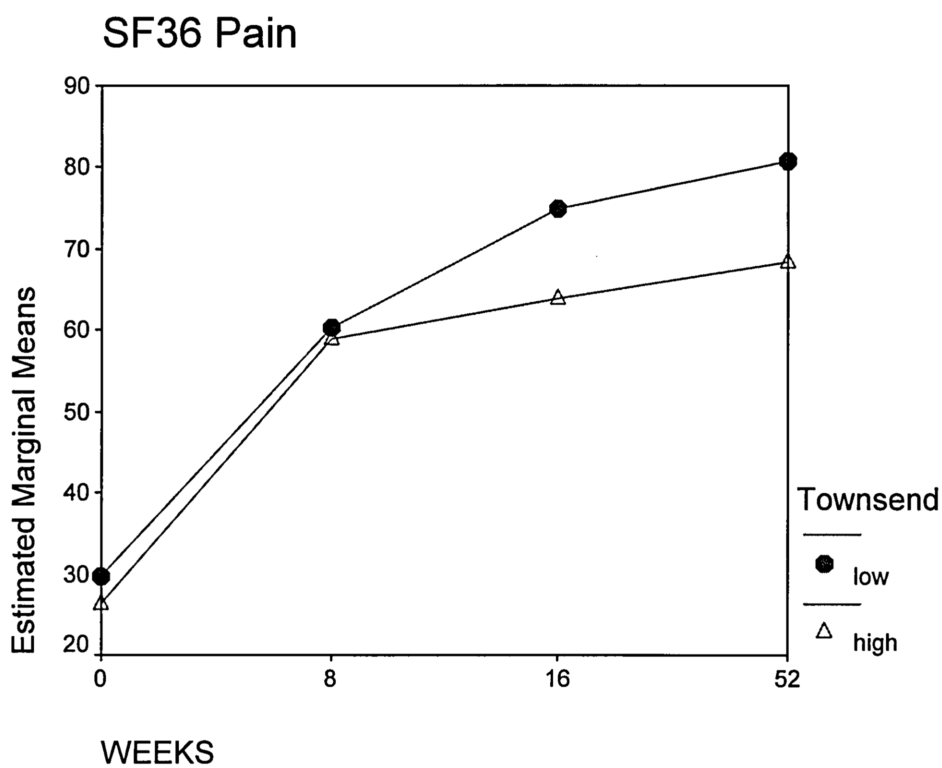


Figure 18: SF-36 Score (Physical Function) by Gender



When level of deprivation (Townsend deprivation index) is included in the model (fig. 19), the trend is similar to that of gender as deprivation levels increasingly influence reported pain ($p<0.05$ at 52 weeks). Thus, patients living in areas of low deprivation reported less pain at both 16 and 52 weeks.

Figure 19: SF-36 Score (Pain) by level of deprivation.



With Physical function (fig.20) the influence of deprivation was even greater than pain as function actually plateaus in areas of high deprivation compared with area of low deprivation. The pattern of role limitation physical (fig.21) showed a decline in physical activity between 8 to 16 weeks, but it improved, and increased, up to 52 weeks.

Figure 20: SF-36 Score (Physical function) by level of deprivation.

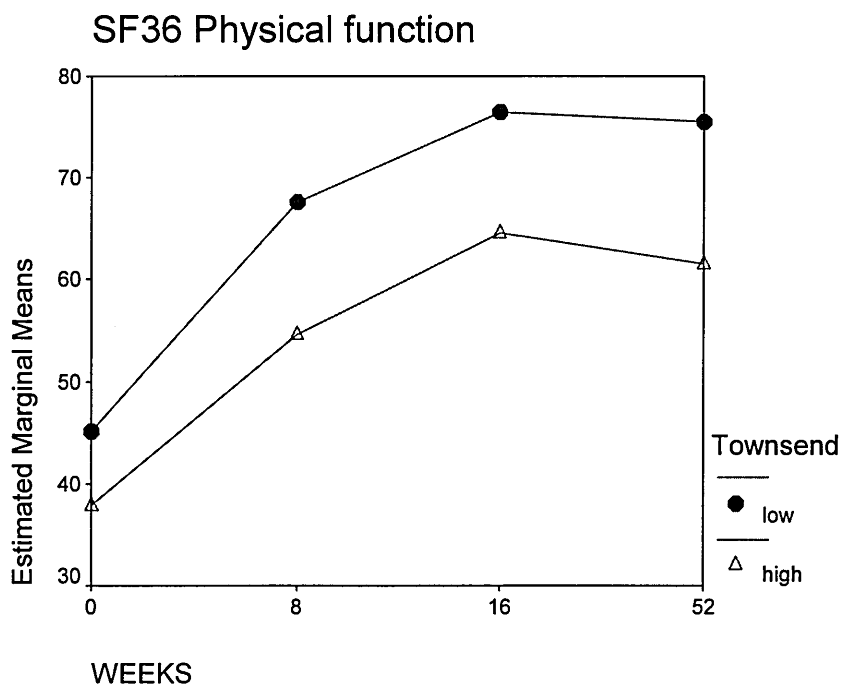
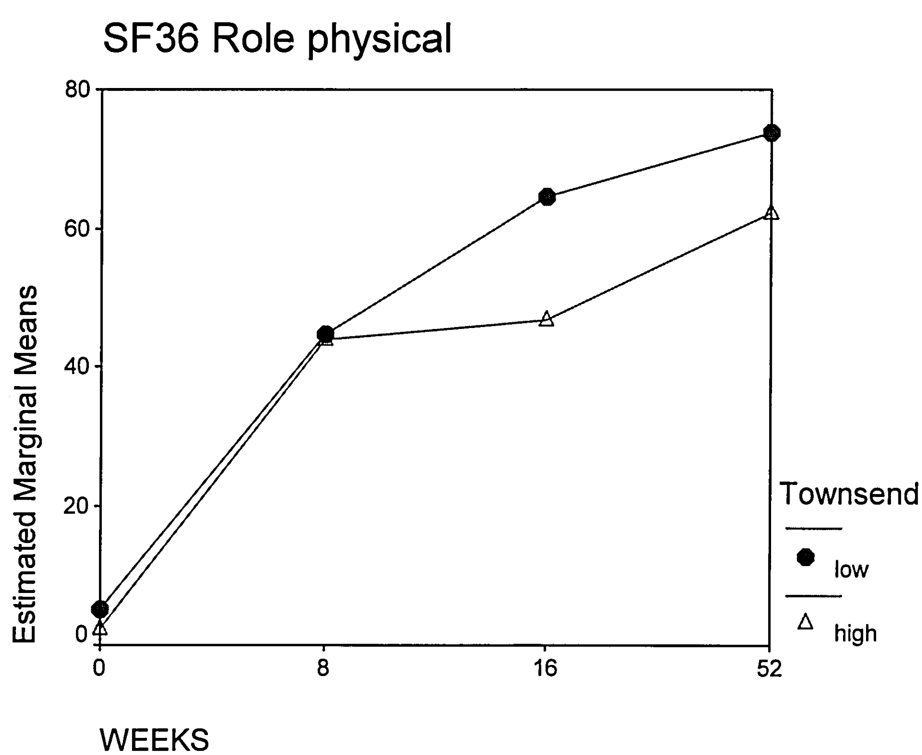


Figure 21: SF-36 Score (Role limitation physical) by level of deprivation.



CHAPTER 5: DISCUSSION

5.1 Introduction

The discussion is divided into seven main parts:

Part 1: UK survey

Part 2: Findings from RCT after one year.

Part 3: Long-term shoulder disability

Part 4: Risk factors in developing shoulder disability

Part 5: Implications for Management

Part 6: Implications for Rehabilitation

Part 7: Conclusions

The discussion is based around the UK Survey, the three experimental hypotheses (page 128), risk factors in developing shoulder disability and separate sections on the implications for fracture management and rehabilitation. PH fracture management is discussed with reference to other epidemiological evidence, both in the UK and in other countries. Further discussion on the management of PH fractures from the survey is made within each section to explore the findings from the study.

The first hypothesis (H1) specifically covers shoulder function in relation to the effects of immediate physiotherapy. The wider impact on the patient's general health status (H2) is discussed within the context of the SF-36 results and the resulting problems over the first year of the initial injury. The long-term results (H3) are assessed by comparing shoulder disability (CSDQ) with other shoulder studies, but with a lack of directly comparable studies in upper humerus fractures, the discussion is widened to include other shoulder problems.

The data from the SF-36 and CSDQ are included in the identification of the risk factors that predict those patients who continue to have prolonged shoulder dysfunction. Within this section, the wider issues of socioeconomic variables are included to test the hypothesis that level of social deprivation affects the level of shoulder disability. Incorporating indices of social deprivation into disability risk models in the field of fracture management is new in orthopaedic research and moves away from the traditional method of predicting PH fracture recovery based on the Neer classification scheme that directs management and treatment solely around radiographic appearance. Thus, this approach recognises the importance of, for example, level of social deprivation and gender in mediating the effects of upper limb disability. This is a novel approach not only to upper limb fracture research, but to the management of all fractures.

Separate sections on rehabilitation, and the implications of this study, are included as this forms the central part of the thesis. Additionally, the effects on immobilisation on recovery are included in this argument and recommendations are made. The conclusions are made against a background of an increasingly ageing population and exponential rise in proximal humerus fractures and, if current predictions are correct, they will have wide-ranging implications for this research.

Current orthopaedic management and rehabilitation is failing patients with PH fractures by relying on outdated treatment approaches that do not incorporate recent research evidence. Furthermore, lack of detailed outcome measures and not including long-term evaluation in most PH fracture research underestimates the continued problems following a PH fracture. This thesis addresses some of these limitations and proposes changes to clinical practice and suggests the direction for future research.

5.2 Part 1: UK Survey

The survey of PH fractures across 70% of all trauma centres in the UK was the first to accurately identify the current management of the PH fracture: the third most common osteoporotic fracture after the hip and wrist. The high return rate of 91% (127/139) was excellent (table 3) and allowing for three questionnaires incorrectly sent to hospitals without trauma services, the adjusted return rate increased to 93% (127/136). This suggests that the results of the survey are robust, but with the caveat that the questionnaires were completed by physiotherapy staff and not medical staff. It was thought that the physiotherapy staff were in the best position to gauge orthopaedic referral patterns, but some PH fractures might have been missed if they were not referred to physiotherapy. This could artificially increase the referral rate for patients to physiotherapy.

No previous study has examined national orthopaedic management of these fractures and the results can not be compared with previous findings, but the author's results suggest that considerable variation exists between and *within* hospitals for the management and rehabilitation of PH fractures. Of the 127 questionnaires returned, 33 (26%) physiotherapists commented on the variability in management of PH fractures within their hospital. The following was typical of the comments by the physiotherapists about management of PH fractures:

"...depends on how 'pro-physio' the orthopaedic team is..."

and

"...[the timing of referral to physiotherapy] can vary not only between consultants but also with any individual consultant."

The comments made were spontaneously given as no specific question was asked about variability within hospitals, and the reliability of the observation needs further investigation if it is to be accepted as current practice (the limitations of the UK survey is considered in a later section). Comprehensive guidelines are virtually non-existent (only two hospitals had a protocol for PH fracture treatment) and management was characterised by wide variations in the period of immobilisation (range one to seven weeks). This research used three weeks and this was the most common period of immobilisation (55%), but clearly some patients were routinely immobilised for longer.

Only 20% (26/127) were not routinely immobilised, but clear reasons for this variation in practice was not given and it would appear that management is based on empirical evidence dictated by the surgeon. The lack of consensus within hospitals was not surprising given the conclusion made by the Cochrane review of PH fractures as:

"Only tentative conclusions can be drawn from the available randomised trials, which do not provide robust evidence for many decisions which need to be made in contemporary fracture management."

Gibson et al. 2001 (Gibson et al. 2001)

Similar findings are reported in the other major osteoporotic fractures including the hip (Handoll et al. 2003) and wrist (Handoll and Madhok 2002). This will be discussed further in the discussion when the results of the main study are considered.

This research was centered on upper limb fractures, but its findings on immobilization and the necessity for long-term evaluation of other osteoporotic fractures are probably equally applicable. Certainly, incorporating the effects of socioeconomic variables on outcome with a range of common fractures would increase the understanding of the wider influences of gender, deprivation and general health status on fracture repair. Existing fracture research does not consider these issues.

Most patients were routinely referred to physiotherapy (81%) and twenty-six percent had sometimes been referred. Referral rates to physiotherapy were high, but some authors claim that physiotherapy makes no difference to patient outcome (Lundberg et al. 1979; Solem-Bertoft et al. 1984), although these studies have several design limitations (see Literature review/ Rehabilitation section) and their results do not stand up to close scrutiny. Despite limited evidence for the benefits of physiotherapy, the high referral rate to physiotherapy by medical staff implies that a clear benefit is perceived, or that patients' expectations for rehabilitation are considerable. Additionally, in a study that followed the long-term effects of upper limb fractures on function (Madhok and Bhopal 1992), it was 'access to physiotherapy' that patients said would most benefit them.

The blanket referral to physiotherapy might not be the best policy and a 'targeting' of certain vulnerable groups i.e. older, female and high levels of socioeconomic deprivation and associated co-morbidities, would maximise recovery against a single programme that lacks specificity and fails to meet individual requirements. This is further explored in the later sections and in the recommendations.

The patients' first contact with a physiotherapist ranges from one to six weeks with most seeing them within three weeks of their injury. With increasing numbers of physiotherapists working along side medical staff in orthopaedic clinics, the time for referral to physiotherapy is probably reducing as the advantage that early resumption of activity can promote restoration of function is been recognised (Buckwalter 1985)

5.2.1 Summary

The results of the UK survey highlight the variable practice in the management, rehabilitation and referral mechanisms between and within hospitals. Management was based on empirical evidence and periods of immobilisation continue to be a central tenet of fracture management without research evidence. Referral to physiotherapy was almost obligatory, but the time frame when this occurred, varied from between one to six weeks. The inconsistency in management and lack of clinical guidelines and unproven rehabilitation efficacy contribute to the weak evidence base for decision making. Furthermore, patients with specific risk factors were not targeted and this 'blanket' approach to physiotherapy probably fails to maximise patient function. The most startling finding of the survey was the use of prolonged periods of immobilisation with 21% of the hospitals resting the shoulder for up to seven weeks without clinical or experimental evidence of its efficacy. Prolonged immobilisation in a highly vulnerable population, such as this one; who are osteoporotic, have compromised neuromuscular status and an increased future fracture risk must be questioned. If changes in shoulder function continue at two years by immobilisation of three weeks, then seven weeks immobilisation will only further reduce shoulder function.

5.3 Part 2: Randomised controlled trial after one year

5.3.1 Introduction

This section starts by discussing the baseline characteristics of the two groups before considering the findings relating to the first two hypotheses (H1 and H2). These hypotheses state that a difference will exist between the group starting immediate physiotherapy compared with conventional treatment (immobilised for three weeks) measured by shoulder function (CSS) and generic health status (SF-36).

5.3.2 Baseline Characteristics

The baseline characteristics (table 4) between the two groups were comparable (mean 70.7 and 69.6 years, Group A and B respectively) and the combined mean age (70.2 years) was similar to other PH fracture studies: 66 years (Young and Wallace 1985; Zyto et al. 1995; Court-Brown et al. 2000) 71 years (Zyto et al. 1995) 70 years (Kristiansen and Christensen 1987). Furthermore, the average age of patients having a PH fracture in Sheffield over an 18 month period (November 1998 to May 2000) was 69.7 years. A larger proportion of women were recruited to the study (4.3:1) and this is slightly higher than epidemiology studies that report female to male ratios of between 2:1 and 4:1 (Donaldson et al. 1990; Baron et al. 1996b; Singer et al. 1998; Barrett et al. 1999)

The author's study used an age of 40 years and over in the inclusion criteria and this makes direct comparisons with other studies difficult as many included younger patients with a PH fracture (Kristiansen and Christensen 1987; Liversley et al. 1992; Koval et al. 1997). By including non-osteoporotic fractures (in most younger patients the PH fracture is usually the result of significant force) these studies fail to recognise the different characteristics of 'osteoporotic fractures' and combining different categories only diminishes the result. Additionally, this study specifically included an older population with associated osteoporosis as these are the fastest growing group (Rose et al. 1982; Baron et al. 1996a; Baron et al. 1996b) and pose the greatest challenge to healthcare providers. This group is more likely to have long-term shoulder problems, and from the increasing incidence, should be the focus of research.

The only significant difference between the groups was in the average number of treatment sessions (9 and 14, Group A and B respectively). Some authors have given a specified number of treatment sessions (Lundberg et al. 1979; Solem-Bertoft et al. 1984) and others fail to report on actual number of treatments (Young and Wallace 1985; Kristiansen et al. 1989; Liversley et al. 1992). Generally the reporting of rehabilitation programmes is woefully inadequate and makes decisions on optimum treatment dosages impossible. A similar finding was reported by the Cochrane group on PH fractures (Gibson et al. 2001). A pragmatic approach was adopted to treatment sessions for two reasons. First, ethically it would be difficult to give a set number of treatments to patients as this is different from conventional practice. Second, patients recover at different rates and it was expected that older patients would require more treatment to achieve an acceptable level of independence (Jull 1979).

As part of a pragmatic trial, treatment was terminated when the therapist and patient were satisfied with the level of upper limb function and the patient was willing to continue with their home exercise programme. Interestingly, Group A, whom had had the shortest period of immobilisation (physiotherapy within one week of their injury), required less treatment than those immobilised for three weeks (conventional management). Other authors have observed that shorter periods of immobilisation require less treatment and allows faster recovery (Clifford 1980; Mills and Horne 1985) and our findings concur with these comments. This has implications for the study findings and possible reasons for this effect are discussed in the next section.

The baseline dimensions for the SF-36 were similar between groups except for physical function (34.7 versus 45.4 Group A and B respectively) and the difference was statistically significant ($p<0.05$). No other dimensions approach statistical significance. This difference with the physical function score could be accounted for several reasons. First, the physical function dimension predominantly measures lower limb activity and upper limb function is limited to lifting, carrying and dressing. The impact of a PH fracture on lower limb activities will vary even if the limitation in the shoulder remains similar. This would contribute to the differences seen at baseline. Second, the wide variation in the score is seen with the wide standard deviation (25.4

and 24.0 Group A and B respectively), a level of variation seen in larger population based studies (Jenkinson et al. 1993; Ruta et al. 1994; Jenkinson et al. 1999). If wide variations exist in the population, then a study with relatively few subjects (n=86), as this one is, is more prone to variations between groups. Third, patients completed the SF-36 within one week of their injury, many the following day after their fracture, when they were probably, distressed and which might have influenced the score. Authors have raised concerns about older persons completing the SF-36 (Hayes et al. 1995; Mallinson 1998) as some questions can be ambiguous and missing data is not uncommon, especially with increasing age (Brazier et al. 1992; Mallinson 1998).

Allowing for these caveats and accepting that the physical function score is correct and Group-B had a higher functional level than then Group A at the start of the study, only reinforces the result. Patients receiving immediate physiotherapy and no period of immobilisation, despite lower physical function, still achieved faster recovery in shoulder function and general health benefits. This is discussed further in the next section.

Finally, before discussing the study hypotheses, it is salient to comment on fracture side. In both groups more people fractured their left side compared with the right (49 versus 37 left and right respectively), even though intuitively one would expect more to break their fall with their dominant arm. This raises two important issues: the aetiology of falling and osteoporosis in the upper limb. One study investigating the aetiology of falls that result in a PH fracture suggests that most people fall in a specific direction and do not, as in a fall resulting in a wrist fracture, break their fall with their arm (Palvenen et al. 2000). Sixty-eight percent of the fallers (who fractured their PH) landed directly onto the shoulder, *without* breaking the fall. This is similar to work in falls resulting in hip fractures as most subjects fell directly onto their hip and contrasts with wrist fractures in that most people fell directly onto their hand (88%) compared with controls. So why do patients more commonly fracture their left side? Could reduced bone density in the non-dominant side result in an increased risk of producing a fracture? Work by Kannus et al. (Kannus et al. 1994) found a 3% difference between dominant and non-dominant sides in the upper limb while Pettersson et al. (Pettersson et al. 2000) reported an increase of 5.5% in bone mineral density in the right upper humerus. These are small differences and Pettersson's work must be viewed with caution as they used young, female cross-country skiers, but assuming the right upper humerus has a higher bone mineral density then these small differences are unlikely to reduce the risk of a fracture. Alternatively, changes in neuro-muscular control mechanisms between sides could account for this inability to correct the fall as only 5% of falls actually result in a fracture. A reduction in neuro-muscular status in people with PH fractures, compared with wrist fractures (Kelsey et al. 1992), is given as a possible explanation for differences in fall mechanisms. This difference might exist between groups who fracture their PH and between different sides in individual people. This is an area for future research.

5.3.3 Shoulder Function after immediate and delayed physiotherapy

At the primary outcome point (16 weeks) patients in Group A who received immediate physiotherapy within one week of their injury had greater shoulder function than those in Group B who started physiotherapy after three weeks immobilisation with 'collar and cuff'. The difference measured with the CSS was statistically significant at both 16 ($p<0.001$) and eight weeks ($p<0.01$), however at one year, no statistical difference existed between the two groups. The null hypothesis (H1) can be rejected as immediate physiotherapy, without a period of immobilisation, resulted in greater shoulder function without increasing complications. The hypothesis (H1) did not state a specific end point by which to judge the outcome between groups and this must be considered. At the primary outcome point of 16 weeks Group A clearly show improved shoulder function ($p<0.001$) compared to Group B and this is to the basis of accepting the hypothesis (H1). The hypothesis should have been more specific to reflect this objective. However, the significant result was made with the non-parametric test and the parametic test was not significance. This suggests that a possible outlier(s) might be affecting the result and caution must be shown when interpreting the result.

Shoulder function increased rapidly in Group A compared to B at both 8 and 16 weeks with mean differences of 0.18 and 0.16 respectively (both $p<0.01$) . At one year the mean difference between the groups (appendix X, table 6) reduced to 0.07 ($p<0.15$) in favour of the immediate group (Group A). This is probably not an important clinical difference, and this pattern of changes between group narrowing over 6 to 12 months as seen in other prospective studies (Kristiansen et al. 1989; Revay et al. 1992). When a comparison was made between groups for shoulder recovery nearly (appendix X, table 3), 60% in Group A versus 40% in Group B achieved full recovery shoulder function compared with their unaffected limb. Therefore, more patients in the immediate group were returning to a level of function similar to that before their injury, but this does assume that the unaffected shoulder was 'normal' before the injury. This difference was not statistically different, but this is not surprising given the relatively small sample size (n=86) and statistical significant result would be achieved with a modest increase in the sample size if the 20% difference between groups was maintained.

There are several advantages to an accelerated rehabilitation programme (Group A), the main being that patients reported less pain and were able to return to their pre-fracture functional status sooner. This has obvious benefits, and by rapidly restoring their neuro-muscular status this may also result in less future fractures. This was certainly the case in this present study when fracture rates since the initial injury were (table 5) compared between groups. Work by Wildner et al (2002) reported that patients were at greatest risk of further fractures within the first two years of their initial injury and only after this period does their risk reduce. This possibly suggests that diminished neuro-muscular status and/or confidence are factors in maintaining fracture risk. An accelerated programme might limit the period of time that the patient is vulnerable to more fractures by restoration of normal function.

Furthermore, an advantage of an accelerated programme is the reduction in the number of treatment sessions (9 versus 14 sessions, Group A and B respectively) necessary for the patient to regain functional independence. This will have obvious fiscal benefits to the health provider by reducing hospital visits and reducing the demands made on physiotherapy departments.

Making comparisons between these studies (Kristiansen et al. 1989; Revay et al. 1992; Wildner et al. 2002) with this study are difficult with the wide variations in outcome measures, design and periods of immobilisation. The questions that emerge from this result are: does physiotherapy accelerate recovery and is immobilisation necessary for fracture healing?

5.3.4 Physiotherapy

The natural history of recovery after a PH fracture is unknown as patients in the UK are routinely referred for physiotherapy and because of ethical considerations a study that monitors recovery following a PH fracture without physiotherapy in unlikely to occur. Surgeons' expectations of the benefit of physiotherapy are high, or why else would they routinely refer so many? Only two studies have evaluated patients having 'physiotherapy' or 'self-training' (Lundberg et al. 1979; Solem-Bertoft et al. 1984), but these question the definition of what comprises physiotherapy (Literature review/page 105) and have serious methodological limitations. Likewise, other authors (Liversley et al. 1992; Revay et al. 1992) reported no difference with the addition of electrotherapy or hydrotherapy on eventual outcome. Once again both studies used self-training and a home exercise programme compared with the use of another modality. Unsurprisingly, they found no difference between the groups and other shoulder research has found no clinical efficacy to electrotherapy (Van der Heijden et al. 1997; Geert and Van der Heijden 1999), but the efficacy of hydrotherapy is unproven.

The author's rehabilitation programme was based on education, advice and graded use of a home exercise programme with the judicious use of joint mobilisation applied to stiff shoulders that were not progressing at the normal rate. The most recent research on shoulder rehabilitation in other common conditions suggests that this is the best approach (Brox et al. 1999; Gibson et al. 2004; Malone et al. 2004; Michener et al. 2004).

Education is a central component to any rehabilitation programme as reinforcing active coping strategies focuses on the positive aspects of functions of daily life (Brox 2003). Following a fracture, patients, understandably, remain fearful on return to normal activities and positive messages help to strengthen their role in rehabilitation.

The study by Brox (2003) is in the area of shoulder instability and impingement, but the evidence base for physiotherapy in PH fractures is weak as high-quality trials do not exist. This study is the first to fully evaluate shoulder function, disability and to use a generic health status measure to investigate the wider issues surrounding PH fracture rehabilitation. More trials are needed before the efficacy of physiotherapy in fracture rehabilitation can be fully evaluated. If patients do not require physiotherapy then two assumptions are made: first, patients make an excellent recovery after the fracture and support is given to this by several studies (Mills and Horne 1985; Young and Wallace 1985; Kristiansen et al. 1989). This is questionable because the outcome measures used were mainly measures of joint impairment and no measure of shoulder function or level of disability was included. As can be seen from our results, impairment measures (CSS) and self-reported shoulder disability (CSDQ) give different results at one year with significant levels of shoulder disability between groups, but no difference with the impairment measure. Impairment and disability are not synonymous and authors have reported low levels of correlation between them in clinical trials (Badley et al. 1984) (MacDermid et al. 2002) failure to evaluate the level of shoulder function will not correctly evaluate recovery.

Second, good epidemiological evidence suggests that shoulder disability in the normal older population (over 65 years), as in the author's study, is between 20-31% (Chakravarty and Webley 1990; Chard et al. 1991; Chakravarty and Webley 1993). Longitudinal studies charting the progression of shoulder pain and dysfunction (Croft et al. 1996; MacFarlane et al. 1998) conclude that shoulder pain does not spontaneously recover and is characterised by recurrence and exacerbation. This work is in a younger age group while the present study's population averaged 70 years. PH fracture patients probably have some reduction in shoulder function before their fracture and this pre-existing shoulder dysfunction will probably effect their eventual recovery. Most PH studies before the author's work, do not include long-term shoulder function evaluation and the results from the author's study (discussed in depth later) clearly show that most patients do not make 'excellent' recovery by one year and problems persist up to two years, and probably longer.

This is the first study in this field that has evaluated the wider impact of a PH fracture on an individual. Only by repeating the research and routinely including a range of outcome measures in future research will its findings be fully evaluated.

5.3.5 Immobilisation

Can our better results with immediate physiotherapy be explained by the avoidance of immobilisation? Most orthopaedic surgeons insist on some period of immobilisation following a PH fracture before starting rehabilitation. As discussed in the literature review (page 91), the clinical and experimental base for this assumption is doubtful as the benefits of early activity are many and compelling.

The main reason given for immobilisation is to reduce pain and prevent displacement of the fracture (Bigliani et al. 1996), although no evidence is given in support of this statement. The results with the pain dimension (SF-36) show that Group A (no immobilisation) reported less pain than those immobilised for three weeks (Group B) at all follow-up points. Immobilising the shoulder produces more pain at 8, 16 and 52 weeks follow-up points. This is counter to the previous literature that suggests that immobilisation actually *reduces* pain.

Furthermore, our evidence would suggest that early restoration to movement without immobilisation does not increase the complication rate (table 5). No complications were reported by any patient in Group A, although one person in Group B did have a 'frozen shoulder' and residual stiffness remained at the one year follow-up. Clearly, from our experience, patients do not suffer complications with early movement or pain exacerbations. Similarly, a smaller study (Jull 1979) found that patients who moved within one week of their injury had 90 degrees abduction in the first session and full shoulder elevation within three weeks. No complications were reported. This study corroborates our results and suggests that PH fractures can be safely moved, without a period of immobilisation, within one week of their injury without complications.

Three weeks was selected for the period of immobilisation in our study, but the findings from the UK survey established that 21% of PH fractures are routinely immobilised between four to seven weeks. If three weeks immobilisation retards recovery, then seven weeks will have more sever consequences. There is no evidence for this practice and our results suggest that it should be reconsidered.

5.3.6 General Health Questionnaire (SF-36) at Year One

The results from the SF-36 relate to the dimensions that are most relevant to orthopaedic patients. Namely, pain, (Beaton and Richards 1996; Wright and Young 1997; MacDermid et al. 2000), physical function (Katz et al. 1992; Beaton and Richards 1996; Beaton et al. 1997; Wright and Young 1997), and physical role limitation (Martin et al. 1997; MacDermid et al. 2000).

At the primary outcome point (16 weeks), both the pain and role limitation (physical) dimensions were statistically significant in favour of Group A compared with Group B. With the total 'area-under-the-curve' analysis (all outcome points included in the calculation), the two dimensions remain statistically significant and suggest that in the first year since the fracture, patients having immediate physiotherapy experienced less bodily pain and their general function was higher than those that were immobilised for three weeks. The null hypothesis (H2) can be rejected. Once again, the difference between the scores at 52 weeks reduces (results: table 8) and no score is statistically significant, but in both pain and role limitation (physical) dimensions Group A score higher. This trend is important and suggests that even at one year patients immobilised for three weeks still experienced more pain and reduced function.

What are the implications for this finding? Following an extensive literature search the author could not find another PH study that has used a generic health questionnaire to assess the wider implications of a fracture. This suggests that other researchers have under estimated the wider impact of an upper limb fracture on general health.

The scores for the pain (65.6) and role limitation (54.4) dimensions in Group B at one year (appendix X, table 4) are lower than population means (Garratt et al. 1993) and in surveys of older adults (aged 64 to 75 years) by Hayes et al. (Hayes et al. 1995) their mean scores for pain and role limitation were 71.1 and 63.1 respectively. Additionally, Brazier et al. (Brazier et al. 1992) in a study based in Sheffield found that in the over 45 years group (n=600) the average pain (72.3) and role limitation scores (71.3) to be higher than those in our study. The lower scores reported in the pain and role limitation dimensions (a score of 100 points represents the absence of pain or no role limitation) suggests that by one year, the population in this present study did not achieve the scores expected from population norms. The ongoing problems experienced by many of the patients having a PH fracture could account for this lower figure, but this could also be explained by their possible pre-fracture status that was lower than the general population. Without a large prospective study that charts health status of people before and after their fracture, it would be impossible to fully interpret the SF-36 scores.

These normative values would suggest that, even at one year, the dimensions have not returned to normal population values and problems persist. However, this assumes that people who fracture their PH have normal health for their specific age group and will eventually return to their pre-injury status. One study that used the SF-36 to evaluate patients after total hip replacement (THR) found that most of the eight subsets (Peterson et al. 2002) had by six months reached 90% of their score at one year. This suggests that little improvement occurs after this type of surgery, but upper limb fractures in the older adult have far greater consequences to patients' health with problems persisting for between two to four years (Madhok and Bhopal 1992). The impact of PH fractures are greater than previously thought and the author's results reinforce the work of Madhok and confirm that PH fractures produce problems for at least two years after the initial injury. This is not considered when planning current treatment and should be re-evaluated in view of these findings.

No reliable evidence exists for the general health status of the PH group, but several authors contest that they have poor general health status with osteoporosis (Kelsey et al. 1992), co-morbidities (Sartoretti et al. 1997), and are vulnerable to further fractures (Lauritzen et al. 1993; Van Staa et al. 2002). When their results are compared with our SF-36 dimensions scores, even the higher scores in Group A do not achieve the normal age-matched controls. If patients are not returning to their normal health status within one year it further questions the statement that patients make excellent or satisfactory recovery in this time period. Some patients probably do make excellent recovery, and do return to pre-injury status, but this is not reflected in the average scores as most patients continue to experience pain and loss of general function.

A key finding from the results, and an important economic consideration, is that those patients in Group A required less treatment sessions than those in Group B (9 versus 14 sessions). Group A recovered faster, possibly because immediate movement (without three weeks immobilisation) did not allowed soft tissues to shorten. Additionally, immediate movement will maintain muscle strength, albeit reduced in the early stages, and this will expedite recovery. This finding is supported in all the outcome measures that consistently show that shoulder function and general health status is greatest over the first year in Group A.

Similarly, patients in Group A had less visits to fracture clinic (measured from the patients medical notes after the study was completed) for review appointments and fewer x-rays. Surgeons do not have set review dates, but re-call patients depending on the recovery seen at the last clinic appointment. If patients are progressing rapidly and raise no specific concerns, they do not have repeat x-rays or additional clinic appointments.

Reducing the number of treatment sessions, clinic appointments and repeat x-rays has obvious cost savings for the Health Service and increases the efficiency of treating PH fractures. If the accelerated rehabilitation programme is adopted throughout the UK, it will have significant cost savings as well as patient benefits. However, as no specific cost-effectiveness analysis was included, any possible economic benefit to an accelerated rehabilitation programme remains speculative and is an area for future research.

5.3.7 Summary

Even if long-term recovery is unchanged by immediate physiotherapy, compared to immobilisation for three weeks, the benefits to the patient are manifest in restoration of general function and possibly prevention of further injury. Interestingly, it is known that people sustaining a PH fracture have poor neuromuscular status (Kelsey et al. 1992) and women have a 16% increase of having another fall resulting in a hip fracture (Lauritzen et al. 1993). Implementing immediate physiotherapy to all PH fractures might reduce the number of people who go onto have hip fractures by maintaining their physical activity. Thus, limiting or preventing the decline in neuromuscular status and reducing the falls risk. This is partially supported by the complication rates gathered over three years from the author's study which shows that Group A had one hip fracture and Group B had three. The increased prevalence in those patients that were immobilised might explain this apparent increase in secondary osteoporotic fractures and warrants further work. Preventing future fractures is not considered to be an essential part of fracture rehabilitation and this belief needs to be challenged.

Ascertaining the individual contribution of physiotherapy or no immobilisation in the accelerated recovery is impossible from this study, but logically the combination of both is most effective. The justification for immobilisation is based on its role in pain reduction and preventing complications. The findings from this study do not support this view and suggests that immobilisation is unnecessary for these reasons.

Even if the benefits of improved shoulder function are not accepted, the patient would have fewer complications and the reduction in treatments necessary for recovery would save money.

5.4 Part 3: Long-term Disability

5.4.1 Introduction

Few studies have evaluated the long-term effects of a PH fracture and most stop at six months (Young and Wallace 1985; Liversley et al. 1992) or one year (Lundberg et al.

1979; Solem-Bertoft et al. 1984). Only one other study (Kristiansen et al. 1989) had a two year evaluation, but it did not include a measure of shoulder disability and had a 50% attrition rate, thus questioning its results. Previous research has failed to evaluate shoulder function or level of disability and tends to rely on impairment measures and radiographic appearance, both of which are unreliable with little correlation to function.

Findings from this study on shoulder disability at both one and two years are discussed related to other research and possible reasons for its continuing high prevalence rates when compared with a normal population.

5.4.2 Shoulder Disability

Follow-up rates at both one year (95%, 82/86) and two years (86%, 74/86) were high and both groups were equally represented (table 10). The two year response is much higher than that reported by Kristiansen et al. (Kristiansen et al. 1989) and our low attrition rates would tend to reinforce our results and suggest that the findings from the questionnaire were representative of the study population.

The total level of shoulder disability (see table 11) in Group A at one year was lower than Group B (42.8% compared with 72.5%) and more patients reported no level of shoulder disability (57.2% compared with 27.5%). This difference was statistically significant ($p<0.01$), but at two years the difference between the groups reduced and it did not reach statistical significance, therefore, the null hypothesis (H3) can not be rejected. Although, the difference between Group A (43%) and Group B (59.5%)

represents a significant clinical difference and once again, more patients in Group A reported no level of shoulder disability compared with Group B (56.8% and 40.5% respectively). Interestingly, at two years nearly the same number of patients in each group (32.4% and 34.2% in Group A and B, respectively) reported high levels of disability. Evidently, whatever the initial treatment is, a cohort remains who do not fully recover within two years. Between one and two years patients with high levels of shoulder disability remained static in Group A (42.8% to 43.2%), but the number in Group B reduced from 72.5% to 59.5%. This suggests that Group A achieved a maximal improvement after one year whereas Group B continued to improve up to two years. This is an additional benefit to starting immediate physiotherapy and this trend does not appear with the CSS. The greater difference at one year with the CSDQ, compared with the CSS is unsurprising as it only measures shoulder function. The CSS measures shoulder impairment and some function. It is less likely to be as responsive to shoulder function as it only measures five shoulder activities compared with the CSDQ that includes 22 questions. Shoulder function is more clinically relevant and is a truer representation of the patient's recovery. Furthermore, the CSDQ is completed by the patient and this form of evaluation is thought to be more sensitive to clinical change (Van der Heijden et al. 2000) as opposed to assessment by the clinician.

If the results of the CSDQ are reliable, and there is not reason to doubt them, then patients reached maximum shoulder function after one year in Group A, but those who were immobilised for three weeks (Group B) continued to improve between year one and two. This is the first study to show that improvement under certain conditions improves after one year. Previous research has failed to detect this difference as it has not included long-term evaluation or used an outcome measure that is sensitive to clinical change.

The author's results suggest that immediate physiotherapy results in maximal shoulder function within one year of the injury and no further improvement occurs to two years. The maximum improvement after two years was consistent with longitudinal evaluation of upper limb fractures (Wildner et al. 2002) who only described very small changes after two to four years of the injury. Group B continued to improve up to two years, thus taking longer to rehabilitate with the possible consequences of re-injury or prolonged symptoms. In both groups, a core of approximately 30% continued to report significant disability (after two years). This incidence of 30% was higher by 5 to 10% compared with older population norms (Chakravarty and Webley 1990; Chard et al. 1991) and patients could continue to improve further, but probably not by significant amounts. However, it is difficult to put an exact figure on the level of shoulder disability in an osteoporotic population, as data does not exist.

When specific shoulder tasks were evaluated (Results: fig.16), the main problems patients continued to report after two years were: lifting (Q12 & Q13) and problems related to dressing (Q4 & Q6). Problems still existed with pain on movement (Q1) and sleep disturbance (Q7). No real differences existed between the groups except for pain with more than twice as many people in Group B reporting pain compared with Group A (13 versus 5) and twice the number in Group B (Q7) changing position more frequently at night (6 versus 12). Pain and sleep disturbances were probably related as the static position of the arm in bed and symptoms would have been exacerbated.

This result was similar to the SF-36 (appendix X, table 4) scores as Group-B reported higher incidence of both bodily pain and self-reported shoulder pain at one year. In recent years, Croft (Croft 1996) in a paper entitled:

'The epidemiology of pain: the more you have, the more you get',

argues that pain experienced in one area of the body will influence the reporting of symptoms in another site. This phenomena is supported by several studies, for example, in the neck (Croft et al. 2001), and people reporting pain in one joint were likely to have multiple joint problems in 85% of cases (Cunningham and Kelsey 1984). Thus, suggesting that pain does not remain, in most cases, limited to a specific area and with time will progress.

The on-going burden of shoulder pain in our patients will probably make them susceptible to additional problems that are remote from the shoulder and work by Ektor-Anderson et al. (Ektor-Anderson et al. 1999) indicates that this occurrence is higher in women. They propose that musculo-skeletal strain in one area of the body causes increased sensitivity to pain in other areas of the body and this might have some physiological basis as women have been shown to be more sensitive than men to equivalent nociceptive stimulation (Fillingim and Maixner 1995). How gender influences the response to pain is unknown in the shoulder, but in assessing patients' response to pain in the knee (Keefe et al. 2000), the authors found that women were more likely to adopt a catastrophising strategy that led to increased rigidity in the limb. Even if patients are not experiencing pain constantly, the fear of pain will change the neuromuscular response (Vlaeyen and Linton 2000). If this occurs in the shoulder, then the combination of pain, immobilisation and fear of pain could explain the higher levels of shoulder disability reported in Group B.

Once more, reported pain was higher in Group B and this reinforces the result of the SF-36 pain dimension. All measures of pain showed an increase in pain with three weeks immobilisation, before starting physiotherapy. Worryingly, it is becoming clear that how the patient is managed within a few weeks of their initial injury influences their pain experience for at least one, if not two years. Resting PH fractures does not only delay recovery, but might produce chronic pain states that will have a direct effect on motor recruitment and control. Thus, perpetuating pain and further reducing shoulder function.

Furthermore, pain is the main symptom reported in musculo-skeletal disorders (Badley et al. 1995) and work by Solem-Bertoff et al. (Solem-Bertoft et al. 1996) found that the presence of pain is the main determinant in performance of shoulder tasks. Thus, pain is a major component of upper limb function and our results suggest that immobilisation at the start of rehabilitation produces more pain at two years. This was not statistically significant, but a constant trend across a range of outcome measures points consistently in this direction.

The important relationship between shoulder pain and disability is highlighted by Badcock et al. (Badcock et al. 2002) who followed people with chronic shoulder pain for two years (n=2606). They found that shoulder pain and disability correlated with severe disability in over 50% of cases and, additionally, anxiety and depression significantly correlated with pain severity. Conversely, Pope et al. (Pope et al. 1996) could find no correlation between pain and disability, but only included 62 subjects. Interestingly, the SF-36 dimension of role limitation (emotional) score was lower in Group B when the overall scores were calculated (P<0.07), suggesting that they have higher levels of emotional distress which possibly limits function. The SF-36 predominantly measures lower limb function, so the impact on upper limb function might be different and Badcock et al. (2002) includes all forms of shoulder disorders (not just PH fractures), but the result could indicate that shoulder pain contributes to emotional distress and increased disability levels.

Several authors consistently report that shoulder disorders are not self-limiting and episodic recurrence is high (Vecchio et al. 1995; Croft et al. 1996; MacFarlane et al. 1998). These are large community-based studies in which not all patients had treatment and raises two important issues. First, having treatment did not reduce shoulder pain or disability and second, many people with shoulder pain did not actively seek medical intervention. This is seen in general musculo-skeletal disorders (Picavet and Schouten 2003) as only 33-42% consulted their GP seemingly due to people accepting their problems as part of growing older. This unwillingness to seek medical intervention and complain with shoulder pain possibly contributes to the under-reporting of symptoms following a PH fracture.

In one of the few studies reviewing function in an elderly population after an upper limb fracture (Madhok and Bhopal 1992), the results indicated that people continued to have problems with cooking (82%), household tasks (88%) and shopping (94%). This study only had a short (31 days post-injury) follow-up period, but Wildner et al.

(Wildner et al. 2002) found that fractures (in either upper or lower limb) continue to cause significant functional limitation at two years. Our results highlighted problems with carrying shopping, dressing and pain on movement, similar to Badcock et al. (Badcock et al. 2002) who found the most commonly reported problem being sleep-related problems with pain and frequent change of position (74%). Persistent problems with carrying objects were reported in over half the population (54%) and this is in a cohort with an average age of 44 years, considerably younger than the present study's population (mean age 70 years). These problems will impact on the patients' level of independence and have implications for carers and social services' support. Thus, further increasing the burden of a shoulder fracture at both a personal and societal level.

As a possible explanation of continued shoulder problems, a study by Visser et al. (1999) examined 141 patients with a PH fracture for signs of nerve damage. Sixty-eight per cent (96/141) had significant nerve damage, and in most cases this resolved within 45 weeks. They sampled a younger population than this present study (mean age 64 years), and as nerve injuries are more likely to occur in the older population, then changes in nerve conduction might affect neuro-muscular control mechanisms, therefore reducing shoulder function. Additionally, even if the nerve lesion recovers, the mal-adaptive motor patterns developed during the early stages of recovery could continue to reduce shoulder function by learnt disuse producing shoulder disability. These changes in shoulder muscle recruitment are seen in many shoulder conditions, for example, excessive shoulder girdle elevation in response to pain and stiffness (Babyar 1996).

Furthermore, in a seminal piece of research by Wadsworth et al. (Wadsworth and Bullock-Saxton 1997) who investigated shoulder pain in swimmers, they recorded altered motor recruitment patterns in the scapula control in the affected limb, but interestingly the changes were also seen in the asymptomatic side. This suggests that pain in one shoulder affects bilateral shoulder control and highlights the interdependence of upper limb function. Conceivably, the loss of control following a PH fracture could influence bilateral shoulder function and ultimately limit upper limb function. Therefore, leading to further fractures as the upper limb is important in the 'saving' mechanism (Palvenen et al. 2000) and the shoulder is thought to 'deflect' the force of the fall (Chiu and Robinovitch 1998). To date, no research has investigated motor recruitment following PH fractures, but it is known that the incidence of hip fractures is nearly three times higher after a PH fracture (Van Staa et al. 2002) and poor neuromuscular status is a risk factor for future PH fractures (Kelsey et al. 1992).

5.4.3 Summary

Two years after their injury, PH patients continued to experience high levels of shoulder disability and limitations in dressing, lifting and, more importantly, pain during activities and at night. Group A achieved maximum improvement by one year, but Group B required two years to achieve the same. Immobilisation for three weeks results in prolonged shoulder disability and has implications to both the patient and society. The impact on the patient being a prolonged period of reduced shoulder function and further risk of re-injury. At a societal level, the loss of independence will affect long-term health care requirements and place an additional burden on carers.

5.5 PART 4: Risk Factors for developing shoulder disability

5.5.1 Introduction

This section discusses the risk factors of developing long-term shoulder disability and the analysis that was made with the baseline data and from the SF-36 scores. When discussing the risk factors, the wider impact of socioeconomic variables and gender differences are considered and related to their influence on disability. Applying socioeconomic factors to fracture recovery is unique to the upper humerus, but little research exists in other upper limb fractures. The only area that has considered the influence of socioeconomic variables is within hip fracture research (Cummings et al. 1995; Lauderdale et al. 1998) and this is related to falls risk and increased mortality within the first year of the injury. This brings the discussion towards the area of falls and associated injuries, but with the extensive nature of falls literature, the thesis only briefly covers this when it relates specifically to upper limb fractures.

5.5.2 Regression Modelling

Within the regression analysis, age was used as a covariate, but only one study linked increasing age as a risk factor in recovery from a PH fracture (Court-Brown and McQueen 2002) and another (Liversley et al. 1992) found that older patients continued to improve after six months of their injury compared with younger patients. With between-group analysis (fig.12) and when age was controlled, the difference between the groups increased with Group A again recovering faster over the 12 month period after the injury. Few other studies have considered age as a risk factor in PH fracture recovery, and certainly non have applied regression analysis to PH fractures. Although, Court-Brown (Court-Brown et al. 2001) investigating translated two-part

PH fractures, stated that age correlated with ability to return to shopping and housework. Also, work by Gaebler (Gaebler et al. 2003) in a large prospective study (n=376) of minimally displaced PH fractures, reported that age was the main determinant of shoulder function and time taken to return to activities of daily living. The large drop-out rate (40%) and reliance on the Neer assessment score (questionable reliability) to judge shoulder outcome in Gaebler's work does question its findings, but the results agree with this work with older patients continuing to have more problems with lifting and household tasks. This must be considered when planning treatment and long-term evaluation is needed, especially for older adults who are more likely to experience ongoing problems.

5.5.3 Gender

Women were four times more likely to report shoulder impairment (table 12) than men and this trend continued with the SF-36 dimensions of pain (fig.17), physical function (fig.18) and role limitation physical. In the bodily pain dimension, women achieved the majority of their improvement within the first eight weeks of their injury and little improvement was seen up to 52 weeks. This contrasts with the men who continued to improve consistently over 52 weeks. Women were recovering from the initial acute pain of the fracture, but appear to be experiencing chronic pain that correlates with the self-reported pain on shoulder function. The exact reason why women have higher levels of shoulder impairment is unknown, but a similar result was observed with the reporting of musculoskeletal problems in two studies based in Sheffield (Saul 1995; Paul et al. 1998). Women complained of more problems compared to men and socioeconomic reasons were suggested as a possible explanation. Another possible explanation is the psychological response to pain: a study examining patients' response to pain (Affleck et al. 1999) found that women used more emotionally-focused coping strategies and this led to an increased reporting of symptoms. A person's health perception is important in mediating pain and Croft et al. (Croft et al. 2001) reported an association between gender (higher in females) and self-reported health status. Population studies on shoulder problems (all shoulder conditions) have reported higher levels in women compared with men (Pope et al. 1997) (Van der Windt et al. 1995). The higher levels of shoulder problems demonstrated in the present study for women might represent the general tendency for women to have more shoulder pain and the PH just compounds this effect. The reason for the gender differences between continuing shoulder problems following a PH fracture will probably be a combination of factors and identifying the specific causes will allow the development of specific rehabilitation strategies.

A different pattern was seen in the physical function and role limitation with the gap between men and women actually widening, suggesting that women deteriorated over time. Work by Wildner et al. 2002 (Wildner et al. 2002) suggests that improvement from upper limb fractures continues between two to four years, but the author's results suggest that patients might actually deteriorate up to this point and PH fractures impact on the patient for longer than initially thought. Interestingly, Wildner et al. (2002) also found that functional limitations were highest in women and especially in older women, a result similar to this study.

5.5.4 Socioeconomic Factors

No other study has examined the impact of socioeconomic factors on upper limb fractures so most of the work used to support our findings relates to general disability following musculo-skeletal disease and their subsequent functional limitations. The author's study was set in Sheffield which, as like many large cities, has high levels of socioeconomic deprivation (Sheffield is within the 20% of areas within the UK with the highest levels of social deprivation) and this might have influenced the general applicability of the results (discussed further in the limitations section).

When the subjects were analysed by socioeconomic factors (Townsend deprivation index) and group allocation is ignored, the patients living in areas of Sheffield with higher levels of deprivation had lower scores for pain (fig.19), physical function (fig. 20) and role limitation (fig. 21) in the SF-36 dimensions. The pattern is similar to that seen in gender, but pain continued to improve after eight weeks but failed to narrow after 52 weeks. Physical function actually widened at 52 weeks and this suggests that the impact of deprivation mediated general activity and socialising. Role limitation reduced at 52 weeks, but a statistical difference remained. In all three dimensions, deprivation mediated general function and bodily pain when age was controlled for in the analysis (i.e. any possible influence of age on the result is nullified).

The link between the factors contributing to high deprivation and functional limitations are strong: low income (Jette and Branch 1985; Cleary et al. 1993), low educational attainment (Maddox and Clark 1992; Cleary et al. 1993; Dunlop et al. 1998), hospital admission and co-morbidity (Stuck et al. 1999). Level of co-morbidity was not recorded in our patients, but work by Saul (based in Sheffield) found a three-fold difference between the highest and lowest areas of deprivation when reporting long-term limiting illness (38% versus 13%). It is not unreasonable to assume that significant levels of patients in our study living in areas of high deprivation have co-morbidities and these contributed to their continuing pain and functional limitations as measured with the SF-36. Indeed, work comparing level of co-morbidities in PH fracture patients (Sartoretti et al. 1997) recorded levels as high as 64%, only slightly behind those patients with hip fractures (72%).

In addition to the above factors in limiting physical function, the role limitation caused by emotional factors is highest in areas of high deprivation. Thus, depression and anxiety levels (Jette 1999) mediate functional decline, as do factors such as social contact (Stuck et al. 1999), and this is important as PH fracture patients in areas of high social deprivation may have less help and this could possibly influence their independence. The importance of carers, especially in the immediate months following an upper limb fracture, is highlighted by MacLennan et al. (MacLennan and Currie 1997) with patients mainly relying on relatives and not the state. Patients in areas of high deprivation will paradoxically have the higher levels of functional limitation, but without the social support mechanisms seen in areas of low deprivation. This is summarised by a large MRC study in the UK (n=10 377) who reported higher morbidity and mortality in less privileged social classes (Melzer et al. 2000). If someone sustains a PH fracture, where they live will influence both their eventual outcome and level of support provided. Currently, this is not considered when planning rehabilitation or social support.

5.5.5 Conclusion

The results suggest that gender and levels of deprivation influence recovery from a PH fracture and this has not been identified before. The functional limitations at one year show no signs of narrowing and actually increase in half the dimensions. This pattern of ongoing problems is supported in orthopaedic literature that has used measures of disability, but not in those only using impairment measures. The finding that socioeconomic factors influence recovery, reinforces our result as Group A contained more patients living in areas of high deprivation compared with Group B (57.7% versus 42.3%), but they still recover faster with immediate rehabilitation.

The exact reasons why low levels of social deprivation influence recovery are not clear and no work has looked exclusively at shoulder fractures. Research in the field of musculoskeletal conditions highlights the influence of educational attainment (Maddox and Clark 1992; Maddox et al. 1994), income (Leveille et al. 1992; Koster et al. 2005) and psychological factors (Urwin et al. 1998) on recovery. The person living in an area of low deprivation who fractures their PH is more likely to be physically active (Leveille et al. 1992) and adopt a more active coping strategy (Koster et al. 2005) than the person living in an area of high deprivation (interestingly, high levels of educational attainment were predictive of high physical activity at two years (Harris et al. 1989)). Additionally, people living in areas of low deprivation make different life choices e.g. lower levels of smoking and obesity. Smoking (Swaminathan et al. 2004; Harrison et al. 2005) and obesity (Stuck et al. 1999) are associated with higher levels of co-morbidities, but if combined with higher activity levels and positive psychological responses, may ensure a better recovery from a PH fracture (or any other musculoskeletal problem). This explanation has not been tested in the area of PH fractures, but could help explain the link between deprivation and recovery as shown in this study.

5.6 Limitations of Study

The limitations can be divided into design, outcome measures, treatment provision and survey.

5.6.1 Study Design

The most obvious limitation is the sample size (n=86) which is considered small when compared to pharmaceutical research, but it is based on the power calculations and, to date, no larger, prospective study in PH fracture exists. Additionally, basing the study in Sheffield, with its high social deprivation might reduce the study's general applicability, but its social profile is not dissimilar to other large cities in the UK. Further multi-site studies would overcome this limitation.

5.6.2 Outcome Measures

The primary outcome measure (CSS) is a combined measure of shoulder impairment and function. Reliability studies for the outcome measure suggest that, as a universal measure of shoulder function, it has limitations and this might create measurement errors. However, it has good reliability with the 'stiff' or arthritic shoulder, not specifically a PH fracture, but it produces similar limitations, and the CSS should reliably detect clinical differences. Additionally, repeat measurement over the first year will add to the reliability of the measure.

Measuring shoulder function with the CSDQ with only 22 questions could produce 'ceiling' or 'floor' effects as the more recently developed Disability, Shoulder and Hand outcome measure (DASH) uses more questions and it has better reliability (Hudak et al. 1996). Although using the DASH would not have been an option at the start of the study, as its reliability had not been tested at this stage and its inherently more complex structure would probably not be acceptable to the older population, especially not as a postal questionnaire.

The SF-36 is the most extensively tested outcome measure of the three used in this study. However the variability in the scoring of the eight dimensions (a standard deviation of approximately 20) and the practice of summing individual scores must be viewed with some caution, but balanced against this is the large pool of normative data and several high quality orthopaedic studies which recommend the SF-36 as part of a comprehensive evaluation. Currently, no obvious replacement for the SF-36 exists that would be suitable for this type of research.

The regression analysis and modelling of the variables was calculated using the 'step wise' method and care must be taken when interpreting the result (Munro 1997). Potential problems arise as the possibility of making type one errors increases dramatically as the number of variables increase (Nunnally and Bernstien 1994). This is a valid point considering the relatively small size of the study population and number of variables. However, the modelling was not aiming to give a definite answer to the possible influences of different factors on recovery following a PH fracture, but was highlighting possible areas of future research. This is the first work to link level of social deprivation or gender to recovery from a PH fracture, and this requires further research to confirm or refute the findings from this study.

Factors that have been shown to influence outcome, for example smoking and osteoporosis were not measured at baseline and could possibly influence the study's outcome. This fact must be considered in future research and a wider range of possible confounding factors be included at baseline. Additionally, not including the baseline scores of Physical functioning and Pain (SF-36) in the regression analysis because of differences that existed due to interpretation problems by some patients is a possible weakness and does not allow complete examination of all the baseline scores.

5.6.3 Treatment Provision

In common with most orthopaedic studies, treatment provision was not blinded as therapists were aware of group allocation and this might contribute to bias. This was necessary for two reasons: firstly therapists needed to be aware of group allocation to detect for early signs of complications, thus necessitating change in management and secondly the ethics committee stipulated that the study must stop if more than five patients had complications in Group A. Blinding of therapist would be practically impossible, as they would recognise the bruising and acute pain in those patients who were not immobilised. Questions relating specifically to treatment provision and variations in practice could have been included in the UK survey. This is a limitation of the survey that answered the questions it set out to investigate, but lack of detailed questions prevented this analysis (how the survey could be improved is discussed in the following conclusions section).

Variations in treatment provision might have occurred with 15 physiotherapists (with different levels experience) used to administer treatment. Although using the treatment protocol would minimise any possible differences and as a 'pragmatic' trial, a treatment provision was selected that reflected current orthopaedic practice, thus maintaining study generalisability.

Every attempt had been made to limit bias and minimise error within the study, but inevitably some problems will exist and these have been explored within the discussion. Some of the limitations could be addressed; for example, sample size, but others such as 'blinding' the therapist to group allocation would encounter resistance on ethical grounds. Overall, the results appear robust and the findings justified as all outcome measures suggest that immediate rehabilitation results in faster recovery and this is reinforced by literature of bone healing and repair. All outcome measures indicate that faster return to function is achieved with early movement and immediate physiotherapy. This work needs repeating with larger multi-site RCT's and possibly the addition of the DASH questionnaire to refute or reinforce the findings.

Chapter 6: Recommendations & Conclusion

6.1 Recommendations

6.1.1 Introduction

The following recommendations are based on the results of this study and integrated into the best evidence from the literature review. They also relate to the type one or 'minimally displaced' PH fractures that were studied in the present study. The findings may have implications for the more complicated PH fractures, but more research is needed in this area before firm conclusions can be made. Considerable gaps in the literature exist, but some evidence is emerging that suggests the direction of 'best practice'.

The recommendations are divided between 'medical management' and 'rehabilitation' of PH fractures only for ease of discussing the different issues-it does not imply that these are separate sections-and indeed, there is considerable overlap. Management of PH fractures is mainly by the orthopaedic surgeon and rehabilitation by the physiotherapist, and sometimes, as suggested in the UK survey, wide variations in how these patients are managed exists, both between and within hospitals. The advent of joint orthopaedic and physiotherapy clinics (already seen in many Hospitals) in which individual treatment is planned with multidisciplinary involvement will optimise the recovery from a PH fracture.

6.1.2 Medical Management

- **Screening**

It is increasingly clear that those patients who fracture their PH are not an homogeneous group and different risk factors exist that will affect recovery rate. Currently, these factors are not included in orthopaedic assessment and should be introduced at the initial clinic appointment to categorise patients into 'low' or 'high' risk of developing future problems. The 'low' risk group are often younger, male, and with low levels of deprivation (income, educational attainment, housing, social support) and no or minimal psychological risk factors. In common with most musculo-skeletal disorders, psychological risk factors such as anxiety, depression and fear avoidance will influence a person's response to rehabilitation. Assessment of these factors should be conducted at the initial assessment.

Patients classified at 'high' risk will have high levels of the factors already mentioned and will be more likely to develop long-term shoulder disability. By identifying this at risk group, they can be referred immediately for physiotherapy and possibly referred to a physiotherapist specialising in shoulder rehabilitation. Groups at 'low' risk could be 'fast tracked' to receive initial advice and home exercises and their progression would be monitored, without the necessity of attending for physiotherapy. Therefore, tailoring rehabilitation to the individual's requirements and targeting the 'at high risk' group, thus maximising resources and optimising recovery.

- **Immobilisation**

From the survey, immobilisation remains a central tenet in the management of PH fractures. However, the results of this study suggest that the practice of routine immobilisation should stop as it retards recovery. The exact mechanism by which this occurs is not clear, but immobilisation is likely to engender greater 'fear avoidance' and this has been linked with changes in musculoskeletal motor patterns and has been suggested to adversely affect a patient's behaviour and motor function (Valeyen 2000. Paradoxically, the reason given for immobilisation is to reduce pain. The author's results consistently show that patients immobilised for only three weeks report more pain over the first year of their injury. Using immobilisation to reduce pain is against all the current ideas on pain management as it produces fear, has deleterious effects on healing and probably contributes to pain sensitisation mechanisms. Additionally, using immobilisation to avoid fracture complications (non-union, mal-union) might actually increase problems as strong experimental evidence states that fracture repair is improved with movement. This evidence is consistent with our observations. If a clinical scenario exists that necessitates immobilisation, that period must be kept to an absolute minimum.

From the author's results, the cost benefits to the health provider of immediate activity and physiotherapy are a reduction in the number of treatment sessions required for the patient to achieve functional independence. The known detrimental effects on soft tissue of stiffness are limited with early movement and moreover, pain is reduced. Thus, the number of clinic appointments and repeat x-rays are reduced as the patient only requires minimum input from the surgeon that is monitoring them.

Immediate physiotherapy offers both patient and cost benefits without increasing complications and this approach should be adopted in the UK.

- **Initial Patient Advice**

Recognising the importance of initial patient advice (and who gives that advice), the referring surgeon should inform the patient that early, active, restoration of movement is the key idea in recovery. This prevents 'mixed messages' from key rehabilitation staff and ensures that the patient remains an active participant in their own rehabilitation. This recognises the central role of the surgeon in the rehabilitation process. Similar multi-disciplinary models are seen, for example, in pain clinics and in the management of vertigo.

- **Referral to physiotherapy**

Most patients are referred routinely for physiotherapy (101/127 79%), but this timing varies between consultants and between hospitals. All 'high-risk' patients should be referred immediately for physiotherapy. Those deemed at lower risk could be referred to, for example, a clinic nurse, to give basic advice and encourage restoration of function. If the patient develops future problems, they could be referred at a later stage for physiotherapy. Thus, directing the patient to the most appropriate health care professional within the shortest period of time. Therefore, the specialist rehabilitation skills of the physiotherapist are channelled toward the most vulnerable groups.

- **Osteoporosis Screening**

Those adults who fracture their PH also have an increased risk of future osteoporotic fractures (Gallagher et al. 1980; Lauritzen et al. 1993). This increased risk is not considered when a person is discharged from the fracture clinic and these patients should be screened for BMD and risk of falling. Identifying the vulnerable group will allow treatment to commence before any general decline in the patient's health status and prevent future fractures. Additionally, falls programmes could be targeted toward the at risk groups, thus preventing future hospital admissions and maintaining the patient's independence.

Patients are not considered for further investigations, and as PH fractures have a residual lifetime risk of 16% (Lauritzen et al. 1993) of a future hip fracture, this is a missed opportunity to prevent other osteoporotic fractures. This new approach is proactive and contrasts with the current situation that merely reacts to the injury.

- **Medication**

The importance of pain management cannot to over-emphasised, especially as patients continue to report high levels of pain after one year of their injury and it has considerable impact on function (Solem-Bertoft et al. 1996). The management of pain should be a priority for orthopaedic clinics and long-term, by the clinic nurse or physiotherapist.

Minimising pain levels will improve the patient's comfort levels, but also maximise recovery, especially in the first six month post-fracture in which recovery is the greatest. The influence of pain on motor patterning in the upper limb cannot be underestimated and failure to consider this only leads to chronic symptoms and maladaptive strategies by the patient.

At this point, it is relevant to stress the importance of a multidisciplinary approach in the rehabilitation of the patient who fractures their PH. The coordination and integration of the key roles of the orthopaedic surgeon, clinic nurse and the physiotherapist are paramount to optimise the patient's recovery. Communication is the key to this process so patients can move effortlessly between accident and emergency, fracture clinic and the physiotherapy department. Each member of staff should give consistent information to the patient and also check for potential complications that could slow recovery or necessitate a change in management strategy, for example, the development of chronic pain syndrome or the non-union of the fracture.

6.1.3 Rehabilitation

- **Programmes**

Treatment should initially start with an educational programme that informs the patient about their injury and empower them to play an active role in their own recovery. If the patient shows signs of fear-avoidance or anxiety, this must be addressed before considering any other treatment. The patient's beliefs about their fracture must be ascertained, but aspects of this will have already been covered by the referring surgeon. Once again, an emphasis on early, active restoration of function is encouraged and removal of the sling at the earliest opportunity.

The home exercise programme should emphasise shoulder function (especially lifting and dressing as these remain a long-term problem). These exercises should start immediately (day one) if that is within the capabilities and tolerances of the patient (some patients on the present study had full shoulder function within one week of their fracture). Obviously, over-loading the fracture site too early would only exacerbate pain and possibly lead to fracture complications, but avoiding any return to activity in the early part of rehabilitation could be equally harmful.

Return to activity should be progressed within the patient's pain tolerance, but this should proceed rapidly. Pain relief with ice or heat can be started, but encouraging movement and restoration of early shoulder function will most effectively reduce pain levels.

- **Mobilisation**

For patients who fail to make appropriate progress for reasons of pain or stiffness, mobilisation of the joint should aim to reduce muscle spasm, pain and restore function. During this period, the physiotherapist should carefully monitor the shoulder for signs of complications, but small movements of the fracture site are inevitable and will only serve to enhance bone healing. This approach was within the study protocol and did not result in more complications in either group. Work by other authors (Jull 1979) achieved 90 degrees passive shoulder abduction in most PH patients (11/14), and interestingly the average number of treatments was nine, the same as that Group A (immediate) had in our study.

- **Follow-up**

The physiotherapist must acknowledge that some patients continue to experience shoulder problems for up to two years and appropriate long-term follow up must be incorporated into rehabilitation. The patients deemed at high risk might be referred to community follow-up or have telephone re-assessment. Certainly, the first year is crucial, but this might be longer in some cases. Current practice is to discharge patients within three months of their initial injury and this is based on traditional practice and case load pressures. Physiotherapists must adopt the long-term assessments as used routinely in orthopaedic clinics (three to six months), but only in the population at high risk of disability or further fractures.

Assessing long-term shoulder disability or general health status by postal questionnaires would identify patients that continue to experience ongoing problems, or more importantly patients who were progressing well, but have deteriorated for whatever reason. The author's results suggest that improvement is not evenly distributed over time and patients may actually deteriorate at certain points, for example after discharge from physiotherapy or if they injure their shoulder again. The questionnaires would identify this deterioration and further intervention could be instigated.

Similar screening and monitoring programmes are currently being developed in Primary care Trusts (PCT) to prevent patients with chronic illnesses being re-admitted to hospital. The proposed plan for PH fractures is along similar lines, but with a longer time span. Pre-empting problems is a shift in the management of PH fractures (and other common illnesses), but would have significant cost benefits.

6.1.4 Summary

These recommendations call for a change in practice in PH fracture management and rehabilitation. Closer co-operation is needed between the referring clinician and physiotherapist to identify high-risk patients and instigate immediate rehabilitation. The practice of routinely immobilising patients must stop as it only produces long-term problems and does not reduce pain after the injury. Pain management should be reviewed to ensure that patients' acute pain is controlled for their early start to rehabilitation. Concurrently, the referring physician must take a central role in rehabilitation by allaying the patients' fears about the fracture and to encourage an early, active return to function.

The practice of developing 'care pathways' within fracture management is necessary to standardise treatment and to help less experienced clinicians - this is seen in the management of, for example, stroke or fall management programmes. This would reduce the wide variation in management of PH fractures as highlighted in the UK survey. Some of these recommendations will inevitably, cause problems with the pressures of patient caseloads and the peaks of demand in fractures during periods of snow or ice. However, set against this are the benefits of targeting specific high risk groups and a reduction in treatment sessions required with immediate rehabilitation. Furthermore, this group also required less orthopaedic clinic appointments and fewer repeat x-rays, thus optimising recovery and reducing costs. Adopting these recommendations will begin to reduce the impact of a PH fracture on a most vulnerable group of patients in society by preventing long-term shoulder disability.

6.2 Conclusions

The western world faces an explosion in the number of patients who will fracture their PH as a result of the rapidly changing demographics and the increase in osteoporosis. Additionally, as life expectancy increases the risk of having a fall will increase and more specifically, falls that result in an injury. The lifetime risk for a 50 year old woman of having an osteoporotic fracture during her remaining life is approximately 30-40% (Delmas 1995). The author's findings suggest that the current management and rehabilitation in the UK of these patients has several limitations and if this is not changed, will result in higher levels of shoulder disability and further burden on health and social care budgets.

PH fractures do not recover within one year of the injury and current beliefs are wrong, and as such, do not recognise the problems faced by many patients. Even the latest paper on PH fractures continues to perpetuate this myth as the authors (Gaebler et al. 2003) concluded that 88% of the patients had excellent or very good recovery. However, they had a 40% attrition rate and the assessment was based on the Neer shoulder assessment that has no proven reliability or ability to detect clinical change. Thus, invalidating their conclusions, but continuing to perpetuate the erroneous belief that no problem exists with this fracture and therefore failing to instigate changes in management or treatment.

The full impact of musculo-skeletal disease on the individual is not fully recognised and in an editorial in the British Medical Journal by two of the leading figures in this area, it was stated in its conclusion that:

"We must recognise the burden of disease and understand the pervasive effects they have on the individuals."

Woolf & Akesson (Woolf and Akesson 2001)

The author's research findings reflect this statement as the current management of PH fractures fails to identify the key risk factors in developing long-term disability and how they impact on the patient. The current practice of basing management on x-ray appearance in setting treatment, needs widening to include the key risk factors and this system must be flexible enough to meet individual requirements. Some patients are at high risk of developing problems and these include socioeconomic factors, gender and age. The screening of patients at an orthopaedic clinic would enable those at risk to receive intensive rehabilitation under the guidance of a physiotherapist specialising in shoulder rehabilitation. Conversely, those identified at low risk of shoulder disability could be given basic advice and their progress monitored, thus targeting patients based on individual requirements and optimising recovery.

The widespread practice of immobilisation has no scientific basis in the literature and our results concur with this view. Early, active movement without a period of immobilisation results in faster recovery without increasing the rate of complications (immobilisation might actually increase complication rates). Movement is a key component to bone repair and our programme, in which early activation of the shoulder is encouraged, results in less shoulder disability. Convincing physicians to recommend accelerated programmes will not be easy as rest had been a central part of fracture management over the centuries and generated great debate since Lucas-Championniere, a French physician, cautioned against the use of immobilisation as it caused irrecoverable joint damage (Salter 1982). Recent evidence of managing wrist and ankle fractures without immobilisation is reporting similar positive results to our own and it is suggested that immobilisation may actually create an iatrogenic medical problem (Maeda et al. 1993). Certain fractures require some level of immobilisation to maintain alignment, but with patients who are frail, osteoporotic and probably already have some level of shoulder dysfunction before the fracture, the effects of immobilisation are detrimental to their recovery. These patients are likely to form the largest section of future orthopaedic provision.

The National survey identified the wide variation in PH fracture management between and within hospitals and suggests that clinicians are basing treatment on empirical evidence without recourse to clinical trials. This practice must change and the introduction of care pathways seen, for example, in stroke rehabilitation and fallers' programmes could be introduced. Further work is still needed in this area and the survey needs repeating to increase its scope in relation to specific treatments (modalities, treatment techniques, home exercise programmes) and to investigate if factors such as workload, level of experience (physiotherapist and surgeon), and existence of waiting lists have an effect on PH fracture management. Additionally, future questionnaires must ascertain what, if any, variation in the management and treatment of PH fractures exists and what influences practice e.g. workload, waiting lists, consultant's view of physiotherapy efficacy. The answer to these questions may prove controversial, but would help in the future provision of PH management and treatment.

The key objective for those patients who have high risk of developing long-term shoulder problems must be to maximise shoulder function by rehabilitating the patient rapidly within their pain tolerances. Pain, from our findings, is minimised by early movement, but this is against the commonly held belief that immobilisation will help reduce pain. Pain relief is often cited as a reason for immobilisation in PH fractures, but this is without scientific basis and in other areas of orthopaedic management, for example, bed rest for low back pain and collars for 'whiplash' injuries, the current evidence advocates restoration of function without a period of immobilisation (Mealy et al. 1986; Malmivaara et al. 1995; Wilkinson 1995). This trend for reducing, and stopping, immobilisation should be adopted in the management of PH fractures. Early movement would accelerate recovery by influencing both physiological and psychological factors. Immediate mobilisation will prevent the deleterious effects of immobilisation on connective tissues (bone, ligament, tendon and muscle) and encouraging immediate shoulder function will limit any loss of muscle strength. Minimising fear avoidance strategies and facilitating active coping mechanisms will probably help in maximising recovery by limiting the time spent immobilised.

Encouraging early shoulder movement will inevitably cause increased stresses across the fracture site and this concerns some clinicians as it is thought to delay fracture repair and "insufficient" immobilisation is cited as a cause of non-union (Apley and Solomon 1993; Bigliani et al. 1996). Once again, no evidence is given for this assertion and leaders in the field of tissue repair suggest that early or almost immediate loading and movement, including induced micromotion at long bone site fractures, promotes fracture healing (Buckwalter 1996). Additionally, bone reacts to mechanical stimulus (Hert 1971; Hert 1971) and our results concur with this observation as immediate movement resulted in optimum recovery, but without increasing complications.

The problems following a PH fracture are not usually related to the fracture site, but to the soft tissue damage that results in restricted joint movement and disruption to the rotator cuff muscles. Physiotherapists must direct treatment towards the vulnerable soft tissue and take the focus away from the fracture. The fracture will heal with movement, but only as the normal stresses are reintroduced across the fracture site with muscular contraction. Our programme encouraged patients to begin active-assisted, functional exercises within days of their fracture. Thus, giving the patient confidence to move their arm and to begin putting controlled stresses across the fracture. Good range of movement can be achieved with early exercise before joint contractions occur. Paradoxically, the use of immobilisation could result in excessive stresses across the fracture site as the patient moves their arm against the joint contractures and possibly leads to fracture complications.

The NHS spent 40% of its budget (£10 billion) on people over the age of 65 years in 1998/9 (the same, year social services spent 50% of their budget of £5.2 billion on the same age group) (DoH 2000). With the changing demographics, and more people over the age of 60 than below 16 years (Statistics 2001), this trend is set to rise and the management of osteoporotic fractures, and specifically the PH fracture, will further increase demands on finite resources.

Any visitor to an orthopaedic trauma ward in the UK would not see many young patients with fractures as a result of road traffic accidents, but would comment on the number of older adults with fractures. Not the high-energy fractures of the relatively young, but the 'low-energy' fractures that will increasingly tax the resources of the NHS (Court-Brown and McQueen 2002). This is the challenge to PH fracture management, but modern orthopaedics continues to overestimate the favourable outcome of these common fractures and remains wedded to the outdated notion that fracture healing is enhanced by immobilisation. The author's results suggest that immobilisation and delayed physiotherapy result, not in more pain or increased complications, but in faster and higher levels of recovery.

Furthermore, PH fracture recovery is strongly influenced by socioeconomic variables, age and gender. Until health workers start to consider these factors in their management and rehabilitation programmes, thus reducing their reliance on measures of movement and strength, then many people sustaining PH fractures will continue to experience long-term shoulder disability and continued pain. PH fractures are not self-limiting and patients continue to experience ongoing problems. They do not complain or seek further medical assistance, but adapt to their given situation (Madhok and Bhopal 1992), but at the cost of chronic pain and loss of function. This situation can be changed with simple measures.

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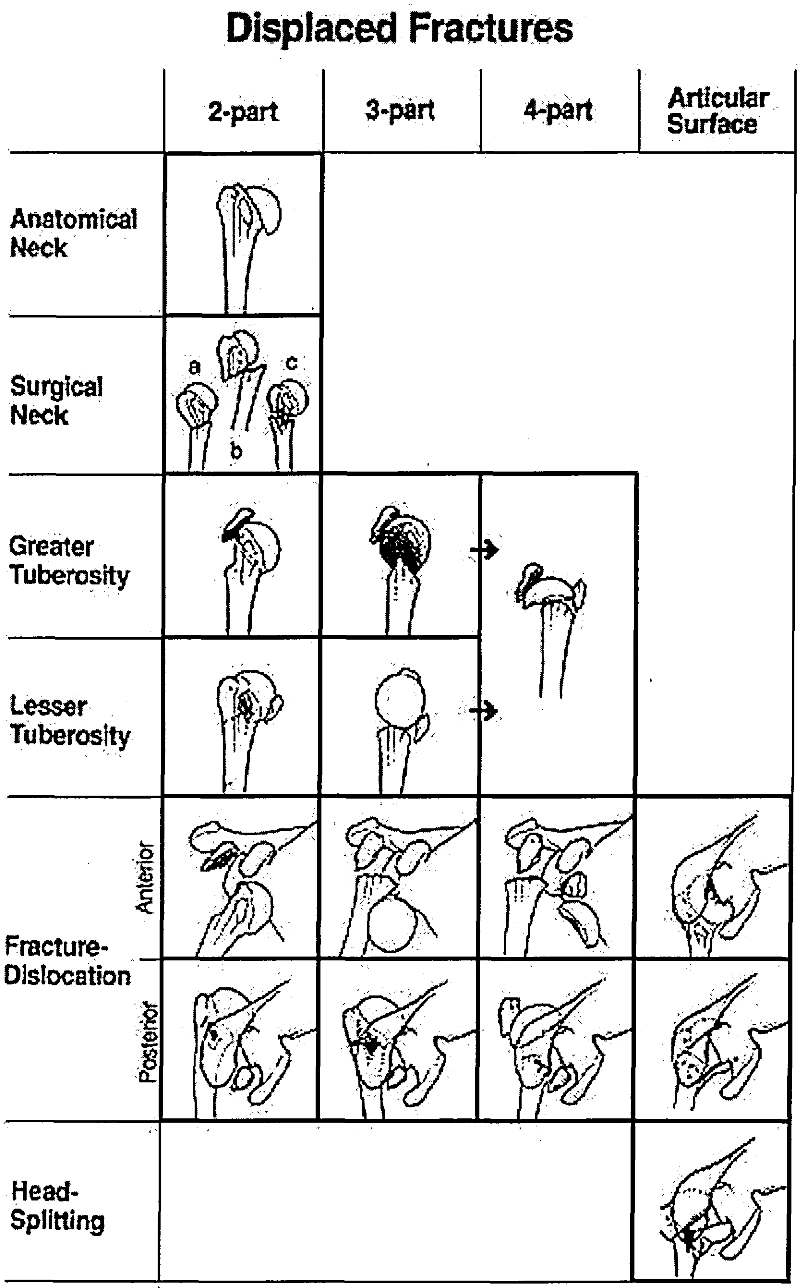
Appendices

Appendix X: Results

Appendix I : Neer Proximal Humerus Classification System



Appendex II: Baseline Assessment

Proximal Humerus Research Trial

A. PATIENT DETAILS

1. **Name**
2. **Identification number (hospital number)**
3. **Gender (F-Female, M-Male)**
3. **Address**
4. **Date of birth**
5. **Telephone number**
6. **Date of fracture**
7. **Physiotherapy assessment date**
8. **Treatment group allocation (E-Early/ L-Later)**
9. **Height (Cms)**
10. **Weight (Kgms)**
11. **Dominant arm (L/R)**
12. **Follow-up dates:** 8 weeks
16 weeks
52 weeks

B. SOCIAL HISTORY

Living status

Lives alone ☐ Lives with partner ☐ Lives with others ☐ (please specify)

Independent ☐ Needs assistance with ADL's ☐

Assistance from: Partner ☐

Social services ☐
Relative/friend ☐
Warden ☐
'Meals on wheels' ☐
Nurse ☐
Other ☐

If other, please specify

How much assistance do you require?

e.g Partner 2 hrs/day
Relative 15/week

How long have you needed this help?

Occupation (if retired, please state previous occupation)

i.e Miner (retired)

Type of accommodation

House ☐ Bungalow ☐ Flat ☐ Other ☐ (please specify)

C. MEDICAL DETAILS

Consultant **D Stanley** ☐ **other** ☐ (please specify)

Type of fracture (ie comminuted/ impacted/greater tuberosity/lesser tuberosity etc)

Mechanism of fracture:

Fall:
- Floor level ☐
- from object ☐

Hit by car ☐
Car driver/passenger ☐
Other (please specify) ☐

Previous falls (number in last year)

Previous Fracture(s) (location and date)

Previous neck or shoulder/arm problem (please specify)

Major health problems (Cardio-vascular disease, diabetes, epilepsy, anaemia, osteoporosis, eye disorders, angina, osteoarthritis, major operations,other……please specify).

Medication (pre and post injury)

Appendex III: Constant Shoulder Score

Patient's name and identification number:

Date of evaluation:

Date of fracture:

MEASURE	Score RIGHT	SCORE LEFT
PAIN		
ACTIVITY OF DAILY LIVING:		
Work		
Recreation		
Sleep		
Position		
Range of movement:		
Abd (include degrees)		
Flex (include degrees)		
Internal rotation		
External rotation		
POWER		
Total	%	%

Appendix IV: Scoring System for the Constant Shoulder Score

Scoring For Individual Parameters

Pain	15
ADL	20
ROM	40
Power	25

Scoring for ADLs

Activity level	
Full work	4
Full recreation	4
Unaffected sleep	2
Positioning	
Up to waist	2
Up to xiphoid	4
Up to neck	6
Up to top of head	8
Above head	10
Total for ADL (max 20)	

Scoring for flexion & abduction

Flexion(degrees)	Points
0-30	0
31-60	2
61-90	4
91-120	6
121-150	8
151-180	10

External Rotation Scoring

Position	Points
HBH-elbow held forward	2
HBH-elbow held back	2
Hand on top of head-elbow held forward	2
Hand on top of head-elbow held back	2
Full elevation from top of head	2
Total	10

Internal Rotation Scoring

Position	Points
Dorsum of hand to lateral thigh	0
Dorsum of hand to buttock	2
Dorsum of hand to L/S junction	4
Dorsum of hand to L3	6
Dorsum of hand to T12	8
Dorsum of hand to T7	10

Scoring for pain

None	15
Mild	10
Moderate	5
Severe	0

The assessment is made when the patient experiences the greatest degree of pain i.e. in bed, at work, during ADLs.

POWER

With the arm abducted 90° (less if patient cannot reach 90°) use a dynamometer to assess strength. Each pound representing a point i.e 15lb= 15 points (maximum 25 points)

Key
ADL: Activities of Daily Living
ROM: Range of movement
HBB: hand behind back
HBH: hand behind head

Appendix V (i) : Short Form SF-36 Health Survey

NAME

DATE

HEALTH STATUS QUESTIONNAIRE (SF-36)

The following questions ask you about your health, how you feel and how well you are able to do your usual activities.

If you are unsure how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

	(tick one)
Excellent	O
Very good	O
Good	O
Fair	O
Poor	O

2. Compared to one year ago, how would you rate your health in general now?

	(tick one)
Much better than one year ago	O
Somewhat better than one year ago	O
About the same	O
Somewhat worse now than one year ago	O
Much worse now than one year ago	O

HEALTH AND DAILY ACTIVITIES

3. **The following questions are about activities that you might do during a typical day. Does your health limit you in these activities?**

   If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No,not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking half a mile	1	2	3
i. Walking 100 yards	1	2	3
j. Bathing and dressing yourself	1	2	3

4. **During the <u>last week,</u> have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>**

(circle one number on each line)

	YES	*NO*
a. Cut down on the **amount of time** you spent on work or other activities	**1**	**2**
b. Accomplished less than you would like	**1**	**2**
c. Were limited in the **kind** of work or other activities	**1**	**2**
d. Had **difficulty** in performing the work or other activities (e.g. it took extra effort)	**1**	**2**

5. **During the <u>last week,</u> have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?**

(circle one number on each line)

	YES	**NO**
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. **During the <u>last week,</u> to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?**

(circle one number)

Not at all 1
Slightly 2
Moderately. 3
Quite a bit 4
Extremely 5

7. **How much bodily pain have you had during the last week?**

(circle one number)

None 1
Very mild 2
Mild 3
Moderate 4
Severe 5
Very severe. 6

8. **During the last week, how much did pain interfere with your normal work (including work both outside the home and housework)?**

(circle one number)

Not at all 1
A little bit...............................2
Moderately 3
Quite a bit 4
Extremely 5

YOUR FEELINGS

9. **These questions are about how you feel and how things have been with you during <u>the last week.</u> (For each question, please indicate the <u>one</u> answer that comes closest to the way you have been feeling.)**

(circle one number on each line)

How much of the time during the past 4 weeks:

How much of the time During the last week:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt down- hearted and low?	1	2	3	4	5	6
g. Did you feel worn-out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6
j. Has your health limited your social activities (like visiting friends or close relatives)	1	2	3	4	5	6

HEALTH IN GENERAL

10. Please choose the answer that best describes how <u>true</u> or <u>false</u> each of the following statements is for you.

(circle one number on each line)

	Definitely true	**Mostly true**	**Not sure**	**Mostly false**	**Definitely false**
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Appendix V (ii) : Short Form SF-36 Health Survey Scoring System.

SF-36 SCORING SYSTEM

The instructions given below are for scoring the eight dimensions of the U.K. SF-36 reproduced in this manual. They show;

- Which items compose each dimension;
- The coding system for each item. ***Important note: not all items in a domain are coded in the same manner.*** For example, in the mental health dimension items 9d and 9h are coded in the reverse manner to 9b, 9c and 9f;
- The scoring algorithms for each dimension.

If you are interested in creating the summary scale scores (the Physical Component Summary (PCS) and the Mental Component Summary (MCS) from UK SF-36 data then please see page 39.

1. Coding Items:

Physical Function

3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	Yes, Limited a lot = 1 Yes, limited a little = 2 No, not limited at all = 3

Role limitation due to physical problems

4a, 4b, 4c, 4d	Yes = 0 No = 1

Role Limitation due to emotional problems

5a, 5b, 5c	Yes = 0 No = 1

Social functioning

6	Not at all = 5 Slightly = 4 Moderately = 3 Quite a bit = 2 Extremely = 1
9j	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6

Mental Health

9b, 9c, 9f	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6
9d, 9h	All of the time = 6 Most of the time = 5 A good bit of the time = 4 Some of the time = 3 A little of the time = 2 None of the time

Energy/vitality

9a, 9e	All of the time = 6 Most of the time = 5 A good bit of the time = 4 Some of the time = 3 A little of the time = 2 None of the time = 1
9g, 9i	All of the time = 1 Most of the time = 2 A good bit of the time = 3 Some of the time = 4 A little of the time = 5 None of the time = 6

Pain

7	None = 6 Very mild = 5 Mild = 4 Moderate = 3 Severe = 2 Very severe = 1
8	Not at all = 5 A little bit = 4 Moderately = 3 Quite a bit = 2 Extremely = 1

General health perception

1	Excellent = 5 Very good = 4.4 Good = 3.4 Fair = 2 Poor = 1
10a, 10c	Definitely true = 1 Mostly true = 2 Not sure = 3 Mostly false = 4 Definitely false = 5
10b, 10d,	Definitely true = 1 Mostly true = 2 Not sure = 3 Mostly false = 4 Definitely false = 5

Change in health

2	Much better now = 5 Somewhat better = 4 About the same = 3 Somewhat worse = 2 Much worse = 1

2. Calculating dimension scores

Physical function (PF)

PF = 3a + 3b + 3c + 3d + 3e + 3f + 3g + 3h + 3i + 3j
Physical function score = ((PF-10)/20) * 100

Role limitation due to physical problems (RP)

RP = 4a + 4b + 4c + 4d
Role limitation due to physical problems score = (RP/4)*100

Role limitation due to emotional problems (RE)

RE = 5a + 5b + 5c
Role limitation due to emotional problems score = (RE/3)*100

Social functioning (SF)

SC = 6 + 9j
Social functioning score ((SC-2)/9)*100

Mental health (MH)

MH = 9b + 9c + 9d + 9f + 9h
Mental health score = ((MH-5)/25)*100

Energy/vitality (EV)

EV = 9a + 9e + 9g + 9i
Energy/vitality score = ((EV-4)/20)*100

Pain (P)

P = 7 + 8
Pain = ((P-2)/9)*100

General health perception (GHP)

GHP = 1 + 10a + 10b + 10c + 10d
General health perceptions = ((GHP-5)/20)*100

Change in health (CH)

CH = 2
Change in health score = ((CH-1)/4)*100

Appendix VI: Croft Shoulder disability Questionnaire

When your shoulder hurts, you may find it difficult to do some of the things you would normally do. This list contains some sentences that people have used to describe themselves when they are having trouble with their shoulder. As you read them, think of yourself **TODAY.**
When you read a sentence that describes you **TODAY**, please tick the ' YES' box. If the sentence does not describe you tick the 'NO' box and go to the next one. Please only tick the 'YES' box for a sentence if you are sure that it describes you today.

	YES	*NO*
Because of the pain in my shoulder, I move my arm or hand with some difficulty.	☐	☐
I do not bath myself completely because of my shoulder.	☐	☐
Because of my shoulder trouble, I get dressed with help from someone else.	☐	☐
I get dressed more slowly than usual because of my shoulder.	☐	☐
Because of my shoulder trouble, I fasten my clothing with some difficulty (e.g. buttons, shoelaces, ties, zips or bra)	☐	☐
I have problems putting on a jersey, coat, shirt, blouse or jacket because of my shoulder problem.	☐	☐
Because of my shoulder problem I change position frequently in bed at night.	☐	☐
I cannot lie on my right side at night because of my shoulder problem.	☐	☐
I cannot lie on my left side at night because of my shoulder problem.	☐	☐
I stay at home most of the time because of my shoulder problem.	☐	☐
Because of my shoulder problem I do less of the household jobs than I would usually do.	☐	☐
I avoid heavy jobs around the house because of my shoulder problem.	☐	☐
Because of my shoulder problem I do not carry any shopping.	☐	☐
Because of my shoulder problem, I am cutting down on some of my usual sports or more active pastimes.	☐	☐
Because of my shoulder problem, I am not doing any of my usual physical recreation or more active pastimes.	☐	☐
Because of my shoulder, I try to get other people to do things for me.	☐	☐
My shoulder makes me more irritable and bad tempered with people than usual.	☐	☐
Because of my shoulder problem, I have more minor accidents (eg dropping things)	☐	☐
I sleep less well because of my shoulder problem.	☐	☐
Because of my shoulder, I rest more often during the day.	☐	☐
My appetite is not very good because of my shoulder problem.	☐	☐
Because of my shoulder problem, I have trouble writing or typing.	☐	☐

Appendix VII: Physiotherapy protocol

Early Rehabilitation (injury to two weeks)

- Educate the patient regarding the benefits of early movement
- Prevent inappropriate shoulder movement patterns
- Passive accessory movements to the shoulder, within pain limit.
- Passive shoulder abduction and lateral rotation, aiming for 90° abduction within the first three sessions.
- Teach the patient gravity assisted pendular exercises for home.
- Pain control with heat or ice.

Intermediate Rehabilitation (two to eight weeks)

- Supervised passive shoulder exercises in supine (flexion and lateral rotation)
- Light functional exercises without causing pain exacerbation.
- Increase passive physiological movements (not into resistance) to full range.
- Proprioceptive exercises (closed and open chain).

Late Rehabilitation (eight weeks plus)

- Active exercise against gravity.
- Isometric muscle work to strengthen rotator cuff muscles.
- Reduce use of sling and encourage functional exercises.
- Passive stretching if soft tissue contractions persist.
- Discharge when independent function regained.

Appendix VIII: Published Papers

Appendix VIII (i). Rehabilitation after two-part fractures of the humerus (JBJS)

Rehabilitation after two-part fractures of the neck of humerus

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Key words: Two-part fracture, proximal, humerus, physiotherapy, rehabilitation, osteoporosis, shoulder, randomised controlled trial

Abstract

We undertook a prospective, controlled trial comparing two rehabilitation programmes on 86 patients who sustained two-part fractures of the proximal humerus was performed. Patients were randomised to receive immediate physiotherapy within one week (Group A) or delayed physiotherapy (Group B) after three weeks collar and cuff immobilisation.

At the primary outcome point 16 weeks after the fracture, Group A experienced less pain ($p<0.01$) and had greater shoulder function ($p<0.001$) compared to Group B.

At 52 weeks the differences between the Groups had reduced and, although Group A still had greater shoulder function and less pain, there was no statistical difference when compared to group B at this single follow-up point. With analysis of area-under-the-curve (this is an overall measure up to the 52 week period) Group A experienced less pain as measured with the SF-36 general health questionnaire (mean difference 486 CI 83 to 889, $p<0.01$) and improved shoulder function (mean difference in AUC 6.4 [95% CI: 2.5 to 10.5], $p< 0.002$).

Our results show that patients with two-part fractures of the proximal humerus who begin immediate physiotherapy experience less pain. The gains in shoulder function persist at 52 weeks and would suggest that patients do not benefit from immobilisation before starting physiotherapy.

Introduction

Fracture of the proximal humerus is a common injury and accounts for approximately 4 to 5 per cent of all fractures[1-4]. The fracture incidence rises with age and accelerates over the age of 50 with women showing the greatest increase compared to men[5,6]. Conservative management of two part (minimally displaced) fractures has been advocated [7] and a short period of immobilisation is recommended before the start of active exercise. The time suggested before active exercise is started varies. Rockwell and Matsen [8] advise 7 to 10 days whilst Adams [9] suggests shoulder movement be deferred for 2 to 3 weeks.

The aims of this study were to prospectively investigate whether a patient with a two part minimally displaced proximal humeral fracture could be safely rehabilitated without a period of immobilisation and to determine whether this resulted in greater shoulder function.

Patients and Methods

Between November 1998 and April 2000, 86 patients over the age of 40 years with minimally displaced two-part proximal humeral fractures were recruited and reviewed at intervals during their rehabilitation (8, 16 and 52 weeks). We used the definition of Neer[7] for the minimally displaced fracture ie. no bone segment is displaced more than 1.0 centimetre or angled more than 45 degrees. Isolated fractures to the greater tuberosity, provided they complied with the above definition, were included.

Subjects were randomly allocated to Group A (physiotherapy started within one week of the fracture) or Group B (physiotherapy started at three weeks) using sequentially numbered, sealed envelopes.

Both groups received the same rehabilitation programme under the guidance of a physiotherapist. Physiotherapy was conducted at two centres in the Sheffield Teaching Hospitals NHS Trust and 16 physiotherapists were involved in the provision of treatment. The physiotherapists followed the same rehabilitation protocol. In the first two weeks the patient was educated about their injury, taught pendular exercises and shown how to passively flex the arm within their pain tolerance as part of a home exercise programme. Between weeks two to four, the patient was progressed to full passive flexion and light functional exercises began. Progressive functional exercises were undertaken from week four. Patients were discharged when both the physiotherapist and patient thought that independent shoulder function had been achieved.

The primary outcome measure was the Constant shoulder score[10]. Since it was impossible to have a pre-injury Constant score both the fractured shoulder and the unaffected arm were measured and the ratio between the two calculated. Secondary measures were the SF-36 health survey[11] and the number of treatment sessions. The SF-36 as a measure of generic health in musculo-skeletal conditions is recommended by Gartsman et al[12] and Beaton et al[13] and the three dimensions that are considered most relevant to these conditions are: Physical Function, Role Limitation (Physical) and Pain. Its validity and reliability has been extensively tested[14,15]. The primary follow-up point was 16 weeks with secondary assessment points at 8 and 52 weeks. A blinded assessor reviewed patients during their follow-up clinic appointment or at home.

Statistical analysis. All analyses were completed on an intention to treat basis. Demographic and clinical data were compared between the two groups. The SF-36 scores were assumed to be continuous data. Mean Constant Scores and SF-36 dimension scores at 16 weeks follow-up were compared between Group A and B by two-independent samples t-tests. Ninety-five percent confidence intervals for the mean differences were also calculated. The Constant score and the SF-36 summary measure were analysed by calculating the area-under-the-curve (AUC) in which all follow up points were included e.g. 8, 16 and 52 weeks as suggested by Matthew et al[16] for serial measurements.

For the purposes of sample size calculation we assumed a mean difference between the two groups of ten points in the Constant shoulder scores at 16 weeks to be of practical importance. Also assuming a standard deviation of 15 points in Constant shoulder score indicated that to have an 80% power of detecting a mean difference of 10 or more points as statistically at the 5% (two-sided) level 36 subjects were required for each group.

Results

The baseline characteristics in each group are comparable (table I) and indicate successful randomisation. However, one difference was noted in the baseline and this relates to the number of males allocated to each group (Group A:11, Group B:5). To check for any possible influence on the result, gender was included as a separate variable in linear regression analysis. Gender did not influence the result when the Constant score at 16 weeks is used as the dependent variable ($p < 0.84$).

Of the original 86 patients (Group A-44, Group B 42) in the study, three patients from Group A were lost to follow-up (one died, one moved area and one was too ill to be assessed). In Group B, two patients were lost to follow-up as one moved area (seen at the 52 week follow-up point) and one withdrew from the review process.

The primary outcome was the Constant shoulder score at 16 weeks follow-up. Table I (and fig.1) shows that Group A had significantly better shoulder function at 16 weeks. When compared to the uninjured (normal) shoulder, the fracture side had 70% 'normal' function in Group A patients compared to only 54% in Group B. A mean difference of 16% (95% Confidence Intervals [CI]: 25% to 68%, $p = 0.001$).

Table II shows the results of the analysis of the SF-36. At 16 weeks Group A have significantly better health-related quality of life on two dimensions of the SF-36 (Role limitation physical, $p<0.02$ and Pain, $p<0.01$).

At 52 weeks the differences between the Groups had reduced and, although Group A still had greater shoulder function and less pain, there was no statistical difference when compared to group B at this single follow-up point. With analysis of area-under-the-curve (this is an overall measure formed by the total number of assessments to the 52 week period) Group A experienced less pain as measured with the SF-36 general health questionnaire (mean difference 486 CI 83 to 889, $p<0.01$) and improved shoulder function (mean difference in AUC 6.4 (95% CI: 2.5 to 10.5), $p< 0.002$). With regards treatment sessions, Group A had on average 9 treatments compared to Group B who had 14.

The only complication was one patient in Group B who developed a 'frozen shoulder' resulting in shoulder stiffness at the 52 week follow-up point. Despite this the patient continued to be followed up and included in the analysis of the results. No patient in either group developed a complication as a result of displacement of the fracture site.

Discussion

Although studies have been undertaken comparing early as opposed to later physiotherapy for minimally displaced two-part fractures of the proximal humerus, no study has previously evaluated the effects of starting physiotherapy within one week of the injury.

Clifford[17] in his study noted that the time spent in a sling was a significant factor in determining the final result. Koval[18] reported that patients starting rehabilitation before 14 days had greater shoulder function at an average follow-up time of 41 months. Bertoft et al[19], however, comparing physiotherapy beginning at one or three weeks found no differences between shoulder function in either group and concluded that patients could be immobilised for three weeks without affecting the long-term outcome.

Shoulder function, as measured with the Constant Score, is greater in Group A, compared to Group B, at the 8 and 16 follow-up points. The difference exists at 52 weeks, but this does not reach statistical significance. However, this difference, in favour of shoulder function in Group A, probably represents an important clinically significant difference and should not be ignored. When all follow-up points are included in the analysis, the overall Constant score is, once again, higher in the immediate physiotherapy group (Group A).

In our study the SF-36 scores at 16 weeks show that patients in Group A (fig 1) had less pain and experienced less problems with work and other activities as a result of immediate mobilisation. Group A continue to experience less pain than Group B when data is analysed from the whole follow-up period (8, 16 and 52 weeks). Kristiansen et al[20] stated that patients had less pain when moved at one compared to three weeks, but no difference was measured after six months. This is the first study to report that patients starting physiotherapy earlier experience less pain over a 52 weeks period. Although initial immobilisation is often advocated in order to allow the acute pain of the fracture to settle[21], our results suggest that this delay might actually prolong their pain.

Several authors have shown that fracture healing is enhanced by the introduction of micro-movement[22-24] and recent clinical trails with colles[25,26] and ankle[27] fractures demonstrated a faster return to function with an accelerated rehabilitation programme without any complications. The addition of micromovement has usually involved the application of gravity in the lower limb. The influence of gravity is probably less important in the upper limb in generating these micro-movements, but Gardner et al[28] showed that muscle activity could produce a force five times greater than those produced by weight bearing. The fracture healing around the head of humerus could conceivably be improved by the early activation of the shoulder muscles.

The association between osteoporosis and the risk of a fracture to the proximal humerus is well documented[29,30]. In addition, patients who fracture their humerus are often in poor general health with reduced neuromuscular function[31]. Their chance of having a fracture of the femoral neck is increased and this risk is most evident in the first few years after the proximal humeral fracture[32]. The frailty of these patients leaves them susceptible to further injury and it is therefore important that they are rehabilitated as fast as possible. Immediate rehabilitation offers them the best chance of regaining function within the shortest possible time period. In addition this approach reduces the total physiotherapy requirement. It should be noted that even at 52 weeks full shoulder recovery is not achieved. The average improvement compared to the uninjured side is only 82 percent. Since a less satisfactory outcome results from initial immobilisation, we believe that early physiotherapy within one week of the proximal fracture is the treatment of choice for this common injury.

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Table I: Baseline characteristics of subjects

Factor	Group A (immediate)	Group B (delayed)
Number of subjects (male:female)	44(11:34)	42(5:36)
Mean Age (SD)	70.7(12.5)	69.6(11.6)
Mean body mass index (SD)	26.8 (5.4)	25.4 (4.7)
Side of fractured limb (left:right)	25:19	24:18
Dominant hand (left:right)	5:40	6:35
Mechanism of fall:		
from floor height (%)	33(73.3)	25(60.5)
from chair height (%)	11(24.4)	10(25.6)
other (%)	1 (2.2)	6 (14.6)
Mean number of treatment sessions(SD)	9(6)	14(9)

Table 2: Constant shoulder score results

	8 week follow-up		16 week follow-up				52 week follow-up					
	Mean (SD)		*Mean (SD)*		*Mean difference (95% CI)*	*p-value for difference*	*Mean (SD)*		*Total area under curve (SD)*		*Mean Difference (95%CI)*	*p-value for differen ce*
Group A (< 1 week)	***n=43***	***0.57 (0.26)***	***n=42***	***0.70 (0.21)***	***0.16 (0.68 to 0.25)***	***0.001***	***n=41***	***0.82 (0.23)***	***n=41***	***34.6 (9.5)***	***6.4 (2.5 to 10.5)***	***0.002***
Group B (at 3 weeks)	***n=40***	***0.39 (0.19)***	***n=40***	***0.54 (0.20)***			***n=41***	***0.75 (0.25)***	***N=40***	***28.2 (8.6)***		

Mean Constant scores represent the ratio between the fractured with the unaffected side ie a score of 1.0 represents an equal shoulder score.

Appendix VIII (ii). Rehabilitation after two-part fractures of the humerus: 2-year follow up (Shoulder & Elbow Surgery Journal-*in press*)

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Key words: Two-part fracture, proximal, humerus, physiotherapy, rehabilitation, osteoporosis, shoulder, randomised controlled trial, shoulder disability

Rehabilitation of Two-part Fractures of the Neck of Humerus (Two Year Follow-up)

Abstract

The two-year results of a randomised prospective controlled trial of minimally displaced proximal humerus fractures treated either by immediate physiotherapy (Group A) or following 3 weeks immobilisation (Group B) are reported.

At one-year shoulder disability, as measured with the Croft shoulder disability questionnaire, was found in 42.8% of patients in Group A and 72.5% in Group B ($p<0.01$). By two-years, shoulder disability in Group A remained unchanged (43.2%), but had reduced in Group B (59.5%). This difference was not statistically significant.

Immediate physiotherapy following a minimally displaced proximal humerus fracture results in faster recovery with maximal functional benefit being achieved at one year. Delayed rehabilitation by 3 weeks shoulder immobilisation produces a slower recovery which continues for at least 2 years from the time of injury.

Introduction

Fractures to the proximal humerus are common injuries which occur most frequently in the elderly population[1] and in women[2,3]. With the recent census[4] reporting that the number of people in the UK over the age of 60 is now greater than those under 16 years of age, the problems of managing this type of fracture are expected to increase.

Previous studies have reported excellent results following minimally displaced (Neer Group-1) fractures to the proximal humerus [5-7]. However, all these studies are retrospective with different follow-up times and used assessment criteria based mainly on impairment measures, i.e. range of movement, strength and radiographic appearance. Although impairment gives useful information regarding the patients' progress following injury, research has shown that the assessment of disability (self reported measure of functional status) gives additional information [8] and may be more sensitive to clinical change [9].

Evaluating disability allows the clinician to quickly assess the function of the arm and recognises the interdependence of the wrist, elbow and shoulder in every day tasks. No previous prospective study has investigated recovery of shoulder function at 2-years following minimally displaced proximal humeral fractures. Thus, the aims of this research were to evaluate shoulder function in this group of patients and to determine whether immediate mobilisation following injury produces greater long term functional benefit than could be achieved by an initial period of 3 weeks immobilisation.

Materials and Methods

A randomised prospective controlled trial of minimally displaced proximal humerus fractures treated either by immediate physiotherapy or following 3 weeks immobilisation, commenced in October 1998. Patients of either gender, and over the age of 40 years were recruited. The only exclusion criteria were an inability to understand written or verbal information. The one-year results of immediate and delayed rehabilitation have already been published [10] and this study follows those patients to the two year follow-up point using the same methodology.

Following informed consent, 86 patients presenting with two-part proximal humerus fractures (Neer type 1) were randomly allocated to one of two groups: Group A (n=44) received immediate physiotherapy following their injury and Group B (n=42) started physiotherapy after 3 weeks immobilisation with a collar and cuff. The Neer type 1 fracture was defined as no segment displaced more than 1cm or angled greater than 45 degrees [11].

Both groups had the same physiotherapy programme aimed at restoring maximum function within the pain tolerance of the patient. The physiotherapy protocol was divided into three sections: early management (0 to 2 weeks) included education, prevention of inappropriate shoulder movement patterns, passive shoulder flexion and abduction up to 90 degrees (within or not increasing the patients pain), pain control with heat or ice and gravity assisted pendular exercises. Intermediate management (2 to 4 weeks) added supervised passive shoulder exercises in supine and light functional exercises (without exacerbating pain). Late management (4 to 8 weeks) progressed to full activity against gravity, isometric rotator cuff muscle activation and passive stretching of any remaining soft tissue tightness.

Patients were discharged when both the physiotherapist and patient judged that independent shoulder function had been achieved. Review, however, continued at 2, 4, 12 and 48 months following their injury. Most patients (88%) were discharged within 4 month of starting treatment by the physiotherapist. Group A (immediate) had on average 9 and Group B (delayed) 14 physiotherapy sessions.

Shoulder disability was evaluated with the Croft shoulder disability questionnaire (CSDQ) [12] at both one and two years. This comprised 22 questions that require a 'yes' or 'no' answer to a series of upper limb functional tasks and is based on 11 of the 12 disability categories in the Functional Limitations Profile. A score of zero indicates no shoulder disability; whilst a score of 5 or more indicates a significant level of shoulder disability. The questionnaire is self-administered and has been tested for its validity and reliability [12]. Within this study, shoulder disability is defined as the self-reported loss of shoulder function in everyday tasks that the patient experiences.

The Mann-Whitney test (statistical significance set at 5%) was used to assess the outcome in the two groups.

Results

From the original 86 patients who entered the study, 74 remained at the two-year review. Group A (immediate) lost 7 patients and group B (delayed) lost 5 patients to follow-up, leaving 37 patients for assessment in both groups. Three patients died during the follow-up period, two had moved area and seven failed to complete the Croft shoulder disability questionnaire.

At one year Group A had 18 (42.8%) patients reporting shoulder disability compared with 29 (72.5%) in Group B ($p<0.01$). By Year 2, shoulder disability in Group A remained constant at 43.2% (16 patients) whereas in Group B disability had reduced to 59.5% (22 patients). At 2 years the number of subjects scoring 5 or more (i.e. significant shoulder disability) on the disability questionnaire was 12 (32.4%) and 13 (35.2%) in Group A and B, respectively.

Seventy-four patients assessed at 2 years, 42.0 % (31 patients) reported continued problems with heavy lifting and 32.4% (24 patients) dressing difficulties. When the individual scores were evaluated, patients in Group B reported nearly three times more pain on movement, twice as many problems at night with changing position and disturbances in sleep compared with Group A.

Discussion

This is the first prospective study to measure shoulder disability over a two-year period for this type of injury. The level of shoulder disability in Group A (immediate physiotherapy) was less at both one and two years compared to Group B (delayed physiotherapy). The difference was statistically significant ($p < 0.01$) at year one, and although this is not maintained at two years, the trend for greater disability at 2 years probably represents an important clinical difference. These results highlight the importance of early rehabilitation in these patients, since a delay in physiotherapy of only 3 weeks produces changes that remain at two years.

The level of shoulder disability in the group receiving immediate physiotherapy (group A) did not change between year one and two (42.8% versus 43.2%) indicating that the maximum functional recovery was reached by the end of year one. However, Group B (delayed) continued to improve between year one and two (72.5% versus 59.5%), suggesting that they had not achieved full recovery and continued to improve for at least until two years after the initial injury. This difference has important implications with regards function and quality of life for patients who are often elderly at the time of their proximal humerus fracture. Patients who fracture their humerus are reported to have poor neuromuscular status with decreased bone mineral density [13]. Any further compromise to their independence could be detrimental to their general health.

At 2 years a third of all patients (Group A 35.2% and Group B 32.4%) continued to have problems with five or more functional tasks (problems with dressing, household tasks, lifting, shopping and restriction in arm movement due to pain). This represents significant levels of shoulder disability and casts doubts on the generally held belief that patients with this type of injury make an excellent or good recovery at 1 year [5, 6] [7]. This difference compared with other studies may be due to the fact that this is a prospective rather than retrospective study and has the longest reported follow-up of patients with this type of injury. Additionally, the Croft shoulder disability questionnaire measures more functional tasks than has been reported in other studies [14] and as such is more sensitive measure of the patients functional capability.

Our research would indicate that following minimally displaced two-part proximal humerus fractures patients who receive immediate physiotherapy achieve a faster recovery which is normally maximal by one year. By contrast, if the shoulder is immobilised for 3 weeks, rehabilitation is slower and recovery is likely to continue for at least two years.

The research was funded following a grant from the Trent Research Scheme. No benefits in any form have been received from a commercial party related directly or indirectly from this study. I would like to thank Julie Harris for her continual help in conducting this research

Table I: Patient Characteristics at 2 Years

Follow-up	**2 Years**	
Factor	**Group A (immediate)**	**Group B (delayed)**
Number of subjects (male:female)	37 (8:29)	37 (5:32)
Mean Age (SD)	68.6 (12.2)	68.2 (11.4)
Mean body mass index (SD)	27.2 (5.5)	25.2 (4.9)
Side of fractured limb (left:right)	21:16	20:17
Lost to follow-up (male:female)	7 (2:5)	5 (0:5)

Table II: Total shoulder disability at 1 and 2 years

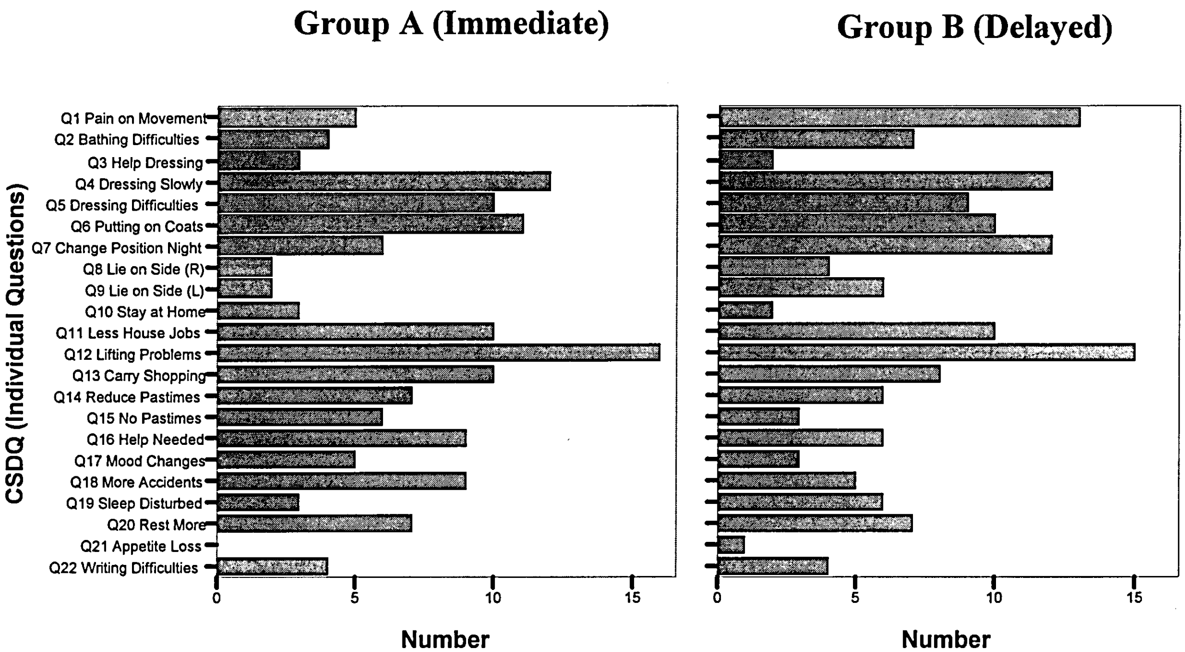
Follow-up point	Group A (immediate)	Group B (delayed)	Follow-up rate (%)
1 Year	42	40	82 (95)
2 Year	37	37	74 (86)

Table III: Shoulder disability by group allocation

Follow-up point	Croft Shoulder Disability Score		
	Score	Group A (immediate)	Group B (delayed)
1 Year	Nil	24 (57.2%)	11 (27.5%)
	1to 4	5 (11.9%)	12 (30.0%)
	5 or more	13 (30.9%)	17 (42.5%)
	Total Disability	**18 (42.8%)**	**29 (72.5%)** *
2 Year	Nil	21(56.8%)	15 (40.5%)
	1to 4	4 (10.8%)	9 (24.3%)
	5 or more	12 (32.4%)	13 (35.2%)
	Total disability	**16 (43.2%)**	**22 (59.5%)**

* denotes statistically significant at p<0.01

Figure I: Bar chart showing Croft Shoulder Disability Questionnaire (CSDQ) scores for each question at 2 year follow-up.



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Appendix VIII (iii). Rehabilitation of Proximal Humeral Fractures: Review

Proximal Humerus Fracture Rehabilitation

Running title: Proximal Humerus Fracture Rehabilitation

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The author certifies that he has no commercial associations that might pose a conflict of interest in connection with the submitted article.

The author certifies that his institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research, and that informed consent was obtained.

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Abstract

The occurrence of proximal humerus fractures will continue to rise with the increasing elderly population. Many patients with proximal humerus fractures are osteoporotic and have poor neuromuscular control mechanisms. This predisposes them to future falls and additional fractures. Patients continue to experience shoulder problems as a result of the fracture for many years after the injury. Rehabilitation is central to addressing the problems caused by the fracture. The review of the literature on proximal humerus rehabilitation suggests that treatment must begin immediately if the harmful effects of immobilization are to be avoided. Electrotherapy or hydrotherapy does not enhance recovery and joint mobilization has limited evidence of its efficacy. In the UK most patients are routinely immobilized for 3 weeks or longer and are referred for physiotherapy. The best available evidence for shoulder rehabilitation emphasizes using advice, exercise, and mobilization of limited joints to restore upper limb function. Placing controlled stresses throughout the fracture site at an early stage will optimize bone repair without increasing complication rates. This approach requires cooperation between the referring surgeon and therapist, and will optimize the patient's shoulder function and maintain their functional independence.

Level of Evidence: Therapeutic Studies- Level II

Introduction

Proximal humerus fracture rates will continue to increase with the ageing population[5-7,58] and the concomitant rise in osteoporosis.[50] These fractures can cause prolonged and severe disability and are often underestimated when compared with hip fractures.[25] This will further increase the demands on health providers and some suggest that society faces an epidemic of fractures in the elderly population.[21] Patients who have proximal humerus fractures are often in poor general health [37] and have an increased risk of sustaining a future hip fracture [41]. Most proximal humerus fractures are a result of minor trauma. [57]

The term "rehabilitation" is used in its widest sense and is defined as, "…restoration either of function or role (within the family, social network or workforce)." [54] The aim of rehabilitation should be to reestablish normal shoulder function, [30] recognizing the functional interdependence of joints and soft tissues in the upper quadrant when treating dysfunction of the shoulder.[4]

The literature review will only include prospective studies for proximal humerus fractures in which conservative management and rehabilitation is advocated. [52]. Surgery is suggested for the more complex fractures, [53] but in two retrospective reviews [19,68] the authors found no difference in outcome between patients who had surgery or conservative management. This evidence suggests that rehabilitation may have a greater role in more complicated fractures; however, that is outside the scope of our study.

Specific evidence for proximal humerus fracture rehabilitation is sparse, which makes recommendations difficult. Research from other common shoulder problems and recently published data by the author [33] are included in the rehabilitation section to make recommendations for proximal humerus rehabilitation.

How patients are rehabilitated is influenced by the referring surgeon, and any period of immobilization before rehabilitation will influence recovery. Immobilization remains central in the management of the proximal humerus fracture. Few studies [40,33] have investigated the optimum period of immobilization or when rehabilitation should start. This review presents unpublished survey findings for the UK (2002) on the use of immobilization and the timing of rehabilitation.

The effect of upper limb fractures on functional tasks continues for many years years, [48,66] especially in older patients. Long-term evaluation is needed to accurately assess the efficacy of rehabilitation. Most studies report up to 1 year or less [19,20,34,43] after the fracture and only one includes a 2 year followup.[40] Future long term evaluation will identify problems still experienced by the patient, and highlight the issues that must be considered when planning a rehabilitation program. Our recommendations for proximal humerus fracture rehabilitation (and future research) ensure that the surgeon and therapist remain central to this process.

The primary aim of the literature review is to determine the optimum rehabilitation program for conservatively managed proximal humerus fractures based on current research evidence. Fundamental to this question is the role of immobilization in managing these fractures and the secondary aim is to establish if immobilization is necessary for these fractures before rehabilitation starts. The survey aims to establish current clinical practice in the rehabilitation of two part proximal humerus fractures in the UK. The objectives are: (1) Are patients routinely immobilized following a two-part proximal humerus fracture? (2) If, so for how long? (3) When are patients referred for rehabilitation?

Materials and Methods

Literature Review

All prospective studies in the rehabilitation of proximal humerus fractures that were managed conservatively were included in the search. The following databases were included in the search strategy: MEDLINE (1980-2005), CINAHL (1982-2005), PEDro (1990-2005) and National Research Register (UK). The search was completed in February 2005. The search terms included: (1) humer*,

(2) fract*, (3) proximal, (4) shoulder, (5) physiotherapy, (6) physical therapy, (7) rehabilitation. From the search, 8 [33, 36, 40, 43, 45, 56, 59, 67] studies were included in the review.

Survey

In 2002, 70% of hospitals in the UK with trauma and orthopaedic centers were sent questionnaires (appendix I). The questionnaire was completed by the senior physiotherapist working in proximal humerus fracture rehabilitation. A stratified random sample of each health region in the UK was obtained using random number tables. One hundred and thirty-nine questionnaires were sent; 127 questionnaires were returned (response rate, 91%).

RESULTS

Literature Review

The general standard of the studies was low with variable outcome points, unreliable outcome measures and lack of detail regarding the rehabilitation programs.

The only study [43] that compared the use of electrotherapy in proximal humerus rehabilitation reported no difference in outcome at 6 months. Similarly, patients gained no benefit by self training and the addition of hydrotherapy [56] compared with self training alone.

Lundberg et al [45] and Solem-Bertoft et al [59] compared conventional physiotherapy with independent exercises and reported no difference between groups at 12 months. Both were small studies (n=42 and n=20 respectively) with no reliable outcome measure, but does challenge the assumption that all patients need referral for physiotherapy.

Two studies have compared different periods of immobilization before starting physiotherapy. [40, 33] Researchers [40] comparing 1 or 3 weeks immobilization reported no difference between groups at 12 months, but those immobilized for only 1 week reported less pain during the first 3 months. This observation is supported by Young and Wallace [67] who found that patients starting physiotherapy earlier had better shoulder function and required less treatment sessions. In the only study comparing no immobilization with immobilisation for 3 weeks [33] before physiotherapy, the patients starting treatment within 1 week of their fracture reported less pain and greater shoulder function at 16 weeks and 1 year.

In the only study investigating the role of joint mobilization [36] in the rehabilitation of proximal humerus fractures, patients regained full shoulder function with 1 month of the injury by the use of joint mobilization. This was a small study (n=14) and did not include a control group, but its findings suggest that adding joint mobilization to a rehabilitation program can help regain shoulder movement.

UK Survey (appendix II)

Of the 127 centers, 73 (57%) always used immobilization and 26 (20%) sometimes immobilized proximal humerus fractures. The period of immobilization varied from 1–7 weeks. The most common period of immobilization was 3 weeks (55%). There were 103 centers (81%) that routinely refer patients for physiotherapy. Most were referred (105 patients, 88%) within 3 weeks.

Discussion

From the available evidence it is only possible to reach certain conclusions about the optimum rehabilitation program for proximal humerus fractures. The overall quality of the studies is poor and "…there is insufficient evidence from randomized trials to determine which interventions are most appropriate." [29] This section discusses the available evidence for modalities (eg, electrotherapy and hydrotherapy), exercise, and mobilization and incorporates research in other areas of shoulder rehabilitation to the reviewed literature. Increasingly, shoulder rehabilitation studies favor programs based on advice, exercise, and joint mobilization.[4, 10] This work is included to develop an approach for proximal humerus fracture rehabilitation.

There is no evidence for the inclusion of electrotherapy in rehabilitation programs, specifically to proximal humerus fractures,[43] other shoulder conditions,[61-63] or for pain relief.[26] The passive nature of electrotherapy might actually slow recovery when a more active, engaging approach is required.[11] Patients with rotator cuff disease receiving an exercise based approach improved considerably despite having a failed physiotherapy program that included electrotherapy.[10] The use of hydrotherapy [56] in proximal humerus fracture rehabilitation produced no improvement in shoulder function, but more research is needed to test the efficacy of hydrotherapy. Several studies [26,43,61] have failed to support the use of electrotherapy in a range shoulder problems and its value in proximal humerus fracture management is questionable.

Therapeutic exercise and joint mobilization are axiomatic to physiotherapy practice, but most interventions in shoulder pain are limited to electrotherapy. In two systematic reviews of interventions for shoulder pain, [61,31] only six studies that included exercise or mobilization met the inclusion criteria out of a possible 51 trials. Exercise is not used exclusively in research programs as it is combined with education, advice, pain control and a graded home exercise program. [10,28]

When exercise was compared with surgery in the treatment of rotator cuff disease, [10] the results in both groups were superior to the placebo group. The exercise program aimed to normalize neuromuscular patterns and a graded increase in resistance to the rotator cuff and scapular stabilizing muscles. Exercise was equally effective as surgery at 2.5 years followup.[10] More people in the exercise group remained at work (80% versus 59%), suggesting that patients maintained their exercise program.[10] Patients given a supervised exercise program for shoulder pain [32] had better improvement at 6 months compared with an injection, but also had fewer consultations with their General Practitioner. From this evidence it appears that exercise programs give the patient greater control of their condition and promote independence.

Following a proximal humerus fracture, changes in the neuromuscular patterning of the shoulder are common as stiffness in the glenohumeral joint results in compensatory movement in the shoulder girdle. Research has identified excessive scapular vertical movement in patients recovering from unilateral upper limb disorders.[3] Early restoration of normal neuromuscular shoulder patterning is paramount in preventing secondary problems and this can be achieved by verbal instruction. [3] Furthermore, the exercise program should address the contribution of the entire body to the control of the shoulder [28] as part of the kinetic chain model.[49]

When joint mobilization is used to accelerate shoulder movement following proximal humerus fractures [36], 11 of 14 patients achieved 90° of abduction within the first treatment session (all started rehabilitation within 14 days post injury). All patients had full active flexion by 27 days.[36] This suggests that mobilization might limit the effects of shoulder stiffness. Not all proximal humerus fractures require joint mobilization, but certain patients might benefit from this approach. No study has evaluated the addition of joint mobilization with proximal humerus fractures. One study [4] suggested combined treatment (mobilization plus exercise) showed better improvement in pain and strength compared to exercise alone. Likewise, in shoulder impingement syndrome, [18] improvements have been reported in pain and range of motion with the addition of joint mobilization. These are relatively small studies with limited followup, but their results suggest that the addition of joint mobilization to an exercise program gives added benefits. Patients with proximal humerus fractures might benefit from this approach.

Immobilization for pain relief [1], [8] or to allow the head and shaft to move as one [52] is often recommended for management of proximal humerus fractures before starting rehabilitation The period of immobilization is about 3 weeks, but up to 7 weeks or longer is not uncommon. Patients who were immobilized for 3 weeks before starting physiotherapy [33] experienced more pain and reported slower recovery of shoulder function (fig 1) when compared with patients that had immediate physiotherapy. From this evidence, immobilization for 3 weeks or longer provides no benefit to the patient and only delays the rehabilitation process. Its routine practice must be questioned.

In the survey, only 20% (26 of 127 patients) of patients were not routinely immobilized, but no clear indication was given for the selection of those not needing immobilization. Considerable variation existed between and within hospitals. The variation in managing proximal humerus fractures was evident from the survey and highlights the lack of research evidence when making clinical decisions.[29] The survey was completed by the physiotherapist and only represents an overall representation of all proximal humerus management in one trauma center. This represents a limitation in the survey and a more detailed evaluation of practice is needed.

Two studies not included in the literature review have reported that the less time spent in a sling appeared to correlate with speed of recovery and restoration of function.[17,39] However, Kristiansen et al [40] found no difference in outcome between 1 or 3 weeks immobilization, although their measure of shoulder function remains untested. Hodgson et al [33] measured a difference in outcome between immediate and delayed physiotherapy, but used a range of outcome measures that gave a more in depth evaluation of shoulder function, pain and general health status.

Early referral to physiotherapy without immobilization appears to accelerate recovery by reducing pain and shoulder stiffness, which contributes to long-term functional loss. Fear of pain will affect behavior and neuromuscular function.[65] Limiting immobilization will reduce this fear if the patient learns to move the limb with early rehabilitation. Shoulder function will be further limited if patients develop chronic pain, as this reduces agonist muscle activity and increases antagonist muscle activity.[44] Concerns that early movement across the fracture site could increase complication rates [8,1] were unfounded with 43 patients having immediate, graded return of shoulder movement, [31] but larger studies are required to provide a definitive answer. Early resumption of activity is promoted for the restoration of function, [12] and connective tissue consistently responds better to early movement than immobilization. [2,34,35] Rehabilitation should begin immediately for most patients. Immobilization might be necessary in the more complex fractures especially if vascular structures are compromised as avascular necrosis is not uncommon in these types of fracture [8]. There is some evidence that short periods of immobilization are acceptable [29], however, it is mostly unnecessary and only delays recovery.[33,29]

The survey results suggest that most proximal humerus fractures are routinely referred to physiotherapy, but some authors report that physiotherapy makes no difference to patient outcome.[45,59] However, both were relatively small studies and detailed measures of shoulder function were not included in the assessment.[45,59] Their findings must be viewed with some caution.

Lundberg's study [45] highlights the problem of what constitutes physiotherapy. Both groups had contact with a physiotherapist for advice and to recommend a home exercise program. Only one group attended the physiotherapy department for joint mobilization and supervised exercises. Physiotherapy in the rehabilitation of the proximal humerus fracture is a complex intervention that is based on advice and a home exercise program, aiming to give the patient control of their recovery. Education is important for any rehabilitation program, as it reinforces active coping strategies for daily functioning.[11] Patients remain fearful of a return to normal activities after a fracture, and positive messages help to strengthen their role in rehabilitation.[11] Joint mobilization and supervised exercises are only required when patients are not making the anticipated progress and additional help is needed. Many patients will only need advice and monitoring, requiring minimal input from a physiotherapist. Other patients with a high risk of developing long-term shoulder problems will need additional input and extended treatment.

Many authors report [51,53,40] that patients make an excellent recovery after the fracture, but the evidence is conflicting. Wildner et al [66] reported patients with upper limb fractures have ongoing problems up to 4 years after the initial injury. Patients at 1 year following 3 week immobilisation [33] only achieved 82% return of shoulder function compared with the normal shoulder. The long-term effects of a proximal humerus fracture are considerable and continue to impact on the patient and their caretakers for many years. Further long-term evaluation is needed to fully assess treatment efficacy in the proximal humerus fracture.

Referring all patients with proximal humerus fractures to physiotherapy might not be the best policy. Targeting certain vulnerable groups might maximize recovery against a single program that lacks specificity and fails to meet individual requirements. Patients should be routinely given advice, education, and an exercise program.

Rehabilitation Program

The rehabilitation program is based on available evidence and the protocol used in the Sheffield study [33] for early restoration of shoulder function. Rehabilitation consists of education, exercise, and joint mobilization (if necessary). Three phases of rehabilitation are described (appendix III): early (first 2 weeks), intermediate (2–8 weeks), and later (≥ 8 weeks).[33]

Early rehabilitation aims are restoring normal shoulder patterns and educating the patient in the benefits of early movement and maintaining their home exercise program. The patient is encouraged to move their arm and prevent compensatory movement in the shoulder girdle. Fear avoidance is limited by reducing the reliance on the sling and promoting early movement. Electrotherapy is not used and joint mobilization is only used if the patient is not achieving 90° abduction within the first three sessions. If necessary, passive movement is applied.[36] The head of the head of humerus is moved passively while keeping the fracture site stable. Many patients only require advice and a home exercise program at this stage. They will require monitoring, but do not need to attend for physiotherapy. Pain control is maintained with medication and heat or cold, depending on the patient's preference.

Progression to the intermediate stage is based on the patient's pain levels and functional ability. At no stage are patients encouraged to push through pain because this might place unacceptable stresses across the fracture site. Physiological movement is increased, and light functional exercises are encouraged that do not exacerbate pain. Proprioceptive exercises are given to improve shoulder control, and close chain exercises are started in the seated position and placing the hand on the wall (scapular plane). Closed chain exercises are progressed by balancing the hand on a ball against the wall. Activation of lateral rotation is started against gravity (side lying). Medial rotation is achieved by pressing the hand onto the stomach, but preventing inappropriate activation of pectoralis major. These are both progressed by the use of light weights or resistance band.

During later rehabilitation, active and resisted exercise is increased to regain full shoulder functional activity. The sling is usually discarded by this stage. If joint contractures persist, passive stretching is started in a controlled manner.

Disability increases with age [60] and sustaining a proximal humerus fracture increases the risk of having a hip fracture 11–16% [41] compared with a control population. Proximal humerus fractures are a result of minor trauma, [57] and the fall is commonly forward and directly onto the shoulder.[55] Patients' inability to break their fall with the upper limb is characteristic of proximal limb fractures and represents a significant loss in neuromuscular control mechanisms. The risk of future fracture is highest within the first 2 years of the injury, [66] and many patients with more complex problems will require a range of professionals to prevent further injury. The increased risk of future osteoporotic fractures must be recognized in this group, and fall prevention programs should be incorporated into long-term evaluation and treatment.

Developing rehabilitation programs that maximize upper limb function following a proximal humerus fracture is crucial because of the increasing elderly population. It is important to minimize the period before rehabilitation starts, inform the patient about their role in the process, and why movement is important. Reducing or stopping any period of immobilization requires trust between the referring surgeon and the therapist as there are concerns about aggressive exercise leading to fracture displacement and mal union.[8] Synovial joints require movement to maintain homeostasis, and the fracture relies on the stimulus of movement [13,27,38] to optimize the repair process.

The risk of a future hip fracture is higher after a proximal humerus fracture, and the mortality rate [9] is increased in this group of patients. Problems persist for many years after the fracture [66] as with other shoulder problems [23,46,64]. Patients do not spontaneously recover and many continue to live with chronic pain.[44] Pain in one area of the body is a risk factor for developing pain in other areas of the body.[22] After a proximal humerus fracture, patients learn to live with limitations in their upper limb function and rely on caretakers for support.[47] The sudden onset of shoulder problems resulting from a fracture can cause greater loss of function when compared with a gradually increasing problem in which the patient has time to adapt.[24] With a normal elderly population comprising approximately 21–34% of patients with shoulder problems,[14-16] proximal humerus fractures will only increase this percentage. Immediate rehabilitation that targets vulnerable groups offers the best approach for limiting future problems.

Patients with proximal humerus fractures often have poor neuromuscular status [37] and this is a risk factor for developing this type of fracture. [42] Any rehabilitation program must recognize these differences and tailor the program to the patients' needs. Some patients only require advice, an exercise program, and monitoring for a short period. Others need more long-term, structured rehabilitation that necessitates greater input from a therapist and possibly other professional groups.

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Appendix VIII (iv). Abstract (Published in AGILE 2001 No 2)

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Proximal Proximal Humerus
Abstract

Fracture to the proximal humerus is a common injury in the older person and its incidence is set increasing. Treatment of the fracture is usually by immobilising the patient (3 to 6 weeks) in a collar and cuff before active shoulder movement is encouraged. At this point the patient is usually referred for physiotherapy. The basis to this period of immobilisation is largely anecdotal and no previous study has investigated if a patient would benefit from immediate physiotherapy. The aims of the study were to investigate if a patient fracturing their humerus could be safely rehabilitated without a period of immobilisation and if this resulted in greater shoulder function.

Following ethical approval and informed consent, 86 patients (mean age 70.1, range 43-94) fracturing their proximal humerus (type-1 or minimally displaced fracture) were randomly allocated into two groups. Group A (n=44) began physiotherapy within 1 week of their fracture and Group B (n=42) started physiotherapy after 3 weeks immobilisation. The physiotherapy given was the same for both groups. Shoulder function was measured with the Constant Shoulder Score and the short form health survey (SF-36) measured generic health status. Blinded follow-up was at 8, 16 and 52 weeks.

At 16 weeks shoulder function was greater in group A, compared to group B ($p<0.01$). At 52 weeks group A had better shoulder function, but the difference was not statistically significant. In the analysis using the total follow-up points (area-under-the-curve analysis) group A had better shoulder overall function ($p<0.01$). In the SF-36 scores at 16 weeks, the pain and role limitation due to physical health dimensions were better for group A, compared to group B ($p<0.01$ and $p<0.05$, respectively). In the area-under-the-curve analysis group A reported less pain ($p<0.01$) over the 52-week period. One patient developed a 'frozen shoulder' in Group B and had residual problems at the 52-week follow-up. There were no complications in Group A.

These results indicate that patients fracturing their proximal humerus can safely begin physiotherapy within one week of their injury and this produces better shoulder function and less pain. These patients are often in poor general health and immediate physiotherapy offers them the best chance of regaining shoulder function.

(358 words)

Appendix IX: Publications, conference proceedings and posters

Appendix IX (i). Abstract & Presentation at the International Shoulder and Elbows Surgeons Conference (Washington, USA May 2-5 2004)

OBJECTIVES

To follow-up patients who fractured their proximal humerus two years ago and were recruited to a Randomised Controlled Trial (RCT) that began in 1998 in Sheffield, UK.

METHODS

Each patient was sent a shoulder disability questionnaire at 2 years following their original injury. The Croft Shoulder Disability Questionnaire (CSDQ) asks the patient to evaluate their shoulder function in response to 22 questions. A score of zero indicates no shoulder disability and a score of over 5 and over represents significant shoulder disability.

DESIGN

This forms part of an RCT involving 86 patients who fractured their proximal humerus (minimally displaced fracture) and were randomly assigned to receive either immediate (Group-A) physiotherapy (within 1 week of injury) or after 3 weeks immobilisation in a collar and cuff (Group-B). Both groups had the same physiotherapy programme based on maximising shoulder function within pain tolerance.

RESULTS

At 2 years 74 patients (86%) completed and returned the CSDQ. In Group-A, 16 (43.2) patients reported some level of shoulder disability compared with 22 (59.5%) in Group-B. At 2 years the number of subjects scoring 5 or more (i.e. significant shoulder disability) on the disability questionnaire was 12 (32.4%) and 13 (35.2%) in Group A and B, respectively.

CONCLUSIONS

This difference is not statistically significant, but the results suggest that patients continue to experience high levels of shoulder disability at 2 years following their original injury. Starting physiotherapy immediately after the fracture does not cause fracture complications and maximises the persons shoulder function, however a large percentage of patients in both groups continue to report some level shoulder disability. The excellent recovery reported by previous papers within 1 year of injury is not supported by these findings.

Appendix IX (ii). Conference proceedings published and presented at the Chartered Society of Physiotherapists Annual Conference (Birmingham, October 2001)

Timing of Physiotherapy in the Management of the Fractured Proximal Humerus: A Randomised Controlled Trial
Hodgson S, Stanley D & Mawson S

Timing of Physiotherapy in the Management of a Fracture to the Proximal Humerus: A Randomised Controlled Trial

Sheffield Hallam University

David Stanley, Consultant Orthopaedic Surgeon at Northern General Hospital, Sheffield

Sue Mawson, Senior Lecturer in Physiotherapy at Sheffield Hallam University

Sheffield Hallam University

Funding

- The Trent Research Scheme

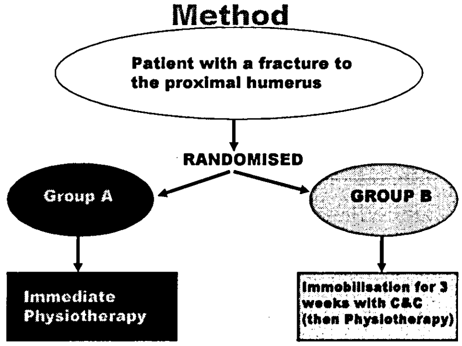
Background

- A body of evidence demonstrates that immobilisation is harmful
- Patients who fracture their proximal humerus are routinely immobilised (3-6weeks)

Aims of the study

- To investigate if immediate rehabilitation following fracture results in better shoulder function.
- To investigate if an immediate rehabilitation programme causes an increase in shoulder complications.

Method



Outcome Measures

- **Constant Shoulder Score (shoulder function)**
- **SF-36 Health Survey (General health status)**

Follow-up

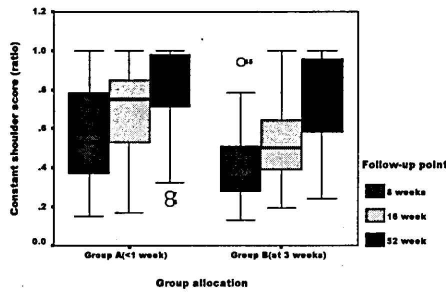
Blinded follow-up at 8,16 & 52 weeks

Baseline Characteristics

Factor	Group A (<1 week)	Group B (at 3 weeks)
Number of subjects (males:females)	44(11:34)	42(5:36)
Mean Age (SD)	70.7(12.5)	69.6(11.6)
Mean body mass index (SD)	26.8 (5.4)	25.4 (4.7)
Side of fractured limb (left:right)	25:19	24:18
Dominant hand (left:right)	5:40	6:35
Mechanism of fall: from floor height (%) from chair height (%) other (%)	 33(73.3) 11(24.4) 1 (2.2)	 25(60.5) 10(25.6) 6 (14.6)
Mean number of treatment sessions(SD)	9(6)	14(9)

Box plot: Constant Shoulder Score

at 8, 16 & 52 weeks.



Short Form SF-36 Health Survey

- **At 16 weeks**
  Role limitation (physical) and Pain dimensions statistically significant ($p < 0.02$ & $p < 0.01$, respectively).
- **At 52 weeks**
  Pain dimension statistically significant ($p < 0.01$)

Conclusions

Immediate rehabilitation:

- **Produces a rapid return of shoulder function**
- **Causes less pain**
- **Does not increase shoulder complications**
- **Results in less treatment sessions**

Discussion 1

- Recent survey of 150 hospitals in UK indicated that patients who fracture their proximal humerus are immobilised for 3-8 weeks
- Immobilisation varies considerably within and between hospitals

Appendix IX (iii). Poster Presentation at the International Study of Fracture Management Conference (Toronto, October 2002)

Two-part surgical neck of humerus fractures:
A Prospective, Randomised Controlled Trial Comparing Immediate and Delayed Rehabilitation (Two Year Follow-up)

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From: Sheffield Hallam University & The Shoulder and Elbow Unit, Northern General Hospital in Sheffield, England

[1]Senior Lecturer in Physiotherapy, Sheffield Hallam University

[2]Consultant in Orthopaedics and Trauma, Northern General Hospital

Introduction

Fracture of the proximal humerus is a common injury and accounts for approximately 4 to 5 per cent of all fractures[1-4]. The fracture incidence rises with age and accelerates over the age of 50 with women showing the greatest increase compared to men[5,6]. Before starting physiotherapy a period of immobilisation is often recommended[7,8] before rehabilitation is started.

This paper reports the results of a 2-year follow-up of patients recruited to a previously published study[9] conducted the Sheffield Central University Hospitals, United Kingdom. Eighty-six patients over the age of 40 years who sustained a fracture to their proximal humerus (Neer Type 1 or minimally displaced fracture) were randomly allocated to receive immediate physiotherapy (Group A) or delayed physiotherapy following three weeks immobilisation in a collar and cuff sling (Group B). Both groups had the same rehabilitation programme designed to maximise shoulder function using an educational programme, active home exercises and passive movement.

Method

To assess levels of shoulder disability long-term, patients were sent the Croft Shoulder Disability Questionnaire[10] at one and two years following their fracture. This is a 22 item self-administered questionnaire that asks the patient to answer 'yes' or 'no' to a series of activities that involve shoulder activity (see Appendex). A score of zero indicates no shoulder disability; a score of 5 or more indicates a significant level of shoulder disability[10].

Results

Eighty-six questionnaires were sent out at both Year 1 and 2. Eighty-two were returned at year 1 and 74 in year 2 (table 1).

Table 1: Total shoulder disability at 1 and 2 years

Follow-up point	Total number at follow-up	Lost to follow-up	Follow-up rate (%)
1 Year	86	4	95
2 Year	86	12	86

When the results are viewed by group (table 2 and fig 1), at one year Group A had 42.8% shoulder disability compared to 72.5% in Group B. By Year 2, shoulder disability in Group A remained constant (43.2%), but Group B decreased to 59.5%.

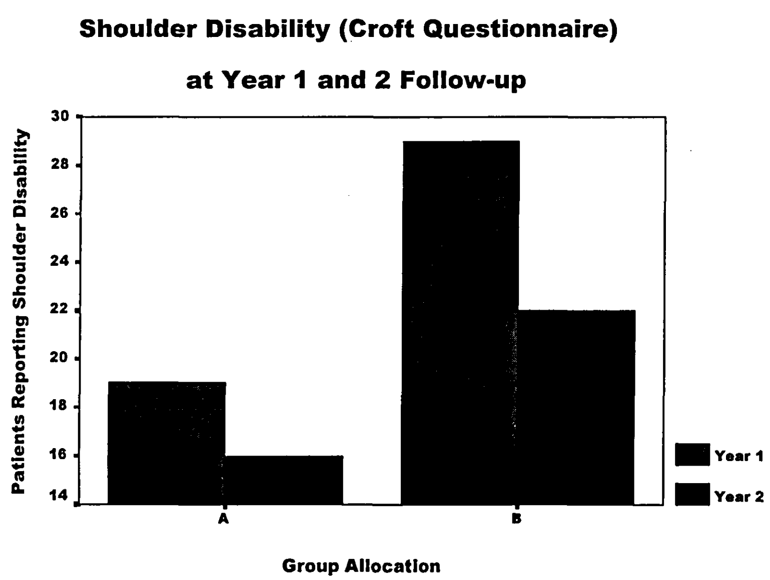
Table 2: Shoulder disability by group allocation

Follow-up point	Shoulder Disability Score		
	Score	Group A (immediate)	Group B (delayed)
1 Year	Nil	24 (57.2%)	11 (27.5%)
	1to 4	5 (11.9%)	12 (30.0%)
	5 or more	13 (30.9%)	17 (42.5%)
	Total disability	**42.8%**	**72.5% ****
2 Year	Nil	21(56.8%)	15 (40.5%)
	1to 4	4 (10.8%)	9 (24.3%)
	5 or more	12 (32.4%)	13 (35.2%)
	Total disability	**43.2%**	**59.5%***

** denotes that statistically significant at $p<0.01$

* denotes that not statistically significant at $p<0.163$

Figure 1: Level of shoulder disability at Year 1 and Year2 follow-up



Discussion

The patients who are not immobilised before starting rehabilitation have lower levels of shoulder disability compared to those who are immobilised for three weeks. This is only statistically significant at 1 Year, but the difference at Year 2 probably represents an important clinically significant difference. Overall, the total shoulder disability in both groups is 57.3% at one year and only reduces to 51.4% at Year 2. Patients who fracture their proximal humerus continue to have significant levels of shoulder disability two years after their injury. Previous research suggests that the majority of patients make an excellent recovery within one year of their fracture[11,12]; this research would challenge that assumption. Rehabilitation should be started immediately to minimise shoulder disability.

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Appendix X: Results

(i). Table 1: Independent Sample T-test of Study Variables

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means					95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Number of physio treatment sessions	Equal variances assumed	10.049	.002	-2.244	74	.028	-4.10	1.829	-7.747	-.459
	Equal variances not assumed			-2.293	67.643	.025	-4.10	1.790	-7.674	-.531
Body Mass Index	Equal variances assumed	1.543	.218	1.323	84	.189	1.438	1.0866	-.7229	3.5989
	Equal variances not assumed			1.328	83.261	.188	1.438	1.0830	-.7160	3.5920
Age	Equal variances assumed	.002	.961	.426	84	.671	1.11	2.606	-4.072	6.291
	Equal variances not assumed			.426	83.936	.671	1.11	2.601	-4.063	6.282
Number of falls	Equal variances assumed	.465	.497	.313	84	.755	.15	.494	-.827	1.137
	Equal variances not assumed			.319	53.831	.751	.15	.485	-.818	1.127
Disability score @ 1 yea	Equal variances assumed	3.907	.052	-.404	80	.688	-.44	1.079	-2.584	1.712
	Equal variances not assumed			-.406	76.023	.686	-.44	1.072	-2.571	1.699
Disability score @ 2 yea	Equal variances assumed	.777	.381	-.111	72	.912	-.14	1.219	-2.565	2.294
	Equal variances not assumed			-.111	71.775	.912	-.14	1.219	-2.565	2.295
Impairment score @ 8 weeks	Equal variances assumed	5.994	.017	3.497	81	.001	.1760	.05034	.07588	.27618
	Equal variances not assumed			3.533	77.539	.001	.1760	.04982	.07684	.27522
Impairment score @ 16 weeks	Equal variances assumed	.092	.763	3.457	80	.001	.1601	.04632	.06796	.25232
	Equal variances not assumed			3.458	79.900	.001	.1601	.04630	.06799	.25229
Impairment score @ 52 weeks	Equal variances assumed	.073	.787	1.590	80	.116	.0790	.04971	-.01991	.17796
	Equal variances not assumed			1.590	79.935	.116	.0790	.04971	-.01991	.17796

Appendix X: Results

(ii). Table 2: Regression modelling for Impairment score (CSS). Co-variates of Group allocation (Group A or B), level of deprivation (high or low) and gender.

Parameter Estimates

Dependent Variable	Parameter	B	Std. Error	t	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Impairment score @ 8 weeks	Intercept	.386	.086	4.508	.000	.215	.556
	[GROUP=1]	.175	.052	3.351	.001	7.116E-02	.280
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	-6.27E-03	.057	-.109	.913	-.121	.108
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	1.955E-02	.073	.267	.790	-.126	.165
	[GENDER=1]	0[a]	.	.	.	.	.
Impairment score @ 16 weeks	Intercept	.580	.079	7.352	.000	.423	.738
	[GROUP=1]	.161	.048	3.325	.001	6.444E-02	.257
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	-2.63E-02	.053	-.497	.621	-.132	7.915E-02
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	-2.78E-02	.068	-.412	.682	-.162	.107
	[GENDER=1]	0[a]	.	.	.	.	.
Impairment score @ 52 weeks	Intercept	.802	.083	9.634	.000	.636	.967
	[GROUP=1]	7.049E-02	.051	1.384	.170	-3.092E-02	.172
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	2.587E-02	.056	.464	.644	-8.528E-02	.137
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	-9.12E-02	.071	-1.281	.204	-.233	5.056E-02
	[GENDER=1]	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Appendix X: Results

(iii). Table 3. Constant Shoulder Score: Comparison at 1-year

Comparison between Groups of Constant Shoulder Score (Percentage scoring less than 0.9 at 52 weeks).

			Study group		
Impairment	No	Coun	A	B	Total
< 0.9 @ 52		% within score < 0.9 @ 52	60.0%	40.0%	100.0
		% within Study	58.5%	39.0%	48.8%
	Yes	Coun	17	25	42
		% within score < 0.9 @ 52	40.5%	59.5%	100.0
		% within Study	41.5%	61.0%	51.2%
Total		Coun	41	41	82
		% within score < 0.9 @ 52	50.0%	50.0%	100.0
		% within Study	100.0	100.0	100.0

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.124[b]	1	.077		
Continuity Correction[a]	2.392	1	.122		
Likelihood Ratio	3.144	1	.076		
Fisher's Exact Test				.121	.061
Linear-by-Linear Association	3.086	1	.079		
N of Valid Cases	82				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 20.00.

Appendix X: Results

(iv). Table 4: SF-36 Scores at 1-Year by Group Allocation

Group Statistics

	Group	N	Mean	Std. Deviation	Std. Error Mean
PF52	A	40	65.38	31.30	4.95
	B	40	68.38	30.18	4.77
RP52	A	40	60.00	44.14	6.98
	B	40	54.38	44.18	6.98
RE52	A	40	80.83	35.32	5.58
	B	40	68.33	42.67	6.75
SF52	A	40	78.61	26.56	4.20
	B	40	80.00	27.24	4.31
MH52	A	40	69.00	22.13	3.50
	B	40	70.70	18.75	2.96
EV52	A	40	55.38	26.95	4.26
	B	40	56.25	26.01	4.11
P52	A	40	69.17	27.16	4.29
	B	40	65.56	26.61	4.21
GHP52	A	40	63.05	19.18	3.03
	B	40	69.35	22.06	3.49

Appendix X: Results

(v). Table 5: CSS mean scores at 8, 16 and 52 weeks

Independent Samples Test

		t-test for Equality of Means						
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference Lower	Upper
CONDIF8	Equal variances assumed	3.497	81	.001	.1760	5.034E-02	7.588E-02	.2762
CONDIF16	Equal variances assumed	3.438	79	.001	.1612	4.691E-02	6.788E-02	.2546
CONDIF52	Equal variances assumed	1.454	79	.150	7.259E-02	4.991E-02	-2.68E-02	.1719

Appendix X: Results

(vi). Table 6: CSS difference between the groups

at 52 weeks. (Non-parametric analysis/Mann-Whitney test)

Test Statistics[a]

	CONDIF52
Mann-Whitney U	642.500
Wilcoxon W	1503.500
Z	-1.840
Asymp. Sig. (2-tailed)	.066

a. Grouping Variable: GP

Appendix X: Results

(vii) Table 7: Multiple Regression Analysis Variables. SF-36 (Pain dimension) and co-variates of Group allocation, Deprivation and Gender.

Parameter Estimates

						95% Confidence Interval	
Dependent Variable	Parameter	B	Std. Error	t	Sig.	Lower Bound	Upper Bound
SF36 Pain 0 weeks	Intercept	26.094	8.376	3.115	.003	9.405	42.784
	[GROUP=1]	7.381	5.174	1.427	.158	-2.927	17.690
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	3.352	5.626	.596	.553	-7.858	14.562
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	-6.954	7.155	-.972	.334	-21.212	7.303
	[GENDER=1]	0[a]	.	.	.	.	.
SF36 Pain 8 weeks	Intercept	53.470	6.939	7.706	.000	39.643	67.297
	[GROUP=1]	14.623	4.286	3.412	.001	6.082	23.163
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	1.422	4.661	.305	.761	-7.865	10.709
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	-3.785	5.928	-.638	.525	-15.597	8.027
	[GENDER=1]	0[a]	.	.	.	.	.
SF36 Pain 16 weeks	Intercept	66.433	7.093	9.366	.000	52.301	80.566
	[GROUP=1]	11.730	4.381	2.677	.009	3.001	20.460
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	11.120	4.764	2.334	.022	1.627	20.612
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	-17.024	6.059	-2.810	.006	-29.098	-4.951
	[GENDER=1]	0[a]	.	.	.	.	.
SF36 Pain 52 weeks	Intercept	81.470	9.278	8.781	.000	62.984	99.957
	[GROUP=1]	1.516	5.731	.264	.792	-9.903	12.935
	[GROUP=2]	0[a]	.	.	.	.	.
	[DEPUPLOW=1]	12.391	6.232	1.988	.050	-2.558E-02	24.808
	[DEPUPLOW=2]	0[a]	.	.	.	.	.
	[GENDER=0]	-27.730	7.926	-3.499	.001	-43.523	-11.937
	[GENDER=1]	0[a]	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Appendix X: Results

(viii). Table 8: Categorical Variables Codings

Binary Logistic main effects model (Outcome: Disability Score & Main effects: study group and gender)

Categorical Variables Codings

			Paramete
		Frequency	(1)
Study group	early	42	.000
	later	40	1.000
Gender	women	68	.000
	men	14	1.000

Appendix X Results

(ix). Table 9: SF-36 dimensions at 16 weeks follow up.

Statistics

		PF16	RP16	SF16	P16	RE16	MH16	EV16	GPH16
N	Valid	81	81	81	81	81	81	81	81
	Missing	191	191	191	191	191	191	191	191
Mean		69.57	51.23	82.59	66.20	75.32	72.64	55.43	65.02
Std. Deviation		24.254	43.464	24.849	21.137	39.725	19.157	22.751	19.715
Skewness		-.810	-.019	-1.384	-.180	-1.204	-.738	-.738	-.123
Std. Error of Skewness		.267	.267	.267	.267	.267	.267	.267	.267
Kurtosis		-.200	-1.771	.997	-.984	-.324	.659	.251	-.651
Std. Error of Kurtosis		.529	.529	.529	.529	.529	.529	.529	.529
Minimum		5	0	0	22	0	4	0	20
Maximum		100	100	100	100	100	100	100	100

Appendix X.

(x). Table 10: SF-36 dimensions at 52 weeks follow up. .

Statistics

		PF52	RP52	SF52	P52	RE52	MH52	EV52	GHP52
N	Valid	80	80	80	80	80	80	80	80
	Missing	192	192	192	192	192	192	192	192
Mean		66.88	57.19	79.31	67.36	74.58	69.85	55.81	66.20
Std. Deviation		30.589	43.971	26.738	26.775	39.421	20.396	26.319	20.778
Skewness		-.732	-.295	-1.312	-.482	-1.089	-.539	-.185	-.079
Std. Error of Skewness		.269	.269	.269	.269	.269	.269	.269	.269
Kurtosis		-.804	-1.720	.897	-.788	-.400	-.244	-.738	-.832
Std. Error of Kurtosis		.532	.532	.532	.532	.532	.532	.532	.532
Minimum		0	0	0	0	0	8	0	15
Maximum		100	100	100	100	133	100	100	100

Appendix X: Results

(xi.) Table 11: Reliability Data for the Constant Shoulder Score

Reliability Data: Constant Shoulder Score

Patient	**1st Measurement**	**2nd Measurement**	**Different between scores**	**Difference squared**
1	**73**	**65**	**-8**	**64**
2	**55**	**54**	**-1**	**1**
3	**59**	**65**	**6**	**36**
4	**29**	**29**	**0**	**0**
5	**47**	**50**	**3**	**9**
6	**48**	**37**	**-11**	**121**
7	**55**	**47**	**-8**	**64**
8	**26**	**34**	**8**	**64**
9	**39**	**45**	**6**	**36**
10	**59**	**62**	**3**	**9**
		Total	**-2**	**404**
		Mean diff	**-0.2**	**40.4**
		Stand Dev.	**6.7**	**13.3**

Within coefficient of variation: 13%

Appendix X: Results

(xii). Table 12: General Linear Repeated Measures Models: SF-36 and Impairment

Outcome	Week	Parameter estimates* and significance				
		Treatment: Immediate [Delayed]	**Gender: Female [Male]**	**Deprivation: Low [High]**	**Age**	**BMI score**
SF-36 Pain	0	7.38 [0.16]	-6.95 [0.33]	3.35 [0.55]	NA	NA
	8	14.62 ***[<0.01]***	-3.79 [0.53]	1.42 [0.76]	NA	NA
	16	11.73 ***[<0.01]***	-17.02 ***[<0.01]***	11.12 ***[0.02]***	NA	NA
	52	1.52 [0.79]	-27.73 ***[<0.01]***	12.39 ***[0.05]***	NA	NA
SF-36 Physical Function	0	-9.66 [0.09]	-10.25 [0.20]	7.25 [0.24]	-0.46 [0.06]	-0.60 [0.29]
	8	7.19 [0.15]	-5.55 [0.44]	12.97 ***[0.02]***	-0.88 ***[<0.01]***	-1.01 ***[<0.05]***
	16	2.32 [0.61]	-10.33 [0.12]	11.89 ***[0.02]***	-1.05 ***[<0.01]***	-0.93 ***[0.05]***
	52	-0.07 [0.99]	-14.37 [0.05+]	13.93 ***[0.02]***	-1.55 ***[<0.01]***	-1.49 ***[<0.01]***
SF-36 Role Physical	0	6.67 [0.06]	4.18 [0.41]	2.69 [0.49]	0.15 [0.36]	NA
	8	20.76 [0.02]	-18.03 [0.16]	0.71 [0.94]	-0.20 [0.63]	NA
	16	19.38 [0.04]	-23.85 [0.08]	17.87 [0.08]	-0.74 [0.08]	NA
	52	0.95 [0.91]	-35.18 ***[<0.01]***	11.65 [0.22]	-1.39 ***[<0.01]***	NA
SF-36 Role Emotional	0	4.61 [0.66]	-21.07 [0.15]	4.04 [0.35]	NA	NA
	8	21.02 ***[<0.01]***	-2.86 [0.78]	22.78 ***[<0.01]***	NA	NA
	16	8.06 [0.37]	-18.09 [0.15]	13.82 [0.16]	NA	NA
	52	11.07 [0.20]	-11.46 [0.34]	24.15 ***[0.01]***	NA	NA
Impairment score	8	0.18 ***[<0.01]***	0.02 [0.79]	-0.06 [0.91]	NA	NA
	16	0.16 ***[<0.01]***	-0.03 [0.68]	-0.03 [0.62]	NA	NA
	52	0.07 [0.17]	-0.09 [0.20]	0.03 [0.64]	NA	NA

Appendix XI: National UK Survey (2001)

Appendix XI (i). Supporting Letter

Dear colleague

I am a research physiotherapist conducting a study investigating the physiotherapy patients receive after sustaining a proximal humeral fracture. To help understand some of the issues surrounding the research I am sending a questionnaire to several hospitals in the United Kingdom. It would be most appreciated if you could find a few minutes to complete the attached questionnaire and return it to me in the stamped addressed envelope.

All answers will be treated with the utmost confidentiality and the hospital's name will not be included in the final report. If you require a copy of the findings please tick the following box:

I would like a copy of the findings sent to me ☐ (please include your name and address for sending the letter)
Name:

Address:

If you require further information please contact: Steve Hodgson (Research physiotherapist) on 0114 225 4431

Thank you for your help in completing this questionnaire.

Steve Hodgson

Questionnaire

The questionnaire concerns the management of the **minimally displaced (Neer type 1 classification) fractured** proximal humerus with patients over 40 years of age in your hospital.

1. Are patients who fracture their proximal humerus (minimally displaced fractures or Neer type 1) routinely immobilised?
Yes/No/Sometimes (please circle the best answer)
If you answered 'sometimes' please clarify your answer.

2. If these patients are immobilised, how long is this period? (if this period varies, please state the most common period of immobilisation and the range eg 4 weeks, range 3 to 8 weeks)
Period of immobilisation ....weeks
Range of possible immobilisation...weeks

3. Do patients receive physiotherapy
Yes/No/Sometimes

If you answered 'sometimes' please clarify your answer.

4. At what time following their fracture do patients attend physiotherapy?
....week(s)

5. Any other comments (please use the other side of the paper if you require further space)

Thank you

Appendix XI (iii). Follow-up Letter

Follow-up Letter (four weeks after first letter)

Dear Colleague

I am a Research Physiotherapist conducting a PhD study investigating the physiotherapy received by patients after sustaining a proximal humerus fracture. About a month ago I sent you a questionnaire requesting information regarding the management and rehabilitation of proximal humeral fractures in your hospital. Unfortunately, I have not received the completed form and am concerned that it might have been lost in the post or misplaced. If this were the case, I would be grateful if you could spare the few minutes to forward it to a member of your staff who treats patients with upper limb trauma, and return it in the stamped addressed envelope provided.

All information will be anonymised and treated with the utmost confidentiality. The name of the hospital will not be included in the final report. If you would like a copy of the findings please indicate this on the reverse of the questionnaire, giving the name and address for correspondence.

If you require further information please contact me on 0114 225 4431.

Thank you for your help in completing this questionnaire.

Yours sincerely

Steve Hodgson
Research Physiotherapist

Enc. Questionnaire
S.A.E.

Appendix XII: Patient Consent Form

PATIENT consent form

Place patient label here-
and on underneath page.

A CONTROLLED, RANDOMISED STUDY INVESTIGATING FUNCTIONAL OUTCOME, WITH EARLY AND LATE PHYSIOTHERAPY, ON PATIENTS FOLLOWING A FRACTURED PROXIMAL HUMERUS.

To be completed by the patient:

Have you read the information sheet about this study?	**YES/NO**
Have you been able to ask questions about this study?	**YES/NO**
Have you received answers to all your questions?	**YES/NO**
Have you received enough information about this study?	**YES/NO**
Who have you spoken to about this study?	Mr/Ms/Dr
Do you understand that you are free to withdraw from this study?	**YES/NO**
At any time	**YES/NO**
Without giving a reason for withdrawing	**YES/NO**
Without affecting your future medical care	**YES/NO**

Do you agree to take part in this study? **YES/NO**

Signed: Date:

Name *(Block Letters)*:

Doctor/ Physiotherapist

Witness

Appendix XIII: Patient Information Sheet

PATIENT INFORMATION SHEET

A CONTROLLED, RANDOMISED STUDY INVESTIGATING FUNCTIONAL OUTCOME, WITH EARLY AND LATE PHYSIOTHERAPY, ON PATIENTS FOLLOWING A FRACTURED PROXIMAL HUMERUS.

You are invited to participate in a clinical study to examine if beginning physiotherapy earlier or later following your fracture, influences your recovery.

" Why has my doctor asked me to take part in this study?"
Following a fracture to the shoulder, patients may experience long-term shoulder stiffness and limited function. Some studies have suggested that early physiotherapy, following the fracture, results in a better functional outcome for the patient. The possible benefits include less pain, faster return of function and less attendance at physiotherapy. The type of fracture you have sustained is unfortunately very common and the number of patients sustaining this fracture, are set to rise. Finding the most effective way of dealing with his problem will benefit patients and save money for the NHS.

"How long will the study last?"
24 months

"What will it involve?"
If you agree to participate in the trial you will be asked to attend the physiotherapy department within one or within three weeks. When you begin physiotherapy is the only difference in the study. You will receive physiotherapy at the Northern General Hospital and will be given treatment and shown a home exercise programme. All patients on the study will receive the same high quality of physiotherapy as any patient fracturing their shoulder.

"Are there any harmful effects from early physiotherpy?"
Patients do begin early physiotherapy now, but this is not common practice. There are no reported studies of patients experiencing increased problems, and some demonstrate an actual benefit with early physiotherapy.

"What tests will I receive and how often will I have to visit the hospital?"
Your progression during treatment will be assessed with a questionnaire (takes 7-10 minutes to complete) and a series of measurements of your shoulder movement and function. These tests are commonly used in the physiotherapy department (these do not involve invasive procedures). Re-assessment will be at the end of your treatment (8 weeks), and again at 4 and 12 months. If the later times do not correspond with your follow-up clinic appointments, you will be given travel expenses.

"What if I do not wish to take part?"
This will in no way affect your treatment.

"What if I change my mind during the study?"
You are free to withdraw from the study at any time without affecting your treatment.

"What will happen to the information from the study?"
All information will be entirely confidential. You will be informed of the results of the study if you wish although the full analysis will not be available for 2 years. Following completion of the study you will not be named in any publication or presentation.

"What if I have further questions"
You should contact: Mr S A Hodgson 0114 XXX XXXX

Appendix XIV

Table 1 : A comparison between United States of America population norms and norms for five common shoulder conditions(adapted from Gartman et al. 1998).

Dimension	U.S general population norms	Glenohumeral instability Average (SD)	Rotator cuff tear Average (SD)	Adhesive Capsulitis Average (SD)	Glenohumeral osteoarthritis Average (SD)	Impingement Average (SD)
Physical Functioning	84.2	71.3 (21.6)	56.9 (25.8)	67.2 (22.4)	57.5 (33.6)	62.9 (23.2)
Role Limitation (Physical)	81.0	24.7 (36.4)	26.8 (69.3)	34.5 (37.0)	41.0 (45.4)	29.8 (38.1)
Pain	75.2	36.8 (22.8)	29.9 (19.3)	37.6 (20.6)	36.6 (22.7)	35.0 (16.5)
General Health	72.0	72.0 (20.6)	67.9 (24.7)	70.2 (25.1)	71.7 (20.2)	70.4 (21.2)
Social Functioning	83.3	62.2 (28.5)	57.1 (31.9)	74.1 (29.2)	72.9 (33.8)	65.0 (26.9)

Appendix XIV

Table 2: Comparison of SF-36 health survey on major medical conditions (Adapted from Gartsman et al. 1998).

SF-36 Dimension	Hypertension	Heart Failure	Diabetes (type-2)	Myocardial Infarction	Clinical Depression
Physical Function	73.4	47.5	67.7	69.7	71.6
Role limitation Physical	62.0	34.3	56.7	51.4	44.4
Pain	72.3	62.6	68.5	72.8	58.8
General Health	63.3	47.1	56.1	59.2	52.9
Social Functioning	86.7	71.3	82.0	84.6	57.1