MONASH University

The effect of duration of immobilisation on function following surgical fixation of distal radius fractures in adults

Narelle Watson

MPhysio(Musc), BAppSc(Physio), BSc(Hons)

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Doctor of Philosophy at Monash University in 2017
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Abstract

Background

Distal radius fracture is common and affects physical and mental health. Surgical fixation was developed to facilitate fracture healing while permitting early mobilisation, but there is considerable uncertainty around the optimal immobilisation period. Best treatment would ideally also include reliable, standardised, evidence-based methods of classifying distal radius fractures and unambiguous treatment guidelines. The primary aim of this research was to investigate the effect of duration of immobilisation following open reduction and internal fixation for distal radius fracture and explore the patient experience of fracture, surgery, immobilisation and health service interactions. In addition this research assessed the accuracy of radiographic assessment procedures for acute distal radius fracture and the consistency in management decisions.

Method

Six investigations were conducted to (1) review the effect of duration of immobilisation on outcomes following surgical fixation for fracture in adults, (2) compare one, three and six weeks of immobilisation following open reduction and internal fixation for distal radius fracture, (3) assess accuracy in measurement of anatomical parameters underpinning treatment decisions, (4) assess consistency in treatment recommendations, and explore (5) participants' experiences following surgically managed distal radius fracture, and (6) interactions with the health system.

Results

The systematic review and meta-analysis found earlier mobilisation following surgical fracture fixation results in comparable or better short-term outcomes than later mobilisation. The randomised controlled trial found that, compared to mobilisation at six weeks, early mobilisation (one or three weeks) following open reduction and internal fixation for distal radius fracture results in comparable long term and superior short-term outcomes [function, active range of motion, pain]. Participant interviews highlighted challenges associated with wrist fracture, surgery and immobilisation. Opportunities were identified for improving the responsiveness and efficiency of care

provision through standardising information conveyed to patients and refining processes for pain management, education and patient engagement. Assessment of clinician accuracy for measuring radiographic anatomical parameters indicated that palmar tilt, ulnar variance and radial angle measurements may be useful for treatment selection, however, intra-articular gap and step appear unreliable. Investigation of the treatment recommendations made by health professionals for acute distal radius fracture indicate that decisions regarding unacceptable fracture alignment are not made using standardised principles. Palmar tilt and intra-articular gap were found to be the parameters typically considered in determining treatment, however, there was no evidence of standardised methods driving treatment choices.

Conclusions

The outcomes of this thesis inform and advance best practice in adult distal radius fracture management. This thesis strengthens the argument that mobilisation at one or three weeks following open reduction and internal fixation provides short-term advantages for function, active range of motion and pain. Participant reports indicated variable needs and the health service provided variable care, resulting in care frequently being suboptimal. Opportunities to improve our management of distal radius fractures include standardisation of factors underpinning treatment decisions, development of guidelines to standardise care provision and adoption of strategies to maximise patient engagement.

Keywords

Distal radius fracture, immobilisation, fracture management, wrist.

General Declaration

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

Signature: 

Print Name: Narelle J. Watson

Date: 22 September, 2017

Thesis including published works declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes one paper published in a peer reviewed journal, 2 papers under review (reviewed and revisions submitted) and 3 submitted publications. The core theme of the thesis is immobilisation following surgical fixation of distal radius fracture. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the student, working within the Faculty of Medicine, Nursing and Health Sciences under the supervision of Emeritus Professor Jennifer Keating.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research. In the case of Chapters 2, 4, 5, 6, 7 and 8 my contribution to the work involved the following:

Table of publications in thesis

Thesis chapter & section	Publication title	Publication status	Nature and % of student contribution	Co-author name(s), nature and % of co-author's contribution	Co-author(s), Monash student Y/N
2	The effect of duration of immobilization following surgical fixation of adult fractures: Systematic review and meta-analysis.	Submitted: International Orthopaedics	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication: 80%	Pile, R. assisted with data collection, and drafting of the manuscript 5% Trivedy, B. assisted with data collection, and drafting of the manuscript 5% Keating, J.L. contributed to the conception of the study, data analysis, and drafting of the manuscript: 10%	N N N
4	A randomized controlled trial comparing one, three or six weeks of immobilization on function and pain following open reduction and internal fixation for distal radius fractures in adults.	Under review (reviewed and revisions submitted): The Journal of Bone and Joint Surgery (JBJS)-American Volume	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication: 80%	Haines, T.P. assisted with data analysis and drafting of the manuscript: 5% Tran, P. contributed to the conception of the study, data collection, and drafting of the manuscript: 5% Keating, J.L. contributed to the conception of the study, data analysis, and drafting of the manuscript: 10%	N N N

Thesis chapter & section	Publication title	Publication status	Nature and % of student contribution	Co-author name(s), nature and % of co-author's contribution	Co-author(s), Monash student Y/N
5	Reliability of radiographic measurements for acute distal radius fractures.	Published: BMC Medical Imaging	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication: 80%	Asadollahi, S. assisted with data collection and drafting of the manuscript: 2.5% Parrish, F. assisted with data collection and drafting of the manuscript: 2.5% Ridgway, J. assisted with data collection and drafting of the manuscript: 2.5% Tran, P. contributed to the conception of the study, data collection, and drafting of the manuscript: 2.5% Keating, J.L. contributed to the conception of the study, data analysis, and drafting of the manuscript: 10%	N N N N N
6	Treatment decisions based on radiographs of acute distal radius fractures.	Submitted: Journal of Orthopaedic Research	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication: 85%	Tran, P. contributed to the conception of the study, data collection, and drafting of the manuscript: 5% Keating, J.L. contributed to the conception of the study, data analysis, and drafting of the manuscript: 10%	N N

Thesis chapter & section	Publication title	Publication status	Nature and % of student contribution	Co-author name(s), nature and % of co-author's contribution	Co-author(s), Monash student Y/N
7	The impact of wrist fracture, surgical repair and immobilization on patients: A qualitative study.	Under review (reviewed and revisions submitted): Clinical Rehabilitation	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication: 85%	Martin, S.A. contributed to the conception of the study, data analysis, and drafting of the manuscript: 5% Keating, J.L. contributed to the conception of the study, data analysis, and drafting of the manuscript: 10%	N N
8	Patient interactions with the health service following wrist fracture, surgical repair and immobilization: A qualitative study.	Submitted: Journal of Orthopaedic Research	Led the conception of the study and data collection, led data analysis & synthesis, drafted and prepared the manuscript for publication: 85%	Martin, S.A. contributed to the conception of the study, data analysis, and drafting of the manuscript: 5% Keating, J.L. contributed to the conception of the study, data analysis, and drafting of the manuscript: 10%	N N

I have renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Student signature: [redacted] **Date:** 22 September, 2017

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author I have consulted with the responsible author to agree on the respective contributions of the authors.

Main Supervisor signature: [redacted] **Date: 25/09/2017**

Acknowledgements

Completion of this thesis has involved many years of dedicated work and I have a number of people to thank for their contributions and support throughout this journey. Firstly I would like to thank the large group of participants who, during a time of injury and pain, agreed to involvement in this research with the aim of improving future care. I express my gratitude to all these participants as their engagement made this research possible.

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Finally I would like to thank Monash University for providing the supportive structures that have enabled the completion of this research.

List of publications

Publications by candidate incorporated into thesis:

Published

1. Watson N. J., Asadollahi S., Parrish F., Ridgway J., Tran P., Keating J. L. Reliability of radiographic measurements for acute distal radius fractures. *BMC Med Imaging.* 2016;16:44. (5 year impact factor = 1.621)

Under review (reviewed and revisions submitted):

1. Watson, N. J., Haines, T. P., Tran, P., Keating, J. L. A randomized controlled trial comparing one, three or six weeks of immobilization on function and pain following open reduction and internal fixation for distal radius fractures in adults. (*Journal of Bone and Joint Surgery-American Volume, 5 year impact factor = 6.11)*

2. Watson, N. J., Martin, S. A., Keating, J. L. The impact of wrist fracture, surgical repair and immobilization on patients: A qualitative study. (*Clinical Rehabilitation, 5 year impact factor = 3.026*)

Submitted

1. Watson, N. J., Pile, R., Trivedy, B., Keating, J. L. The effect of duration of immobilization following surgical fixation of adult fractures: Systematic review and meta-analysis. (*International Orthopaedics, 5 year impact factor = 2.631)*

2. Watson, N. J., Tran, P., Keating, J. L. Treatment decisions based on radiographs of acute distal radius fractures. (*Journal of Orthopaedic Research, 5 year impact factor = 2.982)*

3. Watson, N. J., Martin, S. A., Keating, J. L. Patient interactions with the health service following wrist fracture, surgical repair and immobilization: A qualitative study. (*Journal of Orthopaedic Research, 5 year impact factor = 2.982)*

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1. Chapter 1- Introduction

1.1 Overview

Distal radius fracture is a condition that affects all age groups and results in impaired ability to perform personal care, domestic duties and work tasks. For health services, the provision of efficient and effective management of distal radius fracture remains a challenge. Unravelling the complexities of distal radius fracture management has been the focus of research since the 1800s. The optimal time of immobilisation following open reduction and surgical fixation (ORIF) for distal radius fracture remains to be defined. This thesis contributes to the growing body of work exploring optimal management for distal radius fractures, and focusses on defining the relative advantages of different periods of immobilisation following ORIF for distal radius fracture in adults. The aim of this introductory chapter is to present an overview of information relevant to distal radius fracture: its epidemiology, risk factors, economic impact and the shift towards management with internal fixation. Randomised controlled trials (RCTs) exploring the impact of different periods of immobilisation following ORIF for distal radius fracture are reviewed. This chapter concludes with a brief description of the subsequent chapters in the thesis.

1.2 Background

1.2.1 Epidemiology of distal radius fracture

Distal radius fractures are common. Evidence of increasing incidence(1-3) indicates likely growth in the associated demand on future health care services. A 2009 American investigation using a representative national sample (87 million participants) found distal radius and ulna fractures were the most common upper limb fractures with an annual incidence of 162 per 100,000 persons.(1) A nationwide investigation in the Netherlands during the period 1997 to 2009 for older adults (aged 50 years or older) found a mean annual incidence of wrist fractures of 457.8 per 100,000 for females (95% CI, 434.9-480.7) and 100.4 per 100,000 for males (95% CI, 95.4-105.1).(4) Throughout the period of investigation, a significant increase in hospitalisation rate due to wrist fractures was observed. For the subgroup of females and males aged 50 and older, annual hospitalisation rates per 100,000

increased from 118 to 336 and 23 to 64 respectively.(4) In Australia, wrist fracture admissions to public and private hospitals in New South Wales were investigated between 1993 and 2003.(5) Consistent with the findings of de Putter et al (2013), hospitalisation rates for wrist fractures rose significantly over the period of investigation. For females and males aged over 50 years, the annual hospitalisation rates for wrist fractures per 100,000 increased from 227 to 266 and 44 to 63 respectively.(5)

1.2.2 Risk factors for distal radius fracture

Risk factors for distal radius fracture can be broadly grouped into age, gender, lifestyle and health conditions.

Age

MacIntyre et al (2016), following a literature review of risk factors for distal radius fracture, reported the incidence of adult distal radius fracture as higher for those older (compared to younger) than 50 years.(6) In the large American study, Karl et al (2015) found an exponential increase with age peaking at 254 per 100,000 for those over 65 years.(1) For males and females over 60 years, each 5 year increment in age has been associated with (respectively) a 1.6 and 1.3 fold increase in wrist fracture relative risk.(7)

Gender

Across all adult age groups, rate of distal radius fracture is higher for females than males. Reports of the gender imbalance vary from as high as a 5-times greater risk for females over 65 years(8) to the only slightly higher incidence for females (54.6%) reported by Karl et al (2015). On the other hand, distal radius fracture is reported to be higher for males between 19 and 49 years(9) but higher for females over 50 years.(7, 10)

Lifestyle

Involvement in sporting activities and motor vehicle accidents are common causes of distal radius fractures in young adults.(6) In contrast, low-energy trauma, such as falling from standing, is the most common mechanism of injury in older adults.(11) Weather conditions (e.g. ice, snow and typhoons) have been linked with higher incidence of distal radius fracture, possibly due to falls resulting from suboptimal walking surfaces.(12, 13)

Health conditions

Femoral neck bone mineral density (BMD) has been found to be a significant predictor of wrist fractures. Every 0.1g/cm^2 reduction in femoral neck BMD is associated with a 1.8 and 1.5 fold increase in the risk of forearm and wrist fracture in males and females respectively.(7) A history of falls has also been identified as an independent risk factor for forearm and wrist fracture in females over 60 years (Relative risk 1.9; 95% CI 1.4-2.6).(7)

1.2.3 Economic impact of distal radius fractures

Impacts of distal radius fractures include high health care and productivity costs, impaired physical function, impaired mental health and prolonged absence from work. A nationwide study in the Netherlands during 2007 estimated the total health care and productivity costs (due to absenteeism) associated with injuries to the hand and wrist.(14) Considering both health care and productivity costs, hand and wrist injuries ranked as the most expensive injury group ahead of lower limb fractures and head injuries. The annual cost of hand and wrist injuries was US $740 million, 1.3 times the cost of knee and lower limb fractures, 1.4 times the cost of hip fractures and 2.1 times the cost of skull-brain injury. Compared to direct health care costs, productivity costs comprised the greater proportion (56%) of total costs for hand and wrist injuries (14) and reinforce the need for rehabilitation strategies that facilitate early and safe return to function.

Factors such as the ageing population, increasing life expectancy and higher functional needs of the elderly suggest likely increases in future health care and productivity costs associated with distal radius fracture and emphasise the importance of research aimed at optimising health outcomes while minimising health costs.(14) Examining the 2007 data from U.S. Centers for Medicare and Medicaid Services, and broadly categorising distal radius fracture management into internal fixation, closed treatment, percutaneous pinning and external fixation, the mean payment per beneficiary was highest for internal fixation ($3,832 U.S. dollars) and lowest for closed treatments ($1,459 U.S. dollars).(15)

1.2.4 Use of internal fixation management for distal radius fracture

Internal fixation for wrist fracture appears to be increasing. Nationwide investigations in the Netherlands(4) and Sweden(3) have reported distal radius fractures over a 5 year period (2004-2009 and 2005-2010 respectively). The Swedish investigation reported the proportion of distal radius fractures managed with plate fixation increased from 3.4% in 2005 to 12.2% in 2010.(3) For patients in the Netherlands aged over 50 years, hospitalisation rate for wrist fracture increased significantly for all male and female age groups over the five year period.(4) This was largely due to the increase in plate and screw fixations for distal radius fracture with the relative change from 2004 to 2009 highest in the 50-59 and 60-69 age groups (173% and 248% respectively).(4) Similarly, Mellstrand-Navarro et al (2014) reported a 3.8 fold increase in plate fixation for distal radius fracture in adults between 2005 and 2010 with the largest point estimate of change being a 4.4 fold increase for the 50-74 age group.(3)

1.2.5 Length of immobilisation following internal fixation for distal radius fracture

This research focusses on internal fixation given its increasing use in the management of distal radius fracture. Although internal fixation is recommended in cases that cannot be managed conservatively, it also has the potential benefit of allowing early mobilisation.(16-18) What is not clear is how early it might be safe to commence mobilisation following internal fixation.

A search for information about best practice in immobilisation duration following internal fixation for distal radius fracture was conducted of the full holdings of MEDLINE, Embase, CINAHL plus, Cochrane Central Register of Controlled Trials (CENTRAL) and PEDro electronic databases. A search strategy example is presented in Appendix A.

Three RCTs of distal radius fractures managed with internal fixation (volar plate) reported direct comparisons of different periods of immobilisation. The earliest of these investigations involved 60 adults randomly allocated to either an early motion (one-two weeks following surgery) or late motion group (six weeks following

surgery).(18) Immobilisation was achieved using a thermoplastic splint. At the three and six month post-operative evaluations, no significant differences between groups were found with respect to the injured arm wrist or forearm active movement, grip strength, Gartland and Werley or Mayo wrist scores, ordinal pain scores, DASH scores, radiographic measurements or complication rates. The late mobilisation group was encouraged not to remove their splint other than for showering until the six week post-operative appointment. Adherence with prescribed treatment was a potential limitation of this investigation, given deviation from the specified instructions was enabled with the removable splint. In addition, no measures were taken to enforce or monitor adherence with the prescribed treatment. A further potential source of bias in this investigation was that allocation to group was not concealed during randomisation. Post-operative outcome measures were not recorded until three months following surgery. This prohibits a view of possible advantages in pain, range of movement (ROM) or function that might have been available to those in early mobilisation groups at time points between surgery and first assessment.

In a later trial comparing immobilisation periods following internal fixation (volar plate) for distal radius fracture in adults, participants (n=30) were randomly allocated to either a flexible splint group (flexible orthosis where movement could be blocked in certain directions) or a fixed splint group (dorsal forearm plaster splint).(19) Both groups were immobilised for the initial two weeks following surgery with the flexible splint blocked in 20° dorsal extension. During this two week immobilisation period, the cross-over design involved each group experiencing the alternate immobilisation device for a period of one week. At two weeks following surgery the flexible splint group had their orthosis de-blocked and were allowed to exercise limited wrist movement in the orthosis both independently and during physiotherapy sessions. At two weeks following surgery, patients in the fixed splint group were allowed to remove their splint for active wrist movement under the supervision of their physiotherapist. The extent of movement allowed at the wrist once the orthosis was de-blocked in the flexible splint group was not defined. Four weeks following surgery, splints for both groups were removed and ‘light mobility for the subsequent two weeks without strain’(19) was prescribed. Outcome measures recorded at one and two weeks following surgery were radiograph findings, physical health using the SF-

36 and a questionnaire developed individually for this study aimed at measuring patient satisfaction. At four and 12 weeks following surgery, wrist range of movement, DASH score and radiograph findings were recorded. Group comparisons indicated significantly greater wrist flexion range of movement at four weeks in the flexible splint group, however, the difference was not significant at 12 weeks. No significant group differences were found for DASH score, duration of disability, radiograph findings or complication rates. The questionnaire revealed significantly higher patient satisfaction with the flexible splint. As with the previously described investigation, adherence with prescribed treatment is a potential limitation of this investigation given deviation from the specified instructions for group members was made possible through a removable splint rather than a solid cast. No measures were taken to enforce or monitor adherence with the prescribed treatment. How mobilisation differed between the two groups was difficult to determine. The movement allowed at the wrist for the flexible splint group when the orthosis was de-blocked (two-four weeks following surgery) was not defined. Further potential for bias included small patient numbers (15 and 14 in each group) and a follow-up period of only 12 weeks.

The most recent RCT comparing immobilisation periods following internal fixation (volar plate) for distal radius fracture involved 30 patients being allocated to either early mobilisation (immediately following surgery) or late mobilisation (five weeks following surgery).(16) Patients in the early mobilisation group were fitted with a removable thermoplastic splint the day after surgery and were instructed to wear this for one week. Throughout the first post-operative week, patients in the early mobilisation group were encouraged to remove their splint for active wrist exercises and light daily activities. Patients in the late mobilisation group had a non-removable plaster cast applied on the day after surgery which remained insitu for five weeks. Outcomes measures were recorded over 12 months following surgery. The early mobilisation group had significantly greater wrist flexion/extension active ROM and grip strength at six months following surgery, significantly greater wrist radial/ulnar deviation active ROM at nine weeks and significantly greater active forearm rotation at six weeks following surgery. Patient rated function recorded using the QuickDASH and PRWE was significantly better in the early mobilisation group at six

weeks following surgery. Participants were also assessed with the Green O'Brien score which is a clinician-rated assessment of pain, functional status, ROM and grip strength and involves scoring each of these areas out of 25 points with a total score out of 100. Total scores were significantly higher in the early mobilisation group at 12 months following surgery. No significant group differences in complication rates were found. The small sample size (15 in each group) raises the possibility of sampling bias affecting outcomes.

Evidence from these trials suggest that mobilisation of distal radius fractures as early as 0-14 days following internal fixation with a volar plate is safe and produces functional outcomes that are comparable to those obtained with later mobilisation. Evidence regarding best practice in immobilisation following internal fixation for distal radius fracture is limited by the few studies, their small sample sizes and trial design flaws which include allocation concealment not adopted for all trials, deviations from allocated treatment made possible through removable splints with no measures taken to control or monitor such deviations, outcome recording not occurring until 12 weeks for one trial(18) and (for one trial) a follow-up period of only 12 weeks.(19)

1.3 Thesis proposal

1.3.1 Research aim

The aim of this research was to investigate the effect of duration of immobilisation on function following ORIF (volar plate) for distal radius fractures in adults.

1.3.2 Research overview

This thesis is comprised of six papers. A systematic review and meta-analysis was undertaken to explore the effect of duration of immobilisation following surgical fixation of adult fractures. This review and meta-analysis indicated that high quality large RCTs are required to confirm the likely short-term advantages provided by early mobilisation. This thesis reports such an RCT (n=135) investigating the effect of duration of immobilisation on function following ORIF for distal radius fractures in adults. Trial design involved monitoring of complication rates and assessing functional outcomes and pain at six, 12 and 26 weeks post-operatively. In parallel

with the RCT, two qualitative investigations were undertaken to explore, through participant interview (n=31), the impact of fracture, surgery and immobilisation on patients and their experiences with the health service. Given that radiographs are used to inform decisions regarding which patients receive ORIF or other management (closed treatment, percutaneous pinning or external fixation) following distal radius fracture, an investigation was undertaken to assess the accuracy in radiographic interpretation of acute distal radius fractures. The results enabled investigation into whether the errors associated with measurements were small enough for measurements to be used confidently in decisions regarding fracture management. This work led to a further investigation that explored the factors underpinning health professionals' treatment choices and agreement between health professionals on those choices.

1.3.3 Overview of following chapters

The studies reported in this thesis were conducted between 2011 and 2017 and involved four Australian public hospitals.

Chapter 2, "The effect of duration of immobilization following surgical fixation of adult fractures: Systematic review and meta-analysis" describes the outcomes of a systematic review investigating the effect of immobilisation duration on functional outcomes and post-operative complications.

Chapter 3 presents an overview of work completed to design the RCT reported in Chapter 4.

Chapter 4 "A randomized controlled trial comparing one, three or six weeks of immobilization on function and pain following open reduction and internal fixation for distal radius fractures in adults" reports on the effects of immobilisation of one, three and six weeks on outcomes.

Chapter 5 "Reliability of radiographic measurements for acute distal radius fractures" reports the error associated with radiographic interpretation of acute distal radius fractures and whether the magnitude of the errors enable measurements to be confidently used in fracture management.

Chapter 6 “Treatment decisions based on radiographs of acute distal radius fractures” describes the factors that underpin health professionals’ treatment choices for acute distal radius fractures and the consistency in the treatment recommendations made.

Chapter 7 “The impact of wrist fracture, surgical repair and immobilization on patients: A qualitative study” explores participants’ experiences with navigation of life following surgical fixation for distal radius fracture.

Chapter 8 “Patient interactions with the health service following wrist fracture, surgical repair and immobilization: A qualitative study” examined participant interactions with a health service, barriers and facilitators for recovery and patient involvement in management and treatment decisions.

Chapter 9 summarises the key findings from this research and the applicability of these findings to clinical practice. Strengths and weaknesses of the research included in the thesis are outlined and plans for future research in this area detailed.

Chapter 10 and 11 present the references and appendices.

Each chapter presenting a paper that has been published, or is under review or submitted, will commence with an introductory section and conclude with a section providing key supplementary information not included within the paper. To enhance the flow of text throughout the thesis, tables and figures are numbered consecutively (including in the six papers) with reference to the relevant chapter, and all references and appendices have been combined and located in Chapters 10 and 11 respectively. American spelling has been adopted within the six papers and Australian spelling throughout the rest of the thesis.

2. Chapter 2- The effect of duration of immobilization following surgical fixation of adult fractures: Systematic review and meta-analysis.

2.1 Introduction to systematic review and meta-analysis

Although surgical fixation techniques were developed to facilitate fracture healing while permitting early mobilisation, there is considerable uncertainty around the optimal period of immobilisation. Early mobilisation, if associated with improved or equivalent functional outcomes when compared to late mobilisation, presents opportunity for improving the patient experience and health in addition to reducing the health care and productivity costs associated with surgical fixation of this fracture. Given only three RCTs have investigated different periods of immobilisation following ORIF for distal radius fracture and, considering some principles are common to management of all fractures, a broader search for relevant data was conducted. The following systematic review and meta-analysis investigated the effect of immobilisation duration following surgical management for any adult fracture.

The following text is a copy of the manuscript submitted to *International Orthopaedics:*

Watson, N. J., Pile, R., Trivedy, B., Keating, J. L. (submitted) The effect of duration of immobilization following surgical fixation of adult fractures: Systematic review and meta-analysis.

2.2 Abstract

Purpose

To assess the impact of duration of immobilization on outcomes following surgical fixation for fracture in adults.

Methods

Searches until August 2017 included full holdings of MEDLINE, Embase, CINAHL plus, Cochrane Central Register of Controlled Trials (CENTRAL), PEDro and LILACS databases. Bibliographies of included trials, citations for relevant authors and references in relevant reviews were searched. Randomized controlled trials (RCTs) comparing differing periods of immobilization following surgical fixation of adult fracture were considered. Included trials were independently assessed by two reviewers for risk of bias and relevant data.

Results

11 RCTs (664 participants) involving the wrist (n =5), ankle (n =5) and hind foot (n =1) were included. Early mobilization commenced zero to three weeks post-surgery; late mobilization commenced at six weeks for nine trials. Study quality varied substantially but did not appear to systematically influence results. Meta-analysis point estimates systematically favoured early mobilization for short-term active ROM, function and pain, but were significant only for ankle plantarflexion ROM (mean difference 7°; 95% CI 2°-11°). Long-term outcomes were comparable for early and late mobilization. Early mobilization appeared to have lower rates of hardware irritation and higher rates of infection and wound healing complications. Health service cost savings appear possible with early mobilization. More information is required on patient satisfaction.

Conclusions

Early mobilization following surgical fracture fixation results in comparable or better outcomes compared to mobilization at six weeks and may have social and economic benefit. Unwanted effects on infection rates and wound healing warrant further investigation.

2.3 Introduction

Fracture is very common with 58% of male and 64% of female Australians over 80 years having experienced at least one fracture.(20) Impact of fractures include high health care and work productivity costs, impaired physical function and mental health, and prolonged work absence.(14)

Options for treating fractures include conservative (non-operative) management in a cast or other external support, or surgery using percutaneous pinning (Kirscher wires), external fixation or internal fixation. Surgical fixation is required when significant fracture malalignment persists despite attempted reduction, or significant secondary displacement occurs during conservative management.

Although surgical fixation techniques were developed to facilitate fracture healing while permitting early mobilization, there is considerable uncertainty around the optimal period of immobilization. A static joint is the primary risk factor for post-traumatic movement loss(21) and 'fracture stabilization versus early mobilization' is a key consideration for clinicians.(22) Early joint mobilization following fracture increases circulation of blood and synovial fluid and reduces the joint swelling, disuse atrophy and formation of intra-articular adhesions associated with more than three weeks immobilization.(23) Cochrane reviews comparing immobilization periods following surgical fixation concluded that limited evidence supports early mobilization of the ankle(24), proximal humerus(25) and distal radius,(26, 27) and adequate evidence is not available for elbow fracture.(28)

As some principles are common to management of all fractures, the current review investigated the effect of immobilization duration for any adult fracture. Typically conservatively managed fractures are immobilized for approximately 6 weeks. Considering the aim of surgical fixation is to enhance stability, this review sought data on the minimal period of immobilization possible without compromise to functional outcomes or an increase in post-operative complications. A priori we planned to subgroup for fracture location and summarize participant demographics, range of immobilization periods, surgical procedures and outcome measurements.

2.4 Materials and methods

Protocol and registration

The protocol for this review was registered with PROSPERO (registration number CRD42016046156).

Eligibility criteria

Included trials were randomized or quasi-randomized controlled trials that compared different periods of immobilization following a surgical procedure (percutaneous pinning, internal fixation or external fixation) for predominantly non-pathological fractures. Eligible participants were skeletally mature adults who had a surgical fixation procedure within two weeks of fracture. Trials involving participants with fractures older than two weeks and trials that involved fracture management strategies other than a surgical fixation procedure (e.g. general anesthetic manipulation and plaster) were included if at least 85% of subjects fulfilled the criteria. Trials must have compared at least two different periods of immobilization adopting any form of post-surgical immobilization e.g. cast, splint or brace. Follow-up assessment for a minimum of six weeks following surgical fixation was required. Effects had to be reported using point estimates and measures of variability for at least one measure of function, impairment or patient satisfaction. Trials were included if reported data enabled calculation of these metrics or these data were provided by study authors on request.

Information sources and search

The search included clinical trials until August 2017. Non-English trials were excluded as translation services were not available. We searched the full holdings of MEDLINE, Embase, CINAHL plus, Cochrane Central Register of Controlled Trials (CENTRAL), PEDro and LILACS electronic databases. A search strategy example is presented in Appendix B.

Searching other resources

The bibliographies, reference lists and cited web sites of all included papers and relevant reviews were searched for potentially relevant reports. Citation searches were performed for authors of all relevant trials.

Data collection and analysis

Search results were imported into bibliographic management software and one author (NW) removed all clearly irrelevant reports. The title and abstract of remaining reports were examined by two or more independent researchers (RP, BT, NW) for eligibility. When eligibility remained unclear full text was obtained for review. Full text versions of potentially eligible trials were independently assessed by two reviewers using a standardized, pre-piloted form. A third reviewer was recruited for resolution discussions as required.

Data were extracted from included trials on number of participants, baseline characteristics, type of fixation, control and intervention immobilization periods, methods of controlling for adherence to intended protocols, type of outcomes measured, timing of outcome assessment relative to time of surgical fixation and outcomes for early and late mobilization groups (point estimates e.g. means, proportions, and measures of variability e.g. standard deviations). Key outcome data extracted for early and late mobilization groups were flexion and extension active ROM at the involved joint, function, satisfaction, pain and complications. Where multiple measures were recorded for a particular outcome (e.g. multiple questionnaires for function), the decision rule for selecting the outcome for analysis was the outcome measure more commonly reported in other included trials. Data extraction was performed independently by two researchers (NW and JK).

Dealing with missing data

Point estimates and measures of variability for key outcomes at six and 26 weeks after surgery (or the nearest reported time point) were extracted. The following processes were implemented when data required for meta-analysis were not reported: based on the work of Hozo et al (2005)(29) medians were used as best estimates of the mean for sample sizes >25, and the formula recommended by Hozo et al(29) was applied for smaller samples. The standard deviation was estimated from reports of range using the range divided by four for samples sizes up to 70, and range divided by six for larger samples.(29) The standard deviation [sd] was approximated by dividing the inter-quartile range by 1.35.(30) Standard error [SE]

was converted to sd using the formula SE = sd/(√n). Extracted or estimated data were used to calculate standardized mean differences between groups [SMD] and 95% confidence intervals [CI] using RevMan software[1]. A SMD <0.2 was considered a small effect, 0.5 (>0.2, <0.8) a moderate effect and >0.8 a large effect.(31) If trials did not use intention-to-treat analysis, per-protocol data were extracted for analysis. When data were included only in figures, values were estimated using magnification and direct measurement.

Assessment of risk of bias in included trials

The internal validity of trials was evaluated using the PEDro scale [PEDro, 1999] and its accompanying decision rules.(32) Suitable validity and reliability of this scale for assessing the method quality of clinical trials has been previously reported.(33, 34) The scale assesses 10 key sources of bias in study design and reporting. Each study was independently assessed by two researchers (NW and JK) and disagreements resolved with discussion. Following consensus, decisions were cross-checked with assessments by independent PEDro reviewers. Assessment of publication bias using funnel plots was planned.

Synthesis of results

Results of comparable outcomes were pooled in meta-analysis using RevMan software[1]. A fixed effects model was run and heterogeneity between trials was assessed using the resultant chi^2 and I^2 statistics. Heterogeneity was considered substantial if I^2 was greater than 50% or if the chi^2 result was a p value of less than 0.1. In either case a random effects model was applied.(35) Outcome measure scale directions were aligned by adding negative values where required. To evaluate potential effects of bias on pooled results, trials were arranged in the analysis in order of PEDro total scores, enabling visual assessment of effect sizes in relation to bias control. In addition, subgrouping analysis restricted to trials with randomization with concealment, blinded outcome assessment and limited attrition (<15%) was planned for all meta-analyses.

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[1] Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

2.5 Results

Study selection

Search results are summarized in Figure 2-1. After screening for eligibility, two independent researchers (NW and RP or NW and BT) reviewed the full text of 77 articles and found 11 eligible reports.

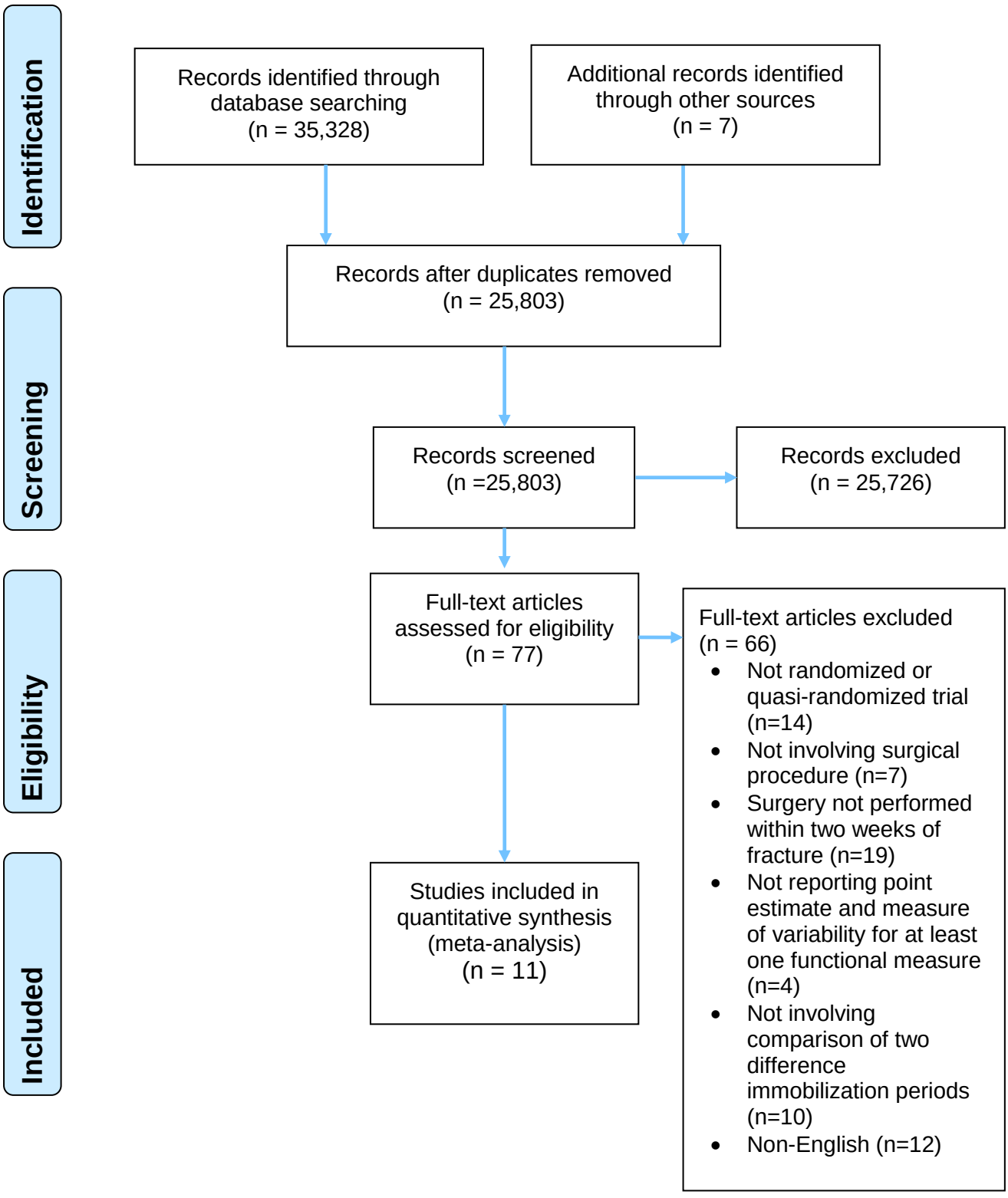


Figure 2-1 Flow chart of included studies

Setting

Six trials(18, 36-40) were single-centre trials, two(41, 42) were multi-centre and information was not provided for three trials.(43-45) Trials were conducted in nine countries: Canada (1); Finland (1); Germany (1); India (1); Norway (2); People's Republic of China (1); Scotland (1); Sweden (2) and USA (1). Period of recruitment for trials ranged from 1 year(40) to 4 years(41, 43); this information was not provided for three trials.(36, 42, 45) Commencement of recruitment ranged from 1983(44) to 2012(40) and was not described in three reports.(36, 42, 45)

Sample sizes and participants

Samples sizes in included trials ranged from 27 to 110 and totalled 664 across trials. Trials involved wrist (n =5), ankle (n =5) and hind foot (n =1) fractures. Mean participant age ranged from 38.7 to 71 years (weighted mean =47.5 years). Mean time from fracture to surgery ranged from one to 11 days. There was a marginally higher proportion of female participants (weighted mean =53%, 16 – 93%). Participant and study characteristics are summarized in Table 2-1.

Table 2-1 Late (L) and Early (E) mobilization group characteristics of included studies

Study	n		Age mean (SD or range)		% female at baseline		AO Fracture classification at baseline		Time from fracture to surgery (days) mean (SD or range)	
	L	E	L	E	L	E	L	E	L	E
Atroshi et al 2006	19	19	71 (57–84)	70 (55–86)	79	84	A2/A3 =8 C2/C3 =11	A2/A3 =11 C2/C3 =8	< 4 (not reported by group)	
Chen et al 2017	35	37	38.7 (11.5)	40.3 (12.6)	16	18	Sanders classification: Type II= 10 Type III= 12 Type IV= 10	Sanders classification: Type II= 9 Type III= 8 Type IV= 11	6.8(1.7)	7.3(1.9)
Dehghan et al 2016	54	56	42.1 (15.4)	41.7 (15.1)	50	43	A1 =2 B1/2/3=26,50,17 C1/2 =4,2	A1/2 =2,4 B1/2/3 =30,36, 20 C1/2 =7,2	6.2(4.3)	7(4.1)
Finsen et al 1989	19	18	40 (14.4)	43 (13.6)	58	56	A =0 B =16 C =3	A =0 B =15 C =3	<7 (not reported by group)	
Franke et al 2008	13	14	40.8 (25-64.1)	44.3 (20.3-59.4)	38	50	B1.1 =13	B1.1/1.2 =13,1	7(0-21)	5(0-13)
Hove et al 2010	35	35	54 (5)	54 (6)	80	66	A3=19 C1/2/3= 6,7,3	A3=20 C1/2/3= 6,5,4	< 10 (not reported by group)	
Kulshrestha et al 2011	30	30	41.2 (6.9)	43 (6.6)	33	30	A =14 B =4 C =12	A =17 B =6 C =7	3.5(1-7) days (not reported by group)	
Lehtonen et al 2003	50	50	41 (13)	41 (13)	38	50	A =2 B =48	A =2 B =48	1.3 (0.8)	1(0.7)
Lozano-Calderón et al 2008	30	30	51	55	67	63	A =11 B =7 C =12	A =12 B =1 C =17	11	11
McQueen 1998	30	30	61 (13)	62 (14)	93	90	A =25 C =5	A =21 C =9	Probably < two weeks (not reported by group)	
Tropp & Norlin 1995*	30		Not stated		Not stated		Not stated		<1	<1

*Reported 30 participants were randomly allocated to two groups without reporting individual group numbers and equal allocation for groups was assumed.

Method of surgical management

The procedures adopted for surgical fracture fixation were internal fixation [n =7 (ankle n=5, wrist n=1, hind foot n=1)] and external fixation (n =4 wrists).

Type and timing of immobilization

Immobilization techniques varied. Nine trialists used fixed immobilization for participants in the late mobilization groups, Lozano-Calderón et al (2008) used removable splints and Chen et al. (2017) did not describe type of immobilization. Early mobilization commenced from zero to three weeks post-surgery. Mobilization commenced at six weeks for the late mobilization group in nine trials and at two weeks for one trial.(40) For the remaining trial(37), commencement of late mobilization was 6 weeks for extra-articular fractures and 8 weeks for intra-articular fractures. Immobilization and rehabilitation program details are summarized in Table 2-2.

Outcomes

Most trials (n=8) measured active ROM and functional activities involving the injured joint. Table 2-2 summarizes outcome measures across trials. Outcomes were assessed at two to eight (mean = 3.9) time points. Initial post-operative assessments were from two to 12 weeks and final outcomes from 10 to 104 weeks (Table 2-2).

Table 2-2 Outcome measure and rehabilitation characteristics of included studies

Study	Key outcomes assessed	Timing for outcome assessment (post-operative)	Type of immobilization		Time of immobilization (weeks)		Rehabilitation program
			Late mobilization	Early mobilization	Late mobilization	Early mobilization	
Atroshi et al 2006	DASH, SF-12 physical health score, grip strength, wrist and forearm active ROM, pain (VAS), patient satisfaction, complications and radiographic variables.	10, 26, 52 weeks	Wrist bridging external fixation	Non-bridging external fixation	6	0	Early motion exercises of the fingers, wrist (non-bridging group), elbow and shoulder. External fixation removed at 6 weeks and physiotherapy program of ROM and strengthening exercises commenced.
Chen et al 2017	American Orthopedic Foot and Ankle Society Ankle-Hind foot Scale (AOFAS), CT and radiographic variables.	52 weeks for function; CT variables at day 1 and 4, 8, 12 weeks; Radiographic variables at 26, 52, 78, 104 weeks	Not stated	None	2	2-3 days	**Control group:** At 2 weeks post-operatively, active motion ankle/subtalar joint if wound healed; draw alphabet with hallux of injured foot or make progressively larger circles with the feet. Partial weight-bearing was week 6, full weight-bearing after fracture healing confirmed using radiography, usually after post-operative week 12. **Intervention group:** Early after surgery active exercise of repaired ankle, subtalar joint and toes increasing as pain permitted. Post-operative days 2-3, non-weight-bearing exercises with crutches. Post-operative day 3, roll bottle beneath foot. Weight bearing post-operative week 3 and gradually increased.

Study	Key outcomes assessed	Timing for outcome assessment (post-operative)	Type of immobilization		Time of immobilization (weeks)		Rehabilitation program
			Late mobilization	Early mobilization	Late mobilization	Early mobilization	
Dehghan et al 2016*	Olerud & Molander Ankle Score, SF-36 Health Survey, ankle active ROM, wound (signs of wound healing problems, dehiscence, and infection), complications, standard questions on return to work and activity and radiographic variables.	2, 6, 12, 26, 52 weeks	Below knee fibreglass cast	Boot orthosis	6	2	Post-operatively all participants placed in below knee posterior plaster slab and instructed not to bear weight on operated limb for 2 weeks. At 2 weeks, the posterior slab was removed. **Control group:** Below knee fiberglass cast at 2 weeks and instructed to remain non-weight bearing for a further 4 weeks. Cast was removed at 6 weeks, ankle active ROM exercises commenced and full weight-bearing using boot orthosis. Instructed to wean from orthosis over next 2 to 4 weeks. **Intervention group:** Boot orthosis at 2 weeks and instructed to remove orthosis 4x/day to perform ankle active ROM exercises. Instructed to wean from boot orthosis over the next 2-4 weeks.
Finsen et al 1989	Clinical demerit points with subgroups for function, pain, ROM and swelling (each subgroup polychotomizing to one of 5 gradings); time of return to work and radiographic variables.	9, 18, 36, 52, 104 weeks	Plaster-of-Paris cast	Plaster-of-Paris splint	6	3 days	Both groups permitted full weight-bearing at 6 weeks post-operative. **Control group:** Ankle active ROM permitted post-operatively at 6 weeks when cast removed. **Intervention group:** Instructed to commence ankle active ROM at 3 days post-operatively when splint removed.

Study	Key outcomes assessed	Timing for outcome assessment (post-operative)	Type of immobilization		Time of immobilization (weeks)		Rehabilitation program
			Late mobilization	Early mobilization	Late mobilization	Early mobilization	
Franke et al 2008	Olerud & Molander Ankle Score, SF-12, ankle active ROM, VAS for pain and comfort, wound complications and time spent delivering services recorded for cost estimations.	6, 10 weeks	Synthetic cast	Dynamic vacuum orthosis	6	2 days	**Control group:** Circular cast applied post-operatively and window cut to permit dorsal extension. 20kg weight-bearing permitted from time of wound healing; full weight-bearing from day 15. Cast removed at 6 weeks and physiotherapy 3x/wk for 4 weeks. **Intervention group:** Orthosis applied post-operatively which permitted 10-0-10 degrees of movement in upper ankle joint. 20kg weight-bearing permitted from 2nd post-operative day; full weight-bearing allowed from day 15. Orthosis removed at 6 weeks.
Hove et al 2010	DASH, grip strength, wrist and forearm active ROM, pain (VAS), complications and radiographic variables.	6, 12, 26, 52 weeks	Static wrist bridging external fixation	Dynamic wrist bridging external fixation	6	1 day	Instructions given to both groups on active ROM exercises for fingers, forearm, elbow and shoulder. External fixation in both groups removed at 6 weeks (range, 6-9 weeks). Formal physiotherapy offered to some participants with long-lasting stiffness. ***Intervention group*:** Wrist active ROM in all directions permitted from 1st post-operative day.

Study	Key outcomes assessed	Timing for outcome assessment (post-operative)	Type of immobilization		Time of immobilization (weeks)		Rehabilitation program
			Late mobilization	Early mobilization	Late mobilization	Early mobilization	
Kulshrestha et al 2011	Gartland & Werley score, DASH, complications and radiographic variables.	12, 26 weeks; DASH only at 104 weeks	Static wrist bridging external fixation	Dynamic wrist bridging external fixation	AO type A fractures= 6 Type B and C fractures = 8	Periarticular fixation= 0 Type B and C fractures = 3	For both groups, fixator removed at 6 weeks in all patients with AO type A fracture and 8 weeks in participants with type B and C fractures. Rehabilitation program continued for 4 weeks after removal of fixator. ***Intervention group:*** For participants with periarticular fixation, wrist movements commenced immediately post-operative and gradually increased. For AO type B and C fracture, at 3 weeks 30° range of wrist motion (20° palmar flexion to 10° dorsiflexion) permitted. Full mobilization of wrist commenced 3x/day at 5 weeks.
Lehtonen et al 2003	Olerud & Molander Ankle Score, Kaikkonen functional score, ankle active ROM, complications, swelling of ankle and atrophy of calf muscles, time of return to work and radiographic variables.	2, 6, 12, 52, 104 weeks	Below knee plaster-of-Paris cast	Functional ankle brace (Aircast)	6	0	Both groups had same post-operative WBing protocol- crutches non weight-bearing for first 2 weeks, partial weight-bearing for next 4 weeks and full weight-bearing when cast/brace removed at 6 weeks. Both groups started an exercise program for ankle following cast/brace removal. ***Intervention group:*** Daily active and passive ROM exercises of the ankle without the brace were encouraged immediately post-operatively.

Study	Key outcomes assessed	Timing for outcome assessment (post-operative)	Type of immobilization		Time of immobilization (weeks)		Rehabilitation program
			Late mobilization	Early mobilization	Late mobilization	Early mobilization	
Lozano-Calderón et al 2008	DASH, modified Gartland & Werley score, Mayo wrist score, grip strength, wrist and forearm active ROM, pain (VAS), complications and radiographic variables.	12, 26 weeks (Ranges between 8-16 weeks and 20-32 weeks)	Volar plaster splint until first post-operative review (average 8 days) and then custom thermoplastic volar splint	Volar plaster splint until first post-operative review (average 8 days) and then custom thermoplastic volar splint	6	8 (7-13) days	Participants in both groups encouraged to perform active and active-assisted digital and forearm ROM exercises and to use injured arm for light functional tasks immediately post-operative. ***Control group:*** Advised to wear splint at all times, except when showering. Wrist active ROM commenced following splint removal at 6 weeks (range, 42-59 days post-operatively). ***Intervention group:*** At the first post-operative visit at 8 days (range, 7-13 days) advised to remove splint and perform active and active-assisted wrist ROM exercises. Encouraged to wean out of the splint. For both groups, no attempt made to confirm adherence to recommended protocol.
McQueen 1998	Grip strength, wrist and forearm active ROM, pain (VAS), complications and radiographic variables.	6, 12, 26, 52 weeks	Wrist bridging external fixation	Non-bridging external fixation	6	0	For both groups external fixation removed after 6 weeks and physiotherapy prescribed as clinically indicated.
Tropp & Norlin 1995	Modified Olerud score, isokinetic dorsiflexion muscle strength, ankle active ROM, muscular hypotrophy of the leg, swelling of ankle; wound healing, complications and radiographic variables.	10, 52 weeks	Conventional boot plaster cast with a sole	Brace designed with a double-hinge position at talocrural jnt.	6	1-2	In both groups weight-bearing permitted immediately post-operative with assistance of crutches. ***Control group:*** Self-training exercise program commenced when cast removed at 6 weeks. ***Intervention group:*** Ankle dorsiflexion and plantarflexion were permitted by the brace and encouraged from 1-2 weeks post-operative. Self-training exercise program commenced when brace removed at 6 weeks.

* Ankle active ROM was reported as total plantarflexion/dorsiflexion arc and these data were included in plantarflexion meta-analysis as this movement constitutes the majority of the movement arc.

Risk of bias in included trials

PEDro scores, indicating the number of sources of bias controlled, are presented after the study identifier in meta-analysis figures. Method of randomization was not described in five trials.(37-39, 44, 45) Allocation was not concealed for four trials.(18, 40, 44, 45) Understandably, blinding of therapists and participants was not achieved for any trial, but only three trials reported assessor blinding.(18, 40, 43). Three trials(36, 40, 45) did not measure key outcomes for more than 85% of participants initially allocated to groups. Five trials did not report intention to treat analysis.(36, 37, 40, 44, 45) All trials involving the wrist controlled for most sources of bias.(18, 37, 39, 42, 43) Four of the six trials involving the ankle and hind foot did not control five or more sources of bias.(36, 40, 44, 45) Only one trial included both randomization with concealment and blinded outcome assessment, which prevented meaningful subgroup analysis of data from trials of high quality.

Rehabilitation programs

Chen et al (2017) did not include information on the rehabilitation program. Rehabilitation programs were delivered through therapist sessions for four trials(36, 37, 39, 43) and written or verbal instructions were given to participants to guide self-driven rehabilitation for six trials.(18, 38, 41, 42, 44, 45) Load-bearing restrictions were not described for any of the five trials involving the wrist. Weight-bearing protocols varied across the five trials involving the ankle, however, were consistent for the early and late mobilization groups of each trial. In the trial involving the hind foot(40), the early mobilization group commenced weight-bearing at post-operative week three and late mobilization group at post-operative week six. Weight-bearing instructions are summarized in Table 2-2.

Effects of interventions

Franke et al (2008) reported that only the late mobilization group engaged in physiotherapy at six weeks following surgery and therefore no outcomes after six weeks were included in meta-analysis. All other extracted data were included in meta-analyses, sub-grouped by body region (Figures 2-2 to 2-5). In most cases, pooling across subgroups was not possible as data from individual studies contributed to more than one subgroup analysis.

Effect of duration of immobilization on short-term active ROM

Random effects meta-analysis for short-term active ROM from eight trials is shown in Figure 2-2. Effects for wrist flexion and extension and ankle plantar and dorsiflexion all tended to favor early mobilization, but only ankle plantarflexion ROM was significantly better (MD 7°; 95% CI 2°-11°).

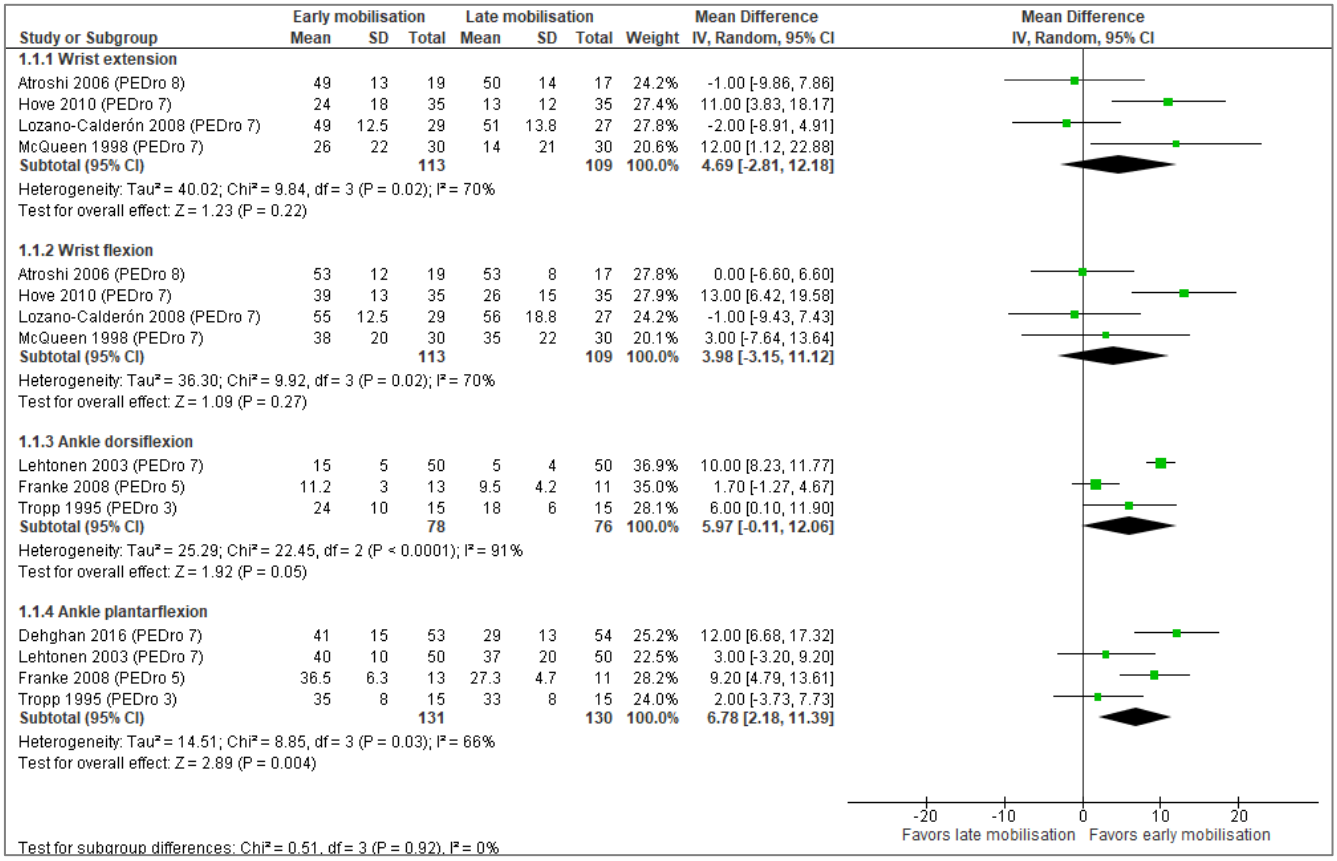


Figure 2-2 Meta-analysis forest plot of short-term active ROM

Effect of duration of immobilization of long-term active ROM

Figure 2-3 presents the meta-analysis derived from seven trials comparing early to late mobilization on long-term active ROM. Outcomes appeared comparable for early and late mobilization groups.

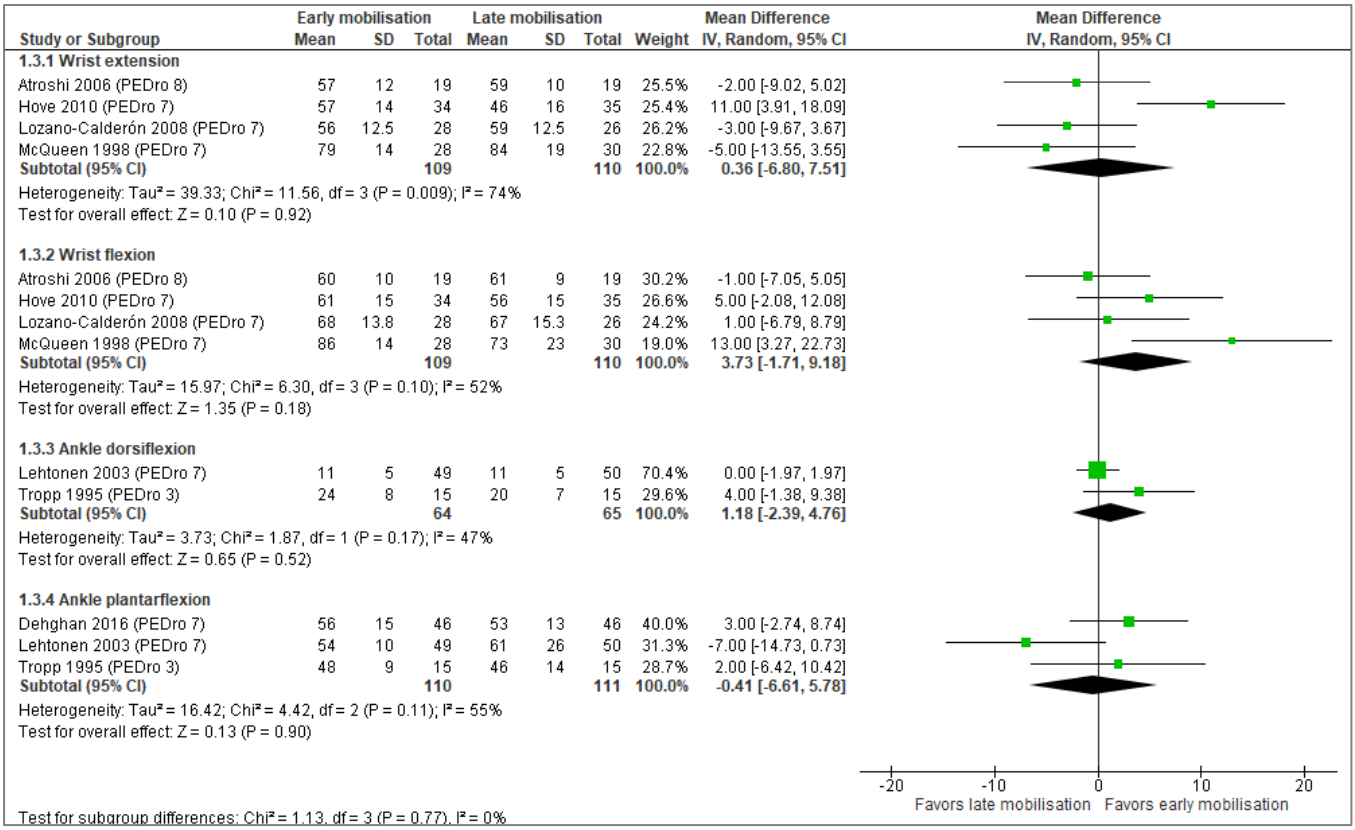


Figure 2-3 Meta-analysis forest plot of long-term active ROM

Effect of duration of immobilization on short-term and long-term function

Figure 2-4 presents meta-analysis derived from eight trials comparing early to late mobilization for short-term function with no significant differences between groups. Meta-analysis for long term functional outcomes derived from nine trials (Figure 2-5) indicated comparable results for early and late mobilization groups.

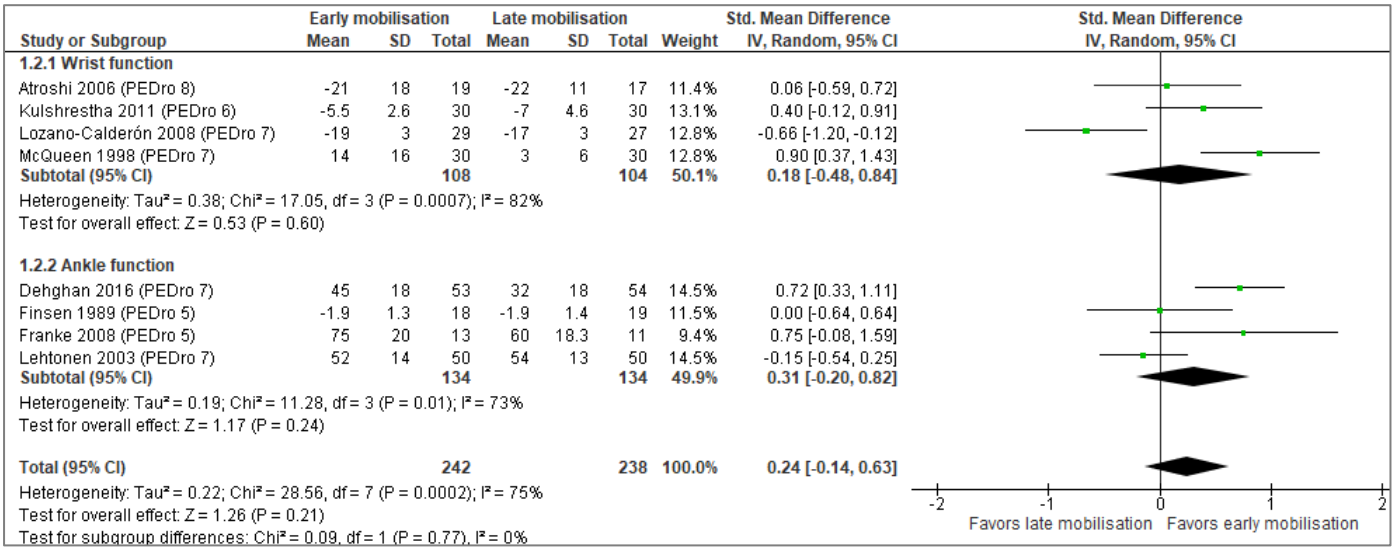


Figure 2-4 Meta-analysis forest plot of short-term function

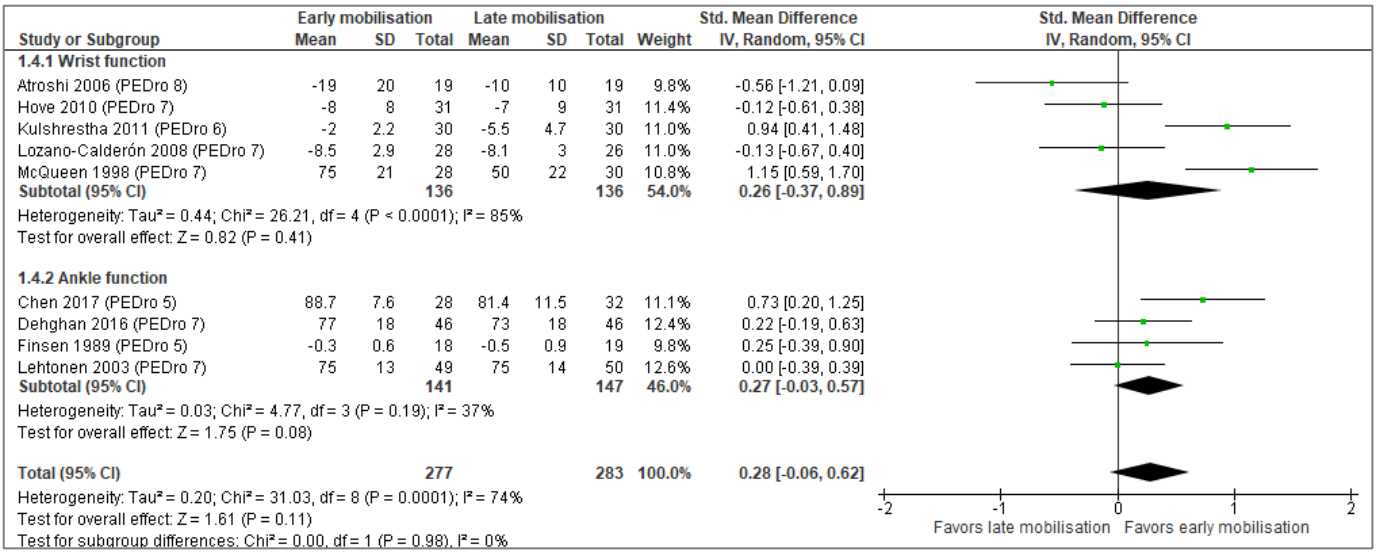


Figure 2-5 Meta-analysis forest plot of long-term function

Effect of duration of immobilization on short-term and long-term pain

Pain measured using a visual analogue scale was recorded for five trials but data not supplied for three of these. Two of the trials with no reported data (39, 42) found that pain scores at short and long-term follow-up were not significantly different and one(36) reported pain at short-term follow-up was significantly better for the early mobilization group (P=0.004). Pain was recorded as a subscale of the clinical demerit point score for the remaining trial.(44) Short-term pain for three trials(18, 43, 44) were pooled using fixed effects meta-analysis. Effects favored early mobilization, however, were not significant (SMD 0.18; 95% CI [-0.16, 0.53]). Random effects meta-analysis of long-term pain for the same trials showed no significant difference comparing early to late mobilization (SMD 0.25; 95% CI [-0.80, 1.29].

Selective reporting and trial heterogeneity

The maximum number of trials in any specific meta-analysis was five, which prevented meaningful statistical assessment of publication bias using funnel plots.(46) Potential causes for heterogeneity (observed within all short and long-term active ROM subgroups, within all short and long-term function subgroups with the exception of long-term ankle function, and for long-term pain) include design flaws, sample differences, and differences in methods and timing of outcome recording. Differences in intervention conditions may have also influenced results e.g. when removable splints were used for immobilization and adherence with immobilization was not confirmed.(18, 36) For all trials, limited information was provided on the method used for recording post-operative complications or when complications occurred e.g. within the six month post-operative period or later. A distal radius complication checklist has been developed,(47) but was not described in any report .

Effect of duration of immobilization on patient satisfaction

Patient satisfaction was recorded in two trials, however, no data were reported. Atroshi et al (2006) found no statistically significant differences for the early and late mobilization groups at short-term or long-term follow-up. Franke et al (2008) did not record patient satisfaction until 10 weeks post-surgery, by which time different

rehabilitation protocols were implemented for the early and late mobilization groups so these data were not included in analysis.

Effect of duration of immobilization on post-operative complications/adverse events

Chi^2 tests were performed to compare rates of reported complications for early and late mobilization groups. Overall numbers of complications were not significantly different. Subgrouping for type of complication revealed the possibility of significantly higher rates of infection (18%; P=0.00) and marginally but significantly more wound healing complications (3%; P=0.02) for the early mobilization group. The rate of hardware irritation and removal was marginally but significantly higher for the late mobilization group (3%; P=0.00). Differences between groups for rate of fracture position loss, complex regional pain syndrome (CRPS), carpal tunnel syndrome, nerve damage and tendon damage were not significant.

2.6 Discussion

The six outcomes of interest were active ROM, function, pain, patient satisfaction, complications and treatment costs. No trial included data on all six outcomes. When data were visually examined in forest plots, there were no apparent systematic effects attributable to potential sources of bias in study design. Overall, meta-analyses tended to favour early mobilization for short-term outcomes (active ROM, function and pain) with significant effects in favour of ankle active ROM. Meta-analysis also indicated a low likelihood of better outcomes with late mobilization and similar long-term outcomes for both groups. Post-operative aims following surgical fixation for fracture include minimizing the pain experienced by patients while maximizing rate of functional goal achievement. Results indicate a faster journey to functional goal achievement is facilitated by early mobilization and this has particular relevance for optimizing patient health outcomes and potentially minimizing productivity and health costs. Meta-analysis tended to favour early mobilization for short-term pain relief. This warrants further investigation as inadequate pain control following fracture and surgery can limit effective rehabilitation and impact negatively on skeletal healing resulting in loss of bone, muscle mass, ROM and reduced function.(48, 49)

Previous Cochrane reviews(24-27) of immobilization times following surgical fracture fixation indicate no apparent advantages of longer periods of immobilization and, if there were any effects, they tended to favour a shorter immobilization period. The meta-analyses in our review provide further evidence that there is no apparent advantage to longer periods of immobilization.

There was a high degree of unexplained heterogeneity for short- and long-term active ROM analyses (I^2 range 47-91%) indicating potential differences in underlying population characteristics attributable to sampling error, small samples, or differences in participants, interventions or measurement procedures. High heterogeneity was also evident for short- and long-term function analyses (I^2 range 37-85%). However, within each outcome assessed in meta-analysis, heterogeneity between subgroup totals was consistently very low, indicating that observed pooled effects favouring early mobilization were remarkably consistent across different body regions.

Compared to late mobilization, early mobilization appeared to have lower rates of hardware irritation, however, infection rate and wound healing complications appeared to be higher. Reasons for higher infection rates may include removal of the protective cast during wound healing phases. Future trials might consider paying particular attention to the protection of healing tissues in early mobilization groups. No authors reported such procedures. The clinical relevance of differences in complication rates found in the current investigation is not clear. The absence of standardized recording procedures for complications resulted in very incomplete data reporting. In addition, it has been argued that a number of complication types do not typically impact on outcomes.(50)

Goldhahn et al. (2014)(51) surveyed an international group of clinicians, methodologists, epidemiologists, researchers, industry, and patients about the five outcomes they considered most important in fracture. Patients' sense of recovery ranked third behind function and complications. Patient reported outcomes have increasingly been adopted by clinicians and researchers over the past 25 years(51)

and the absence of a measure of patient satisfaction in the majority of trials may reflect the fact that data collection for 80% of included trials commenced more than 10 years ago.

There was considerable variation in type of rehabilitation programs. Therapist-coordinated rehabilitation occurred for four trials while six trials involved self-management by patients following therapist delivery of written or verbal instructions. The interaction between type of rehabilitation schedule and time of cast removal is not known and warrants investigation. For example, when casts are removed early, patients may need specific advice to enable the confidence required to commence and progress movements.

Earlier achievement of pain relief and functional recovery has relevance for patient health and satisfaction, work productivity and health costs. However, short-term outcomes were not taken until 10-13 weeks post-operatively for four trials. This prohibits a view of possible advantages in pain, range of movement or function that might have been available to those in early mobilization groups at time points between surgery and first assessment. Early mobilization appears to have potential for even greater cost savings for health services with Franke et al (2008) indicating a considerable reduction in health professional time and consumable expenditure when compared with late mobilization. Economic analyses should form part of future research.

Limitations

Included trials were reported in English, thus excluding possible non-English reports. Observed heterogeneity raises questions regarding conditions that affect outcomes and indicates opportunities for standardization in study design and choice of outcomes in future studies.

2.7 Conclusions

Earlier functional recovery following surgical fracture fixation has considerable social and economic value given the potential for a more rapid return to work, daily activities and reduced period of compensation. Evidence from this investigation indicates it is likely that early mobilization typically has no effect or a positive effect on short-term pain, active ROM and functional outcomes. Early mobilization, while potentially advantageous for reducing hardware irritation, may be associated with higher rates of infection and wound healing complications and a focus on strategies to protect healing tissues in early mobilization groups is warranted. It is hypothesized that longer immobilization periods result in greater financial costs to patients (i.e. delayed return to work) and health services (i.e. prolonged rehabilitation) and an economic evaluation was included in only one of the 11 trials in this investigation. Preliminary data indicates potential cost savings for health services through early mobilization and further economic evaluation is warranted. Further information is required on patient satisfaction, however, considering that pain, active ROM and functional outcomes tended to be better with early mobilization, an association with patient satisfaction appears likely. High quality large RCTs, with careful monitoring of complication rates, are required to confirm the likely short-term advantages provided by early mobilization.

2.8 Chapter conclusion

This introductory chapter provides a comprehensive review of the evidence for early mobilisation following surgical fixation of acute (within 2 weeks of injury) fracture. Appendix C presents the search strategies used for Embase (OVID Online), CINAHL Plus (EBSCO), Cochrane Central Register of Controlled Trials (CENTRAL), PEDro and LILACS. Appendix D details the area of fracture, eligibility criteria and fixation characteristics of the 11 included trials. Appendix E summarises, for each of the 11 included trials, PEDro scores estimated by reviewers and provides a website link to PEDro criteria underpinning decisions. The meta-analysis outcomes of pain data were reported in the paper and the forest plots and meta-analysis statistics are provided in Appendix F. Funnel plots were created but are not reported because the small numbers in each subgroup prohibited a confident view of publication bias.(46) Limitations of evidence described in the systematic review include the use of

removal splints with no monitoring or control of adherence, small sample sizes and many trials not controlling for five or more sources of potential bias. There is an absence of standardised recording and incomplete data reporting for post-operative complication rates and an absence of patient satisfaction measurement in the majority of trials. One third of reviewed trials recorded short-term outcomes 10-13 weeks post-operatively, prohibiting a view of possible advantages in pain, ROM or function that might have been available to those in early mobilisation groups at time points between surgery and first assessment. High quality large RCTs, with careful monitoring of complication rates, pain and patient satisfaction, are required to confirm the likely short-term functional advantages provided by early mobilisation. In the next chapter, these factors and others are considered in the design of a RCT to assess outcomes following internal fixation for distal radius fracture, managed with different periods of rigid immobilisation.

3. Chapter 3- Designing an investigation into the effect of immobilisation time on outcomes following ORIF for distal radius fracture

3.1 Introduction

Considerable work was undertaken to design a high quality RCT that would provide information on the effects of varying periods of immobilisation following ORIF for distal radius fracture. This chapter describes key components of this preparatory work and provides background to decisions that were made in the design of the RCT. While the key design elements in a trustworthy RCT have been extensively argued, conducting a trial in the context of a health service and concurrent with usual care requires additional organisational considerations.(52) This preparatory work is reported in three sections: 1) determining outcome measures and standardising measurement techniques, 2) developing a rehabilitation program and training trial therapists, and 3) developing methods to engage referring and treating clinicians and sustaining this engagement.

3.2 Determining outcome measures and standardising measurement techniques

This section describes the selection of trial outcome measurements. It also briefly summarises an unpublished investigation into the reliability and refinement of wrist and forearm active ROM measurements that were planned for application in the RCT.

3.2.1 Investigation into the reliability of wrist and forearm active ROM measurements using a goniometer in adults (unpublished report)

Background

Treatment goals following distal radius fracture include restoring the functional anatomy of the distal radioulnar joint using methods that minimise compromise to hand function. Adequate active wrist and forearm movements are required for successful completion of everyday tasks such as eating and dressing and the RCT included measurement of all wrist and forearm active ROMs (wrist flexion, extension, radial and ulnar deviation, forearm pronation and supination). Measurements of wrist and forearm active ROM are routinely taken by treating health professionals following distal radius fracture to determine the success of management strategies, the level of impairment in upper limb movements and to monitor progression. In clinical practice, the goniometer is commonly used as a measurement tool for wrist and forearm AROM given it is simple to use, portable and inexpensive. These measurements inform clinical decision making. Interpretation of goniometric measurements requires consideration of the error inherent in measurements. These errors impart confidence to decisions regarding true changes in ROM and changes associated with treatment. Errors in measurements have a number of possible sources. Sources of measurement variation include differences between patients, variation in the demonstrable range of a person's measurements, observer variation (within observer and between observers) and variation due to interactions between the person, observers and/or measurement occasion.

Five trials have investigated the inter-rater reliability of goniometry measurements for active movements at the wrist involving participants with and without conditions affecting the upper limb.(53-57) Excluding the values reported by Geertzen et al (1998), which are unusually high and need further investigation, the range of standard deviations reported for active wrist flexion, extension, radial and ulnar deviation fell between 3.6° and 9.9°.

Four trials have investigated the inter-rater reliability of goniometry measurements for active forearm rotation, three involving participants with a condition involving the

elbow, forearm or wrist.(58-60) The remaining trial involved participants with and without a previous upper limb injury.(61) The range of standard deviations reported (or calculated from reported SEM)(60, 61) for active forearm rotation fell between 5.4° and 15.9°.

The clinical application of these results is complicated by variation in both the statistical methods used to report error and the methods used to take goniometry measurements. No reported investigations included refinement of measurement methods to reduce measurement error. A systematic and iterative process of measurement, estimation of errors, method refinement and repeated measurement was designed to evolve methods with optimal repeatability in the sample of therapists who would participate in the planned RCT. Two identified sources of observer variation with goniometer measurements are reading from the goniometer and placement of the goniometer on anatomical landmarks.(62) End digit preference and recording values have been identified as sources of variation in the recording process.(62) End digit preference is where assessors demonstrate a bias for reading values that end with a particular digit. Low et al (1976), using 50 assessors, found assessors had a preference for recording values that ended in zero. A zero-starting position technique involving measurements that start from zero and progress to end range has been proposed to minimise reporting error.(62) This information was applied in refining measurement method options.

The aims of this investigation were to investigate sources of variation when using a goniometer to measure wrist and forearm active ROM (extension, flexion, radial deviation, ulnar deviation, pronation and supination), to identify and apply methods of goniometer measurement that minimise measurement variation, and to reassess errors after refinement and practice.

Participants

Six participants and the principal researcher were involved in this investigation. The six physiotherapists were all employees at the trial health service with a minimum of five years' experience in the area of musculoskeletal physiotherapy. The six physiotherapists' roles typically involved them assessing and reviewing people

during rehabilitation following wrist fracture. Physiotherapists meeting the criteria for participation in this investigation were invited to participate by the principal researcher who provided them with investigation details. Agreeing participants were consented and enrolled until the quota of six was reached. Participants served as both as therapists and participants.

Approval was granted by Western Health Low Risk Human Research Ethics Panel (HREC/12/WH/28)

Study settings

The investigation took place in the health service Outpatient Department.

Measurements

Two types of goniometers and an inclinometer were used for measurements.

Goniometer 1

Standard clear plastic 180° goniometer with 1° increments marked, an axis of rotation and two movable arms of 20cm.

Goniometer 2

Standard clear plastic 180° goniometer with 5° increments marked, an axis of rotation and two moveable arms of 15cm.

Inclinometer

Liquid pendulum inclinometer with 2° increments marked, a dial able to be fully rotated 360° and lockable at 90° intervals.

Standardised participant positioning:

Participants were positioned in a sitting position for all measurements. Elbows were resting on the table for measurement of wrist active ROM. Elbows were firmly pressed against the torso with the elbow at 90° flexion and the wrist in a neutral position for measurement of forearm active ROM.

Previously described methods of measuring wrist and forearm active ROM were followed and are outlined below.(59, 63)

Measurement method described by Carter et al (2009) for wrist flexion, radial and ulnar deviation active ROM (dorsal-volar technique):
The axis of the goniometer was centred over the centre of wrist rotation (centre of the capitate). The point was located using the midpoint of the line in the coronal plane connecting the tips of the radial and ulnar styloids. The proximal arm of the goniometer was aligned centrally (visual estimation) on the dorsal surface of the forearm and the distal arm was aligned with the third metacarpal.

Measurement method described by Carter et al (2009) for wrist extension active ROM (dorsal-volar technique):
The axis of the goniometer was centred over the centre of wrist rotation (centre of the capitate). The proximal arm of the goniometer was aligned centrally (visual estimation) on the volar surface of the forearm and the distal arm was aligned with the third metacarpal.

Measurement method described by Carter et al (2009) for wrist flexion and extension active ROM (radial-ulnar technique):
The proximal arm of the goniometer was aligned parallel to the long axis of the outer border of the radius or ulna and the distal arm of the goniometer was aligned parallel to the third metacarpal.

Measurement method described by Colaris et al (2010) for forearm active ROM:
One arm of the goniometer was lined up parallel to the upper arm of the patient and the other arm of the goniometer was placed parallel to the distal third of the forearm.

Previous investigations(63, 64) have adopted the method where each goniometer measurement was repeated three times and these measurements averaged. The time poor environment of clinical practice required pragmatic methods. Subsequently this investigation involved one measurement of range of motion using the

goniometer. To counter the potential for creep in range associated with repeated measurements, participants were shown, and asked to repeat, the target movement three times before measurement.

Methods

The six participants and the principal researcher performed measurements of wrist and forearm active movements (extension, flexion, radial deviation, ulnar deviation, pronation and supination) on each other in random order. One participant or the principal researcher had their wrist and forearm active ROM measured by the other six individuals and this position was then rotated so that different individuals had movements measured for each experimental condition. For each experimental condition, each participant completed all measurements on the subject before the next participant commenced their measurements. Order of measurements (for each participant under each experimental condition) were determined by random allocation using concealed cards.

Participants performed measurements under five experimental conditions and these are detailed below:

Experiment 1 (determining use of goniometer 1 or 2 for each measurement)

Unilateral goniometer measurement of wrist and forearm active ROM with standardised bony landmark identification (not marked). Measurements of wrist flexion and extension using both the dorsal-volar and radial-ulnar techniques were taken. Measurements were taken with Goniometer 1 and then repeated with Goniometer 2. The reliability results of Experiment 1 were used to guide the choice of goniometer for Experiments 2-5. Experiment 1 involved each participant recording a total of 20 measurements.

Experiment 2 (marking of bony landmarks)

Bilateral goniometer measurement of wrist and forearm active ROM with standardised bony landmark identification. Skin markers (small pieces of non-irritating tape) were added to bony landmarks before measurements commenced. Measurements of wrist flexion and extension using both the dorsal-volar and radial-ulnar techniques were taken. Experiment 2 involved each participant recording a total of 20 measurements.

Experiment 3 (developing technique of reading from goniometer)

Bilateral goniometer measurement of wrist and forearm active ROM using skin markers and checking technique of reading from the goniometer. Measurers were reminded of the phenomenon of end digit preference. A systematic method of reading from the goniometer was developed through participant and principal researcher collaboration. Experiment 3 involved each participant recording a total of 20 measurements.

Experiment 4 (reaching consensus)

Based on the estimates of error from the three previous experimental conditions, and other observations made by the team, consensus was reached regarding the method that appeared to produce the smallest error variance. This method was followed for goniometer measurement of wrist and forearm active ROM. Team consensus led to inclusion of an inclinometer for measurement of forearm pronation and supination active ROM. For inclinometer measurements, the inclinometer was placed at the midpoint of the dorsal aspect of the forearm located 5cm from the centre of the capitate. The inclinometer was aligned parallel to the sagittal plane of the forearm. Experiment 4 involved each participant recording a total of 20 measurements.

Experiment 5 (assessing stability in the variance)

The methods developed in Experiment 4 to minimise variation were repeated on two participants for wrist and forearm active ROM to assess stability in the variance. Experiment 5 involved each participant recording a total of 24 measurements.

Results

The standard deviations calculated from the measurements performed by each participant and principal researcher in Experiment 1 and 5 are shown in Table 3-1.

Table 3-1 Measurements and standard deviations for all participants in Experiment 1 and 5.

Experiment 1 measurements	Experiment 1 Standard deviation	Experiment 5 measurements (Right side)	Experiment 5 Standard deviation (Right side)	Experiment 5 measurements (Left side)	Experiment 5 Standard deviation (Left side)
WF D-V Goniometer 1	7.9	WF P1	5.1	WF P1	6.2
WF D-V Goniometer 2	5.0				
WF RT Goniometer 1	9.1				
WF RT Goniometer 2	6.9	WF P2	6.7	WF P2	8.1
WF UT Goniometer 1	5.9				
WF UT Goniometer 2	6.8				
WE D-V Goniometer 1	7.7	WE P1	3.7	WE P1	7.9
WE D-V Goniometer 2	6.2				
WE RT Goniometer 1	5.4				
WE RT Goniometer 2	4.4	WE P2	5.5	WE P2	3.9
WE UT Goniometer 1	2.3				
WE UT Goniometer 2	5.5				
RD Goniometer 1	3.8	RD P1	4.0	RD P1	1.2
RD Goniometer 2	2.3	RD P2	3.9	RD P2	2.9
UD Goniometer 1	7.9	UD P1	2.3	UD P1	1.0
UD Goniometer 2	4.8	UD P2	3.4	UD P2	1.8
FP Goniometer 1	9.2	FP P1	2.3	FP P1	5.6
FP Goniometer 2	9.2	FP P2	8.6	FP P2	7.7
FS Goniometer 1	5.5	FS P1	4.0	FS P1	4.6
FS Goniometer 2	7.2	FS P2	5.8	FS P2	3.7

WE= wrist extension; WF=wrist flexion; RD=radial deviation; UD=ulnar deviation;
FP=forearm pronation; FS=forearm supination; D-V= dorsal-volar technique; RT=radial technique; UT=ulnar technique;
P1=participant 1; P2=participant 2

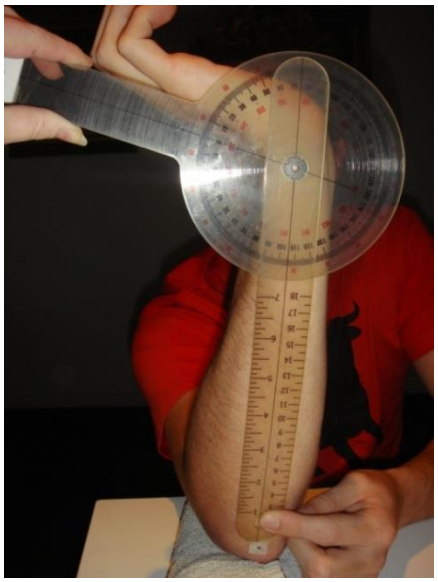
The final method (Experiment 5) resulted in standard deviations for active wrist flexion, extension, radial and ulnar deviation ranging from 1.0° to 8.1° for the six participants and principal researcher. For forearm pronation and supination active ROM, standard deviations for the six participants and principal researcher ranged from 2.3° to 8.6°.

The measurement methods, described below, evolved following the systematic and iterative process of measurement, estimation of errors, method refinement and repeated measurement.

Measurement techniques for wrist and forearm active ROM

For consistency in instructions, participants were advised to demonstrate the movement to be measured. They then repeated that movement gently until they felt they had achieved maximum movement. Participants were asked to 'warm up' with two full range repeated movements prior to measurement. Each movement was measured once and measurements taken to the nearest degree.

1. Wrist extension



Technique:

- Ulnar technique- Goniometer 1
- A zero starting position with measurements recorded from zero and progressing to end of range

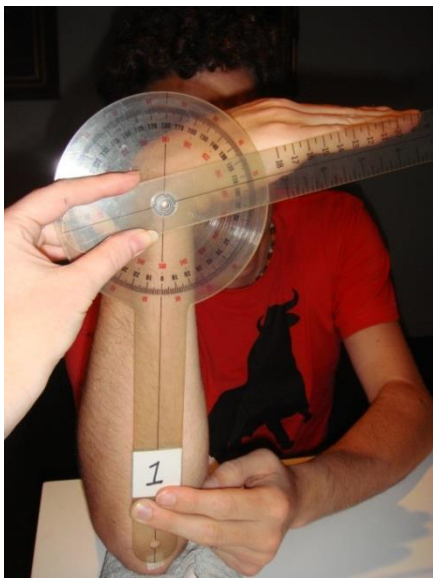
Position:

- Block or rolled towel under elbow
- Elbow flexed to 90º
- Forearm held in neutral supination/pronation
- Fingers held in relaxed position

Landmarks:

- Axis of the goniometer placed over the tip of the ulnar styloid
- Distal arm of the goniometer aligned parallel with the 5th metacarpal
- Proximal arm of the goniometer aligned along the ulnar border of the forearm in line with the midpoint of the distal aspect of the olecranon

2. Wrist flexion



Technique:

- Ulnar technique- Goniometer 1
- A zero starting position with measurements recorded from zero and progressing to end of range

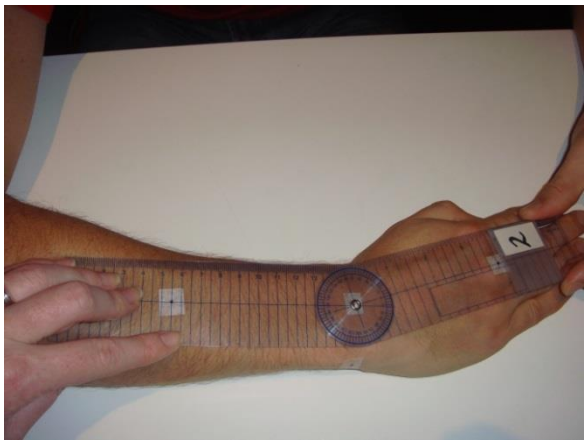
Position:

- Block or rolled towel under elbow
- Elbow flexed to 90º
- Forearm held in neutral supination/pronation
- Fingers together with MCP, PIP and DIP joints extended (as able)

Landmarks:

- Axis of the goniometer placed over the tip of the ulnar styloid
- Distal arm of the goniometer aligned parallel with the 5th metacarpal
- Proximal arm of the goniometer aligned along the ulnar border of the forearm in line with the midpoint of the distal aspect of the olecranon

3. Wrist radial deviation



Technique:

- Using goniometer 2
- A zero starting position with measurements recorded from zero and progressing to end of range

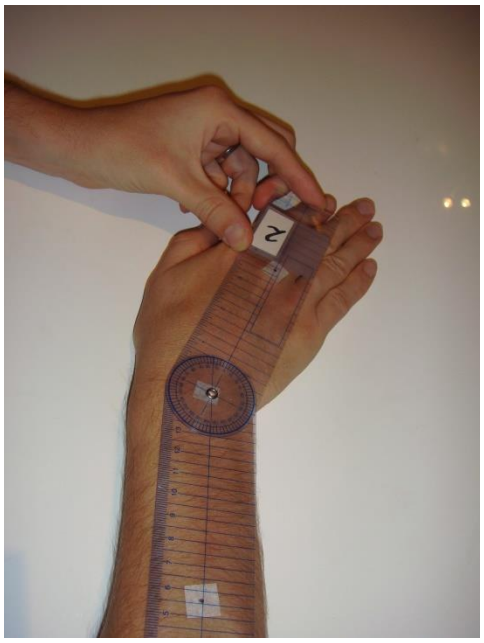
Position:

- Neutral wrist position with no flexion or extension (or as close to this as possible)
- Palm and forearm flat on table if able. If unable to achieve flat palm and forearm on table then palm and forearm placed on a flat surface in comfortable forearm pronation
- Elbow flexed to 90°

Landmarks:

- Axis of the goniometer placed over the centre of the capitate on the dorsal aspect of the wrist. Centre of capitate located by finding the midpoint of the line connecting the radial and ulnar styloid tips
- Distal arm of the goniometer aligned with the third metacarpal head
- Proximal arm of the goniometer aligned with a point at the midpoint of the dorsal aspect of the forearm located 10cm from the centre of the capitate

4. Wrist ulnar deviation



Technique:

- Using goniometer 2
- A zero starting position with measurements recorded from zero and progressing to end of range

Position:

- Neutral wrist position with no flexion or extension (or as close to this as possible)
- Palm and forearm flat on table if able. If unable to achieve flat palm and forearm on table then palm and forearm placed on a flat surface in comfortable forearm pronation
- Elbow flexed to 90°

Landmarks:

- Axis of the goniometer placed over the centre of the capitate on the dorsal aspect of the wrist. Centre of capitate located by finding the midpoint of the line connecting the radial and ulnar styloid tips
- Distal arm of the goniometer aligned with the third metacarpal head
- Proximal arm of the goniometer aligned with a point at the midpoint of the dorsal aspect of the forearm located 10cm from the centre of the capitate

5. Forearm pronation

Technique:

- Inclinometer positioned on dorsal surface of forearm and not pushed into skin
- Starting movement from a position of neutral (0°) supination/pronation and moving to maximum pronation

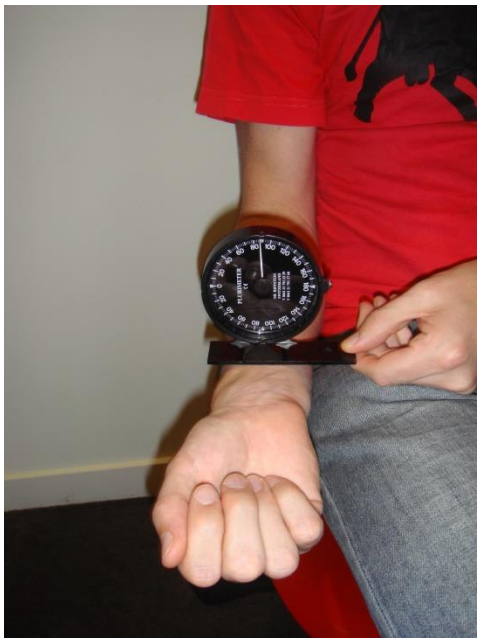
Position:

- Sitting away from table
- Elbow against torso
- Elbow flexed to 90°

Landmarks:

- Inclinometer placed a point at the midpoint of the dorsal aspect of the forearm located 5cm from the centre of the capitate
- Inclinometer aligned parallel with the sagittal plane of the forearm

6. Forearm supination



Technique:

- Inclinometer positioned on volar surface of forearm and not pushed into skin
- Starting movement from a position of neutral (0°) pronation/supination and moving to maximum supination

Position:

- Sitting away from table
- Elbow against torso
- Elbow flexed to 90°

Landmarks:

- Inclinometer placed at the midpoint of the volar aspect of the forearm,5cm from the centre of the capitate
- Inclinometer aligned parallel with the sagittal plane of forearm

Conclusions

The techniques developed in this investigation, following the systematic and iterative process of measurement, estimation of errors, method refinement and repeated measurement were adopted for the RCT. All participants in this investigation were recruited as rehabilitation physiotherapists or blind assessors for the RCT and additional participating therapists were trained in these methods.

3.2.2 Methods for measuring function, active ROM, pain and complications in RCT

Patient-rated wrist evaluation (PRWE)

The PRWE was chosen as the primary outcome measure for the RCT given its focus on the joint of interest and its reliability, validity and responsiveness. (65) It is a questionnaire measuring wrist pain and disability in activities of daily living. The questionnaire includes 15-items; five items assess symptoms and 10 assess disability. Scale width is 0-100 points with higher scores reflecting greater pain and disability. PRWE raw scores can be adjusted for missing data by replacing individual missing item scores with the mean score for the subscale.

Visual Analogue Scale (VAS) for pain

The 10cm VAS is a single-item measure of pain. Crossley et al (2004) assessed the reliability of the VAS using 20 participants with patellofemoral pain. An overall assessment of pain was measured asking participants to specify the VAS for worst (VAS-W) and usual (VAS-U) pain in the past week. The standard error of measurement for test-retest data of both VAS-W and VAS-U was 0.6cm.(66) Consistent with Crossley et al (2004), the RCT involved asking participants to specify the VAS for their worst and their usual pain over the past week.

Active ROM

The methods outlined in section 3.2.1 were followed for the recording of wrist and forearm active ROM in the RCT. The investigation into the reliability of wrist and forearm active ROM measurements identified accuracy with locating anatomical landmarks as a potential source of intra- and inter-rater error when measuring wrist and forearm active ROM. To minimise this source of error, henna, a natural plant extract, was applied to provide a skin mark lasting up to two weeks. The henna mark was used to standardise anatomical landmarks for goniometer and inclinometer placement. Bilateral measurement enabled comparison to the uninjured side and single measurements of active ROM using the goniometer or inclinometer were performed on each measurement occasion. The RCT reported absolute

measures of wrist and forearm joint range of movement in preference to movement arcs (e.g. wrist flexion-extension arc). The basis for this decision was that reduction in range of movement at the wrist and forearm following distal radius fracture is not uniform for all planes/directions of movement and is linked with the type of residual deformity at the distal radius.(67)

Grip strength measurement

Grip strength was recorded bilaterally using the Jamar hand dynamometer. Two Jamar dynamometers were calibrated and aligned prior to measurements and recalibrated regularly throughout the duration of the RCT. Previously reported standardised positioning and instructions were adopted. (68) One measurement of grip strength was used for this investigation. This has been reported to be comparable to the average of three grip strength trials.(69)

The grip strength assessment procedure was demonstrated by the examiner and participants were advised to perform their maximum within the limits of pain. Once the participants were positioned they were instructed "Are you ready? Squeeze as hard as you can. Harder! ..... Harder! ..... Harder! ... Relax." These verbal instructions are similar to those adopted previously.(70)

Disabilities of the Arm, Shoulder and Hand (DASH)

While there is some overlap in information gained from the DASH and PRWE, the DASH was adopted as a secondary outcome measure for the RCT. The DASH is a health-related quality of life questionnaire that measures disability and symptoms in single or multiple conditions of the upper limb.(71) The DASH scale width is 0-100 points with higher scores reflecting greater disability.

Complications

Post-operative complications were assessed using review of clinical entries in the participants' hospital records for the period of post-operative hospitalisation in addition to ED presentations, outpatient orthopaedic appointments, and rehabilitation (physiotherapy) outpatient appointments for the six months follow-up period. Documentation of any wound infection, persistent neuropathy or tendinopathy, tendon rupture, and loss of fixation or ligament damage requiring surgical repair was recorded as an adverse event.

3.3 Developing rehabilitation program and training trial therapists

Details of the rehabilitation program developed for RCT participants are included as an appendix in the RCT paper (Chapter 4). Details of the home exercise program for participants, comprising part of their rehabilitation, are described in Appendix G. Training was provided to the eight trial rehabilitation physiotherapists on assessment, education, exercise prescription and support for participants. This involved observation of the principal researcher providing treatment (initial and review appointment) for a patient following ORIF for distal radius fracture and the principal researcher observing and providing feedback to the physiotherapist following treatment provision. The observation and feedback sessions provided by the principal researcher ranged in number from two to four depending on the demonstrated skill and needs of the treating physiotherapist.

The principal researcher also provided education and training on measurement techniques to the rehabilitation physiotherapists not involved in the investigation into the reliability of wrist and forearm active ROM measurements using a goniometer (section 3.2.1). Both blind assessors participated in the measurement reliability refinement study and subsequent training was not required. Training was given to additional rehabilitation therapists who were not participants in the reliability trial. This involved 30 minutes of individual instruction and observation of the principal researcher performing these measurements on a patient with a previous distal radius fracture. In addition, the principal investigator observed and provided feedback to the rehabilitation physiotherapist after they performed these measurements on a patient with a healed distal radius fracture. Repeated wrist and forearm measurements were performed on the principal investigator to assess stability in error variance and were used to determine that an acceptable standard had been reached.

3.4 Methods of engaging clinicians and sustaining engagement

At the time of RCT commencement, routine practice at the health service for a patient presenting to the ED with a distal radius fracture requiring surgical reduction (excluding open fracture or fractures requiring immediate surgery) involved the following: potential reduction of fracture positon in ED, application of temporary immobilisation and discharge with an appointment for outpatient orthopaedic fracture clinic in the following week. Following review at the outpatient orthopaedic fracture clinic, a time for surgery was scheduled (usually within the following few days). The patient would return to the hospital for the scheduled surgery and remain on the hospital orthopaedic ward for one-two days following ORIF. They would be discharged with a below elbow volar splint overlying the post-operative dressing. At the time of discharge from hospital, a review appointment would be scheduled for an outpatient orthopaedic fracture clinic appointment seven-10 days following surgery. Repeat radiographs would be taken at this appointment, a decision made on duration of immobilisation, an outpatient orthopaedic fracture clinic appointment scheduled for six weeks following surgery, and a referral made for outpatient physiotherapy to commence at the time of removal of immobilisaton.

For the period of RCT recruitment, the principal researcher functioned as the central point of contact and liaison for all the trial participants and all clinicians involved with the care of trial participants. Key stakeholders (e.g. Head of Orthopaedic Department, orthopaedic trauma surgeons) at the trial health service were involved from the point of RCT inception with the dual purpose of maximising engagement and enhancing the quality of trial design.

As recruitment for the RCT occurred over a 3.5 year period (September 2012 to May 2016), strategies were required to sustain clinician engagement. Clinician engagement was essential for ensuring trial researchers were aware of, and recruited, all potential participants, and adhered to standardised trial procedures. Initial strategies for engaging clinicians included education of rotating orthopaedic registrars about the RCT background and protocols. In addition, regular in-services and trial updates were scheduled for key stakeholder groups (Orthopaedic and Physiotherapy Departments). The orthopaedic registrars had elected to notify trial

recruitment staff when patients meeting RCT eligibility criteria presented to their first post-discharge, outpatient orthopaedic fracture clinic. A review of this process after the trial commenced revealed that trial recruitment staff were not consistently being notified of all eligible participants. A change in process was then implemented whereby trial recruitment staff performed daily theatre list checks to capture all patients undergoing ORIF for distal radius fracture. Recruitment rate markedly improved following this change. A further issue identified early in the recruitment phase of the trial was that some participants were advised about duration of immobilisation based on traditional care practices. Allocation to group occurred at the first post-operative review appointment seven-10 days following surgery. When the allocated immobilisation period differed from earlier advice provided to participants, this caused understandable concern for participants. To address this, regular presentations to the orthopaedic team were scheduled to reinforce trial procedures. Orthopaedic staff were reminded that information conveyed to consenting participants should include that they would be notified of group allocation at the post-operative review appointment seven-10 days following surgery. An information sheet, clearly detailing the group allocation and management, was attached to the front of participants' hospital clinic notes at every review appointment to enhance clinician adherence with trial protocols (Appendix H).

In an effort to maximise the delivery of key information to participants and promote a sense of self-control in planning the path to recovery, participants were asked during the recruitment process whether they would prefer to be notified of their group allocation prior to their first post-operative review appointment. Upon request, the principal researcher was responsible for notifying participants of their group allocation once concealed randomisation had occurred (see Chapter 4) and prior to their initial review appointment. This strategy was particularly appreciated by participants allocated to the one week immobilisation group and it enabled participants time to plan and prepare for mobilisation following their initial post-operative review appointment. A bimonthly newsletter (see examples in Appendix I) was introduced early in the RCT recruitment phase and proved to be an effective means of communicating observed deviations from trial procedures and for sustaining staff engagement.

3.5 Chapter conclusion

This chapter has provided information on some of the preparatory steps taken to establish a standardised, robust and sustainable trial protocol. The strategies employed to enhance clinician engagement and sustain this engagement appeared to contribute to the high retention of trial rehabilitation therapists and the two blind assessors who remained constant throughout the duration of the trial, and to the effective recruitment of participants.

4. Chapter 4- A randomized controlled trial comparing one, three or six weeks of immobilization on function and pain following open reduction and internal fixation for distal radius fractures in adults.

4.1 Introduction to RCT

The systematic review and meta-analysis (Chapter 2) indicted that high quality large RCTs, with monitoring of complication rates, pain and patient satisfaction, were required to enhance confidence in the likely short-term functional advantages provided by early mobilisation. The following RCT design involved comparison of three different immobilisation periods following ORIF for distal radius fracture. Based on WHO recommendations regarding important health domains(72), outcomes of active ROM, function, pain, complication rates and patient satisfaction (through interview) were collected. Outcomes were recorded over a six month period with the initial outcomes taken at six weeks, enabling a view of the potential short-term advantages of early mobilisation. Selection of immobilisation periods was based on one week being the minimum possible at the health service (considering wound management and the logistics of scheduling the initial post-operative review appointment), six weeks being standard practice at the health service, and three weeks as it provided an intermediate period of immobilisation and a view of the 'dose-response' relationship of immobilisation duration.

The following text is a copy of the manuscript currently under review with Journal of Bone and Joint Surgery-American Volume (5 year impact factor = 6.11):

Watson, N. J., Haines, T. P., Tran, P., Keating, J. L. A randomized controlled trial comparing one, three or six weeks of immobilization on function and pain following open reduction and internal fixation for distal radius fractures in adults.

4.2 Abstract

Background

Optimum immobilization periods following open reduction and internal fixation (ORIF) of distal radius fractures are not established.

Methods

One hundred and thirty-three adults with distal radius fracture treated with ORIF (locked volar plate) were randomly allocated stratified for age to one, three or six weeks of post-operative immobilization in a parallel design, assessor blinded, randomized controlled trial (RCT). After cast removal, a standardized education and exercise program was followed for 6 weeks. Primary outcomes were function (PRWE), worst (VAS-W) and usual (VAS-U) pain in the past week, and wrist extension and supination active range of movement (ROM). All measures were recorded at 6, 12 and 26 weeks following surgery. Secondary outcomes were wrist flexion, radial deviation, ulnar deviation and forearm pronation active ROM, function (DASH), grip strength, post-operative adverse events, return to work/usual daily activities and adherence with home exercise program.

Results

Ninety percent of participants received treatment as allocated and 87% completed the 6 month follow-up. At 6 weeks, both the one and three week groups had significantly better PRWE scores, wrist extension and flexion active ROM than the six week group. However, no one treatment group was superior to another for primary or secondary outcomes at 12 weeks or 6 months following surgery. Analyses considering only the main effect of the intervention group indicate a preference for the three week group which performed significantly better for the outcomes PRWE, pain (VAS-W, VAS-U), wrist flexion, ulnar deviation, forearm pronation active ROM and DASH when compared with the six week group.

Conclusions

For function, ROM and pain, this investigation indicates that immobilization periods of one and three weeks produce superior short-term outcomes when compared with

six weeks of immobilization. These differences are not evident long-term with immobilization period having no significant effect on function, active ROM or pain from three months following surgery. There were no significant differences in adverse events associated with shorter immobilization periods.

Level I evidence

4.3 Introduction

Distal radius fracture is common, representing 10-25% of all fractures,(73) with consequences including high health care and productivity costs, impaired physical function, impaired mental health and prolonged work absence.(14)

Distal radius anatomy affects hand function. Fracture management targets restoration of typical anatomical position.(39, 74-77) Length of immobilization following distal radius fracture varies and 'fracture stabilization versus early mobilization' is a key consideration.(22) Systemic influences, mechanical stability and blood supply are crucial for successful fracture repair. Our understanding of relationships between these processes and optimal conditions for fracture healing continues to develop.

Three RCTs of internal fixation using volar locked plates for distal radius fractures compared different periods of immobilization.(16-18) Mobilizing either immediately or two weeks after surgery was compared to mobilizing at four, five or six weeks. Two trials found no differences in wrist active ROM or Disability of the Arm, Shoulder and Hand (DASH) scores at 3(17, 18) or 6 months(18) following surgery. One trial(16) found significantly better active ROM and function at 6, 26 and 52 weeks with early mobilization. Threats to internal validity of these trials included small samples [n=60(18), n=30(17)], no assessor blinding (17) and unmonitored treatment adherence (17, 18). No authors reported between group differences in post-operative complications indicating that immediate mobilization following internal fixation appears safe. No trial has compared several periods of immobilization to a reference standard to assess a dose response relationship.

In this RCT, we sought high quality evidence on effects of immobilization period. We compared immobilization of one, three and six weeks following open reduction and internal fixation for distal radius fracture. At the health service, immobilization periods of one week were the minimum possible, six weeks were standard practice and three weeks enabled a view of systematic effects associated with immobilization period. Based on previous studies, we hypothesised that function and pain scores would not be superior for any group at six months following surgery, however differences might be evident earlier.

4.4 Materials and Methods

Design

A parallel design RCT, with stratification for age, compared outcomes for one, three or six weeks immobilization following ORIF.

Participants

Inclusion criteria were 18 years or older, fracture involving the distal 3cm of the radius with or without associated ulna fracture, operative management involving an isolated distal radius volar locked plate, and fracture deemed stable by surgeon after ORIF. Exclusion criteria were pathological fractures, cognitive impairment, open fractures, gait-aid use involving the injured upper limb, or ongoing management following ORIF not occurring at the investigation health service.

Study settings

Participants were recruited from a large Australian metropolitan health service between September 2012 and May 2016. Eligible patients were invited to participate while inpatients, usually within 24 hours of operation.

Interventions

All participants received standardized treatment during the first post-operative week. Overlying the post-operative dressing, a below elbow volar splint was applied immediately following ORIF and remained in-situ for seven days. During this time,

participants were encouraged to perform light functional activities and active ROM of all joints excluding the injured wrist. The splint was removed at the one week post-operative review. A full circumferential below elbow cast was applied for participants in the three and six week groups. Within three days of removal of the splint/circumferential cast, participants were engaged in a standardized physiotherapy education and exercise program weekly for six weeks (Appendix J). When adverse events were detected, planned immobilization time remained unchanged whenever possible and deviations from intended interventions were recorded.

Orthopaedic trauma consultants performed all surgical procedures. One of eight physiotherapists trained in assessment, education and support for participants, provided physiotherapy. Two other physiotherapists, blind to group allocation, measured outcomes. Training and pilot studies were implemented to standardize measurement methods. Four plaster technicians managed casts.

Outcome measures

Outcomes were recorded at 6, 12 and 26 weeks following surgery. Primary outcomes were function (PRWE)(78), worst (VAS-W) and usual (VAS-U) pain in the past week, extension and supination active ROM. Secondary outcomes were wrist flexion, radial deviation, ulnar deviation and forearm pronation active ROM, function (DASH)(71), grip strength, post-operative adverse events, return to work/usual daily activities and adherence with home exercise program (HEP)(Appendix K). Adverse events included wound infection, persistent neuropathy or tendinopathy, tendon rupture, and loss of fixation or ligament damage requiring surgical repair within 6 months post-operatively. The principal investigator also contacted participants by phone after the 26 week assessment and recorded information on return to work/usual daily activities and associated barriers or enablers. At each assessment participants described adherence with home exercises over the past week as 0) Did not complete any exercises in the past week; 1) Completed exercises on some days in the past week; 2) Completed exercises on most days in past week; 3) Completed exercises on all days in past week.

Sample size

Power analyses were performed for analysis of covariance (ANCOVA) using 'fpowever' in Stata IC 13.1. To detect a difference in PRWE scores of 14.5 (SD 20.6) points with significance level of 0.05 and power of 80%, 40 participants per group were required. A difference in PRWE scores of 14.5 points represents almost three-quarters of a scale step, where the steps that describe function are no limitations (0), minimal (1-20), mild (21-40), moderate (41-60), severe (61-80) and very severe (81-100).(79) The standard deviation of 20.6 points was based on data from a study of a similar participants (n=129).(79) Anticipating a dropout rate of 12.5%, the target enrolment was 135 participants.

Randomization: sequence generation and type

The principal researcher used text and email to advise the off-site allocation officer of participant enrolment and age. The allocation officer was not aware of any other participant details or involved with assessments or treatments. A computer generated random allocation sequence determined group allocation following stratification for age above or below 55 years due to the potential impact of age-related changes (e.g. osteoporosis) on outcomes. The principal researcher advised the treating team of allocation at the one week post-operative review.

Blinding

It was not possible to blind treating physiotherapists or participants. Outcome assessors were blinded to group allocation and participants were asked not to reveal duration of immobilization to assessors.

Statistical methods

Age at time of ORIF, gender, ORIF involving dominant side, AO(80) fracture classification, associated ulnar styloid/head fracture and days from incident to surgery were summarized using means (SDs) or numbers (percent) of participants. Analysis followed intention-to-treat principles. A multilevel, mixed-effects, generalized linear model compared one, three or six weeks of immobilization. Analyses compared primary outcomes at 6, 12 and 26 weeks in the one model using the six week group as the reference. Repeated measurements within each

participant were treated as random effects. These analyses considered only the main effect of intervention group and, by combining all follow-up assessment points in one model, assumed that the effect of group allocation was relatively consistent across follow-up time points. As this assumption may not hold we also examined whether the effect of group allocation varied over the follow-up period. Similar multilevel, mixed-effects, generalized linear model analyses were performed using a "treatment group" by "time since surgery" interaction term in the fixed effects part of the model. Time from ORIF was continuous in this model. One-way analysis of variance compared treatment groups at each assessment point. Statistical analyses were carried out using Stata IC version 13.1. The significance level was set at 5%.

Secondary outcomes were analysed using the same approach. Given the exploratory nature of these secondary analyses, no alpha adjustments were made. Post-operative adverse events were compared using Fischer's exact test. All analyses were repeated with differences between affected and contralateral side replacing raw measurements in the analyses to assess the implications of using difference scores in contrast to raw scores.

No funding supported this investigation.

Trial registration

Australian New Zealand Clinical Trials Registry ACTRN12612000902897.

4.5 Results

Between 2012 and 2016, 133 participants were randomized. Of those assigned to one, three and six week groups, 44 (96%), 38 (93%) and 42 (91%) respectively were immobilized as allocated (Figure 4-1). Demographic data are reported in Table 4-1.

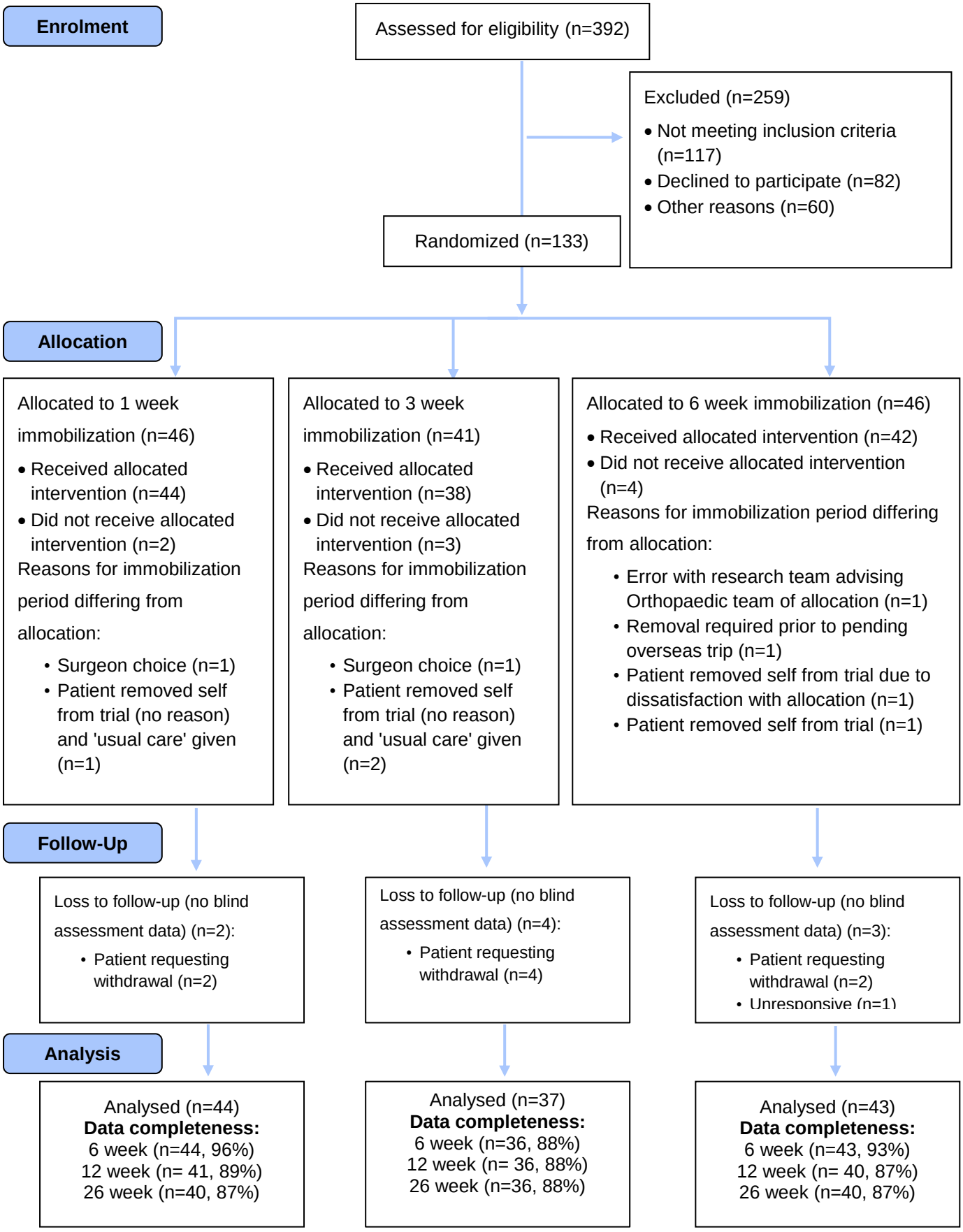


Figure 4-1 Flow of participants through trial

Table 4-1 Baseline demographic and clinical information*

	Immobilization (treatment) group		
	1 week (n=46)	**3 weeks (n=41)**	**6 weeks (n=46)**
Age (years) at time of ORIF	54.0 (15.6)	51.1 (14.9)	52.0 (15.9)
Age <55 at time of ORIF (n)	20 (43.5)	21 (51.2)	21 (45.7)
Female (n)	29 (63.0)	31 (75.6)	25 (54.3)
ORIF on dominant side (n)	19 (41.3)	12 (29.3)	18 (39.1)
Pre-operative AO classification	A=4 (A2=1, A3=3) B=34 (B1=7, B2=16, B3=11) C=6 (C1=1, C2=5) Pre-operative radiograph unavailable = 2	A=7 (A2=3, A3=4) B=25 (B1=1, B2=18, B3=6) C=8 (C1=5, C2=2, C3=1) Pre-operative radiograph unavailable = 1	A=5 (A2=1, A3=4) B=30 (B1=4, B2=20, B3=6) C=10 (C1=1, C2=8, C3=1) Pre-operative radiograph unavailable = 1
Associated ulnar styloid/head fracture	24 (52.2)	25 (61.0)	28 (60.9)
Time from injury to surgery(days)	8.6 (6.3)	8.0 (6.1)	8.6 (6.2)
Time in immobilization (days)	12.1 (5.3)	22.2 (4.3)	37.5 (8.5)

*Data are means (SD) or numbers (%)

Primary outcomes

Function

Significant main effects were found (Figure 4-2) with the one and three week groups having significantly lower PRWE scores (indicating less pain and disability) compared to the six week group (P= .03; P=.001 respectively). A significant interaction effect was observed (Figure 4-2) with more rapid improvement for the six week group across the 6 month follow-up compared to the three and one week groups (P=.04, P=.02 respectively). One-way ANOVA found one (P = .003) and three (P=.001) week groups had significantly lower PRWE scores than the six week group at 6 weeks following ORIF. No significant differences were found at 12 or 26 weeks.

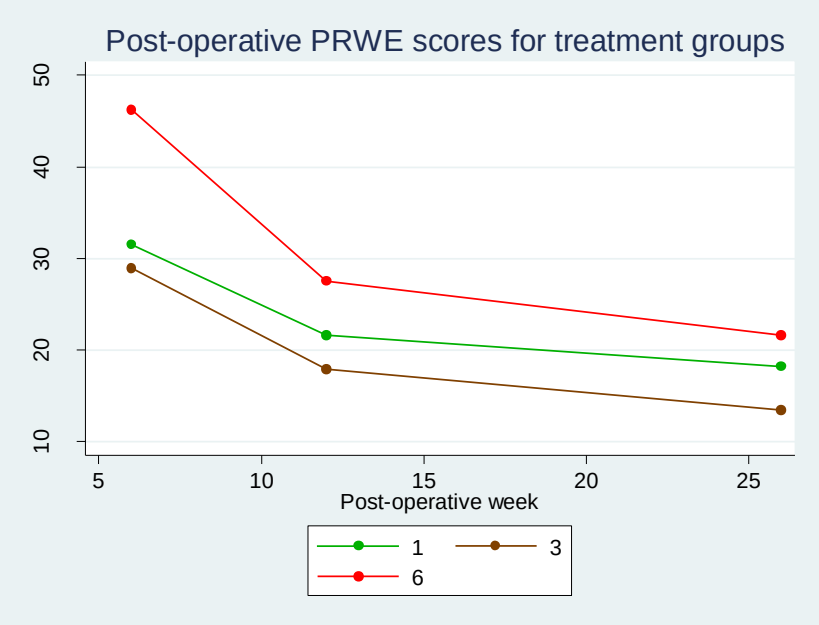


Figure 4-2 PRWE scores for participants in the 3 treatment groups recorded at 6, 12 and 26 weeks from ORIF (lower sores indicate better function)

Pain

Significant main effects were found with the three week group having significantly lower VAS-W and VAS-U scores (less pain) compared to the six week group (P= .03; P=.007 respectively). No significant interaction effects between group and assessment time were found. The one and three week groups had significantly lower VAS-W (P = .02) and VAS-U (P=.03) scores respectively than the six week group at 6 weeks. No significant differences in VAS-W or VAS-U scores were found at 12 or 26 weeks.

Active ROM

No main effects for wrist extension active ROM were found. A significant interaction effect between group and assessment time was observed with more rapid improvement (Figure 4-3) for the six week group across the 6 month follow-up period compared to the three week and one week groups (P=.04, P=< .01 respectively). The one and three week groups had significantly more wrist extension than the six week group at 6 weeks (P=.03, P=.04 respectively). No significant differences in wrist extension were found at 12 or 26 weeks.

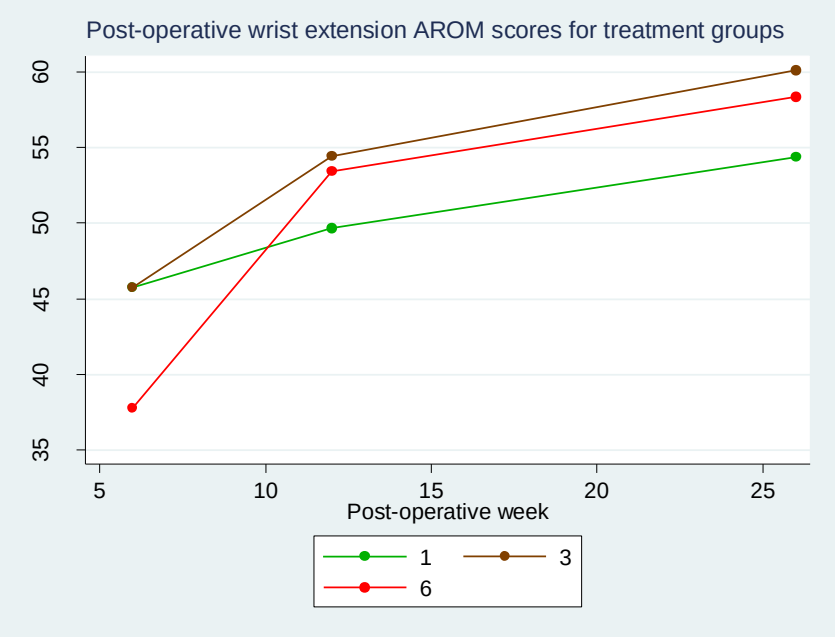


Figure 4-3 Wrist extension active range of movement for participants in the 3 treatment groups recorded at 6, 12 and 26 weeks from ORIF

No significant main or interaction effects for group and assessment time were found for forearm supination, nor were there any differences between groups at any time point.

Analyses were repeated when differences between affected and contralateral sides replaced raw measurements. No notable differences were found except that wrist extension ROM for the three and six week groups were no longer significantly different at 6 weeks. These differences did not impact on conclusions made from this investigation.

Secondary outcomes

The three week group had significantly lower DASH scores (less disability) (P= .04) and significantly greater wrist flexion, ulnar deviation and forearm pronation active ROM (P=.03, P=.04, P=.03 respectively) compared to the six week group. No significant main effect was found for grip strength, nor were there any differences between groups at any assessment. The one week group had significantly lower DASH scores (less disability) than the six week group at 6 weeks (P=.03). The one and three week groups had significantly more wrist flexion (P< .01, P=.005

respectively) than the six week group at 6 weeks. No significant differences in DASH scores and wrist flexion were found at 12 or 26 weeks. Radial and ulnar deviation and forearm pronation active ROM were not significantly different at any assessment.

Return to work/usual daily activities at 26 weeks was achieved for 90-100% of participants (Table 4-2). PRWE and DASH responses at 26 weeks were cross checked against patient self-reports. There were no significant group differences at 26 weeks based on PRWE, DASH items or self-reports.

Table 4-2 Means (SD) for primary and secondary outcome measures by immobilization period at 6 weeks and 6 months following ORIF.

	6 week assessment						26 week assessment					
	1 week group		3 week group		6 week group		1 week group		3 week group		6 week group	
	Mean (SD)	N	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
PRWE	31.5 (19.9)	44	29.0 (19.0)	36	46.3 (22.1)	43	18.2 (23.8)	40	13.5 (14.8)	36	21.6 (20.6)	40
VAS-W(mm)	27.7 (23.8)	44	34.0 (27.6)	36	43.2 (27.1)	43	19.8 (28.4)	40	12.2 (18.2)	36	23 (25.7)	40
VAS-U(mm)	14.7 (13.3)	44	12.8 (15.4)	36	22.3 (19.3)	43	11.4 (18.3)	40	4.9 (9.7)	36	12.2 (17.5)	40
*Wrist extension (degrees)	45.7 (14.5)	44	45.7 (14.3)	36	37.8 (13.9)	43	54.4 (13.4)	40	60.1 (11.8)	36	58.3 (8.7)	40
*Supination (degrees)	65.9 (15.6)	44	66.5 (15.1)	36	59.7 (17.2)	43	72.0 (12.6)	40	75.1 (10.6)	36	70.5 (11.3)	40
*Wrist flexion (degrees)	52.3 (15.9)	44	50.3 (11.4)	36	39.8 (15.2)	43	61.0 (15.0)	40	63.8 (12.6)	36	61.7 (11.1)	40
*Radial deviation (degrees)	14.8 (5.5)	44	13.1 (4.9)	36	12.9 (5.2)	43	17.0 (5.2)	40	18.0 (5.8)	36	17.4 (6.1)	40
*Ulnar deviation (degrees)	18.0 (7.9)	44	18.6 (6.5)	36	15.1 (7.4)	43	19.7 (8.4)	40	21.9 (7.1)	36	19.5 (6.6)	40
*Pronation (degrees)	74.2 (14.4)	44	76.2 (9.1)	36	70.2 (15.6)	43	78.3 (10.2)	40	80.5 (10.7)	36	78.1 (9.3)	40
DASH	29.6 (18.3)	24	33.1 (17.5)	23	44.7 (23.9)	25	12.9 (19.6)	26	10.4 (14.7)	27	14.4 (17.7)	31
Grip strength (kg)	14.9 (9.9)	44	14.1 (9.2)	36	12.0 (9.1)	43	22.7 (12.4)	40	22.6 (11.5)	36	24.5 (16.8)	40
Return to work/usual tasks (PRWE)							38 (90)†	42	34 (94)†	36	40 (100)†	40
Return to work/usual tasks (DASH)							41 (95)†	43	36 (97)†	37	43 (100)†	43
Return to work/usual tasks (self-report)							23 (92)†	25	31 (97)†	32	23 (92) †	25

*Data are absolute active ROM; † Data- number (%)

Adherence with home exercise program (HEP)

A significant main effect was found (Figure 4-4) with the three week group being significantly less compliant with their HEP compared to the six week group (P= 0.01). The three week group were significantly less compliant (P=.01) with their HEP than the six week group at 12 weeks. At the 12 week assessment, 'not completing any exercises in the past week' was reported by 22% and 5% of participants in the three week and six week groups respectively. At 12 weeks, 'completion of exercises on all days in the past week' was reported by 28% and 61% of participants in the three and six week groups respectively. No significant differences in adherence with HEP were found between groups at 6 and 26 weeks following ORIF.

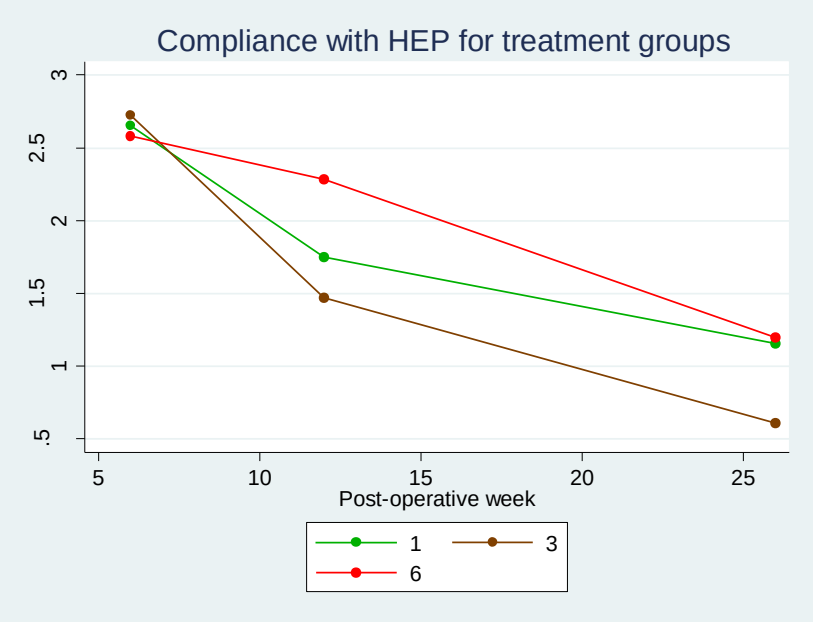


Figure 4-4 Adherence with home exercise program reported by participants in the 3 treatment groups at 6, 12 and 26 weeks from ORIF where HEP score of 0 =Did not complete any exercises in the past week, and 3 =Completed exercises on all days in past week.

Adverse events/complications

Post-operative adverse events for the one, three and six week groups were 15%(n=6), 3%(n=1) and 13%(n=5) respectively, and not significantly different. The most common adverse events were loss of fracture position [n=5 (n=4 in one week group; n=1 in six week group)], nerve damage (n=3 in six week group) and carpal tunnel syndrome [n=2 (n=1 in one week group; n=1 in six week group)]. Two participants with loss of fracture position required further surgery, both being from

the one week immobilization group. Ligament damage (volar intercalated segment instability) and tendon damage (extensor pollicus longus) requiring surgical repair were each recorded on a single occasion (one week and three week groups respectively).

4.6 Discussion

We found no immobilization group significantly superior to another for primary or secondary outcomes at 12 or 26 weeks following surgery. Earlier achievement of pain relief and function has relevance for patient health, productivity and health costs. Differences between groups were only significant at 6 weeks. Both the one and three week groups had significantly better outcomes than the six week group for PRWE, wrist extension and wrist flexion active ROM. Compared with the six week group, the one week group had significantly better outcomes for VAS-W, while the three week group had significantly better outcomes for VAS-U. Comparisons between the one and three week groups at 6 weeks following surgery indicated no significant difference for any primary or secondary outcome measures.

Averaged across all assessment points, the three week group performed significantly better than the six week group for PRWE, VAS-W, VAS-U, wrist flexion active ROM, ulnar deviation active ROM, forearm pronation active ROM and DASH. The one week group performed significantly better for function (PRWE) compared to the six week group. Although there was no significance difference between groups in adverse events, we observed a higher occurrence of loss of position in the one week group (n=4) compared to six weeks (n=1). Further research is required to re-assess this finding in a larger study.

The current RCT (n=133) is larger than the three previous trials of immobilization periods for distal radius fractures managed with internal fixation (volar locked plate) (n=60(18), n=29(17), n=30(16)). Differences in time of outcome assessments make direct comparison with earlier work difficult. Quadlbauer et al (2016)(16) compared outcomes following early (immediately post-surgery) mobilization to five weeks of immobilization and, consistent with the current investigation, found the early mobilization group had significantly greater wrist flexion and extension active ROM,

PRWE and DASH scores at 6 weeks. Contrary to the current investigation, significantly greater wrist flexion and ulnar deviation active ROM were evident for the early mobilization group 6 and 12 months following ORIF.(16) The rehabilitation program used for the current and previous trial differed and the impact of these differences on outcomes is unknown. It is possible the rehabilitation program in the current investigation facilitated improvement in outcomes for the three and six week groups making early differences no longer evident at the 12 and 26 week assessments.

More rapid improvement in PRWE scores and wrist extension active ROM was observed for the six week group when compared to one and three week groups across the 6 month follow-up period. This finding was expected given the first assessment occurred at 6 weeks following ORIF and therefore coincided with the time of cast removal for the six week group. The rapid improvement in PRWE score and wrist extension active ROM for the six weeks immobilization group was largely achieved during the initial 6 weeks following cast removal (Figure 4-2 & 4-3).

PRWE(79) mean scores at the 26 week assessment indicated minimal severity for both the one and three week groups and mild severity for the six week group (Table 4-2). Participant reports of pain indicated it was not a key feature 6 months following ORIF with low VAS-W and VAS-U mean values (1.2 to 2.3cm and 0.5 to 1.2cm respectively) (Table 4-2).

The reduced adherence with home exercises observed for the three week group may have been due to higher functional goal achievement. There was also a time effect as adherence with home exercises for all treatment groups was observed to steadily reduce from initial to final assessment (Figure 4-4).

4.7 Limitations and strengths

An unavoidable limitation of this investigation was the inability to blind participants and treating therapists. Given participants were blinded to the study hypothesis, it is unlikely this had a systematic effect on outcomes. It is possible that the improved outcomes achieved with early mobilization of patients might translate to lower costs for health care provision, and this economic evaluation will be the focus of future research. A further limitation is that analyses of the secondary outcomes measures were exploratory and no conclusions or recommendations can be made from these findings. A trend towards a lower rate of post-operative adverse events/complications was found for the three week group and warrants further investigation in a trial powered for complication rate.

Strengths include this investigation being the largest RCT to-date comparing immobilization times for distal radius fractures managed with internal fixation and that it involved controls for adherence and violations of protocol. Treatment adherence was good with over 90% of participants receiving treatment as allocated. Outcome measures utilized are consistent with current clinical practice and follow the core set of measures defined for inclusion in clinical research involving distal radius fracture.(51)

4.8 Chapter conclusion

Quality of this trial is indicated through the design controlling for eight of 10 key sources of bias in study design.(32) The two potential sources of bias not controlled for were blinding of therapists and participants and these remain an unavoidable limitation. Procedures were implemented that controlled for adherence and violations of protocol (e.g full circumferential cast, not splint, for three and six week mobilisation groups). This RCT is the first large, high quality trial to show that for function, active ROM and pain, early mobilisation (one and three weeks post-surgery) produces superior short-term outcomes when compared with late mobilisation (six weeks post-surgery). The subsequent investigations into the patient experience of difference immobilisation periods following ORIF for distal radius fracture adds perspective to these conclusions and are reported in Chapters 7 and 8.

5. Chapter 5- Reliability of radiographic measurements for acute distal radius fractures.

5.1 Introduction to radiograph reliability trial

Historically, the discovery and utilisation of roentgenography in late 1895 resulted in significant advances in the assessment and treatment of distal radius fractures. While previous management decisions relied on clinical examination alone, radiographs enabled the visualisation of direction and degree of displacement in addition to the presence or absence of articular involvement and impaction. The availability of this information resulted in the development of various classification systems for distal radius fracture, some of which are still utilised in current practice. The clinical value of fracture classification systems is based on their utility in guiding treatment decisions. A useful classification system should enable selection of best treatments (i.e. that result in the best outcomes) in addition to providing adequately reliable information both within (intra-observer) and between (inter-observer) health professionals.

Belloti et al (2007) following a survey of 439 orthopaedic surgeons found the Frykman, Universal and AO/ASIF to be the most commonly used classification systems.(81) Investigations of the inter-observer reliability of these classification systems have reported kappa values ranging from 0.26-0.36 for the Frykman(82, 83), 0.41 for Universal(83) and 0.19-0.25 for AO/ASIF.(82) The reliability of each of these appears unacceptably low and suggests that treatment selection based on any of these classification systems will likely result in variable and inconsistent treatment decisions.

The measurement of radiographic anatomical parameters presents an alternative to classification systems for describing distal radius fracture. It appears that while the measurement of anatomical parameters and classification systems have overlapping applications, the measurement of anatomical parameters (e.g. degree of dorsal/volar tilt) can also prove useful to monitor reduction and progress with healing. Despite

this, no standardised, evidence-based method for interpreting radiographic images has been broadly adopted. Furthermore, while it is commonly agreed that abnormalities of a single parameter should not be considered in isolation for the purpose of treatment selection, considerable uncertainty and debate surround the clinical significance of combinations of abnormal parameters.

Eight anatomic parameters of distal radius fracture are traditionally reported.(84) These are intra-articular step (mm), intra-articular gap (mm), radial angle (degrees), radial height (mm), radial shift (mm), ulnar variance (mm), palmar tilt (degrees) and dorsal shift (mm). Inter- and intra-observer consistency in assessing these eight anatomic features was investigated by Kreder et al (1996). The investigation utilised six radiographs of healed distal radius fractures that displayed all parameters. Sixteen observers assessed the films and repeated this assessment two to four weeks later. The intra-class correlation coefficient (ICC), used to quantify measurement consistency for continuous numerous data, was calculated for each parameter. Calculations of tolerance limits were also made in this investigation to enable estimation of the 90% error estimate for each parameter. Inter-observer and intra-observer ICCs for palmar tilt and ulnar variance were reported as having the highest consistency (point estimates of ICC), however, as 95% CIs for each ICC were not reported, this could not be stated with certainty.(84) The ranges, minimal detectable changes based on a 90% confidence interval (MDC90s), intra- and inter-observer ICCs for each anatomical parameter reported by Kreder et al 1996 are outlined in Table 5-1.

Table 5-1 Ranges, MDC90s, intra- and inter-observer ICCs for each anatomical parameter (84)

Parameter	Range	(Minimum, Maximum)	Intra-observer tolerance limit (MDC90)	Inter-observer tolerance limit (MDC90)	MDC90 expressed as proportion of range	Intra-observer ICC	Inter-observer ICC
Step	4mm	(0, 4)	+/- 2mm	+/- 3mm	3/4 =0.75	0.22	0.27
Gap	5mm	(0, 5)	+/- 2mm	+/- 3mm	3/5 =0.6	0.37	0.35
Radial angle	24°	(3, 27)	+/- 10°	+/- 11°	11/24 =0.46	0.39	0.38
Dorsal shift	17mm	(2,19)	+/- 8mm	+/- 8mm	8/17 =0.47	0.48	0.42
Radial length	14mm	(0, 14)	+/- 8mm	+/- 10mm	10/14 =0.71	0.49	0.44
Palmar tilt	55°	(-31, 24)	+/- 12°	+/- 15 °	15/55 =0.27	0.71	0.74
Radial shift	14mm	(11, 25)	+/- 5mm	+/- 5mm	5/14 =0.36	0.72	0.67
Ulnar variance	12mm	(-2, 10)	+/- 3mm	+/- 4mm	4/12 =0.33	0.85	0.82

Correlations between repeated measurements are affected by both errors in the estimates of deformity as well as the range of scores associated with each parameter.(85) They do not reveal the magnitude of error (in the units of measurement) associated with estimates. Reviewing the range of raw measurements for each anatomic parameter utilised in the investigation by Kreder et al (1996) reveals that as the error becomes a larger proportion of the available range, the intra-observer ICC value gets smaller (Table 5-1). The only exception to this is the assessment of radial length with a possible explanation is that observers may find it easier to measure a straight line as opposed to an angle. The importance of reporting the error in absolute terms as well as calculating values that enable us to differentiate one observer from another is illustrated in Table 5-1. While error in measurement readings have similar values (i.e. step inter-observer tolerance limit 3mm and ulnar variance intra-observer tolerance limit 3mm), quite different ICC values can be produced based on the scale width and range of readings taken (i.e. step inter-observer ICC 0.27 and ulnar variance intra-observer ICC 0.85). The findings of Kreder et al (1996) also indicate that the ICC values calculated for each

anatomical parameter were very similar whether for the same assessor or between assessors.

While an ICC provides an estimate of the amount of agreement for the measurement of a specific parameter, further information can be obtained from the calculation of tolerance limits. Calculation of the 90% inter-observer and intra-observer tolerance limits for data collected by Kreder et al (1996) provided values for differences associated with all but the extreme 10% of differences in observations made with repeated measurements. For all measurements, Kreder et al (1996) found the intra-observer errors were equal to or less than inter-observer errors (Table 5-1).

Limitations of data obtained from the Kreder et al (1996) investigation include the fact that the error estimates were based on a small sample of radiographs (n=6). This small sample size reduces the reliability of calculations obtained for correlations between repeated measurements based on the limited range of deformity and spread of scores associated with each parameter. Kreder et al (1996) involved radiographs of healed distal radius fractures and errors in measurements for anatomic parameters could differ when based on radiographs of acute fractures. It is possible that the greater deformity associated with acute injuries, combined with the clean edge of the fractured bone cortex might enable considerably greater accuracy in estimates than previously observed. In addition, if through trial and error, or application of automated assessment methods, the sources of systematic error in reading images could be identified and minimised, further advances in accuracy might be achievable. As current practice utilises computerised images, not available at the time of the Kreder et al (1996) investigation, independent verification of the data in the Kreder et al (1996) investigation is warranted. Further research into the inter- and intra-observer consistency in applying these eight anatomic measures for distal radius fractures is both desirable and defensible.

The following investigation involved assessment of the error associated with radiographic interpretation of acute distal radius fractures and whether the errors associated with measurements were small enough for measurements to be used confidently in fracture management.

The following text is adapted, with the permission of BioMed Central (Appendix L), from the work published in 2016. The article citation is:

Watson N. J., Asadollahi S., Parrish F., Ridgway J., Tran P., Keating J. L. Reliability of radiographic measurements for acute distal radius fractures. *BMC Med Imaging.* 2016;16:44. A copy of the published article is in Appendix M.

5.2 Abstract

Background

The management of distal radial fractures is guided by the interpretation of radiographic findings. The aim of this investigation was to determine the intra- and inter-observer reliability of eight traditionally reported anatomic radiographic parameters in adults with an acute distal radius fracture.

Methods

Five observers participated. All were routinely involved in making treatment decisions based on distal radius fracture radiographs. Observers performed independent repeated measurements on 30 radiographs for eight anatomical parameters: dorsal shift (mm), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), ulnar variance (mm). Intraclass correlation coefficients (ICCs) and the magnitude of retest errors were calculated.

Results

Measurement reliability was summarized as high (ICC > 0.80), moderate (0.60-0.80) or low (< 0.60). Intra-observer reliability was high for dorsal shift and palmar tilt; moderate for radial angle, radial height, ulnar variance and radial shift; and low for intra-articular gap and step. Inter-observer reliability was high for palmar tilt; moderate for dorsal shift, ulnar variance, radial angle and radial height; and low for radial shift, intra-articular gap and step. Error magnitude (95% confidence interval) was within 1-2mm for intra-articular gap and step, 2-4mm for ulnar variance, 4-6mm for radial shift, dorsal shift and radial height, and 6-8º for radial angle and palmar tilt.

Conclusions

Based on previous reports of critical values for palmar tilt, ulnar variance and radial angle, error margins appear small enough for measurements to be useful in guiding treatment decisions. Our findings indicate that clinicians cannot reliably measure values ≤1mm for intra-articular gap and step when interpreting radiographic parameters using the standardized methods investigated in this study. As a guide for treatment selection, palmar tilt, ulnar variance and radial angle measurements may be useful, but intra-articular gap and step appear unreliable.

5.3 Background

Comprising 2.5% of all Emergency Department (ED) presentations, fracture of the distal radius is the most common skeletal fracture type.(87) It occurs in approximately 10% of Caucasian women over 65 years.(10) After cast removal, immediate functional limitations include loss of strength (particularly grip) and range of movement.(88, 89) A decade following fracture, ongoing pain and reduced function of the wrist and hand can still occur with heavy tasks.(90)

Radiographs of the distal radius are used for diagnosis, to guide treatment choices, assess fracture reduction and monitor healing. There are no standardized, evidence-based methods for interpreting radiographic parameters. Eight anatomic parameters of distal radius fracture have been described. These are dorsal shift (mm), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), and ulnar variance (mm).(84) Relationships have been described between functional outcome and the anatomical parameters of intra-articular gap and step(91-93), dorsal(75, 94, 95) and palmar tilt(96), radial angle(97, 98), radial height(94, 99, 100), radial shift(101) and ulnar variance.(102, 103) No such relationships have been described for dorsal shift suggesting it may have no clinical utility, may not be adequately reliable and/or its close correlation with dorsal tilt(104) renders this measurement less important. This investigation explored the reliability of these eight parameters in preparation for a study of their utility in guiding treatment decisions.

We assessed the error associated with radiographic interpretation of acute distal radius fractures and whether the errors associated with measurements were small enough for measurements to be used confidently in fracture management. We investigated the intra- and inter-observer reliability of eight anatomic parameters in skeletally mature patients with an acute distal radius fracture using digitised radiographs. This investigation extends and updates the work of Kreder et al.(84) by using a larger sample of radiographs (30 acute fractures) and the computerized images and measurement procedures used in current practice. The majority of choices regarding treatment for distal radius fractures occur in the acute period. This investigation utilized radiographs of acute distal radius fractures in contrast to the healed distal fracture radiographs utilized by Kreder et al.(84)

5.4 Materials and methods

Participants: selection of radiographs

Posteroanterior (PA) and lateral wrist radiographs of all patients with distal radius fractures presenting to a large outer metropolitan ED in Victoria, Australia during the period July 2009 to January 2010 were retrospectively selected for review. Standardized positioning of neutral forearm rotation was adopted for the PA and lateral views. Inclusion criteria for radiographs were skeletal maturity, fracture within 3cm of the distal end of the radius, and presenting to the ED within seven days of fracture. Exclusion criteria were pathological fracture and evidence of previous distal radius fracture on the affected side. Radiographs meeting the inclusion/exclusion criteria were assembled and stratified by fracture deformity to either Group A (mild deformity) or Group B (severe deformity) based on decision rules defining estimates of severity (Table 5-2). In the absence of guidelines, decisions regarding cut points separating mild from severe were arbitrary and intended only to enable the spectrum of injury to be appropriately represented in the assembled targets. Fifteen radiographs from each group were randomly selected based on a computer generated sequence. The sample size of 30 repeated measurements for each observer was chosen as difference scores for repeated measures in samples of 30 or more are likely to assume a normal distribution.(105)

Table 5-2 Radiographic characteristics for classification as mild or severe deformity

Group A Mild deformity: must meet all criteria	**Group B Severe deformity: must have at least one criteria**
Intra-articular step: ≤ 2mm	Intra-articular step: > 2mm
Intra-articular gap: ≤ 2mm	Intra-articular gap: > 2mm
Dorsal tilt: ≤ 10°	Dorsal tilt: > 10°
Volar tilt: ≤ 20	Volar tilt: > 20°

Participants: Selection of assessors

To accommodate the influence of site specific practices, observers were invited from two independent health networks. Health professionals were invited to participate if their role included making treatment decisions based on radiographic images of upper limb fractures. Invitations were sent to ED, orthopaedic and radiology staff, and upper limb specialists. Potentially eligible professional groups included orthopaedic consultants and registrars, radiologists, ED consultants and registrars, and advanced practice musculoskeletal physiotherapists. A total of 10 observers (five from each health network) meeting these criteria were invited to participate. Ensuring at least two observers from each health network, the first five observers to consent were enrolled in the investigation.

Observer training

Prior to commencing this study, each observer completed a self-directed tutorial that provided standardized instructions and examples illustrating measurement techniques for assessing each of the eight parameters. Observers were then given three wrist radiographs of acute distal radius fractures and asked to measure each of the eight anatomical parameters. The standardized method developed by Kreder et al.(84) for measuring these eight anatomic parameters at the distal radius was followed (Figures 5-1 to 5-3).(84) Observers utilised picture archiving and communication system (PACS) computerized images through the Synapse(86) display system that includes measurement calibration. Two views, PA and lateral, were utilised to obtain measurements for each of the eight parameters. Observers were asked to save all working lines used in computations. Each observer was then

provided with written and verbal feedback from the principal investigator on departures from standardized measurement techniques. Participants were asked to repeat measurements where incorrect technique was noted and again save measurement decision rules for review and feedback from the principal investigator. Observer training was completed over a two week period. The purpose of this preparation was to identify and minimize sources of systematic and random error in reading images.

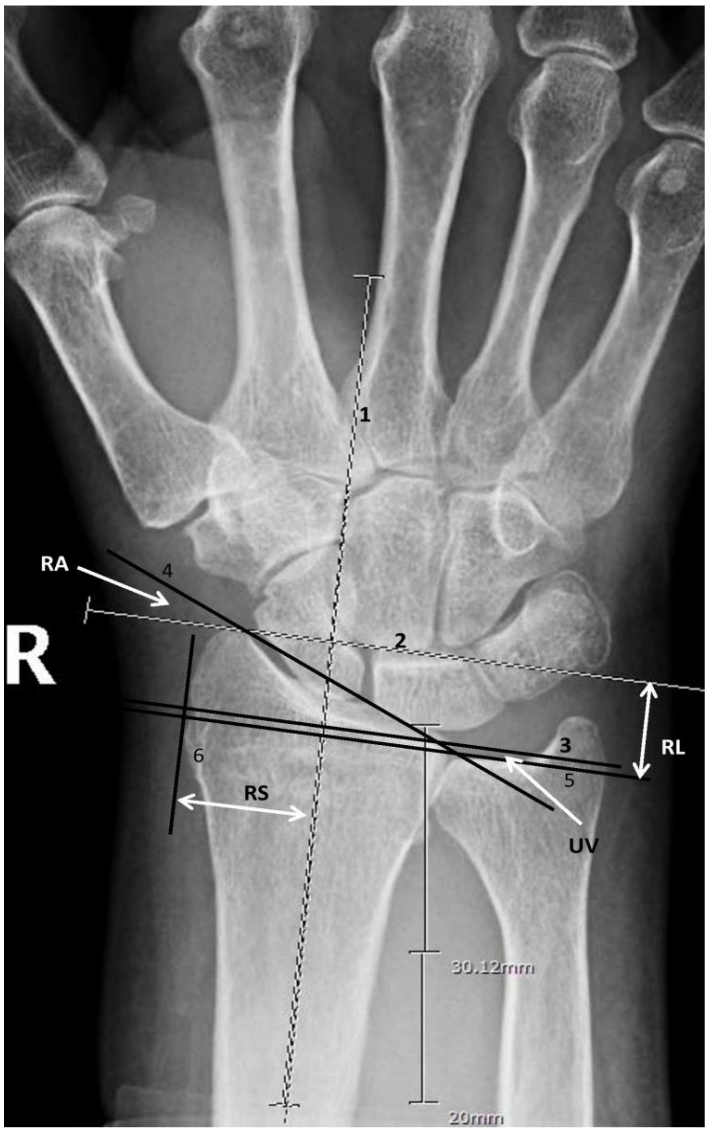


Figure 5-1 Posterioanterior measurement guidelines as described in Kreder et al. 1996.

RA, radial angle; RL, radial length; UV, ulnar variance; RS, radial shift;

1. This line represents the long axis of the radius. The center of the radius shaft is determined at 3cm and 5cm below the mid-region of the proximal lunate articular surface.
2. A line perpendicular to the center long axis of the radius is drawn at the level of the most distal aspect of the radial articular surface.
3. A line perpendicular to the central long axis of the radius is drawn at the level of the ulnar margin of the distal radial articular surface.
4. The radial and ulnar margins of the distal radial articular surface are connected.
5. A line perpendicular to the central long axis of the radius is drawn at the level of the distal ulnar articular surface.
6. A line tangential to the most radial point on the radial metaphysis is drawn parallel to the central long axis of the radius.

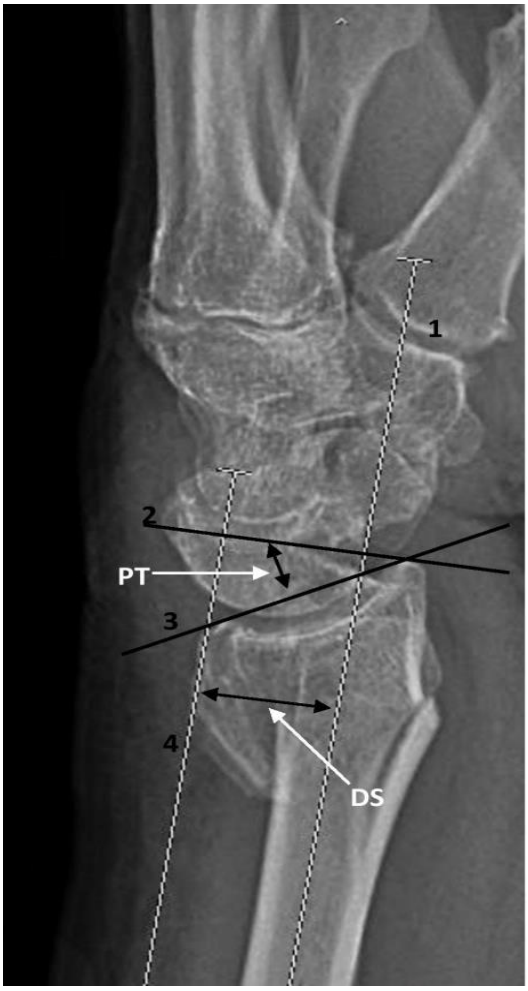


Figure 5-2 Lateral measurement guidelines as described in Kreder et al. 1996

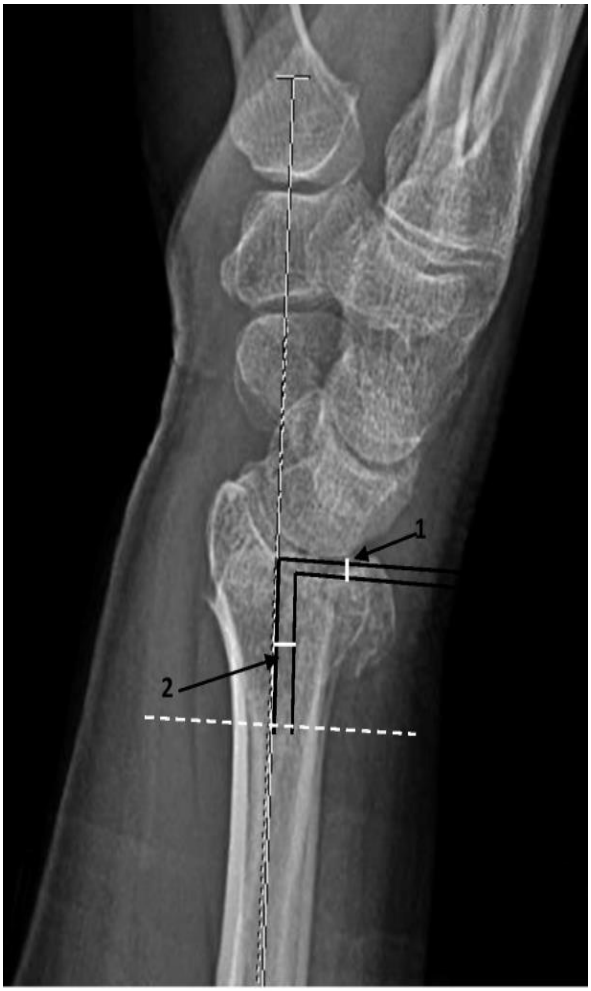


Figure 5-3 Step and gap measurements as described in Kreder et al. 1996

PT palmar tilt angle (dorsal tilt = negative palmar tilt); DS, dorsal shift

1. This line represents the long axis of the radius. The center of the radial shaft is determined at 3cm and 5cm below the mid-region of the proximal lunate articular surface.
2. A line perpendicular to the central long axis of the radius is drawn at a convenient level.
3. The dorsal and anterior margins of the distal radial articular surface are connected.
4. A line tangential to the most dorsal point on the radial metaphysis is drawn parallel to the central long axis of the radius.

1. Step-off at the distal radius articular cortical margin is measured by drawing lines perpendicular with the central long axis of the radius from the most distal margin of each side of the cortical discontinuity.
2. Gap deformity is measured by dropping lines that are parallel from the central long axis of the radius from the most distal margin of each side of the cortical deformity. The gap distance is measured along a line perpendicular to the central long axis of the radius.

Measurement parameters

The five observers were asked to measure the following parameters for each of the 30 radiographs: dorsal tilt (degrees), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), and ulnar variance (mm) using methods described in the observer training tutorials.

Measurements

On the first measurement occasion, observers were presented, in random sequence, with 30 fully de-identified radiographs with no unique identifying features. No earlier than two weeks and no later than three weeks later, observers were presented with the same set of radiographs, again in random sequence and without access to measurements taken on the first measurement occasion. To reduce the potential impact of measurement fatigue, observers were instructed to disperse their measurements over a two week period.

Statistics

Data were analysed using the recommendations by Rankin and Stokes(106) (correlational indices) and Bland and Altman(107) (metricated error estimates). The ICC quantifies the relationship between two variables with r = 1 indicating perfect agreement and r = 0 indicating no agreement.

Intra-observer reliability

Intra-observer ICCs were calculated for each of the eight anatomical parameters on data produced from a two-way repeated analysis of variance (ANOVA). The test retest values for each observer were compared for each anatomical parameter. Using equations provided by Fleiss(108) for repeated measurements by the same observer, the ICC(1,1) was calculated using the formula:

Equation 1: $ICC(1,1) = BMS - WMS/BMS + (k-1)WMS$

where *k* is the number of measurements, and mean squares (MS) of variance estimates were obtained from ANOVA: *BMS* (between-subjects variance) and *WMS* (within subjects variance).

Bland and Altman(107) analysis was used to quantify agreement between measurements made by the same observer; the difference between two measurements was plotted against the average of the two measurements. The 95% confidence intervals (CIs) around the mean differences were calculated using the standard errors in estimates of the mean and a t multiplier appropriate for the sample size (2.05).(107)

Inter-observer reliability

The first set of measurements of the eight anatomical parameters for each of the 30 radiographs were used to calculate the inter-observer reliability. The analyses were repeated for fractures dichotomized by severity of deformity to assess whether reliability changed with fracture severity. Variance estimates were derived from a one-way repeated ANOVA. The ICC(3,1) was calculated based on recommendations and equations by Shrout and Fleiss(109) for inter-observer reliability:

Equation 2: ICC(3,1) = BMS - EMS/BMS + (k-1)EMS

The ICC(3,1) was chosen as each radiograph in the current investigation was rated by each of the same *k* observers who were the only observers of interest. As the observers for this investigation were selected from the general population, ICC(1,1) could have been used, however the more conservative equation was chosen. Bland and Altman(107) analysis was again applied to quantify inter-observer agreement.

As this investigation involved exploring agreement between more than two fixed observers, a representative average of the reliability between pairs within the five observers was calculated using an overall concordance correlation coefficient (OCCC) based on recommendations and equations by Barnhart et al.(110) The OCCC provides an overall correlation that takes into account the correlation between individual pairs of observers.

A number of investigations have recommended conservative management for distal radius fractures when intra-articular gap or step is less than 1mm.(91-93) Intra-articular gap and step measurements were therefore converted to a dichotomy of less than or equal to 1mm or greater than 1mm and pairwise inter-observer agreement values (kappa) were calculated. Further pairwise inter-observer agreement values (kappa) were calculated when intra-articular gap and step measurements were converted to a dichotomy of presence (any gap or step recorded) or absence (zero gap or zero step recorded) of intra-articular step or gap. Data from the first set of measurements was used for the conversions to dichotomies.

5.5 Results

The professional roles of the five observers who reviewed radiographs were orthopaedic surgeon (upper limb), orthopaedic registrar, ED consultant, ED primary care advanced practice musculoskeletal physiotherapist and radiologist.

Measurement reliability was summarized as high (ICC > 0.80), moderate (0.60-0.80) or low (< 0.60). Intra-observer reliability was high for dorsal shift and palmar tilt; moderate for radial angle, radial height, ulnar variance and radial shift; and low for intra-articular gap and step. Inter-observer reliability was high for palmar tilt; moderate for dorsal shift, ulnar variance, radial angle and radial height; and low for radial shift, intra-articular gap and step (Table 5-3). OCCC values ranged from 0.11 for intra-articular gap to 0.94 for palmar tilt (Table 5-3). ICC values appeared higher in the current investigation compared with Kreder et al.(84) for all parameters except radial shift and ulnar variance (Table 5-3). Error magnitude (95% confidence interval) was within 1-2mm for intra-articular gap and step, 2-4mm for ulnar variance, 4-6mm for radial shift, dorsal shift and radial height, and 6-8º for radial angle and palmar tilt (Table 5-4).

Table 5-3 Intra- and inter-observer ICCs & OCCCs for each anatomical parameter based on ANOVA output and Equations 1 and 2 are compared to data from Kreder et al.(84)

Anatomical parameter	Intra-observer	Inter-observer (using 1st measurements)	OCCC (using 1st measurements)	Kreder et al.(84) intra-observer	Kreder et al.(84) inter-observer
Dorsal shift	0.91	0.75	0.77	0.48	0.42
Intra-articular gap	0.56	0.30	0.11	0.37	0.35
Intra-articular step	0.54	0.31	N/A	0.22	0.27
Palmar tilt	0.89	0.93	0.94	0.71	0.74
Radial angle	0.80	0.66	0.66	0.39	0.38
Radial height	0.79	0.61	0.61	0.49	0.44
Radial shift	0.68	0.47	0.50	0.72	0.67
Ulnar variance	0.75	0.69	0.70	0.85	0.82

Table 5-4 Range of measurements, standard error of measurement (SEM) and 95% confidence intervals (95%CI) for each anatomical parameter using first set of measurements of 30 radiographs, compared to data from Kreder et al.(84) based on six radiographs

Parameter	Mean (SD)	Minimum, Maximum	SEM (inter-observer using 1st measurements)	Upper limit 95% CI	Minimum, Maximum Kreder et al.(84)
Dorsal shift (mm)	15.03 (4.85)	(3, 23.4)	2.42	4.97	(2, 19)
Intra-articular Gap (mm)	0.76 (1.13)	(0, 5.7)	0.94	1.94	(0, 5)
Intra-articular step (mm)	0.27 (0.62)	(0, 3.95)	0.52	1.06	(0, 4)
Palmar tilt (degrees)	-6.29 (14.28)	(-36, 42)	3.78	7.75	(-31, 24)
Radial angle (degrees)	18.18 (5.67)	(3, 30)	3.31	6.78	(3, 27)
Radial height (mm)	8.71 (4.07)	(0, 24)	2.54	5.21	(0, 14)
Radial shift (mm)	18.71 (3.00)	(13, 30.8)	2.18	4.48	(11, 25)
Ulnar variance (mm)	0.68 (1.96)	(-4.5, 5.7)	1.09	2.24	(-2,10)

Dichotomizing intra-articular gap and step measurements as above or below 1mm produced pairwise inter-observer agreement values ranging from -0.06 to 0.52 and -0.11 to 0.43 respectively (Table 5-5 & 5-6). Dichotomizing intra-articular gap and step measurements by the presence or absence of intra-articular involvement produced pairwise inter-observer agreement values ranging from -0.07 to 0.67 and 0 to 0.63 respectively (Table 5-5 & 5-6).

Table 5-5 Kappa values for inter-observer agreement for intra-articular gap (taken from 1st recording) using raw scores and scores dichotomized with recoding

Pairwise comparison	**Uncoded data (as recorded)**	**Coding: 0 = < 1mm 1 = equal or > 1mm**	**Coding: 0= unable to see gap 1= able to see gap**
P1P2	0.24	0.52	0.54
P1P3	0.16	0.39	0.53
P1P4	0.22	0.52	0.67
P1P5	0.03	0.08	0.06
P2P3	0.08	0.15	0.23
P2P4	0.27	0.25	0.60
P2P5	-0.03	-0.06	-0.07
P3P4	0.15	0.45	0.47
P3P5	0.02	0.09	0.05
P4P5	0.03	0.11	0.07

Table 5-6 Kappa values for inter-observer agreement for intra-articular step (taken from 1st recording) using raw scores and scores dichotomized with recoding

Pairwise comparison	**Uncoded data (as recorded)**	**Coding:** **0 = < 1mm** **1 = equal or > 1mm**	**Coding:** **0 = unable to see step** **1 = able to see step**
P1P2	0.25	0.38	0.63
P1P3	0.13	0.07	0.29
P1P4	0.22	0.30	0.56
P1P5	0.00	0.00	0.00
P2P3	0.25	0.43	0.53
P2P4	0.23	0.14	0.56
P2P5	0.00	0.00	0.00
P3P4	0.11	-0.11	0.26
P3P5	0.00	0.00	0.00
P4P5	0.00	0.00	0.00

Dichotomizing data based on fracture severity resulted in a systematic improvement in inter-observer reliability values for more severe fractures with all measurements except dorsal shift (Table 5-7). No systematic reductions in error were seen for more severe fractures when calculations of standard error of measurement (inter-observer) were performed (Table 5-7).

Table 5-7 Inter-observer ICCs and SEMs (taken from 1st recording) using data dichotomized for severity of fracture deformity

Anatomical parameter	ICC All 5 observers- 30 radiographs	ICC Grp 1 (mild deformity)- 15 radiographs	ICC Grp 2 (severe deformity)- 15 radiographs	SEM Grp 1 (mild deformity)- 15 radiographs	SEM Grp 2 (severe deformity)- 15 radiographs
Dorsal shift	0.75	0.76	0.71	3.09	1.46
Intra-articular gap	0.30	0.15	0.30	0.39	0.66
Intra-articular step	0.31	0.26	0.30	0.18	0.39
Palmar tilt	0.93	0.92	0.96	7.75	6.52
Radial angle	0.66	0.62	0.71	3.00	2.59
Radial height	0.61	0.49	0.74	2.07	1.95
Radial shift	0.47	0.27	0.55	1.18	1.77
Ulnar variance	0.69	0.67	0.70	0.93	1.00

Stratifying data based on professional subgroups e.g. isolating the analysis to the orthopaedic surgeon and radiologist, did not result in systematically higher reliability values. The highest correlations were obtained when data for all five observers were included in analysis.

Bland and Altman

Bland and Altman(107) graphs (Figures 5-4 & 5-5) indicated no clear relationship between an individual measurement and the magnitude of error in measurement. Figures 5-4 & 5-5 illustrate this using the example of palmar tilt showing data for observers with high (1 & 5) and low (2 & 4) measurement correlations.

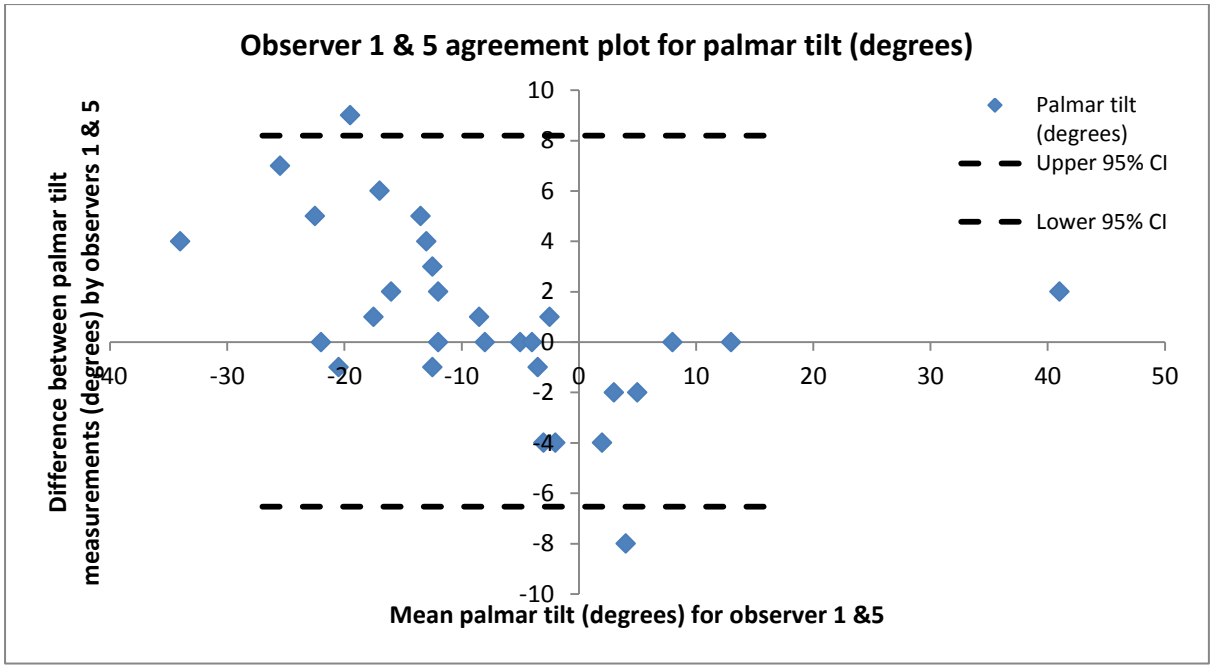


Figure 5-4 Bland and Altman(107) distribution plot for palmar tilt, showing the difference between measurements by observers 1 & 5 plotted against the average measurement for the two observers using data from the first set of measurements.

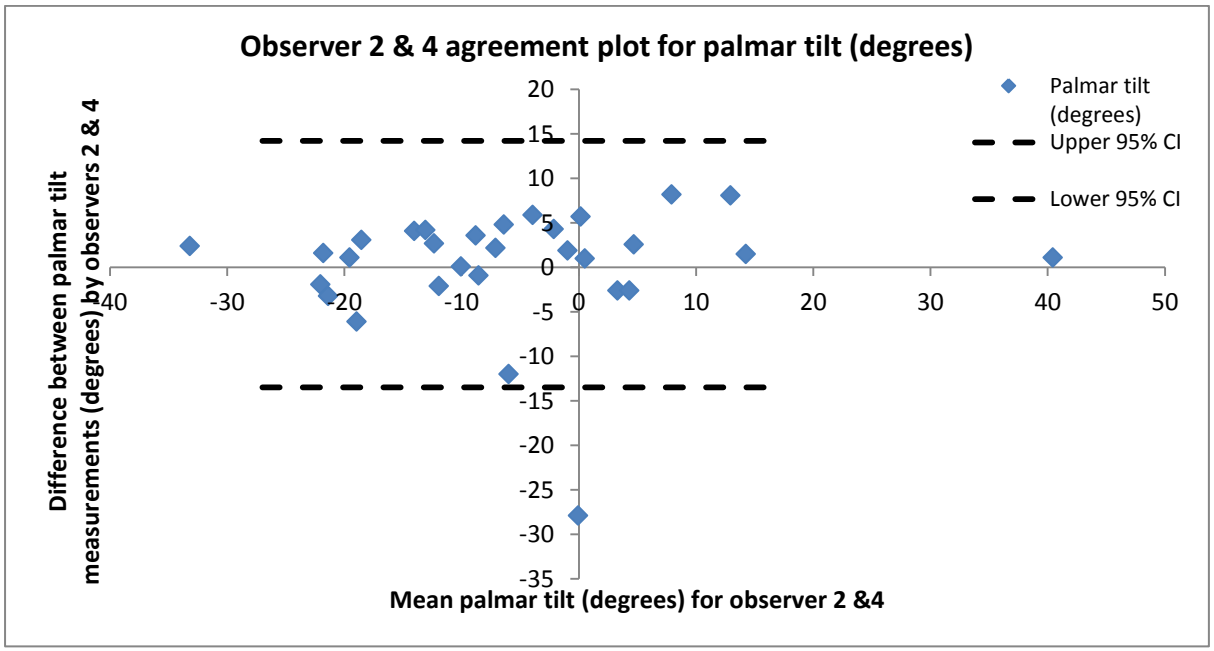


Figure 5-5 Bland and Altman(107) distribution plot showing for palmar tilt, the difference between observer 2 & 4 measurements plotted against the average measurement for the two observers using data from the first set of measurements.

5.6 Discussion

Distal radius fractures are typically managed non-operatively with cast immobilization or surgically with either percutaneous pinning (Kirscher wires), external fixation or internal fixation.(111) However, the evidence behind treatment choices based on deformation and radiographic parameters is limited. Best treatment for the various types of distal radius fracture would ideally include a reliable, standardized, evidence-based method of classifying distal radius fractures and unambiguous decision guidelines for treatment.

The rationale for this investigation was to quantify the intra- and inter-observer reliability of eight traditionally reported anatomic parameters in skeletally mature patients with an acute distal radius fracture using PACS computerized images and display systems [Synapse(86)]. Bland and Altman(107) graphs (Figures 5-4 & 5-5) indicate no clear relationship between an individual measurement and the magnitude of error in measurement. Consequently, in clinical practice, errors associated with these measurements are better estimated using degrees or millimetres of error (e.g. +/- 4°) than error expressed as a percentage of the range (e.g. 10% of range).

Despite adopting standardized measurement techniques and observer training, the intra- and inter-observer consistency when applying these measures varied greatly for the eight anatomic parameters. Intra-observer ICC values appeared higher than inter-observer for all anatomic parameters except palmar tilt and may indicate the potential for additional training to remediate inconsistencies between clinicians for measurements.

Kreder et al.(84) published the results of intra- and inter-observer consistency in assessing these eight anatomic parameters with repeated assessments at 0 and 2-4 weeks of six radiographs of healed fractures conducted by 16 observers. Printed films were assessed on flat view boxes and measured using protractors and rulers. Limitations of the Kreder et al.(84) investigation were the small sample of radiographs and that radiographs were of healed fractures.

For intra-observer reliability in the current investigation, ICC values were found to be above 0.80 for palmar tilt and dorsal shift (Table 5-3). Only one parameter, palmar tilt, was associated with an inter-observer ICC value above 0.80. Unlike the current investigation, Kreder et al.(84) found ulnar variance was the only parameter to have an intra-and inter-observer ICC value above 0.80.

Comparison of error margins in millimeters or degrees (e.g. using the SEM in Table 5-4) is preferable to comparison of ICC values. This is because the magnitude of ICCs is affected by the range of raw scores included in the computation. This effect is referred to as attenuation of range and has the consequence that the ICC will increase as the variance in raw scores increases despite the same absolute differences (error) in repeated measurements. We were unable to determine the extent to which the higher ICCs obtained in the current investigation were a consequence of a larger range of raw scores as we did not have the variance estimates for Kreder et al.'s(84) data. However, on examination of the range of raw scores for the data analysed in both studies (Table 5-4), it is possible that attenuation of range might explain at least some of the observed differences.

It is difficult to be unequivocally confident that the use of computerized images and measurement procedures facilitates additional accuracy. If we were studying a similar spectrum of measurements, some differences in study design may account for observed differences. These include the digital methods we employed, our larger number of radiographs (30 versus 6) and that we studied acute fractures while Kreder et al.(84) studied healed fractures. This may have afforded us better visibility of the cortical disruption. The use of acute fracture images that mirror authentic practice confirms Kreder et al.'s(84) findings and extends the validity of claims regarding measurement utility across a representative spectrum of deformity.

Our classification of radiographs into Group 1 (mild deformity) and 2 (severe deformity) was undertaken to enable the spectrum of mild to severe deformity to be represented in the radiographs. While the accuracy of this step cannot be defended based on our analysis of the reliability of radiographic measurements, the range of obtained measurements in this study were comparable to the range of measurements obtained in the study by Kreder et al.(84), suggesting some success in capturing the spectrum of severity.

5.7 Clinical relevance

Intra-articular gap and step

A number of investigations have recommended conservative management for distal radius fractures when intra-articular gap or step is less than 1mm; accelerated development of arthritis, increased severity of degenerative changes and poor functional outcome has been linked with intra-articular gap or step greater than 1mm.(91-93) Intra-articular gap and step measurements in both the current investigation and previous literature (Table 5-3, 5-5 & 5-6) were associated with low intra- and inter-reliability ICC values. Given the poor reliability for assessing intra-articular gap or step, we question the suitability of using these radiographic interpretations as criteria for guiding treatment choices. It is possible that additional training in measurement technique might improve the accuracy of these measurements and the cost-benefits of computerized tomography for improving reliability warrants exploration.

Dorsal and palmar tilt

It has been argued that functional outcomes are significantly affected when dorsal tilt (negative palmar tilt) exceeds 10° or 12°(75, 94, 95) or palmar tilt exceeds 25°.(96) Allowing for error in estimates, dorsal tilt would need to be less than 2.2° to be confident that in 95% of cases it is actually less than 10°. Error estimates indicate that palmar tilt measurement would need to be less than 17.2° to be confident that in 95% of cases it is less than 25°.

Ulnar variance

Positive ulnar variance greater than 3mm has been reported to negatively impact functional ability.(102, 103) Allowing for error in estimates we would need to see no more than 0.8mm of positive ulnar variance to be confident that true ulnar variance is no more than 3mm.

Radial angle

Radial angle generally reduces with displaced distal radius fractures and a radial angle of less than 15° has been used to indicate operative management.(97, 98) We would need to see more than 21.8° radial angle to be confident that in 95% of cases we have more than 15°.

Radial height

A reduction in radial height of 3-6mm has been linked with a decline in functional outcome.(99, 100) Error estimates and a 95% CI upper limit of 5.2mm raise questions about the utility of this measure using the standardized methods described.

Dorsal shift and radial shift

There is limited information in the literature linking the measurements of dorsal shift and radial shift with functional outcomes raising questions around the importance of these anatomical parameters for guiding treatment decisions. The current investigation indicates that dorsal shift can be reliably measured [inter-observer ICC value (0.75)] and therefore exploration of its relationship with functional outcomes is warranted.

5.8 Conclusions

In summary, when interpreting computerised images of acute distal radius fractures, reliability measures and error margins from this investigation support the use of palmar tilt, radial angle and ulnar variance measurements for guiding treatment choices. However, consideration needs to be given to error margins when using these measurements to guide treatment choices. Reliability measures and error margins indicate that intra-articular gap and step cannot reliably be used to guide treatment choices for acute distal radius fractures when using the methods for interpreting radiographic parameters investigated in this study. This study did not investigate the reliability of the scan itself, and this warrants further investigation.

The next step from this investigation is to use evidence-based methods to develop decision rules for treatment guidelines following acute distal radius fracture. It is known that clinicians do not routinely measure all eight anatomical parameters in clinical practice. Further investigation is required to quantify whether there is consistency and agreement with the anatomical parameters that clinicians deem important for decision making for acute distal radius fractures.

5.9 Chapter conclusion

This chapter provides useful information for health professionals on the inter- and intra-observer agreement for eight traditionally reported radiographic anatomical parameters of distal radius fractures. Appendix N details the training module in measurement techniques that was completed by all observers. Appendix O provides an example of the written and verbal feedback on departures from desirable measurement techniques provided, as required, to observers. Comparisons of observer measurements before and after training indicated a reduction in number of systematic errors. The reduction in systematic errors following feedback and repeated measurements cannot confidently be attributed to the provision of feedback. Given the investigation did not include a group that received no feedback, it is not possible to separate the effects of feedback from improvement due to practice.

The findings from the investigation described in this chapter indicate that palmar tilt, radial angle and ulnar variance measurements are useful for guiding treatment choices providing error margins are considered. The measures of intra-articular gap and step were found to be unreliable for guiding treatment choices. It is known that all eight anatomical parameters are not routinely used by clinicians to guide treatment choices, and therefore a further investigation was conducted to determine which anatomical parameters were deemed most important by clinicians for guiding treatment choices. Variation in treatment choices made by clinicians for distal radius fracture would potentially be minimised if the anatomical parameters deemed important by clinicians were adequately reliable. An investigation into factors underpinning treatment choices made by clinicians and the consistency in management decisions made by clinicians is described in Chapter 6.

6. Chapter 6- Treatment decisions based on radiographs of acute distal radius fractures.

6.1 Introduction to treatment choice trial

Health professionals base treatment selection on factors such as fracture classification, degree of displacement, stability of the fracture, and age and physical demands of the patient. Although distal radius fracture is known to have a negative impact on physical function, mental health and ability to work, factors that affect treatment outcomes have not been well defined.

Conservative (non-operative) treatment of distal radius fractures dominated the last century and involved reduction of the displaced fracture and immobilisation in a plaster cast or some form of external support. Particularly in the elderly population, the results of conservative management are not consistently satisfactory with loss of the reduced fracture position commonly occurring.(22) The surgical techniques of percutaneous pinning, external fixation and internal fixation were developed to enhance the accuracy and stability of distal radius fracture reduction. A marked swing toward surgical fixation, and in particular ORIF, in the elderly population has been reported during the past 15 years.(3, 4) Despite the rise in surgical fixation rates, little evidence guides selection of surgical technique.(4, 15, 112) Given the economic implication of increasing surgical fracture fixation rates and different costs associated with choice of fixation technique, health care agendas are requesting economic analyses to complement research into comparative effectiveness.(15) Prior to conducting research into the development of guidelines for the best treatment for each type of distal radius fracture, a reliable, standardised, evidence-based method of classifying distal radius fractures and prescribing treatment is required.

Belloti et al (2007) surveyed 439 orthopaedic surgeons regarding the factors deemed most important when making treatment decisions for distal radius fractures. Responses indicated the most important factors for the surveyed cohort of surgeons

were whether the fracture was intra-articular (27%), whether there was shortening of the distal radius (22%) and the patient's age (18%).(81) The questionnaire did not, however, specify how orthopaedic surgeons link these factors to treatment decisions.

Chapter 5 reported that palmar tilt, ulnar variance and radial angle measurements may be useful to guide treatment selection, but intra-articular gap and step appear unreliable. It is known that clinicians do not routinely measure all eight anatomical parameters in clinical practice. This chapter describes an investigation into the anatomical parameters that clinicians consider important when determining treatment for distal radius fracture.

The following text is a copy of the manuscript currently submitted to *Journal of Orthopaedic Research (5 year impact factor = 2.982):*

Watson, N. J., Tran, P., Keating, J. K. (submitted) Treatment decisions based on radiographs of acute distal radius fractures.

6.2 Abstract

Introduction

The aim of this investigation was to explore decisions and agreement on treatment choices for acute distal radius fractures based on radiographic measurements.

Design

Prospective cohort investigation.

Setting

Large outer metropolitan Emergency Department (ED) in Victoria, Australia

Participants

Five observers routinely involved in making treatment decisions based on distal radius fracture radiographs participated. Each reviewed 30 radiographs.

Main outcomes measured

Observers performed independent repeated measurements on 30 radiographs of eight traditionally reported anatomical parameters. Agreement on the acceptability of overall fracture alignment, parameter alignment, treatment choices and the fracture characteristics that influenced choices were investigated.

Results

Agreement on acceptability of fracture alignment was poor to fair and agreement on treatment choice was poor. When considering the anatomical parameters important for treatment decisions, palmar tilt was most commonly selected (four of five observers), and intra-articular gap considered the key parameter by the remaining observer. Ulnar variance and radial shift were rarely rated as important. Inter-observer reliability calculations indicated random agreement (-0.04 kappa) for the importance of individual anatomical parameters in making treatment decisions. Based on measurements, agreement that parameter alignment was acceptable or unacceptable was moderate to high for palmar tilt, radial angle and radial height (0.69, 0.58 and 0.53 kappa values respectively) and consistently low for intra-articular gap and step (0.29 and 0.31 kappa values respectively).

Conclusions

Eight radiographic anatomic parameters of distal radius fracture have been described. This investigation indicates that palmar tilt and intra-articular gap are the parameters that are typically considered in determining treatment. Further work is required to standardize methods used by clinicians in assessing fractures and determining treatment.

6.3 Introduction

Distal radius fracture is a common skeletal fracture. A decade following fracture, pain and reduced wrist and hand function can still affect heavy tasks.(90) Considering the aging population, management of distal radius fractures will increasingly burden health systems.

Distal radius radiographs are used for diagnosis, to guide treatment choices, assess fracture reduction and monitor healing. Eight anatomic parameters of distal radius fracture have been described: dorsal shift (mm), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), and ulnar variance (mm).(84) Relationships have been described between functional outcome and the anatomical parameters of intra-articular gap and step,(91, 92, 113) dorsal(75, 94, 95) and palmar tilt,(96) radial angle,(97, 98) radial height,(94, 99, 100) radial shift(101) and ulnar variance.(102, 103) Dorsal shift is rarely linked to function suggesting aberrations may have no clinical implications, may be detected unreliably and/or close correlation with dorsal tilt(104) renders this measurement less important.

Distal radius anatomy affects hand function.(39, 74-77) Treatments aim to restore typical anatomical position, however, limited evidence links measurements of anatomical parameters with treatment choices or outcomes.(112, 114-117)

Dorsal displacement [dorsal shift and dorsal tilt (aka negative palmar tilt)] and compression (radial angle and height) appear to be correlated(104) and it may be unnecessary to routinely measure all parameters. In addition, all recommended radiographic criteria may not be equally relevant in determining treatment.

This study was designed to investigate treatment choices for acute distal radius fractures based on assessment of radiographic parameters.

Approval was granted by the Melbourne Health, Monash University and Peninsula Health Human Research Ethics Committees involved with this investigation (MH 2010.113, CF10/2330-2010001327, HREC/10/22).

6.4 Materials and methods

This cohort investigation is compliant with the STROBE criteria.(118)

Participants: selection of radiographs

We retrospectively assessed posteroanterior (PA) and lateral wrist radiographs taken in neutral forearm rotation of all patients with a distal radius fracture presenting to a large outer metropolitan ED in Victoria, Australia over a six month period. Inclusion criteria were skeletal maturity, fracture within 3cm of the distal end of the radius, and ED presentation within seven days of fracture. Exclusion criteria were pathological fracture and evidence of previous distal radius fracture on the affected side. Radiographs were stratified by fracture deformity to mild deformity or severe deformity based on predetermined decision rules (Table 6-1). In the absence of guidelines, decisions regarding cut points separating mild from severe deformity were arbitrary and intended to enable an appropriate representation of the spectrum of injury. Fifteen radiographs from each group were randomly selected using a computer generated sequence. The sample size was chosen as difference scores for repeated measures in samples of 30 or more are likely to assume a normal distribution.(105)

Table 6-1 Radiographic characteristics for classification as mild or severe deformity

Group A Mild deformity: must meet all criteria	**Group B Severe deformity: must have at least one criteria**
Intra-articular step: ≤ 2mm	Intra-articular step: > 2mm
Intra-articular gap: ≤ 2mm	Intra-articular gap: > 2mm
Dorsal tilt: ≤ 10°	Dorsal tilt: > 10°
Volar tilt: ≤ 20	Volar tilt: > 20°

Participants: Selection of assessors

Observers were invited from two independent health networks. Health professionals making treatment decisions based on radiographic images of upper limb fractures were invited to participate. Potentially eligible staff included orthopaedic consultants and registrars, radiologists, ED consultants and registrars, and advanced practice musculoskeletal physiotherapists. Five observers from each health network meeting these criteria were invited to participate. Ensuring a minimum of two from each health network, the first five to consent were enrolled.

Observer training

Each observer completed a self-directed tutorial with standardized instructions on measurement technique for each anatomical parameter developed by Kreder et al(84) (Figures 6-1 to 6-3). Observers utilised picture archiving and communication system (PACS) computerized images through the Synapse(86) display system and saved all working lines used in computations. For three test radiographs, the principal investigator provided observers with written and verbal feedback on departures from standardized measurement techniques. Observers repeated measurements where incorrect technique was noted with further feedback provided. Observer training was intended to identify and minimize sources of systematic and random error with measurements and was completed over two weeks.

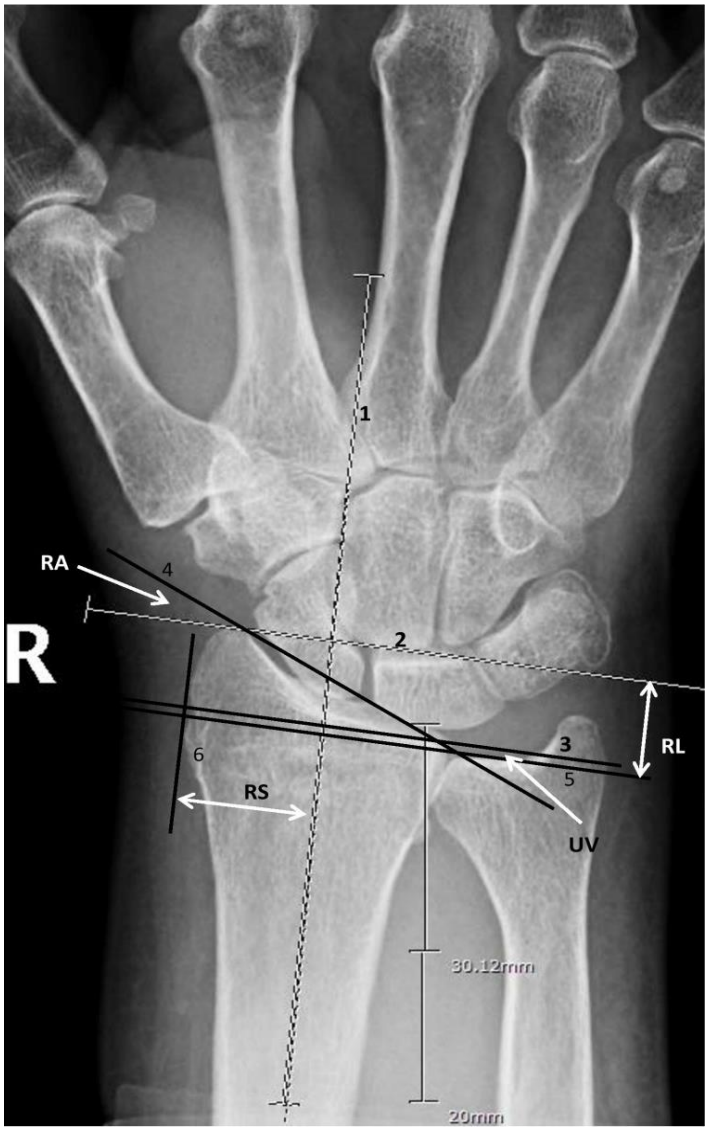


Figure 6-1 Posterioanterior measurement guidelines as described in Kreder et al. 1996.

RA, radial angle; RL, radial length; UV, ulnar variance; RS, radial shift;

1. This line represents the long axis of the radius. The center of the radius shaft is determined at 3cm and 5cm below the mid-region of the proximal lunate articular surface.
2. A line perpendicular to the center long axis of the radius is drawn at the level of the most distal aspect of the radial articular surface.
3. A line perpendicular to the central long axis of the radius is drawn at the level of the ulnar margin of the distal radial articular surface.
4. The radial and ulnar margins of the distal radial articular surface are connected.
5. A line perpendicular to the central long axis of the radius is drawn at the level of the distal ulnar articular surface.
6. A line tangential to the most radial point on the radial metaphysis is drawn parallel to the central long axis of the radius.

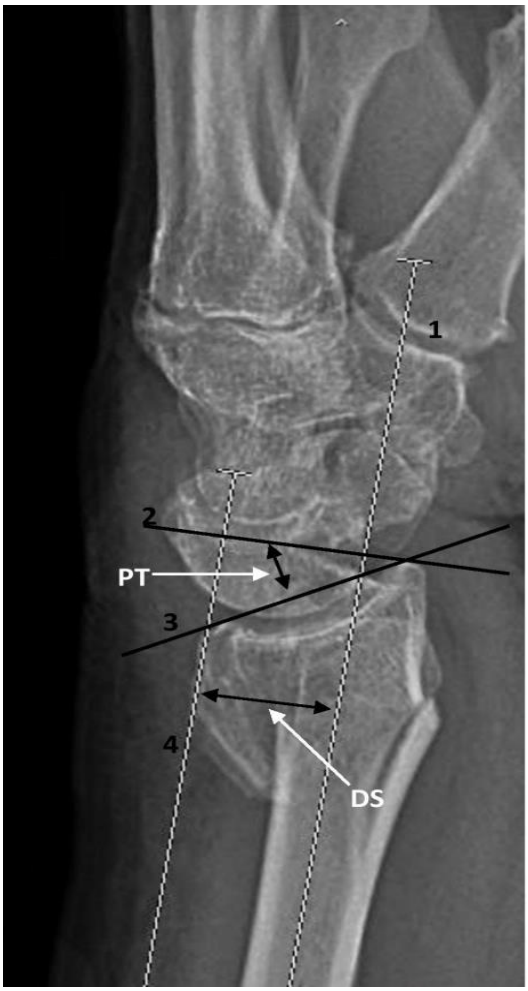


Figure 6-2 Lateral measurement guidelines as described in Kreder et al. 1996

PT palmar tilt angle (dorsal tilt = negative palmar tilt); DS, dorsal shift

1. This line represents the long axis of the radius. The center of the radial shaft is determined at 3cm and 5cm below the mid-region of the proximal lunate articular surface.
2. A line perpendicular to the central long axis of the radius is drawn at a convenient level.
3. The dorsal and anterior margins of the distal radial articular surface are connected.
4. A line tangential to the most dorsal point on the radial metaphysis is drawn parallel to the central long axis of the radius.

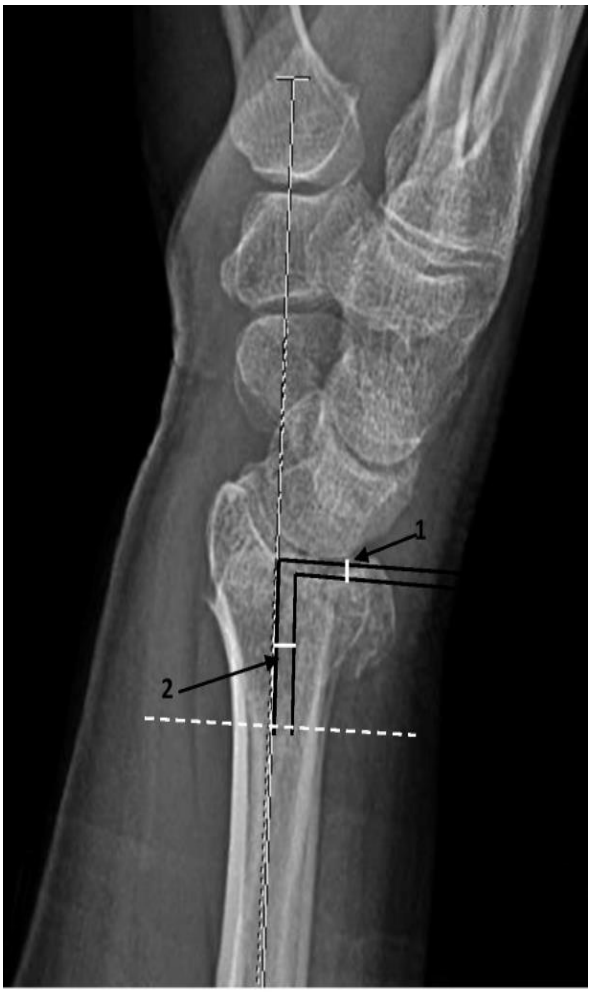


Figure 6-3 Step and gap measurements as described in Kreder et al. 1996

1. Step-off at the distal radius articular cortical margin is measured by drawing lines perpendicular with the central long axis of the radius from the most distal margin of each side of the cortical discontinuity.
2. Gap deformity is measured by dropping lines that are parallel from the central long axis of the radius from the most distal margin of each side of the cortical deformity. The gap distance is measured along a line perpendicular to the central long axis of the radius.

Measurements

Each observer measured eight parameters on each of the 30 radiographs using methods refined in training.

To determine factors affecting management decisions, observers completed three tasks for each radiograph: i) define the position of each distal radius fracture as acceptable or unacceptable; ii) rank the eight anatomical parameters from most (1) to least (8) important in making decisions regarding fracture management; iii) specify (orthopaedic surgeon and registrar only) the preferred management for each fracture as either; a) acceptable position - conservative management; b) reduction required, however, unsure of appropriate technique; c) closed reduction under general anaesthetic; d) closed reduction under local anaesthetic; e) dorsal plate; f) volar plate; g) percutaneous pinning; h) external fixation; i) other.

Observers applied the assumptions the fracture involved the dominant limb, the patient was younger than 55 years, and an absence of co-morbidities that could affect surgical management.

Repeated measurements

Observers were presented, in random sequence, with 30 fully de-identified radiographs. Two weeks later, observers were presented with the same set of radiographs, again in random sequence. Observers had no access to the first measurements or treatment choices made.

Statistics

Kappa and percentage agreement have their strengths and limitations for reporting inter-observer agreement and both were chosen for this investigation. A limitation of using percentages of agreement is the failure to correct for agreements expected by chance and subsequently agreement is overestimated.(119) Kappa corrects for agreement expected by chance but is not directly interpretable, and bias and prevalence cause over and underestimation respectively.(119) Landis and Koch(120) guidelines were used for interpreting kappa values. All analyses were conducted using data from the first set of observations and findings compared to the second test occasion. Where results were similar, only the first analysis is reported.

Determining observer agreement for acceptable or unacceptable fracture alignment

Observers classified fracture alignment as acceptable or unacceptable. Concordance was expressed as percentage agreement between observers. For each observer pair, kappa was calculated and averaged across pairs to provide a single index for inter-observer reliability.(121, 122)

Analysing observer agreement on anatomical parameters important for treatment decisions

Concordance in observer's rankings of the importance of anatomical parameters for driving treatment choices were expressed as percentage agreement. Inter-rater reliability was expressed as a combined kappa for all anatomical parameters and calculated by an appropriately weighted average of individual kappas.(121) Since the frequency with which an anatomical parameter drives management decisions is in part related to the frequency with which it is observed to be unacceptable, the number of times a parameter was classified as unacceptable and ranked important was recorded.

Determining agreement on acceptability of anatomical parameters

Raw measurements for each anatomical parameter were converted to a dichotomized outcome (acceptable or unacceptable position) using decision rules. Rules (Table 6-2) were based on published normal values (derived from population data) for each parameter and used to define cut points separating typical (acceptable) from atypical (unacceptable) values. Kappa was calculated using Stata(121) for observer agreement on the acceptability of each anatomical parameter.

Table 6-2 Decision rules used to separate typical (acceptable) values from unacceptable values

Anatomical parameter	Acceptable range
Dorsal shift	19.61-26.07mm(123)
Intra-articular gap	>0mm
Intra-articular step	>0mm
Palmar tilt	0-22° volar tilt(124)
Radial angle	16-28°(124)
Radial height	9.9-17.3mm(125)
Radial shift	Excluded due to absence of published normative data
Ulnar variance	-0.72 to 2.2mm(126)

Investigations into dorsal shift, radial shift and ulnar variance have typically expressed measurements relative to an uninjured side.(101, 104) Radiographic measurements of an uninjured limb are not common in clinical practice due to unnecessary radiation exposure, cost, and clinical importance, and were not feasible for this investigation. In clinical practice acceptable dorsal shift, radial shift and ulnar variance could be determined by comparing obtained measurements to normative data. Normative data for dorsal shift (19.6-26.1mm)(123) and ulnar variance (-0.7 to 2.2mm)(126) enabled raw measurement conversion to a dichotomized outcome (acceptable or unacceptable). No published normative data could be found for radial shift.

Examining agreement between orthopods on treatment choice

Percentage agreement and kappa(121) were calculated for treatment decisions for each fracture.

6.5 Results

The five participants were orthopaedic surgeon (upper limb), orthopaedic registrar, ED consultant, ED primary care advanced practice musculoskeletal physiotherapist and radiologist specialising in musculoskeletal imaging.

Agreement on acceptable alignment

The frequency of agreement regarding radiographs showing unacceptable alignment was 37% (11/30 radiographs) for all observers and 63% (19/30) for four or more observers. For the five observers, inter-observer reliability calculations (kappa) indicated fair observer agreement (0.25).(120) Stratifying data based on the professional subgroups of orthopaedic staff (surgeon and registrar) and consultants (Radiology, Orthopaedics, Emergency Medicine) produced agreements of 63.3% and 73.3% respectively and kappa values of 0.20 (slight agreement)(120) and 0.27 (fair agreement)(120) respectively. Pairwise agreements are shown in Table 6-3.

Table 6-3 The pairwise observer agreement on radiographs showing acceptable or unacceptable fracture alignment.

Observer pairwise comparison	% agreement
1 & 2	50
1 & 3	83.3
1 & 4	73.3
1 & 5	83.3
2 & 3	60
2 & 4	50
2 & 5	53.3
3 & 4	63.3
3 & 5	66.7
4 & 5	90

Anatomical parameters deemed important in treatment decisions

Table 6-4 presents a summary of the number of occasions an anatomical factor was ranked either first or second for influencing treatment decisions.

Table 6-4 Anatomical parameters ranked as important (either first or second) in making treatment decisions

Anatomical parameter	**Observer 1**	**Observer 2**	**Observer 3**	**Observer 4**	**Observer 5**
Dorsal shift	4	10	0	12	0
Intra-articular gap	16	11	2	7	1
Intra-articular step	12	8	0	6	0
Palmar tilt	17	2	27	24	28
Radial angle	1	1	0	2	0
Radial height	1	0	22	9	1
Radial shift	1	4	0	0	0
Ulnar variance	5	0	0	0	0
All parameters acceptably aligned (therefore no parameter selected)	0	8	0	0	0

=anatomical parameter most commonly selected by each observer

Palmar tilt was the anatomical parameter most commonly selected by four of the five observers. Ulnar variance and radial shift were rarely considered important. Inter-observer reliability (kappa) for the importance of individual anatomical parameters (1^{st} or 2^{nd} ranking) in making treatment decisions was calculated as -0.04, indicating no evidence of systematic agreement.(120)

Table 6-5 summarizes the number of occasions observers agreed on the parameters that influenced decisions regarding fracture management. At least four of the five observers agreed on the top ranking parameter for 10 (first measurement occasion) and nine (second measurement occasion) radiographs (Table 6-5).

Table 6-5 Agreement on factors ranked first or second for importance in fracture management decisions.

	Occasions of agreement (numbers and % of radiographs) on the specific measurements that influenced management decisions			
	1st recording		**2nd recording**	
	Ranked #1	**Ranked #1 or 2**	**Ranked #1**	**Ranked #1 or 2**
	Number (%) of radiographs			
All 5 observers agreed	1 (3.3)	1 (3.3)	1 (3.3)	1 (3.3)
4/5 observers agreed	9 (30)	13 (43.3)	8 (26.7)	13 (43.3)
No observer agreement	0 (0)	0 (0)	0 (0)	0 (0)

Agreement on parameter acceptability

The frequency with which observer measurements for each anatomical parameter were classified as unacceptable and the kappa values for agreement between observers are summarized in Table 6-6.

Observer concordance for parameter alignment being unacceptable (Table 6-6) was categorized as high (observers differed for 0 to 2 radiographs), moderate (observers differed for 3 to 6 radiographs) and low (observers differed for >6 radiographs). Using these criteria, agreement was high for radial angle, radial height and ulnar variance, moderate for dorsal shift and palmar tilt and low for intra-articular gap and step. Inter-observer reliability values (kappa) ranged from 0.26 to 0.69 (Table 6-6) indicating substantial agreement for palmar tilt, moderate agreement for radial angle and radial height and fair agreement for dorsal shift, intra-articular gap, intra-articular step and ulnar variance.(120) Considering percentage agreement and kappa statistics, palmar tilt, radial angle and radial height were the only parameters associated with moderate to high agreement.

Table 6-6 Frequency of observer measurements across the 30 radiographs indicating a deviation from acceptable range for each anatomical parameter and agreement between observers

	Number of times measurements by each observer indicated an unacceptable value for each anatomical parameter					Kappa values for inter-observer agreement
	1	**2**	**3**	**4**	**5**	
Dorsal shift	25	27	29	26	28	0.26
Intra-articular gap	16	11	17	15	1	0.29
Intra-articular step	12	7	3	8	0	0.31
Palmar tilt	23	21	18	20	24	0.69
Radial angle	10	10	11	9	10	0.58
Radial height	19	18	20	19	18	0.53
Ulnar variance	14	14	16	14	15	0.31

The number of times a parameter was classified as unacceptable (Table 6-6) and ranked important (Table 6-4) was also analysed. The results were similar if measurements were only included in the analysis when categorized as unacceptable.

Agreement on treatment choice by orthopods

Table 6-7 summarizes the treatment choices made by orthopods. The orthopaedic surgeon and registrar agreed on management in 23% and 37% of cases (first and second measurement occasions respectively). Inter-observer reliability calculations (kappa) for the first and second measurement occasions indicated slight agreement (0.1 and 0.2 respectively).(120)

Table 6-7 Orthopaedic observer's treatment choices based on radiographs (first recording)

Radiograph	Orthopaedic observer 1	Orthopaedic observer 2
1	GA	AP
2	VP	VP
3	VP	PP
4	VP	PP
5	GA	PP
6	GA	AP
7	AP	PP
8	GA	LA
9	GA	VP
10	GA	PP
11	VP	PP
12	PP	VP
13	AP	AP
14	GA	AP
15	PP	AP
16	GA	VP
17	VP	AP
18	PP	PP
19	VP	Not specified
20	AP	AP
21	PP	PP
22	PP	AP
23	AP	AP
24	AP	PP
25	VP	AP
26	VP	AP
27	GA	PP
28	AP	AP
29	GA	PP
30	GA	AP

AP=Acceptable position-conservative management; R=Reduction required, however, unsure which technique is appropriate; GA=closed reduction under general anaesthetic; LA=Closed reduction under local anaesthetic; DP=Dorsal plate; VP=Volar plate; PP=Percutaneous pinning; EF=External fixation; O=Other

6.6 Discussion

Distal radius fractures are typically managed non-operatively with cast immobilization or surgically with either percutaneous pinning (Kirscher wires), external fixation or internal fixation.(111) Evidence behind treatment choices based on deformation and radiographic parameters is limited.(112, 114-117) Best treatment for distal radius fracture would ideally include a reliable, standardized, evidence-based method of classifying distal radius fractures and unambiguous guidelines for treatment decisions.

The relatively poor pairwise agreements (Table 6-3) and inter-observer reliability value of 0.25 suggest that decisions regarding unacceptable fracture alignment are not made using standardized rubrics. Results appeared minimally influenced by the professional background of observers. Potential sources of variability in classifying fracture alignment include ability to accurately measure radiographic anatomical parameters, technique adopted for measurement of parameters, weighted importance for individual parameters and the cut-points for acceptability assigned to each parameter. Previous investigations of measurement reliability for distal radius fractures found inter-observer reliability to be high [intraclass correlation coefficient (ICC) >0.80] for palmar tilt; moderate (ICC 0.60-0.80) for dorsal shift, ulnar variance, radial angle and radial height; and low (ICC<0.60) for radial shift, intra-articular gap and step.(84, 127) A structured review of the literature addressing the use of radiographic measures and the definition of acceptability for distal radius fractures found a standardized measurement technique was reported for 52% of the referenced studies with substantial variability in the techniques described.(128) For weighting importance of individual anatomical parameters, the review found measurements commonly used included radial angle, palmar tilt, intra-articular gap/step and a measure of ulnar variance/radial shortening.(128) Consideration of palmar tilt in treatment decisions is consistent with the findings of the current investigation, however, a measure of radial shortening (radial height) was considered important by only two of the five observers and both ulnar variance and radial angle were rarely considered.

When observers ranked importance of anatomical parameters for driving treatment decisions, palmar tilt was commonly selected while ulnar variance and radial shift were rarely considered important (Table 6-4). Poor inter-observer reliability (kappa-0.04) signals little relationship between specific anatomical parameters and treatment decisions.

When unacceptable alignment was observed in palmar tilt, four of five observers ranked it in the top two drivers for treatment choices on over 70% of occasions. In contrast, when ulnar variance was measured unacceptable, it rarely influenced treatment choice. The importance of dorsal shift, radial shift and ulnar variance for guiding treatment decisions is not clear given the absence of measurements for the uninjured limb in current practice, limited information linking dorsal shift and radial shift with functional outcomes and the relatively large normal range for ulnar variance.

It may be that there are features of distal radius fracture radiographs rendering them more or less likely to lead to agreement on the parameter(s) driving treatment choices. Magnitude of deformity is a likely contributing factor to greater agreement on the parameter(s) driving treatment choices. Supporting this, where there was strong concordance that the primary driver of treatment decisions was palmar tilt, measurements by all observers indicated an unacceptable value for palmar tilt.

When observers ranked anatomical parameters they deemed important for driving treatment decisions (Table 6-4), a high importance for dorsal tilt (negative palmar tilt) was coupled with a low importance for dorsal shift for four of five observers. A high importance for radial height was coupled with a low importance for radial angle for two of five observers. These findings and previously reported correlations between anatomical parameters(104) support clinician preference for dorsal tilt (negative palmar tilt) and radial height over dorsal shift and radial angle. Radiographic measurement reliability(127) supports clinician preference for dorsal tilt over dorsal shift as a measure of dorsal displacement.

Concordance between observer measurements indicating an unacceptable value for each anatomical parameter (Table 6-6) were moderate to high for palmar tilt, radial angle and radial height when considering both agreement and kappa calculations. Agreement was consistently low for intra-articular step and gap across both methods of statistical analysis (Table 6-6). Low intra- and inter-observer reliability of intra-articular gap and step(84, 127) supports and may account for these findings.

Variability in treatment decisions based on radiographic measurements (e.g. inconsistency with choosing cast immobilization versus surgical management) may be a consequence of the poor pairwise agreement found for fracture alignment acceptability [23% (first recording data, Table 6-7), 37% (second recording)]. The relative impact of specific treatment choices on functional outcomes is not known. A systematic review examined outcomes of treatment for unstable distal radius fracture in the elderly when managed conservatively (cast immobilization) or surgically.(112) Despite significantly worse radiographic measurements associated with cast immobilization (palmar tilt and ulnar variance), functional outcomes were not different from those undergoing surgical management and there was a significantly higher complication rate with volar plate fixation.(112) Such findings highlight the value of investigations into how treatment decisions are made for distal radius fractures and the consequences of such decisions on outcomes and health service costs.

6.7 Limitations and strengths

Investigating the variability in the cut points used by clinicians for defining acceptable/unacceptable alignment of individual anatomical parameters fell outside the scope of this investigation and might be considered for future investigations.

This investigation provides key information for clinicians regarding the link between radiological measurements and treatment choices. Treatment decisions for distal radius fractures in current practice are made by a range of health professionals. Our results should be verified through replication of this work in other settings.

6.8 Conclusions

Observers most commonly based treatment decisions for distal radius fractures on palmar tilt. The value of measurements of intra-articular gap and step, dorsal shift, radial height, radial shift and ulnar variance in making treatment choices is questionable given clinician's low rating of the importance of these measurements and previous reports of poor reliability.

Variation in anatomical parameters deemed important in treatment decisions, inconsistent classification of unacceptable fracture position and discrepancies in treatment choice based on radiograph interpretation indicate the need for further work in this area.

6.9 Chapter conclusion

For acute adult distal radius fractures, the relationship between specific anatomical parameters and treatment decisions was not strong and suggests that decisions regarding unacceptable fracture alignment are not made using standardised principles.

Research is required to progress the field of intervention choice in the management of distal radius fracture. In addition, more information is needed about the comparative effects of different types of interventions and their relative costs.

7. Chapter 7- The impact of wrist fracture, surgical repair and immobilization on patients: A qualitative study.

7.1 Introduction to patient experience qualitative study

No qualitative research reports participants' experience of recovery in the immediate period following wrist fracture. Although not directly investigating acute wrist fractures, Bialocerkowski (2002) explored participant difficulties associated with wrist disorders (fractures, soft tissue injuries, carpal tunnel syndrome and osteoarthritis).(129) The study involved 42 volunteer participants, recruited from a wide range of health care settings with unilateral, localised wrist disorders and a 19 month average length of symptom duration. The focus of the interviews was to elicit information on functional difficulties, perceived reasons for these difficulties and compensatory practices. When participants were asked about activities they found difficult, they most frequently reported using cutlery for eating and work activities involving grasping and lifting. Pain was the most frequently cited reason for these difficulties with wrist and hand weakness being the second most frequently cited reason. Exploring interactions with the health service(s), management of the condition, and barriers/facilitators throughout the participants' journey to recovery fell outside the scope of the study.

The following paper describes participant reports of the experience of wrist fracture. It was of interest to better understand the needs and perspectives of participants in the RCT reported in Chapter 4. Participant feedback provides opportunities for health services to improve care and support and, in this case, to also better understand the effects of short compared to longer periods of immobilisation.

The following text is a copy of the manuscript currently under review with *Clinical Rehabilitation (5 year impact factor = 3.026):*

Watson, N. J., Martin, S. A., Keating, J. L. The impact of wrist fracture, surgical repair and immobilization on patients: A qualitative study.

7.2 Abstract

Objective

To investigate patient experience of wrist fracture, surgical repair and immobilization.

Design

A qualitative investigation involving individual participant interviews.

Setting

A large metropolitan teaching health service.

Subjects

31 participants were consecutively recruited from three groups within a randomized controlled trial comparing immobilization for one (n=11), three (n=10) or six weeks (n=10) following surgical fixation for wrist fracture.

Intervention

Individual interviews were conducted within three months of cast removal. Questions prompted discussion of the experience of fracture, surgery and immobilization. Interviews were audio-recorded, transcribed verbatim. At least two independent researchers performed coding and theming following principles of thematic analysis.

Results

Two themes were identified: 1) impact of the injury varies widely; and 2) health care consumers want trustworthy dialogue. Participant reports indicated recovery from wrist fracture, surgery and immobilization is challenging with significant changes to social role and increased dependence. For many, lack of empathy from health professionals and limited acknowledgement of the personal impact of injury led to dissatisfaction. Health professionals did not consistently tailor communication or adopt strategies to address specific needs for pain management, education and support requirements. There was no evidence that processes were implemented to enhance patient recall and comprehension. Most participants viewed their cast as a barrier to function, despite which, a number of participants immobilized for one week felt cast removal occurred too soon.

Conclusions

Participant reports indicate recovery from surgically repaired wrist fracture is challenging. Opportunities exist to refine care in pain management, education and active engagement of patients in their care.

7.3 Introduction

Wrist fracture represents 10% to 25% of all fractures.(73) Reduced bone mineral density, falls, and increasing age are major risk factors.(7) Wrist fracture affects physical function, mental health and ability to work.(14) The ageing population, increasing life expectancy, and higher functional expectations may increase future health care and productivity costs.(14)

Outcome measures reported over the past 25 years in trials and studies involving distal radius fractures (n=165) indicate a bias towards impairment, in particular radiographic measurements (n=113).(51) Patient-reported outcomes, while used considerably less (n=82), have increasingly been adopted by clinicians and researchers.(51) Goldhahn et al. (2014) surveyed an international group of clinicians, methodologists, epidemiologists, researchers, industry, and patients about the five outcomes they considered most important in wrist fracture. Patients' sense of recovery ranked third behind function and complications.(51) Participants with wrist disorders(129) have reported that eating and work involving grasping and lifting were difficult. Little other information is available on the experience of recovery from wrist injury.

The aim of this investigation was to examine the patient journey through wrist fracture, surgery and immobilization with a focus on identifying opportunities to improve service delivery. Information was sought across the continuum of care, from presentation to the Emergency Department to discharge following rehabilitation.

7.4 Methods

Approval was granted by Melbourne Health, Monash University and Western Health (Australia Human Research Ethics Committees 2011.255, 2012000502, HREC/11/MH/375).

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12612000902897.

This qualitative investigation involved individual participant interviews following wrist fracture, surgical repair and immobilization. Inclusion criteria were 18 years or older, fracture involving the distal 3cm of the radius with or without ulna fracture and operatively managed with volar locked plate. Exclusion criteria were pathological fracture, cognitive impairment, gait aid use involving the injured upper limb, or management following surgery not occurring at the investigation health service.

All interviews were conducted by a physiotherapist (SM) experienced with interview. The facilitator had no relationship with participants prior to interview. Recruitment occurred from within a randomized controlled trial comparing immobilization for one, three or six weeks (manuscript under review). All trial participants in 2014 and 2015 were invited to participate in interview while inpatients, usually within 24 hours of operation. A formal invitation and explanatory statement described interview procedures, risks and benefits, confidentiality and anonymity of results. Researchers' backgrounds were made explicit and, following the consenting process, interviews were scheduled at a convenient time for participants and conducted at the health service. All consenting participants were recruited until the quota of at least 10 participants from each of the three trial immobilization groups (with five < 55 years and five ≥ 55 years in each group) was reached. Interviews were conducted 2-3 months following cast removal.

All participants received standardized treatment during the first post-operative week. At the one week post-operative review, the splint was removed and a full circumferential below elbow cast was applied for participants in three and six week

groups. Within three days of splint/cast removal, participants were engaged in a standardized rehabilitation program with attendance once weekly for six weeks. A surgical team member (orthopaedic doctor) reviewed participants at one and six weeks following surgery. Additional reviews were at the discretion of the surgical team.

The standardized rehabilitation program was provided by physiotherapists trained in assessment, education and support for participants. The principal investigator coordinated all appointments for participants including the two surgical team appointments, and was the central point of contact and liaison for participants and health professionals.

Interview data collection

Age at time of surgery, gender, surgery involving dominant side and days from incident to surgery were recorded. Individual face-to-face interviews were guided by pre-determined questions with opportunities for unprompted participant contributions. Interview questions were refined with pilot testing and those relevant to this report are summarized in Appendix P. Questions were structured to prompt participants to discuss their experience of fracture, surgery and immobilization, and the care provided by the health service. Interviews lasted approximately 60 minutes and were audio-recorded and transcribed verbatim by the principal investigator assisted by voice recognition software. Following interview, a facilitator debrief form was completed summarizing participant's verbal and non-verbal communication and any salient features of the interview. Debrief information was included with transcribed recordings in analysis. Participants were invited to provide feedback on transcript accuracy. Transcripts were assigned a code number that included immobilization period.

Data analysis

Data were analysed with thematic analysis.(130) Analysis focused on examining and interpreting underlying ideas and concepts in the data. The assumption of a predominantly unidirectional relationship between language and experience facilitated an essentialist/realist approach. To enhance credibility, three researchers

performed independent data coding. Theme development and consensus was reached through at least two of these researchers collaborating during three rounds of coding. Dependability between the participant experience and diagnosis was achieved through defined criteria for wrist fracture and surgical management type. Dependability of data was achieved by a single facilitator performing all interviews which were audio-recorded, transcribed verbatim and returned to the facilitator and, on request, to the participant, to confirm accuracy. Confirmability was enhanced through the facilitator completing a de-brief form immediately after interview summarizing emergent themes, ease of interaction and body language. This information was cross-referenced with participants' comments during analysis. Consensus between independent researchers in theme identification also supported confirmability. Transferability of results was enhanced by random sampling across the target population with balanced representation of older and younger participants. Transferability of results was narrowed by inclusion of comprehensive trial measurement procedures and the trial coordinator role which was not part of routine clinical practice.

7.5 Results

Thirty-one participants consented and attended interview from April 2014 to February 2016 (Figure 7-1). Demographics are summarized in Table 7-1. Thirteen participants requested transcript review and none requested changes.

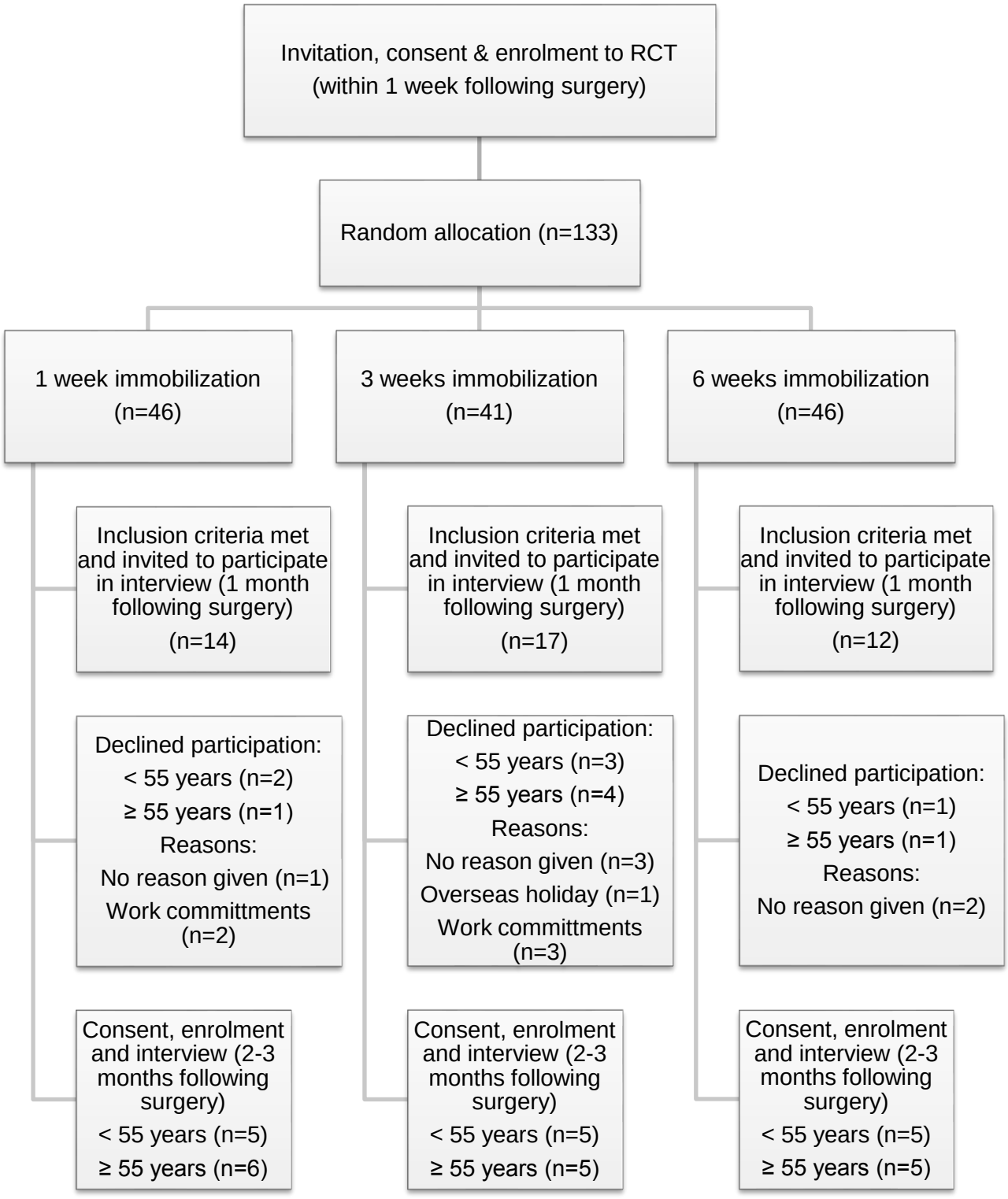


Figure 7-1 Participant flow during investigation

Table 7-1 Baseline demographic and clinical information

	Overall (n=31)	Immobilization (treatment) group					
		1 week (n=11)		3 weeks (n=10)		6 weeks (n=10)	
		<55 (n=5)	≥55 (n=6)	<55 (n=5)	≥55 (n=5)	<55 (n=5)	≥55 (n=5)
Age (years) at time of surgery: mean (SD)	53.2 (13.4)	47.8 (12.2)	63.6 (8.1)	44.6 (5.5)	65.6 (7.9)	36 (10.4)	60.2 (5.2)
Female: n (%)	20 (64.5)	2	4	4	5	3	2
Surgery on dominant side: n (%)	12 (38.7)	2	3	1	2	1	3
Time from injury to surgery(days) mean (SD)	7.9 (6.6)	8 (7.7)	5.4 (6.4)	6 (7.2)	10.4 (5.0)	8.2 (5.9)	9 (9.4)

Two overarching themes (Figure 7-2) were identified: (1) impact of injury varies widely; and (2) health care consumers want trustworthy dialogue. Quotes were selected from transcripts to illustrate data summaries.

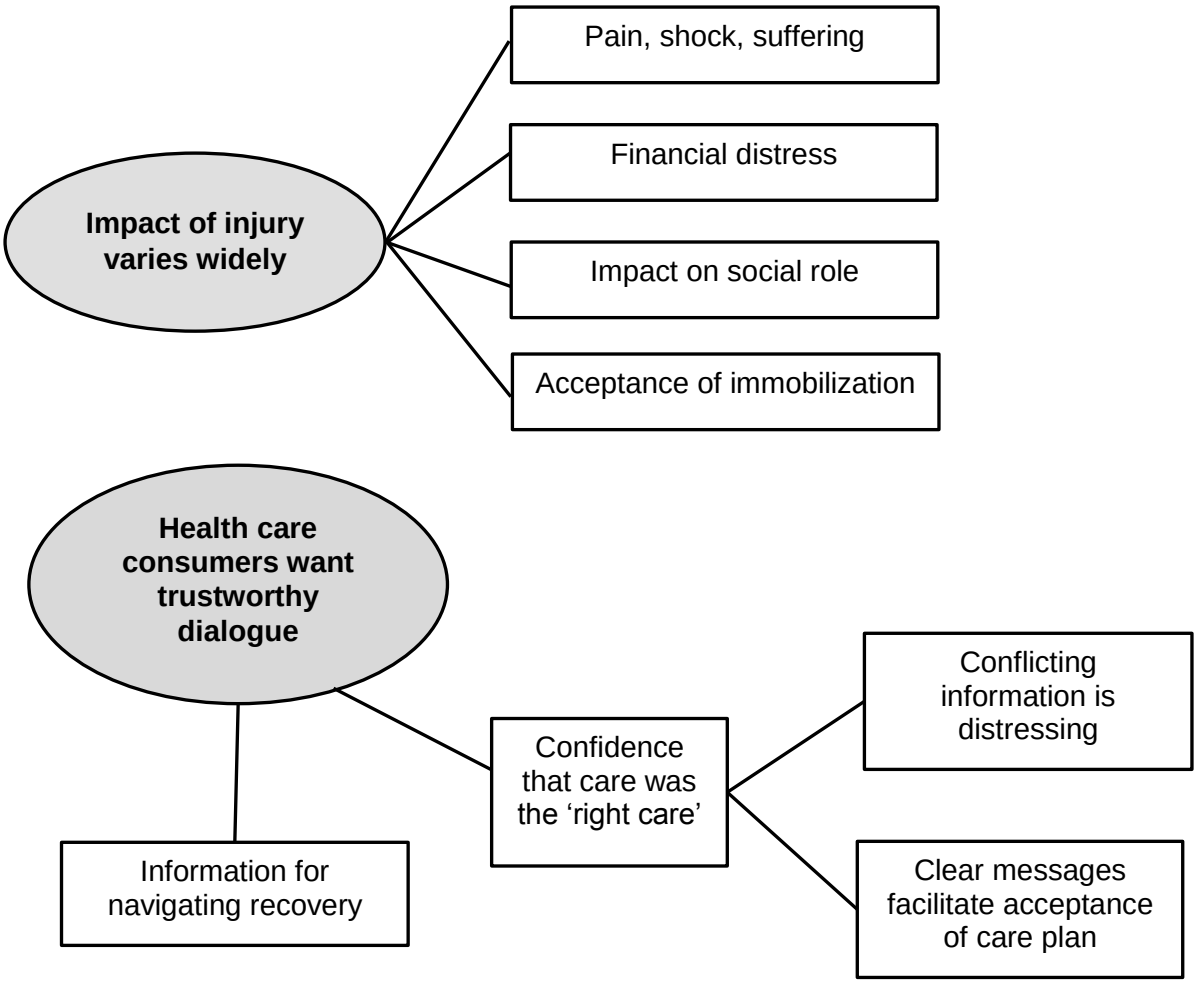


Figure 7-2 Thematic map of participant experience following wrist fracture, surgery and immobilization

Impact of injury varies widely

Pain, shock, suffering

Most participants responded to the initial injury with a sense of calmness and acceptance (n=25), however, some participants (n=5) reported a sense of alarm and devastation at the time of, and immediately following injury.

Participant aged 62:

'I hate to think back to that fall because….it was a very, very anxious experience this fall…..it was just anxious-anxiety all around.'

Participant aged 26:
'Playing lacrosse and fell on it. It wasn't really anything eventful. I sat around and watched the end of the game.'

Pain experience varied with some reporting severe and others mild pain. Pain management was a focus for participants during initial assessment in the Emergency Department and the two weeks following surgery. Little information was provided on what pain to expect, and information was inconsistent with respect to options for pain relief, side effects and appropriate timing of medication. No participant received written instructions about pain management. The majority of participants (n=26) felt their pain was well managed in the Emergency Department, however, some (n=5) reported it was inadequate.

Participant aged 67:
'Pain relief was as adequate as it could be….ED were very attentive as far as pain management goes.'

Participant aged 54:
'It was ridiculous what (pain relief) ED sent me home with…..not enough, there is no way that could have even taken the edge off it.'

Following surgery, most participants (n=26) felt pain was well managed, however, five participants found it to be inadequate.

Participant aged 52:
'….happened to work out that the pain dropped in severity by the time I'd run out of morphine, I didn't need it and [paracetamol] was doing the job.'

Participant aged 30:
'When I was at the hospital they weren't keen to send me home with any painkillers….they just wanted me to stop taking them and go back to nothing straightaway….I convinced them to give me some pain medication to take home.'

When asked if fracture related pain affected their recovery, reports included no impact (n=16), unsure (n=2) and that pain affected recovery (n=13).

Participant aged 26:
'It was …. weakness that slowed it….. pain was fine.'

Participant aged 57:
'For sure…if it hurts too much then you just don't do it….I'll do as much as I can but if it hurts, I'll stop.'

All participants reported a significant level of disability in the first week or two following surgery. A quarter of participants had not returned to their pre-injury work role/usual daily activities at the time of interview.

Financial distress

A number of participants reported experiencing financial distress following fracture. Factors impacting on the extent of financial distress included employment status (e.g. self-employed, sessional or casual), type of work (e.g. physical labour) and number of dependents (e.g. children, elderly parent). No participants reported a health professional discussing the impact of injury on financial status. A number of participants felt financial distress was amplified when health professionals did not provide timelines for milestones related to return to work e.g. driving or lifting.

Participant aged 57:
'It's quite bothering because I can't even afford to be off work all this time. …. I'm re-drawing from my house. It's ridiculous. I can't, I can't keep doing that.'

Impact on social role

All participants reported the injury had an impact on social role and increased their dependence. Common concerns included changes to relationship dynamics, increased carer burden for family members, and reduced ability to work and generate income. Factors appearing to play a role in the extent of impact included the importance of their injured arm for livelihood (e.g. tradesperson) and the nature of their social role (e.g. young children dependent on them for transport etc.).

Participant aged 30:
'I couldn't lift the kids, I couldn't drive, couldn't do most of the housework, my balance wasn't very good….I was pretty useless.'

Acceptance of immobilization period (one, three or six weeks)

While most participants were satisfied with the timing of cast removal, a few were not. Some (in the one week immobilization group) were concerned the cast was removed too soon, and this concern appeared amplified by beliefs that usual practice typically involved a longer immobilization period.

Participant aged 56:
'You know there are different periods of removal of cast, of course humanly speaking, you know, we don't take risk, you'd rather go by the norm.'

On the other hand, some participants from the 3 and 6 week immobilization groups would have preferred earlier cast removal.

Participant aged 34:
'I would have preferred it [cast] to have been removed a lot sooner….I just felt really uncomfortable, very restricted…I was very relieved when it came off.'

When the cast was removed, the majority of participants (n=27) reported a sense of relief, improved function and the start of recovery. The ability to use the injured arm while showering and to drive again was particularly valued.

Participant aged 48:
'I felt more independent…..and I felt like I could actually start recovering now.'

Participant aged 56:
'….the driving thing was huge. Particularly difficult.'

Participant aged 54:
'Main difference is you haven't got the extra weight on your arm….you can have a shower.'

A third of participants reported feelings of concern and anxiety following cast removal due to a sense of reduced protection for their wrist and apprehension that it could easily be re-injured. They also reported a sense of alarm with loss of the symbol to others that they had an injured arm.

Participant aged 47:
'I felt vulnerable. I felt really scared. I really held it close….when I took it off it was like….can you have some sort of the bandage, something on there …. like I could knock [it] at any minute it's going to hurt, nobody stand next to me sort of thing.'

Health care consumers want trustworthy dialogue

Some participants were dissatisfied with the lack of empathy from health professionals and felt the individual impact of injury was not acknowledged.

Participant aged 53:
'Well the fracture clinic, that was very poor because they just called me, they said it's all going well and that's it. And I mentioned I can't straighten and it was still a bit swollen….the lady just told me- well it will never be the way it was. And that was it.'

Confidence that care was the 'right care'

A number of participants were not confident that the care they were receiving was the 'right care' and felt uncomfortable asking questions about their management due to a perception that health professionals were too busy.

Participant aged 48:
'Yeah, but sometimes I didn't feel like it was accurate….I would ask them something and they would answer but not listening to my question. So the answer they gave me was what they thought I was asking and not actually listening to what I was actually asking….I think that's because they're so busy and they're rushed.'

Conflicting information is distressing

A number of participants felt their distress was amplified when conflicting information was provided and this appeared to reduce their confidence in receiving the 'right care'.

Participant aged 47:

'I asked the question whether I could go up from 4kg to 4.5 or 5kg doing weights because the physio. encouraged me to rehabilitate….when I asked the doctor, I think she was a trainee….can I go up to 4.5 or 5kg? And she goes 'what!' And I said….because I'm doing some rehab….And then she goes, I'll be back in a minute….she came back and she goes- you shouldn't be lifting anything more than a cup of tea. And I said, that was at the beginning…. this is six, seven weeks on- I'm sure I should be lifting something more. So there was a lot of confusion there. And I sort of went all red thinking I hope I haven't hurt myself. And I so I ask- well how did my X-ray come up…. was it OK? And she said, yes, but don't do anything until three months, don't start, don't do anything. And I'm thinking, well why was I at physio. all these weeks?'

Clear messages facilitate acceptance of care plan

All participants appreciated the standardized and structured management provided in the rehabilitation program, particularly its allocated question time, written instructions, longitudinal tracking of progress and structured exercises.

Participant aged 54:

'It made it easier to keep doing the exercises….there was such positive feedback. So it sort of gave you that boost….even though I could feel the difference….it was just nice to hear it from someone else.'

Information for navigating recovery

Most participants identified that involvement of family, friends or carer (support person) reduced anxiety and assisted with recall and interpretation of information both before and after surgery. Importantly, 10 participants reported no support person during hospitalization following surgery and 13 participants reported no support person during the six week rehabilitation program. Only four participants reported assistance with daily life being considered prior to hospital discharge.

Participant aged 54:
'When I went home, I had no help whatsoever. I really struggled….one day I cried because I just dropped something and [it was] like a nightmare cleaning it up….but no one even asked……no one sort of asked about your situation, what happens after you leave.'

No participants reported psychological support being offered at any stage.

Participant aged 52:
'I wouldn't have minded some psychological counselling just to get through it mentally. That was a bit of a bad trip, mainly because of the timing of the accident and the type of work I'm in.'

Participants reported that exposure to peers with similar experiences provided motivation and encouraged persistence.

Participant aged 52:
'I did a lot of trolling of musician's websites……that made it very helpful understanding what that person had gone through and the fact that she stuck to it, her exercises and so on.'

7.6 Discussion

Participants sought dialogue, active involvement in treatment decisions and empathetic health professionals who provide information to facilitate a more autonomous role for them in their individual recovery. Participants described variable needs and the health service exhibited variable care provision which led to the match between needs and services frequently being imperfect. Health professionals did not consistently tailor communication to address specific participant needs or adopt strategies that might have reduced anxiety for those who were alarmed or distressed by the injury. Similarly, there was considerable variation in pain levels experienced by participants but little evidence of a systematic approach to identifying and addressing pain. Participant reports provided no evidence that processes were implemented to enhance patient recall and comprehension. Most participants viewed their cast as a barrier to function, despite which, a number of participants immobilized for one week felt cast removal was too soon. Patients' sense of recovery has been identified as a key outcome to consider following wrist fracture.(51) No previous investigations have explored the patient experience in the immediate period following wrist fracture and the current investigation provides helpful insight. While efforts were made to enhance transferability of results (consecutive recruitment from a random sample of the target population and a balance of ages above and below 55 years), limitations of this investigation were that conclusions were based on a select group of participants and that service provision involved a trial coordinator providing a central point of contact and oversight which was additional to routine clinical practice. While these factors limit the generalizability of some of the findings, participants were representative of the typical wrist fracture patient and factors such as the need for tailored pain management, informative dialogue, and engagement in the rehabilitation process are likely to apply to the broader population of patients.

Participants wanted to feel confident they were receiving the 'right care' and sought information on the expected pathway to recovery. Anxieties and uncertainty about cast removal indicate potential advantages in providing structured advice on what might be expected. Considering participants' anxiety due to a sense they were

losing protection of their fracture, recommendations following cast removal might emphasize the functional advantages of early removal and include a short period of time wearing an elastic bandage to 'signal' vulnerability. Exposure to peers with a similar experience provided motivation and encouraged persistence with rehabilitation. A library of shared experiences could provide opportunities to reinforce key messages pertaining to care of the injured arm, adherence to exercises, and incorporate dialogue around typical concerns. In other areas of health, apps are improving patient and carer access to health information and assisting with conversations between patients, carers and health professionals.(131, 132) Apps may be effective for providing standardized messages and engaging support people in care of the person with fracture.

Approximately one-third of participants reported having no support person during hospitalization or rehabilitation. Previous research supports the positive influence of family involvement during rehabilitation and that education of family members enhanced participant self-efficacy and pain control and reduced psychological disability.(133) With hindsight, participants reported the benefits of support person involvement in their recovery. Health professionals might encourage patients to involve significant others in their care. A support person is likely to have better uptake and recall of key messages than the acutely injured patient and health professionals might take time to educate and involve support people from initial presentation.

Few participants reported assistance with daily life being discussed prior to discharge. A history of previous wrist fracture in women 65 years of age or older is associated with increased risk of hip fracture (relative risk, 1.9; 95%CI 1.4 to 2.7).(134) Assessment of patients' need for assistance with functions of daily life should form part of standard practice following wrist fracture and surgery. The reported low occurrence of this assessment reflects the absence of unambiguous health service procedures for wrist fracture management. It is possible wrist fracture is perceived as too trivial to warrant such enquiry or staff may be unaware of how to provide support services if required. This area warrants future research.

All participants reported that injury affected their social role and dependence. Recovery from wrist fracture imposes limitations on activities such as driving, work and sports. Standardized instructions should include typical timelines for permitted activities. Early psychological interventions have been recommended(135), but were not offered to any participants. Roh et al (2014), investigating similar patients, found pre-operative anxiety and catastrophic pain ideation were linked with delayed functional recovery. Psychological support may be cost-effective if it improves patients' coping skills and sense of control.(136) Participants in this investigation identified single parent status, self-employment, dependent children and level of disability as factors affecting the impact of their fracture and these factors, in addition to pre-operative anxiety, catastrophic pain ideation and self-reported need, could be considered in prioritisation of psychological support.

A number of participants reported financial distress associated with injury. They needed timelines for recovery to navigate financially. Discussions regarding financial status did not occur for any participants. As financial pressure has been linked to lower exercise adherence(137), exploration of the cost-benefits of assisting patients identify financial support options is warranted.

Given the distress and pain associated with acute fracture, it might be prudent for health professionals to assume that only part of the messages they deliver will be retained by patients and this is well evidenced.(138-141) Potential impacts of suboptimal patient recall of clinical and treatment information include additional contacts with the health service for clarification, errors in decisions made by patients, confusion regarding timing of future events and costs to patients of being ill prepared during the recovery phase. It is likely that ability to recall information enhances adherence to recommended treatment.(142) Delivering standardized instructions to patients with minimal medical jargon, simplified language and that reinforce essential information, has been found to significantly improve recall of illness-related instructions and advice.(143) Health professionals involving and educating support people, and providing standardized instructions that use simplified language to reinforce key information, might improve patient recall and presents potential

advantages for enhancing patient outcomes following surgically managed wrist fracture. Practices resulting in a better informed and less anxious patient are likely to decrease demands on health services, improve patient outcomes and reduce avoidable health service costs.

7.7 Clinical messages

- Despite the status of a relatively minor injury, patients find recovery from surgically managed wrist fracture challenging.
- Procedures could be standardized in the key areas of involving support people, pain assessment and management, education in cast/forearm care, recovery expectations, and strategies to support navigation of daily needs and financial challenges.

7.8 Chapter conclusion

Appendix Q presents the debrief form completed by the facilitator following each participant interview.

Encouragingly the past 25 years has seen a shift from outcome reporting following distal radius fracture largely focusing on radiographic measurements to inclusion of more patient-reported outcomes. The rich data provided with in-depth patient interviews adds detail to the information captured in questionnaires. This information enables development of person-centred care where management aims target the most important outcomes identified by patients.

There was no evidence from participant reports that processes were implemented to enhance patient recall and comprehension. Potential reasons for these strategies not being adopted by health professionals include limited awareness of the strategies, uncertainty around key information for patients to recall, a perception that this was the role of another health professional/discipline or low prioritisation of the importance of recall strategies in the patients' journey to recovery.

Participant reports indicated an absence of a coordinated and standardised approach to managing distal radius fracture. The impression given was one of patients and health professionals both attempting to navigate the system and this, unsurprisingly, did not consistently result in best care. Reports indicated that participants' acceptance of management (e.g. early mobilisation) was influenced by their confidence that it was the 'right care'. It is likely that implementation of a coordinated approach and standardised guidelines for the management of distal radius fracture would result in consistent staff confidence in managing this condition with a flow on effect to enhanced patient confidence with receiving the 'right care'. When considering participant reports in the context of findings from the RCT, most participants were satisfied with the timing of cast removal, however, some participants were concerned cast removal was too soon. This concern appeared amplified by beliefs that usual practice typically involved a longer immobilisation period. Adopting early mobilisation as routine practice through standardised guidelines, tailoring rehabilitation programs for early mobilisation, and providing education on the benefits of early mobilisation may assist patients' acceptance of early mobilisation and improve confidence that it is the 'right care.'

Patient interactions with the health service following wrist fracture, surgical repair and immobilisation are further explored in chapter 8.

8. Patient interactions with the health service following wrist fracture, surgical repair and immobilization: A qualitative study.

8.1 Introduction to patient interactions with the health service study

Methods for creating a health service that is more responsive to the needs of patients are increasingly a focus and driven by the recognition that responsiveness to patients is a determinant of effective health systems.(144) WHO supports this endeavour through inclusion of indicators of responsiveness in World Health Reports.(145) Patients appreciate health professionals who are good communicators, clearly explain treatment and management options, display interest in what they have to say and allow time for questions.(146) Patients have also expressed a greater expectation of involvement in their treatment decisions. Responses to a survey of 8,119 European patients aged 16 and over reflected patients' desire to be actively involved in treatment decisions.(144) A model where health professionals and patients equally share the responsibility for decision making was the most popular option for survey respondents. Older people (> 55 years) were more likely to view the doctor as the primary decision maker with 31% of respondents aged over 55 preferring a doctor to decide on management compared with 24% aged under 35.(144)

The qualitative investigation in Chapter 7 reported on the patient experience following wrist fracture. This chapter includes a further qualitative investigation which shifts the focus to explore patients' interactions with the health service throughout their recovery from wrist fracture. Patient feedback is a particularly useful tool for identifying service gaps and presents opportunity for the systematic improvement of care provision. No previous investigations have explored patient interactions with the health service following wrist fracture. Key areas of interest included the patients' interpretation and understanding of information provided, the

type of information sought by patients, aspects of care provision that were empowering or disempowering, and inefficiencies in service delivery.

The following text is a copy of the manuscript currently submitted to *Journal of Orthopaedic Research (5 year impact factor = 2.982):*

Watson, N. J., Martin, S. A., Keating, J. L. Patient interactions with the health service following wrist fracture, surgical repair and immobilization: A qualitative study.

8.2 Abstract

Objective

To explore participant interactions with the health service following wrist fracture, surgery and immobilization.

Design

Participant interactions with the health service were explored through individual interviews. Interview participants were recruited from within a parallel design randomized controlled trial (RCT) comparing immobilization of either one, three or six weeks following surgical fixation for wrist fracture.

Setting and participants

Adult participants with surgically managed wrist fracture enrolled in a RCT conducted at a large metropolitan teaching health service in 2014 and 2015 were invited to participate.

Main outcome measures

Individual interviews (n=31) were conducted within three months of cast removal. Interviews were audio-recorded, transcribed verbatim and three independent researchers performed coding and theming following principles of thematic analysis.

Results

Identified themes were: (1) variation in service delivery causes confusion; (2) interactions with services can be empowering or disempowering; (3) health care consumers want information. All participants reported inconsistencies with information provided and the management of their condition. Participants sought active involvement in their treatment decisions and appreciated structured rehabilitation.

Conclusions

Unambiguous processes for wrist fracture management, defined discipline responsibilities for information delivery and scripted narratives to facilitate standardized messages would assist teaching hospitals to provide consistent and appropriate services. Opportunity exists to test the effect of a coordinator role for implementing management procedures, standardizing information conveyed to patients and improving the responsiveness, flexibility and efficiency of health services.

Trial Registration

Australian New Zealand Clinical Trials Registry ACTRN12612000902897. http://www.ANZCTR.org.au/ACTRN12612000902897.aspx

8.3 Introduction

Considering health care and productivity costs, hand and wrist injuries are expensive.(14) Wrist fracture affects physical and mental health.(14) The cost burden of wrist fracture is increasing with 2009 hospitalization rates approximately threefold those in 1997 for people over 50 years.(4) The ageing population, increasing life expectancy and higher functional needs of older people, are likely to increase management costs.(14)

Responsiveness to care-seeker needs is a determinant of effective health systems.(144) Care seekers appreciate health professionals who are good

communicators, clearly explain treatment and management options, display interest in their views, allow time for questions(146), and involve them in treatment decisions. (144) Little is known about patient interactions with health services following surgery and immobilization for wrist fracture. This investigation explored patient interactions with a health service, barriers/facilitators for recovery and patient involvement in management and treatment decisions. Information was sought across the continuum of care, from presentation to the Emergency Department (ED) to discharge following rehabilitation.

8.4 Methods

This investigation received Human Research Ethics Committee approval (2011.255, 2012000502, HREC/11/MH/375).

Design

Interview participants were recruited from within a RCT comparing immobilization of one, three or six weeks following surgical fixation for wrist fracture.

Characteristics of participants and facilitator

RCT inclusion criteria were 18 years or older, fracture of distal 3cm of the radius with or without ulna fracture, and surgically managed with volar locked plate. Exclusion criteria were pathological fracture, cognitive impairment, gait aid use with injured upper limb, or management following surgery not occurring at the investigation health service.

All interviews were conducted by a physiotherapist (S.M.) experienced with interviewing. The facilitator was not involved with the RCT or participants prior to interview.

Recruitment method

RCT participants were recruited from a large metropolitan teaching hospital between September 2012 and May 2016. Eligible patients were invited to participate while inpatients, usually within 24 hours of operation. All RCT participants in 2014 and 2015 were subsequently invited to participate in interview. A formal invitation described interview procedures, risks and benefits, confidentiality and anonymity of

results. Researchers' backgrounds were made explicit. All consenting participants were recruited until the quota of at least 10 participants from each of the three trial immobilization groups (with five < 55 years and five ≥ 55 years in each group) was reached. Interviews were conducted at the health service, 2-3 months following cast removal.

Interventions

All participants received standardized treatment during the first post-operative week. Post-operative review (one week following surgery) involved splint removal and immobilization with a circumferential below-elbow cast for participants allocated to three or six weeks immobilization. Within three days of splint/circumferential cast removal, participants began a weekly rehabilitation program for six weeks. The surgical team reviewed participants again at six weeks. Additional reviews were at the discretion of the surgical team.

A standardized rehabilitation program was provided by one of eight physiotherapists trained in assessment, education and support for participants. The principal investigator coordinated all participant appointments (including the two surgical team appointments) and was the point of contact and liaison for participants and health professionals.

Interview data

Age at time of surgery, gender, surgery involving dominant side and days from incident to surgery were recorded. Individual, 60 minute, face-to-face interviews were guided by pre-determined questions with opportunities for unprompted participant contributions. Questions prompted discussion about the experience of fracture, surgery, immobilization and the health service care provision and were refined with pilot testing. Those relevant to this report are summarized in Table 8-1. Interviews were audio-recorded and transcribed verbatim by the principal investigator assisted by voice recognition software. Following interview, a facilitator debrief form was completed summarizing participant verbal and non-verbal communication and salient features of the interview. This was analysed with transcribed recordings. Participants were invited to provide feedback on transcript accuracy. Transcripts were assigned a code that included immobilization period.

Table 8-1. Interview questions relevant to experiences with the health service

1. What were you doing at the time of your wrist injury?
2. Let's talk about the time period from your first contact with [name of hospital] for this injury until surgery: **a.** Tell me about when you arrived at this health service for treatment of your wrist- what happened and what information were you given? **b.** What were you told about your injury? **c.** What were you told about your surgery? **d.** Did you feel that you were given enough information and were able to understand this information?
3. Let's talk about the period of time you spent in hospital after your surgery: **a.** Did you get given enough information about your injury, surgery and what to expect during the recovery period? **b.** Did you get given enough information about how to look after your wrist? If yes, what were you told and if no, what did you need to know? **c.** Were you given information on what follow-up visits you would need? **d.** Were you given information on how long your recovery would take? **e.** Were your family involved? **f.** Which health professionals did you see while in hospital? **g.** Did you get the information you needed from all the health professionals you met during your hospital stay? If no, what might have been helpful? **h.** Was any of this information confusing and if so, in what way?
4. Let's talk about your rehabilitation which is the time after you left hospital: **a.** Did you feel that you were given enough information about how to look after your wrist? **b.** If yes what were you told and if no, what did you need to know? **c.** Were you given information on how long your recovery would take? **d.** Were your family involved? **e.** Which health professionals did you see during your rehabilitation? **f.** Were you provided with information from all the health professionals you saw during your rehabilitation? **g.** Was any of this information confusing and if so, in what way? **h.** What information about your progress was useful? Is there anything other information you would have liked?
5. Let's talk about all stages following your injury: **a.** Did you feel that you were given the information you needed in time? If no, what would have been better? **b.** Were you usually provided with an opportunity to ask questions? If no, are you able to provide some examples of when you wanted to ask questions but felt that this was not possible? **c.** Is there anything more you feel the health professionals could have done to support you through the time you spent in hospital or your recovery period after leaving hospital?
6. Let's talk about the impact your wrist injury had on your family: **a.** How do you feel the injury affected your family? **b.** Is there any other information that health professionals could have given you and your family to reduce the impact on your family? If so, what would that be?
7. The following are some general questions regarding your wrist: **a.** How many times were you reviewed by your surgeon? **b.** Tell us how you felt about the number of appointments that were made for you? Did you feel you had the right number of appointments, not enough or too many? **c.** Throughout your recovery from your wrist surgery, did you arrange any appointments with health care professionals (e.g. your GP, private physiotherapist) outside of Western Health for treatment for your wrist injury?
8. Let's discuss your physiotherapy treatment: **a.** Were you satisfied with the number of times you were reviewed by your physiotherapist. If not, what would you have preferred? **b.** Did you get information or advice from your physiotherapist that helped your recovery? If so, what was useful? **c.** Did you do the exercises? If not, what were the main barriers? **d.** Were the exercises helpful? If so, in what way were the exercises helpful? **e.** Did you feel comfortable approaching your physiotherapist with questions? **f.** Were your questions answered? **g.** Were there any measurements of your progress taken by the physiotherapist that you found particularly helpful? **h.** What goals did you set for yourself during your recovery period following wrist surgery? **i.** Do you feel you achieved these goals and if not, what goals are you still working towards?

Data analysis

Thematic analysis principles were followed in analysing and reporting data.(130) Analysis focused on examining and interpreting underlying ideas and concepts in the data. The assumption of a predominantly unidirectional relationship between language and experience facilitated an essentialist/realist approach.

To enhance credibility, three researchers independently coded data. Theme development and consensus was reached through collaboration between two researchers over three rounds of coding. Dependability of data collection was enhanced through recruitment occurring within the RCT with stratified allocation to treatment by age. A single facilitator conducted all interviews which were audio-recorded, transcribed verbatim and returned to the facilitator and, on request, to the participant, to confirm accuracy. Confirmability was enhanced through the facilitator summarizing emergent themes, ease of interaction and body language immediately after interview. This information was cross-referenced with participants' comments during analysis. Consensus of independent researchers in theme identification also supported confirmability. Transferability of results was enhanced by random sampling across the target population with balanced representation of older and younger participants. Transferability of results was narrowed by inclusion of comprehensive trial measurement procedures and the trial coordinator role which was not part of routine clinical practice.

8.1 Results

Thirty-one participants attended interviews from April 2014 to February 2016 (Figure 8-1). Thirteen participants requested transcript review and none requested changes. Participant demographics are summarized in Table 8-2.

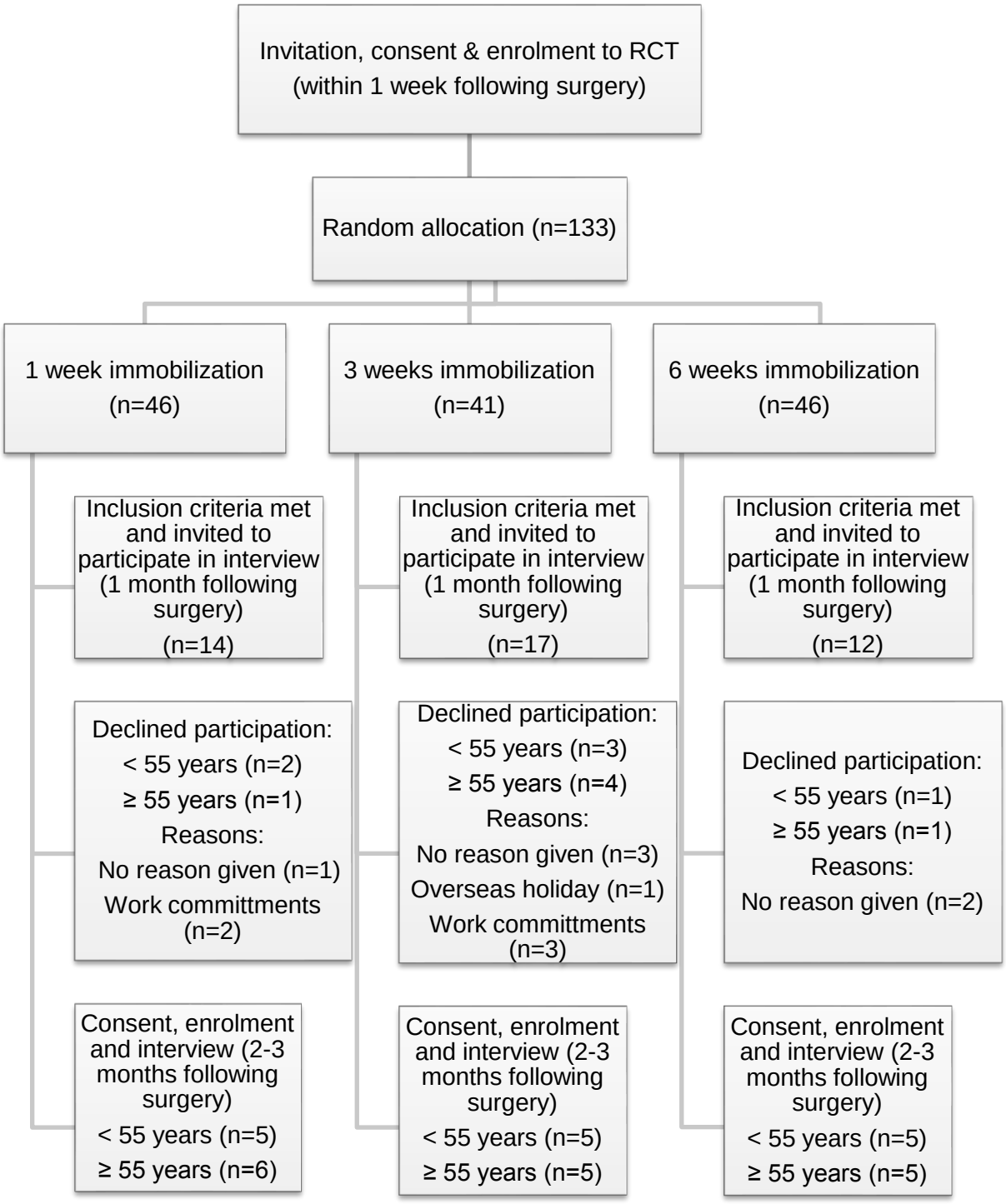


Figure 8-1 Participant flow during investigation

Table 8-2 Baseline demographic and clinical information

	Overall (n=31)	Immobilization (treatment) group					
		1 week (n=11)		3 weeks (n=10)		6 weeks (n=10)	
		<55 (n=5)	≥55 (n=6)	<55 (n=5)	≥55 (n=5)	<55 (n=5)	≥55 (n=5)
Age (years) at time of surgery: mean (SD)	53.2 (13.4)	47.8 (12.2)	63.6 (8.1)	44.6 (5.5)	65.6 (7.9)	36 (10.4)	60.2 (5.2)
Female: n (%)	20 (64.5)	2	4	4	5	3	2
Surgery on dominant side: n (%)	12 (38.7)	2	3	1	2	1	3
Time from injury to surgery(days) mean (SD)	7.9 (6.6)	8 (7.7)	5.4 (6.4)	6 (7.2)	10.4 (5.0)	8.2 (5.9)	9 (9.4)

Three overarching themes (Figure 8-2) were identified: (1) variation in service delivery causes confusion; (2) interactions with services can be empowering or disempowering; (3) health care consumers want information.

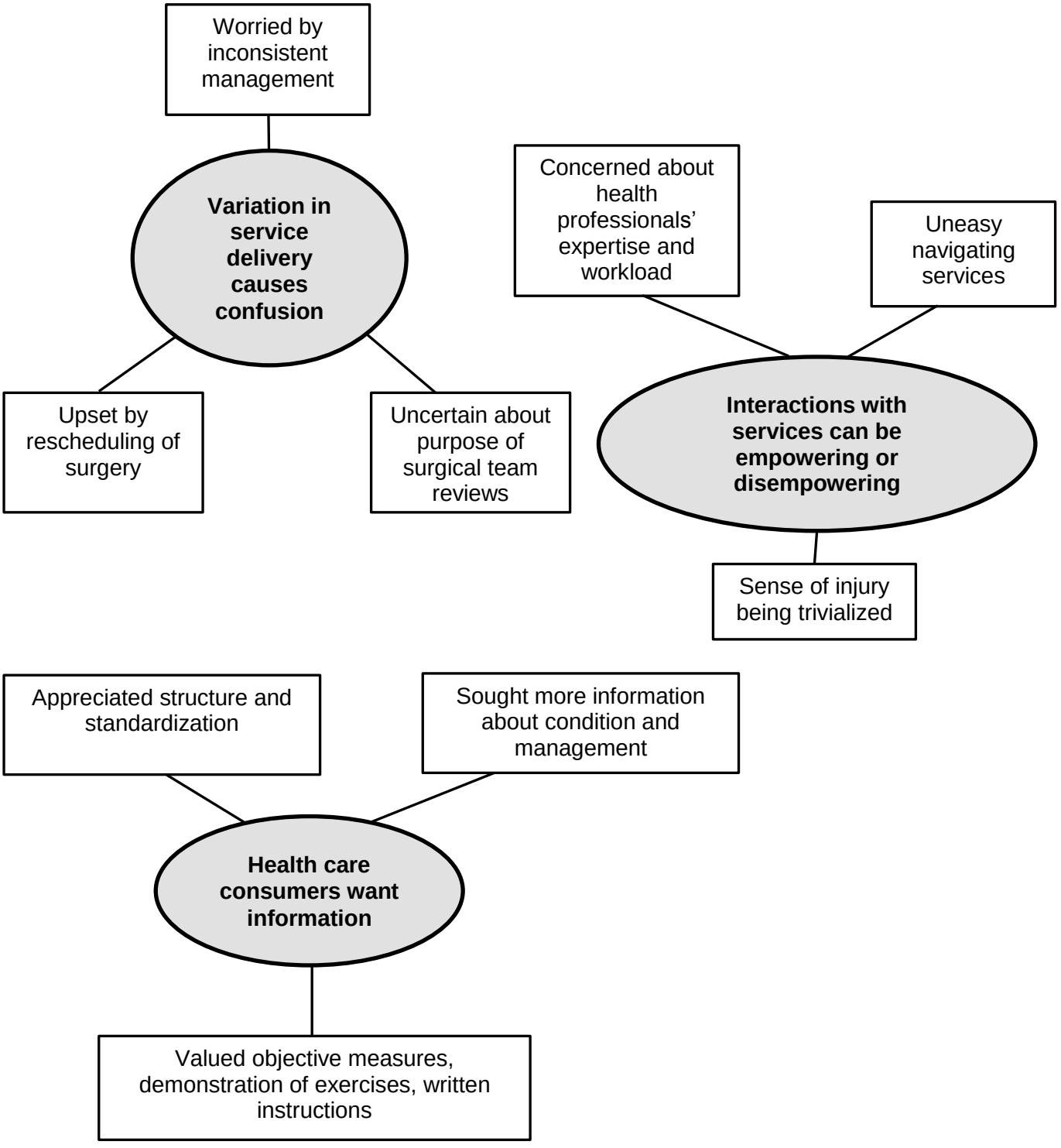


Figure 8-2 Thematic map of participant interactions with the health service following wrist fracture, surgery and immobilization

Variation in service delivery causes confusion

Participants reported considerable variation in care. Before entering the RCT, 11 participants reported receiving good information, a clear management plan and coordinated services while 20 participants were markedly dissatisfied with these aspects of care.

Participant aged 54:
'Quickest I've ever been through casualty….I was basically just straight in, operated on and then back out again.'

Participant aged 47:
'Went to the hospital, waited about an hour just to see the triage nurse, it was crazy….I was seen in about four or five hours….They said it's okay we can pull it back into place….they laid me down and were just about to put me to sleep and then the orthopaedic surgeon came down. He goes- 'no stop' she's actually shattered her radius. They just sort of plastered, or bandaged it, sent me back home and said we'll get back to you in two weeks- which I wasn't happy about.'

Worried by inconsistent management

All participants reported inconsistencies in management information and that staff varied in ability to answer questions. Particular areas of confusion were instructions for sling use, precautions (e.g. lifting and weight-bearing), restrictions (e.g. returning to driving and work) and permitted functional activities.

Participant aged 47:
'My last visit to the hospital, I asked ….whether I could go up from 4kg to 4.5 or 5kg doing weights because the physio encouraged me to rehabilitate….when I asked the doctor, I think she was a trainee…. because I've stopped my appointments with physiotherapy, can I go up to 4.5 or 5kg? And she goes 'what!'….then she goes, I'll be back in a minute….she came back and she goes- you shouldn't be lifting anything more than a cup of tea. And I said, that was at the beginning….this is six, seven weeks on- I'm sure I should be lifting something more. So there was a lot of

confusion there. And I sort of went all red thinking I hope I haven't hurt myself….I asked- well how did my X-ray come up…. was it OK? And she said, yes, but don't do anything until three months, don't start, don't do anything. And I'm thinking, well why was I at physio all these weeks?'

Participants said the delivery of information was not coordinated across health professionals, staff seemed unclear about who should deliver information, information was sometimes confusing and timing of information delivery was not routinely considered. Some participants sought answers to questions on the internet.

Participant aged 56 (when asked if they received enough information):
'I was sedated with painkillers….I wouldn't have a clue. I was sort of in two different worlds there.'

Upset by rescheduling of surgery

Seven participants had surgery re-scheduled up to three times. Prolonged periods of fasting and uncertainty around timing of surgery caused discomfort and anxiety.

Participant aged 48:
'They said I was going to have the operation first thing in the morning….the doctors came in - I'm pretty sure it was 6 o'clock in the morning and they said we can't do you yet or today, we'll just have to wait and see….I just cried because I couldn't do anything….I guess the main thing I felt was I, my injury wasn't that important- that I could keep getting pushback and pushback….like I understood but, at the same time I was very, you know, insignificant.'

Uncertain about purpose of surgical team reviews

The number of surgical team reviews (median 3, range 1-5) were not standardized. Participants were not aware of the likely number of reviews required. Comparison of interview data for immobilization groups (one, three or six weeks) revealed no differences in median number of these reviews.

Interactions with services can be empowering or disempowering

Concerned about health professionals' expertise and workload

Health professionals' experience, knowledge, communication skills and workload were important in empowering or disempowering participants. Some participants felt uncomfortable asking questions due to a perception that health professionals were too busy.

Participant aged 56:
'Not totally comprehensive. Plus they are busy. The more questions I ask- I take more of their time. And every visit, sometimes I wait I think one and a half hours, two hours before I see the doctor….I can tell they are busy so I didn't want to ask too many questions…. If they had time and I don't see them so pressured, I would have asked more questions. But I didn't want to, you know, also trouble them.'

All participants reported feeling comfortable asking questions during the rehabilitation program which included regular dedicated question time.

Participant aged 54:
'I just felt really comfortable with the physios….they were more approachable and whatnot if you had a worry. And sort of didn't fob you off like it was a stupid question.'

All participants reported at least one occasion of feeling empowered by an interaction with a health professional. The majority of these occasions occurred during the rehabilitation program.

Uneasy navigating services

Most participants reported instances of uneasiness with navigating processes in ED, hospital or outpatient surgical team reviews.

Participant aged 48:

'So they said, "we're going to do the reduction and then we're going to do the CT scan to see how that went"….I was left in a room and I sat there for about half an hour and I asked someone what's going on…. And they said you're getting a CT scan done and I said no, they told me I was getting a reduction done. No, no no, and I say can you check because they told me that I was getting [the CT] done after the reduction. Anyway, they didn't check, had the CT scan done….went back to the ward and then the doctor came in and said "why did you have the CT scan done, you weren't supposed to have that done yet?" It was horrible, like I was getting in trouble for it.'

Sense of injury being trivialized

Some participants felt their injury was trivialized by health professionals.

Participant aged 67:

'But my last meeting with the surgeon…….he was so happy with the wound and the position of the plate and the bone and everything and I just said to him, well that's great you're happy, but I still can't use my….hand. And then he didn't seem to think that that was an issue.'

Health care consumers want information

Sought more information about condition and management

Ten participants reported considerable anxiety when discharged from ED with no clear management plan or instructions regarding future health service contact. At discharge from ED, four participants reported surgical intervention had not been discussed. This appeared to reduce acceptance of subsequent surgery.

Participant aged 52:

'Had I known that from the outset that they were preparing me for surgery, I would have been able to accept that a bit better….They set it and, like there was no option for surgery. I was sent home …….I came back in a week…. they told me that they were going to reset it and that there was a chance that if it didn't look like it was

going to heal on its own they were going to put a plate in. And that's when I had an inkling of what might go on. And I went through a kind of grieving process for a few days wondering about the surgery.'

Appreciated structure and standardization

Most participants reported a distinct difference in care before and after recruitment into the RCT. Prior to recruitment, most participants described concerns around lack of information about their condition, recovery, and planned management and discomfort with asking questions.

Participant aged 48:
'I guess I didn't know what the follow-up was surgeon wise….I didn't get that information at the start or when I left hospital that you'll be seeing the surgeon here and here, or whenever.'

The rehabilitation program in the RCT played a key role in guiding participants through the recovery process and all participants reported satisfaction with this aspect of care. When rehabilitation commenced, participants reported relief associated with standardized information on their condition and recovery.

Participant aged 52:
'It didn't seem like on a need-to-know basis as it did with the surgeons and everything previous to that. I suppose with the ethics of the research study they had to make sure that they were quite clear about what was going on and what the candidates were getting themselves in for.'

Valued objective measures, demonstration of exercises, written instructions

All participants appreciated exercise demonstrations and written instructions and were motivated by weekly objective measurements.

Participant aged 56:

'It became a bit of a competition with myself……it felt like I would be failing if I hadn't improved and so I was very keen to know…….it was very helpful to have the feedback of the measurements……I wanted to know to see if there had been progress and then that spurred me on to continue.'

8.2 Discussion

Results of this investigation reinforce previous findings(144, 146) that patients want active involvement in treatment decisions and seek health professionals with good communication skills who are sympathetic, display interest in their condition, allocate adequate time for discussion and provide clear and definitive information .

Around two-thirds of participants reported dissatisfaction with information that was fragmented and without a 'big picture' of expected recovery and timelines for milestone achievement. A picture emerged of health care providers with variable knowledge and communication styles. Essential information that care-seekers require had not been defined, nor had a system for routine delivery of standardized information been implemented. Key information was not timed with consideration of the shock and pain of acute fracture. These findings may reflect the absence of unambiguous health service procedures for treatment of wrist fractures with resultant variations in service delivery. Although beyond the scope of this investigation, inefficiencies in service delivery following surgically managed wrist fracture are likely to increase health service costs. Considering all conditions managed in Australian public hospitals, it is estimated that avoidable costs are around $1 billion each year.(147) Suggested strategies to reduce avoidable costs include increasing efficiency at the individual hospital level through operational and decision making changes.(147) Development and implementation of health service procedures for fracture management might reduce inefficiency and avoidable costs, support health professionals and involve patients in treatment decisions.

Almost a quarter of participants experienced re-scheduling of surgery on multiple occasions. Re-scheduling of planned surgery, while sometimes unavoidable, is inefficient, negatively affects hospital flow and increases costs. “Upstream” effects include acute bed availability and subsequent ED access.(148) Health service factors responsible for surgery re-scheduling warrant investigation.

A standardized narrative could assist health professionals deliver consistent information, particularly in teaching hospitals where staff rotations are inevitable. The Teach-back method(149), where patients recall and restate information, might assist assessment of comprehension. Procedures might include determining staff best-suited to deliver standardized information. Participants indicated they needed specific information following ED assessment: the wrist is broken; the break is quite severe; it is broken in multiple places; it may need surgery; surgery will occur within two weeks; we need to plaster your wrist now to prepare it for surgery; we will discuss your pain and medications to help you. Following surgery participants sought information on type, timing and number of appointments required at the health service during rehabilitation; estimated times for expected return to activities (e.g. work, driving); and restrictions (including reasoning for restrictions).

The number of surgical team review appointments varied, and feasibility of a standardized approach might be investigated. Investigators of 96 extra-articular distal radius fractures managed with closed reduction and plaster cast concluded that two clinic visits after reduction were adequate.(150) These fractures are prone to re-displacement.(100) Two reviews in uncomplicated, surgically stabilized, distal radial fractures might therefore pose little risk.

Every participant appreciated the structured and standardized management of the rehabilitation program. No adverse events were associated with rehabilitation (n=133); there was a single point of contact between the rehabilitation program and orthopaedic unit (streamlined information); progress was tracked longitudinally; and there were no reports of needing additional information. Likely advantages of the program include opportunities to maximise patient outcomes and minimize unsolicited enquiry. A perception of personal control with expert oversight may empower patients and reduce demand for assistance. These factors may deliver cost benefits to health services.

8.3 Conclusions

Inconsistencies in surgical management of wrist fracture highlight the need for unambiguous health service procedures. Some variations in care may be due to different approaches by individual surgeons and rotation of trainees through orthopaedic practice. Health professionals' experience, knowledge, communication skills and workload affected participant satisfaction. A case exists for providing one point of contact with patients with a sophisticated overview of likely management, able to guide and educate patients effectively. A fracture management coordinator might streamline information delivery and facilitate standardization of procedures. This has the potential to improve responsiveness and flexibility of health services and deliver cost-savings through streamlining service delivery. Considering common principles for fracture management, recommendations from this investigation may be extrapolated to management of other fractures.

8.4 Chapter conclusion

Consistent with Chapter 7, participants' reports detailed in this chapter indicate the need for unambiguous health service guidelines to reduce variations reported in service delivery. Some participants felt their injury was trivialised by health professionals. The underestimation of the impact of wrist fracture on patients' functional ability and mental health may be a potential factor contributing to the absence of health service management guidelines. Other potential barriers to successful implementation of heath service guidelines include surgeon preference for individual protocols, inevitable staff rotations, variable staff skills and absence of a coordinator role. This investigation has outlined the key information participants sought following ED assessment and surgery, facilitating easy incorporation into future health service guidelines.

Some participants felt uncomfortable asking questions due to a perception that health professionals were too busy. Growing demands in public health systems are well recognised and likely to continue. Strategies such as implementing unambiguous health service guidelines and clearly defining staff responsibilities for information delivery present potential for improving both the efficiency and

effectiveness of management following wrist fracture. From participant reports prior to commencement in the trial rehabilitation program, a picture emerged of individual units within the health service operating in relative isolation (e.g. ED, orthopaedics). Segmented care is likely to result in inconsistencies in service delivery, variable care and potentially result in conflicting information conveyed to patients. The development of common management principles, an understanding of each unit/discipline's role, and defined staff responsibilities throughout the patients' journey would likely reduce task duplication, improve consistency in management, streamline service delivery and enhance patient confidence in receiving the 'right care'.

Almost a quarter of participants reported re-scheduling of their surgery with this occurring up to three times for some. Observational evidence suggests that the timing of surgical fixation affects functional outcome following acute distal radius fracture.(151) In addition to impacting negatively on patient outcomes, inefficiencies with re-scheduling surgeries result in increased health service costs. Further investigation of the factors leading to re-scheduling are warranted.

The investigations outlined in chapters 7 and 8 indicate that patients seek active involvement in treatment decisions and the provision of information to facilitate a more autonomous role in their individual recovery. In the public health service where staffing shortfalls are commonplace, adopting apps for the delivery of standardised information and education to patients and carers may be useful. Potential advantages include improved patient outcomes, a more informed and less anxious patient that may reduce unsolicited patient enquiry, and cost-savings through streamlining service delivery.

9. Chapter 9- Summary of main findings and conclusions

9.1 Introduction

The following sections summarise the key findings of this research, outline strengths and limitations of the work and discuss future plans for continuation of this research. The Human Research Ethics Committee documents for all investigations comprised within this research are included in Appendix R.

9.2 Summary of main findings and implications

The aim of this research was to investigate the effect of duration of immobilisation on function following ORIF (volar plate) for distal radius fractures in adults. A systemic literature search identified three RCTs involving comparison of immobilisation times following ORIF (volar plate) for distal radius fracture. The evidence suggested potentially favourable short-term functional results following early mobilisation, however, small sample sizes and identification of a number of potential sources of bias in trial design meant firm conclusions could not be formed. A systematic review and meta-analysis broadened the search for evidence of the effect of duration of immobilisation to any surgical fixation procedure for any adult fracture. Evidence from this investigation indicated a potential positive effect of early mobilisation on short-term function, active ROM, and pain. A possible association between early mobilisation and higher infection rates was also detected. However, firm conclusions on the impact of early mobilisation on function and pain were still not possible after this broaden systematic search for evidence given small sample sizes and identification of a number of potential sources of bias in trial design. It was concluded that high quality large RCTs were required to confirm the likely short-term advantages provided by early mobilisation. The design, implementation and completion of a high quality, large RCT comparing the impact of immobilisation time on function and pain following ORIF (volar plate) for distal radius fracture subsequently formed part of this research. Results from the RCT indicated that for function, active ROM and pain, immobilisation periods of one and three weeks produce superior short-term outcomes when compared with six weeks of immobilisation. No significant increase in adverse events was associated with shorter immobilisation periods.

Evidence drives practice change and this is the first high quality RCT to show the short-term advantages for function and pain of early mobilisation with no associated increase risk of complication. While clinicians have hypothesised regarding the advantages of early mobilisation, this research provides evidence to support these beliefs. Translation of this evidence into practice will facilitate earlier achievement of functional goals and pain relief which has relevance for patients' physical and mental health in addition to productivity and health service costs. Considering both health care and productivity costs, hand and wrist injuries have been ranked as the most expensive injury group.(14) Compared to direct health care costs, productivity costs have been found to comprise the greater proportion (56%) of total costs for hand and wrist injuries. (14) Evidence from the RCT indicates potential for improved productivity following early mobilisation and subsequently presents the possibility of economic benefits for patients and health services.

Distal radius fracture managed with ORIF (volar plate) was the focus of this investigation. Considering radiographs are used to inform decisions regarding which patients receive ORIF or other management (closed treatment, percutaneous pinning or external fixation), investigations were undertaken to assess the accuracy in radiographic interpretation and agreement between health professionals' treatment choices. When describing acute distal radius fracture from radiographic images, palmar tilt, radial angle and ulnar variance measurements were found to be useful for guiding treatment choices (providing consideration of error margins), however, intra-articular gap and step were found to be unreliable. Exploring health professionals' treatment choices for distal radius fracture indicated that decisions were most commonly based on palmar tilt. However, for decisions regarding unacceptable fracture alignment, the relatively poor pairwise agreements and inter-observer reliability value of 0.25 suggest that decisions are not made using standardised principles. These findings indicate that research is required to progress the field of intervention choice in the management of distal radius fracture and to provide information on the relative effects and costs of different types of interventions.

To enhance our understanding of the needs and perspectives of participants in the RCT, detailed participant reports of the experience of wrist fracture were obtained and analysed. These reports highlight barriers and enablers experienced by participants throughout their journey. Participants' interactions with the health service were explored and provide opportunities for health services to improve care and support, and to better understand the effects of short compared to longer periods of immobilisation. Participants indicated they want to be actively involved in treatment decisions and seek health professionals with good communication skills who are sympathetic, display interest in their condition, allocate adequate time for discussion and provide clear and definitive information. Health professionals' ability to be responsive to patients is more difficult in situations of clinical uncertainty and can result in adoption of an inconsistent or dogmatic clinical approach.(152) Care provision for patients following distal radius fracture that is effective and responsive is challenging. Evidence for treatment choices based on deformation and radiographic parameters is limited(112, 114-117) and a recent Cochrane review(153) concluded insufficient evidence is available from RCTs to establish the effectiveness of rehabilitation options for adults following distal radius fracture. Inconsistencies in the management of wrist fracture highlight the need for unambiguous health service procedures. A case exists for providing one point of contact with patients with a sophisticated overview of likely management, who is able to guide and educate patients effectively. A fracture management coordinator could potentially streamline information delivery and facilitate standardisation of procedures. This has the potential to improve responsiveness and flexibility of health services and deliver cost-savings through streamlining service delivery.

Health services are increasingly adopting clinical support systems to assist with clinical decision making.(154) A systematic review exploring features of clinical support systems critical for improving clinical practice found 68% of trials involving decision support systems had significant improvements in clinical practice.(155) Features identified as independent predictors of improved clinical practice were automatic provision of decision support, provision of recommendations rather than just assessments, decision support provided at the time of decision making and computer based decision support.(155) Inclusion of these features in the

management of distal radius fracture may assist with streamlining information delivery and standardising procedures.

9.3 Strengths of the research

The RCT included in this research is the largest study to compare early and late mobilisation following surgical fixation of distal radius fracture. Furthermore, this RCT was the first study to quantify the rate of change in outcomes following mobilisation. This enables a view of early changes in pain and function and the potential advantages to patients associated with early mobilisation. The RCT is a high quality trial, indicated through the design controlling for eight of 10 key sources of bias in study design(32) The two potential sources of bias not controlled for were blinding of therapists and participants and these remain an unavoidable limitation. The RCT provides evidence to support the hypothesised advantages of early mobilisation and will help guide future practice following ORIF (volar plate) for distal radius fracture.

The investigations into the reliability of radiographic measurements and treatment choices made by health professionals (Chapter 5 and 6) are the first reliability investigations to acknowledge that independent treatment decisions for distal radius fractures in current practice are made by health professionals outside the medical profession (e.g. Advanced Practice Physiotherapists). Stratifying data based on professional subgroups e.g. isolating the analysis to the orthopaedic surgeon and radiologist, did not result in systematically higher reliability values for radiographic measurements or change conclusions made in the treatment choices investigation. This information may prove useful for future workforce redesign and planning.

The qualitative research reports (Chapters 7 and 8) are the first to report on the patient experience of recovery in the immediate period following wrist fracture. These reports provide a better understanding of the needs and perspectives of participants in the RCT. Information included in these reports will assist health services with improving the responsiveness of care provision for patients following distal radius fracture, streamlining service delivery and potentially reducing health service costs.

The health service where the RCT was conducted provides care for a culturally diverse community with 15.3% of inpatients in the 2015/16 financial year having a non-English speaking background (NESB). Patients with a NESB were proportionately represented in the qualitative research and comprised 19.4% (n=6) of the participant cohort. No participants from a NESB requested an interpreter for interview.

9.4 Limitations of the research

Limitations were associated with this research. Participant inclusion in the RCT was dependent on the distal radius fracture being deemed stable by the surgeon after ORIF. While such a criterion is potentially warranted, the decision rules for post fixation stability are not defined and variability between surgeons due to the subjective nature of this classification seems likely.

The RCT in this research recorded post-operative complications that were assessed using review of clinical entries in participants' hospital records for the period of post-operative hospitalisation in addition to ED presentations, outpatient orthopaedic appointments, and rehabilitation (physiotherapy) outpatient appointments for the six months follow-up period. Documentation of any of wound infection, persistent neuropathy or tendinopathy, tendon rupture, and loss of fixation or ligament damage requiring surgical repair was recorded as an adverse event. There was no discussion with clinicians regarding the conditions under which documentation of a complication was warranted and variation between clinicians seems likely. Tracking of late complications was prevented by follow-up ceasing at six months following surgery. RCTs comparing immobilisation times following surgical fracture fixation aim to identify the minimal period of immobilisation achievable without associated increase in complication risk. There seems to be a disparity between the importance placed on post-operative complications and the rigour in their recording. As with the RCT in this research, there was no evidence of standardised recording procedures for complications in any of the 11 trials included in the systematic review and meta-analysis (Chapter 2). Given the importance of minimising risk of post-operative

complications in clinical practice, it is also important that consensus is reached on the method and criteria for recording complications in research. A distal radius complication checklist has been developed(47) and would be a useful tool for enhancing consistency in complication recording in future research.

A further limitation of the RCT was deviation from the trial protocol with the PSFS, a secondary outcome, not being reported. Further research is required to guide our management of events that occur when participants achieve specified targets and proceed to set new targets. The PSFS data has not yet been analysed and analysis of this data is planned for the future.

As outlined in the limitation section of the systematic review and meta-analysis paper, included trials were reported in English, thus excluding possible non-English reports.

9.5 Future directions

This thesis forms only part of a large body of work that is planned to further current knowledge on the optimal management of distal radius fractures. In addition to the completion of six papers, the work that contributed to this thesis involved the collection of a large body of data that is planned for use in future research.

The earlier functional goal achievement and reduced pain resulting from early mobilisation of distal radius fractures following ORIF presents potential for economic savings for health services. An economic analysis of the impact of early mobilisation on health service costs is planned. Data available for analysis of direct health care costs include number of post-operative appointments with the health service and consumables expenditure. Data available for analysis of productivity costs include period of time unable to work due to injury.

The qualitative investigations in this research present a case for providing one point of contact with patients with a sophisticated overview of likely management and ability to guide and educate patients effectively. It is planned that a fracture management coordinator role will be developed at the health service where the RCT was conducted, aimed at streamlining service delivery, defining discipline

responsibilities for information delivery and standardising procedures. The impact of this role on health service responsiveness, patient outcomes and health service costs will be measured.

Investigators of 96 extra-articular distal radius fractures managed with closed reduction and plaster cast concluded that two clinic visits after reduction were sufficient.(150) The qualitative study reported in this thesis identified that the number of surgical team reviews following ORIF for distal radius fracture (median 3, range 1-5) were not standardised. Future research will explore the optimum number of health service surgical team appointments required following surgically managed distal radius fracture. Following implementation of standardised procedures (e.g. defining the clinical indicators for referral for surgical team review by rehabilitation therapists), the effects of two (compared to more) clinic visits for this patient cohort will be investigated.

Observational evidence suggests that the timing of surgical fixation affects functional outcome following acute distal radius fracture. A retrospective cohort investigation compared functional outcomes for participants following internal fixation (volar locking plate) performed either early (operation on the day of injury or next day, n=76) or late (operation at 7 days after injury or later, n=30).(151) Short-term functional outcomes were found to be better in the early treatment group with significantly better wrist AROM, grip strength and DASH score at 4 and 12 weeks following surgery. There were no significant differences between groups for wrist AROM, grip strength or DASH scores at 48 weeks following surgery.
Future research is planned around the surgical waiting time for distal radius fractures, reasons for delay and the cost implications to patients and health services of such delays.

The RCT in this research involved provision of identical rehabilitation programs to participants. The question arises as to whether achievement of even better function, active ROM and pain outcomes may be possible for patients following early mobilisation if the rehabilitation program was tailored for individuals. Future research is planned to quantify the impact of an individual specific rehabilitation program associated with early mobilisation on function, pain and the patient experience.

9.6 Thesis conclusion

This thesis has addressed the research aim which was to investigate the effect of duration of immobilisation on function following ORIF (volar plate) for distal radius fractures in adults. The question now arises, what impact would inclusion of the findings from the RCT in this research have on the forest plots and mean difference values for the short-term outcomes investigated in the meta-analysis?

The following forest plots include data from the RCT in this research in addition to the data in the meta-analysis reported in Chapter 2. Given the RCT involved 3 comparison groups (one, three and six weeks of immobilisation), early mobilisation data or the one and three week immobilisation groups was pooled and compared to data for the six week immobilisation group.

Effect of duration of immobilisation on short-term active ROM

Random effects meta-analysis for short-term active ROM from wrist trials included in the earlier described meta-analysis (Chapter 2) with the addition of the RCT results [Watson et al. 2017 (PEDro 8)] are shown in Figure 9-1. Effects tend to favour early mobilisation. For wrist extension, the test for overall effect was P=0.22 prior to inclusion of Watson et al. 2017 data and approaches significance with inclusion, P=0.06. Similarly for wrist flexion, the test for overall effect was P=0.27 prior to inclusion of Watson et al. 2017 data and approaches significance with inclusion, P=0.06.

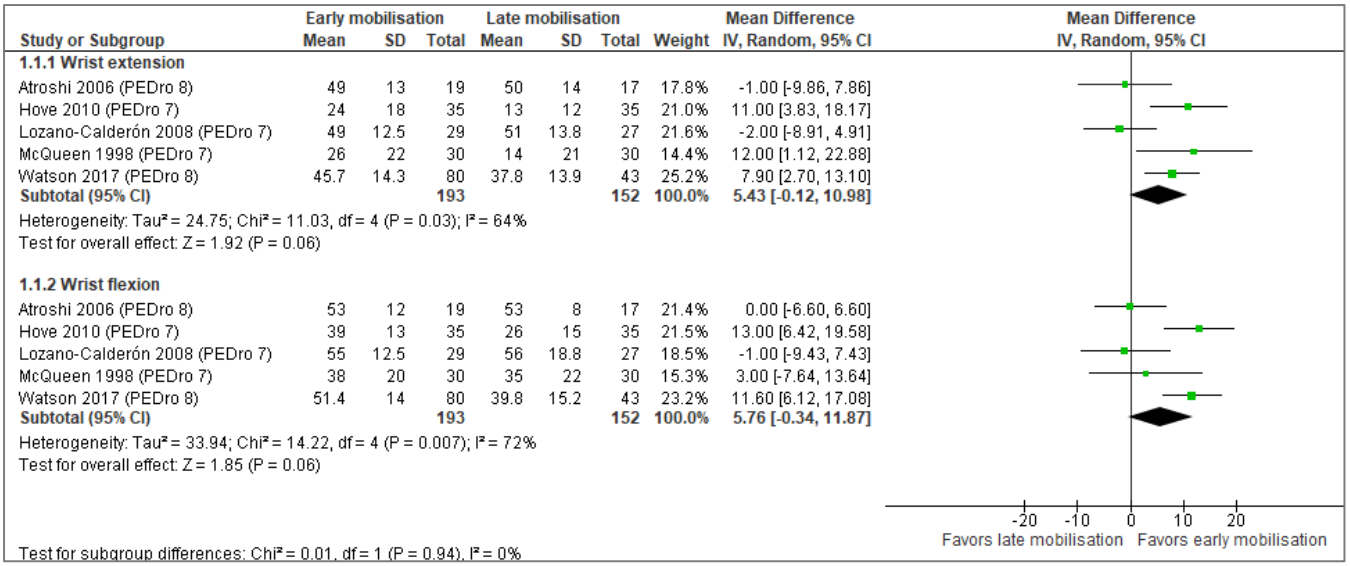


Figure 9-1 Meta-analysis forest plot of short-term active ROM with addition of RCT data (Watson et al. 2017)

Effect of duration of immobilisation on short-term function

Figure 9-2 presents the meta-analysis derived for short-term function from trials included in the earlier described meta-analysis (Chapter 2) with the addition of the RCT results [Watson et al. 2017 (PEDro 8)]. Effects for all subgroups tend to favour early mobilisation. The test for overall effect was P=0.21 prior to inclusion of Watson et al. 2017 data and approaches significance with inclusion, P=0.08.

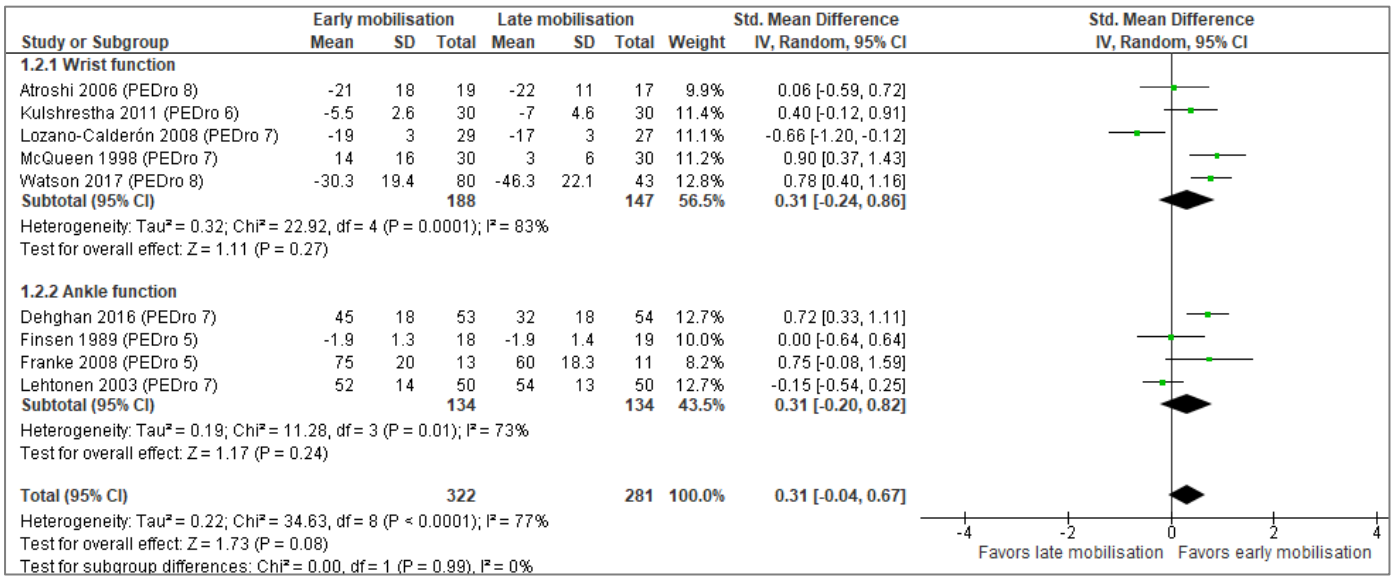


Figure 9-2 Meta-analysis forest plot of short-term function with addition of RCT data (Watson et al. 2017)

Effect of duration of immobilisation on short-term pain

Fixed effects meta-analysis for short-term pain from trials included in the earlier described meta-analysis (Chapter 2) with the addition of the RCT results [Watson et al. 2017 (PEDro 8)] are shown in Figure 9-3. The test for overall effect was P=0.30 prior to inclusion of Watson et al. 2017 data and reaches significance with inclusion, P=0.009.

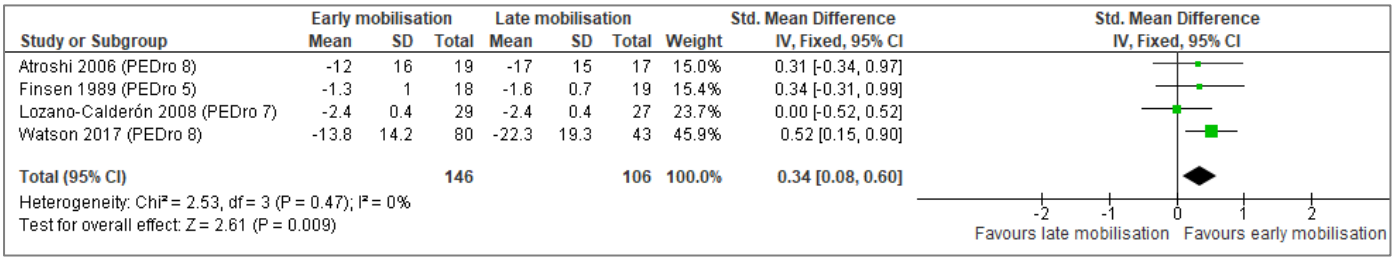


Figure 9-3 Meta-analysis forest plot of short-term pain with addition of RCT data (Watson et al. 2017)

The addition of the large, high quality RCT data from this research strengthens the evidence for short-term advantages for function and pain provided by early mobilisation. Translation of this evidence into practice has the potential to improve the physical and mental health of patients following surgical fracture fixation and presents opportunities to reduce health service costs.

10. Chapter 10- References

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11. Chapter 11- Appendices

Appendix A. Systematic review (length of immobilisation following internal fixation for distal radius fracture) search strategy used for MEDLINE (OVID Online- 1948 to present). (Completed August 2017)

1. fractur* or trauma* or break* or bone* or osseous* or osteo*
2. surg* or operat*
3. "open reduction internal fixation" or "ORIF" or "(ORIF)"
4. fix* adj2 (internal or fragment* or device*)
5. plate or plates or screw or screws or screwing or screwed or hardware
6. 2 or 3 or 4 or 5
7. fix* or plaster* or splint* or immobil* or mobil* or cast*
8. radius or wrist
9. 1 and 6 and 7 and 8
10. randomized controlled trial.pt.
11. controlled clinical trial.pt.
12. randomized.ab.
13. placebo.ab.
14. drug therapy.fs.
15. randomly.ab.
16. trial.ab.
17. groups.ab.
18. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. 9 and 18

Appendix B. Systematic review and meta-analysis search strategy used for MEDLINE (OVID Online- 1948 to present).

MEDLINE (OVID Online- 1948 to present)

1. (fractur* or trauma* or break* or bone* or osseous* or osteo*).ab,ti.
2. (surg* or operat*).ab,ti.
3. ("open reduction internal fixation" or "ORIF" or "(ORIF)").ab,ti.
4. (fix* adj2 (internal or external or fragment* or device*)).ab,ti.
5. (plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired).ab,ti.
6. 2 or 3 or 4 or 5
7. (fix* or plaster* or splint* or immobil* or mobil* or cast*).ab,ti.
8. 1 and 6 and 7
9. randomized controlled trial.pt.
10. controlled clinical trial.pt.
11. randomized.ab.
12. placebo.ab.
13. drug therapy.fs.
14. randomly.ab.
15. trial.ab.
16. groups.ab.
17. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. 8 and 17

Appendix C. Search strategies for Embase (OVID Online), CINAHL Plus (EBSCO), Cochrane Central Register of Controlled Trials (CENTRAL), PEDro and LILACS.

EMBASE (OVID Online)

1. (fractur* or trauma* or break* or bone* or osseous* or osteo*).ab,ti.
2. (surg* or operat*).ab,ti.
3. ("open reduction internal fixation" or "ORIF" or "(ORIF)").ab,ti.
4. (fix* adj2 (internal or external or fragment* or device*)).ab,ti.
5. (plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired).ab,ti.
6. 2 or 3 or 4 or 5
7. (fix* or plaster* or splint* or immobil* or mobil* or cast*).ab,ti.
8. 1 and 6 and 7
9. randomized-controlled-trial/ or randomization/ or controlled-study/ or multicenter-study/ or phase-3-clinicaltrial/ or phase-4-clinical-trial/ or doubleblind-procedure/ or single-blindprocedure/ or (random* or cross?over* or multicenter* or factorial* or placebo* or volunteer*).mp. or ((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*)).ti,ab. or (latin adj square).mp.
10. 8 and 9

CINAHL Plus (EBSCO)

1. TI (fractur* or trauma* or break* or bone* or osseous* or osteo*) OR AB (fractur* or trauma* or break* or bone* or osseous* or osteo*)
2. TI (surg* or operat*) OR AB (surg* or operat*)
3. TI ("open reduction internal fixation" or "ORIF" or "(ORIF)") OR AB ("open reduction internal fixation" or "ORIF" or "(ORIF)")
4. TI (fix* n2 (internal or external or fragment* or device*)) OR AB (fix*n2 (internal or externalor fragment* or device*))
5. TI (plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired) OR AB (plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired)
6. S2 OR S3 OR S4 OR S5
7. TI (fix* or plaster* or splint* or immobil* or mobil* or cast*) OR AB (fix* or plaster* or splint* or immobil* or mobil* or cast*)
8. S1 AND S6 AND S7
9. (MH "Clinical Trials+")
10. PT Clinical trial
11. TX clinic* n1 trial*
12. TX ((singl* n1 blind*) or (singl* n1 mask*)) or TX ((doubl* n1 blind*) or (doubl* n1 mask*)) or TX ((tripl* n1 blind*) or (tripl* n1 mask*)) or TX ((trebl* n1 blind*) or (trebl* n1 mask*))
13. TX randomi* control* trial*
14. (MH "Random Assignment")
15. TX random* allocat*
16. TX placebo*
17. (MH "Placebos")
18. (MH "Quantitative Studies")
19. TX allocat* random*
20. S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19
21. S8 AND S20

COCHRANE CENTRAL REGISTER OF CONTROLLED TRIALS (CENTRAL)

1. fractur* or trauma* or break* or bone* or osseous* or osteo*:ti
2. fractur* or trauma* or break* or bone* or osseous* or osteo*:ab
3. #1 or #2
4. surg* or operat*:ti
5. surg* or operat*:ab
6. "open reduction internal fixation" or "ORIF" or "(ORIF)":ti
7. "open reduction internal fixation" or "ORIF" or "(ORIF)":ab
8. fix* near/2 (internal or external or fragment* or device*):ti
9. fix* near/2 (internal or external or fragment* or device*):ab
10. plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired:ti (Word variations have been searched)
11. plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired:ab (Word variations have been searched)
12. #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
13. fix* or plaster* or splint* or immobil* or mobil* or cast*:ti
14. fix* or plaster* or splint* or immobil* or mobil* or cast*:ab
15. #13 or #14
16. #3 and #12 and #15

PEDro simple search

1. fractur* surg* fix*
2. fractur* operat* fix*
3. fractur* surg* plaster*
4. fractur* operat* plaster*
5. fractur* surg* splint*
6. fractur* operat* splint*
7. fractur* surg* immobil*
8. fractur* operat* immobil*
9. fractur* surg* mobil*
10. fractur* operat* mobil*
11. fractur* surg* cast*
12. fractur* operat* cast*
13. open reduction internal fixation
14. “open reduction internal fixation”
15. ORIF

PEDro advanced search

Abstract & Title: - various search terms applied (outlined below)

1. and Therapy: orthoses, taping, splinting
2. and Method: clinical trial
3. fractur* surg*
4. fractur* operat*
5. trauma* surg*
6. trauma* operat*
7. break* surg*
8. break* operat*
9. bone* surg*
10. bone* operat*
11. osseous* surg*
12. osseous* operat*
13. osteo* surg*
14. osteo* operat*
15. open reduction internal fixation
16. “open reduction internal fixation”
17. ORIF

These searches using Advanced Search were then re-run with Method changed to systematic review.

LILACS search

fracture or fractures or fractured or trauma or traumas or break or breaks or breakage
or breakages or bone or bones or osseous or osteoporosis [Words] and surgery or surgeries or surgical or surgically or surgeon or surgeons or operate or operation or operations or "open reduction internal fixation" or ORIF or "fracture fixation device" or "fracture fixation devices" or plate or plates or screw or screws or screwing or screwed or pin or pins or pinned or pinning or rod or rods or hardware or wire or wires or wiring or wired [Words] and fix or fixation or plaster or plasters or splint or splints or immobile or immobility or immobilise or immobilize or immobilisation or immobilization or mobile or mobility or mobilise or mobilize or mobilisation or mobilization or cast or casts [Words]

Appendix D. Area of fracture, eligibility criteria and fixation characteristics of the 11 included trails

Study	Fractured area	Eligibility criteria	Type of fixation
Atroshi et al 2006	Wrist	***Inclusion criteria:*** Women ≥ 50yrs, men ≥ 60yrs, acute dorsally displaced distal radius fracture, extraarticular or intraarticular with at least 2 large articular fragments, dorsal angulation ≥ 20 degrees from neutral and/or radial shortening (ulnar variance) ≥ 5 mm. ***Exclusion criteria:*** Articular stepoff > 2 mm, fracture of ulna proximal to styloid, additional fractures in same or contralateral arm, nerve or tendon injuries, multiple injuries, high-energy trauma (eg MVA or fall from height), previous fracture of injured radius, inflammatory joint disease, cerebrovascular disease or other severe medical illness, inability to give written informed consent or complete questionnaires, abuse of drugs or alcohol.	External fixation: For wrist-bridging fixation, the Hoffmann external fixator. For the non-bridging external fixation we used the Hoffmann II Compact external fixator
Chen et al 2017	Hind foot	***Inclusion criteria:*** Unilateral closed intraarticular calcaneal fractures, Sanders II, III, or IV fractures confirmed by CT examination, patients who accepted and followed a postoperative functional exercise plan designated using a random number table. ***Exclusion criteria:*** Bone fractures at other sites of the ipsilateral lower extremity, injuries of vital organs, craniocerebral injury and experienced a loss of consciousness after being injured, severe internal medical disease, disordered or traumatized spine or an ischemic and necrotic femoral head that affected the function of the ipsilateral lower extremity and patients who could not walk normally due to congenital skeletal malformations of the lower extremities.	Open reduction internal fixation: Minimally invasive technique involving two K-wires and fixation with an anatomic plate and some compression bolts.
Dehghan et al 2016	Ankle	***Inclusion criteria:*** Acute unstable unilateral ankle fracture that required surgical fixation. ***Exclusion criteria****:* Skeletal immaturity, previous ipsilateral ankle surgery, non-ambulatory before injury, inability to comply with postoperative protocol (i.e. advanced dementia), medical comorbidity precluding operative intervention, workers compensation, polytrauma.	Open reduction internal fixation: The lateral malleolar fracture was fixed by use of a lag screw if possible, followed by the addition of a plate and screws (minimum 3 screws proximal, 2 screws distal). The medial malleolus was secured by use of 1 or 2 lag screws depending on the size of the fragment.
Finsen et al 1989	Ankle	***Inclusion criteria:*** Operation performed within one week of fracture, displaced ankle fracture including lateral malleolus, stable osteosynthesis, follow-up visits at same hospital. ***Exclusion criteria:*** Concomitant injury preventing early mobilisation.	Open reduction internal fixation: Fractures of the lateral malleolus stabilized with plate and fractures of the medial malleolus with tension band or screws.

Study	Fractured area	Eligibility criteria	Type of fixation
Franke et al 2008	Ankle	***Inclusion criteria:*** Age 18-65, mono-traumatised with surgically treated Weber type B ankle fractures, simple and bi-malleolar fractures, Volkmann's triangle did not require treatment. ***Exclusion criteria:*** Open fractures, multi-fragmentary fractures and fractures requiring a positioning screw, any other disorders involving restriction of mobility, limited ambulation on forearm crutches, or situations affecting the healing process (e.g. joint disease, neurological disorder, amputation).	Internal fixation- no further details given on fixation type.
Hove et al 2010	Wrist	***Inclusion criteria:*** Fracture fewer than 10 days old, AO type A and C wrist fracture, considered unstable and not able to be managed with cast alone; incongruity had to be reducible using closed means. ***Exclusion criteria:*** Open fractures and those requiring supplemental percutaneous Kirschner-wire fixation. .	External fixation: The static bridging fixators used were the Hoffmann II Compact bridging external fixator and the Pennig (static) wrist bridging external fixator. The dynamic fixator used was the (DYNAWRIST), a flexible distractor through which continuous dynamic traction is applied to the fracture site.
Kulshrestha et al 2011	Wrist	***Inclusion criteria:*** Age >20 years, reported within 7 days of injury, displaced unstable comminuted fracture of distal radius with >20° dorsal angulation, metaphyseal comminution with or without intra-articular extension, and >10 mm loss of radial height or a displaced shear fracture. ***Exclusion criteria:*** Open or pathological fracture, injury severity score (ISS) >17, ipsilateral upper limb fracture, fracture of the scaphoid or scapho–lunate dissociation of same wrist, pre-existing inflammatory or degenerative arthritis of injured wrist, ipsilateral elbow, or shoulder.	External fixation: Static fixation was the JESS fixator. In AO type B and C fractures, percutaneous fragment fixation screws and/or K-wires were used. Dynamic fixation was the Penning wrist fixator. Application. Once reduction was achieved, K-wires, 4-mm lag screw, and/or percutaneous fragment fixation screws were used.
Lehtonen et al 2003	Ankle	***Inclusion criteria:*** Acute fracture <72 hours after injury, fracture displaced or unstable, classified according to AO-Weber system as A or B, treated operatively at study hospital between November 1995 and April 1998. ***Exclusion criteria:*** Fracture considered insufficiently stable for early mobilisation, open fracture, pilon fracture of tibia, Weber type-C fracture requiring screw across syndesmosis, other severe injuries, unable to cope with post-operative routines.	Internal fixation- no further details given on fixation type.
Lozano-Calderón et al 2008	Wrist	***Inclusion criteria:*** Age ≥18, fractured distal radius and no other skeletal injury, operative treatment with fixed-angle volar plate and screws alone.	Internal fixation: Volar plate and screws

Study	Fractured area	Eligibility criteria	Type of fixation
McQueen 1998	Wrist	***Inclusion criteria:*** Unstable fracture distal radius (defined as failure to hold the reduced position of the fracture within a forearm cast, and those with redisplacement to dorsal angulation of more than 10°). ***Exclusion criteria:*** Residual dorsal angulation after primary reduction, >2 weeks from injury to identifying instability, displaced articular fracture or a fracture with < 1 cm intact volar cortex on distal fragment, previous malunion or unable to perform functional evaluation.	External fixation: Bridging fixation was a Pennig external fixator. Two pins were inserted into the second metacarpal and two into the shaft of the radius using the open placement technique. The ball joint was locked for the period of treatment. Non-briding fixation as also a Pennig fixator. Two fixator pins were placed parallel to the surface of the joint in the distal radial fragment from the dorsal to the volar aspects and engaging the volar. Two pins were inserted into the radial shaft again using an open placement technique.
Tropp & Norlin 1995	Ankle	***Inclusion criteria:*** Age 18-60, fracture classified B or C (Danis-Weber), no large posterior tibial fragment, stable fracture fixation and satisfactory reduction based on surgeon interpretation of post-operative radiograph.	Internal fixation: Rigid or non-rigid fixation of the fibular fracture according to the AO principles or according to Cedell. The syndesmosis was secured by one or two staples and, if possible, by osteosutures as well. The medial malleolus was fixed with multiple pins.

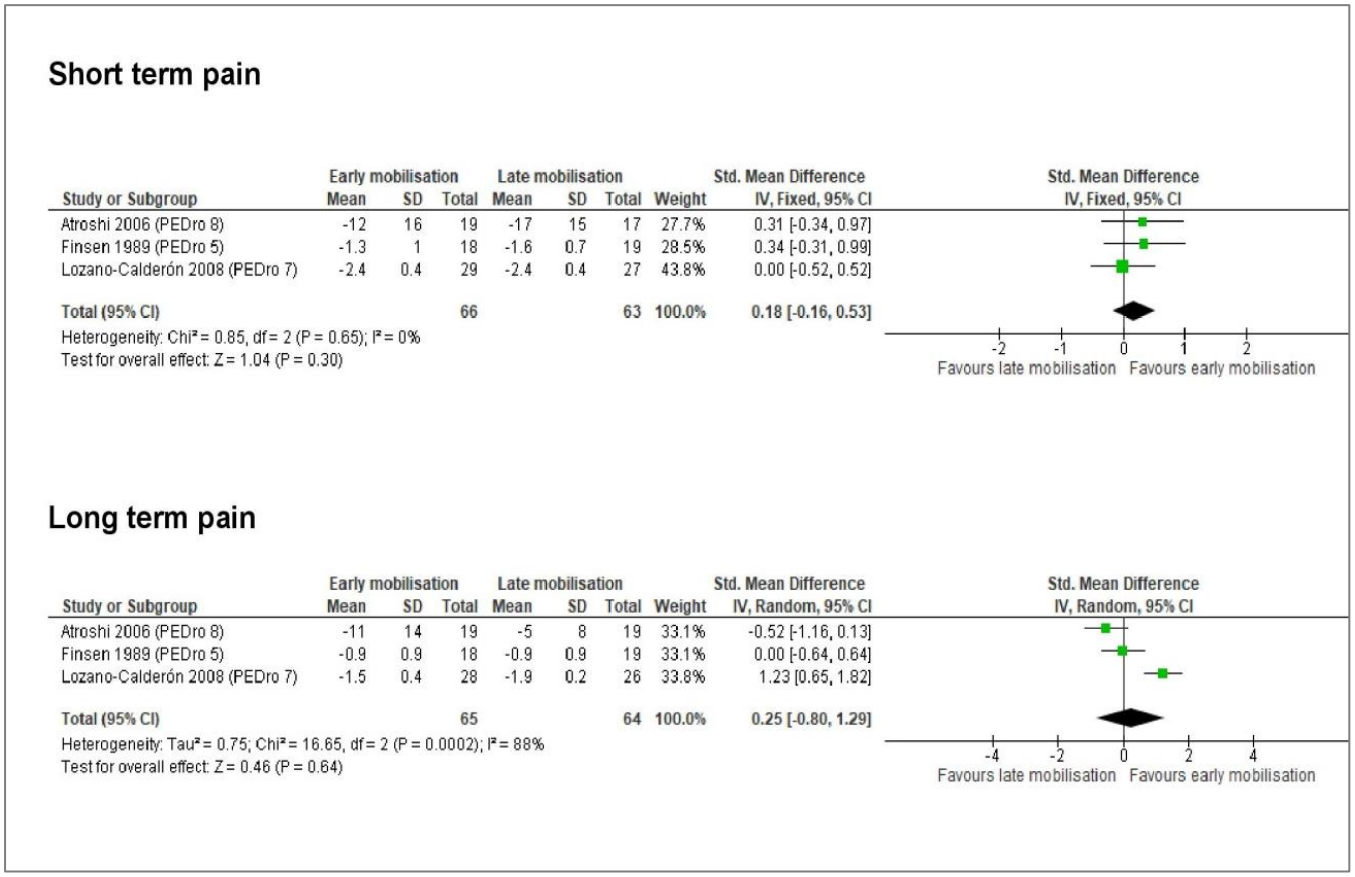
Appendix E. PEDro scores for trials included in systematic review and meta-analysis

Author, year	PEDro scale criteria (details outlined below)										Total	Score on PEDro database
	1	2	3	4	5	6	7	8	9	10		
Atroshi et al 2006	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	8	N/A
Chen et al 2017	Yes	No	Yes	No	No	Yes	No	No	Yes	Yes	5	N/A
Dehghan et al 2016	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7	6
Finsen et al 1989	Yes	No	Yes	No	No	No	Yes	No	Yes	Yes	5	3
Franke et al 2008	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes	5	5
Hove et al 2010	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7	N/A
Kulshrestha et al 2011	Yes	Yes	Yes	No	No	No	Yes	No	Yes	Yes	6	N/A
Lehtonen et al 2003	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7	6
Lozano-Calderón et al 2008	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	7	5
McQueen 1998	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	7	N/A
Tropp & Norlin 1995	Yes	No	No	No	No	No	No	No	Yes	Yes	3	2

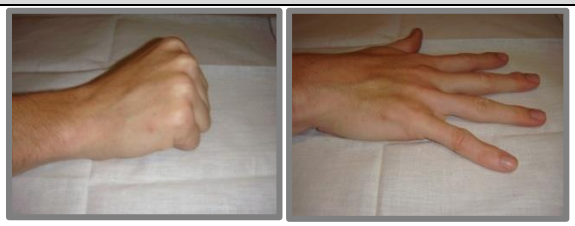
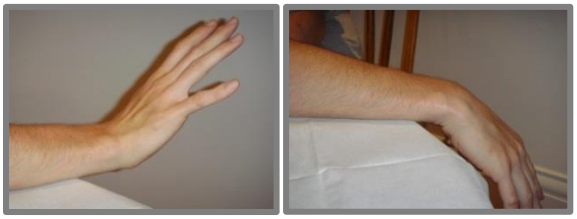
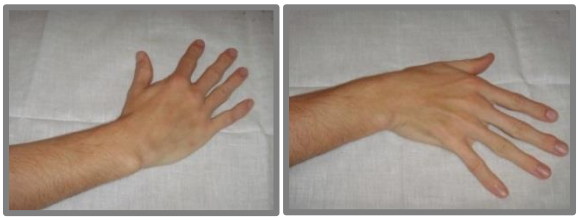
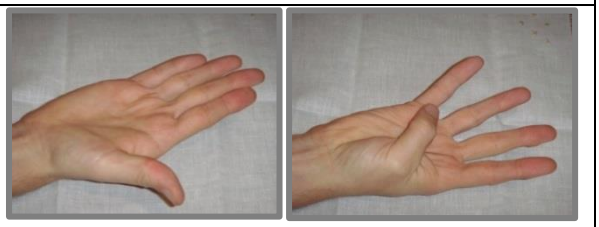
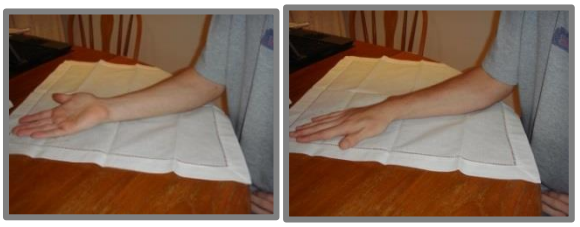
Note: Item number 1 (eligibility criteria were specified) of the 11 item PEDro scale is not included in table given it is not used to calculate the PEDro score.

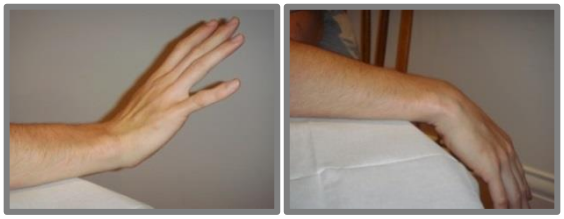
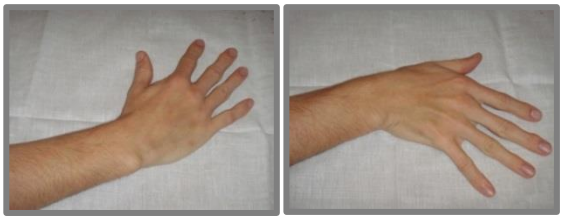
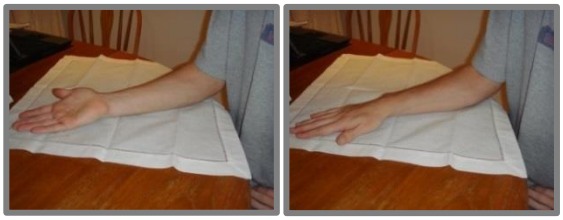
Item descriptions for PEDro scale (PEDro Physiotherapy Evidence Database):
https://www.pedro.org.au/english/downloads/pedro-scale/

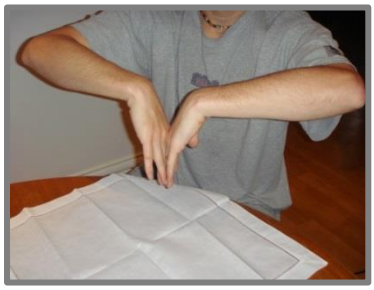
Appendix F. Meta-analysis forest plots of short-term and long-term pain

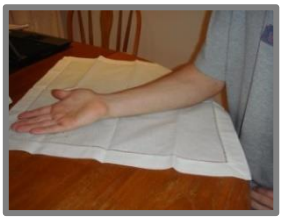


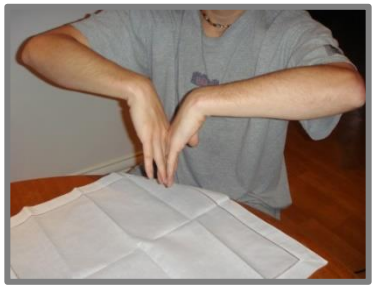
Appendix G. Home exercises comprising part of the RCT rehabilitation program for participants

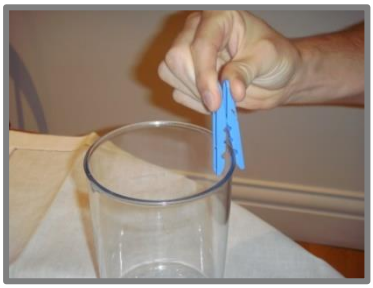
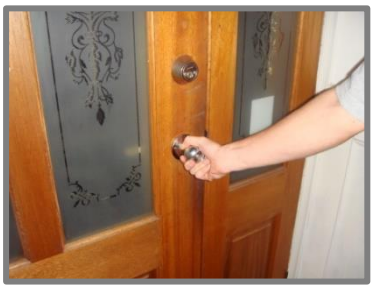
Week number following removal of splint/cast	Description of exercises	Frequency per day	Image of exercise
Week 1	**Making a fist:** Straighten and bend your fingers so you are opening and closing a fist.	1 x 15 reps	
	Waving: Rest your forearm on the table so that your hand hangs over the edge. While your forearm remains on the table, wave your hand up and down so that your hand moves above and below the level of the table.	1 x 15 reps	
	Windshield wiper: Rest your forearm and hand flat on the table with your palm facing down. Move your hand in the direction of your thumb and then in the direction of your little finger. Your forearm should remain in the same position on the table with only your hand moving.	1 x 15 reps	
	Thumb movement across hand: Move your thumb across your hand towards the base of your little finger and then back past your index finger.	1 x 15 reps	
	Alternate palm up and down: Rest your forearm and hand on the table with your palm facing upwards. Keep your elbow on the table and twist your forearm so that your palm shifts from facing upwards to resting on the table.	1 x 15 reps	

Week number following removal of splint/cast	Description of exercises	Frequency per day	Image of exercise
Week 2	**Waving:** Rest your forearm on the table so that you hand hangs over the edge. While your forearm remains on the table, wave your hand up and down so that your hand moves above and below the level of the table.	1 x 15 reps	
	Windshield wiper: Rest your forearm and hand flat on the table with your palm facing down. Move your hand in the direction of your thumb and then in the direction of your little finger. Your forearm should remain in the same position on the table with only your hand moving.	1 x 15 reps	
	Alternate palm up and down: Rest your forearm and hand on the table with your palm facing upwards. Keep your elbow on the table and twist your forearm so that your palm shifts from facing upwards to resting on the table.	1 x 15 reps	
	Squeezing: Make a fist squeezing the water out of a wet household sponge for a few seconds.	1 x 15 reps	
	Reach and grip: Using your uninjured arm, hold a round object (e.g. orange or apple) in front of you and above your head height. Make sure you are sitting at a table for this exercise. Reach with your injured arm and grab the object, take it to the table and then return it to the hand above your head.	1 x 15 reps	

Week number following removal of splint/cast	Description of exercises	Frequency per day	Image of exercise
Week 3	**Squeezing:** Make a fist squeezing the water out of a wet household sponge for a few seconds.	1 x 15 reps	
	Reach and grip: Using your uninjured arm, hold a round object (e.g. orange or apple) in front of you and above your head height. Make sure you are sitting at a table for this exercise. Reach with your injured arm and grab the object, take it to the table and then return it to the hand above your head.	1 x 15 reps	
	Stretch palms together: Rest you elbows on the table so that the palms of your hands are together. Slowly slide your elbows outwards until you feel a mild stretch at the wrist. Hold for a few seconds.	1 x 15 reps	
	Stretch back of hands together: Place the knuckles of your hand together and gently push your wrists together until you feel a mild stretch at the wrist. Hold for a few seconds.	1 x 15 reps	
	Overhead stretch: Make a fist and stretch your arm over your head so that your upper arm is near your ear. Slowly stretch your arm down the side of your body straightening your elbow and opening your hand.	1 x 15 reps	

Week number following removal of splint/cast	Description of exercises	Frequency per day	Image of exercise
Week 4	**Strengthening:** Holding a half full small water bottle in your hand, place your hand at the edge of the table with your palm facing upwards. Move your hand above and below the level of the table while keeping hold of the water bottle.	1 x 15 reps	 
	Strengthening: Holding a half full small water bottle in your hand, place your hand at the edge of the table with your palm facing downwards. Move your hand above and below the level of the table while keeping hold of the water bottle.	1 x 15 reps	 
	Alternate palm up and down: Rest your forearm and hand on the table with your palm facing upwards. Keep your elbow on the table and twist your forearm so that your palm shifts from facing upwards to resting on the table.	1 x 15 reps	 
	Stretch palms together: Rest you elbows on the table so that the palms of your hands are together. Slowly slide your elbows outwards until you feel a mild stretch at the wrist. Hold for a few seconds.	1 x 15 reps	
	Stretch back of hands together: Place the knuckles of your hand together and gently push your wrists together until you feel a mild stretch at the wrist. Hold for a few seconds.	1 x 15 reps	

Week number following removal of splint/cast	Description of exercises	Frequency per day	Image of exercise
Week 5	**Strengthening:** Holding a full small water bottle in your hand, place your hand at the edge of the table with your palm facing downwards. Move your hand above and below the level of the table while keeping hold of the water bottle.	1 x 15 reps	
	Strengthening: Holding a full small water bottle in your hand, place your hand at the edge of the table with your thumb facing upwards. Move your hand above and below the level of the table while keeping hold of the water bottle.	1 x 15 reps	
	Strengthening: Holding a full small bottle of water in your hand, place your hand over the edge of the table with your palm facing upwards. Keep your elbow on the table and twist your forearm so that your palm shifts from facing upwards to facing downwards while keeping hold of the water bottle.	1 x 15 reps	
	Stretch palms together: Rest you elbows on the table so that the palms of your hands are together. Slowly slide your elbows outwards until you feel a mild stretch at the wrist. Hold for a few seconds.	1 x 15 reps	
	Stretch back of hands together: Place the knuckles of your hand together and gently push your wrists together until you feel a mild stretch at the wrist. Hold for a few seconds.	1 x 15 reps	

Week number following removal of splint/cast	Description of exercises	Frequency per day	Image of exercise
Week 6	**Strengthening:** Place a hand towel in a bucket of water or the sink and wring out the water.	1 x 15 reps	
	Brushing teeth: Brush your teeth as usual with the injured arm.	2 x 2 min	
	Strengthening: Pick up a peg and attach it to the side of a container. Release the peg and place it back on the table.	1 x 15 reps	
	Strengthening: Find a round door nob and use your injured arm to open and close the door.	1 x 15 reps	
	Strengthening: Find a medium sized jar and use your injured arm to take the lid of the jar on and off.	1 x 15 reps	

Appendix H. RCT participant information sheet attached to the front of participants' hospital clinic notes at every review

Date: _____

Patient identification number: _____

Please note:

This patient is a participant in the randomised controlled trial into the optimal time of immobilisation following ORIF for distal radius fracture.

Group allocation for this participant:

- ☐ 1-2 weeks of immobilisation post ORIF
- ☐ 3 weeks of immobilisation post ORIF
- ☐ 6 weeks of immobilisation post ORIF

Today's treatment plan for this participant:

- ☐ Removal of volar slab and application of tubigrip
- ☐ Removal of volar slab and application of full below elbow POP
- ☐ Removal of full below elbow POP

It is important that the treatment plan for this participant remains as specified above. Please only make changes to this plan if there are significant concerns with wound healing or stability. On the rare occasion that a change to the above plan is required, please specify this on the instruction sheet the participant has with them for the plaster technicians.

Please do not hesitate to contact the Principal Researcher: Narelle Watson on * *** *** if you have any concerns.**

Thank-you

Appendix I. Examples of bimonthly RCT newsletter

Issue 6

Randomised controlled trial: Optimal time of immobilisation following ORIF for distal radius fracture

Research team

Principal researcher:
Narelle Watson [redacted]

Researchers:
Professor Jenny Keating
Jackson Boyd
Darren Fraser
Collin McIlveen
Rebecca Pile
Paul Silk
Louise Taylor
Caitlin Thompson

Orthopaedic support
Mr Phong Tran
WH Orthopaedic surgeons
WH Orthopaedic registrars

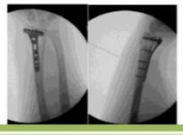
Related article of interest:

Driessens et al. (2013): A retrospective cohort investigation of active range of motion within one week of open reduction and internal fixation of distal radius fractures. *Journal Hand Therapy; 26: 225-31.*

Click on below article to read:

Adobe Acrobat Document

Update on participant recruitment



Target RCT enrolment: 135

Recruitments to date: 41

Summary of recruitment Aug & Sept 2013

ORIFs for DR fracture performed at WH in Aug & Sept 2013: 18

Number of participants recruited: 5

Reason unable to recruit	Total
Surgeon specified patient not for trial	6
Comprehension not adequate for informed consent	2
Patient declined participation	3
Patient not local to WH catchment	1
Excluded due to ORIF involving dorsal not volar plate	1

Q& A

1. **Why is it important that treating physiotherapists record range and strength measurements prior to giving hands on treatment at each session?**
   It is important in research trials that every effort is made to reduce the impact extraneous variables have on the relationship being examined. Maintaining consistency for physiotherapy treatment sessions with measurements followed by hands on treatment is necessary to eliminate the risk of measurement/treatment order being an extraneous variable.

2. **Are patients under Workcover funding eligible to participate in this investigation?**
   Patients under Workcover funding are not excluded from this investigation. It is important that the recruiting physiotherapists provide patients under Workcover with the choice of receiving treatment through a private physiotherapist or Western Health. Patients selecting to receive physiotherapy treatment at Western Health are eligible to participate in this investigation providing they meet the inclusion/exclusion criteria and consent. For ease of processing it would be appreciated if recruiting physiotherapists could please make the principal investigator aware of any participants under Workcover funding.

Issue 12

Randomised controlled trial: Optimal time of immobilisation following ORIF for distal radius fracture

Research team

Principal researcher:
Narelle Watson [redacted]

Researchers:
Professor Jenny Keating
Darren Fraser
Collin McIlveen
Rebecca Pile
Paul Silk
Louise Taylor
Caitlin Thompson
Bhavna Trivedy

Orthopaedic support
Mr Phong Tran
WH Orthopaedic surgeons
WH Orthopaedic registrars

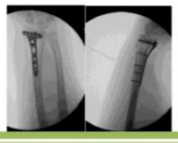
Related article of interest:

Kim et al. (2014): What is the Minimum Clinically Important Difference in Grip Strength? *Clinical Orthopaedics & Related Research* 472: 2536–2541

Click on below article to read:

Adobe Acrobat Document

Update on participant recruitment



Target RCT enrolment: 135

Recruitments to date: 78

Summary of recruitment August & September 2014

ORIFs for DR fracture performed at WH in Aug & Sept 2014: 16

Number of participants recruited: 5

Reason unable to recruit	Total
Surgeon specified patient not for trial	2
Patient not local to WH catchment	5
Excluded due to ORIF involving screw fixation not volar plate	1
Excluded due to ORIF for both DR # and scaphoid #	1
Excluded due to no backslab applied post-op	1
Excluded as patient younger than 18 years	1

Q & A

1. **Does a fracture clinic appointment need to be scheduled at the time of cast removal for participants allocated to the 3 week immobilisation group?**

Routinely at WH patients who have undergone an ORIF for distal radius fracture are followed up 1-2 weeks and then 6 weeks post-operatively. If there are concerns then further reviews are scheduled as appropriate. Therefore, to reduce demands on the orthopaedic team, an appointment is not required at the time of cast removal for participants allocated to the 3 week immobilisation group. The principal investigator will arrange for the plaster technicians to remove the participant's cast at 3 weeks post-operative. The principal investigator will also arrange for one of the research physiotherapists to check the participant's UL sensation, wound condition and document these details in the patient record. For participants allocated to the 3 week immobilisation group, an appointment at the time of cast removal is only required when there exists concerns around the participant's condition.

2. **How soon after cast removal is physiotherapy commenced for participants in the trial?**

All participants in this research trial commence physiotherapy at either Footscray or Sunshine Hospital within 3 days of removal of their cast.

Appendix J. Standardized 6 week education and exercise program with physiotherapist

Within three days of removal of the splint/cast, all participants attended an individual appointment with one of the treating physiotherapists. At this appointment, and at the six subsequent weekly appointments, the following nine areas were addressed in a standardized format:

1. *Information on surgery, prognosis, expectations*
   At the first review after slab/cast removal, the therapist and participant discussed the type of surgery, the typical recovery pattern and the relevance of the exercise program. The therapist discussed the wrist radiographs and the position of the fixation with the participant (e.g. explained that the volar plate does not cross the wrist joint and does not restrict movement at the joints). The participant was asked to explain their usual daily activities and discussion focused on appropriate use of the injured upper limb for these activities.

2. *Patient-Specific Functional Scale (PSFS)* (Chatman et al 1997)
   At the first review after slab/cast removal, the therapist introduced the participant to the PSFS, and the reasons for assessing with this scale. Once the participant demonstrated understanding of the PSFS they were asked to specify a minimum of three activities of importance to them and that they were unable to perform adequately because of the injury to their upper limb. The PSFS involved giving each activity listed a score, with 0 indicating unable to perform and 10 indicating an ability to perform the activity at the same level as before the injury to the upper limb. The therapist discussed the tasks listed by the participant. Together they reached consensus on an appropriate way of breaking down the tasks and determining scores. The tasks and the allocation of scores for components of tasks were recorded. Scores for each task, participant progress and exercises/activities that would assist in achieving the best possible score for tasks were discussed at each weekly therapist/participant review session. Participants were responsible for nominating tasks and monitoring progress towards performing the task at the targeted level of ability. Participants were asked to add a further task to the PSFS once a score of 10 had been achieved or if both the participant and therapist agreed that progress on a task had

plateaued and further progress would be slow. At the final therapist/participant review (six weeks following cast removal), the PSFS was reviewed and the participant asked to specify at least one short-term and one long-term activity they would continue to independently work towards. Appropriate activities/exercises to assist in achieving the best possible score for these task(s) were designed and discussed in addition to methods for participants to monitor their own progression following discharge. Barriers/enablers to progress were discussed and a plan for the participant's ongoing independent action plan developed.

3. *Recording of wrist and forearm active range of movement, grip strength and pain on VAS*

   In addition to the information gained from reviewing tasks in the PSFS, participants were able to track their progress on standardized measurements that were recorded at each review session. Following a standardized protocol, wrist flexion/extension, wrist ulnar/radial deviation, forearm supination/pronation and grip strength were recorded on the participant's injured and uninjured upper limbs. Henna was applied to the participant's injured upper limb on the standardized landmarks for measurement of wrist and forearm active ROM measurements. The therapist re-applied the henna as required to the injured upper limb in the weekly sessions. Grip strength was measured following a standardized protocol. Participants were asked to complete a visual analogue scale for worst pain and usual pain during the past week.

4. *Discussion and therapist demonstration of weekly exercises from standardised exercise program*

   The nature and purpose of the exercise program were discussed. This exercise program was adapted from that described by Krischak et al (2009).(156) The expected level of discomfort during this exercise program was discussed. Indications that the participant was pushing too hard or not pushing hard enough with exercises were clarified. The therapist demonstrated each of the exercises scheduled for practice in the week ahead, wherever possible linking these to the performance of daily activities.

5. *Participant demonstration of weekly exercises from standardised exercise program*

   Following the therapist demonstration, the participant was asked to demonstrate each exercise and errors in technique were adjusted. Discomfort with the exercises was assessed so that an appropriate level of discomfort and exertion could be determined for each exercise. Previous investigations have revealed that motivated people who enact behaviour generally have detailed plans regarding the how, when and where components for their exercise completion.(157) To enhance the adherence with the exercise program, therapists assisted participants to plan appropriate times for exercise, discussed barriers to exercise completion and methods for enhancing exercise enjoyment.

6. *Training diary*

   The concept and relevance of an exercise diary was discussed with the participant. All participants were asked to complete a daily training diary from the time of slab/cast removal to ascertain adherence with the home exercise program. At each review appointment the exercise program and diary were discussed. Discussion of the barriers and facilitators to daily exercise was encouraged.

7. *Complications following surgery*

   Participants were advised about possible complications including delayed wound healing, infection and fixation position loss or concerns. The importance of prompt attention to complications was discussed. The participant was instructed on how to care for their wound and the importance of scar massage. The therapist demonstrated appropriate scar massage (providing adequate wound closure had occurred).

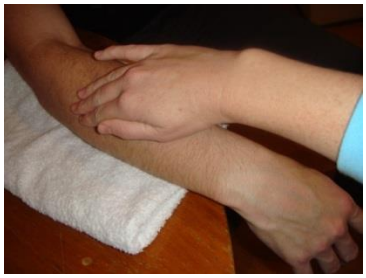
8. *Questions*

   Treating physiotherapists were asked to create interactive follow up appointments that focused on participant empowerment in the rehabilitation process. Therapists were advised to facilitate frank and comfortable discussion and avoid didactic instruction. Activities that promoted the use of the injured arm were designed to be as enjoyable as possible. Participants were encouraged to ask questions at any time during the appointment.

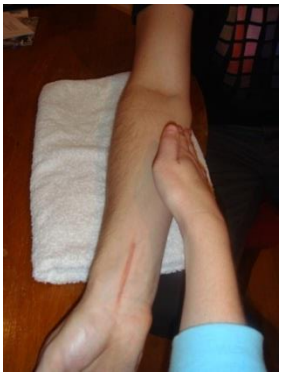
9. *Soft tissue work*

Treating therapists performed the following soft tissue work on participants at each treatment:

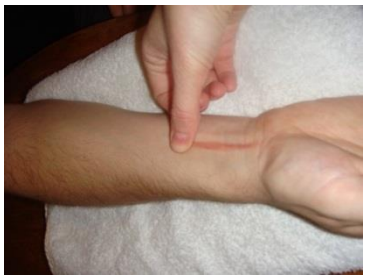
- 3 minutes retrograde massage of wrist extensors muscle body with wrist in flexion



- 3 minutes retrograde massage of wrist flexors muscle body with wrist in extension



- 3 minute scar massage (providing adequate wound closure had occurred)



Appendix K: Description of measurement techniques

Patient-rated wrist evaluation (PRWE)

The PRWE is a 15-item health-related quality of life questionnaire that measures wrist pain and disability in activities of daily living; five items assess symptoms and 10 assess disability.(65) Scale width is 0-100 points with higher scores reflecting greater pain and disability. PRWE raw scores were adjusted for missing data by replacing individual missing item scores with the mean score for the subscale.

Visual Analogue Scale (VAS) for pain

The 10cm VAS is a single-item measure of pain. The current investigation involved asking participants to specify the VAS for worst (VAS-W) and usual (VAS-U) pain over the past week.

Grip strength measurement

Grip strength was recorded bilaterally using the Jamar hand dynamometer. Previously reported standardised positioning and instructions (68) were adopted. One measurement of grip strength was used for this investigation given it has been reported to be comparable to the average of three grip strength trials.(69)

Two Jamar dynamometers were calibrated and aligned prior to commencement of outcome recording and recalibrated throughout the investigation. The grip strength assessment procedure was demonstrated by the examiner and participants were advised to perform their maximum within the limits of pain. Once the participants were positioned they were instructed “Are you ready? Squeeze as hard as you can. Harder! ..... Harder! ..... Harder! ... Relax.” These verbal instructions are similar to those adopted previously.(70)

Disabilities of the Arm, Shoulder and Hand (DASH)

The DASH is a health-related quality of life questionnaire that measures disability and symptoms in single or multiple conditions of the upper limb.(71) The DASH scale width is 0-100 points with higher scores reflecting greater disability.

Active range of movement (AROM)

Accuracy with locating anatomical landmarks was identified in a pilot investigation as a potential source of intra- and inter-rater error when measuring wrist and forearm AROM. Henna, a natural plant extract, was applied to provide a skin mark lasting up to two weeks and standardise anatomical landmarks for goniometer and inclinometer placement. Bilateral measurement enabled comparison to the uninjured side and single measurements of active ROM using the goniometer or inclinometer were performed on each measurement occasion. To counter the potential for creep in range associated with repeated measurements, participants were shown, and asked to repeat, the target movement several times before they were measured. The current investigation reported absolute measures of wrist and forearm joint range of movement in preference to movement arcs (e.g wrist flexion-extension arc). The basis for this decision was that reduction in range of movement at the wrist and forearm following distal radius fracture is not uniform for all planes/directions of movement and is linked with the type of residual deformity at the distal radius.(67)

Forearm range of movement

A liquid pendulum inclinometer was used to quantify pronation and supination AROM. Previously reported positioning was followed (59) with the elbow held in 90° flexion and the wrist in neutral. Positioning, technique and anatomical landmarks were standardised.

Wrist active range of movement

A standard manual goniometer was used to quantify wrist active ROM using a previously reported technique (63) with participants positioned in sitting, arm pressed against torso and elbow held in 90° flexion and standardised anatomical landmarks.

Measurement techniques for wrist and forearm active range of movement

Wrist and forearm range of movement

Two types of goniometers and an inclinometer were used for measurements.

Goniometer 1

Standard clear plastic 180° goniometer with 1° increments marked, an axis of rotation and two movable arms of 20cm.

Goniometer 2

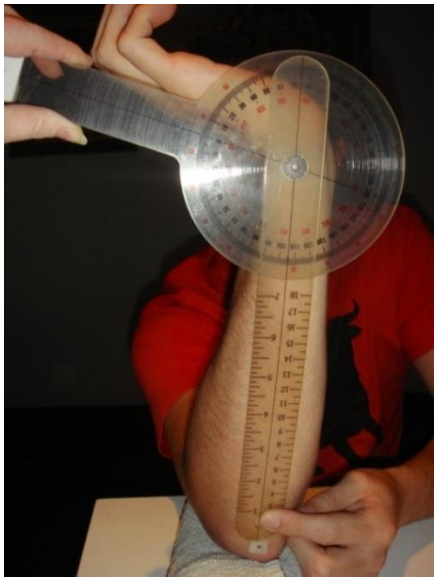
Standard clear plastic 180° goniometer with 5° increments marked, an axis of rotation and two moveable arms of 15cm.

Inclinometer

Liquid pendulum inclinometer with 2° increments marked, a dial able to be fully rotated 360° and lockable at 90° intervals.

For consistency in instructions, participants were advised to demonstrate the movement they were about to measure and then asked to repeat that movement gently until they felt they had achieved maximum movement. Participants were asked to 'warm up' with two repeated movements prior to recording of each movement by the therapist. Each movement was recorded once only and measurements taken to the nearest degree.

1. Wrist extension



Technique:

- Ulnar technique- Goniometer 1
- A zero starting position with measurements recorded from zero and progressing to end of range

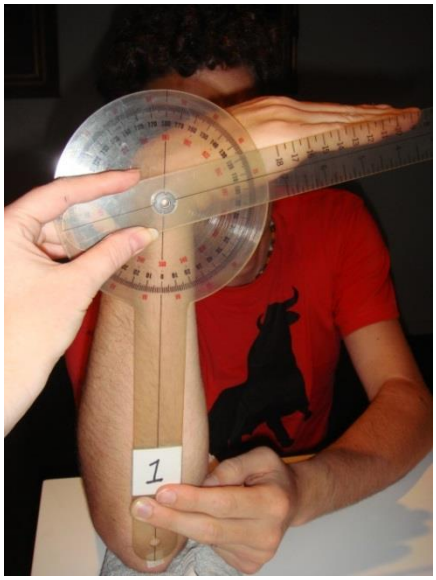
Position:

- Block or rolled towel under elbow
- Elbow flexed to 90º
- Forearm held in neutral supination/pronation
- Fingers held in relaxed position

Landmarks:

- Axis of the goniometer placed over the tip of the ulnar styloid
- Distal arm of the goniometer aligned parallel with the 5th metacarpal
- Proximal arm of the goniometer aligned along the ulnar border of the forearm in line with the midpoint of the distal aspect of the olecranon

2. Wrist flexion



Technique:

- Ulnar technique- Goniometer 1
- A zero starting position with measurements recorded from zero and progressing to end of range

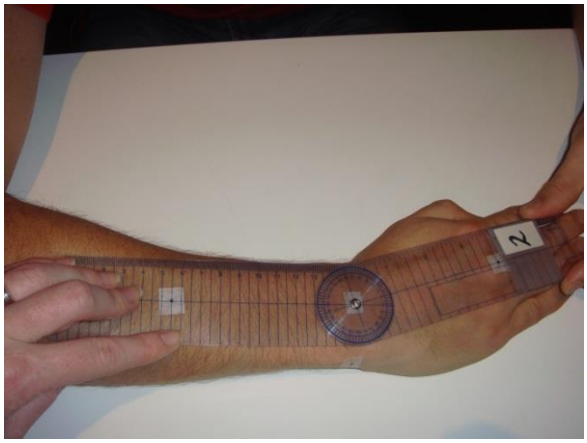
Position:

- Block or rolled towel under elbow
- Elbow flexed to 90º
- Forearm held in neutral supination/pronation
- Fingers together with MCP, PIP and DIP joints extended (as able)

Landmarks:

- Axis of the goniometer placed over the tip of the ulnar styloid
- Distal arm of the goniometer aligned parallel with the 5th metacarpal
- Proximal arm of the goniometer aligned along the ulnar border of the forearm in line with the midpoint of the distal aspect of the olecranon

3. Wrist radial deviation



Technique:

- Using goniometer 2
- A zero starting position with measurements recorded from zero and progressing to end of range

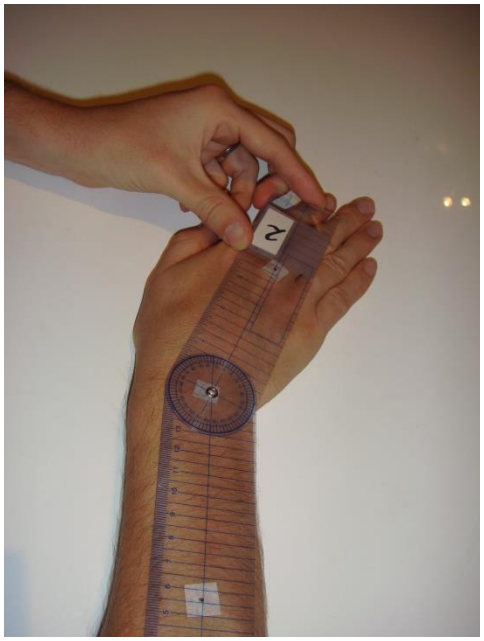
Position:

- Neutral wrist position with no flexion or extension (or as close to this as possible)
- Palm and forearm flat on table if able. If unable to achieve flat palm and forearm on table then palm and forearm placed on a flat surface in comfortable forearm pronation
- Elbow flexed to 90°

Landmarks:

- Axis of the goniometer placed over the centre of the capitate on the dorsal aspect of the wrist. Centre of capitate located by finding the midpoint of the line connecting the radial and ulnar styloid tips
- Distal arm of the goniometer aligned with the third metacarpal head
- Proximal arm of the goniometer aligned with a point at the midpoint of the dorsal aspect of the forearm located 10cm from the centre of the capitate

4. Wrist ulnar deviation



Technique:

- Using goniometer 2
- A zero starting position with measurements recorded from zero and progressing to end of range

Position:

- Neutral wrist position with no flexion or extension (or as close to this as possible)
- Palm and forearm flat on table if able. If unable to achieve flat palm and forearm on table then palm and forearm placed on a flat surface in comfortable forearm pronation
- Elbow flexed to 90°

Landmarks:

- Axis of the goniometer placed over the centre of the capitate on the dorsal aspect of the wrist. Centre of capitate located by finding the midpoint of the line connecting the radial and ulnar styloid tips
- Distal arm of the goniometer aligned with the third metacarpal head
- Proximal arm of the goniometer aligned with a point at the midpoint of the dorsal aspect of the forearm located 10cm from the centre of the capitate

5. Forearm pronation

Technique:

- Inclinometer positioned on dorsal surface of forearm and not pushed into skin
- Starting movement from a position of neutral (0°) supination/pronation and moving to maximum pronation

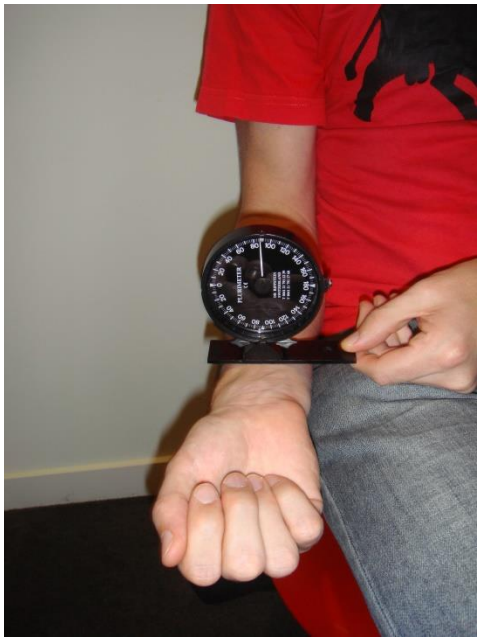
Position:

- Sitting away from table
- Elbow against torso
- Elbow flexed to 90°

Landmarks:

- Inclinometer placed a point at the midpoint of the dorsal aspect of the forearm located 5cm from the centre of the capitate
- Inclinometer aligned parallel with the sagittal plane of the forearm

6. Forearm supination



Technique:

- Inclinometer positioned on volar surface of forearm and not pushed into skin
- Starting movement from a position of neutral (0°) pronation/supination and moving to maximum supination

Position:

- Sitting away from table
- Elbow against torso
- Elbow flexed to 90°

Landmarks:

- Inclinometer placed at the midpoint of the volar aspect of the forearm,5cm from the centre of the capitate
- Inclinometer aligned parallel with the sagittal plane of forearm

Appendix L. Authorisation to include published manuscript in thesis

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BMC Medical Imaging

RESEARCH ARTICLE Open Access

Reliability of radiographic measurements for acute distal radius fractures

Narelle J. Watson[1*], Saeed Asadollahi[2,5], Frank Parrish[3,4], Jacqueline Ridgway[3], Phong Tran[5] and Jennifer L. Keating[6]

Abstract

Background: The management of distal radial fractures is guided by the interpretation of radiographic findings. The aim of this investigation was to determine the intra- and inter-observer reliability of eight traditionally reported anatomic radiographic parameters in adults with an acute distal radius fracture.

Methods: Five observers participated. All were routinely involved in making treatment decisions based on distal radius fracture radiographs. Observers performed independent repeated measurements on 30 radiographs for eight anatomical parameters: dorsal shift (mm), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), ulnar variance (mm). Intraclass correlation coefficients (ICCs) and the magnitude of retest errors were calculated.

Results: Measurement reliability was summarised as high (ICC > 0.80), moderate (0.60–0.80) or low (<0.60). Intra-observer reliability was high for dorsal shift and palmar tilt; moderate for radial angle, radial height, ulnar variance and radial shift; and low for intra-articular gap and step. Inter-observer reliability was high for palmar tilt; moderate for dorsal shift, ulnar variance, radial angle and radial height; and low for radial shift, intra-articular gap and step. Error magnitude (95 % confidence interval) was within 1–2 mm for intra-articular gap and step, 2–4 mm for ulnar variance, 4–6 mm for radial shift, dorsal shift and radial height, and 6–8° for radial angle and palmar tilt.

Conclusions: Based on previous reports of critical values for palmar tilt, ulnar variance and radial angle, error margins appear small enough for measurements to be useful in guiding treatment decisions. Our findings indicate that clinicians cannot reliably measure values ≤1 mm for intra-articular gap and step when interpreting radiographic parameters using the standardised methods investigated in this study. As a guide for treatment selection, palmar tilt, ulnar variance and radial angle measurements may be useful, but intra-articular gap and step appear unreliable.

Keywords: Distal radius fracture, Radiographs, Reliability

Background

Comprising 2.5 % of all Emergency Department (ED) presentations, fracture of the distal radius is the most common skeletal fracture type [1]. It occurs in approximately 10 % of Caucasian women over 65 years [2]. After cast removal, immediate functional limitations include loss of strength (particularly grip) and range of movement [3, 4]. A decade following fracture, ongoing pain and reduced function of the wrist and hand can still occur with heavy tasks [5].

Radiographs of the distal radius are used for diagnosis, to guide treatment choices, assess fracture reduction and monitor healing. There are no standardised, evidence-based methods for interpreting radiographic parameters. Eight anatomic parameters of distal radius fracture have been described. These are dorsal shift (mm), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), and ulnar variance (mm) [6]. Relationships have been described between functional outcome and the anatomical parameters of intra-articular gap and step [7–9], dorsal [10–12] and palmar tilt [13], radial angle [14, 15], radial height [10, 16, 17], radial shift [18] and ulnar variance [19, 20]. No such relationships have been described for dorsal shift suggesting it may have no clinical utility, may not be adequately reliable and/or its close correlation with dorsal tilt [21] renders this measurement less

* Correspondence: Narelle.Watson@wh.org.au
[1]Allied Health Department & School of Primary Health Care, Western Health & Monash University, Melbourne, Victoria, Australia
Full list of author information is available at the end of the article

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important. This investigation explored the reliability of these eight parameters in preparation for a study of their utility in guiding treatment decisions.

We assessed the error associated with radiographic interpretation of acute distal radius fractures and whether the errors associated with measurements were small enough for measurements to be used confidently in fracture management. We investigated the intra- and inter-observer reliability of eight anatomic parameters in skeletally mature patients with an acute distal radius fracture using digitised radiographs. This investigation extends and updates the work of Kreder et al. [6] by using a larger sample of radiographs (30 acute fractures) and the computerised images and measurement procedures used in current practice. The majority of choices regarding treatment for distal radius fractures occur in the acute period. This investigation utilized radiographs of acute distal radius fractures in contrast to the healed distal fracture radiographs utilized by Kreder et al. [6].

Methods

Participants: selection of radiographs

Posteroanterior (PA) and lateral wrist radiographs of all patients with distal radius fractures presenting to a large outer metropolitan ED in Victoria, Australia during the period July 2009 to January 2010 were retrospectively selected for review. Standardised positioning of neutral forearm rotation was adopted for the PA and lateral views. Inclusion criteria for radiographs were skeletal maturity, fracture within 3 cm of the distal end of the radius, and presenting to the ED within seven days of fracture. Exclusion criteria were pathological fracture and evidence of previous distal radius fracture on the affected side. Radiographs meeting the inclusion/exclusion criteria were assembled and stratified by fracture deformity to either Group A (mild deformity) or Group B (severe deformity) based on decision rules defining estimates of severity (Table 1). In the absence of guidelines, decisions regarding cut points separating mild from severe were arbitrary and intended only to enable the spectrum of injury to be appropriately represented in the assembled targets. Fifteen radiographs from each group were randomly selected based on a computer generated sequence. The sample size of 30 repeated measurements for each observer was chosen as difference scores for repeated measures in samples of 30 or more are likely to assume a normal distribution [22].

Table 1 Radiographic characteristics for classification as mild or severe deformity

Group A Mild deformity: must meet all criteria	Group B Severe deformity: must have at least one criteria
Intra-articular step: ≤ 2 mm	Intra-articular step: > 2 mm
Intra-articular gap: ≤ 2 mm	Intra-articular gap: > 2 mm
Dorsal tilt: ≤ 10°	Dorsal tilt: > 10°
Volar tilt: ≤ 20°	Volar tilt: > 20°

Participants: selection of assessors

To accommodate the influence of site specific practices, observers were invited from two independent health networks. Health professionals were invited to participate if their role included making treatment decisions based on radiographic images of upper limb fractures. Invitations were sent to ED, orthopaedic and radiology staff, and upper limb specialists. Potentially eligible professional groups included orthopaedic consultants and registrars, radiologists, ED consultants and registrars, and advanced practice musculoskeletal physiotherapists. A total of 10 observers (five from each health network) meeting these criteria were invited to participate. Ensuring at least two observers from each health network, the first five observers to consent were enrolled in the investigation.

Observer training

Prior to commencing this study, each observer completed a self-directed tutorial that provided standardised instructions and examples illustrating measurement techniques for assessing each of the eight parameters. Observers were then given three wrist radiographs of acute distal radius fractures and asked to measure each of the eight anatomical parameters. The standardised method developed by Kreder et al. [6] for measuring these eight anatomic parameters at the distal radius was followed (Fig. 1a, b, c) [6]. Observers utilised picture archiving and communication system (PACS) computerised images through the Synapse [23] display system that includes measurement calibration. Two views, PA and lateral, were utilised to obtain measurements for each of the eight parameters. Observers were asked to save all working lines used in computations. Each observer was then provided with written and verbal feedback from the principal investigator on departures from standardised measurement techniques. Participants were asked to repeat measurements where incorrect technique was noted and again save measurement decision rules for review and feedback from the principal investigator. Observer training was completed over a two week period. The purpose of this preparation was to identify and minimise sources of systematic and random error in reading images.

Measurement parameters

The five observers were asked to measure the following parameters for each of the 30 radiographs: dorsal tilt (degrees), intra-articular gap (mm), intra-articular step (mm), palmar tilt (degrees), radial angle (degrees), radial height (mm), radial shift (mm), and ulnar variance (mm) using methods described in the observer training tutorials.

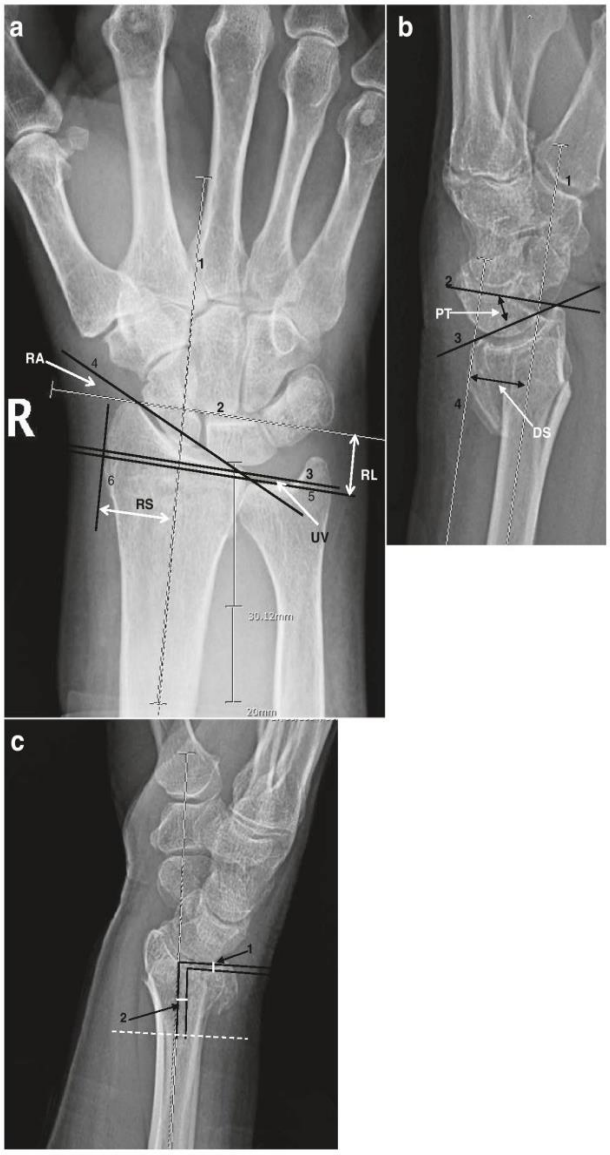

Fig. 1 **a** Posterioanterior measurement guidelines as described in Kreder et al. [6]. **b** Lateral measurement guidelines as described in Kreder et al. [6]. **c** Step and gap measurement as described in Kreder et al. [6]. **a** RA, radial angle; RL, radial length; UV, ulnar variance; RS, radial shift. 1) This line represents the long axis of the radius. The center of the radius shaft is determined at 3 cm and 5 cm below the mid-region of the proximal lunate articular surface. 2) A line perpendicular to the center long axis of the radius is drawn at the level of the most distal aspect of the radial articular surface. 3) A line perpendicular to the central long axis of the radius is drawn at the level of the ulnar margin of the distal radial articular surface. 4) The radial and ulnar margins of the distal radial articular surface are connected. 5) A line perpendicular to the central long axis of the radius is drawn at the level of the distal ulnar articular surface. 6) A line tangential to the most radial point on the radial metaphysis is drawn parallel to the central long axis of the radius. **b** PT palmar tilt angle (dorsal tilt=negative palmar tilt); DS, dorsal shift. 1) This line represents the long axis of the radius. The center of the radial shaft is determined at 3 cm and 5 cm below the mid-region of the proximal lunate articular surface. 2) A line perpendicular to the central long axis of the radius is drawn at a convenient level. 3) The dorsal and anterior margins of the distal radial articular surface are connected. 4) A line tangential to the most dorsal point on the radial metaphysis is drawn parallel to the central long axis of the radius. **c** 1) Step-off at the distal radius articular cortical margin is measured by drawing lines perpendicular with the central long axis of the radius from the most distal margin of each side of the cortical discontinuity. 2) Gap deformity is measured by dropping lines that are parallel from the central long axis of the radius from the most distal margin of each side of the cortical deformity. The gap distance is measured along a line perpendicular to the central long axis of the radius.

Measurements

On the first measurement occasion, observers were presented, in random sequence, with 30 fully de-identified radiographs with no unique identifying features. No earlier than two weeks and no later than three weeks later, observers were presented with the same set of radiographs, again in random sequence and without access to measurements taken on the first measurement occasion. To reduce the potential impact of measurement fatigue, observers were instructed to disperse their measurements over a two week period.

Statistics

Data were analysed using the recommendations by Rankin and Stokes [24] (correlational indices) and Bland and Altman [25] (metricated error estimates). The ICC quantifies the relationship between two variables with $r = 1$ indicating perfect agreement and $r = 0$ indicating no agreement.

Intra-observer reliability

Intra-observer ICCs were calculated for each of the eight anatomical parameters on data produced from a two-way repeated analysis of variance (ANOVA). The test retest values for each observer were compared for each anatomical parameter. Using equations provided by Fleiss [26] for repeated measurements by the same observer, the ICC(1, 1) was calculated using the formula:

$$\mathrm{ICC}(1,1) = \mathrm{BMS\text{-}WMS}/\mathrm{BMS} + (\mathrm{k\text{-}1})\mathrm{WMS} \qquad (1)$$

where k is the number of measurements, and mean squares (MS) of variance estimates were obtained from ANOVA: *BMS* (between-subjects variance) and *WMS* (within subjects variance).

Bland and Altman [25] analysis was used to quantify agreement between measurements made by the same observer; the difference between two measurements was plotted against the average of the two measurements. The 95 % confidence intervals (CIs) around the mean differences were calculated using the standard errors in estimates of the mean and a t multiplier appropriate for the sample size (2.05) [25].

Inter-observer reliability

The first set of measurements of the eight anatomical parameters for each of the 30 radiographs were used to calculate the inter-observer reliability. The analyses were repeated for fractures dichotomised by severity of deformity to assess whether reliability changed with fracture severity. Variance estimates were derived from a one-way repeated ANOVA. The ICC(3,1) was calculated based on recommendations and equations by Shrout and Fleiss [27] for inter-observer reliability:

$$\mathrm{ICC}(3,1) = \mathrm{BMS\text{-}EMS}/\mathrm{BMS} + (\mathrm{k\text{-}1})\mathrm{EMS} \qquad (2)$$

The ICC(3,1) was chosen as each radiograph in the current investigation was rated by each of the same k observers who were the only observers of interest. As the observers for this investigation were selected from the general population, ICC(1,1) could have been used, however the more conservative equation was chosen. Bland and Altman [25] analysis was again applied to quantify inter-observer agreement.

As this investigation involved exploring agreement between more than two fixed observers, a representative average of the reliability between pairs within the five observers was calculated using an overall concordance correlation coefficient (OCCC) based on recommendations and equations by Barnhart et al. [28]. The OCCC provides an overall correlation that takes into account the correlation between individual pairs of observers.

A number of investigations have recommended conservative management for distal radius fractures when intra-articular gap or step is less than 1 mm [7–9]. Intra-articular gap and step measurements were therefore converted to a dichotomy of less than or equal to 1 mm or greater than 1 mm and pairwise inter-observer agreement values (kappa) were calculated. Further pairwise inter-observer agreement values (kappa) were calculated when intra-articular gap and step measurements were converted to a dichotomy of presence (any gap or step recorded) or absence (zero gap or zero step recorded) of intra-articular step or gap. Data from the first set of measurements was used for the conversions to dichotomies.

Results

The professional roles of the five observers who reviewed radiographs were orthopaedic surgeon (upper limb), orthopaedic registrar, ED consultant, ED primary care advanced practice musculoskeletal physiotherapist and radiologist.

Measurement reliability was summarised as high (ICC > 0.80), moderate (0.60–0.80) or low (<0.60). Intra-observer reliability was high for dorsal shift and palmar tilt; moderate for radial angle, radial height, ulnar variance and radial shift; and low for intra-articular gap and step. Inter-observer reliability was high for palmar tilt; moderate for dorsal shift, ulnar variance, radial angle and radial height; and low for radial shift, intra-articular gap and step (Table 2). OCCC values ranged from 0.11 for intra-articular gap to 0.94 for palmar tilt (Table 2). ICC values appeared higher in the current investigation compared with Kreder et al. [6] for all parameters except radial shift and ulnar variance (Table 2). Error magnitude (95 % confidence interval) was within 1–2 mm for intra-articular gap and step, 2–4 mm for ulnar variance, 4–6 mm for radial shift, dorsal shift and radial height, and 6–8° for radial angle and palmar tilt (Table 3).

Table 2 Intra- and inter-observer ICCs & OCCCs for each anatomical parameter based on ANOVA output and Equations 1 and 2 are compared to data from Kreder et al. [6]

Anatomical parameter	Intra-observer	Inter-observer (using 1st measurements)	OCCC[13] (using 1st measurements)	Kreder et al. [6] intra-observer	Kreder et al. [6] inter-observer
Dorsal shift	0.91	0.75	0.77	0.48	0.42
Intra-articular gap	0.56	0.30	0.11	0.37	0.35
Intra-articular step	0.54	0.31	N/A	0.22	0.27
Palmar tilt	0.89	0.93	0.94	0.71	0.74
Radial angle	0.80	0.66	0.66	0.39	0.38
Radial height	0.79	0.61	0.61	0.49	0.44
Radial shift	0.68	0.47	0.50	0.72	0.67
Ulnar variance	0.75	0.69	0.70	0.85	0.82

Dichotomising intra-articular gap and step measurements as above or below 1 mm produced pairwise inter-observer agreement values ranging from −0.06 to 0.52 and −0.11 to 0.43 respectively (Tables 4 and 5). Dichotomising intra-articular gap and step measurements by the presence or absence of intra-articular involvement produced pairwise inter-observer agreement values ranging from −0.07 to 0.67 and 0 to 0.63 respectively (Tables 4 and 5).

Dichotomizing data based on fracture severity resulted in a systematic improvement in inter-observer reliability values for more severe fractures with all measurements except dorsal shift (Table 6). No systematic reductions in error were seen for more severe fractures when calculations of standard error of measurement (inter-observer) were performed (Table 6).

Stratifying data based on professional subgroups e.g. isolating the analysis to the orthopaedic surgeon and radiologist, did not result in systematically higher reliability values. The highest correlations were obtained when data for all five observers were included in analysis.

Bland and Altman

Bland and Altman [25] graphs (Figs. 2 and 3) indicated no clear relationship between an individual measurement and the magnitude of error in measurement. Figures 2 and 3 illustrate this using the example of palmar tilt showing data for observers with high (1 & 5) and low (2&4) measurement correlations.

Discussion

Distal radius fractures are typically managed non-operatively with cast immobilisation or surgically with either percutaneous pinning (Kirscher wires), external fixation or internal fixation [29]. However, the evidence behind treatment choices based on deformation and radiographic parameters is limited. Best treatment for the various types of distal radius fracture would ideally include a reliable, standardised, evidence-based method of classifying distal radius fractures and unambiguous decision guidelines for treatment.

The rationale for this investigation was to quantify the intra- and inter-observer reliability of eight traditionally reported anatomic parameters in skeletally mature patients with an acute distal radius fracture using PACS computerised images and display systems (Synapse [23]). Bland and Altman [25] graphs (Figs. 2 and 3) indicate no clear relationship between an individual measurement and the magnitude of error in measurement. Consequently, in clinical practice, errors associated with these measurements

Table 3 Range of measurements, standard error of measurement (SEM) and 95 % confidence intervals (95 % CI) for each anatomical parameter using first set of measurements of 30 radiographs, compared to data from Kreder et al. [6] based on six radiographs

Parameter	Mean (SD)	Minimum, Maximum	SEM (inter-observer using 1st measurements)	Upper limit 95 % CI	Minimum, Maximum Kreder et al. [6]
Dorsal shift (mm)	15.03 (4.85)	(3, 23.4)	2.42	4.97	(2, 19)
Intra-articular Gap (mm)	0.76 (1.13)	(0, 5.7)	0.94	1.94	(0, 5)
Intra-articular step (mm)	0.27 (0.62)	(0, 3.95)	0.52	1.06	(0, 4)
Palmar tilt (degrees)	−6.29 (14.28)	(−36, 42)	3.78	7.75	(−31, 24)
Radial angle (degrees)	18.18 (5.67)	(3, 30)	3.31	6.78	(3, 27)
Radial height (mm)	8.71 (4.07)	(0, 24)	2.54	5.21	(0, 14)
Radial shift (mm)	18.71 (3.00)	(13, 30.8)	2.18	4.48	(11, 25)
Ulnar variance (mm)	0.68 (1.96)	(−4.5, 5.7)	1.09	2.24	(−2,10)

Table 4 Kappa values for inter-observer agreement for intra-articular gap (taken from 1st recording) using raw scores and scores dichotomised with recoding

Pairwise comparison	Uncoded data (as recorded)	Coding: 0 = < 1 mm 1 = equal or > 1 mm	Coding: 0 = unable to see gap 1 = able to see gap
P1P2	0.24	0.52	0.54
P1P3	0.16	0.39	0.53
P1P4	0.22	0.52	0.67
P1P5	0.03	0.08	0.06
P2P3	0.08	0.15	0.23
P2P4	0.27	0.25	0.60
P2P5	−0.03	−0.06	−0.07
P3P4	0.15	0.45	0.47
P3P5	0.02	0.09	0.05
P4P5	0.03	0.11	0.07

are better estimated using degrees or millimetres of error (e.g. +/− 4°) than error expressed as a percentage of the range (e.g. 10 % of range).

Despite adopting standardised measurement techniques and observer training, the intra- and inter-observer consistency when applying these measures varied greatly for the eight anatomic parameters. Intra-observer ICC values appeared higher than inter-observer for all anatomic parameters except palmar tilt and may indicate the potential for additional training to remediate inconsistencies between clinicians for measurements.

Kreder et al. [6] published the results of intra- and inter-observer consistency in assessing these eight anatomic parameters with repeated assessments at 0 and 2–4 weeks of six radiographs of healed fractures conducted by 16 observers. Printed films were assessed on flat view boxes and measured using protractors and rulers. Limitations of the Kreder et al. [6] investigation were the small sample of radiographs and that radiographs were of healed fractures.

Table 5 Kappa values for inter-observer agreement for intra-articular step (taken from 1st recording) using raw scores and scores dichotomised with recoding

Pairwise comparison	Uncoded data (as recorded)	Coding: 0 = < 1 mm 1 = equal or > 1 mm	Coding: 0 = unable to see step 1 = able to see step
P1P2	0.25	0.38	0.63
P1P3	0.13	0.07	0.29
P1P4	0.22	0.30	0.56
P1P5	0.00	0.00	0.00
P2P3	0.25	0.43	0.53
P2P4	0.23	0.14	0.56
P2P5	0.00	0.00	0.00
P3P4	0.11	−0.11	0.26
P3P5	0.00	0.00	0.00
P4P5	0.00	0.00	0.00

For intra-observer reliability in the current investigation, ICC values were found to be above 0.80 for palmar tilt and dorsal shift (Table 2). Only one parameter, palmar tilt, was associated with an inter-observer ICC value above 0.80. Unlike the current investigation, Kreder et al. [6] found ulnar variance was the only parameter to have an intra-and inter-observer ICC value above 0.80.

Comparison of error margins in millimeters or degrees (e.g. using the SEM in Table 3) is preferable to comparison of ICC values. This is because the magnitude of ICCs is affected by the range of raw scores included in the computation. This effect is referred to as attenuation of range and has the consequence that the ICC will increase as the variance in raw scores increases despite the same absolute differences (error) in repeated measurements. We were unable to determine the extent to which the higher ICCs obtained in the current investigation were a consequence of a larger range of raw scores as we did not have the variance estimates for Kreder et al.'s [6] data. However, on examination of the range of raw scores for the data analysed in both studies (Table 3), it is possible that attenuation of range might explain at least some of the observed differences.

It is difficult to be unequivocally confident that the use of computerised images and measurement procedures facilitates additional accuracy. If we were studying a similar spectrum of measurements, some differences in study design may account for observed differences. These include the digital methods we employed, our larger number of radiographs (30 versus 6) and that we studied acute fractures while Kreder et al. [6] studied healed fractures. This may have afforded us better visibility of the cortical disruption. The use of acute fracture images that mirror authentic practice confirms Kreder et al.'s [6] findings and extends the validity of claims regarding measurement utility across a representative spectrum of deformity.

Our classification of radiographs into Group 1 (mild deformity) and 2 (severe deformity) was undertaken to enable the spectrum of mild to severe deformity to be represented in the radiographs. While the accuracy of this step cannot be defended based on our analysis of the reliability of radiographic measurements, the range of obtained measurements in this study were comparable to the range of measurements obtained in the study by Kreder et al. [6], suggesting some success in capturing the spectrum of severity.

Clinical relevance

Intra-articular gap and step

A number of investigations have recommended conservative management for distal radius fractures when

Table 6 Inter-observer ICCs and SEMs (taken from 1st recording) using data dichotomized for severity of fracture deformity

Anatomical parameter	ICC All 5 observers-30 radiographs	ICC Grp 1 (mild deformity)-15 radiographs	ICC Grp 2 (severe deformity)-15 radiographs	SEM Grp 1 (mild deformity)-15 radiographs	SEM Grp 2 (severe deformity)-15 radiographs
Dorsal shift	0.75	0.76	0.71	3.09	1.46
Intra-articular gap	0.30	0.15	0.30	0.39	0.66
Intra-articular step	0.31	0.26	0.30	0.18	0.39
Palmar tilt	0.93	0.92	0.96	7.75	6.52
Radial angle	0.66	0.62	0.71	3.00	2.59
Radial height	0.61	0.49	0.74	2.07	1.95
Radial shift	0.47	0.27	0.55	1.18	1.77
Ulnar variance	0.69	0.67	0.70	0.93	1.00

intra-articular gap or step is less than 1 mm; accelerated development of arthritis, increased severity of degenerative changes and poor functional outcome has been linked with intra-articular gap or step greater than 1 mm [7–9]. Intra-articular gap and step measurements in both the current investigation and previous literature (Tables 2, 4 and 5) were associated with low intra- and inter-reliability ICC values. Given the poor reliability for assessing intra-articular gap or step, we question the suitability of using these radiographic interpretations as criteria for guiding treatment choices. It is possible that additional training in measurement technique might improve the accuracy of these measurements and the cost-benefits of computerised tomography for improving reliability warrants exploration.

Dorsal and palmar tilt

It has been argued that functional outcomes are significantly affected when dorsal tilt (negative palmar tilt) exceeds 10° or 12° [10–12] or palmar tilt exceeds 25° [13]. Allowing for error in estimates, dorsal tilt would need to be less than 2.2° to be confident that in 95 % of cases it is actually less than 10°. Error estimates indicate that palmar tilt measurement would need to be less than 17.2° to be confident that in 95 % of cases it is less than 25°.

Ulnar variance

Positive ulnar variance greater than 3 mm has been reported to negatively impact functional ability [19, 20]. Allowing for error in estimates we would need to see no more than 0.8 mm of positive ulnar variance to be confident that true ulnar variance is no more than 3 mm.

Radial angle

Radial angle generally reduces with displaced distal radius fractures and a radial angle of less than 15° has been used to indicate operative management [14, 15]. We would need to see more than 21.8° radial angle to be confident that in 95 % of cases we have more than 15°.

Radial height

A reduction in radial height of 3–6 mm has been linked with a decline in functional outcome [16, 17]. Error estimates and a 95 % CI upper limit of 5.2 mm raise questions

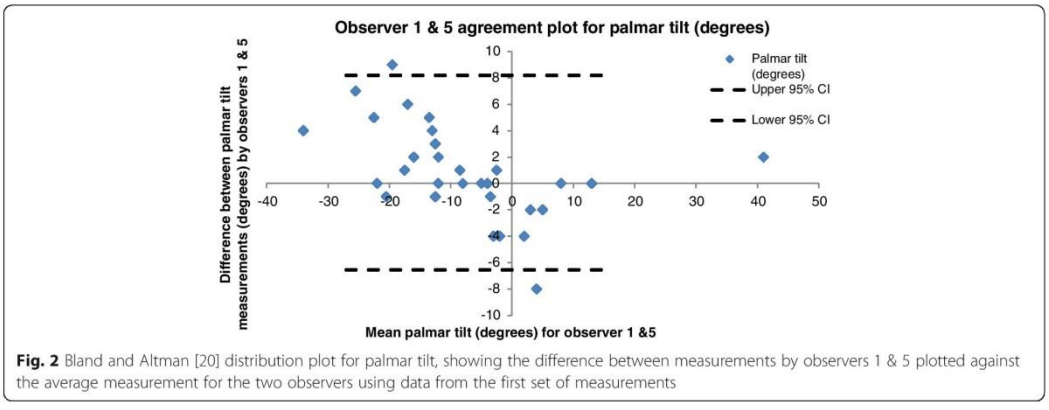

Fig. 2 Bland and Altman [20] distribution plot for palmar tilt, showing the difference between measurements by observers 1 & 5 plotted against the average measurement for the two observers using data from the first set of measurements

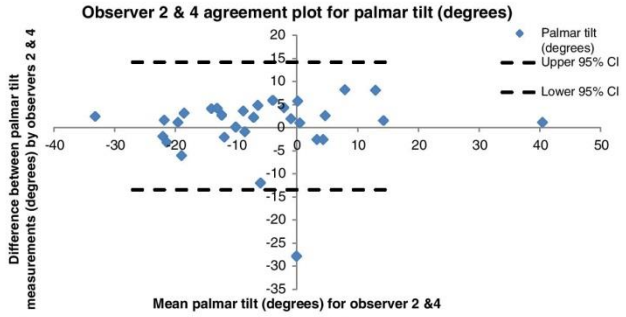

Fig. 3 Bland and Altman [20] distribution plot showing for palmar tilt, the difference between observer 2 & 4 measurements plotted against the average measurement for the two observers using data from the first set of measurements

about the utility of this measure using the standardised methods described.

Dorsal shift and radial shift

There is limited information in the literature linking the measurements of dorsal shift and radial shift with functional outcomes raising questions around the importance of these anatomical parameters for guiding treatment decisions. The current investigation indicates that dorsal shift can be reliably measured [inter-observer ICC value (0.75)] and therefore exploration of its relationship with functional outcomes is warranted.

Conclusions

In summary, when interpreting computerised images of acute distal radius fractures, reliability measures and error margins from this investigation support the use of palmar tilt, radial angle and ulnar variance measurements for guiding treatment choices. However, consideration needs to be given to error margins when using these measurements to guide treatment choices. Reliability measures and error margins indicate that intra-articular gap and step cannot reliably be used to guide treatment choices for acute distal radius fractures when using the methods for interpreting radiographic parameters investigated in this study. This study did not investigate the reliability of the scan itself, and this warrants further investigation.

The next step from this investigation is to use evidence-based methods to develop decision rules for treatment guidelines following acute distal radius fracture. It is known that clinicians do not routinely measure all eight anatomical parameters in clinical practice. Further investigation is required to quantify whether there is consistency and agreement with the anatomical parameters that clinicians deem important for decision making for acute distal radius fractures.

Additional file

Additional file 1: Data set- Repeated measurements by five observers for the eight anatomical parameters. File contains the raw values for the repeated measurements recorded by the five observers for the 30 radiographs. (XLS 49 kb)

Abbreviations

ANOVA, analysis of variance; *BMS*, between-subjects variance; CIs, confidence intervals; ED, Emergency Department; ICCs, intraclass correlation coefficients; MS, mean squares; OCCC, overall concordance correlation coefficient; PA, posteroanterior; PACS, picture archiving and communication system; SEM, standard error of measurement; *WMS*, within subjects variance

Acknowledgements

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Monash University and Western Health (Melbourne, Australia) are acknowledged for their support of this study and the staff that participated.

Funding

Not applicable.

Availability of data and materials

The datasets supporting the conclusions of this manuscript are included within the manuscript (and in Additional file 1).

Authors' contributions

NW conceived of the study and design, coordinated the study, participated in the statistical analysis and coordinated manuscript drafting. SA made substantial contributions to the acquisition of data, was involved with drafting the manuscript and has given final approval of the version to be published. FP made substantial contributions to the acquisition of data, was involved with drafting the manuscript and has given final approval of the version to be published. JR made substantial contributions to the acquisition of data, was involved with drafting the manuscript and has given final approval of the version to be published. PT made substantial contributions to the acquisition of data, was involved with drafting the manuscript and has given final approval of the version to be published. JK made substantial contributions to conception and design of the study, participated in the analysis and interpretation of data, was involved with drafting the manuscript and has given final approval of the version to be published. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication
Not applicable.

Ethics approval and consent to participate
Approval was granted by the Melbourne Health, Monash University and Peninsula Health Human Research Ethics Committees involved with this investigation (MH 2010.113, CF10/2330-2010001327, HREC/10/22). Observer consent was obtained for this investigation and a waiver of consent was given for radiograph usage as part of the ethical approval.

Author details
[1]Allied Health Department & School of Primary Health Care, Western Health & Monash University, Melbourne, Victoria, Australia. [2]Nepean hospital, Penrith, NSW, Australia. [3]Peninsula Health, Melbourne, Victoria, Australia. [4]I-TeleRAD, Melbourne, Victoria, Australia. [5]Orthopaedic Department Western Health, Melbourne, Victoria, Australia. [6]Department of Physiotherapy, School of Primary Health Care, Faculty Medicine Nursing and Health Sciences, Monash University, Melbourne, Victoria, Australia.

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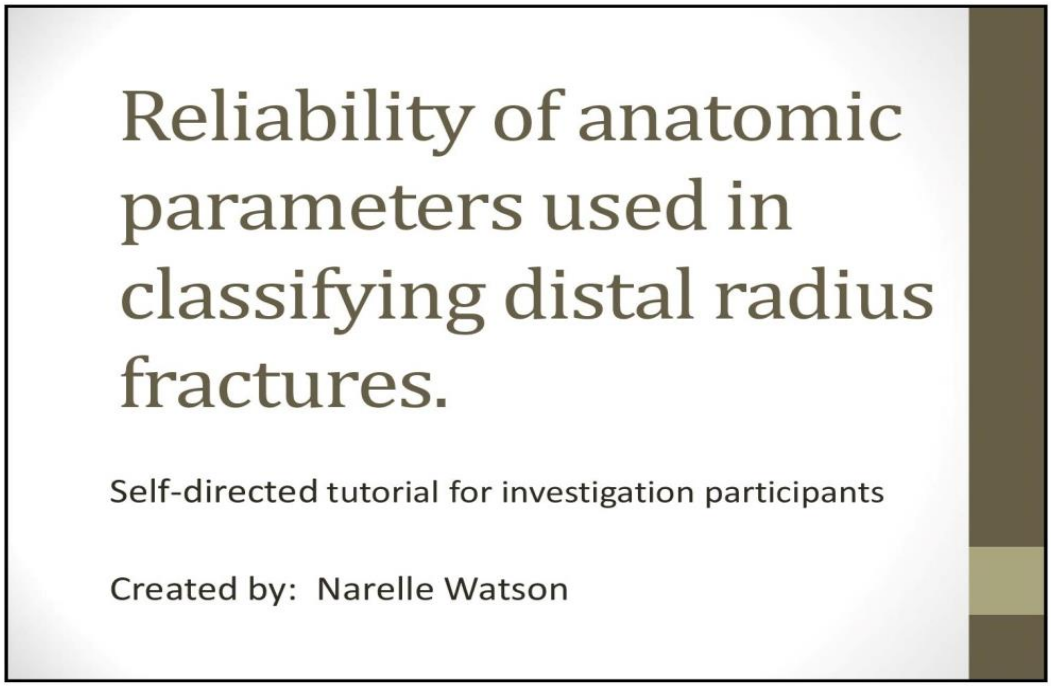
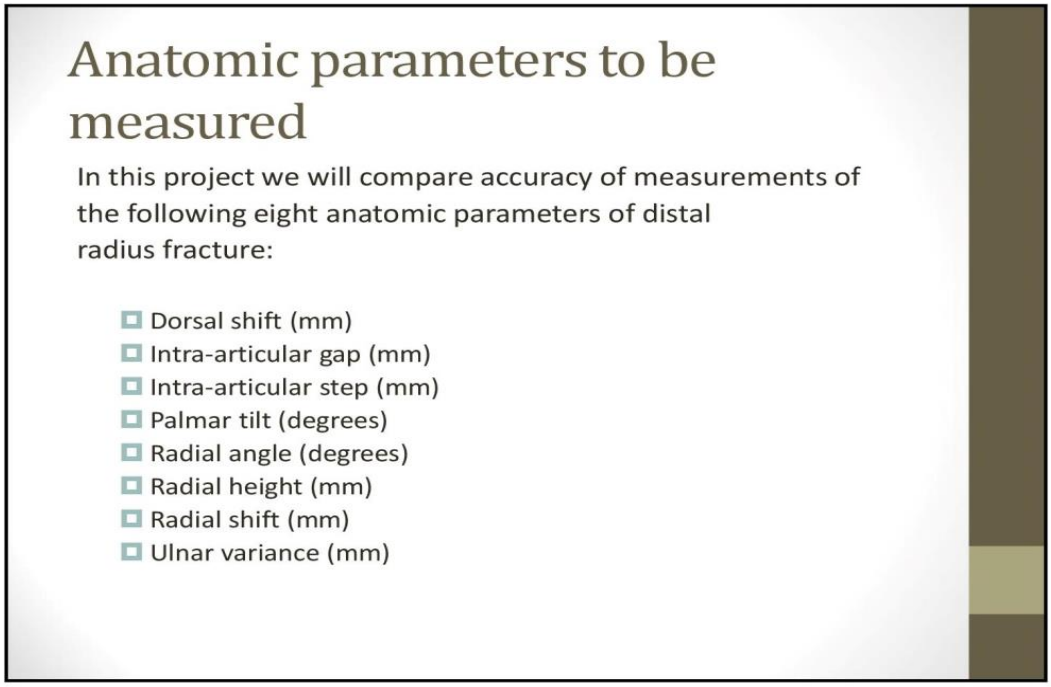
Appendix N. Observer training module on measurement of eight radiographic anatomical parameters of acute distal radius fractures.





X-ray views of the wrist

The 3 standard X-ray views of the wrist are:

- PA view
- Oblique view
- Lateral view

Only the PA and Lateral views are included in this investigation

Definitions

Knowledge of these definitions will assist measurement of the anatomical parameters.

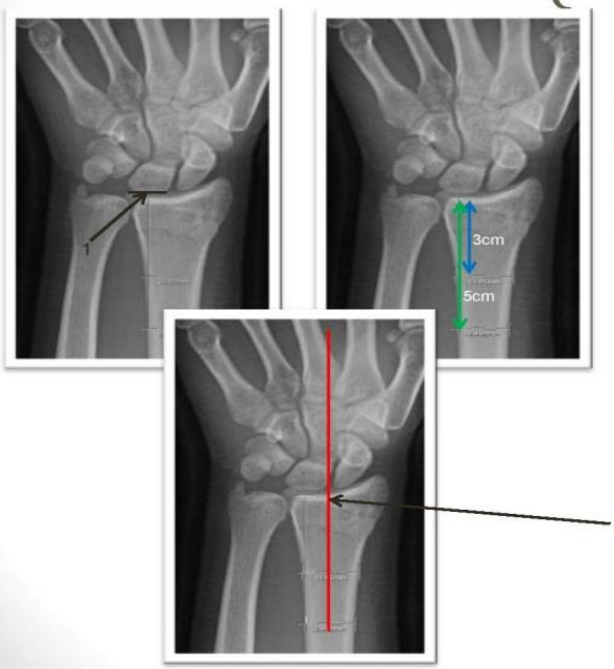
Sigmoid notch

- Is the part of distal radius that articulates with the ulnar head

Central point of reference

- Using the central point of reference circumvents orientation errors associated with locating the most distal point of the ulnar side of the radius given this may occur on either the volar or dorsal side given individual variations for the tilt of the radius.
- The central point of reference is found by bisecting a line drawn between the dorsal and volar corners of the sigmoid notch.

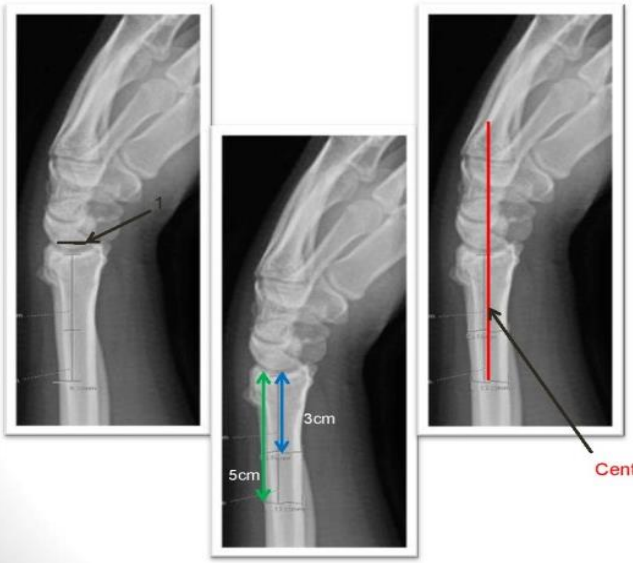
Definitions (continued)



Central long axis of the radius (PA view)

- This axis is determined by finding the mid point of the radius at the level of 3cm and 5cm below the mid-region of the proximal lunate articular surface (1) and extending the axis through these points

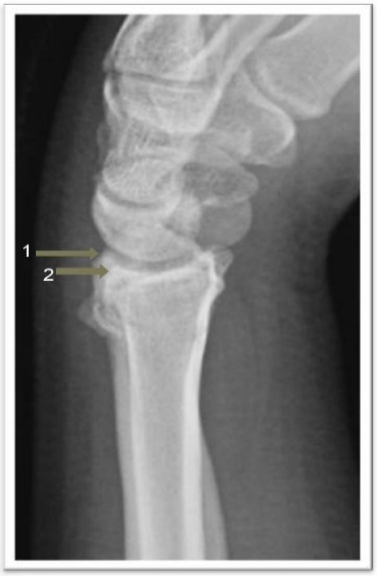
Definitions (continued)



Central long axis of the radius (lateral view)

- This axis is determined by finding the mid point of the radius at the level of 3cm and 5cm below the mid-region of the proximal lunate articular surface (1) and extending the axis through these points

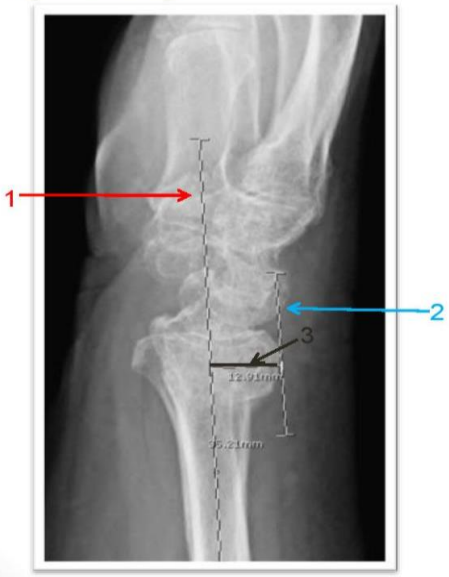
Clarification



Choice of landmarks

- Significant differences in measurements can occur as a result of the observer's choice of landmarks
- For the purpose of this investigation, the most distinct outer cortical margin (e.g. 2) will be always be used as the preferred reference point over less distinct cortical margins (e.g. 1) (including osteophyte margins)

Measurement of dorsal shift (mm)

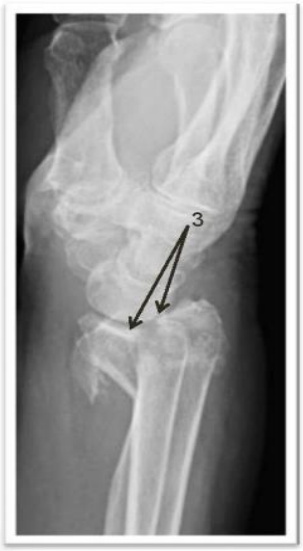


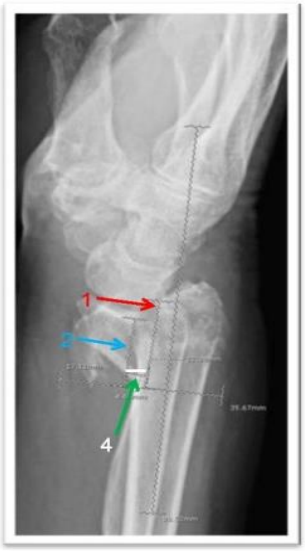
Dorsal shift (mm) is measured as the distance between the following 2 lines:

- Central long axis of the radius (1)
- A line parallel to the central long axis of the radius drawn tangential to the most dorsal point of the radial metaphysis (2)

In this example the dorsal shift (3) is 12.9mm.

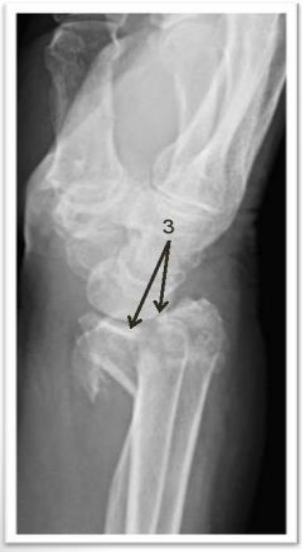
Measurement of intra-articular gap





- Intra-articular gap (mm) is more easily measured using the zoom function
- Intra-articular gap is the distance between lines parallel to the central long axis of the radius (1& 2) drawn from the most distal margins of each side of a cortical discontinuity (3)
- In this example the intra-articular gap (4) is 4.7mm

Measurement of intra-articular step (mm)



- Intra-articular step (mm) is more easily measured using the zoom function
- Intra-articular step (mm) is measured as the distance between peripendicular lines (1 & 2) to the central long axis of the radius drawn from the most distal margins of each side of a cortical discontinuity (3)
- In this example the intra-articular step (4) is 5.7mm

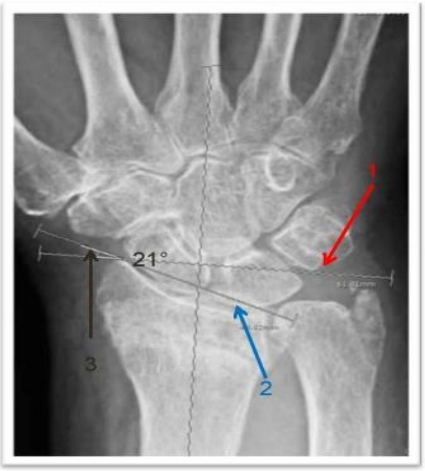
Measurement of palmar tilt (degrees)

Palmar tilt (degrees) is measured as the angle between the following 2 lines:

1. A line perpendicular to the central long axis of the radius drawn at a convenient level (1)
2. A line connecting the most distal dorsal and anterior margins of the distal radial articular surface (2)

In this example the palmar tilt (3) is minus 6 degrees given the tilt is in the dorsal direction

Measurement of radial angle (degrees)

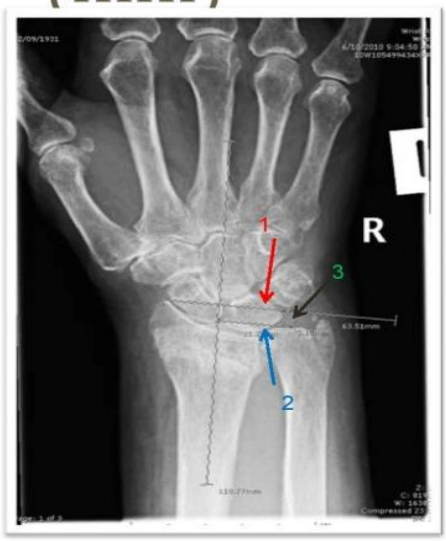


The radial angle (degrees) is measured as the angle between the following 2 lines:

1. A line perpendicular to the central long axis of the radius drawn at the level of the most distal aspect of the radial articular surface (1)
2. A line connecting the radial margin and the 'central point of reference' of the distal radial articular surface (2)

In this example the radial angle (3) is 21 degrees

Measurement of radial height (mm)



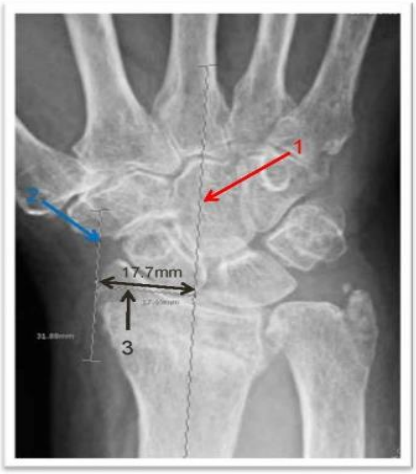
The radial height (mm) is measured as the distance between the following 2 lines:

1. A line perpendicular to the central long axis of the radius drawn at the level of the most distal aspect of the radial articular surface (1)

2. A line perpendicular to the central long axis of the radius drawn at the level of the distal ulnar articular surface (2)

In this example the radial height (3) is 5.1mm

Measurement of radial shift (mm)



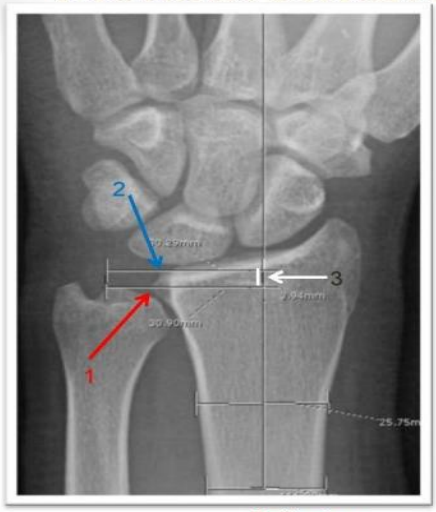
The radial shift (mm) is measured as the distance between the following 2 lines:

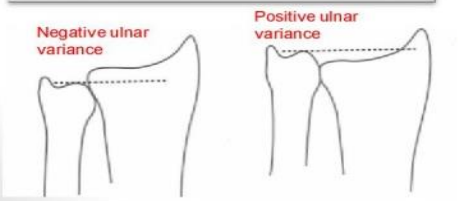
1. The central long axis of the radius (1)

2. A parallel line to the central long axis of the radius drawn tangential to the most radial point on the radial metaphysis (2)

In this example the radial shift (3) is 17.7 mm.

Measurement of ulnar variance (mm)





Ulnar variance (mm) is measured as the distance between the following 2 lines:

1. A line perpendicular to the long axis of the radius drawn at the level of the distal ulnar articular surface (1)

2. A line perpendicular to the long axis of the radius drawn at the level of the 'central point of reference' of the distal radial articular surface (2)

In this example the ulnar variance negative 3.9mm (3)

Ulnar varirance is negative when:

- The ulnar articular surface is situated below the level of the 'central point of reference'

Ulnar variance is positive when:

- The ulnar articular surface is situated above the 'central point of reference'

Appendix O. Example participant feedback following tutorial measurements of eight radiographic anatomical parameters of acute distal radius fracture

Measurement	Adequate measurement technique (Yes/No)	Comments
Central long axis of the radius (PA view)	No	The centre of the radial shaft is determined at 3cm and 5cm below the mid-region of the proximal lunate articular surface. Your measurement is starting at the lunate itself and it should start at the radial articular surface just below the mid-point of the lunate (refer to figures in tutorial instructions for example).
Central long axis of the radius (lateral view)	No	As above.
Dorsal shift	Yes	None.
Intra-articular gap	Yes	None
Intra-articular step	Yes	None
Palmar tilt	Yes	None
Radial angle	Yes	None
Radial height	Yes for radiograph series 1. No for radiograph series 2 & 3	Please check that you are measuring radial height as the distance between the most distal aspect of the radial articular surface and the distal ulnar articular surface not the central point of reference. The measurement technique is correct in the first radiograph series, however, you changed to using the central point of reference in radiograph series 2 and 3.
Radial shift	Yes	None
Ulnar variance	Yes	None

Appendix P. Interview questions relevant to patient experiences following fracture

1. **What were you doing at the time of your wrist injury?**
2. **Let's talk about all stages following your injury:**
   a) Did you feel that you were given the information you needed in time? If no, what would have been better?
   b) Were you usually provided with an opportunity to ask questions? If no, are you able to provide some examples of when you wanted to ask questions but felt that this was not possible?
   c) Were your family involved?
   d) Is there anything more you feel the health professionals could have done to support you through the time you spent in hospital or your recovery period after leaving hospital?
3. **Let's talk about your cast:**
   a) How did you feel about your cast being removed and the timing of this?
   b) What were you able to do with your cast on?
   c) What kind of things couldn't you do?
   d) While the cast was on, were you restricted in any way with your usual life roles?
   e) What changed when the cast was removed?
   f) Were you able to do more once the cast was removed and if so, what types of tasks?
   g) Are you now able to use the affected arm for all your usual daily tasks? If no, what tasks are you currently unable to perform?
   h) How long did it take before you felt comfortable using your affected arm for your usual daily tasks?
   i) Do you currently work and if so, how long were your unable to work following your wrist injury?
4. **Let's talk about the impact your wrist injury had on your family:**
   a) How do you feel the injury affected your family?
   b) Is there any other information that health professionals could have given you and your family to reduce the impact on your family? If so, what would that be?
5. **Let's discuss your pain levels:**
   a) Do you feel your pain levels were well managed? If not, please outline how you think this could have been improved.
   b) Please discuss how you feel your pain in the affected upper limb impacted on your recovery.
6. **Are satisfied with how your wrist has recovered from this injury and the surgery?** Please discuss any areas you are particularly satisfied or dissatisfied with.
7. **Are you back doing all the tasks you did prior to your surgery?** If not, what are you unable to do and why do you feel you can't?
8. **Are there any other comments that you would like to make about the care you received, things that helped or were unhelpful and things you would like to see changed if this happened to you again?**

Appendix Q. Interview debrief form used in qualitative investigations

Distal Radius Fracture RCT Interview Debrief Form

Audio recorder file number:
Date:
Completed by:

1. What were the main issues or themes that emerged from this interview?
2. What new information did you gain through this interview?
3. What new questions emerged for you as a result of this interview?
4. Anything else that was salient, interesting, illuminating, curious or important during this interview?
5. What new or remaining concerns, inconsistencies, or challenges emerged during this interview?
6. How would you describe the general atmosphere of the interview?
7. Overall, how would you describe the non-verbal communication?
8. What did you observe that would not be evident from reading a transcript of the interview?
9. What problems did you encounter (e.g. logistical, behaviour of the individual, questions that were confusing etc.)?

Appendix R. Human Research Ethics Committee ethical approval documentation

[redacted]

OFFICE FOR RESEARCH

MELBOURNE HEALTH

MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL OF A RESEARCH PROJECT

Ms Narelle Watson
Footscray Hospital
Physiotherapy Department
Western Health
FOOTSCRAY VIC 3011

3rd April 2012

Dear Ms Watson,

MH Project Number: 2011.255

Project Title: A randomised controlled trial investigating the effect of duration of immobilisation on function following open reduction and internal fixation for distal radius fracture in adults

HREC Approval Date: 3rd April 2012

I am pleased to advise that the above project has received ethical approval.

Participating Sites:

- Western Hospital – Western Health

Approved Documents:

- Protocol Version 2 dated February 2012
- Western Health Participant Information and Consent Form Version 2 dated 12th February 2012
- Diagnostic Medical Physics Assessment – Western Health
- Disabilities of the Arm, Shoulder and Hand (DASH) Questionnaire dated 2006
- Patient Rated Wrist Evaluation dated 1996

Site Specific Assessment:

Please note: Please forward this HREC approval certificate to the Director of Research at Western Health together with your Research Governance-Site Specific Assessment application. You cannot commence this study until you have completed all the requirements of the Site Specific Assessment and have received written approval to conduct your research project at Western Health.

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.

HREC Approval Of New Project (non SERP) - Western Health *Page 1 of 2*

Conditions of Ethics Approval:

In order to comply with the National Statement on Ethical Conduct in Human Research 2007, Guidelines for Good Clinical Research Practice and Melbourne Health Research Policies and Guidelines you are required to:

- Submit a copy of this letter to the Radiation Safety Officer (RSO) at Western Health, for addition of the project to the Licence for Research Involving Human Volunteers held by the Department of Human Services Radiation Safety Section Radiation Safety Licence (if your project involves exposure to ionising radiation). Note: You cannot commence the project until you have received notification from the RSO that the project has been added to the Licence;
- Notify the HREC of the actual start date of the project;
- *Submit to the HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure;*
- *Notify the HREC of any adverse events in accordance with the Melbourne Health Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009;*
- *Notify the HREC of any unforseen events;*
- *Notify the HREC of your inability to continue as Principal Investigator or any other change in research personnel involved in the project;*
- *Notify the HREC if a decision is taken to end the study prior to the expected date of completion or failure to commence the study within 12 months of the HREC approval date;*
- *Notify the HREC of any other matters which may impact the conduct of the project.*

Reporting

You are required to submit to the HREC:

- *An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report in a timely manner; and*
- *A comprehensive Final Report upon completion of the project.*

The HREC may conduct an audit of the project at any time.

Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health:
http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

A list of those HREC members present at the review of this project can be obtained from the above website.

Yours sincerely,

[redacted]

Ms. Angela Gray
Manager, Melbourne Health Human Research Ethics Committee

[redacted]

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**20 April 2012**
Project Number:	**2012000502**
Project Title:	**A randomised controlled trial investigating the effect of duration of immobilisation on function following open reduction and internal fixation for distal radius fractures in adults**
Chief Investigator:	**Prof Jenny Keating**
Approved:	**From: 20 April 2012 To: 20 April 2017**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research**.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. **Complaints:** The researchers are required to inform MUHREC promptly of any complaints made about the project, whether the complaint was made directly to a member of the research team or to the primary HREC.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Mrs Narelle Watson

[redacted]

Western Health

[redacted]

APPROVAL TO CONDUCT A RESEARCH PROJECT AT WESTERN HEALTH
SITE SPECIFIC ASSESSMENT (SSA) AUTHORISATION

12 April 2012

Mrs Narelle Watson
Coordinator Advanced Practice, Allied Health (Grade 4 Physiotherapist), Western and Sunshine Hospitals
Western Health
Western Hospital Footscray
Gordon Street
Footscray, VIC 3011

Dear Mrs Watson,

MH Local Number: 2011.255

HREC Reference Number: HREC/11/MH/375

Project Title: A randomised controlled trial investigating the effect of duration of immobilisation on function following open reduction and internal fixation for distal radius fractures in adults.

SSA Approval Date: 12 April 2012

HREC Approval Date: 03 April 2012

Site(s) Approved: Sunshine Hospital and Western Hospital

I am pleased to advise that the above project is approved to be conducted at Western Health. This approval is subject to compliance with any conditions imposed by the reviewing HREC.

Approved Documents:

Document	*Version*	*Date*
SSA Application	1.0(2009)	02 December
HREC Approval Letter		03 April 2012
Ethics Application: NEAF		
Victorian-Specific Module		23 November 2011
Protocol: Project proposal	2	February 2012
Site Specific Participant Information sheet and Consent form	2	12 February 2012
Disabilities of the arm shoulder and hand (DASH) Questionnaire – Institute for work and Health		2006

SSA Approval no RSO template version August 2011
www.westernhealth.org.au

Patient Rated Wrist Evaluation		1996
Diagnostic Medical Physics Assessment signed by Paul Einsiedel		24 November 2011
CV of researcher: Narelle Watson	1	06 December 2011
CV of researcher : Jennifer Keating	1	17 January 2012

You are required to notify the Office for Research of:

1. The actual start date of the project at Western Health.
2. Any amendments to the project after these have been approved by the reviewing HREC.
3. Any adverse events or unforeseen events that require reporting to the reviewing HREC and involve Western Health Participants.
4. Any changes to the indemnity, insurance arrangements or Clinical Trial Research Agreement for this project. This includes changes to the project budget or other changes which may have financial or other resource implications for Western Health.
5. Your inability to continue as Principal Investigator or any other change in research personnel involved in the project.
6. Any other matters which may impact the conduct of the project at Western Health.

You are also required to submit to the Office for Research:

1. An Annual Progress Report every 12 months for the duration of the project. This report is due on the anniversary of HREC approval. Ongoing approval for the project is contingent upon receipt of this report.
2. A comprehensive Final Report upon completion of the project.

The Office for Research may conduct an audit of the project at any time.

The Office for Research Western Health wishes you and your colleagues every success in your research.

Yours sincerely,

[redacted]

Dr Tam C. Nguyen PhD
Manager
Office for Research –Western Health
[redacted]

[redacted]

OFFICE FOR RESEARCH

MELBOURNE HEALTH

MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE
- ETHICAL APPROVAL OF A RESEARCH PROJECT

Ms Narelle Watson
Coordinator Advance Practice
Physiotherapy Department
Footscray Hospital
Footscray VIC 3011

09 June 2010

Dear Ms Watson,

MH Project Number: 2010.113

Project Title: Inter- and intra-observer reliability of anatomic parameters of radiographs that are used in classifying distal radius fractures in adults

HREC Approval Date: 07 June 2010

I am pleased to advise that the above project has received ethical approval.

Participating Sites:

- Footscray Hospital, Western Health.

Approved Documents:

- Project Proposal
- Western Health Participant Information and Consent Form Version 2 dated 20th May 2010.

Site Specific Assessment:

Please note: You cannot commence this study until you have completed all the requirements of the Site Specific Assessment and have received the "Approval to Conduct a Research Project at Melbourne Health" certificate.

Conditions of Ethics Approval:

In order to comply with the National Statement on Ethical Conduct in Human Research 2007, Guidelines for Good Clinical Research Practice and Melbourne Health Research Policies and Guidelines you are required to:

- Submit a copy of this letter to the Radiation Safety Officer (RSO) at Melbourne Health, for addition of the project to the Licence for Research Involving Human Volunteers held by the Department of Human Services Radiation Safety Section Radiation Safety Licence (if your project involves exposure to ionising radiation). Note: You cannot commence the project until you have received notification from the RSO that the project has been added to the Licence;
- Notify the HREC of the actual start date of the project;
- Submit to the HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure;

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.

HREC Approval Of New Project (non SERP) template version 03_06_2010

- Notify the HREC of any adverse events in accordance with the Melbourne Health *Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009;*
- Notify the HREC of any unforseen events;
- Notify the HREC of your inability to continue as Principal Investigator or any other change in research personnel involved in the project;
- Notify the HREC if a decision is taken to end the study prior to the expected date of completion or failure to commence the study within 12 months of the HREC approval date;
- Notify the HREC of any other matters which may impact the conduct of the project.

Reporting

You are required to submit to the HREC:

- An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report in a timely manner; and
- A comprehensive Final Report upon completion of the project.

The HREC may conduct an audit of the project at any time.

Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health: http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

A list of those HREC members present at the review of this project can be obtained from the above website.

Yours sincerely,

[redacted]

Ms. Angela Gray
Manager, Melbourne Health Human Research Ethics Committee

[redacted]

The Melbourne Health HREC operates and is constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007.

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**6 September 2010**
Project Number:	**CF10/2330 - 2010001327**
Project Title:	**Inter and intra-observer reliability of anatomic parameters of radiographs that are used in classifying distal radius fractures in adults**
Chief Investigator:	**Prof Jenny Keating**
Approved:	**From: 6 September 2010 to 6 September 2015**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research**.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

Cc: Ms Narelle Watson

[redacted]

Peninsula Health

PO Box 52
Frankston Victoria 3199 Australia
Telephone 03 9784 7777

2007
PREMIER'S AWARD
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HEALTH SERVICE

HUMAN RESEARCH & ETHICS COMMITTEE
RESEARCH APPLICATION
FULL APPROVAL

RESEARCH PROGRAM

HUMAN RESEARCH & ETHICS COMMITTEE SECRETARIAT

[redacted]

25 June 2010

Ms Narelle Watson
Physiotherapy Department
Footscray Hospital
Western Health
Footscray Vic 3011

Dear Ms Watson

TRIAL: HREC/10/22
TITLE: Inter- and intra-observer reliability of anatomic parameters of radiographs that are used in classifying distal radius fractures in adults.

Thank you for submitting the above project which was first considered by the Peninsula Health Human Research and Ethics Committee (HREC) on 5th May 2010 in accordance with the National Statement on Ethical Conduct in Human Research (2007). Following review of requested amendments I am please to advise that full approval to commence has now been granted.

The documents reviewed and approved include:

Application (NEAF):	AU/17608/26511/1/590
Application (SSA):	AU/17608/25489/5/707/27520/8041
Participant Information and Consent Form:	Version 2: 20 June 2010
Project Proposal:	Received 15 April 2010

Please note the following requirements of the Peninsula Health HREC:

1. The principal investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
   - any serious or unexpected adverse events
   - unforeseen events that might affect continued ethical acceptability of the project.

2. Proposed changes to the research protocol, conduct of the research, or research completion date will be provided to the HREC for review in the specified format.

3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. The principal investigator will provide an annual report to the HREC and at completion of the study a final report, in the specified format.

Frankston Hospital • Rosebud Hospital • Psychiatric Services • Aged Care, Rehabilitation & Palliative Care Services • Primary and Community Health

www.peninsulahealth.org.au

At Peninsula Health we value:
Service Integrity Compassion Respect Excellence Professionalism

Peninsula Health

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HEALTH SERVICE

Should you have any queries about the HREC's consideration of your project please contact Ms Lee-Anne Clavarino, Manager, Research Program. Details of review processes and guidelines are available on the Peninsula Health website http://www.peninsulahealth.org.au/humanresearchandethicscommittee or http://www.phcn.vic.gov.au/departments/research/HREC/.

Please quote the Peninsula Health Project Number in all correspondence.

The Committee wishes you every success in your research

Yours sincerely

[redacted]

Dr Susan Sdrinis
Executive Director Medical Services
and Quality and Clinical Governance

Executive Sponsor
Research

Frankston Hospital

•

Rosebud Hospital

•

Psychiatric Services

•

Aged Care, Rehabilitation & Palliative Care Services

•

Primary and Community Health

www.peninsulahealth.org.au

At Peninsula Health we value:
Service Integrity Compassion Respect Excellence Professionalism

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**20 April 2012**
Project Number:	**2012000492**
Project Title:	**Inter- and intra-observer reliability of wrist and forearm active range of motion measurements using a goniometer in adults following distal radius fracture**
Chief Investigator:	**Prof Jenny Keating**
Approved:	**From: 20 April 2012 To: 20 April 2017**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research**.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. **Complaints:** The researchers are required to inform MUHREC promptly of any complaints made about the project, whether the complaint was made directly to a member of the research team or to the primary HREC.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Mrs Narelle Watson

[redacted]

Western Health

Office for Research

[redacted]

WESTERN HEALTH LOW RISK HUMAN RESEARCH ETHICS PANEL
APPROVAL TO CONDUCT RESEARCH AND
SITE SPECIFIC ASSESSMENT (SSA) AUTHORISATION

03 April 2012

Mrs Narelle Watson
Coordinator Advanced Practice
Allied Health
Western Health

Dear Mrs Watson,

HREC Project Number: HREC/12/WH/28

Project Title: Inter- and intra-observer reliability of wrist and forearm active range of motion measurements using a goniometer in adults following distal radius fracture.

HREC Approval Date: 30 March 2012

SSA Approval Date: 30 March 2012

Site(S) Approved: Western Hospital

I am pleased to advise that the above project has been given ethics approval by the Western Health Low Risk Ethics Panel.

This project has also been issued with site specific approval to be conducted at Western Health.

Approved Documents:

- NEAF version 20. (2008) dated 28 March 2012
- Victorian Specific module version July 2011 dated 04 March 2012
- Site Specific Form
- Patient information consent form version1 dated 26 February 2012
- Patient information consent form Physiotherapist Observer version1 dated 26 February 2012
- Protocol version 2.0 dated February 2012
- Statement of Approval Language Services Department dated 02 March 2012
- Statement of Approval Physiotherapy Department dated 02 March 2012
- Statement of Approval Orthopaedic Department dated 02 March 2012
- Statement of Approval Western Hospital Outpatient Department dated 02 March 2012

You are required to notify the Office for Research of:

1. The actual start date of the project at Western Health.
2. Any unforeseen events.
3. Your inability to continue as Principal Investigator or any other change in research personnel involved in the project.
4. Any other matters which may impact the conduct of the project at Western Health.

You are also required to submit to the Office for Research:

1. Any proposed amendments to the project including any proposed changes to the Protocol and the Patient Information and Consent Form for review by the Panel.
2. An Annual Progress Report every 12 months for the duration of the project. This report is due on the anniversary of this approval. Ongoing approval for the project is contingent upon receipt of this report.
3. A comprehensive Final Report upon completion of the project.

The Office for Research may conduct an audit of the project at any time.

The Office for Research Western Health wishes you and your colleagues every success in your research.

Yours sincerely,

[redacted]

Dr Tam C. Nguyen PhD
Manager, Office for Research Western Health