The Effectiveness of Hand Splinting to Prevent Muscle Contracture Following Acquired Brain Impairment

N.A. Lannin
Doctorate of Philosophy
2006
University of Western Sydney
Acknowledgements

I owe so much to my supervisors, Professor Anne Cusick, Dr Annie McCluskey, and Dr Robert Herbert who have been the ‘godfathers’ of this research from its beginning. Their sympathetic encouragement and good judgement have both inspired me and steadied the project from start to finish and their acceptance of this thesis is its best recommendation.

I am grateful to the participants who took part in the trials. Your commitment and enthusiasm encourages me still. Thank you.

I wish to express my appreciation to my colleagues for their assistance during the clinical trials. In particular I would like to recognise the roles of Sally Horsley during Study 2 and of Rachael McQueen, Belinda Armstrong, Annemieke Clark, Nadia Downey, Merilyn Ferris, Glade Vyslysel, Michelle Turnbull, Valerie Webster, Melani Boyce, Joanne Glinsky, Jan Hancock, Jenni Johnson, Alison Pearce, Natalie Fairbairn and Lauren Wade during Study 3. I thank them for their commitment and professionalism during their involvement with this project.

The financial assistance of a University of Western Sydney Postgraduate Research Award towards this research is hereby acknowledged. Financial support for the studies was also provided through part-time employment during my candidature by the Dean’s Unit (College of Health and Science) and the School of Exercise and Health Science, University of Western Sydney, and by the School of Physiotherapy, University of Sydney.

The faculties of the School of Exercise and Health Science at University of Western Sydney and the School of Physiotherapy at University of Sydney, and my colleagues have provided ongoing interest and support throughout this project. I thank them for helping place this work in context and their generosity with time. A special word of thanks must go to Julia Bowman for her friendship and practical assistance throughout this journey.

Finally, I acknowledge the ongoing support of my family; thank you for encouraging me through all my academic efforts. This is the culmination. Thank you seems inadequate, however, to show my appreciation for my husband, Ben, for the advice he gave me on points about which I consulted him, for allowing me to spend countless hours in the office, and for never doubting that the end was in sight.
Statement of Authentication

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material, either in full or in part, for a degree at this or any other institution.

(Signature)
# Table of Contents

**Chapter One: Introduction** ........................................................................................................................................ 1
  1.1 Background ...................................................................................................................................................... 2
  1.2 Context of the Study ........................................................................................................................................... 2
  1.3 Research Aims and Objectives .......................................................................................................................... 6
  1.4 Scope of the Study .............................................................................................................................................. 8
  1.5 Definition of Terms ........................................................................................................................................... 9
  1.6 Synopsis ........................................................................................................................................................... 13

**Chapter Two: Literature Review** .......................................................................................................................... 15
  2.1 Introduction ....................................................................................................................................................... 16
  2.2 Adults with Acquired Brain Impairment ........................................................................................................... 17
  2.3 Neuromusculoskeletal changes after acquired brain impairment ................................................................. 18
  2.4 The Wrist ......................................................................................................................................................... 22
  2.5 Occupational Therapy for adults with contracture following acquired brain impairment ................................ 23
  2.6 The Prevention of Contracture ......................................................................................................................... 28
  2.7 Measurement Issues ........................................................................................................................................ 43
  2.8 Key Issues to Emerge from the Literature Review ........................................................................................... 53
  2.9 Synopsis ........................................................................................................................................................... 57

**Chapter Three: A Systematic Review** .................................................................................................................... 58
  3.1 Chapter Overview ............................................................................................................................................... 59
  3.2 Background to the Study ................................................................................................................................... 59
  3.3 Rationale for the Study Design .......................................................................................................................... 61
  3.4 Aim of the Study ................................................................................................................................................ 62
  3.5 Method .............................................................................................................................................................. 62
  3.6 Results ............................................................................................................................................................. 69
  3.7 Discussion ........................................................................................................................................................ 71
  3.8 Synopsis ........................................................................................................................................................... 76

**Chapter Four: A Randomised Controlled Trial Comparing Splinting plus Stretch to Stretch Alone in Adults with Hemiplegia following Acquired Brain Impairment** ........................................................................................................... 82
  4.1 Chapter Overview ............................................................................................................................................... 83
  4.2 Background ....................................................................................................................................................... 83
  4.3 Description and Rationale for Study Design ..................................................................................................... 84
  4.4 Aim ................................................................................................................................................................. 85
  4.5 Research Question .......................................................................................................................................... 85
  4.6 Method ........................................................................................................................................................... 85
  4.7 Results ............................................................................................................................................................ 96
  4.8 Discussion ....................................................................................................................................................... 103
  4.9 Conclusion from the Study ............................................................................................................................... 109
  4.10 Synopsis ........................................................................................................................................................ 109
Chapter Five: Effectiveness of two types of hand splints for preventing contractures in adults who are not receiving hand stretches post-stroke: a single blind, randomised controlled trial

5.1 Chapter Overview
5.2 Background
5.3 Aim
5.4 Research Questions
5.5 Description and Rationale for Study Design
5.6 Method
5.7 Results
5.8 Discussion
5.9 Conclusion
5.10 Synopsis

Chapter Six: Discussion

6.1 Introduction
6.2 Key Findings
6.3 Strengths and Limitations
6.4 Recommendations and Implications
6.5 Conclusion

References

Appendices
List of Tables

Table 3.1  Electronic search strategy ................................................................. 63
Table 3.2  Oxford Centre for Evidence-Based Medicine levels of evidence ........ 65
Table 3.3  PEDro scoring criteria and implementation guidelines .................... 68
Table 3.4  Methodological rating of randomised controlled trials ....................... 70
Table 3.5  Summary of studies – interventions and participants ....................... 78
Table 3.6  Summary of studies – research methods ............................................. 80
Table 4.1  Upper Limb Subscale of the Motor Assessment Scale (UL-MAS) item 6, 7 and 8 ........................................................................................................ 95
Table 4.2  Baseline characteristics ........................................................................ 97
Table 4.3  Numbers of participants in each group who did not adhere to the protocol ........................................................................................................ 99
Table 4.4  Baseline performance of groups on dependent variables ................. 99
Table 4.5  Compliance with splinting program .................................................... 103
Table 5.1  Baseline characteristics of groups ....................................................... 130
Table 5.2  Baseline performance of groups on dependent variables .................. 133
Table 5.3  Numbers of participants in each group who did not adhere to the protocol ........................................................................................................ 134
Table 5.4  Compliance with splinting protocol .................................................... 139
**Figures and Illustrations**

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Wrist splint illustrating three points of pressure</td>
<td>39</td>
</tr>
<tr>
<td>2.2</td>
<td>Static Palmar-Mitt Splint</td>
<td>40</td>
</tr>
<tr>
<td>2.3</td>
<td>Device used to measure extensibility of the long finger flexor muscles</td>
<td>46</td>
</tr>
<tr>
<td>4.1</td>
<td>A seated weight-bearing stretch of the upper limb</td>
<td>89</td>
</tr>
<tr>
<td>4.2</td>
<td>A seated stretch of the upper limb demonstrating the use of an air splint</td>
<td>90</td>
</tr>
<tr>
<td>4.3</td>
<td>Static palmar-mitt splint with the wrist and fingers positioned in the ‘functional position’</td>
<td>91</td>
</tr>
<tr>
<td>4.4</td>
<td>Participant flow diagram</td>
<td>100</td>
</tr>
<tr>
<td>4.5</td>
<td>Mean (95% confidence intervals) of differences between torque-controlled wrist extension range of motion of the splint and control groups</td>
<td>101</td>
</tr>
<tr>
<td>5.1</td>
<td>Static palmar-mitt splint which positioned the wrist and fingers in the ‘functional position’</td>
<td>119</td>
</tr>
<tr>
<td>5.2</td>
<td>Static palmar-mitt splint with the wrist and fingers positioned in extension</td>
<td>120</td>
</tr>
<tr>
<td>5.3</td>
<td>Participant flow diagram</td>
<td>132</td>
</tr>
<tr>
<td>5.4</td>
<td>Mean (95% Confidence Interval) of differences between torque-controlled wrist extension range of motion of the control, functional splint and extension splint groups</td>
<td>135</td>
</tr>
</tbody>
</table>
## Abbreviations

<table>
<thead>
<tr>
<th>Acronym/Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAOS</td>
<td>American Academy of Orthopedic Surgery</td>
</tr>
<tr>
<td>ANCOVA</td>
<td>Analysis of Covariance</td>
</tr>
<tr>
<td>CEBP</td>
<td>Centre for Evidence Based Physiotherapy</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>cm</td>
<td>Centimetre</td>
</tr>
<tr>
<td>CVA</td>
<td>Cerebrovascular Accident; stroke</td>
</tr>
<tr>
<td>DASH</td>
<td>Disabilities of the Arm, Shoulder, and Hand Questionnaire</td>
</tr>
<tr>
<td>FMA</td>
<td>Fugl-Meyer Assessment</td>
</tr>
<tr>
<td>ICC</td>
<td>Intraclass Correlation Coefficient</td>
</tr>
<tr>
<td>ICIDH</td>
<td>International Classification of Impairments, Disabilities and Handicaps</td>
</tr>
<tr>
<td>LOCF</td>
<td>Last observation carried forward</td>
</tr>
<tr>
<td>MAS</td>
<td>Motor Assessment Scale</td>
</tr>
<tr>
<td>MMSE</td>
<td>Mini Mental State Examination</td>
</tr>
<tr>
<td>n</td>
<td>Number (sample size)</td>
</tr>
<tr>
<td>OT Australia</td>
<td>Australian occupational therapy professional association</td>
</tr>
<tr>
<td>OTA</td>
<td>American Occupational Therapy Association</td>
</tr>
<tr>
<td>p</td>
<td>Probability</td>
</tr>
<tr>
<td>PEDro</td>
<td>Physiotherapy Evidence Database</td>
</tr>
<tr>
<td>r</td>
<td>Pearson’s product-moment correlation coefficient</td>
</tr>
<tr>
<td>ROM</td>
<td>Range of Motion</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>UL-MAS</td>
<td>Upper Limb subscale of Motor Assessment Scale</td>
</tr>
<tr>
<td>US</td>
<td>United States of America</td>
</tr>
</tbody>
</table>
Abstract

**Aim:** The aim of the thesis was to evaluate the effectiveness of static hand splints for the prevention of muscle contracture during early rehabilitation following acquired brain impairment. **Design:** Three studies were undertaken and are reported in this thesis. The aim of the first study was to appraise the existing research on the effects of hand splinting for adults with hemiplegia following acquired brain impairment. A systematic review and methodological critique of published scientific literature were conducted. The aim of the second study was to evaluate the effectiveness of static hand splints which position the wrist and fingers in the common ‘functional position’ when provided in conjunction with a rehabilitation program which included daily motor training and prolonged stretches. This study was an assessor-blinded randomised controlled trial. Study 3 was also an assessor-blinded randomised trial. The aim of the final study was to evaluate the effectiveness of two hand splinting positions, the ‘functional position’ and a position of wrist and finger extension, in comparison to a control group that did not receive prolonged stretches. **Setting:** Studies two and three were conducted in inpatient rehabilitation centres in Australia. **Participants:** In the second study, 28 adults who had hemiplegia following acquired brain impairment were randomly allocated to receive either a static palmar hand splint which positioned their wrist in a ‘functional position’, or the control group. Both groups in Study 2 received one hour of upper limb stretches and approximately 30 minutes of upper limb motor training five days per week. In the third study, 63 adults with hemiplegia following stroke were randomly allocated to receive a hand splint which positioned their wrist and fingers in either a ‘functional position’ or with their wrist and fingers in an extended position, or to be in the control group. In Study 3, none of the groups received prolonged stretches to their wrist or finger flexor muscles for the duration of the study. **Outcome measures:** The primary outcome across both randomised controlled trials
(studies two and three) was extensibility of the wrist and finger flexor muscles as estimated by torque-controlled range of movement of the wrist joint with the fingers held in extension. A device designed to measure extensibility of the wrist and finger flexor muscles was used in both studies. Secondary outcome measures included the upper limb subscale of the Motor Assessment Scale (UL-MAS), visual analogue scale of pain, the Tardieu scale, and the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire. **Results:** The results of the systematic review indicated that there were no randomised controlled trials which investigated the effect of static hand splints on the prevention of contracture in the finger and wrist flexor muscles, and that the majority of evidence to date has been of low quality. Study 2, a randomised controlled trial, indicated that wearing a hand splint in addition to participating in upper limb stretches and motor training for four weeks did not improve wrist extensibility. Compared to the control group (stretch alone), wearing the splint increased wrist extension by a mean of 1.0° (95% CI -3.7° to 6.1°). Study 3, also a randomised controlled trial, indicated that wearing a hand splint with the wrist and fingers in either the ‘functional position’ or maximum extension for four weeks did not improve wrist extensibility. Compared to the control group (no stretch), wearing the ‘functional’ splint increased wrist extension by a mean of 1.5° (95% CI -5.7° to 8.7°); and wearing the extension splint reduced wrist extension by a mean of 2.5° (95% CI -9.6° to 4.6°).

**Conclusion:** Findings indicate that splinting the hand in the ‘functional’ position or in a position of greater wrist extension did not prevent contracture following acquired brain impairment over the course of the study periods (four weeks with follow up at 4 and 6 weeks in studies 2 and 3 respectively).
CHAPTER ONE

Introduction
Chapter One: Introduction

1.1 Background

Hand splints are often used to provide a stretch to hemiplegic muscles, however therapists disagree about the value of providing this intervention. What little research is available represents low-level evidence which cannot answer the question of whether or not splints are worthwhile. This research was motivated by a desire to evaluate the efficacy of hand splinting after brain impairment.

1.2 Context of the Study

Acquired brain impairment is one of a number of terms used to describe impairment due to injury to the brain (Collins & Dean, 2002; Stanton, Jessop, & Henstridge, 1994). Acquired brain impairment caused by a stroke or injury and may lead to a range of disabilities, one of the most common being loss of hand and arm movement (Scottish Intercollegiate Guidelines Network, 2002). Some recovery of movement typically occurs in people who survive acquired brain impairment, but often the secondary complication of muscle contracture (Gracies, 2001) limits rehabilitation and reduces functional outcomes.

Both the Commonwealth Department of Health (Priorities and Quality Branch Commonwealth Department of Health and Ageing, 2002) and the World Health Organisation (1982) have highlighted a growing concern about the management of adults with acquired brain impairment. One particular area of concern is the use of allied health treatments to address hemiplegia (National Health and Medical Research Council, 2000). Approximately 70 to 85% of people with acquired brain impairment experience hemiplegia
(Sivenius, 1982; Kotila, Waltimo, Niemi, Laaksonen, & Lempinen, 1986) and this proportion is higher among the elderly (Kalra, Smith, & Crome, 1993). An estimated 48 to 95% of people never regain functional arm or hand use as a result of hemiplegia (Gowland, 1982; Mayo et al., 1999). This loss of hand use is particularly devastating as everyday activities of life become uniquely challenging.

The scientific literature on management of hemiplegia is inconclusive and provides limited guidance for practice (Dobkin, 1989; Dromerick, 2003; Jutai & Teasell, 2003; Kwakkel, Wagenaar, Koelman, Lankhorst, & Koetsier, 1997; Scottish Intercollegiate Guidelines Network, 2002). Existing studies also lack the statistical power needed to guide clinical practice (for example, when deciding whether or not to as splint the hemiplegic hand). Research reported in this thesis was undertaken to address this gap in knowledge. In particular, research was planned which would examine the efficacy of common interventions used during rehabilitation to mitigate finger and wrist contractures after brain impairment.

1.2.1 Contractures Post-Brain Impairment

Apart from the loss of movement, hemiplegia predisposes people to contracture (Farmer & James, 2001; O’Dwyer & Ada, 1996; Pandyan & Granat, 1997). Contractures are a shortening of the muscle accompanied by increased resistance to passive stretch (Gordon, 1990; Pandyan & Granat, 1997). Contractures can occur in the elbow, but contractures in the wrist and fingers are thought to be more common and often more disabling (Pandyan & Granat, 1997; Yarkony & Sahgal, 1987). Wrist and finger flexor muscle contracture can limit the range of extension at the wrist, increasing the amount of resistance when the hand and fingers are stretched. These collective impairments lead to reduced function in the upper limb.
When the wrist and finger joints become contracted following acquired brain impairment, it becomes more difficult for a person to remain independent (Carr & Shepherd, 1987). For example, wrist contractures make it difficult to dress a hemiplegic arm independently. Contractures limit the ability to passively straighten the fingers and place the hand into the sleeve, and reduce the ability to actively assist to don a shirt, a movement requiring wrist extension (Bukowski, 2000). Contractures also create unsightly deformities and are thought to predispose people to spasticity, pressure areas, sleep disruption (Scott & Donovan, 1981; Yarkony & Sahgal, 1987) and unnecessary pain and distress (Horin & Reardon, 2000). Contracture is thus considered one of the main complications of acquired brain impairment and treatment is aimed at preventing contracture in those people with full range of movement, and reducing the amount in those people with contracture.

1.2.2 Handsplinting for the treatment of Contractures

A number of interventions are used to prevent and treat contracture. These interventions include: positioning, pharmacology, therapeutic exercise, serial casting and splinting (Atwood, 1999). Currently, the evidence base for these interventions is limited. It is therefore open to conjecture whether any of these interventions benefit people with hemiplegia. This thesis focuses on one intervention in particular: hand splinting.

Hand splinting has been recommended since 1911 to prevent and treat contracture (Neuhaus et al., 1981). This intervention is used by occupational therapists, orthotists and physiotherapists, and its use is endorsed by rehabilitation physicians and neurologists (Fess, 2002). Over the past 100 years, therapists have disagreed about whether or not splints are effective. Even those therapists who promote the use of splints hold differing opinions regarding mechanisms by which splints prevent and treat contracture (Milazzo & Gillen, 1998; Neuhaus et al., 1981; Ryerson, 2001).
1.2.3 Theories which Underpin Hand Splinting

Neuhaus and colleagues (1981) identified two different approaches to treatment for hemiplegia which have influenced current splinting practices. The first is the biomechanical approach, which emphasises the prevention or correction of deformity by mechanical application of splints. The second is the neurophysiological approach which concentrates on the use of movement and handling to reduce spasticity. With the introduction of the neurophysiological approach, splinting became ‘inhibitory’ in design and studies began to test the central tenet of this theoretical approach, which was the ‘inhibition’ of spasticity. Brennan (1959) stated that splinting decreased flexor tone. Kaplan (1962) stated that dorsal splinting decreased flexor spasticity. Chait (1968) reported dorsal splinting to be more effective than volar splinting in decreasing muscle tone. More recently Rose and Shah (1987) reported that both dorsal and volar splints reduce spasticity. Unfortunately various limitations in research methodology threatened the internal validity of all of these results, an issue investigated and discussed in Chapter 3: A Systematic Review.

In recent times allied health professionals have returned to the biomechanical approach toward splinting. The biomechanical approach is one where a splint is prescribed to reduce soft-tissue contractures and increase the range of movement. Linden and Trombly (1995), Gutman (2001), and Milazzo and Gillen (1998) advocate splinting to prevent deformity of the upper limb and to “maintain or lengthen soft tissues” (Milazzo & Gillen, 1998, 173). Although leading allied health professionals assert that splints can hold the hand in a position which prevents contracture by providing a gentle stretch to the muscles and tendons, no clinical trials have tested this theory (Ashburn, Cornall, Melville, Simpson, & Wright, 1998).
1.2.4 The Gap in Empirical Evidence for Hand Splinting

One major assumption of occupational therapists working in rehabilitation, irrespective of the underlying theoretical approach, is that contracture can be managed by using a hand splint (Hill, 1988; Pedretti, Smith & McHugh-Pendleton, 1996; Scott & Dow, 1995; Wilton, 1997; Woodson, 2002). Although the biomechanical theory has gained favour amongst therapists (Neuhaus et al., 1981), there is no definitive support for the efficacy of this approach. There have been no randomised controlled trials on contracture splinting for people with hemiplegia following acquired brain impairment (Milazzo & Gillen, 1998). Further, no research with this population has focused on muscle contracture as the primary outcome despite clear evidence that contracture has a major effect on function and is the primary reason that hand splints are prescribed (Neuhaus et al., 1981). The lack of research in this area constitutes a major gap in knowledge about the use of hand splints which this thesis aims to remedy.

1.3 Research Aims and Objectives

The purpose of this program of research is to test the hypothesis that hand splinting produces a positive effect on the wrist and finger flexor muscles of adults in acute rehabilitation following acquired brain impairment. The theoretical framework underlying this study is the biomechanical approach for splinting, first proposed in early 1900s and extended in recent years by a greater understanding of the neural and mechanical bases for movement (Milazzo & Gillen, 1998). Central to this theoretical framework is the acceptance that the hand splint applies a stretch which is thought to prevent contracture in those people who have yet to develop one and prevent further contracture in those people whose joints have begun to contract (and potentially reduce the amount of contracture in such cases). The program of research aims to systematically review and meta-analyse relevant literature (Chapter 3), and
then investigate the effectiveness of hand splinting both with and without prolonged stretching (Chapters 4 and 5).

The program of research will address three studies and five research questions. The studies will be planned to provide evidence that will fill a knowledge gap and guide clinical practice decisions regarding the use of hand splints for people with hemiplegia following acquired brain impairment.

Study 1: A systematic review of splinting for adults with hemiplegia following stroke.

Question 1. Do adults with acquired brain impairment who participate in a splinting program experience greater function, less contracture, less spasticity and/or less pain, than those who do not participate in a splinting program?

Study 2: A randomised, controlled trial of splinting for adults with hemiplegia following acquired brain impairment who receive hand stretches

Question 2. Do adults with acquired brain impairment who wear a hand splint nightly for four weeks in addition to receiving routine daily upper limb stretches, experience less contracture and pain, and more function than those who receive only routine daily stretches?

Study 3: A randomised, controlled trial of splinting in two wrist positions for adults with hemiplegia following acquired brain impairment who are not receiving hand stretches.

Question 3. Do adults with a recent stroke who wear a hand splint nightly for four weeks in the ‘functional position’ experience less contracture, spasticity and pain, and more function than those who do not wear a splint?
Question 4. Do adults with a recent stroke who wear a hand splint nightly for four weeks in a position of greater wrist extension experience less contracture, spasticity and pain, and more function than those who do not wear a splint?

Question 5. Do adults with a recent stroke experience less contracture, spasticity and pain, and more function when their wrist is positioned in increased extension in a splint compared to a ‘functional’ resting splint?

1.4 Scope of the Study

The first study (Chapter 3) is a systematic review designed to summarise the evidence supporting the use of hand splinting for the stroke population. The systematic review employs methods to minimise bias in its conclusions (Cook, Mulrow & Haynes, 1997; Mulrow, 1994; Oxman & Guyatt, 1988). The quality of trials is assessed in an objective way (Maher, Sherrington, Herbert, Moseley & Elkins, 2003) and the results of studies are collated. A critical appraisal of the results of the systematic review provides the opportunity to refine hypotheses, recognise and avoid pitfalls of previous work, estimate sample sizes, and identify important covariates that warrant consideration in the planned studies (Mulrow, 1994). This thesis and one of its subsequent publications provide an original synthesis and appraisal of current research in this area (Lannin & Herbert, 2003).

Study 2 (Chapter 4) is a randomised clinical trial designed to determine the effectiveness of hand splinting in conjunction with prolonged stretching. Specifically, this study examines the effect of four weeks of nightly hand splinting. The value of this study is that it investigates a typical clinical question common to therapists working in Australian acute care hospitals: “if patients are receiving stretches and upper limb rehabilitation daily, is it
still beneficial to prescribe a hand splint?” In this thesis (and another subsequent publication), Study 2 provides evidence that splinting is not clinically beneficial when provided in conjunction with prolonged stretching (Lannin, Horsley, Herbert, McCluskey, & Cusick, 2003).

The third study (Chapter 5) is also a randomised controlled trial. The results from study 2 refined questions about the efficacy of hand splinting, and identified that both wrist position when splinting and use of stretching were factors that need to be controlled. To achieve this, study 3 used a three-group design that compared not wearing a splint with the effect of four weeks of night hand splinting in either neutral or maximal wrist extension. Participants in study 3 did not receive upper limb stretches. In this thesis (and in the final manuscript submitted for publication), Study 3 provides evidence that splinting in either a neutral position or a position of wrist extension is not clinically beneficial when compared to a control group who received no stretching or splinting (Lannin, Cusick, Herbert, & McCluskey, 2006).

The randomised controlled trials (Chapters 4 and 5) used hand splints and the position of the wrist in the splints as independent variables. The dependent variables, in order of priority, were: contracture of the wrist and finger flexor muscles, functional movement of the hand and arm, spasticity and pain. Time post-impairment was a covariate.

1.5 Definition of Terms

One of the challenges in research related to contracture is the lack of clarity in the definition of specific terms. Terminology used in this thesis has been defined in the following glossary and provides an orientation and overview.
Acquired Brain Impairment

Acquired brain impairment is non-congenital damage to the brain which results from head trauma, and non-traumatic brain injuries such as those caused by strokes, tumours, hypoxia, and neurodegenerative diseases such as Parkinson’s disease and multiple sclerosis (Collins & Dean, 2002). Although acquired brain impairment may arise from these multiple causes, the focus within this thesis will be restricted to people with stroke and head trauma. Since acquired brain impairment can lead to hemiplegia, which predisposes adults to contracture, no delineation between stroke and head trauma is made within the literature review.

Head trauma

A traumatic brain injury is an acquired brain impairment caused by a traumatic event, for example a blow to the head, or from a motor vehicle accident (Sahgal, 1988; Scott & Dow, 1995). Brain tissue damage results from both the direct injury and from secondary reactions that contribute to delayed tissue damage and cell death (Frantseva, Kokarovtseva, Naus, Carlen, MacFabe, & Velazquez, 2002; Laurer, Lenzlinger, & McIntosh, 2000).

Stroke

A stroke, also known as a cerebrovascular accident (CVA), occurs due to disease of the cerebral blood supply (Bierman & Atchison, 2000; Heitzner & Teasell, 1998). A stroke occurs when an artery supplying blood to the brain becomes blocked, cutting off the blood supply (ischaemic stroke), or when the blood leaks from arteries and into the brain (haemorrhagic stroke) (Bierman & Atchison, 2000; Stroke Australia Taskforce, 1996; Woodson, 2002). Although there are varied causes and types of stroke, all lead to tissue anoxia due to a cessation of cerebral blood flow (Pedretti, Smith & McHugh-Pendleton, 1996; Woodson, 2002).
**Hemiplegia**

Damage to the brain may disrupt the function of several descending neurological pathways, including the corticospinal pathway, which is responsible for executing muscle movement. Such damage results in a reduced ability of the brain to activate the muscles and leaves the muscles immobilised (Gracies, 2001). Such muscle immobilisation is called paralysis. When paralysis arises from acquired brain impairment it commonly affects only one side of the body contralateral to the side of the brain damaged, and is known as hemiplegia (Trombly, 1995).

**Hypertonia**

Muscle tone consists of several distinct components: (1) physical inertia of the limb, (2) mechanical-elastic characteristics of muscles and connective tissues, and (3) reflex muscle activity (Katz, 1999). After acquired brain impairment, the tone of a muscle may change. An increase in tone is known as hypertonia (Gans & Glenn, 1990), meaning an increased resistance to passive stretch of a muscle (Boyd & Ada, 2001). Since tone is a reflection of different components working together, it stands to reason that hypertonia may thus arise from several causes. The two most common causes of hypertonia are a decrease in the elastic characteristics of the muscles and connective tissue (commonly known as contracture), and an increase in reflex muscle activity (of which the most common form is spasticity).

**Contracture**

The term contracture defines the lack of mobility of a joint, and is caused by stiffening and shortening of soft tissues (Pandyan & Granat, 1997). Immobilisation of a muscle in its shortened position as a consequence of hemiplegia may lead to changes in muscle fibre and surrounding connective tissues, and cause contracture (Ada & Canning, 1990; Goldspink &
Williams, 1990; Gracies, 2001; Herbert, 1988). The detrimental effects of contracture on hand function and the reasons why therapists use interventions to manage contracture will be discussed in Chapter 2 (Literature Review). Because of the importance placed on managing contracture within current rehabilitation settings, contracture is viewed as the primary dependent variable in the following studies that form this thesis.

**Spasticity**

Spasticity is characterised by a velocity-dependent increase in muscle resistance, in response to a passive stretch which results from hyperexcitability of the stretch reflex (Lance, 1990). In this thesis, spasticity is considered to be only one component of hypertonia. The terms spasticity and hypertonia are not synonymous, since spasticity is felt only when moving a limb passively through range at a high velocity (Boyd & Ada, 2001). The potential role of spasticity on upper limb performance is discussed in Chapter 2 (Literature Review). The decision by a therapist to splint in order to prevent contracture may not, however, be associated with spasticity (Feldman, 1990). Therefore, spasticity is viewed as a secondary dependent variable in the following studies that form this thesis.

**Stretch**

Stretch refers to the sustained and uninterrupted positioning of a muscle in its most elongated position (Ada & Canning, 1990; DeDeyne, 2001). Stretch of the wrist and long-finger flexor muscles requires both the wrist and fingers to be positioned in extension, thus elongating the flexor muscles that cross these joints. The use of the modality of stretch by occupational therapists will be extensively discussed in Chapter 2 (Literature Review).
Hand Splint

Throughout this thesis a hand splint refers to an external device designed to apply, distribute or remove forces to or from the body in a controlled manner (Edwards & Charlton, 2002). When the term ‘splint’ is used in this thesis it specifically means a static hand splint. These devices do not allow motion and serve as a rigid support to the wrist and fingers. In this manner the splint is able to act as a positioning device (Ashburn et al., 1998). The use of hand splinting by occupational therapists is discussed in Chapter 2 (Literature Review). The evidence for and against splinting is discussed in Chapter 3 (A Systematic Review).

Joint range of motion

Range of movement refers to the amount of movement available at a single joint and is influenced by the associated bony structure, connective tissue, and the length of muscles crossing the joint (Norkin & White, 1995).

Muscle Length

Muscle length refers to the ability of the muscle surrounding a joint to lengthen, allowing one or more joints to move through the available joint range of motion. The term muscle length is used in this thesis to refer to the end of range of the muscle across a joint (Berryman Reese & Bandy, 2002). Muscle length is expressed as and measured by degrees of joint motion (Kendall, McCreary & Provance, 1993).

1.6 Synopsis

This chapter has introduced the problem of wrist contracture following acquired brain impairment and the need for contracture prevention. The literature on hand splinting for contracture prevention in the wrist lacks comparative studies. The scientific evidence upon
which therapists base their treatment decisions is lacking. For many years, decisions about whether or not to splint the wrist, and which splint position to use have been based more on personal experience and theoretical principles than on scientific evidence. Accordingly, there is a need for a better understanding of the efficacy of hand splinting for adults who have experienced acquired brain impairment.
CHAPTER TWO

Literature Review
Chapter Two: Literature Review

2.1 Introduction

This thesis seeks to determine the effectiveness of a common occupational therapy intervention for people after acquired brain impairment: hand splinting for contracture prevention. Anecdotal reports suggest therapists are highly variable in the way they treat people with splints following brain impairment. Such variation leads to different hand splinting practices between therapists, which may potentially result in different outcomes for people with acquired brain impairment. To help reduce some of these inconsistencies, there is a need to better understand the effectiveness of hand splinting for the prevention of contracture following acquired brain impairment. Using two cornerstones of evidence-based practice (Craig, Irwig, & Stockler, 2001), the systematic review and randomised controlled trial, the management of contracture in the wrist following acquired brain impairment will be investigated. Findings will help to answer important questions about the effectiveness of hand splinting post-brain impairment and provide high quality evidence to guide clinicians during rehabilitation.

In this Chapter, three important topics relevant to the study aim will be reviewed. First, background literature on acquired brain impairment in Australia will be summarised, providing a context for the study. The impact of acquired brain impairment on motor performance will also be considered. Second, the development of muscle contracture in this population will be reviewed. Fundamental characteristics of contracture and models of contracture prevention will be considered. Finally, the use of therapy interventions to address contracture following acquired brain impairment will be reviewed. The chapter will
demonstrate inconsistencies in practice, gaps in the evidence and a need for evidence-based recommendations about the treatment of contracture following acquired brain impairment.

2.2 Adults with Acquired Brain Impairment

Throughout the western world, acquired brain impairment is the most common cause of long-term disability (American Heart Association, 2005; Australian Bureau of Statistics, 1993; The Stroke Association, n.d.). Between 70,000 and 100,000 Australians experience acquired brain impairment each year (Australian Institute of Health and Welfare, 2003; Fortune & Wen, 1999). Causes include stroke, head trauma, neurodegenerative conditions, hypoxia and tumours (Department of Human Services and Health, 1994).

Acquired brain impairment leads to socio-economic consequences for the people affected and their families and health services. Little is known about the cost of care for various subgroups of people with acquired brain impairment, however, it is estimated that every year the Australian Commonwealth and State Governments spend over $700 million on the management of acquired brain impairments (Fortune & Wen, 1999). Furthermore, the present value of total lifetime costs for all strokes is AUS $1.3 billion (US $985 million) with the average lifetime cost of treatment and ongoing care for a disabled stroke patient exceeding AUS $44,428.00 (Dewey, et al., 2003). Clearly this population represents a large proportion of the health-spending budget. In addition to the substantial cost, acquired brain impairment is the most common diagnostic client group seen by occupational therapists in Australia (Griffin & McConnell, 2001), the United States of America (Trombly & Ma, 2002) and Europe (Rijken & Dekker, 1998).

Adults with acquired brain impairment experience changes in body structure and function as a result of damage to their cortex. For example, many experience limb paralysis, hemiplegia,
and other secondary consequences such as contracture due to immobilisation. These changes in body function affect the performance of tasks and activities such as eating and driving. Occupational therapy and physiotherapy interventions aim to target impairments and activity limitations arising from acquired brain impairment.

### 2.3 Neuromusculoskeletal changes after acquired brain impairment.

Impaired upper limb function is one of the most common and challenging sequelae of acquired brain impairment (Cirstea & Levin, 2000; Hiroka, 2001; Shelton & Reding, 2001). Although it is difficult to estimate the extent of disability in this population, between 48 and 95% of people do not regain functional upper limb use (Gowland, 1982; Williams, Galea, & Winter, 2001). Considerable expense and therapy time is dedicated to upper limb rehabilitation and to understanding the causes of movement problems. For occupational therapists to effectively treat upper limb dysfunction, a thorough understanding of the motor problems following acquired brain impairment is required (Cirstea & Levin, 2000).

Movement problems affecting the upper limb are typically caused by muscle weakness (Burke, 1988; Carr & Shepherd, 1987; Ding, Yao, Lai, & McAllister, 2001; Poole & Whitney, 1992), abnormal muscle tone (Lance, 1990; Burke, 1988; Ding, et al., 2001; Gracies, 2001; Poole & Whitney, 1992), incorrect timing of movement (Carr & Shepherd, 1987) and loss of dexterity (Ada & Canning, 1990; Ada, Canning, & Dwyer, 2000). Many people with acquired brain impairment experience upper limb paralysis followed by gradual recovery of some isolated upper limb movements. Many, however, are left with considerable disability (Dobkin, 2005).
2.3.1 Positive and Negative Symptoms of Abnormal Motor Function

Motor impairments following acquired brain damage can be classified as either positive or negative (Ada, Canning, & Dwyer, 2000; Becher, Harlaar, Lankhorst, & Vogelaar, 1998; Gardiner, 1996; Jackson, 1873 (as cited in Pearce, 2004); O’Dwyer, Ada, & Neilson, 1996; Reynolds, 1861 (as cited in Pearce, 2004); Sheean, 2001). Positive symptoms include abnormal postures; exaggerated proprioceptive reflexes producing spasticity; and exaggerated cutaneous reflexes of the limbs producing flexion withdrawal spasms, extensor spasms, and the Babinski response (Ada & O’Dwyer, 2001; Burke, 1988; Landau, 1980; O’Dwyer, et al., 1996). Negative symptoms include cerebral and spinal shock, weakness, loss of coordination and loss of dexterity (Burke, 1988; Landau, 1980; O’Dwyer, et al., 1996; Sheean, 2001).

Traditionally, the positive symptoms associated with acquired brain impairment were believed to be the principle underlying cause of movement disorders (Gardiner, 1996). This belief led occupational therapists to adopt what is known as the neurophysiological approach to treatment (Milazzo & Gillen, 1998; Stockmeyer, 1967). That approach will be discussed in 2.6.1. Therapists using this approach choose therapy interventions aimed at reducing positive symptoms, and in particular spasticity.

In this thesis, spasticity is viewed as one of several impairments that may be experienced following acquired brain impairment. The most widely used definition of spasticity is that of Lance (1990): a “motor disorder characterised by a velocity-dependent increase in muscle tone with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neurone syndrome” (Lance, 1980; p. 485). This definition indicates that spasticity results from an abnormality of the reflex system. Further, it indicates that spasticity is not the whole problem, rather only one feature of a motor
disorder. In fact in 1990, Lance reiterated this definition and added that “spasticity does not include impaired voluntary movement and an abnormal posture” (p. 606). While therapists commonly argue that spasticity and hypertonicity are interchangeable terms, Lance’s definition argues that spasticity is a separate phenomenon, produced only during high-velocity movement (O’Dwyer, et al., 1996; Sheean, 2001). In this thesis spasticity is differentiated from contracture in line with the biomechanical approach (Boyd and Ada, 2001; Wilton, 1997). This distinction will be discussed in 2.6.2.

Despite spasticity historically being seen as an important focus for treatment by occupational therapists, research suggests that spasticity is usually not the limiting factor for the production of active movement. There is no high quality research available to demonstrate that ‘treating’ spasticity improves functional recovery from hemiplegia; indeed there is much evidence to the contrary, both theoretical (Burke, 1988; Landau, 2004) and clinical (Ada, Vattanaslip, O’Dwyer, & Crosbie, 1998; Davies, Mayston, & Newham, 1996; Landau & Hunt, 1990; O’Dwyer, et al., 1996; Sommerfeld, Eek, Svensson, Holmqvist, & von Arbin, 2004). For most people post-brain impairment, the major functional deficits are largely due to negative impairments such as weakness and dexterity (Ada, et al., 2000; Ada, Canning, Low, 2003; Burke, 1988; Landau, 1980, 2004; O’Dwyer, et al., 1996).

2.3.2 Changes in the Mechanical-Elastic Properties of the Muscle and Connective Tissue due to immobilisation

Muscle weakness and loss of dexterity following acquired brain impairment may immobilise the upper limb. While the upper limb is immobile, muscle stiffness and contractures frequently develop which often compromise recovery of movement. Contracture is recognised when a loss of range of motion and increased resistance to passive movement are
present (Ada, Goddard, McCully, Stavrinos, & Bampton, 2005). Studies of people with acquired brain impairment have confirmed that resistance to passive movement is due to changes in mechanical-elastic properties of the muscle and connective tissue (Ada, et al., 1998; Berger, Quintern, & Dietz, 1982; Dietz, Trippel, & Berger, 1991; Hufschmidt & Mauritz, 1985; O’Dwyer, et al., 1996; Pandyan, Cameron, Powell, Stott, & Granat, 2003; Sahrmann & Norton, 1977); and not due to spasticity alone, as previously believed.

Animal studies have shown that adaptations of muscle length and extensibility occur in response to immobilisation depending upon the position in which the muscle is immobilised (Booth, 1982; Herring, Grimm, & Grimm, 1984; Wren, 2003). It has been demonstrated that animal muscles increase in length when immobilised in a lengthened position and decrease in length when immobilised in a shortened position through the loss or addition of sarcomeres (Tabary, Tabary, Tardieu, Tardieu, & Goldspink, 1972; Tardieu, Tabary, Tabary, & Tardieu, 1982; Williams & Goldspink, 1978). When a muscle is immobilised in a shortened position the amount of tension applied to the muscle is reduced (Herbert, 1988). This has been shown to be the first mechanism towards contracture (Gracies, 2001). A muscle which no longer has tension applied will have structural changes in contractile and connective tissue which leads to the muscle generating tension at a new, shorter resting length (Herbert & Balnave, 1993; Herbert & Crosbie, 1997). Observable structural changes include muscle shortening, shortening of the connective tissue within a muscle (Goldspink & Williams, 1990) and disruption of the workings of the synovial fluid, membrane and articular cartilage (Trudel, Himori, Goudreau, Ulthoff, 2003). These changes in the mechanical-elastic properties of the muscle and connective tissue cause limited range of movement (McClure, Blackburn, & Dusold, 1994; Vattanasilp, Ada, & Crosbie, 2000).
Although no studies have been performed on time course development of contractures in the wrist after acquired brain impairment in humans, anecdotal evidence is compelling (Gossman, Sahrmann, & Rose, 1982; Pandyan et al., 2003). Loss of wrist extension has been documented following acquired brain impairment (Pandyan, et al., 2003; Pandyan & Granat, 1997; Twitchell, 1951). On average, people without wrist movement after stroke lost on average 14° of wrist extension over 8 weeks (Pandyan et al., 2003). Muscles vulnerable to contracture at the wrist (causing wrist flexion contractures) include the long-finger flexor muscles in addition to wrist flexor muscles.

### 2.4 The Wrist

The central nervous system plans and regulates movement, but it cannot do so without taking into account the mechanical properties of the muscles and skeletal system (Winters & Crago, 2000). The wrist comprises of eight carpal bones with numerous articular surfaces, ligaments, tendons, and neurovascular structures (Hamill & Knutzen, 1995; Moojen, Snel, Ritt, Venema, Kauer & Bos, 2003; Sennwald, Zdravkovic, Kern, & Jacob, 1993). Whilst available range will vary with torque, on average, the wrist flexes from 0° to between 65 and 80°, and extends from 0° to between 55 and 70° (Neumann, 2002; Norkin & White, 1995; Sarrafian, Melamed, & Goshgarian, 1977).

When a person is asked to perform grip tasks without specifying the wrist angle, a joint position is automatically selected for optimal performance (such as comfort or maximal force production). On average, able-bodied people require a minimum of 60° of wrist extension to perform activities of daily living such as personal care tasks, food preparation, and activities such as turning a key or doorknob and using a telephone (Brumfield & Champoux, 1984; Ryu et al., 1991). A minimum of 25° of wrist extension is also necessary
for grip strength (O’Driscoll, Horii, Ness, Cahalan, Richards & An, 1992). People use their hands and fingers extensively during daily activities and many tasks require a person to be able to attain and sustain wrist extension (Brumfield & Champoux, 1984; Bulthaup, Cipriani, & Thomas, 1999; Hazelton, Smidt, Flatt, & Stephens, 1975; Safaee-Rad, Shwedyk, Quanbury, & Cooper, 1990). Loss of wrist extension as a result of contracture thus impairs performance of everyday tasks (Atwood, 1999; Cooper, Shwedyk, Quanbury, Miller, & Hildebrand, 1993; Doubilet & Polkow, 1977; Grover, Gellman, & Waters, 1996; Herbert & Balnave, 1993; MacKay-Lyons, 1989).

Therapists are concerned with the loss of wrist extension because of the subsequent limitation to performance of tasks which impact on a person’s ability to participate in meaningful activities. For example, wrist flexor contractures and the subsequent limitation in wrist extension make it difficult to perform simple activities of dressing (Bukowski, 2000). Contractures also create deformities in the appearance of the limb and are thought to predispose people to spasticity, pressure areas resulting in skin breakdown, sleep disturbances and pain (Atwood, 1999; Dalyan, Sherman, & Cardenas, 1998; Scott & Donovan, 1981). Limitations in task performance are less severe if the extensibility of muscles can be maintained – that is, if contractures can be prevented (Perry, 1980).

### 2.5 Occupational Therapy for adults with contracture following acquired brain impairment

Australians require access to health interventions that are based on sound scientific evidence (Wooldridge, 1998). The practical use of such evidence by health professionals promises better health outcomes by delivering healthcare that is effective, appropriate, feasible and meaningful to consumers (Pearson, 1998; Sackett & Rosenberg, 1995; Sackett, Rosenberg,
Muir Gray, Haynes, & Richardson, 1996). The last decade has been characterised by calls for continued improvement of treatment effectiveness (Greener & Langhorne, 2002; Koes & Hoving, 1998; Lloyd, King, & Bassett, 2002; Mulrow & Lohr, 2001; Rodwin, 2001; Taylor, 1997; Van Der Weyden & Armstrong, 2004). Treatment improvement is required in all health professions: medicine, the allied health professions, and nursing. The focus of this study is occupational therapy and an intervention (hand splinting) commonly used by occupational therapists. There is a need for an increase in the base of clinical decisions in occupational therapy (Bennett & Bennett, 2000; Brown & Rodger, 1999; Cusick, 2001; Law & Baum, 1998; Lloyd-Smith, 1997). Evidence-based practice is the use of current best evidence when making clinical decisions, usually evidence from high quality clinical research (Herbert, Sherrington, Maher, & Moseley, 2001; Sackett, Richardson, Rosenberg, & Haynes, 1997). Occupational therapists have been urged to provide evidence-based practice for some time now (Cusick, 2001; Dubouloz, Egan, Vallerand, von Zweck, 1999; Taylor, 1997).

The penetration of evidence-based practice into clinical practice is increasing (McKenna, Bennett, Dierselhuis, Hoffmann, Tooth & McCluskey, 2005) although it has not been uniform across occupational therapy practice (Walker, Drummond, Gatt, & Sackley, 2000). There are still underdeveloped areas of practice. One such area is neurological occupational therapy, which focuses on the treatment of impairments and disability arising from acquired brain impairment (Steultjens, Dekker, Bouter, van de Nes, Cup, & van den Ende, 2003). Research suggests that occupational therapists working in neurology do not make the choice between rehabilitation techniques and approaches based on relevant research, published papers or scientific theory (Walker et al., 2000). Instead, therapists appear to rely more on habits and tradition to guide their clinical reasoning (Eakin, 1997). This reliance may be related to the limited profession-specific evidence available to occupational therapists.
working in neurological rehabilitation. Convincing evidence concerning the usefulness of specific rehabilitation interventions for adults following acquired brain impairment remains limited (Dobkin, 2005; Langhorne, Legg, Pollock, & Sellars, 2002; Pomeroy & Tallis, 2003; Teasell, Foley, Bhogal, & Speechley, 2003; Teasell, Jutai, Bhogal, & Foley, 2003). More research is required to enable the profession to become evidence-based (Steultjens et al., 2003).

Therapy provided to someone with wrist contracture following acquired brain impairment is generally determined by individual occupational therapists’ assumptions about motor control and their understanding of factors contributing to motor control problems (Cirstea & Levin, 2000; Gordon, 2000). Interventions thus vary considerably depending on the occupational therapist’s preferred theoretical approach (Woldag & Hummelsheim, 2002).

Occupational therapists use a number of approaches to prevent wrist contracture in adults with hemiplegia. These approaches are usually based on one of two main frames of reference (Poole, Whitney, Hangeland, & Baker, 1990), known as neurophysiological and biomechanical approaches.

### 2.5.1 The Neurophysiological Approach

Rehabilitation beliefs underlying the neurophysiological approach are that recovery takes place from proximal to distal in the body, stability and control of the shoulder are necessary before the hand can be used, and spasticity must be inhibited before active use of the upper limb can occur (Milazzo & Gillen, 1998; Stockmeyer, 1967). This approach uses neuromuscular facilitation, sensory input and developmental sequences to facilitate change in the organisation of the central nervous system, and thereby improve the overall function
of the person with acquired brain impairment (Morgans & Gething, 2002). Techniques common to the neurophysiological approach include the “Bobath” or neurodevelopmental approaches (Bobath, 1990), proprioceptive neuromuscular facilitation (Knott & Voss, 1968), “Brunnstrom” approach (Brunnstrom, 1970; Perry, 1967); the “Rood” approach (Rood, 1954; Stockmeyer, 1967), and the “Ayres” approach (Davies, 1985).

Therapies based on the neurophysiological approach have been developed through clinical experience and have a tendency to be based on now outdated beliefs about what does and what does not promote neurological recovery (Burgess, 1989; Milazzo & Gillen, 1998). The Bobaths (1990), perhaps the most important proponents of the neurophysiological approach, considered spasticity to always coexist with hemiparesis after stroke. However, as already discussed in section 2.4, no relationship has been found between the degree of functional movement and the level of spasticity (Ada, et al., 1998; Fellows & Thilmann, 1994; Sommerfeld, Eek, Svensson, Holmqvist, & von Arbin, 2004; Yelnik, Albert, Bonan, & Laffont, 1999). This body of research contradicts the assumptions of the neurophysiological theory. Another example of practice contrary to research that underlies the use of facilitation and inhibition techniques, is the assumption that both posture and movement are primarily controlled by reflexes. Controlled outcome studies have also failed to demonstrate that the neurophysiological treatment approach is more effective than other approaches to stroke rehabilitation (Langhammer & Stanghelle, 2000; Luke, Dodd, & Brock, 2004; van Vliet, Lincoln, & Foxall, 2005). Despite such scientific evidence, the neurophysiological approach is still commonly used by occupational therapists working with people after acquired brain impairment (Milazzo & Gillen, 1998; Pierson, 2002).

Occupational therapists who choose to apply the neurophysiological theory to practice do not do so based on research evidence or scientific theory (Walker et al., 2000). If they did
therapists would find that the theory behind the treatment approach is unsupported by evidence. In contrast to the neurophysiological theory underlying treatment, the biomechanical theory has been influenced by modern research findings. The biomechanical approach will now be described.

2.5.2 The Biomechanical Approach to Therapy

The biomechanical approach is so named because of the adherence to principles of normal alignment, mobility and stability (Wilton, 1997). The theoretical basis of the biomechanical approach includes a need to maintain soft tissue length (including muscle, tendon, and ligament) and train movement. The biomechanical approach builds on research findings that demonstrate that impaired movement is a result of the negative features of brain impairment (such as weakness and loss of dexterity). Further, it is these features which lead to the secondary complications, including mechanical-elastic changes in the muscle and contracture. This approach assumes that the clinical manifestation of ‘spasticity’, being resistance to passive stretch, occurs primarily because of mechanical-elastic changes in muscles and not spasticity (Carr & Shepherd, 1998; Boyd & Ada, 2001). This is in line with research evidence (Davies, Mayston, & Newham, 1996; O'Dwyer et al., 1996). As immobilisation frequently results in mechanical-elastic changes in muscles, it is appropriate for occupational therapists to use treatments that will address immobilisation and contracture (Carr & Shepherd, 1998; Gracies, 2001; Lincoln, Parry, & Vass, 1999).

Irrespective of the treatment approach used, most therapists accept that contracture formation indicates poor prognosis for upper limb function. The maintenance of passive range of movement and prevention of deformity are thus important early goals in rehabilitation (Pedretti et al., 1996). Prevention or reduction of shortening of muscle and
non-contractile tissue must therefore be included in rehabilitation management of people with acquired brain impairment (Gardiner, 1996).

### 2.6 The Prevention of Contracture

Prevention of contracture is one of many challenges facing occupational therapists and physiotherapists working with adults following acquired brain impairment. To improve upper limb movement and task performance, therapists favour treatments which are thought to selectively lengthen muscles at risk of contracture (Carey, 1990). Stretch is the main physical modality used to selectively lengthen muscles (Farmer & James, 2001; Gracies, 2001; Harvey & Herbert, 2002; Hepburn, 1987; Hill, 1988). Stretch has been traditionally used by occupational therapists (Atwood, 1999; Hill, 1988).

#### 2.6.1 Stretch Interventions

Clinically, two broad types of stretch interventions are used to prevent and treat contracture. The first involves placing ‘at-risk’ muscles (such as the wrist and long finger flexor muscles) in a position of stretch for lengthy periods of time. The proposed benefit of stretch interventions are that they will result in decreased hypertonicity (resistance) in the hemiplegic muscles, thus preventing loss of joint range of motion. *Prolonged low-load stretches*, using positioning, casting and splinting, are the most common way of administering stretches (Dean, Mackey, & Katrak 2000; Milazzo & Gillen, 1998; Moseley, 2002; Schultz-Johnson, 1996). The second approach to stretching involves stretching ‘at risk’ muscles for short periods of time. *High-load brief stretches*, passive ranging movements, and proprioceptive neuromuscular facilitation exercises are examples of short-duration stretches (Moseley, 2002). The best available evidence suggests that prolonged stretches are more effective than brief stretches in preventing and treating contractures in
people with acquired brain impairment (Light, Nuzik, Personius, & Barstrom, 1984; Milazzo & Gillen, 1998; Steffen & Mollinger, 1995). The remaining discussion will therefore focus on long-duration stretch.

2.6.2 Research on prolonged low-load stretching in animals and humans

Several studies provide evidence that the use of prolonged low-load stretch can produce positive and beneficial effects on muscle lengths. This type of stretching has been investigated both in animal and human muscle.

1. Animal studies have found that the length of muscle can be increased as the result of stretch. Studies have also demonstrated that lower intensity stretch, applied for longer periods of time (known as low-load, long-duration stretch) can effect change in muscles which have been immobilised in a shortened position (Goldspink 1977; Williams, 1988; Williams, Catanese, Lucey, & Goldspink, 1988; Williams & Goldspink, 1978).

2. The use of long-duration stretch to treat and prevent contractures is usually justified by animal studies, as there is an absence of high quality human studies (Goldspink, 1999; Goldspink & Williams, 1990; Herbert, 1988; Williams, 1990).

3. Stretch has been shown to produce additional actin and myosin filaments and new sarcomeres in series and in parallel in animal muscles (Goldspink, 1999; Cox et al., 2000).

4. An animal study comparison of stretching methods and durations also revealed that stretch for a minimum period of 30 minutes a day was sufficient to prevent the loss of sarcomeres and the muscle atrophy characteristically associated with immobilisation of mice muscles in the shortened position (Williams, 1988; Williams, 1990).
Human studies have investigated the effect of long-duration stretch on the extensibility of soft tissues, particularly around the knees of older adults. These studies examined the effects of long duration stretch on joint mobility and range of motion in people with musculoskeletal conditions. These human studies provide support for the theory that increasing the amount of time that a muscle spends positioned in its lengthened end-of-range will improve passive range of movement (Flowers & LaStayo, 1994; Light, Nuzik, Personius, & Barstrom, 1984). These studies, however, were conducted on orthopaedic or able-bodied adults and not people with acquired brain impairment.

For people with brain impairment, evidence that long-duration stretch lengthens shortened muscles or maintains their length is limited (Harvey, Herbert, & Crosbie, 2002). Limitations in study design limit the usefulness of much of the data for therapists wanting to apply results to their clinical practice. For example, many studies have measured the effect of stretch on joint mobility and range of motion within minutes of stopping the stretch intervention and without follow-up (MacKay-Lyons, 1989; Rose & Shah, 1987). Such studies are problematic because increases in range of motion observed soon after stopping stretching are primarily due to changes in viscoelastic properties (Herbert, 1993; Magnusson, Simonsen, Dhyre-Poulsen, Aagard, Mohr, & Kyaer, 1996; Muir, Chesworth, & Vandervoort, 1999) rather than real structural changes to muscle and other soft tissue (Harvey & Herbert, 2002). Without structural change there is little likelihood of lasting increases in muscle length.

More recent studies are promising, but even these have failed to provide a conclusive answer on the efficacy of stretch, as there were methodological problems apparent in these study designs. For example, Ada and colleagues (2005) addressed the issue of timing of measurement but failed to use torque-controlled range of movement in their
investigation of the effect of stretch. If torque is not standardised, changes in the range of motion and joint angle may simply be due to an increased tolerance to stretch, rather than real changes in the muscle structure. Changes in joint angle measured manually with a goniometer may give the illusion of an increase in range of movement without lasting structural adaptations occurring within the muscle (Folpp, Deall, Harvey, & Gwin, 2005). Another recent trial controlled for torque during range of movement testing, but had poor compliance with the study protocol and a small sample size (Turton & Britton, 2005). These limitations reduce confidence in the study’s main finding that there was no effect after prolonged stretching in people with stroke. There is clearly still a gap in the knowledge about the effect of stretch after acquired brain impairment.

2.6.3 Optimal Timing of Stretch

For optimal efficacy, several authors have recommended that long-duration stretch be implemented as early as possible after acquired brain impairment (Ada & Canning, 1990; Feldman, 1990). Because muscle changes are detectable a few hours after a muscle is immobilised in its shortened position, implementation of prolonged stretch in muscles at risk of shortening may be beneficial early after acquiring a brain impairment. High-level evidence, such as that provided by well-designed randomised controlled trials, is required before firm conclusions can be drawn about the benefits of early prolonged stretch of the upper limb after acquired brain impairment. The application of prolonged stretch proved successful in a randomised controlled trial of serial leg casts, which were applied within 14 days of traumatic brain injury for the prevention of foot deformity (Moseley, 1997). There were, however, some methodological flaws in that study (such as non-blinded measurement of outcomes) which again reduce confidence in results.
2.6.4 Therapeutic Interventions used to apply Low-Load Prolonged Duration Muscle Stretch

The literature regarding various stretch modalities used to prevent and manage contracture lacks large, well-designed randomised controlled trials. For the many years, decisions to use stretch interventions have been based on clinical opinion and habit rather than on scientific evidence (Gracies, 2001). Common to all stretch interventions is the assumption that joints should be positioned with at-risk muscles in their most lengthened positions (Farmer & James, 2001). Both the neurophysiological and biomechanical approaches agree that continuous stretching of muscles is a key factor in producing decreased resistance to movement and increasing range of movement (Anderson, Snow, Dorey, & Kabo, 1988; Barnes, 1998; Booth, Doyle, & Montgomery, 1983; Gossman, Sahrmann, & Rose, 1982; Heart and Stroke Foundation of Ontario, 2000; Kaplan, 1962). Often only relatively simple equipment is required to apply low-load, prolonged duration muscle stretch. Common stretch interventions include passive stretching, plaster casting, and hand splints (Farmer & James, 2001; Gracies, 2001; Harvey & Herbert, 2002; Schultz-Johnson, 1996). Each of these will now be described in relation to the intervention choices made for the studies in this thesis.

Passive Stretching

Passive stretching, or positioning, is a technique frequently used by therapists to address contracture (Ada et al., 2005; Akeson, Amiel, Abel, Garfin, & Woo, 1987; Atwood, 1999; Cherry, 1980). To passively stretch a joint, the joint is held by the therapist (or client) at the limit of range of movement and tension is sustained (Leong, 2002). Currently, animal physiology studies and lesser quality studies on humans provide the majority of evidence to inform clinical decisions. Recent animal models
suggest that the critical stimulus for stretch is strongly related to time – that is, muscles will respond only to the average amount of stretch experienced in a 24 hour period (Wren, 2003). Periods of longer stretching appear to lead to positive structural changes. In a non-randomised, cross-sectional study of passive stretching of the lower limb in children with cerebral palsy, Tardieu and colleagues (1988) found that contractures did not occur when muscles were stretched using positioning for more than six hours a day. In a randomised trial comparing low-load, prolonged stretch (one hour duration) with high-load brief stretch (one minute), Light and colleagues (1984) demonstrated a preference for low-load, long duration stretch conducted with elderly musculoskeletal participants. This length of time exceeds that normally used for passive stretching of adults with acquired brain impairment. Thus, based on the limited human studies available, it would seem that for passive stretching to be effective it must be maintained for a long period of time (Farmer & James, 2001). For this reason, therapists frequently consider using other modalities which prolong the stretching time, such as casting and splinting.

In a recent clinical trial of adults following stroke (Ada et al., 2005), 30-minutes of passive stretching to shoulder internal rotator muscles using limb positioning significantly reduced the development of contracture post-stroke. The group who did not receive stretches lost on average 11.8° more range of movement over the study period than those who did receive stretches (Ada et al., 2005). In that same study, however, positioning or stretching the shoulder for 30 minutes into 90° of flexion did not prevent contractures. Measurements taken in this study were not torque-controlled which introduces the possibility that the positive finding was simply an increase in tolerance to stretch, rather than physiological changes to the mechanical-elastic properties of the shoulder internal rotator muscles.
Ada and colleagues (2005), in their randomised controlled trial, found a small effect at low torque when stretching human shoulder muscles for 30 minutes. This finding is consistent with earlier animal studies by Williams (1988; 1990). In their lower quality study, however, Tardieu and colleagues (1988) found that much longer periods of stretch were required, consistent with more recent work by Wren (2003). Wren (2003) hypothesised that average muscle length and minimum tendon strain govern muscle and tendon length adaptations. Wren’s model predicts that muscle length increases when a muscle is immobilised in a lengthened position and decreases when the muscle is immobilised in a shortened position. Wren’s model contrasts to earlier models (such as those proposed by Goldspink and Williams) in its suggestion that it is the average muscle length that governs tissue adaptation, and not a shorter period of time spent in the most lengthened position.

The limited number of studies and conflicting results regarding the duration of stretch to improve mechanical-elastic properties are reflected in clinical practice, with little consistency amongst clinicians. Currently there are no published clinical guidelines on stretching following acquired brain impairment to prevent contracture. In the absence of high quality scientific evidence on stretch duration, studies such as those presented in this thesis must rely on lower level studies (Tardieu et al., 1988; Wren, 2003). Findings from both these studies suggest that the prolonged duration of stretch appears to be a critical stimulus for preventing contracture. Consequently the options of casting and splinting were further explored as potential study interventions.

Casting

Casting is one treatment option for applying a stretch to muscles. Casts are typically made from plaster or synthetic ‘fiberglass’, and used to hold a joint in a specific
position (Copley & Kuipers, 1999; Mortenson & Eng, 2003). To achieve a low-load, prolonged duration muscle stretch, a plaster cast is applied to a joint at the limit of range of movement (Cherry, 1980; Farmer & James, 2001; Feldman, 1990; Hill, 1988; Pierson, 2002; Tardieu, Tardieu, Colbeau-Justin, & Lespargot, 1982). The most common wearing time (or stretch duration) for a cast is three to seven days (Mortenson & Eng, 2003). In some instances, the casts are changed sequentially every few days (i.e., serial casting) to incrementally increase joint range of movement (Gracies, 2001; Hill, 1988; Mortenson & Eng, 2003; Teplicky, Law & Russell, 2002). Casts have been used to prevent contractures in patients with acquired brain impairments, mainly in lower but also in upper limbs (Barnard et al., 1984; Garland, Thompson, & Waters, 1980).

In a prospective, randomised controlled trial, Moseley (1997) reported that casting the ankle soleus muscle combined with stretching the gastrocnemius muscle resulted in significant increases in ankle range of movement. The effect of casting on muscles and joints of the upper limb has not been researched using a randomised controlled trial design. Much of the research on casting in the upper limb of adults with acquired brain impairment uses single case study designs (Copley, Watson-Will, & Dent, 1996; Freehafer, 1977; King, 1982; Steer, 1989). Casts applied by Freehafer (1977), King (1982) and Steer (1989) to elbow flexion contractures for 24 hours per day over several weeks resulted in significant gains in range of motion and functional movement. Although there is hardly any more evidence for hand splinting than casting, the difficulties inherent in applying casts to the fingers and hand have meant that occupational therapists have historically favoured splinting over casting to prevent contracture.
Splinting

A hand splint offers a therapeutic means of maintaining a static position and thus applying a prolonged stretch to muscles (Duncan, 1989; Farmer & James, 2001; Fess, 1995; Hill, 1988; Lowe, 1989; Milazzo & Gillen, 1998; Trombly, 1989; Wilton, 1997). Hand splints, like casts, are able to place a joint in any position that the therapist chooses, allowing for customised stretch positions between individuals. Splints differ from casts with regard to the materials used and the wearing regime; hand splints are generally made from thermoplastic material and are designed to be removed daily whereas casts are generally not. Hand splints are the most frequently used stretch intervention following acquired brain impairment by occupational therapists in Australia (Griffin & McConnell, 2001). This is in spite of a paucity of research to guide practice decisions. Although the research base for splinting is no more or less convincing than that available for casting, the use of splinting is far more widespread particularly with people after stroke. What little evidence is available will be reviewed in the next section.

2.6.5 Use of Hand Splinting to Prevent Contracture Following Acquired Brain Impairment

Splinting and Contracture:

The use of hand splints in rehabilitation following acquired brain impairment developed largely from the clinical experiences of therapists (Kogler, 2002). As already highlighted, many controversies exist regarding the theoretical basis for splinting following acquired brain impairment, and regarding their influence on muscle length (Neuhaus et al., 1981). In general, however, many therapists apply a splint to the hemiplegic hand and wrist to achieve one or more of the following aims:
a. **To protect joint integrity by immobilising the joint** which is believed to decrease mechanical irritation caused by overstretching of a joint. Overstretching is thought to occur due to decreased proprioception within the joint following acquired brain impairment (Neuhaus et al., 1981; Milazzo & Gillen, 1998).

b. **To maintain correct joint alignment.** Static splinting in a functional position is usually considered to maintain correct alignment and increase the patient’s functional hand use while more controlled movement is being regained (Duncan, 1989; Milazzo & Gillen, 1998; Rose, 1986).

c. **To prevent or correct developing contractures.** The wrist and fingers assume a ‘relaxed’ position of flexion following acquired brain impairment, which contributes to the formation of a contracture. The splint is thought to act as an opposing force against the flexion contracture by providing a sustained stretch (Duncan, 1989; Lowe, 1989; Milazzo & Gillen, 1998; Rose, 1986).

d. **To achieve improved function at a joint.** For example, positioning a flexed wrist in more extension may place the fingers at a better functional advantage for active movement (Milazzo & Gillen, 1998; Wilton, 1997; Woolcott, 1966).

e. **To reduce pain** (Neuhaus et al., 1981; Pedretti et al., 1996; Wilton, 1997).

f. **To decrease spasticity** (Kogler, 2002; Milazzo & Gillen, 1998; Neuhaus et al., 1981; Pedretti et al., 1996; Wilton, 1997).

There is a shortage of published data pertaining to the efficacy of hand splinting to prevent contracture following acquired brain impairment (Duncan, 1989; Fess, 1995; Milazzo & Gillen, 1998; Paternostro-Sluga & Steiger, 2004). The existing body of literature on hand splinting in this population will be systematically reviewed in Study 1 of this dissertation (Chapter 3). In brief, most published studies involve case reports or case series, with only three high quality studies identified (randomised controlled trials). All three of these trials
were of poor methodological quality. The limited research and lack of a no-splint control group in all trials to date limits the usefulness of these results for therapists. This gap in knowledge will be addressed in the program of studies for this thesis.

There has been much debate about the mechanism by which splinting appears to be effective (Barnes, 1998; Carlson, 1984; Edwards & Charlton, 2002; Paternostro-Sluga & Steiger, 2004; Ryerson, 2001). Different mechanisms are proposed based on the neurophysiological or biomechanical approaches (Feldman, 1990; Hill, 1988; Milazzo & Gillen, 1998). Both biomechanical and neurophysiological approaches have their advocates (Pierson, 2002) and opponents (Barnes, 1998; Kogler, 2002). There is also a lack of consensus about splint designs, hand position, duration and wearing compliance. In short, the use of hand splints for people post-brain impairment remains controversial. The following sub-section discusses the variety of opinions for splinting and examines theories that govern splint design, wrist positions within the splint, and splinting compliance in the management of contracture. In keeping with the overall design and focus of this program of research, evidence on the efficacy of splinting will be rigorously examined in Chapter 3: A Systematic Review, rather than via a narrative literature review.

The most common reason for splinting following acquired brain impairment, and the one which is central to this thesis, is to prevent contractures and deformity (Milazzo & Gillen, 1998; Neuhaus et al., 1981). Although splints are widely used to provide stretch, there is limited empirical evidence to support their use. Instead, tradition and underlying logic of related theories provides justification. While splints offer distinct practical advantages to apply stretch over passive range of motion and casting, splinting is only a modality used to achieve prolonged stretch. The splint in and of itself is not a ‘cure’. The underlying principle is that muscles must be placed under constant tension for a period of time if they
are to lengthen. Consequently, clinical choices regarding the modality for applying stretch using a hand splint are important.

Type of Hand Splint Design:

Static splinting is used to apply stretch for the prevention of contracture. Regardless of their shape, splints applied to people following acquired brain impairment generally use three points of pressure to control joint motion (Fess, 1995; Fess & Kiel, 1998; Duncan, 1989). These three points of pressure are arranged with a middle force directed opposite to the proximal and distal forces (Figure 2.1). The palmar aspect of the splint acts as the resistance arm to the weight of the hand and the pull of the flexors on the wrist and fingers (Duncan, 1989). Contracture of the wrist and finger flexor muscles means that these muscles are shorter and generate greater tensions at shorter lengths. Contracted flexor muscles thus increase their pull on the wrist and fingers, forcing the fingers to rest in flexion. The theory behind splinting considers that the hand splint applies the lever force as a counterforce against this flexion pull, and thus, the flexor muscles are lengthened (stretched).

![Figure 2.1  Wrist splint illustrating three points of pressure](image-url)
The splint provides the greatest mechanical advantage (i.e. least force to produce greatest torque force at the wrist) if the forearm component of the splint is lengthened. For any given level of stretch (torque), this results in decreased force on the proximal anterior forearm thereby creating a more comfortable splint. Lengthening the forearm component also decreases the magnitude of the middle reciprocal force, making the splint more durable and more comfortable at the wrist strap (Fess, 1995; Fess & Philips, 1987). For these reasons, the splints used in this study series were constructed with a long forearm component.

Occupational therapists can choose between many splint designs all of which position the hand similarly; alternative designs are described in the literature while others remain unpublished (Tenney & Lisak, 1986; Copley & Kuipers, 1999). A ‘static palmar-mitt splint’ (Figure 2.2) is a common design used to reduce abnormal posturing of the wrist and hand following acquired brain impairment (Copley & Kuipers, 1999). The aim of the splint is to provide muscle stretch and positioning to the hemiplegic wrist and hand, thereby preventing contracture (Copley & Kuipers, 1999; Tenney & Lisak, 1986). As no hand function is possible when wearing the splint, it is also known as a ‘resting splint’. The static palmar-mitt splint design was used in the study series to maintain wrist and finger positions.

Figure 2.2 Static Palmar-Mitt Splint
Positioning the wrist in the splint:

The wrist position in splints has been inadequately described in published splinting literature. No clear identification of the amount of muscle tension required to induce muscle length changes has been documented (Gracies, 2001; Ryerson, 2001). The optimal amount of extension that the wrist should be ‘stretched’ to when it is positioned in the splint is not known. The choice of wrist position in a splint appears to be more a matter of clinical tradition.

Historically, the hand is splinted in a ‘functional’ position post-brain impairment. The ‘functional’ position is where the wrist is positioned between 0 and 10º extension (Hill, 1988; Ryerson, 2001; Tenney & Lisak, 1986; Wilton, 1997). The ‘functional’ position is a notion that applies to orthopaedic therapy, where the preferred resting position is one that provides balance of soft tissue on either side of the joint (Gracies, 2001). It has long been assumed that immobilising the hand in the ‘functional position’ post-brain impairment offers the best opportunity for function, if and when the patient is able to move their hand again. There is, however, still no evidence to either support or refute the effectiveness of hand splinting in the ‘functional’ position. As the ‘functional’ position is currently the most common position that therapists choose for splints to immobilise a person’s hand following acquired brain impairment, this position was selected for the study series.

Despite the lack of evidence, preference for the choice of splint position has been influenced by respected opinion leaders in rehabilitation. Bobath (1979; 1990), for example, insisted that splinting on full stretch (or maximal range of wrist extension) increased spasticity thus leading to further muscle contracture. Consequently, the ‘functional’ position was preferred.
The use of the ‘functional’ position has not been supported scientifically and appears to contradict the beneficial effects of full stretch in animal studies discussed earlier. An unwillingness to provide full stretch when splinting has meant that a potentially effective treatment has not been offered to a patient by therapists. This rejection may deprive people following acquired brain impairment of an opportunity to apply stretch at its optimal muscle lengthening efficacy if, in fact, stretch to end of joint range is effective (Flowers & LaStayo, 1994; Gracies, 2001).

In Study 3 (Chapter 5) I therefore hypothesise that to achieve the necessary intensity of stretch and prevent contracture, the amount of wrist extension must go beyond the ‘functional position’ (Gracies, 2001). Few authors have experimented with positions of maximal muscle stretch; this intervention is relatively new. At this stage, there have been no high-quality trials investigating the efficacy of splinting for contracture prevention in a position that provides greater stretch intensity at the wrist (Gracies, 2001). The impact of altering stretch intensity by changing the amount of extension at the wrist within the splint is one focus of this study series (Chapter 5). As variables of frequency and duration are also able to alter the amount of stretch delivered by a splint, these were kept constant.

_Splinting Compliance:

The oft-cited shortcomings of using splinting to provide stretch following acquired brain impairment include poor patient compliance, low acceptance of the splint and problems with the wearing regime (Gracies, 2001). Casts optimise compliance to stretch because they are difficult to remove, whereas splints are easily removed by the wearer and others. Since wearing compliance directly affects frequency and duration of stretch (and thus, the dose of
stretch received), researchers and clinicians need to consider wearing compliance strategies when planning a splinting program.

Patient compliance with splint wearing is thought to improve when the splint’s purpose and goals have been explained, when the splint fits comfortably and can be applied independently, and when the splint meets the needs of the person wearing it (Lowe, 1989; Tenney & Lisak, 1986). Wearing tolerance may be enhanced if the benefits of wearing the splint are discussed (Fess & Kiel, 1998). In this study series, participant education was considered pivotal to the success of any splinting intervention (Collins, 1999; Fess & Kiel, 1998; Lowe, 1989). Strategies proposed in the literature to enhance wearing compliance will be used in the study series, such as monitoring splint wearing. Compliance strategies are reported in both studies (Chapters 4 and 5).

### 2.7 Measurement Issues

#### 2.7.1 Measurement of Passive Range of Movement

As previously discussed, wrist range of motion is an integral part of human movement; in order for an individual to move efficiently and with minimal effort, full range of motion across all joints is imperative. The amount of motion available at a joint depends on the length and extensibility of both muscles and periarticular connective tissues (Sanders, 1990). Contracture is characterised by a loss of range of motion and increased resistance to passive movement (Ada, et al., 2005). The extent of contracture can be measured by finding the angle at which passive muscle stretch is limited (i.e. end of passive joint range of movement).
To explore methods for measuring passive wrist extension range of movement, factors related to joint range of movement, muscle length, and measurement technologies will now be discussed. Traditionally, muscle length has been measured by measuring passive range of motion (Berryman Reese & Bandy, 2002; Roberson & Giurintano, 1995; Singer, Dunne, & Allison, 2001). Passive range is a more appropriate measure than active range because splinting aims to increase passive range, by lengthening tissues that passively restrict movement. Active range of movement may be limited by other additional factors such as impaired motor function or cognition and thus will not necessarily provide a measure of contracture.

The goniometer remains the most widely used instrument for measuring muscle length, however limitations in the application of the device have been found. Goniometric measurements are regarded clinically to be objective since they give numerical data about a joint, but there are concerns about reliability. The amount of change necessary to decide that a true change has occurred (rather than simply measurement error) is a function of measurement reliability. A change of more than 5° in goniometric measurements is often considered a reflection of an actual change in range rather than simply measurement error (McClure, Blackburn, & Dusold, 1994). Studies of wrist goniometric reliability have demonstrated high intrarater and interrater reliability (LaStayo, Wheeler, & Flowers, 1994; Horger, 1990). Studies of goniometry have, however, trended towards intrarater reliability being slightly better than interrater reliability, meaning that measurements made by different therapists may need to be interpreted more conservatively than measurements made by the same therapist.

In addition to concerns about interrater reliability, there are also concerns about the application of forces during measurement. The main criticism is that consistent forces are
not typically applied when assessing passive range of movement (Breger-Lee, Bell-Krotoski, & Brandsma, 1990; Breger-Lee, Voelker, Giurintano, Novick, & Browder, 1993; Roberson & Giurintano, 1995; Rothstein, Miller, & Roettger, 1983; Singer et al., 2001). Goniometric measurement of range of movement involves joint movement by the examiner, and is subject to variation in the amount of force applied. Since joint angle is dependent on the force applied and distance from the axis where the force is applied (i.e. joint angle is dependent on torque), then control of these variables is necessary for reliable passive range of movement measurement. Alternative measurement technologies address these force-related problems while retaining the numeric qualities of goniometry.

In contrast to traditional goniometry methods, torque-controlled methods apply a constant, known force when moving a joint passively through its range of motion (Breger-Lee et al., 1990). This method records both the torque applied and the position of the joint (Roberson & Giurintano, 1995). Torque-controlled measurement of range of motion is not only objective but is also a non-invasive method for evaluating the mechanical properties of tissues that resist movement (Breger-Lee et al., 1990; Breger-Lee et al., 1993). In this study series, torque-controlled measurements of passive wrist extension will therefore be used.

Torque-controlled measurement of passive wrist extension, with the metacarpophalangeal and interphalangeal joints maintained in extension, is an appropriate means of evaluating the extensibility of the extrinsic finger flexor muscles. For muscles that pass over two joints, such as the extrinsic finger flexor muscles, normal muscle length is typically less than the total range of joint motion over which the muscle passes (Kendall, McCreary, & Provance, 1993). It is therefore appropriate for extrinsic finger flexor muscles to be placed in their most elongated position across all finger and wrist joints when measuring range (Berryman Reese & Bandy, 2002). This position ensures that the observed range reflects limited
extensibility in the extrinsic finger flexor muscles, rather than other muscles and soft tissues that span the flexor aspect of the wrist. A device for measuring the extensibility of the extrinsic finger flexor and wrist flexor muscles (Harvey, King, & Herbert, 1994) that addresses these factors will therefore be used throughout this series of studies (see Figure 2.3).

Figure 2.3  Device used to measure extensibility of the long finger flexor muscles (Harvey et al., 1994).

The device consists of a hand board hinged to a base. The hand and forearm are fastened to the hand board and base using Velcro straps. The metacarpophalangeal and interphalangeal joints are held in extension, with the wrist crease overlying the hinge. Since wrist extension is at a maximum during neutral deviation (Marshall, Mozrall, & Shealy, 1999), neutral wrist deviation needs to be checked and maintained when positioning the hand. The forearm is stabilised in pronation whilst the wrist is slowly pulled into extension using a spring balance attached perpendicular to the distal end of the hand board. By applying a constant moment...
arm of 24 cm (distance between the wrist joint and point of contact of the spring load balance, see Figure 2.3), the wrist extensor torque is standardised (Harvey et al., 1994). The angle of wrist extension is then measured either from a goniometer attached to the side of the device, or from photographs taken at the point of maximum passive wrist extension. The wrist angle is defined according to the American Academy of Orthopedic Surgery (AAOS), where 0° wrist extension indicates a neutral wrist position (and therefore limited extensibility of the extrinsic finger flexor muscles) (AAOS, 1965).

The wrist extensibility measuring device has been tested on patients with spinal cord lesions, another diagnostic group who experience loss of movement in the hand/wrist (Harvey et al., 1994). The wrist extensibility measurement procedure used in the thesis study series, has previously been found to have strong test-retest reliability (intraclass correlation coefficient (ICC) 0.85) (Harvey et al., 1994). Measurements taken by Harvey et al., (1994) on day one were within 5° of the measurements taken on day two 83% of the time indicating that a change greater than 5° in muscle extensibility represents real change rather than measurement error. The device can thus be used to produce reliable measures of wrist extensibility, allowing for a 5° measurement error.

There are other potential sources of error when using any torque-angle measure, including the device used in this series of studies. One source of error is the effect of active resistance by the participant. Active resistance to wrist extension movement introduces an opposing force and which can reduce the range of passive movement recorded (Ellis & Bruton, 1998). This source of potential error needs to be minimised in study designs to ensure measurement validity. In this study series, such error will be minimised though exclusion criteria for both studies 2 and 3; participants were not included in the studies if they were capable of wrist flexor muscle contractions.
Accurate measurement of muscle length across the wrist requires stabilisation of the proximal segment of the joint being measured, in this case stabilisation of the forearm. When using the measurement device (Harvey et al., 1994) in supine or when seated, the forearm is stabilised in full pronation helping to increase the reliability of the measurement of muscle length (Berryman Reese & Bandy, 2002). Research has shown that the extrinsic finger flexor muscles also contribute significant force to movement of the wrist (Bawa, Chalmers, Jones, Segaard, & Walsh, 2000). Consequently when evaluating the torque-range relationship at the wrist in this study series, the extrinsic finger flexor muscles will be held in maximum extension.

2.7.2 Measurement of Spasticity

Muscle overactivity also influences the available joint range and muscle length (Becher, Harlaar, Lankhorst, & Vogelaar, 1998; Gracies, Elovic, McGuire, & Simpson, 1997; Katz & Rymer, 1989; Tardieu, Huet de la Tour, Bret, & Tardieu, 1982; Tardieu, Tardieu, Colbeau-Justin, & Lespargot, 1982). As previously mentioned, the most common reason that therapists provide a hand splint following acquired brain impairment is to address contracture. As studies in this series address the issue of contracture, both trials assess the relative contribution of contracture to upper limb dysfunction through the measurement of muscle length (as outlined above). However, because therapists also aim to reduce spasticity through splinting, it was considered important to measure spasticity in the second randomised controlled trial (Study 3).

Spasticity is typically measured using rating scales such as the Ashworth (Ashworth, 1964) and the modified Ashworth (Bohannon & Smith, 1987) scales. The Ashworth scale involves
rating an individual’s spasticity by moving the affected limb quickly from maximum flexion to extension. The clinician rates muscle tone based on the response to quick stretch on a scale from 0 to 4. Due to frequent groupings of lower scores, the original Ashworth scale was modified to include a grade of 1+, which denotes a slight increase in tone; this scale is known as the modified Ashworth scale (Bohannon & Smith, 1987). Since neither of these common scales standardise the velocity at which to test the limb, and as spasticity can only be distinguished from contracture by the increase in resistance at high imposed speeds of movement, neither scale has the capacity to distinguish between spasticity and contracture (Bakheit et al., 2003; Pandyan, 1999; Pandyan, Price, Barnes & Johnson, 2003; Pomeroy, et al., 2000).

Unlike the Ashworth and modified Ashworth scales, the Tardieu scale has both a velocity and movement quality component, thus explicitly comparing the occurrence of a catch at low and high speeds (Ivanhoe & Reistetter, 2004). Given the addition of velocity, the Tardieu is effective in measuring the velocity-dependent component of hypertonia, that is, spasticity.

The Tardieu scale was originally developed by Tardieu and colleagues (Tardieu, Shentoub, & Delarue, 1954), and more recently published in English by Gracies and colleagues (Gracies, Marosszeky, Renton, Sandanam, Gandevia, & Burke, 2000). Whilst psychometric studies of the Tardieu Scale involving post-brain impairment adults are lacking, studies involving children with cerebral palsy have shown promising results. One study by Boyd and colleagues (Boyd, Barwood, Baillieu, & Graham, 1998) compared the Tardieu Scale as a spasticity measurement with the Ashworth Scale and found that the Tardieu Scale demonstrated better repeatability, and therefore greater reliability than the modified Ashworth score. Another study demonstrated both interrater reliability (ICC 0.7) and
acceptable standard error of measurement (SEM) for repeated measures of the Tardieu Scale (SEM 5°) in children with cerebral palsy (Fosang, Galea, McCoy, Reddihough, & Story, 2003).

When administering the Tardieu rating scale, the stretch reflex of wrist flexors is elicited by passively extending the wrist at various speeds (once at a speed faster than gravity, and once at a speed slower than gravity). The angular displacement of the wrist is then measured from photographs taken at the point of end of range using a slow velocity, and then at the point of catch using a fast velocity. As the scale can assess range and velocity of passive movement, the Tardieu will be used in study 3 (a randomised controlled trial) to measure the relationship between passive torque, velocity, and displacement at the wrist.

### 2.7.3 Measurement of Motor Function

Since contractures can affect task performance, it is also important to measure the effect of splinting on motor performance and function. Outcome measures used to assess motor function post-brain impairment vary considerably in their focus and rigor (Duncan, Goldstein, Matcharr, Divine, & Fussner, 1992; Heller et al., 1987; Nakayama, Jorgensen, Raaschou, & Olsen, 1994; Olsen 1990; Williams, Galea, & Winter, 2001). Some measures focus on body structure and function (that is, the motor recovery and function of the hemiplegic upper limb), and others focus on task performance (Williams et al., 2001). It has been recommended that outcome studies for people with hemiplegia following stroke should use measures that take into account both upper limb motor function and task performance (Williams et al., 2001).

The Motor Assessment Scale (MAS) takes into account both function and task performance (Carr, Shepherd, Nordholm, & Lynne, 1985). It is the only upper limb measure
recommended by the Post-Stroke Rehabilitation Clinical Practice Guideline (Gresham, Duncan, Stason, et al., 1995). The MAS contains true functional test items, that is, participants are asked to perform functional as opposed to simulated tasks (Okkema & Culler, 1998). The MAS is commonly used in Australian rehabilitation centres (Williams et al., 2001) and will be used across this study series to measure upper limb motor function.

The MAS incorporates active movement, speed of performance and functional ability to provide a thorough assessment of the affected upper limb (Williams et al., 2001). The MAS consists of nine items, three of which relate to upper limb movements (Item 6: Upper Arm Function, Item 7: Hand Movements, and Item 8: Advanced Hand Activities). Each upper limb item contains six tasks, with hierarchical scoring for each item ranging from 0 (unable to perform the first task) to 6 (optimal performance as patient can perform all six tasks) (Carr et al., 1985).

The upper limb items of the MAS (the UL-MAS subscale) provide an objective measure of patient progress and can be used to study the effects of a treatment program. Previous studies have shown that the UL-MAS is sensitive to change in motor function post-stroke (Bernhardt, Ellis, Denisenko, & Hill, 1998; Brock, Goldie & Greenwood, 2002; Dean & Mackay, 1992) and is suitable for use as an outcome measure in research studies (Bernhardt et al., 1998; Kjendahl, Sallstrom, Osten, Stanghelle & Borchgrevink, 1997; Langhammer & Stanghelle, 2000; Weiss, Suzuki, Bean, & Fielding, 2000) The UL-MAS subscale items also discriminate between varying abilities of people with stroke (Dean & Mackay, 1992; Williams et al., 2001), demonstrating the ability of the UL-MAS subscale to provide clinical outcome data for a range of ability levels.
Two studies (Malouin, Pichard, Bonneau, Durand, & Corriveau, 1994; Poole & Whitney, 1988) have examined the concurrent validity of the UL-MAS subscale against the upper limb section of the Fugl-Meyer Assessment (Sanford, Moreland, Swanson, Stratford, & Gowland, 1993) as the criterion test. The FMA is a commonly used assessment of upper limb movement after stroke (Filiatrault, Arsenault, Dutil, & Bourbonnais, 1992; Loewen & Anderson, 1988) with recognised validity and reliability (Malouin et al., 1994). Both studies computed the correlations between the individual items of the UL-MAS subscale and the corresponding items of the FMA (using Spearman’s rho), and found that they ranged from 0.89 to 0.92 (Malouin et al., 1994; Poole & Whitney, 1988) with a median correlation of 0.90. The correlation (Spearman’s rho) between the total score of the UL-MAS subscale and the FMA (upper limb items) was 0.91 (p<0.001) in chronic stroke patients (Poole & Whitney, 1988) and 0.93 (p<0.001) in acute stroke patients (Malouin et al., 1994). In summary, UL-MAS has excellent concurrent validity with other, well-known rehabilitation measures of upper limb function.

The UL-MAS has also been shown to be reliable for the purposes of assessing the functional outcome of the upper limb following acquired brain impairment. Test-retest reliability of the MAS was first established using a group of 14 people post-stroke, each rated by a single, experienced physiotherapist. Rating was carried out on two occasions one month apart. This yielded correlation coefficients (Pearson’s r) for all items ranging from 0.87 to 1.00 with an average correlation of 0.98 (unfortunately which of these correlation scores relate to upper limb items of the scale was not reported) (Carr et al., 1985). The items of the MAS were then further tested by Loewen and Anderson (1988) who tested test-retest reliability using videotaped performances of seven people post-stroke (videos re-evaluated after one month). Items included in the UL-MAS subscale yielded a mean Kendall’s rank order correlation
coefficient of 0.94, 1.0 and 1.0 for items 6, 7, and 8 respectively (Loewen & Anderson, 1988).

Testing of the MAS using five stroke patients and 20 physical therapists and students has also indicated interrater reliability (ICC) of 0.95 (Carr et al., 1985). In a subsequent study, two therapists observed 24 chronic stroke patients and yielded an interrater reliability coefficient (Spearman’s Rho) of 0.99 for the total MAS, and 1.00 (p<.001) for each upper limb item (Poole & Whitney, 1988). The finding of high interrater reliability has since been replicated (Loewen & Anderson, 1988).

The UL-MAS subscale is thus a valid and reliable measure of the motor function of the wrist and hand following acquired brain impairment. It was therefore chosen for use throughout this series of studies.

2.8 Key Issues to Emerge from the Literature Review

Adults who experience acquired brain impairment (from stroke, traumatic brain injury, or one of the less common causes such as hypoxia) represent the greatest proportion of Australians living with a permanent disability. Many are at risk of limited muscle extensibility. Limited muscle extensibility can result in disabling contractures. Even a small decrease in extensibility can have profound effects on task performance post-brain impairment. For example, loss of extensibility in the wrist flexor muscles can prevent wrist extension with fingers extended, which is essential during reach to grasp. In a similar way, loss of extensibility can also have profound implications for those people who do not regain movement after acquired brain impairment, making provision of dependent care difficult as
well. Clearly limited muscle extensibility is an important and common problem for this population. However, there is currently limited available evidence to inform best practice regarding the prevention of contracture.

The rationale for splinting adults following acquired brain impairment is that muscle contractures and their subsequent deformities can be corrected passively, and the desired position can be maintained with a static hand splint. This rationale forms the basis for the planned series of studies to be reported in this thesis. Controlled studies are urgently needed to investigate the effectiveness of splinting (Steultjens, Dekker, Bouter, van de Nes, Cup, & van den Ende, 2003). There is a lack of evidence regarding the side-effects and possible harm, and rigorous evidence about the usefulness of this intervention is needed.

**Rationale for Study 1:**

Hand splinting to prevent contractures and deformity following acquired brain impairment is common in practice (Neuhaus et al., 1981). This practice occurs despite the limited evidence to inform decisions regarding the intensity, frequency and duration of hand splinting. Clinical decisions regarding splint type, wearing regime, and whether or not to use splints at all need to be underpinned by quality evidence. Whilst doctors and therapists have published on the topic for years, this literature review has demonstrated that there is little high, quality literature on the effectiveness of hand splinting to guide clinical practice. The existing body of research will be systematically reviewed in **Study 1: A systematic review of splinting for adults with hemiplegia**.

In this chapter, the theoretical perspectives on hand splinting and the relationship between contracture and spasticity were critiqued. While the neurophysiological theory is the most common approach used by occupational therapists working with adults following acquired
brain impairment, this approach is scientifically flawed. Recent research has disproven many of the theories upon which the neurophysiological approach is based, for example, those relating to movement and brain impairment. An alternate theory, the biomechanical approach, was also critiqued. This theory has more scientific support. The biomechanical approach therefore undepinned the study series with the primary aim to examine the efficacy of hand splinting for the management of contracture following acquired brain impairment.

The biomechanical approach was considered most appropriate as there is theoretical support for the mechanism of contracture assumed in this approach. Throughout this dissertation study series the primary dependent variable will be the presence of contracture in the hemiplegic wrist. Earlier in this chapter, the clinical importance of range of movement was discussed and the limitations of the common use of goniometry for assessing this were highlighted. In the study series the amount of force producing the extension range being measured was controlled via the consistent use of a device purpose built for the measurement, thus allowing the presence of contracture in the wrist and long finger flexor muscles to be accurately measured. This permitted comparability and discussion of results across studies.

Whilst the primary dependent variable was muscle contracture, secondary variables of function and spasticity were also deemed clinically important. The role of the occupational therapist in the treatment of acquired brain impairment revolves around improving functional use of the hemiplegic upper limb and restoring the person to his or her maximum level of independence (Pedretti et al., 1996). The variable of functional upper limb movement should thus be monitored across studies. Finally, whilst spasticity has been shown to be only weakly (if at all) related to upper limb movement (Ada et al., 1998; Berger et al., 1982; Dietz et al., 1981; Hufschmidt & Mauritz, 1985; O’Dwyer & Ada, 1996;
Sahrmann & Norton, 1977), the prevalence of its use as a variable in previous research and its perceived importance to clinicians (Neuhaus et al., 1981; Dobkin, 2005) means that it too was measured as a secondary dependant variable (Study 3).

**Rationale for Study 2:**
Hand splinting is often used concomitantly with various methods of stretch such as motor training and prolonged muscle stretching. There is thus a need to compare the effects of people with acquired brain impairment who are receiving routine rehabilitation interventions (including movement training and prolonged stretches to the wrist) with those who receive routine rehabilitation plus wear a hand splint. This is the premise for **Study 2: a randomised, controlled trial of splinting for adults with hemiplegia following acquired brain impairment who are receiving hand stretches.** The results of this study will provide much needed guidance for therapists who work in rehabilitation with adults following brain impairment.

**Rationale for Study 3:**
As will be demonstrated in Study 1, literature is unable to provide guidance, not only on the basic question of efficacy of hand splinting, but also on the issue of which position the wrist joint should be placed in to effect stretch (discussed earlier in this chapter). This is the premise for **Study 3: a randomised, controlled trial of splinting for adults with hemiplegia following stroke who are not receiving hand stretches.** This study will not only allow comparison of outcomes with a control group, but will also provide guidance on the optimal position for splinting in light of the biomechanical approach since it randomly allocates those subjects who wear a hand splint into one of two splinting positions.

**Contribution of the study series:**
Do splints prevent contracture after acquired brain impairment? If people are receiving daily stretches, does wearing a splint at night further prevent contracture? And, in what position should the wrist be stretched in the splint? This study series will help fill a gap in the literature by systematically answering these important questions. In addition to filling the gaps in existing literature, this study series should also stimulate further research on the response of muscles to intensive stretch.

2.9 Synopsis

This chapter has presented a critique of the literature on upper limb dysfunction following acquired brain impairment. The need for evidence-based interventions for use with adults post-acquired brain impairment has been discussed. Factors which contribute to the experience of disability have been presented, with specific emphasis on the development of contracture and the role that occupational therapists and physiotherapists can potentially play in the prevention of contractures. Finally, measurement issues in the management of contracture were discussed. The following chapter will present Study 1 which aimed to systematically review the literature on hand splinting.
CHAPTER THREE

Study 1: A Systematic Review

[This study was published as: Lannin, N.A. & Herbert, R. D. (2003). Is hand splinting effective for adults following stroke? A systematic review and methodological critique of published research. Clinical Rehabilitation, 17, 807-816]
3.1 Chapter Overview

A number of studies have reported the effects of hand splinting with adults who have hemiplegia following acquired brain impairment. However, there is little consensus on the prescription of hand splints and whether or not this treatment is associated with reduced impairment. Furthermore, few studies have attempted to use rigorous research methodologies, such as the randomised controlled trial design, which would provide evidence for use in the clinical setting. The overall aim of this study series is to investigate management of contracture in the wrist and hand after acquired brain impairment, primarily quantifying the effect of prescribing hand splints. This first study was therefore designed to appraise the existing literature base for splinting post-stroke and the effect on impairments.

3.2 Background to the Study

After stroke, people often experience motor deficits that interrupt normal upper extremity function, as discussed in Chapter 2. Hand splints are a common component of rehabilitation programs (Kogler, 2002; Pedretti, Smith & McHugh-Pendleton, 1996; Woodson, 2002), however splinting with the acquired brain impairment population has historically been controversial (Edwards & Charlton, 2002; Langlois, Pederson, & MacKinnon, 1991; McPherson, Kreimeyer, Aalderks, & Gallagher, 1982; Milazzo & Gillen, 1998). Such controversy has continued unabated, largely as a result of the lack of scientific evidence on hand splinting (Ashburn, Cornall, Melville, Simpson, & Wright, 1998; McPherson et al., 1982; Perry, 1980; Wilton, 1997). Despite the controversies, splints continue to be used widely in the clinical setting.
A survey of therapists about their use of upper extremity splinting following stroke revealed a range of design principles, wearing schedules, splinting materials and clinical aims (Neuhaus et al., 1981). As discussed in Chapter 2, the clinical aims for splinting following stroke include reduction in spasticity (Kogler, 2002; Pedretti et al., 1996; Neuhaus et al., 1981; Wilton, 1997), reduction in pain (Neuhaus et al., 1981; Wilton, 1997), improvement of functional movement (Kogler, 2002; Milazzo & Gillen, 1998; Wilton, 1997), prevention of contracture (Kogler, 2002; Pedretti et al., 1996; Milazzo & Gillen, 1998; Wilton, 1997) and prevention of oedema (Pedretti et al., 1996; Neuhaus et al., 1981; Wilton, 1997). Despite the variety of aims, there are only two theoretical rationales for splinting after acquired brain impairment: the biomechanical (Neuhaus et al., 1981; Langlois et al., 1991; Wilton, 1997; Gossman, Sahrmann, & Rose, 1982) and the neurophysiological approaches (Neuhaus et al., 1981; Langlois et al., 1991; Wilton, 1997). Therapists who apply the biomechanical approach recommend splinting to prevent length-associated changes in muscles and connective tissue, whereas therapists who apply the neurophysiological approach recommend splinting to inhibit reflexive contraction of muscles.

With varied clinical aims, splint designs and opposing theoretical rationales, it is not surprising that there is much controversy surrounding this common rehabilitation practice. The research literature on splinting to date has not resolved such controversies, and knowledge on the absolute and relative efficacy of splinting is incomplete (Ma & Trombly, 2002). Published research was therefore systematically reviewed to understand the current level of evidence on hand splinting for adults following stroke, and randomised controlled trials (RCTs) of any hand or wrist splint for hemiplegia were appraised to assess the evidence of efficacy.
3.3 Rationale for the Study Design

An essential component of evidence-based practice has been the production of systematic reviews, to integrate existing scientific literature and provide data appropriate for both clinical and research decision-making (Mulrow, 1994). Systematic reviews of rigorous studies provide the best evidence of the effectiveness of health care intervention (Greener & Langhorne, 2002; National Health and Medical Research Council, 2000). A systematic review is a synthesis of the results of multiple primary studies (Cook, Mulrow, & Haynes, 1997). Reviews are produced using a prospective formal methodology which aims to eradicate systemic and random errors as well as minimise bias (Cook et al., 1997; Cook, Sackett, & Spitzer, 1995). A systematic review must first begin with a comprehensive search of all potentially relevant articles which are then appraised, results synthesised and interpreted.

The benefit of a systematic review is that it can establish whether findings are consistent, and can be generalised across populations, settings and treatment variations, or can determine whether findings vary across groups (Mulrow, 1994). The outcomes from a review are therefore useful both in clinical practice (Garfield, 1987) and in research, since reviews may highlight the need for additional studies (Mulrow, 1987; 1994). A systematic review methodology was chosen by the candidate for this program of research to first identify and refine hypotheses for future studies in the program of research, and second, to recognise and avoid the pitfalls of the existing literature base, ensuring that the proposed program of research filled a clinical gap in the knowledge base.
3.4 **Aim of the Study**

The aim of the review was to identify and critically appraise all experimental research on the effects of hand splinting for adults with hemiplegia. This objective led to a content analysis of published literature, and a systematic review of the evidence obtained from randomised trials.

3.5 **Method**

3.5.1 *Data Collection Procedures*

This review used the search strategy developed by the Cochrane Stroke Review Group to identify studies involving people who have experienced a stroke. This search strategy was combined with key words specific to the topic (see Table 3.1). Terms were exploded where possible then combined. The Cochrane Central Register of Controlled Trials\(^1\) was used to identify any controlled trials not published on the topic of hand-splinting. The following sources were searched on 26 May 2003. Databases were searched up to 26 May 2003\(^2\):


b) Citation index databases: Science Citation Index (SCI), and Social Sciences Citation Index (SSCI)

c) Websites of 15 relevant professional organisations, and

d) Citation-tracking of primary studies, review articles and books.

---

\(^1\) [www.cochrane.org](http://www.cochrane.org)

\(^2\) It is acknowledged that there is a time delay between completion of the systematic review and submission of the thesis. A Medline search conducted November 2005 yielded no additional published RCTs of hand splinting in adults with hemiplegia following stroke. Although there were additional lower levels studies, these do not refute the consistency or direction of effect of the results of this systematic review. Chapter 2 reviewed the breadth of all recent work, and therefore includes these later studies.

\(^3\) [www.pedro.fhs.usyd.edu.au](http://www.pedro.fhs.usyd.edu.au)
### Table 3.1  Electronic Search Strategy

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>exp cerebrovascular disorders/</td>
</tr>
<tr>
<td>2</td>
<td>stroke$.tw.</td>
</tr>
<tr>
<td>3</td>
<td>cerebrovascular$.tw.</td>
</tr>
<tr>
<td>4</td>
<td>(cerebral or cerebellar or brainstem or vertebrobasilar).tw.</td>
</tr>
<tr>
<td>5</td>
<td>(infarct$ or isch?emi$ or thrombo$ or emboli$).tw.</td>
</tr>
<tr>
<td>6</td>
<td>4 and 5</td>
</tr>
<tr>
<td>7</td>
<td>carotid$.tw.</td>
</tr>
<tr>
<td>8</td>
<td>(cerebral or intracerebral or intracranial or parenchymal).tw.</td>
</tr>
<tr>
<td>9</td>
<td>(brain or intraventricular or brainstem or cerebellar).tw.</td>
</tr>
<tr>
<td>10</td>
<td>(infratentorial or supratentorial or subarachnoid).tw.</td>
</tr>
<tr>
<td>11</td>
<td>8 or 9 or 10</td>
</tr>
<tr>
<td>12</td>
<td>(haemorrhage or hemorrhage or haematoma or hematoma).tw.</td>
</tr>
<tr>
<td>13</td>
<td>(bleeding or aneurysm).tw.</td>
</tr>
<tr>
<td>14</td>
<td>12 or 13</td>
</tr>
<tr>
<td>15</td>
<td>11 and 14</td>
</tr>
<tr>
<td>16</td>
<td>thrombo$.tw.</td>
</tr>
<tr>
<td>17</td>
<td>(intracranial or (venous adj5 sinus$) or (sagittal adj5 venous) or (sagittal adj5 vein)).tw</td>
</tr>
<tr>
<td>18</td>
<td>16 and 17</td>
</tr>
<tr>
<td>19</td>
<td>transient isch?emic attack$.tw.</td>
</tr>
<tr>
<td>20</td>
<td>reversible isch?emic neurologic$.tw.</td>
</tr>
<tr>
<td>21</td>
<td>venous malformation$.tw.</td>
</tr>
<tr>
<td>22</td>
<td>arteriovenous malformation$.tw.</td>
</tr>
<tr>
<td>23</td>
<td>21 or 22</td>
</tr>
<tr>
<td>24</td>
<td>11 and 23</td>
</tr>
<tr>
<td>25</td>
<td>exp aphasia/</td>
</tr>
<tr>
<td>26</td>
<td>hemianopsia/</td>
</tr>
<tr>
<td>27</td>
<td>hemiplegia/</td>
</tr>
<tr>
<td>28</td>
<td>(aphasi$ or dysphasi$ or hemianop$).tw.</td>
</tr>
<tr>
<td>29</td>
<td>(hemiplegi$ or hemipar$).tw.</td>
</tr>
<tr>
<td>30</td>
<td>25 or 26 or 27 or 28 or 29</td>
</tr>
<tr>
<td>31</td>
<td>or/1-3,6-7,15,18-20,24,30</td>
</tr>
<tr>
<td>32</td>
<td>leukomalacia, periventricular/</td>
</tr>
<tr>
<td>33</td>
<td>cerebral anoxia/</td>
</tr>
<tr>
<td>34</td>
<td>exp dementia, vascular/</td>
</tr>
<tr>
<td>35</td>
<td>exp vascular headache/</td>
</tr>
<tr>
<td>36</td>
<td>migrain$.tw.</td>
</tr>
<tr>
<td>37</td>
<td>32 or 33 or 34 or 35 or 36</td>
</tr>
<tr>
<td>38</td>
<td>31 not 37</td>
</tr>
<tr>
<td>39</td>
<td>physical therapy techniques [MESH]</td>
</tr>
<tr>
<td>40</td>
<td>splint$.exp</td>
</tr>
<tr>
<td>41</td>
<td>splint$.tw.</td>
</tr>
<tr>
<td>42</td>
<td>splints[MESH]</td>
</tr>
<tr>
<td>43</td>
<td>cast$.exp</td>
</tr>
<tr>
<td>44</td>
<td>cast$.tw.</td>
</tr>
<tr>
<td>45</td>
<td>Casts, Surgical [MESH]</td>
</tr>
<tr>
<td>46</td>
<td>orthotic$.tw.</td>
</tr>
<tr>
<td>47</td>
<td>thermoplastic$.tw.</td>
</tr>
<tr>
<td>48</td>
<td>ortho$.tw.</td>
</tr>
<tr>
<td>49</td>
<td>brace.tw.</td>
</tr>
<tr>
<td>50</td>
<td>or/39-49</td>
</tr>
</tbody>
</table>
3.5.2 Data Collection

3.5.2.1 Inclusion Criteria

English language studies on the effects of splinting that fulfilled the following criteria were included in the review:

a. Type of study: studies which generated level IV evidence or higher (Phillips et al., 1988). While it is acknowledged that the best available evidence is that which is least susceptible to bias, such as that provided by Levels 1a and 1b evidence (See Table 3.2), a broader search strategy was used to also identify studies more prone to bias (Levels 2, 3 and 4) for content analysis.

b. Type of intervention: studies that involved the administration of upper extremity splinting programs for adults following stroke. For the purpose of this review, splints were defined as an external, removable device “designed to apply, distribute or remove forces to or from the body in a controlled manner,” to control body motion and alteration or prevention in the shape of body tissue (Ashburn et al., 1998, p. 1).
c. Types of subjects: studies that involved humans in which more than 50% of the subjects were adults who had experienced a stroke.

d. Types of outcome measures: Studies that included a measure of functional hand use, joint range of motion, tone, spasticity, oedema, or pain.

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1a</td>
<td>Systematic reviews and meta-analyses of randomised controlled trials</td>
</tr>
<tr>
<td>Level 1b</td>
<td>Randomised controlled trials (RCTs)</td>
</tr>
<tr>
<td>Level 2a</td>
<td>Systematic reviews and meta-analyses of randomised and non-randomised controlled trials</td>
</tr>
<tr>
<td>Level 2b</td>
<td>Controlled trials, cohort and poor quality RCTs</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control studies</td>
</tr>
<tr>
<td>Level 4</td>
<td>Case series</td>
</tr>
<tr>
<td>Level 5</td>
<td>Expert opinion including literature/narrative reviews, consensus statements and individual case studies</td>
</tr>
</tbody>
</table>

*Note:* Abbreviated from Phillips et al., 1988. Used with permission.

### 3.5.2.2 Exclusion Criteria

The following study designs and publications were excluded from the review:

a. Diagnostic, or prognostic study,

b. Less than 50% of the splints were applied to the wrist or hand,

c. A second publication of the same study presented the same results.

A single reviewer applied these criteria when determining whether to include/exclude studies. Abstracts from conference proceedings were excluded because of the paucity of information provided. Studies published in non-English language journals were not included because of potential error in the translation and interpretation of findings (Kelley, 1999).
3.5.3 **Data Analysis**

A single reviewer extracted data from the selected studies. Data extracted included study methodology, outcome measures used, key results, and study conclusions. First, each study was assigned a level of evidence using the system developed by the Oxford Centre for Evidence-based Medicine (Phillips et al., 1988) (Table 3.2). The second part of the process included an internal and external validity rating. Studies were rated according to criteria developed by AOTA’s Evidence-Based Literature Review Project as ‘high’ (no threats present), ‘moderate’ (one or two threats exist), or ‘low’ (more than two threats to validity exist) validity (Trombly & Ma, 2002).

3.5.3.1 **Content Analysis**

A content analysis of published research located through the search strategy was made (Weber, 1990) by grouping studies which produced similar levels of evidence into common categories with subcategories of splint designs. Each study was only counted once to ensure robust findings and minimal interpretation by the investigator.

3.5.3.2 **Systematic Review**

In line with published recommendations for reviews of treatment efficacy, the systematic review excluded non-randomised trials (Bandolier, 2000; Khan, Ter Riet, Glanville, Sowden, & Kleijnen, 2000). Two independent reviewers, both with previous training and experience in study design and critical appraisal, assessed the methodological quality of all randomised controlled trials. The systematic review was conducted with multiple reviewers to limit bias, minimise error and improve the reliability of findings (Chalmers, Levin, Sacks, Reitman, Berrier, & Nagtalingam,
1987; Magee, Oborn-Barrett, Turner & Fenning, 2000). There were no rating discrepancies between reviewers.

The tool chosen for quality rating was the PEDro scale, developed by the Centre for Evidence-Based Physiotherapy (CEBP) in Australia (Maher, Sherrington, Herbert, Moseley & Elkins, 2003). The PEDro scale consists of 10 criteria each receiving either a ‘yes’ or ‘no’ score (providing a total score maximum of 10). The scale and implementation of the scoring system are detailed in Table 3.3 (taken from Teasell, Doherty, Speechley, Foley, & Bhogal, 2003). The PEDro scale score has acceptable reliability, and has been shown to be appropriate for rating randomised controlled trials of physical therapy interventions, such as required for this review of hand splinting (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). In relation to methodological quality and susceptibility to bias, it was established a priori that studies which attained a particular PEDro score would be considered as follows: seven or more= ‘high quality’, five or six= ‘moderate quality’, and those four or less= ‘poor quality’ (Harvey, Herbert, & Crosbie, 2002).

The intention was to conduct a meta-analysis on the located data if there was sufficient clinical and statistical homogeneity between studies (Laird & Mosteller, 1990).
<table>
<thead>
<tr>
<th>Table 3.3</th>
<th><strong>PEDro Scoring Criteria and Implementation Guidelines</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Subjects were randomly allocated to groups.</strong></td>
<td>A point for random allocation was awarded if random allocation of patients was stated in its methods. In a crossover study, subjects were randomly allocated an order in which treatments were received. The precise method of randomisation need not be specified; quasi-randomisation allocation procedures did not satisfy this criterion.</td>
</tr>
<tr>
<td><strong>2. Allocation was concealed.</strong></td>
<td>A point was awarded for concealed allocation if this was explicitly stated in the methods section or if there was reference that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “offsite”.</td>
</tr>
<tr>
<td><strong>3. The groups were similar at baseline regarding the most important prognostic indicators.</strong></td>
<td>A point for baseline comparability was given if at least one key outcome measure at baseline was reported for the study and control groups. This criterion was satisfied even if only baseline data of study completed-only subjects were presented.</td>
</tr>
<tr>
<td><strong>4. There was blinding of all subjects.</strong></td>
<td>The subject was considered blinded if he/she did not know which group they had been allocated to. In addition, subjects were only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups.</td>
</tr>
<tr>
<td><strong>5. There was blinding of all therapists who administered the therapy.</strong></td>
<td>The therapist was considered blinded if he/she did not know which group the subject had been allocated to. In addition, therapists were only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups.</td>
</tr>
<tr>
<td><strong>6. There was blinding of all assessors who measured at least one key outcome.</strong></td>
<td>The assessor was considered blinded if he/she did not know which group the subject had been allocated to.</td>
</tr>
<tr>
<td><strong>7. Adequacy of follow-up.</strong></td>
<td>Follow-up was considered adequate if 85% of the subjects that had been originally randomised were measured on the main outcome at the end of the study.</td>
</tr>
<tr>
<td><strong>8. Intention to treat.</strong></td>
<td>All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analyzed by “intention to treat”. For purpose of the present evidence-based review, a trial was awarded a point for intention-to-treat if the trial explicitly stated that an intention-to-treat analysis was performed.</td>
</tr>
<tr>
<td><strong>9. The results of between-group statistical comparisons are reported for at least one key outcome.</strong></td>
<td>The analysis was considered a between-group analysis if either a simple comparison of outcomes measured after the treatment was administered was made, or a comparison of the change in one group with the change in another was made. The comparison may be in the form of hypothesis testing (e.g. p-value) or in the form of an estimate (e.g. the mean, median difference, difference in proportion, number needed to treat, relative risk or hazard ratio) and its confidence interval. A trial was awarded a point for this criterion if between group comparison on at least one outcome measure was made and its analysis of comparison was provided.</td>
</tr>
<tr>
<td><strong>10. The study provides both point measures and measures of variability for at least one key outcome.</strong></td>
<td>A point measure was referred as to the measure of the size of the treatment effect. The treatment effect was described as being either a difference in group outcomes, or as the outcome in (each of) all groups. Measures of variability included standard deviations, standard errors, confidence intervals, interquartile ranges (or other quartile ranges), and ranges. Point measures and/or measures of variability that were provided graphically (for example, SDs may be given as error bars in a Figure) were awarded a point as long as it was clear what was being graphed (e.g. whether error bars represent SDs or SEs). For those outcomes that were categorical, this criterion was considered to have been met if the number of subjects in each category was given for each group.</td>
</tr>
</tbody>
</table>

*Note: Although the identification of eligibility criteria is also considered under the PEDro scoring system, it is not used to calculate PEDro scores.*
3.6 Results

Of the 106 papers retrieved using the above search strategy, 18 studies met the criteria for appraisal. Reasons for exclusion of papers were: less than 50% or non-described proportion of population were adults who had experienced a stroke (20%); the splint was applied to a body part other than the hand/wrist (10%); the study did not investigate effectiveness of splinting (17%); and the paper was a narrative opinion/literature review without explicit appraisal (44%). A further eight papers were excluded because the purpose of the splint was to provide functional electrical stimulation and not to apply forces to the muscles of the hand/wrist.

3.6.1 Results of Content Analysis

Eighteen studies were appraised, rated for method and quality, and underwent content analysis (Tables 3.3 and 3.4). There was a scarcity of randomised controlled trials. Overall, one study provided Level 5 evidence (5%), 12 studies (63%) provided Level 4 evidence, 2 (10%) provided Level 3 evidence, and 4 (21%) provided Level 2 evidence (RCTs with methodological limitations). No studies identified using the search strategy provided Level I evidence (high quality randomised controlled trial or systematic review). Moreover, all studies were found to have threats to internal validity on appraisal: 17 (90%) rated as having low internal validity and 2 (10%) as having moderate internal validity. A common threat to the validity of statistical conclusions was the lack of power. A common threat to statistical conclusion validity was the lack of power. Appraisal of external validity provided better results, with 5 (26%) rated as high, 13 (69%) rated as moderate, and 1 (5%) rated as low.

3.6.2 Results of Systematic Review

Four randomised controlled trials were included in the systematic review. The trials differed in relation to the type of intervention used (such as splint designs and wearing regimes), the
outcome measures used, and the duration of the intervention period. This heterogeneity precluded meta-analysis.

The methodological quality and susceptibility to bias of each included randomised controlled trial is presented in Table 3.4. All papers were of either ‘moderate’ (Poole, Whitney, Hangeland & Baker, 1990) or ‘poor’ quality (Langlois et al., 1991; McPherson et al., 1982; Rose & Shah, 1987). None of the randomised controlled trials met the criteria for a ‘high’ quality study. PEDro scores ranged from two to six (median score = 3.5). While all studies used random allocation, none used concealed allocation and only one study (Poole, Whitney, Hangeland & Baker, 1990) used blinded assessors.

Table 3.4
Methodological Rating of Randomised Controlled Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>PEDro criterion score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 3 4 5 6 7 8 9 10 11 TOTAL</td>
</tr>
<tr>
<td>McPherson et al., 1982</td>
<td>Y Y N N N N Y N Y Y Y 4</td>
</tr>
<tr>
<td>Rose et al., 1987</td>
<td>Y Y N N N N N N N Y N 2</td>
</tr>
<tr>
<td>Poole et al., 1990</td>
<td>N Y N Y N N Y Y N Y Y 6</td>
</tr>
<tr>
<td>Langlois et al., 1991</td>
<td>Y Y N N N N N N Y Y Y 3</td>
</tr>
</tbody>
</table>

Note: Explanation of score items: Item score N=absent or not clearly present, Y=present; The PEDro scale criteria are: (1) specification of eligibility criteria; (2) random allocation; (3) concealed allocation; (4) prognostic similarity at baseline; (5) subject blinding; (6) therapist blinding; (7) assessor blinding; (8) >85% follow-up of at least one key outcome; (9) intention-to-treat analysis; (10) between group statistical comparison for at least one key outcome; and (11) point estimates of variability provided for at least one key outcome. Only items 2–11 are summed to provide total score. NB Item (1) is not included in the calculation of PEDro score.

Data from the one study of ‘moderate’ methodological quality (Poole, Whitney, Hangeland, & Baker, 1990) showed no difference in motor function of the wrist and hand after wearing an inflatable pressure splint which positioned the shoulder in 90° of flexion and maximum external rotation with full elbow extension (hand and wrist not enclosed in air splint) for 30 minutes/day. The mean difference on the 57-point Fugl-Meyer Assessment was -0.12, 95% CI -9.8 to 9.6 (where a negative difference indicates a beneficial effect).
The three remaining studies, which were all rated as being of ‘poor’ methodological quality, investigated the effect of thermoplastic hand splints. One study reported that hand splinting in the functional position for two hours (total time to outcome) using either a volar or dorsal splint, resulted in a statistically significant increase in passive range of wrist extension and a decrease in hypertonus (Rose & Shah, 1987). Point measures and measures of variability were not reported. This study also had a very short follow-up period (2 hours). Another trial reported no significant difference in hypertonus between dorsal and volar splints (mean difference = 0.1 lb, 95% CI -1.4 to 1.5) (McPherson et al., 1982). In that study, the splints were worn for two hours/day for five weeks (McPherson et al., 1982). The methodological limitations of both studies (threats to internal validity) which include a short follow-up (Rose & Shah, 1987) and lack of no-splint comparison (McPherson et al., 1982)) limit the usefulness of these results. The final study by Langlois and colleagues (1991) reported no difference in wrist stiffness (hypertonus) after two weeks of wearing a finger-spreader splint for six hours compared to longer wearing times of 12 hours or 22 hours (mean difference between groups = 0.001 Nm.rads, 95% CI -0.42 to 0.41). A limitation of this study was the lack of a no-splint control group.

3.7 Discussion

Therapists working with adults following stroke often fabricate hand splints. Despite the widespread use of splints, surprisingly few studies (n=18), and even fewer randomised controlled trials (n=4), have examined the effect of splinting in this population. Studies of thermoplastic hand splinting for adults following stroke were nearly all of low methodological quality. Heterogeneity of study design, methods, splint design and regime, and outcomes hindered the pooling of data.
The majority of papers located using the search strategy were found to be based on opinion without explicit appraisal (44%) and did not, therefore, meet the criteria for inclusion in this study. Of those studies which did meet the criteria for inclusion in the content analysis (i.e. those papers which were classified as quantitative research), the most popular research method design used was the case series design. Few investigators have employed more rigorous designs, such as randomised n-of-one studies (also known as a single case experimental design) or randomised controlled trials. Overall, less than 17% of the included studies were based on true-experimental designs (Robson, 1993). The quality of those few, existing randomised controlled trials was further rated using the systematic review methodology. This methodology provided guidance for the thesis studies and ensured that previous errors in methodology are not replicated.

This review was limited by the inclusion and exclusion criteria since only trials in which more than 50% of the participants were adults who had experienced a stroke were included. As shown in Chapter 2, the motor and contracture effects following stroke are essentially the same as those experienced following any other acquired brain impairment. Therefore, including studies with participants who had other forms of acquired brain impairment may have yielded more studies for inclusion in this review. Furthermore, non-English language reports were excluded.

In addition to these methodological limitations, the findings of this systematic review are also limited by the small number of randomised controlled trials, and their poor methodological quality. Furthermore, one trial did not estimate the magnitude of effects (Rose & Shah, 1987); the authors of that study were contacted to request the missing data, but without response. The aim of the review was to provide a reliable estimate of the effects
of hand splinting, based on a weighted average of the results of all included studies (Laird & Mosteller, 1990). However, study results varied across included trials, with standard deviations missing in some studies, and change scores were reported in some studies while post-intervention results in others. Such variability precluded data comparison (Smith & Egger, 1998).

Although this review located four trials, one study investigated an inflatable arm splint while the other three investigated thermoplastic hand splints. Ambiguous findings result from all studies, with wide confidence intervals and small sample sizes in those studies with non-significant findings. No trial commented on the long-term benefit of hand splinting, nor did they assess or comment on potential adverse effects. Like much stroke rehabilitation literature (Bhogal, Teasell, Foley, & Speechley, 2003), hand splinting research was found to lack rigor in its methodology. Further trials, using more rigorous methods, adequate sample sizes, a control group that has baseline comparability which does not wear a splint, and appropriate outcome measures, are needed before conclusions can be drawn regarding the effect of hand splinting for adults following stroke.

### 3.7.1 Implications for Future Research

Those areas requiring further empirical evaluation can be identified by future researchers through the assignment of levels of evidence to studies in the systematic review (Boyd & Hays, 1997). This review identified a paucity of rigorous evidence. The efficacy of hand splinting will not be known until well-designed randomised controlled trials compare hand splinting to a control condition which does not involve hand splinting. The only published randomised controlled trial which used a control group was limited in its clinical usefulness by the short time to outcome (two-hours) and absence of any further follow-up measure (Rose & Shah, 1987). For the effects of stretch to be clinically useful to people post-stroke,
the stretch must last longer than two hours. Lasting effects of stretch involve underlying structural and biochemical adaptations (Tabary et al., 1972; Williams & Goldspink, 1978; 1984). Results from animal studies indicate that a two-hour stretch, and measurement immediately following the removal of stretch (as was the case in the study by Rose and Shah (1987)) is likely to result in transient viscous deformation only and not lasting muscle length changes (Herbert, 1993). The study by Rose and Shah (1987), therefore, does not provide clinically useful information about the longer term effect of splinting on muscle extensibility. Future trials should adhere to recommendations made by Pocock (1983), which include using clear eligibility criteria, a priori calculation of sample size and specification of primary and secondary outcomes, randomisation, allocation concealment, and blinding.

The problem of heterogeneity between studies examining hand splinting was partly due to the diversity of outcome measures used in studies. Future researchers should therefore aim to use consistent outcome measures. Earlier splinting literature focused on measurement of spasticity. Since scientific evidence demonstrates that spasticity is at best only weakly related to function following stroke (Ada et. al., 1998; O’Dwyer et al., 1996), continuing to measure spasticity as the primary outcome measure in future trials is unlikely to be helpful for therapists or people with acquired brain impairment. As the most common reason for hand splinting following stroke is to prevent deformities and contracture (Neuhaus et. al., 1981), future trials should focus on measuring the effect of splinting on contracture prevention and management.

Research on hand splinting following stroke was relatively scarce and provided conflicting results. Existing literature focused on the debate about which splint design might be most efficacious, rather than whether splinting a joint in a particular position of stretch is in itself
efficacious. More recent theorists suggest that rather than considering the effects of different hand splints on muscle contracture and upper limb performance, researchers should compare the amount of time the splint is worn (Langlois et al., 1991), and the position of the hand with respect to elongation of particular muscles (Ada & Canning, 1990). Animal research suggests that outcomes from hand splinting may be enhanced when patients are positioned with ‘at risk’ muscles in their most elongated state (such as with the wrist positioned in maximum extension to elongate flexor carpi-radialis and ulnaris). Although this relationship has been tested in relation to lower limb casting with adult neurological patients (Moseley, 1997), this is not the case for hand splinting for stroke patients.

The following research questions need to be addressed, to inform both therapists and patients about hand splinting for the management of contracture following acquired brain impairment:

1. Does hand splinting prevent wrist and finger flexor muscle contracture?
2. How much stretch should be applied using a hand splint to prevent contracture (how often should the splint be worn, for what duration, and in what position of stretch)?
3. What types of hand splints are most acceptable to patients and health service managers in terms of cost?
4. What clinical indicators, if any, help therapists to determine whether or not a splint will be effective following acquired brain impairment?

### 3.7.2 Implications for Clinical Practice

On the basis of this review, there is insufficient evidence to either support or refute the effectiveness of hand splinting for adults following stroke. This ongoing uncertainty stems
from the lack of unbiased evidence comparing the effect of hand splinting with not wearing a hand splint for a period longer than two hours.

There is medium quality evidence that the use of an inflatable arm splint does not improve hand and wrist function (Poole et al., 1990). However, this conclusion is based on one randomised controlled trial which produced wide confidence intervals around the mean difference, and a small sample size. Poor quality evidence from two randomised controlled trials suggested that dorsal and volar hand splintings produce similar effects on hypertonicity. Wide confidence intervals around the mean effect, and small sample size in one of the studies (n=10; McPherson et al., 1982) limits the validity of such findings. Finally, poor quality evidence was located which suggests that a hand splint worn for 6 hours a day produces equivalent results as splinting for longer periods (12 hours or 22 hours a day) (based one poor quality randomised controlled trial with wide confidence intervals around mean effects, and small sample size of 13 participants with stroke; Langlois et al., 1991). These results should be interpreted with caution because no study was considered to be of high quality. Further, the relative effect of splinting may have been exaggerated in the moderate and poor quality studies as a result of the presence of biases (Harvey et al., 2002).

3.8 Synopsis

The results of this systematic review demonstrate that there is insufficient evidence to either support or refute the effectiveness of hand splinting in the treatment of adults following stroke. None of the studies provided evidence of long-term benefits or of adverse effects. It should be emphasised, however, that a lack of evidence of benefit is not the same as evidence of a lack of benefit (Greener & Langhorne, 2002), therefore further research is imperative. There is still much that is not understood about the effect of hand splinting in
the stroke population. It is only with the benefit of new research that therapists will be able to make informed choices about the use of hand splinting as an intervention. Findings of this systematic review led to the development of new research questions and methods for Studies 2 and 3, which are reported in subsequent chapters.
<table>
<thead>
<tr>
<th>Study</th>
<th>Splinting Intervention(s)</th>
<th>Control Intervention</th>
<th>Diagnosis</th>
<th>Total n</th>
<th>Mean Age (range)</th>
<th>Time post-Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hand Splint (ill-defined)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brennan, 1959</td>
<td>Splint (worn to keep joint fully extended)</td>
<td>Corresponding muscles controlling a neighbouring joint (no splint)</td>
<td>CVA</td>
<td>14</td>
<td>56 years (13-82)</td>
<td>Average months 18</td>
</tr>
<tr>
<td>Bowen et al., 1988</td>
<td>Resting wrist-hand orthosis worn 24 hours/day plus PROM every 2 hours during day</td>
<td>No splint (unknown co-interventions)</td>
<td>Right CVA</td>
<td>2</td>
<td>64 years (63-65)</td>
<td>Not specified</td>
</tr>
<tr>
<td>Dorsal Hand Splint</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan, 1962</td>
<td>Dorsal splint worn minimum of 8 hours/day</td>
<td>None</td>
<td>CVA</td>
<td>10</td>
<td>(28-70 years)</td>
<td>6 months-40 years</td>
</tr>
<tr>
<td>Woodson, 1988</td>
<td>Dorsal splint with finger spreaders worn 6 hours/day</td>
<td>None</td>
<td>Left CVA</td>
<td>2</td>
<td>24.5 years (26-23)</td>
<td>10-14 months</td>
</tr>
<tr>
<td>Scherling et al., 1988</td>
<td>Dynamic dorsal splint worn 16-22 hours/day</td>
<td>None</td>
<td>CVA</td>
<td>18</td>
<td>Not specified</td>
<td>6 months - 3 years</td>
</tr>
<tr>
<td>Volar Hand Splint</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Takami et al., 1992</td>
<td>Wrist cock-up splint (unknown wearing regime)</td>
<td>None</td>
<td>Right CVA</td>
<td>1</td>
<td>66 years</td>
<td>Not specified</td>
</tr>
<tr>
<td><strong>Comparison Dorsal v. Volar Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zislis, 1964</td>
<td>Dorsal splint (unknown wearing regime)</td>
<td>None</td>
<td>CVA</td>
<td>1</td>
<td>64 years</td>
<td>Not specified</td>
</tr>
<tr>
<td>Charait, 1968</td>
<td>Volar splint worn 2-23 hours/day plus PROM 30 minutes 5 days/week and graded resistive exercises 30 minutes 3 days/week</td>
<td>None</td>
<td>CVA</td>
<td>20</td>
<td>(30-80 years)</td>
<td>4 days to 6 years</td>
</tr>
<tr>
<td>McPherson et al., 1982</td>
<td>Dorsal splint (similar to “Snook Splint”) worn 2 hours/day</td>
<td>None</td>
<td>CVA (n= 6), traumatic brain injury (n=1), cerebral palsy (n=3)</td>
<td>10</td>
<td>(24-76 years)</td>
<td>More than 1 year</td>
</tr>
<tr>
<td>Rose et al., 1987</td>
<td>Dorsal splint (worn 2 hours), Volar splint (worn 2 hours)</td>
<td>No splint (unknown cointerventions)</td>
<td>CVA</td>
<td>30</td>
<td>64 years (34-87)</td>
<td>Not specified</td>
</tr>
</tbody>
</table>
Table 3.5 continued…

<table>
<thead>
<tr>
<th>Study</th>
<th>Splinting Intervention(s)</th>
<th>Control Intervention</th>
<th>Diagnosis</th>
<th>Total n</th>
<th>Mean Age (range)</th>
<th>Time post-Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dorsal-Volar Hand Splint (Snook Splint)</strong></td>
<td>Dorsal-volar splint (“Snook Splint”) worn 6 hours on, 6 hours off.</td>
<td>None</td>
<td>Right hypoxic brain injury (n=1)</td>
<td>2</td>
<td>38 years (27-50)</td>
<td>14 years</td>
</tr>
<tr>
<td>Snook, 1979</td>
<td></td>
<td></td>
<td>CVA (n=1), injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Finger Spreader/Abduction Splint</strong></td>
<td>Finger abduction splint worn all day (removed for therapy and meals) plus “standard treatment in therapy sessions”</td>
<td>None</td>
<td>CVA</td>
<td>15</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>Doubilet et al., 1977</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Langlois et al., 1991</td>
<td>Finger spreader splint (worn 6, 12, 22 hours/day)</td>
<td>None</td>
<td>CVA</td>
<td>13</td>
<td>64 years</td>
<td>Over 12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cone Splint</strong></td>
<td></td>
<td></td>
<td>CVA</td>
<td>3</td>
<td>81 years (75-84)</td>
<td>5 years to 7 years</td>
</tr>
<tr>
<td>Dayhoff, 1975</td>
<td>Firm cone splint worn all day, removed for therapy.</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jamison et al., 1980</td>
<td>Cone splint worn 24 hours/day</td>
<td>None</td>
<td>CVA</td>
<td>15</td>
<td>76 years (58 - 96)</td>
<td>36 months-11 years</td>
</tr>
<tr>
<td>Mathiowetz et al., 1983</td>
<td>Volar resting splint (immediate wearing effect recorded only)</td>
<td>No splint (unknown cointerventions)</td>
<td>CVA</td>
<td>4</td>
<td>44 years (19-96)</td>
<td>4-9 years</td>
</tr>
<tr>
<td></td>
<td>Finger spreader splint (immediate wearing effect recorded only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cone splint (immediate wearing effect recorded only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inflatable Pressure Splint</strong></td>
<td></td>
<td></td>
<td>CVA</td>
<td>18</td>
<td>70 years (55-82)</td>
<td>Not specified</td>
</tr>
<tr>
<td>Poole et al., 1990</td>
<td>Inflatable arm splint worn for 30 minutes 5 days/week plus “traditional occupational therapy” 5 days/week</td>
<td>No splint plus “traditional occupational therapy” 5 days/week</td>
<td>CVA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dynamic Splint</strong></td>
<td></td>
<td></td>
<td>CVA</td>
<td>8</td>
<td>77 years (67-86)</td>
<td>Not specified</td>
</tr>
<tr>
<td>McPherson et al., 1985</td>
<td>Dynamic splint (“Becker splint”) worn 1 hour 3 days/week</td>
<td>Passive range of motion 3 days/week</td>
<td>CVA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lycra Splint</strong></td>
<td></td>
<td></td>
<td>CVA</td>
<td>16</td>
<td>65 years (36-85)</td>
<td>11 weeks</td>
</tr>
<tr>
<td>Gracies et al., 2000</td>
<td>Custom-made lycra arm and glove splint worn 3 hours</td>
<td>None</td>
<td>CVA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Research Design</td>
<td>Level of Evidence</td>
<td>Internal Validity</td>
<td>External Validity</td>
<td>Treatment Duration</td>
<td>Splinting n</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Hand Splint (ill-defined)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brennan, 1959</td>
<td>Case series</td>
<td>4</td>
<td>Low <strong>†‡§</strong></td>
<td>Moderate ***</td>
<td>19.8 weeks (7-36 weeks range)</td>
<td>14</td>
</tr>
<tr>
<td>Bowen et al., 1988</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>High</td>
<td>8 weeks</td>
<td>1</td>
</tr>
<tr>
<td><strong>Dorsal Hand Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaplan, 1962</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate §§</td>
<td>20 weeks (12-24 week range)</td>
<td>10</td>
</tr>
<tr>
<td>Woodson, 1988</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate ***</td>
<td>6 weeks</td>
<td>2</td>
</tr>
<tr>
<td>Scherling et al., 1988</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate ***</td>
<td>Varied (2-7 months)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Volar Hand Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Takami et al., 1992</td>
<td>Single case study</td>
<td>5</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate ***</td>
<td>Unknown</td>
<td>1</td>
</tr>
<tr>
<td><strong>Comparison Dorsal v. Volar Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zislis, 1964</td>
<td>Single case study (crossover design)</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate §§</td>
<td>Unknown</td>
<td>1</td>
</tr>
<tr>
<td>Charait, 1968</td>
<td>Cohort study</td>
<td>3</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate §§</td>
<td>Varied (2 months to 3 years)</td>
<td>n(dorsal)=10</td>
</tr>
<tr>
<td>McPherson et al., 1982</td>
<td>Randomised trial</td>
<td>2b</td>
<td>Low <em>†‡§</em>*</td>
<td>High</td>
<td>5 weeks</td>
<td>n(dorsal)= 5</td>
</tr>
<tr>
<td>Rose et al., 1987</td>
<td>Randomised trial</td>
<td>2b</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate §§</td>
<td>2 hours</td>
<td>n(dorsal)=10</td>
</tr>
<tr>
<td><strong>Dorsal-Volar Hand Splint (Snook Splint)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snook, 1979</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate §§</td>
<td>Varied (4 days to 1 week)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Finger Spreader/Abduction Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doubilet et al., 1977</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate ***</td>
<td>1 week</td>
<td>15</td>
</tr>
<tr>
<td>Langlois et al., 1991</td>
<td>Randomised trial</td>
<td>2b</td>
<td>Low <em>†‡§</em>*</td>
<td>High</td>
<td>2 weeks (+ 2 weeks follow-up)</td>
<td>n(6hrs/day)= 3</td>
</tr>
</tbody>
</table>
Table 3.6 continued…

<table>
<thead>
<tr>
<th>Study</th>
<th>Research Design</th>
<th>Level of Evidence</th>
<th>Internal Validity</th>
<th>External Validity</th>
<th>Treatment Duration</th>
<th>Splinting n</th>
<th>Control (no splint) n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cone Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dayhoff, 1975</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>†‡§</em>*</td>
<td>Moderate §§</td>
<td>6 weeks (follow-up to 1 year)</td>
<td>3</td>
<td>No control group</td>
</tr>
<tr>
<td>Jamison et al., 1980</td>
<td>Case series</td>
<td>4</td>
<td>Low <em>‡§</em>*</td>
<td>High</td>
<td>4 weeks</td>
<td>15</td>
<td>No control group</td>
</tr>
<tr>
<td>Mathiowetz et al., 1983</td>
<td>Case series (using non-CVA controls)</td>
<td>4</td>
<td>Moderate *§</td>
<td>Low §§***</td>
<td>Immediate effects measured (all conditions provided in one session, with rest in between)</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td><strong>Inflatable Pressure Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poole et al., 1990</td>
<td>Randomised controlled trial</td>
<td>2b</td>
<td>Moderate ***††</td>
<td>High</td>
<td>3 weeks</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td><strong>Dynamic Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>McPherson et al., 1985</td>
<td>Cohort study (matched controls)</td>
<td>3</td>
<td>Low <em>‡§</em>*</td>
<td>Moderate ***</td>
<td>6 weeks</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Lycra Splint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gracies et al., 2000</td>
<td>Case series (cross-over)</td>
<td>4</td>
<td>Moderate §**</td>
<td>Moderate §§</td>
<td>3 hours</td>
<td>16</td>
<td>Subjects served as own controls</td>
</tr>
</tbody>
</table>

**Note:** * Internal Validity Concern: threat to statistical conclusion validity; † Internal Validity Concern: threat of maturation present; ‡ Internal Validity Concern: threat of measurement/instrumentation bias present; § Internal Validity Concern: threat of selection bias present; §§ Internal Validity Concern: threat of co-intervention bias present; §§§ Internal Validity Concern: threat of intervention bias present; †† Internal Validity Concern: threat of contamination present; ††† Internal Validity Concern: threat that treatment may not represent current practice; *** External Validity Concern: threat that participants may not be representative of population; †††† External Validity Concern: research was not conducted in clinical (natural) setting.
CHAPTER FOUR

Study 2: A Randomised Controlled Trial Comparing Splinting plus Stretch to Stretch Alone in Adults with Hemiplegia following Acquired Brain Impairment

[This study was published as: Lannin, N.A., Horsley, S., Herbert, R., McCluskey, A., & Cusick, A. (2003). Splinting the hand in the functional position after brain impairment: a Randomized controlled trial. Archives of Physical Medicine and Rehabilitation, 84, 297-302]
Chapter Four: Randomised Controlled Trial of Splinting plus Stretch

4.1 Chapter Overview

Management of contractures of the wrist and finger flexor muscles following acquired brain impairment is a challenge for clinicians. There is still insufficient evidence on how to effectively prevent or manage contractures. This chapter presents the findings from a randomised controlled trial that investigated the effectiveness of hand splints with an existing inpatient rehabilitation population of people post stroke, who were also receiving wrist extension stretches. This study was designed to determine whether or not prescribing a hand splint in acute rehabilitation (where active training and stretches are commonly practiced) benefits adults with hemiplegia following acquired brain impairment.

4.2 Background

Reduction of disability due to stroke and other acquired brain impairments is a recognised national health priority in Australia (National Health Priority Action Council, 2002). Hemiplegia is one of the most prevalent types of disability in this population (Ing, Tesio, Arnould, Zancan, & Thonnard, 2001; Sato, Kaji, Tsuru, & Oizumi, 1999). As described in Chapter One, one of the most common and preventable complications of hemiplegia is the development of contractures (Farmer & James, 2001; O’Dwyer & Ada, 1996; Yarkony & Sahgal, 1987). Contractures limit the available movement at the joints affected, preventing full use of the hand and arm, and are associated with poor functional recovery (Carr & Shepherd, 1987). Occupational therapists and other health care professionals have the opportunity during rehabilitation to minimise contracture following brain impairment. A number of treatment modalities are used to address such contracture, including passive stretching, splinting (Farmer & James, 2001), casting and movement training (Ada &
Canning, 1990). In most rehabilitation units, patients who experience hemiplegia are routinely provided with a hand splint by their occupational therapist (Kogler, 2002), whilst also receiving prolonged stretching and movement training by their occupational therapist and/or physiotherapist. There are, however, still discrepancies in occupational therapy splinting practices, and use of hand splints with this population is controversial (Edwards & Charlton, 2002; Langlois, Pederson & Mackinnon, 1991; McPherson, Kreimeyer, Aalderks & Gallagher, 1982; Milazzo & Gillen, 1998; Wilton, 1997). As outlined in-depth in Chapter 2, the most common aim of hand splinting in the neurological population, and the one used as a basis for the present study, is the prevention of contracture (Neuhaus et al., 1981) based on the biomechanical rationale. While some therapists reportedly aim to reduce muscle spasticity (Langlois, Mackinnon, & Pederson, 1989; Neuhaus et al., 1981), the clinical relevance of spasticity as an outcome is questionable, since published research suggests that spasticity is unrelated, or only weakly related, to functional ability following stroke (O’Dwyer, Ada, & Neilson, 1996).

4.3 Description and Rationale for Study Design

The efficacy of splinting was investigated using a randomised controlled study. As adjunct to splinting, rehabilitation interventions such as passive stretching and movement training are commonly used in Australia. The conduct of the study in a typical clinical setting (which includes passive stretching and movement training) thus increases the applicability of the results so that the very real concerns of clinicians working in the Australian health care setting are addressed.

Recommendations from Pocock (1983) and criticism of previous research methodologies (Ashburn, Cornall, Melville, Simpson, & Wright, 1998) were used to assist in the development of the study protocol. Specifically, those researchers advocate making sure there are sufficient numbers of participants to provide statistical power, accounting for
participant demographics and baseline performance, use of blinding (masking), random, concealed allocation, and using validated and well-established outcome measures.

4.4 **Aim**

The primary aim of this study was to determine the effect of four weeks of splint wearing on the length of the wrist and finger flexor muscles, in patients who were in the early stages of rehabilitation following acquired brain impairment. Secondary aims were to determine whether splint wearing affected recovery of hand function and pain in the upper limb.

4.5 **Research Question**

In adults who were receiving daily stretching and movement training for treatment of hemiplegia following acquired brain impairment, does splinting in the traditional, ‘functional’ position prevent contracture of the wrist and finger flexor muscles, improve function and/or decrease pain, compared to those who do not wear a splint?

4.6 **Method**

4.6.1 **Ethics approval**

Ethics approval was gained through the University of Western Sydney Ethics Review Committee (Human Subjects) – Protocol Number: 2000/054, and Townsville General Hospital Ethics Committee-Protocol Number: Q02/128 (Appendix B).

4.6.2 **Participants**

4.6.2.1 **Inclusion Criteria:**

Participants were required to meet the following criteria for inclusion in the study:

a) History of a single acquired brain impairment resulting in upper limb hemiplegia of no greater than six months duration;
b) Be unable to actively extend the affected wrist; and

c) Be aged over 18 years.

As it is not customary in clinical practice to provide a hand splint to patients with
active movement, participants with active wrist extension were excluded from taking
part in the study. Age limitations were imposed to ensure the study met Australian
guidelines as outlined by the National Statement of Ethical Conduct in Research
Involving Humans (2001).

4.6.2.2 Exclusion criteria

Participants were excluded from the study if they met any of the following criteria:

a. Previous stroke which had resulted in upper limb hemiplegia

b. Previous upper limb trauma causing structural imbalance or reduced range of
   movement at the wrist or fingers (for example, due to colles fracture)

c. Osseous abnormality in the wrist or fingers

d. Arthritic condition of the wrist or fingers.

Participants were ineligible if they had language comprehension, perceptual or
cognitive deficits that would prevent written informed consent or participation in the
program.

4.6.3 Power Analysis and Sample size

The required sample size was calculated using the pooled estimate of within-group standard
deviations (5.1°) obtained from pilot data (Pocock, 1983). A 5° change in measured muscle
extensibility at the wrist was selected as the minimum clinically important change which
would be considered worthwhile following the extensive period of splint wearing. Power
calculations indicated that a sample of 28 subjects would provide an 80% probability of

---

4 People under 18 years of age are required by legislation to have the consent of their parent/guardian to participate in research.
detecting a $5^\circ$ effect on wrist and finger flexor length, with non-compliance and loss to follow-up of 20% and alpha set at .05.

The minimum clinically important change ($5^\circ$ effect on the primary outcome, wrist and finger flexor muscle lengths) was determined after consideration of the anticipated financial cost of making a hand splinting versus the burden of wearing a hand splint each night for four weeks from the patient perspective, and the amount of change in wrist extensibility that would make a measureable difference to hand function.

4.6.4 Randomisation

Participants were randomly allocated to control and experimental groups using a simple randomisation process (Pocock, 1983); participants were allocated to groups according to a random number sequence generated using a random number table (Altman & Bland, 1999a). Group allocation was concealed from the investigator, with the random numbers generated by a third person not involved in the study and located at an external site. Random allocation followed baseline measurement (Moher, Shulz, & Altman, 2001). The investigator contacted an independent, third person via telephone to obtain group allocation for each subject, thereby ensuring concealed randomisation.

4.6.5 Blinding

This trial used single blinding where the assessors (those obtaining outcome measures) were unaware of group allocation and whether participants had been allocated a hand splint or not. Due to difficulty blinding individuals to a physical therapy such as hand splints, participants were not blinded. Some but not all treating therapists were blind to group allocation (the therapist providing the daily stretching program was blind to group allocation). Although lack of participant and therapist blinding was a potential source of bias, the main outcome measure (the extensibility measure of range of movement) and one
of the secondary outcome measures (hand function) were rated by the blinded assessor. The data from these measures were quantitative and there was no subjective interpretation by the investigator or the participants who were unblinded. Therefore, bias was minimised as much as possible given the physical constraints of researching this form of therapy.

### 4.6.6 Intervention

This study was designed to reflect current Australian rehabilitation practice and to ensure applicability of results. In Australia, and elsewhere, hand splinting is typically provided in combination with routine upper limb therapy. The usual alternative to hand splinting (and therefore the most appropriate ‘control’ comparison) is routine therapy without a splint. Therefore, the control group received only routine therapy and the experimental group wore a hand splint for up to 12 hours a night, for four weeks in addition to routine therapy. The routine therapy of individual motor training and upper limb stretches provided five days per week to all study participants was:

**Upper limb motor training:** An individually designed motor training program was provided (Carr & Shepherd, 1987, 1998; Dean & Shepherd, 1997). The program aimed to improve upper limb task performance. Each participant received approximately 30 minutes of training a day, five days a week. The training typically involved attempts to elicit muscle contraction. No limits were placed on the amount of finger or wrist extension and participants were encouraged to practice outside of therapy.

**Stretching:** The second component of routine therapy received by both the control and experimental groups was daily upper limb stretching. Two 30-minute stretches were applied to the upper limb five-days a week for the duration of the study and follow-up period (five weeks in total). These stretches provided a prolonged low-load stretch to muscles at risk of
developing contracture (Carr & Shepherd, 1995; Ada & Canning, 1990), including the long finger and wrist, elbow flexors, forearm pronator and thumb abductor muscles. The first stretch was a seated weight-bearing stretch, with (i) the shoulder joint positioned in external rotation, abduction, and slight extension, (ii) the elbow in extension, (iii) the forearm in supination, and (iv) the wrist and fingers in extension (Figure 4.1). The second stretch was a seated stretch of involving use of an inflatable long-arm air splint\(^5\) with (i) the shoulder joint positioned in external rotation and abduction, (ii) the elbow positioned in extension, (iii) the wrist positioned in extension and (iv) the thumb positioned in abduction (Figure 4.2). Participants were helped to move into and maintain stretch positions by their treating physiotherapist who was blind to treatment allocation. If necessary, the therapist remained with the participant throughout the duration of the stretch.

\[\text{Figure 4.1} \quad \text{A seated weight-bearing stretch of the upper limb}\]

\(^5\) URIAS Pressure Splint; Svend Andersen Plastic Industri, Maersk Medical A/S, Engmosen 1, 3540 Lynge, Denmark.
4.6.6.1 Control Program

Control participants did not wear a hand splint at any time during the study period. They continued to receive routine therapy as outlined above.

4.6.6.2 Splinting Program

In addition to the routine motor training and stretching described above, participants in the experimental group wore a hand splint on a daily basis, for a maximum of 12-hours each night for the four-week intervention period. The chief investigator and nursing staff on the hospital ward were responsible for ensuring that the splints were applied and fitted correctly for the duration of the study.
Splint design: A static palmar-mitt splint (Copley & Kuipers, 1999) was custom made by the chief investigator using Ezeform® thermoplastic. The splint held the hand in the ‘functional’ resting position: wrist positioned in 10° extension, thumb in opposition and abduction, and semiflexion of the finger joints (Figure 4.3) (Hill, 1988; Lowe, 1989; Wilton, 1997). Splints were checked daily by the chief investigator for fit and comfort. No adjustments to the splints were required during the study period to maintain the ‘functional’ resting position.

![Static palmar-mitt splint with the wrist and fingers positioned in the ‘functional position’](image)

**Figure 4.3**
**Static palmar-mitt splint with the wrist and fingers positioned in the ‘functional position’**

Wearing Regime: In this study, the hand splints were worn overnight for a maximum of 12-hours. This splint wearing regime was chosen on the basis of the best available literature as discussed in Chapter 2.

Compliance with the splinting program: Compliance with the splint wearing regime was important for the overall success of the trial. As non-compliance with the splinting program could influence results, the study protocol addressed compliance...
through participant and family education (Bond & Burt, 2002). Participants were all resident in a single inpatient rehabilitation unit which allowed the chief investigator to put the splints on each evening and remove them each morning to improve and monitor compliance.

4.6.6.3 Potential Contaminants

The effect of practicing wrist extension (motor training) and of stretches may have affected the primary outcome, muscle extensibility of the wrist and long-finger flexor muscles, and as such could contaminate the results of the study. The amount of stretching and time spent in therapy was consistent across all participants involved in the trial. This was made possible as all participants were located in a single rehabilitation unit and treating therapists remained constant during the study period.

4.6.7 Data Collection

Age, gender, ethnicity, hand dominance, hemiplegic hand, location and type of acquired brain impairment, and time post-impairment were recorded to provide demographic and background information on the participants. Outcome measures were obtained on three occasions: before random allocation (baseline), at the end of the 4-week experimental period on the 30th day (post-intervention), and one-week after the experimental intervention was ceased on the 38th day (follow-up). Measurements on the 30th day were taken at least 3 hours after the splint had been removed. Measurements were conducted by trained physiotherapists who were blind to group allocation (blinded assessors).
4.6.7.1 Outcome Measures

Three outcomes were recorded. These were length of wrist and finger flexor muscles (primary outcome), hand and arm function, and pain levels (secondary outcomes).

Primary Outcome: The length of the wrist and finger flexor muscles was obtained using a standard procedure which provided a torque-controlled measurement of wrist extension with the fingers extended (Harvey, King, & Herbert, 1994). The measurement procedure and its psychometric properties were discussed in Chapter 2 (2.7.1 Measurement of Passive Range of Movement). To ensure that muscle length was being measured (as opposed to range of joint motion) the following guidelines were followed:

   a. Muscles to be measured (long finger flexors and wrist flexors) were placed in the fully elongated position by holding both the fingers and the wrist in extension;
   
   b. The muscle should be isolated across one or possibly two joints; and
   
   c. The bony landmarks to be used to align the measurement tool should be palpable and in proper alignment.

The extensibility device used to measure the primary outcome ensured that all of these guidelines could be met. The extensibility of the wrist flexor muscles (flexor digitorum superficialis and profundus, flexor carpi radialis and ulnaris, palmaris longus and flexor pollicus longus) was reflected by the angle of wrist extension that corresponded with a standardised torque. Torque was standardised for a particular participant but not across all participants. Angle of wrist extension was measured using skin surface markers and a goniometer attached to the side of the instrument (see Figure 4.3). Three consecutive measurements were taken on each occasion, with the mean reading of the three used for analysis.
Secondary Outcomes: Secondary outcomes included the upper limb domains (items six, seven and eight) of the Motor Assessment Scale at four and five weeks; and self-reported pain level in the wrist at four and five weeks.

Motor Assessment Scale:

Upper limb function was measured using items 6 (upper limb function), 7 (hand movements) and 8 (advanced hand activities) of the Motor Assessment Scale (MAS) (see Table 4.1) (Carr, Shepherd, Nordholm, & Lynne, 1985; Dean & Mackey, 1992; Poole & Whitney, 1988). Psychometric properties of this scale were discussed in Chapter 2 (2.7.3 Measurement of Motor Function). As required by the standardised procedure, three consecutive measurements were taken on each occasion and the best performance recorded for analysis. Summed scores from items 6, 7, and 8 were used to provide an overall indicator of upper limb function.

Upper Limb Pain:

Upper limb pain was measured using a 10-centimeter vertical visual analogue scale (Chapman, Casey, Dubnar, Foley, Gracely & Reading, 1985; Tiplady, Jackson, Maskrey, & Swift, 1998), which is shown in the literature to be a sensitive (Jensen, Karole & Braver, 1994; Ohnhaus & Adler, 1975), valid (Jensen et al., 1994; Ohnhaus & Adler, 1975) and reliable method of collecting subjective pain intensity (Jensen et al., 1994). Pain intensity was recorded prior to measuring the wrist and finger flexor muscle length to avoid contamination between outcome measures.
Table 4.1 Upper Limb Subscale of the Motor Assessment Scale (UL-MAS): Items 6, 7 and 8

| 6. Upper arm function | 1. lying protract shoulder girdle with arm in elevation  
| | 2. lying hold extended arm in elevation for 2 seconds  
| | 3. flexion & extension of elbow to take palm to forehead with arm as in 2  
| | 4. sitting hold extended arm in forward flexion at 90° to body for 2 seconds  
| | 5. sitting patient lifts arm to above position and holds it there for 10 seconds, then lowers it  
| | 6. standing, hand against wall maintain arm position while turning body towards wall  
| 7. Hand movement | 1. sitting extension of wrist  
| | 2. sitting radial deviation of wrist  
| | 3. sitting elbow into side pronation and supination  
| | 4. reach forward, pick up large ball of 14 cm diameter with both hands & put it down  
| | 5. pick up a polystyrene cup from table & put it down on table across other side of body  
| | 6. continuous opposition of thumb and each finger more than 14 times in 10 seconds  
| 8. Advanced hand activities | 1. picking up the top of a pen and putting it down again  
| | 2. picking up one jelly bean from a cup and placing it in another cup  
| | 3. drawing horizontal lines to stop at a vertical line ten times in 20 seconds  
| | 4. holding a pencil, making rapid consecutive dots on a sheet of paper  
| | 5. taking a desert spoon of liquid to the mouth  
| | 6. holding a comb and combing hair at back of head  

Splinting Program Compliance: In addition to these clinical outcome measures, compliance with the splint wearing schedule was logged daily using ‘time-on/time-off’ recording charts. Data were recorded by nursing staff on the hospital ward, and monitored by the chief investigator. The splint wearing recording sheets were based on the concept of a time-use diary, one of the most accurate methods of measuring time-use (Harvey, 1993; Pentland, Harvey, & Walker, 1998; Stanley, 1995).
4.6.8 Data Analysis

Change in the length of wrist and finger flexor muscles, upper limb function scores, and pain scores in control and experimental groups were compared using two-tailed independent sample t tests. Parametric data were reported for all outcomes, including the UL-MAS which is considered a long ordinal scale with parametric data being presented in previous studies (for example, Baskett, Broad, Reekie, Hocking & Green, 1999). Parametric tests are also robust to violations of their assumptions (Box, Leonard, & Wu, 1983; Armitage & Berry, 1994) and the results of parametric tests are generally more useful to clinicians; for example, it is easier to generate confidence intervals for parametric tests, and parametric test results can be included in meta-analyses. To avoid controversy about the most appropriate statistical tests to use for rank-ordinal data, a secondary analysis of the differences between the two groups on the upper limb function (UL-MAS) scores was performed using the non-parametric Mann-Whitney test.

Significance levels were pre-established at the $p \leq 0.05$ level. Size of treatment effect was estimated by differences in group means and their 95% confidence intervals. Where possible, outcome measures were obtained for all participants allocated to the trial. Each participant's data were analysed in the group to which the participant was allocated, in accordance with the principle of intention-to-treat (Lachin, 2000; Hollis & Campbell, 1999). Missing data were imputed using the last observation carried forward method (Pocock, 1983).

4.7 Results

Results will be presented in the following order. First, the baseline characteristics of participants are presented (Table 4.2). These data are followed by a participant flow diagram demonstrating the progression of participants through the trial. After this,
comparisons of effectiveness will be made between the two groups: the primary outcome is presented first, followed by the secondary outcomes.

### 4.7.1 Baseline Characteristics

Following baseline measurement, 11 participants were randomly assigned to the control group, and 17 were assigned to the two splinting intervention. Subjects in the two groups were similar, on average, at the time of recruitment to the study (Table 4.2). Mean age of the sample was 66 years. Just over half of the sample were women (54%) and 89% were Caucasian. Twenty seven participants had experienced a stroke or subarachnoid haemorrhage and one participant had experienced a traumatic brain injury.

<table>
<thead>
<tr>
<th>Table 4.2</th>
<th>Baseline Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Control Group (n=11)</td>
</tr>
<tr>
<td></td>
<td>stretch only</td>
</tr>
<tr>
<td>Age in years</td>
<td>68 years, 1 month</td>
</tr>
<tr>
<td></td>
<td>(7.4)</td>
</tr>
<tr>
<td>Gender: number of women (%)</td>
<td>6 (54.5%)</td>
</tr>
<tr>
<td>Time post-impairment in days</td>
<td>57 (63.6)</td>
</tr>
<tr>
<td>Dominance: number of right-hand dominant (%)</td>
<td>11 (100%)</td>
</tr>
<tr>
<td>Number of right-sided hemiplegia</td>
<td>7 (63.63%)</td>
</tr>
</tbody>
</table>

*Note: Values are means (+ standard deviations) unless otherwise stated.*
4.7.2 Participant Flow Details

Fifty three adults underwent eligibility screening of which 30 were eligible for participation (eligibility fraction\(^7\) for study was therefore 56.6%). Reasons for exclusion included: active wrist extension (n=19), concurrent fracture of the hemiplegic arm (n=2), and decreased ability to provide informed consent (n=2). Two eligible participants elected not to participate in the study. Twenty eight adults who met entry criteria and agreed to take part were enrolled in the study and completed baseline measurements (enrolment fraction\(^8\) was therefore 93.3% and recruitment fraction\(^9\) 52.8%). Baseline data was not collected from non-participants.

Of the 28 participants randomised, 25 (11 from the control group and 14 from the experimental group) participated in all interventions and assessments as allocated (Figure 4.4). Outcome measures were obtained from 26 participants post-intervention, and from 27 participants at follow-up. One participant in the experimental group withdrew from the study during the intervention period as a result of self-discharge from the rehabilitation unit. Two additional participants in the splint group refused post-intervention measurement but participated in follow-up measurements (one participant continued to receive interventions as allocated). One participant in the control group reported a pain rating of 0 at baseline, of 0 at post-intervention and increased her rating by 100% (maximum score of 10) at the follow-up measure one week later. As this follow-up value for pain differed so greatly that it was omitted from all analyses.

---

\(^{7}\) The proportion of participants deemed eligible for the study of all potential participants screened is termed the \textit{eligibility fraction}.

\(^{8}\) The proportion of eligible people who enroll in the study of those who were eligible for participation is termed the \textit{enrolment fraction}.

\(^{9}\) The product of the eligibility and the enrolment fractions represents the proportion of potential participants who actually enrolled in the study and is termed the \textit{recruitment fraction}. 
Numbers of participants in each group who were non-compliant with the protocol are shown below in Table 4.3. Non-compliance with protocol included participants: refusing part of the outcome assessment protocol, not wearing their assigned hand splint for a minimum of 5 hours in a 24 hour period, or using an alternative hand splint (not assigned).

Table 4.3
*Numbers of participants in each group who did not adhere to the protocol*

<table>
<thead>
<tr>
<th>Time</th>
<th>Control Group ((n=11)) (stretch only)</th>
<th>Intervention Group ((n=14)) (stretch plus splint)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Weeks</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>5 Weeks</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

At study commencement, differences between the two groups for key outcomes (contracture, function, and pain) were small and insignificant (see Table 4.4). Data are mean (SD) baseline values of wrist extensibility, and subjective pain rating, and median (frequency) baseline values of function for participants in the two groups. Although there were no systematic differences between groups, parameters did vary between subjects. Some participants appeared to have normal, or near-normal, wrist muscle extensibility at baseline while others had signs of clinical contracture when compared to their non-affected hand.

Table 4.4  
*Baseline performance of groups on dependent variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group ((n=11)) (Routine therapy only)</th>
<th>Intervention Group ((n=17)) (routine therapy plus splint)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-affected wrist extensibility</td>
<td>80.8 (9.5)</td>
<td>83.4 (7.8)</td>
</tr>
<tr>
<td>in degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemiplegic wrist extensibility</td>
<td>79 (10.5)</td>
<td>76 (13.9)</td>
</tr>
<tr>
<td>in degrees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Function on UL-MAS</td>
<td>0.8 (1.8)</td>
<td>1.8 (3.0)</td>
</tr>
<tr>
<td>Pain (%)</td>
<td>1.6 (2.7)</td>
<td>2 (2.9)</td>
</tr>
</tbody>
</table>

*Note:* Data are mean (SD) baseline values of wrist extensibility, and subjective pain rating, and median (frequency) baseline values of function and spasticity rating for participants in both groups.
Patients screened at initial appointment (N=53)

Registered Participants (N=28)

Baseline Assessment (N=28)

Randomised to CONTROL group: Stretch only (n=11)

Randomised to SPLINT group: Splint plus Stretch (n=17)

Provided FUNCTIONAL WRIST SPLINT for 4 weeks (n=17)

1 month review (n=11)
dropout (n=0)
noncompliant (n=0)

Analysed (n=11)

6 week review (n=11)
dropout (n=0)
noncompliant (n=0)

Analysed (n=11)

1 month review (n=14)
dropout (n=1)
noncompliant (n=2)

Analysed (n=14)

6 week review (n=16)
dropout (n=1)
noncompliant (n=0)

Analysed (n=16)

Reasons behind patients who were approached not taking part were: able to extend the wrist (19), refused- no reason given (2), medically unfit- non-brain impairment related medical condition (2), unable to provide informed consent (2).

Figure 4.4  **Participant flow diagram**

The effects of splinting (the difference between the experimental and control groups) were not clinically important or statistically significant.
4.7.3 Primary Outcome: Effect of splinting on contracture

Splinting increased wrist extension by a mean of 1° after the intervention (95% CI -3.7° to 6.1°), and reduced wrist extension by a mean of 2° at follow-up (95% CI -7.2° to 3.2°). Neither result was large enough to be of clinical importance (see Figure 4.5).

Figure 4.5 Mean (95% confidence intervals) of differences between torque-controlled wrist extension range of motion of the splint and control groups at the commencement of the study (initial), then after four weeks of splint intervention (post-intervention), then one week after the removal of the splint (follow-up).

A negative effect indicates that the splint treatment did not have an advantageous effect on the extensibility of the wrist extensor muscles in relation to the control group.
4.7.4 Secondary Outcome: Effect of splinting on function

Splinting decreased upper limb function (MAS component 6) by a mean of 0.3 points on a 6-point scale after the intervention (95% CI -1.5 to 0.9) and decreased upper limb function by 0.8 points at follow-up (95% CI -2.0 to 0.3). Splinting decreased performance of hand movements (MAS component 7) by 0.4 points after the intervention (95% CI -1.4 to 0.7) and by 0.5 points at follow-up (95% CI -1.5 to 0.6). Splinting decreased performance of advanced hand activities (MAS component 8) after the intervention by 0.03 points after the intervention (95% CI -0.5 to 0.4), and by 0.1 point at follow-up (95% CI -0.8 to 0.5). None of these differences were statistically significant or clinically important.

Splinting decreased overall upper limb function, measured by the summed scores of UL-MAS, by 0.06 points on an 18-point scale after the intervention (95% CI -2.5 to 2.7) and by 0.2 points at follow-up (95% CI -2.7 to 2.3). Non-parametric analyses yielded zero effects (median difference of all paired differences between groups) for all comparisons of MAS scores at both final measurement and follow up, and confidence intervals for differences between medians (Armitage & Berry, 1994) were similar, or tighter, to those obtained with parametric analyses.

4.7.5 Secondary Outcome: Effect of splinting on pain

Splinting increased the reported intensity of upper limb pain by a mean of 0.2 cm on a 10 cm visual analogue scale after the intervention (95% CI -2.3 to 2.7) and reduced the reported pain intensity by 1 cm at follow-up (95% CI -4.6 to 2.2). These differences were not considered statistically or clinically significant.
4.7.6 Splint compliance and participant satisfaction

All participants in the experimental group wore hand splints, but as could be expected in a clinical setting, there was some daily variability compliance to the splinting protocol. Compliance with the splint wearing protocol was, however, very high (see Table 4.5). Participants appeared motivated to wear the splints with no additional encouragement. No participant in the experimental group demonstrated evidence of skin breakdown or adverse reactions following splint wearing. On the contrary, the typical subjective response was that the splinting procedure was comfortable. At the end of the study, participants in the experimental group were surveyed about the level of ‘annoyance’ related to wearing a splint. Fifteen participants rated their level of annoyance at wearing the splint, on a 10 cm visual analogue scale. The mean level of reported ‘annoyance’ at the completion of the study was 3.9 cm, which is considered to be low.

<table>
<thead>
<tr>
<th>Table 4.5 Compliance with Splinting Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Average total wear time (sd) in hours</td>
</tr>
<tr>
<td>Average weekly wear time (sd) in hours</td>
</tr>
<tr>
<td>Average nightly wear time (sd) in hours</td>
</tr>
</tbody>
</table>

4.8 Discussion

4.8.1 Key Findings

The key finding from this study was that wearing a hand splint in addition to participating in upper limb stretches and motor training five days a week did not improve wrist extensibility or prevent contracture development. Hand splinting was therefore ineffective as an
intervention for maintaining muscle extensibility, improving functional use, and decreasing pain in people with recently acquired brain impairment.

4.8.2 Findings in Detail

Primary Outcome

Participants with acquired brain impairment who were already receiving routine motor training and prolonged, upper limb stretches did not show detectable or important changes in wrist and finger flexor extensibility after wearing a splint daily for four weeks during this study. Contrary to expectations, participants in the control group did not lose wrist and finger flexor extensibility (i.e. acquire a contracture) in this four week period if they did not wear a hand splint.

The literature recommends that splints for this population should be worn for between two and six hours per day (Wilton, 1997; Milazzo & Gillen, 1998). In this study, splints were worn for up to 12 hours a day (daily mean 11 hours, range 0–13 hours, SD 3 hours). In spite of this intensive regime of splinting, no significant differences in muscle extensibility and contracture rate were detected between groups.

Secondary Outcomes

Findings related to the study’s secondary outcomes also indicate no effect. First, there was no evidence of clinically significant effects of splinting on upper limb function, as measured by individual item or summed UL-MAS scores. Second, the 4-week splint wearing program did not significantly reduce upper limb pain levels. It is acknowledged that the pain scores were low at baseline which may have made reduction in pain difficult to detect. These two findings do suggest, however, that the practice of splinting to improve function (Wilton, 1997; Hill, 1988; Neuhaus et al., 1981; Milazzo & Gillen, 1998; Wilson & Caldwell, 1978)
and reduce pain levels (Perry, 1980; Snook, 1979; Wilson & Caldwell, 1978) following acquired brain impairment should be questioned if patients are already receiving motor training and upper limb stretches as part of their rehabilitation.

Sample Characteristics

The mean age of participants was 66 years, similar to that of inpatients with acquired brain impairments in other Australian rehabilitation units (67.4 years) (Eagar et al., 1997). This variation is also similar to that reported in other studies of hand splinting, which include participants with diagnoses of either stroke or traumatic brain injury (for example, McPherson et al., 1982). As outlined above, only one participant in the study had experienced a traumatic brain injury. However, irrespective of the underlying cause, upper motor neuron damage leads to hemiplegia and the motor impairments affecting both groups are similar (Eng, Rows, & McLaren, 2002). The conclusions from this study are therefore likely to be applicable to the majority of adults undergoing inpatient rehabilitation in Australia with hemiplegia from acquired brain impairment, irrespective of the cause.

Drop-outs and non-compliance

One participant self-discharged from the rehabilitation unit, and returned to live in a rural area where follow-up was not possible. No other participants dropped out of the trial. The splint group had two participants who refused to participate in the primary outcome measurement at the end of the treatment arm (i.e. at 4 weeks). All remaining participants adhered to the protocol. Loss to follow-up was therefore low (10.7% at four weeks, and 3.6% at five weeks).
**Strengths and limitations of this study**

The study’s strengths include its prospective design, the standardised protocol for the experimental and control groups, and the blinded, torque-controlled assessment of contracture. The randomised controlled trial methodology provides the strongest form of evidence when determining the effectiveness of treatments (Roberts & Dicenso, 1999; Sackkett & Wennberg, 1997). In addition, this trial employed design features which help to minimise bias (randomisation, allocation concealment, and blinded assessment of outcomes).

This trial used rigorously validated outcome measures, including a torque-controlled measure of wrist range of movement as the primary outcome measure. Only one previous randomised controlled trial of hand splinting measured contracture (Rose & Shah, 1987). The measure of contracture used in that study was passive range of movement using a goniometer without standardising the torque force used to produce the range of movement (Rose & Shah, 1987). If torque is not standardised then changes in a person’s ability to tolerate uncomfortable stretch torques may result in corresponding increases in joint angle (Folpp, Deall, Harvey, & Gwin, 2005). The previous study by Rose and Shah (1987) is likely to have measured tolerance to stretch rather than the effect of a hand splint on contracture.

There are limitations of this study that need to be considered. Although this trial was randomised it was not double blind (i.e. the participants were not blinded to the treatment received) because it is difficult to blind the participants when the therapy – the hand splint – is visible. To minimise observer bias, primary and secondary outcomes were measured by a blinded assessor and were not self-reported by the participant who was aware of group allocation.
The present trial was conducted in Australia. Consequently, care is needed when
generalising the results to participants outside of Australia. When interpreting the findings,
the routine therapy provided needs to be considered. Participants in both the treatment and
control groups received upper-limb motor training and upper-limb stretches, which may
have been enough to negate or mask the effect of the additional stretch applied by the splint.
Literature indicates that the routine therapy received in this study does not commonly occur
in countries outside of Australia, for instance in the United Kingdom (“Journal review”,

4.8.3 Implications for Future Research

The results of this study suggest that splinting the hand in the functional resting position
does not produce clinically useful effects in adults with acquired brain impairment.
However, it could be that hand splinting in other positions, which administer greater torque
at the wrist, may be beneficial. Further research studies should continue to use simple,
accurate and reliable assessment measures of torque-controlled range of motion, motor
function, and pain. Results do not suggest post-acquired brain impairment sub-groups
which may benefit from splinting. Analysis of future studies could use predetermined
covariates for use in analysis, which may provide guidance relating to the effect of
participant age, time post-lesion and lesion type.

The absence of an effect following splint wearing on wrist and finger flexor extensibility
may have been because the routine motor training and upper limb stretches were already
maintaining the length of wrist and finger flexor muscles. These therapies may have
rendered the additional ‘stretch’ (the stretch provided by the hand splints) redundant. Future
research should examine the effect of splinting in the absence of prolonged stretches in
adults following acquired brain impairment.
There is, however, still no clear evidence that prolonged stretches do in fact reverse contracture of the wrist and finger flexor muscles following acquired brain impairment. While a number of animal studies have found that short periods of daily stretching can prevent the development of muscle contracture in animal muscle (Goldspink, 1977; Herbert & Balnave, 1993; Williams, 1988, 1990; Williams, Cantonese, Luey & Goldspink, 1988; Williams & Goldspink, 1978), clinical studies on human muscles have yet to demonstrate the same benefits (Farmer & James, 2001). Further research is still needed to determine whether or not prolonged stretching at maximum wrist extension prevents or reduces contracture at the wrist in adults post-brain impairment.

Finally, the importance of replication of research is acknowledged, particularly given the statistically non-significant results (Ottenbacher, 1995). It is, however, noted that results do indicate a precise treatment effect of 0° with a narrow confidence interval. The narrow confidence interval, coupled with the a priori sample size calculation providing greater than 80% power to detect a difference, does suggest that no true difference between group’s performance exists.
4.8.4 Implications for Clinical Practice

One of the research questions was: Did the hand splint prevent or manage contractures for people with hemiplegia following acquired brain impairment who participated in an active rehabilitation program? The answer is no; there was no difference between groups.

Participants who wore the splint at night for up to 12 hours did not show greater wrist and finger flexor muscle extensibility, nor did they demonstrate greater functional return or less pain after four weeks than those participants who did not wear a splint. Therefore, a splint, when applied during rehabilitation which included prolonged stretching, had no effect on the intervention group. The findings of this study are of great clinical relevance for occupational therapists (Walker, 2003).

4.9 Conclusion from the Study

This randomised controlled trial demonstrated that in people with hemiplegia from an acquired brain impairment, splinting the hand in the traditional ‘functional’ position does not prevent contracture of the wrist and finger flexor muscles, improve function or decrease pain, in comparison to the group who do not wear a splint.

4.10 Synopsis

The study was designed to evaluate the effect of hand splinting post-brain impairment. Specifically, the study aimed to determine the effect of splinting when prescribed in acute rehabilitation, a setting where people with acquired brain impairment are typically receiving active training and prolonged stretching of the upper limb. The effect of hand splinting was examined over a four week period using a randomised, controlled trial design with a one week follow-up period.
The splint wearing regime produced no statistically significant or clinically important benefits. The study makes an important contribution to the evidence-base in relation to splinting. The results of the study provide compelling evidence that the extensibility of the muscles in the wrist did not respond to the application of a hand splint. However, patients in both the treatment and control groups received intensive upper-limb motor training and upper-limb stretches, and this may have been enough to negate or mask the effect of the additional stretch applied by the splint. Inclusion of a third group (no additional training or stretches) may have resulted in statistical or clinical benefits from the splint-wearing regime. The following chapter will therefore present the findings of a study specifically designed to examine the effect of hand splinting on wrist muscle extensibility in a group who did not receive stretching.
CHAPTER FIVE

Study 3: Effectiveness of two types of hand splints for preventing contractures in adults who are not receiving hand stretches post-stroke: a single blind, randomised controlled trial.

[This study has been submitted for publication: Lannin, N.A., Cusick, A., Herbert, R.D., & McCluskey, A. A (2006) randomised trial of the effectiveness of two hand splint positions to apply stretch to the wrist of adults with hemiplegia following stroke.]
Chapter Five: Randomised Controlled Trial of Splinting in Two Positions

5.1 Chapter Overview

This chapter presents a second randomised controlled trial (Study 3) that evaluated the effectiveness of two different hand splints for preventing wrist and finger flexor muscle contractures after stroke.

5.2 Background

The randomised controlled trial presented in this chapter was informed by findings from Chapters 2, 3 and 4. The literature reviewed in Chapter 2 indicated that several types of hand splints were commonly used post-stroke, and that the primary aims of therapists who make such splints is to prevent or reduce contractures. The systematic review conducted in Chapter 3 (Study 1) demonstrated a lack of high quality research on the effect of splinting for contracture prevention post-stroke. No clinical trials were found which evaluated the effect of the commonly used functional splint position, compared to no splint.

Chapter 4 (Study 2) demonstrated no difference in contracture prevention between participants who received splinting in the functional position plus routine motor training and hand stretching, compared to controls who received training and stretching only. In order to test whether it was the position of wrist and finger stretch which influenced contracture development, and not simply the presence or absence of a splint, the following randomised controlled trial was conducted.
5.3 **Aim**

The aim of this study was to determine whether providing a hand splint within eight weeks of stroke reduced the development of wrist and long-finger flexor muscle contracture in adults with dense hemiplegia compared to wearing no splint. The study also aimed to determine if there was a difference in contracture development when the wrist was positioned in extension or in neutral in the splint.

5.4 **Research Questions**

1. Does splinting in the traditional, *functional* position prevent contracture of the wrist and finger flexor muscles, improve function and/or self-reported quality of life post-stroke, in comparison to no-splint, in the absence of routine hand stretching?

2. Does splinting with the wrist and fingers positioned in *extension*, prevent contracture of the wrist and finger flexor muscles, improve function and/or self-reported quality of life, in comparison to no-splint, in the absence of routine hand stretching?

3. Which of these treatment options (no splint, functional splint, or extension splint) is more effective in preventing contracture?

5.5 **Description and Rationale for Study Design**

The present study builds on the findings of Study 2. As a result of the previous randomised controlled trial (Lannin et al., 2003) there was a need: to compare the efficacy of two different wrist positions used for splinting after stroke; to include an appropriate control
condition which does not receive routine hand stretches; to attain an adequate sample size, necessitating involvement of a number of clinical sites rather than one; and to employ change-score statistics to conserve statistical power. The second randomised controlled trial was an assessor-blind, controlled, randomised, three-group study that evaluated the efficacy of overnight wrist splinting in the extended wrist position versus neutral (‘functional’) wrist splinting involving adults with hemiplegia post-stroke.

5.6 Method

5.6.1 Ethics approval

Ethics approval was obtained from seven ethical review committees: (1) the University of Western Sydney Ethics Review Committee (Human Subjects) – Protocol Number: 01/166, (2) Sydney Adventist Hospital Ethics Committee (letter of approval 12 July 2002), (3) St Joseph’s Hospital Quality Care Committee (letter of approval- 13 June 2002), (4) South Eastern Sydney Area Health Service Human Research Ethics Committee Eastern Section – Protocol Number: 02/152, (5) South Western Sydney Area Health Service Research Ethics Committee – Protocol Number: 02/113, (6) St Vincent’s Hospital Sydney Human Research Ethics Committee – Protocol Number: Q02/128, and (7) Western Sydney Area Health Service Human Research Ethics Committee – Protocol Number: HREC2003/12/4.18(1737) (Appendix C).

5.6.2 Study Participants

5.6.2.1 Inclusion Criteria:

Participants were required to meet the following criteria for inclusion in the study:

a. Medical diagnosis of stroke, which had occurred within the previous eight weeks

b. Aged 18 years or older
c. UL-MAS (Item 6) score of zero, indicating no active wrist extension
d. Sufficient cognitive and hearing function to be able to provide informed consent
   and fully participate in the trial
e. Resident of Sydney metropolitan area to be seen for follow-up clinical
   examinations.

The Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975)
was used to determine a participant’s competency to provide informed consent. The
MMSE is a widely used, standardised method for assessing cognitive mental status.
The assessment tests orientation, attention, immediate and short-term recall, language,
and the ability to follow simple verbal and written commands. Potential participants
who attained a MMSE score of $\geq 18$ provided independent consent. Those who
scored between 10 and 17 on the MMSE provided consent together with a proxy
(typically a relative), in line with research recommendations (Pucci, Belardinelli,
Borsetti, Rodriguez, & Signorino, 2001). Potential participants who scored less than
10 on the MMSE were excluded, unless the relevant hospital ethics committee
clearance permitted next of kin to give consent.

5.6.2.2 Exclusion criteria

Participants were excluded from the study if they met any of the following criteria
a. Previous stroke resulting in upper limb hemiplegia
b. Previous upper limb trauma causing structural imbalance, or reduced range of
   movement, at the wrist or fingers (for example, a colles fracture)
c. Osseous abnormality in the wrist or fingers
d. Arthritic condition of the wrist or fingers.
5.6.3 **Power Analysis and Sample size**

A prospective sample size calculation was performed (Pocock, 1983). Consistent with Study 2, a difference of $5^\circ$ in wrist muscle extensibility measure was chosen as the minimum clinically important difference. A $5^\circ$ difference also reflects the minimum measurable objective change in range of movement about the wrist; any less is likely to be affected by measurement error. The standard deviation of $4.1^\circ$ was derived from the previous randomised controlled trial and used in this sample size calculation. A sample size of 63 participants (21 per group) provided 80% power to detect a $5^\circ$ difference at an alpha level of 0.05. A dropout and non-compliance rate of 20% was included in the sample size calculation.

5.6.3.1 **Selection of Data Collection Sites and Recruitment**

To ensure adequate recruitment, the study used a multi-centre design. Occupational therapists from nine rehabilitation or stroke units in the greater Sydney metropolitan area were enlisted to assist with recruitment. Strategies based on best evidence about recruitment to trials were used (Lannin & Cusick, 2006). These strategies included presentations to staff, regular face-to-face, telephone and email contact before and during the trial, study and recruitment reminders, newsletters and information about recruitment progress (Cavalieri, 2003; Visanji, & Oldham, 2001). Hospitals were selected partly on the volume of people with stroke admitted in the previous year, to help maximise recruitment. Recruiting therapists identified potential eligible participants from their in-patient caseload, explained the goals of the study and treatment options to potential participants, then introduced them to the investigator who then confirmed eligibility and obtained consent.
5.6.4 **Randomisation**

Participants were allocated to groups using computer-generated random numbers generated using Microsoft Excel. Simple randomisation was performed (Altman & Bland, 1999b; Pocock, 1983).

Group allocation was concealed from the investigator. Random numbers were generated by a third person not involved in the study and located at an external site. Opaque envelopes with participant numbers in sequence were used to maintain concealed allocation. After recruiting a new participant, and completing their baseline assessments, the envelope containing group allocation was opened by the investigator.

5.6.5 **Blinding**

This trial used single blinding, where the assessors (those obtaining outcome measures) were unaware of the group allocation and whether or not participants had been allocated a hand splint. Assessors were local therapists not involved in the participants’ rehabilitation program who were paid to collect measurement data. Due to the difficulty of keeping participants and treating therapists unaware group allocation, treating therapists and participants were not blinded.

5.6.6 **Intervention**

The study period was six weeks in total, consisting of a four-week intervention and two-week follow-up period. Hand splints were withdrawn during the follow-up period. There were three study groups: Group 1 (control, no splint); Group 2 (experimental, functional splint); and Group 3 (experimental, extension splint).
5.6.6.1 Control Program (Group 1)

Participants did not wear a hand-splint for the six week study period and continued to receive their usual rehabilitation. Usual inpatient rehabilitation in Sydney rehabilitation centres included physiotherapy and occupational therapy five days per week (Canning, Ada, Adams, & O’Dwyer, 2004) involving upper limb motor training based on either a neurophysiological or biomechanical frame of reference. Training may or may not have included passive range of movement exercises (high-load, brief stretches of less than 10 seconds duration). Participants in Group 1 were offered a splinting program after completion of the six-week intervention period (i.e. after all measures had been obtained and the study concluded).

5.6.6.2 Splinting Programs

Functional splinting program (Group 2): Participants wore a hand-splint which positioned the wrist in less than 10º extension (Wilton, 1997; Gillen & Burkhardt, 1998) for the four weeks of intervention. Participants did not wear a hand splint during the final two weeks of the study period. Splints were made by the primary investigator (NL) (Figure 5.1).
Extension splinting program (Group 3): Participants wore a hand-splint which positioned their wrist in comfortable end-of-range position (greater than 45° wrist extension) for four weeks of intervention. This position of stretch is commonly achieved through other means within rehabilitation programs, for example positioning or casting. Stretching the wrist in an end-of-range position is based on recommendations of clinical experts who propose that unwanted effects of muscle length changes (i.e. contracture) can be minimised if a joint is positioned at end-of-range (Gracies, 2001). Participants did not wear a hand splint during the final two weeks of the study period. Splints were made by the primary investigator (NL) (Figure 5.2).
Splint design (Groups 2 and 3): A resting pan-mitt splint (Copley & Kuipers, 1999) was custom made for each participant allocated to a splinting program. Only the angle of wrist extension in the splint differed between groups. Custom-made splints were used to accommodate changes in the degree of extension at the wrist (Swedberg, 1997) allowing the investigator to choose between neutral to 10° wrist extension or greater than 45° extension when fabricating the splint. All splints were fabricated from low-temperature thermoplastic material (Synergy® splinting material\textsuperscript{10}) and used soft-foam strapping (Alpha Strap). The splints had three strapping points: the forearm, wrist and fingers. To prevent wrist flexion within the extension splint (group 3), a cross-over strapping method was used to provide a band of pressure across the dorsum of the wrist (See Figure 5.2). To prevent a loss of wrist extension angle in the splint over time, all extension splints (Group 3) were

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{Figure_5.2}
\caption{Static palmar-mitt splint with the wrist and fingers positioned in extension}
\end{figure}

\textsuperscript{10} Synergy® Splinting Material; Smith & Nephew plc, 15 Adam Street, London WC2N 6LA United Kingdom.
reinforced with a thermoplastic bar on the outside of the splint running from the palm across the wrist.

Wearing Regime (Groups 2 and 3): In this study, the hand splints were worn overnight, for a minimum of five hours and a maximum of 12-hours. Splints were typically applied at 7:00pm and removed at 7:00am although there was variance depending on the evening routine of the rehabilitation units. This wearing regime was based on clinical experience and research findings as outlined in Chapter 2.

Compliance with the splinting program: Compliance with the splint wearing regimen was important. Whilst non-compliance may arise due to participant-related factors, such as forgetfulness or lack of motivation (Meichenbaum & Turk, 1987), the patient–therapist relationship and the clinical environment may also affect the degree to which participants comply with a protocol regime (Gleeson, Chant, Cusick, Dickson, & Hodgers, 1991). As non-compliance with the splint wearing regime would influence results, the following evidence-based procedures were followed:

1. Participant and family education (Bond & Burt, 2002): Participants and their families were informed about the theory behind their splint, the wearing regime, risk factors and were shown how to correctly apply and remove the splint.

2. Support staff training (Levin et al., 2002): Nurses, nurse assistants and carers in each centre received education which covered the theory behind the splint, the wearing regime and risk factors. They were shown how to correctly apply and remove the splint by the primary investigator. This education included written information and photographs which remained on the wards following the
sessions. For those participants who were discharged to the community during the trial, this training was also provided to care facilities and/or families dependent on the discharge destination.

3. Reminder system (Levin et al., 2002): A telephone reminder system was used each evening to remind staff or family members to assist each participant to put on their splint. All calls were made by the primary investigator every evening (seven days a week).

4. Participant choice (Ickovics & Meisler, 1997): Participants were informed of the risks, benefits and the level of evidence related to hand splinting.

5.6.6.3 Potential Contaminants

Prolonged upper limb stretches and the effect of practicing wrist extension may have provided an effect on the primary outcome measure, muscle extensibility, and as such could contaminate the results of the study. Potential contaminants were addressed within the study protocol in the following ways:

Prolonged stretching: Stretches to wrist or long-finger flexor muscles were not performed during the six week study period. If participants had been receiving stretches prior to involvement in the study, there was a two week ‘wash-out’ period to prevent contamination effects. Participants could still receive shoulder (Ada et al., 2005) or elbow stretches, if these were part of usual care at their treating centre.

Time spent in therapy: Therapy time dedicated to eliciting and training wrist and finger extensor muscle activity was limited to a maximum of 10 minutes practice each day. Ten minutes was chosen based on research which suggested that this amount of practice is greater than that usually received by patients in rehabilitation.
units both in Australia (Ada, Mackey, Heard & Adams, 1999; Mackey, Ada, Heard, & Adams, 1996) and overseas (Lincoln, Willis, Philips, Juby, & Berman, 1996; Tinson, 1989). Ten minutes is also less than the critical 30-minute minimum reported to be necessary to increase muscle length (Williams, 1988; Williams, 1990).

Passive range of movement (‘passive ranging’) exercises were not controlled, because of the lack evidence of effect from short-duration stretches (Halbertsma & Goeken, 1994; Nafziger, Lee, & Huang, 1992).

Compliance with these study procedures was monitored at least weekly by the investigator using site visits, telephone and email contact.

5.6.7 Data Collection

Age, gender, hand dominance, side of hemiplegia, location and type of stroke, time post-stroke, and years of education were recorded from the medical notes by the treating occupational therapist. Outcome data were collected at three time points during the study: at baseline (prior to concealed, random allocation), at the end of the intervention period (end of week four), and at the end of the follow-up period (end of week six). At each time point, both primary and secondary outcome measures were administered and recorded by one of the blinded assessors. Blinded assessors were trained occupational therapists and physiotherapists with experience working with people after stroke; all assessors had undergone training and were accredited to use the UL-MAS instrument.
5.6.7.1 Outcome Measures

Primary Outcome: The primary outcome was wrist extensibility, recorded in degrees and obtained using a torque-controlled measurement device. The primary outcome was measured at four and six weeks.

The validated procedure for measuring the extensibility of the wrist and finger flexor muscles has been discussed in detail previously, in Chapters Two and Four. In addition to following this standard procedure, the angle of torque controlled wrist extension was measured from a photograph taken at the time of measurement. Recording the joint angles from a photograph was used in preference to reading directly from the goniometer on the side of the measurement apparatus for two reasons. First, this method was more efficient for one assessor and necessitated fewer blinded research personnel at each measurement occasion than in Study 2 (one assessor rather than two). Second, photographic procedures have been shown to be more reliable than goniometry for measurements of elbow joint position (Fish & Wingate, 1985), and the reliability and accuracy is comparable with goniometry for measurements of finger (Georgeu, Mayfield, & Logan, 2002) and shoulder joint position (Hayes, Walton, Szomor, & Murrell, 2001).

When recording the wrist joint angle for use in analysis, each photograph was randomly presented by the primary investigator to three blinded raters who then applied a goniometer to the photograph. The goniometry method described by Trombly (1989) was followed, with one exception. Rather than aligning the moveable arms of the goniometer with the body, lines were drawn by the blinded raters on the photograph and the wrist extension angle between these lines was measured. To assist this process, markers were placed on the 5th digit MCP head,
ulnar styloid process, mid-ulnar, and proximal ulnar head by the blinded assessor, prior to taking the photographs during the measurement session.

**Secondary Outcomes:** Secondary outcomes included:

a. The upper limb domains (Items 6, 7 and 8) of the UL-MAS at baseline, four and six weeks.11

b. The Tardieu scale for spasticity at four and six weeks.

c. Disabilities of the Arm, Shoulder and Hand (DASH) subjective rating of arm and hand symptoms (which included self-reported pain).

b. The Tardieu Scale: Many therapists advocate measuring upper limb spasticity after stroke, and the effect of treatments on spasticity (Haas, 1994; Morris, 2002; Schmit, 2001; Worley et al., 1996). Spasticity was therefore chosen and measured as a secondary dependent variable in this study. Although the Modified Ashworth Scale is the most widely used measure of spasticity (Pomeroy et al., 2000), this scale was not chosen as the measure for spasticity in this study because that scale does not distinguish between components of hypertonia associated with contracture and those caused by spasticity (Bakheit et al., 2003; Schmit, 2001). The modified Ashworth Scale also only has marginal intrarater and interrater reliability (Allison, Abraham, & Petersen, 1996; Haas, Bergstrom, Jamous, & Bennie, 1996). Therefore, spasticity was measured using a method developed by Tardieu (1954).

The Tardieu method is based on the difference between the angle of ‘catch and release’ at fast speed of stretch and the angle of ‘arrest’ at a very slow speed, the

---

11 The Motor Assessment Scale was discussed in detail previously in 4.6.6.1 “Secondary Outcomes”. The same principles, description and rationale apply here (pages 99 to 100).
latter measuring exactly the passive range of motion angle (Gracies et al., 2000; Gracies, Weisz, Yang, Flanagan, & Simpson, 2002). The difference between these angles is known as the ‘spasticity angle’. This spasticity angle is unique to the Tardieu Scale. While the scale also includes an ordinal clinical rating of tone (Held & Pierrot-Deseilligny, 1969), it is the spasticity angle which provides an estimate of the relative contribution of spasticity and mechanical restraint of soft tissues (Morris, 2002).

c. Patient-Rating of Impairment, Disability and Handicap: Measuring client-centred outcomes post-stroke, particularly at the level of activity and participant has been emphasised by a number of authors in recent years (for example, Gold, Burchett, Shipp, Pieper, & Lyles, 1999; Kramer, 1997; Long, McQueen, Bangalore, & Schurman, 2005; Stewart & Ware, 1992). However, there are no post-stroke patient-rated wrist outcome measurement tools that capture features of the World Health Organisation International Classification of Functioning, Disability and Health (ICF) (World Health Organisation, 2002). In the current study, this information was captured using the Disabilities of the Arm, Hand and Shoulder (DASH) questionnaire (Marx et al., 1999), an instrument designed for a broader population.

The DASH is an upper limb scale that measures function, symptoms and quality of life related to upper limb disorders (MacDermid, Richards, Donner, Bellamy & Roth, 2000). The 30-item questionnaire includes 21 physical function items, 6 symptom items and 3 social/role function items. The DASH symptom score\(^{12}\) is out of a maximum of 100, with a higher score indicating greater disability. Question 24

\(^{12}\) A transformed score.
(“Please rate the severity of the following symptoms in the last week: Arm, shoulder or hand pain”) was also used as a secondary outcome measure to capture self-reported pain, with rating from 1 to 5, with a higher score indicating greater pain.

The DASH questionnaire has been shown to be valid, reliable and responsive for measuring the wrist and hand (Beaton et al., 2001; MacDermid et al., 2000; MacDermid & Tottenham, 2004). Studies of the validity (against constructs of function and pain) and reliability (alpha, 0.96; test-retest reliability, ICC 0.96) of the DASH have been performed by both test-developers (Beaton, et al., 2001; Hudak, Amadio, Bombardier, & Upper Extremity Collaborative Group, 1996; McConnell, Beaton, & Bombardier, 1999) and others (MacDermid et al., 2000; MacDermid & Tottenham, 2004). The DASH has concurrent validity with objective clinical measures of function, disability and pain ($r \geq 0.70$ (Pearsons)) (Beaton, et al., 2001). Test developers have additionally validated the use of the pain item (question 24) of the DASH as an independent scale (Hudak, Amadio, Bombardier, & Upper Extremity Collaborative Group, 1996). Psychometric validation with the stroke population, or any neurological population, has not been conducted.

**Splinting Program Compliance:** Compliance with the splinting program was recorded using a time-use diary as in Study 2. Diaries were completed by nursing staff responsible for participants at each shift. The use of a time diary is reported to be the most accurate method of measuring time use (Harvey, 1993; Pentland et al., 1998; Stanley, 1995). To monitor recording, the investigator telephoned nursing staff each evening to ensure splints were correctly donned and the time recorded accurately. In addition, treating occupational therapists checked that splints were removed the following morning, and the time recorded.
5.6.8 Data Analysis

To compare outcome data, a linear regression approach to analysis of covariance (ANCOVA) was used since all outcome measures – including the MAS – provided a continuous, ordinal measure of the latent variable (Davison & Sharma, 1990). The baseline measure and time post-stroke were used as covariates in the analysis of each variable. Statistical significance was set at the conventional level of \( p<0.05 \). The size of treatment effect was estimated by comparing differences in group means and their 95% confidence intervals.

Where possible, outcome measures were obtained for all participants recruited to the trial, irrespective of compliance. Each participant’s data were analysed in the group to which they had been allocated, in accordance with the principle of intention-to-treat (Lachin, 2000). The conventional last-observation-carried-forward (LOCF) approach was used to impute missing data (Pocock, 1983). Resource costs were derived from records kept during the trial, which allowed calculation of the average cost of splinting materials and staff time.

5.7 Results

Results are presented in the following order: (a) baseline characteristics of participants (Table 5.1); (b) participant flow diagram (Figure 5.4); (c) comparisons of effectiveness across the three groups (primary outcome followed by secondary outcomes); and (d) resource costs.
5.7.1 Baseline Characteristics

Following baseline measurement, 21 participants were randomly assigned to the control group, and to each of the two splinting intervention groups (21 participants each). Baseline characteristics of participants in the three treatment arms were nearly identical; there were no significant differences between groups at baseline (p>0.05). Mean age was 71 years; just over half were women (51%); and 59% were Caucasian. Participant characteristics at baseline are presented in Table 5.1.

5.7.2 Participant Flow Details

Ninety five adults underwent eligibility screening of which 82 were eligible for participation (eligibility fraction$^{13}$ for study was therefore 86.3%). Sixty three adults met eligibility criteria and agreed to take part. They were enrolled in the study and completed baseline measurements (enrolment fraction$^{14}$ was therefore 76.8% and recruitment fraction$^{15}$ 66.2%). Baseline data were not collected from non-participants.

Four weeks after the baseline assessment and again at six weeks, 63 participants remained in the study. This represents a 100% retention rate, with nil loss to follow-up and reduces susceptibility to bias. One participant from each group was non-compliant with the primary outcome measure at six-week follow-up (n=3).

---

$^{13}$ The proportion of participants deemed eligible for the study of all potential participants screened is termed the *eligibility fraction*.

$^{14}$ The proportion of eligible people who enroll in the study of those who were eligible for participation is termed the *enrolment fraction*.

$^{15}$ The product of the eligibility and the enrolment fractions represents the proportion of potential participants who actually enrolled in the study and is termed the *recruitment fraction*. 

Chapter 5 129

Study 3: Randomised controlled trial of splinting in two positions.
### Table 5.1  
**Baseline Characteristics of Groups**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group</th>
<th>Functional Splint Group</th>
<th>Extended Splint Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>75 years, 5 months</td>
<td>70 years, 3 months</td>
<td>68 years, 8 months</td>
</tr>
<tr>
<td></td>
<td>(11.0)</td>
<td>(12.6)</td>
<td>(12.1)</td>
</tr>
<tr>
<td>Gender: number of women (%)</td>
<td>12 (57%)</td>
<td>11 (52.3%)</td>
<td>9 (42.8%)</td>
</tr>
<tr>
<td>Time post-stroke in days</td>
<td>30 (1.3)</td>
<td>27.8 (14.5)</td>
<td>25 (11.6)</td>
</tr>
<tr>
<td>Mini-Mental State Exam Score&lt;sup&gt;16&lt;/sup&gt;</td>
<td>22 (5.9)</td>
<td>21.9 (5.4)</td>
<td>24.5 (3.6)</td>
</tr>
<tr>
<td>Canadian Neurological Scale Score&lt;sup&gt;17&lt;/sup&gt;</td>
<td>4.6 (1.3)</td>
<td>4.4 (1.5)</td>
<td>4.9 (1.1)</td>
</tr>
<tr>
<td>Dominance: number of right-hand dominant (%)</td>
<td>20 (95.2%)</td>
<td>19 (90.5%)</td>
<td>21 (100%)</td>
</tr>
<tr>
<td>Number of right-sided hemiplegia</td>
<td>11 (52.3%)</td>
<td>10 (47.6%)</td>
<td>10 (47.6%)</td>
</tr>
<tr>
<td>Years of education, including school</td>
<td>10.3 (3.2)</td>
<td>8.1 (4.7)</td>
<td>10.5 (3.6)</td>
</tr>
<tr>
<td>Ethnicity: number from a non-English speaking background (%)</td>
<td>7 (33.3%)</td>
<td>11 (52.4%)</td>
<td>9 (42.9%)</td>
</tr>
</tbody>
</table>

*Note:* Values are means (± standard deviations) unless otherwise stated.

There were no differences in key baseline characteristics such as age, time post-stroke, or level of education between those who provided data at both end-points and those who did not. One participant was randomised to the ‘functional splinting program’ group and completed the study protocol as planned but was not included in analysis because the initial diagnosis of stroke was revised by an independent physician unaware of group allocation. Non-inclusion of this participant’s data is in line with recommendations by Ferguson and colleagues (2002). Figure 5.1 presents the participant flow diagram.

<sup>16</sup> Maximum possible score on Mini-Mental State Exam is 30.
<sup>17</sup> Maximum possible score on Canadian Neurological Scale is 11.5
Baseline comparability on key outcomes:

At study commencement, differences between the three groups were small and insignificant for all outcome variables (contracture, function, spasticity, pain and the participants’ rating of performance) (Table 5.2). Data compared were mean and standard deviation (SD) baseline values for maximum passive wrist extensibility, the angle at which spasticity was detected, subjective pain rating and disability scores, and median baseline values for hand function and spasticity rating across all three groups. There were no significant differences between groups at the commencement of the study for any of these variables. Performance did vary between participants for muscle extensibility. Some participants had normal, or near-normal, wrist muscle extensibility while others exhibited clinical contracture when compared to their unaffected hand.
Patients screened at initial appointment (N=95)

Participants initially randomised (N=63)

Randomised to CONTROL group (n=21)
Randomised to EXTENDED WRIST SPLINT group (n=21)
Randomised to FUNCTIONAL WRIST SPLINT group (n=21)

Baseline Assessment (n=21)
Baseline Assessment (n=21)
Baseline Assessment (n=21)

Provided EXTENDED WRIST SPLINT for 4 weeks (n=21)
Provided FUNCTIONAL WRIST SPLINT for 4 weeks (n=21)

1 month review (n=21) dropout (n=0)
1 month review (n=21) dropout (n=0)
1 month review (n=21) dropout (n=0)

Analysed (n=21)
Analysed (n=20)
Analysed (n=21)

6 week review (n=21) dropout (n=0) noncompliant (n=1)
6 week review (n=21) dropout (n=1) noncompliant (n=2)
6 week review (n=21) dropout (n=0) noncompliant (n=1)

Analysed (n=21)
Analysed (n=20)
Analysed (n=21)

One participant was randomised to the ‘functional splinting program’ group but not included in the primary analysis of data following revision of their initial diagnosis of stroke by an independent physician blinded to treatment and outcome after the participants completion of trial participation.

Reasons behind patients who were approached not taking part were: able to extend the wrist (8), outside the 8-weeks post-stroke (3), refused randomisation- wanted a splint (3), refused randomisation- did not want a splint (3), refused- no reason given (6), medically unfit- stroke related medical condition (2), medically unfit- non-stroke related medical condition (3), unable to provide informed consent (2), lived outside Sydney metropolitan area (2).

Figure 5.3 Participant flow diagram
Table 5.2  
Baseline Performance of Groups on Dependent Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control Group (n=21)</th>
<th>Functional Splint Group (n=21)</th>
<th>Extended Splint Group (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaffected wrist passive range of movement</td>
<td>64.5 (10.1)</td>
<td>65.8 (12.3)</td>
<td>65.2 (15.0)</td>
</tr>
<tr>
<td>(Degrees)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrist extensibility</td>
<td>56.2 (15.0)</td>
<td>62.1 (16.4)</td>
<td>56.8 (12.4)</td>
</tr>
<tr>
<td>(Degrees)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Function on UL-MAS (0 to 18)</td>
<td>0 (19)</td>
<td>0 (16)</td>
<td>0 (15)</td>
</tr>
<tr>
<td>Spasticity Rating on Tardieu Scale (0 to 4)</td>
<td>2 (9)</td>
<td>1.5 (8)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Spasticity Angle (Degrees)</td>
<td>-1.2 (1.1)</td>
<td>-0.9 (1.5)</td>
<td>-0.8 (1)</td>
</tr>
<tr>
<td>Patient Rated Wrist Evaluation (%)</td>
<td>56.6 (16.4)</td>
<td>61.4 (14.9)</td>
<td>57.1 (23.1)</td>
</tr>
<tr>
<td>Pain (%)</td>
<td>23.9 (26.9)</td>
<td>36.0 (26.3)</td>
<td>34.3 (26.1)</td>
</tr>
<tr>
<td>Disabilities of the Arm, Shoulder and Hand questionnaire (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>60.8 (21.7)</td>
<td>57.6 (24.0)</td>
<td>62.8 (24.4)</td>
</tr>
</tbody>
</table>

The numbers of participants in each group that were non-compliant with their respective protocols are presented in Table 5.3. Non-compliance with protocol could include any one of the following reasons: refusing part of the outcome assessment protocol (n=3), wearing the assigned hand splint for less than five hours in a 24 hour period (n=1), using an alternative hand splint (not assigned) (n=1), or receiving prolonged wrist extension stretches (n=1).
Table 5.3  
Numbers of participants in each group who did not adhere to the protocol

<table>
<thead>
<tr>
<th>Time</th>
<th>Control Group (n=21)</th>
<th>Functional Splint Group (n=21)</th>
<th>Extended Splint Group (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Weeks</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6 Weeks</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

5.7.3  Primary Outcome: Effect of splinting on contracture

There were no statistically significant or clinically important differences in contracture rate between the three study groups (Figure 5.4).

Wrist extensibility at the end of treatment (four weeks): Between group comparisons.

After four weeks, splinting the wrist in a functional position increased wrist extension by a mean of 1.5° (95% CI -5.7 to 8.7°) when compared to the control group. Splinting the wrist in maximum extension reduced wrist extension by a mean of 2.5° (95% CI -9.6 to 4.6°) compared to the control group.

Wrist extensibility at follow-up (six weeks): Between-group comparisons

After follow-up (six weeks), splinting the wrist in a functional position increased wrist extension by a mean of 4.3° (95% CI -3.2 to 11.8°) when compared to the control group. Splinting the wrist in maximum extension increased wrist extension by a mean of 1.6° (95% CI -5.7 to 8.9°) when compared to the control group.
Figure 5.4  Mean (95% Confidence Interval) of differences between torque-controlled wrist extension range of motion of the control, functional splint and extension splint groups at the commencement of the study (initial), then after four weeks of splint intervention (post-intervention), then two weeks after the removal of the splint (follow-up).

A negative effect indicates that the splint treatment did not have an advantageous effect on the extensibility of the wrist extensor muscles in relation to the extensibility of the muscles in the control group.

Wrist extensibility: within-group comparisons.

Within-group analysis indicated that participants in all three groups lost wrist extension range during the trial. The control group lost 8.6° and 15.8° of wrist extension range at four and six weeks respectively ($p=0.001$, $p=0.0001$). The functional splint group lost 9.0° and 14.0° at four and six weeks respectively ($p=0.003$, $p=0.00001$). Finally, the extension splint group lost 11.3° and 14.7° of wrist extension range at four and six weeks respectively ($p=0.0008$, $p=0.00003$).
5.7.4 Secondary Outcome: Effect of splinting on upper limb function

After four weeks (end of treatment), splinting the wrist in a functional position had not improved function (95% CI -0.7 to 0.7) and splinting the wrist in maximum extension reduced function by a mean of 0.1 points on the UL-MAS (95% CI -0.8 to 0.6) when compared to the control group. After six weeks (follow-up), splinting the wrist in a functional position increased function by a mean of 0.1 points (95% CI -1.0 to 1.2) and splinting the wrist in maximum extension reduced function by a mean of 0.2 points (95% CI -1.3 to 0.9) on the UL-MAS when compared to the control group. These results ostensibly indicate no difference and demonstrate that splinting in either ‘functional’ position or a position of ‘maximum extension’ stretch had no clinically meaningful effect on hand function when compared to a control group, as measured by the UL-MAS.

5.7.5 Secondary Outcome: Effect of splinting on spasticity

Spasticity was measured using the spasticity angle and rating (Tardieu scale).

Spasticity Angle: After four weeks, splinting the wrist in a functional position increased the available wrist extension range before spasticity was elicited by 2.4° (95% CI -5.1° to 9.9°) in comparison to the control group. Splinting the wrist in maximum extension reduced the available range by 1° (95% CI -8.4° to 6.3°) in comparison to the control group. After six weeks, splinting the wrist in a functional position increased available wrist extension range before spasticity was elicited by 8.3° (95% CI -0.2° to 16.9°) in comparison to the control group. Splinting the wrist in maximum extension increased the available range before spasticity was elicited by 7.0° (95% CI -1.5° to 15.5°) in comparison to the control group. Results at four and six weeks for the splinted groups did not differ statistically significantly from those of the control group.
Spasticity Rating: After four weeks (end of treatment), splinting the wrist in a functional position increased the spasticity rating by a mean of 0.2 points on the 5 point Tardieu scale (95% CI -0.3 to 0.7) and splinting the wrist in maximum extension increased the spasticity rating by a mean of 0.3 points on the Tardieu scale (95% CI -0.2 to 0.8) in comparison to the control group. After six weeks (follow-up), splinting the wrist in a functional position decreased the spasticity rating by a mean of 0.3 points on the Tardieu Scale (95% CI -0.8 to 0.2) and splinting the wrist in maximum extension decreased the spasticity rating by a mean of 0.3 points on the Tardieu Scale (95% CI -0.8 to 0.2) in comparison to the control group. Results at four and six weeks for the splinted groups did not differ statistically significantly from those of the control group.

5.7.6 Secondary Outcome: Effect of splinting on participants’ perception of their upper limb disability and pain

Using the DASH, results at four and six weeks for perceived upper limb disability in either splinted group did not statistically differ significantly from those of the control group. After four weeks (end of treatment), those participants who had their wrist splinted in a functional position perceived less upper limb disability, with a mean reduction of 8.3 points on the 100 point DASH scale (95% CI -20.4 to 3.8), compared to the control group. Those who had their wrist splinted in maximum extension perceived less upper limb disability, with a mean reduction of 7.0 points on the DASH scale (95% CI -18.8 to 4.7) compared to the control group. After six weeks (follow-up), those who had their wrist splinted in a functional position perceived less upper limb disability, with a mean of 5.4 points on the DASH scale (95% CI -18.3 to 7.5) and those who had their wrist splinted in maximum extension
perceived less upper limb disability with a mean reduction of 10.0 points on the DASH scale (95% CI -22.6 to 2.5) compared to the control group.

**Pain**

Using the DASH, results at four weeks indicated that splinting the wrist in a functional position decreased perceived pain by a mean of 17.4% (95% CI -38.6% to 9.9%) and splinting the wrist in maximum extension decreased perceived pain by a mean of 12.3% (95% CI -34.5% to 9.9%) compared to the control group. After six weeks (follow-up) those who had their wrist splinted in a functional position perceived less pain, with a mean of 27.2% (95% CI -46.3% to -8.1%), and those who had their wrist splinted in maximum extension perceived less pain, with a mean of 20.3% (95% CI -40.2% to -0.3%) compared to the control group. Results were statistically significant at the six week end-point (p=0.006 and p=0.046 for functional and extension splint groups respectively).

**Upper-limb related self-efficacy:**

In response to the DASH question “I feel less capable, less confident or less useful because of my arm, shoulder or hand problem” results at four weeks indicate that those who had their wrist splinted in a functional position perceived greater capability, confidence and/or usefulness with a mean of 0.4 points (95% CI -1.0 to 0.3) on a five point DASH scale, and those who had their wrist splinted in maximum extension perceived less capability, confidence and/or usefulness, with a mean of 0.2 points (95% CI -0.4 to 0.8) in comparison to the control group. Neither result was statistically significant. At follow-up, those participants who had worn a splint with their wrist in a functional position perceived greater capability, confidence and/or usefulness, with a mean of 1.1 points (95% CI -1.7 to -1.2) on a five point DASH scale (p=0.0019) when compared to controls. Those who had their wrist
splinted maximum extension perceived less capability, confidence and/or usefulness by a mean of 0.3 points (95% CI -0.3 to 0.9) when compared to controls.

5.7.7 Splint compliance

Overall, there was high compliance with the overnight splinting regimes prescribed in the study. Participants wore their hand splints for an average of 10 hours 11 minutes per night, for four consecutive weeks (SD 2 hours). Individual and group differences were observed (Table 5.4). There was a significant difference in compliance between groups. The functional splint group wore their splint for an average of 1.67 hours more each night than the extended splint group (95% CI 2.8 to 0.5 hours, \( p=0.0054 \)).

<table>
<thead>
<tr>
<th>Table 5.4</th>
<th>Compliance with Splinting Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Functional Splint Group (n=21)</td>
</tr>
<tr>
<td>Total wear time in hours</td>
<td>297.52 (44.61)</td>
</tr>
<tr>
<td>Average weekly wear time in hours</td>
<td>74.66 (11.19)</td>
</tr>
<tr>
<td>Average nightly wear time in hours</td>
<td>11.02 (1.16)</td>
</tr>
</tbody>
</table>

*Note:* Data are mean (SD) values of total wear time, average weekly wear time, and average nightly wear time for participants in the two experimental groups.

5.7.8 Average cost of making a splint: therapist time and cost of materials

Data indicated that each functional splint required the time of a single therapist for 17 to 80 minutes (mean 37 minutes, SD 13.8), and each extension splint required the time of either one or two therapists (median 1) for 25 to 70 minutes (mean 44 minutes, SD 13.1).

Materials for fabricating each splint cost between $11.20 and $19.23 (mean $15.41). Added to this should be the purchase of a small heat pan (approximately AUS$150.00), a heat gun (approximately AUS$124.00), a scratch awl (approximately AUS$24.00) and splinting
scissors (approximately AUS$80.00). Finally, costs associated with staff education time should also be considered, calculated within the study to be a mean of 10 minutes per splint (SD 9.6).

To calculate the average cost of splinting programs, personnel was costed at New South Wales Public Hospital (Physiotherapists, Occupational Therapists and Speech Pathologists) Award rate for Grade Two therapists (AUS$32.20 per hour). The cost of resources/equipment such as the heat pan, was divided among those participants who received splints (n=42). The cost of a simple functional hand splint was therefore AUS$49.79 and the cost of an extension splint was AUS$53.57, excluding costs associated with putting on and removing the splint nightly by nursing staff.

5.8 Discussion

5.8.1 Key Findings

Muscle extensibility of wrist and long finger flexors of all participants decreased during the study. That is, all participants developed a contracture. Differences between the groups were neither statistically nor clinically significant at either four or six weeks. Hand splinting was therefore no more effective than the control intervention (no splint, no stretch) with regard to maintaining muscle extensibility, improving functional use, and decreasing spasticity and pain.

5.8.2 Findings in Detail

Baseline Characteristics

The study sample well represented the general stroke population in terms of age and stroke nature. The mean age of participants was 71.7 years (±12.4). The sample mean age was similar to other trials which have evaluated the effectiveness of rehabilitation following
stroke (for example, Duncan et al., 2003). The sample mean age is also in line with national statistics which indicate that around two-thirds of stroke hospitalisations occur among Australians aged 70 years and over (Australian Institute of Health and Welfare, 2004). The mean number of days post-stroke on recruitment was 27.8 (±13.1) and all participants had strokes that were moderate to severe. The conclusions from this study are therefore likely to be applicable to the majority of stroke patients undergoing rehabilitation.

Drop-outs and non-compliance

One participant had the diagnosis of stroke revised and this participant’s data was subsequently omitted from analyses. Otherwise, no participants dropped-out of the trial. Each group had one person refuse to participate in the primary outcome measure (4.8%) at follow-up (i.e. at 6 weeks), and one participant in the extension splint group deviated from the study protocol by not wearing the splint for a minimum of 5 hours in a 24-hour period (1.6%). Although all other participants adhered to the protocol, there were differences between the two splint groups with respect to length of time wearing the splint. Interestingly, those in the extension splint group wore their splints on average of 1.6 hours less than those in functional splint group. This difference in wearing times may be due to the extension splints being less comfortable to wear, however this is speculative.

Primary Outcome

Results from analysis of the primary outcome showed no difference between the control group, the functional hand splint group and the extended hand splint group for the development of contracture. Differences between groups were neither statistically significant, nor large enough to be clinically important. After four weeks, splinting the wrist in a functional position increased wrist extension by a mean of only 1.5° (95% CI -5.7° to 8.7°) and splinting the wrist in maximum extension reduced wrist extension by a mean of
2.5° (95% CI -9.6° to 4.6°), in comparison to the control group. When assessing the upper confidence limits, the effect would still not be considered clinically important even if measurement error (5°) was considered.

On average, participants in the trial lost 10° muscle extensibility in their wrist during the first 4 weeks and had lost closer to 17° by the end of the study. These decreases represent a loss of approximately 17% and 29% of baseline available range respectively. This finding of progressive loss of muscle extensibility in adults following stroke who participated in a contracture management study is not new. In a recent trial evaluating stretch positioning in the upper limb (Turton & Britton, 2005) a loss of approximately 40% of wrist extension range was reported after four weeks, regardless of whether or not participants received prolonged stretching. Further, Ada and colleagues (2005) reported a progressive loss of range in their trial which investigated the effect of stretch on shoulder musculature contracture. Unlike the current trial and that of Turton and Britton (2005), the trial by Ada and colleagues (2005) study found a statistically significant reduction in contracture development in the shoulder internal rotator muscles but not in shoulder flexors.

Animal muscle physiology studies have also shaped current thinking on muscle contracture and stretch (Herbert, 1988; Williams, 1988). Growth is considered a response to the average position that a muscle is held in (Wren, 2003). However results from the current trial are contrary to findings that could be expected based on animal models. In the current study, participants’ wrists were held in positions of maximum stretch for an average of nine hours overnight (extension splint group) but this did not result in an increase in torque-controlled range of movement when compared with the control group who received no stretching. In fact, all three groups of participants in this study lost range at a similar rate.
Secondary Outcomes

Secondary outcome analyses were conducted using data from the UL-MAS, the Tardieu scale, and the DASH questionnaire. Before discussing findings from the secondary outcomes, it must be noted that the primary outcome analysis provides the most important and statistically rigorous results of this randomised controlled trial. The probability of Type 1 error increases as the number of tests increases (Bauer, 1991). Twelve inferential tests were conducted in analysis of secondary outcomes. Using $p<0.05$ as the critical significance level, there is thus a probability of 46% of finding one or more significant differences from the 12 analyses, due to chance alone. The power of these secondary outcome analyses, and their ability to detect true differences, is therefore diminished and caution is warranted when interpreting these results. Nevertheless, secondary analyses do provide further information which largely supports the analysis of the primary outcome.

Analyses of the secondary outcome variables of function, spasticity and pain provide a similar picture to those data from the primary outcome of contracture. The splint groups did not differ from the control (non-splinted) group in functional hand use, spasticity management, or reported pain levels at either four or six weeks when compared to the control group. There was no ostensible difference. Findings demonstrate that splinting, with the wrist in a position of either neutral or extended stretch, did not have a clinically meaningful effect on these secondary outcomes. Not only were the mean differences between groups not statistically significantly different from zero (LeFort, 1993), but confidence intervals around the results were relatively narrow. Even with greater power, (i.e. a larger sample size), the results are unlikely to become clinically significant. Similar to the analyses of primary outcomes, groups demonstrated little difference at four or six weeks. As with previous analyses, these results add support to the finding that there is no
benefit from splinting the hand in either a ‘functional’ resting position or an ‘extended’ position of stretch following stroke.

**Strengths and limitations of this study**

There are a number of strengths in this study. The ‘gold-standard’ methodology – a randomised controlled trial – was used to evaluate the effectiveness of two different hand splints to manage contracture following stroke. The randomised controlled trial methodology provides the strongest form of evidence when comparing treatments (Roberts & Dicenso, 1999; Sackett & Wennberg, 1997). In addition, the current trial employed appropriate randomisation, allocation concealment, and blinded assessment of outcomes to further minimise bias. The research protocol also used rigorously validated outcome measures, including a torque-controlled range of movement of the wrist as the primary outcome measure. And finally, the research protocol was carefully designed to be similar to clinical practice (for example, the hand splints used were representative of the splints most commonly used in clinical practice). The results should, therefore, have good generalisability.

There are limitations of this study that need to be taken into account. Firstly, although this trial was randomised it was not double blind (i.e. the participants were not blinded to the treatment the participants received). It is widely recognised that to reduce observer bias it is best to blind the assessors (Day & Altman, 2000; Delgado-Rodriguez, Llorca, 2004; Forder, Gebski, Keech, 2005; Kaptchuk, 1998; Schulz, Chalmers & Altman, 2002). Nevertheless, when dealing with physical therapies such as hand splints, it is difficult to blind the participants because the therapy can be seen. That said, there are randomised trials of lower-limb orthoses in different clinical populations who have achieved participant blinding (for example, Conrad, et al., 1996, and Wu, Ng, & Mak, 2001). To minimise observer bias as
much as possible in this present trial, the primary outcome and the majority of secondary outcomes were measured by a blinded assessor and were not self-reported by the participant who was aware of group allocation.

The present trial and the study that preceded it (Study 2) were conducted in Australia. Consequently, care is needed when interpreting the results to participants outside of Australia as routine therapy may differ. Baseline characteristics of the participants in this trial are similar to previous rehabilitation trials of people following stroke in the United States and the United Kingdom, so it is reasonable to assume that the results would be reproducible in these countries.

5.8.3 Implications for Future Research

There are a number of research projects that could be performed which would build upon the findings of this study. This randomised trial did not set out to investigate the effect of hand splinting for adults who were not receiving rehabilitation. It is uncertain whether the finding of no effect in this study would be generalisable to the population of adults who are living in the community and not receiving upper limb training; therefore trials that specifically investigate the effect of hand splinting with a community-based sample of adults not receiving rehabilitation (e.g. nursing home residents or community-dwelling adults with chronic stroke) would be worthwhile.

This trial did not measure the long-term effect of hand splinting. Although best available research indicates that muscle contracture would be likely to occur within the study time frame (4 weeks), it is not possible to comment on the long-term efficacy of hand splinting for adults following stroke; therefore trials that investigate the effect of hand splinting over
a longer period of time are likely to provide useful information for long term rehabilitation management of contracture. If future randomised trials are conducted, the results could be made as applicable to the clinical setting as possible by using a similar protocol to that employed by this study. Double-blinding would also be an advantage, however the complexity of achieving this makes double-blinding a costly exercise.

### 5.8.3 Implications for Clinical Practice

Evidence to support the effectiveness of hand splinting is lacking. The findings of this study present new challenges to clinicians making decisions on how to manage contracture for people following stroke. The trial findings suggest an abandonment of splinting intervention post-stroke. Study limitations and other issues previously discussed make the following question a difficult one for therapists: Should clinical practice be changed on the basis of this clinical trial data, or do we require data on the long-term implications of not providing hand splints to people following stroke? Potentially even more important, and in light of the accumulating evidence that stretch is unable to prevent contracture of the hand following stroke (for example, Turton & Britton, 2005), what are the implications for deciding whether a patient is a candidate for stretch intervention at all? The implications for clinical practice are complex, but we currently have few data from clinical trials for guidance when making such complex choices. Results from this study provide the highest level of evidence currently available to guide clinicians in making these choices, and, taken together with the results of Study 2, suggest that clinicians should begin to rethink current clinical practice which involves the provision of a hand splint early in rehabilitation following stroke.
5.9 Conclusion

At the beginning of Chapter 3, three research questions were presented. Each question is answered below, with a brief synopsis of the findings. In people with hemiplegia following stroke:

a. Splinting the hand in the traditional, ‘functional’ position does not prevent contracture of the wrist and finger flexor muscles, improve function and/or self-reported quality of life, in comparison to the group who do not wear a splint;

b. Splinting with the wrist and fingers positioned in extension does not prevent contracture of the wrist and finger flexor muscles, improve function and/or self-reported quality of life, in comparison to the group who do not wear a splint; and

c. There is no clinically or statistically important difference between choosing not to provide a splint, or providing a functional splint, or providing an extension splint in an acute clinical setting. People in all three groups lost, on average, similar amounts of wrist extensibility at the end of the trial.

5.10 Synopsis

Results show that early post-stroke splints which hold the wrist in a functional (neutral) or extended position have no greater therapeutic effect than providing no splint. Over the duration of the study, there were no differences in therapeutic effect for any outcomes. All participants lost passive range of movement at the wrist, and at similar rates. Chapter 6 draws together issues and findings from the literature review and study series.
CHAPTER SIX

Discussion
Chapter Six: Discussion

6.1 Introduction

Contracture is a common consequence of acquired brain impairment which can have negative effects on upper limb function. Contracture affects the ability of individuals to participate fully in daily activities. Although the problem of contracture is well recognised, there is limited evidence to inform clinical decisions regarding intervention. In the absence of evidence, therapists continue a practice a tradition of passive stretching and hand splinting to prevent or reduce contracture.

This thesis explored the effects of splinting on upper limb contractures after acquired brain impairment. The program of research contributes new knowledge about the effect of hand splinting in preventing contracture of the wrist and finger flexor muscles early after acquired brain impairment. The literature review established the clinical importance of the program of research, demonstrating that acquired brain impairment is prevalent in Australian society and that upper limb contracture post-acquired brain impairment is common. Hand splinting is frequently used after acquired brain impairment to manage such contractures despite the paucity of evidence to inform splinting decisions.

Further, the literature review in Chapter 2 highlighted the considerable controversy that exists about treatment choices, theories and practice traditions regarding the use of splints to reduce or prevent contracture. The systematic review presented in Chapter 3 revealed a lack of research concerning hand splinting for contracture prevention (Lannin & Herbert, 2003). While animal studies had been conducted into effect of stretch on contracture, and four human trials have been conducted into the effect of hand splinting (Langlois et al., 1991;
McPherson et al., 1982; Poole, Whitney, Hangeland, & Baker, 1990; Rose & Shah, 1987), this collective evidence has not moved the clinical debate forward.

Two randomised controlled trials were therefore conducted. First, the commonly used ‘functional’ wrist position splint was compared to those not wearing a splint after recent acquired brain impairment (Chapter 4, and also published in Lannin, Horsley, Herbert, McCluskey, & Cusick, 2003). Next, the impact of a maximum attainable ‘extended’ position splint was investigated in comparison to the ‘functional’ splint and no splint (Chapter 5, and also submitted for publication as Lannin, Cusick, Herbert & McCluskey, 2006). The long finger flexor and wrist flexor muscles were chosen for splinting because these muscles have a large impact on hand function and are the common targets of contracture intervention following acquired brain impairment. A four-week study period was chosen as it is consistent with most in-patient admissions for acquired brain impairment rehabilitation and is considerably longer than the time period used in previous hand splinting trials, which examined only short-term impact (for example 12 hours in the trial by Rose and Shah, 1987)). The two studies reported in this thesis contribute new knowledge for therapists, people post-brain impairment and their families regarding the effectiveness of splinting for contracture prevention.

This discussion chapter reviews the key findings and explores these further in the context of existing literature. The contribution of the three studies to the existing body of knowledge is discussed. Limitations of the studies are outlined and implications for practice, education, and research discussed.
6.2   Key Findings

Splinting the wrist for four weeks did not prevent or reverse contracture in the wrist or long
finger flexors, after either four or six weeks in adults post-acquired brain impairment.

Splinting the wrist in a neutral (or functional) position for four weeks was no better than no
splint. Further, an extension wrist splint was no better than no splint for the purpose of
contracture prevention at four or six weeks.

6.2.1   Major findings and their significance

At the beginning of this program of research, five questions were presented. Three studies
were conducted and with five major findings, answering the questions posed in Chapter 1.
First, the systematic review revealed that there was a paucity of evidence to support
common splinting practices. Second, splinting in neutral or in maximum attainable
extension had no effect on contracture after four or six weeks. Third, splinting did not have
any clinically meaningful effect on function. Fourth, neither splint position had any effect
on spasticity. Finally, those who wore a splint during the study reported an increase in
perceived pain when the splint was removed, but compared to perceived pain in the control
group there was no difference between groups. These major findings are now discussed, and
implications for practice, research and policy proposed.

The literature reviewed in Chapter 2 identified a belief that stretch applied to muscles
through splints may prevent or reduce contracture. The review also identified that there was
little evidence to support hand splinting post-brain impairment. Previous trials did not
provide convincing evidence when critically evaluated, because outcome measures were not
blinded in these studies (Rose & Shah, 1987; McPherson et al., 1982). Absence of blinded
assessment is likely to produce over-estimates of treatment efficacy (Bandolier, 2000). The
systematic review (Chapter 3) confirmed a paucity of evidence to support use of splints for
contracture prevention. These findings were brought to the attention of therapists through international literature (Lannin & Herbert, 2003) and conference presentations. The dissemination of findings led to a healthy questioning of splinting practices (Intercollegiate Stroke Working Party, 2004).

The second study (Chapter 4), a randomised controlled trial, investigated the application of neutral position wrist splints on contracture development at four weeks in conjunction with low-load long-duration stretches. The study showed no significant effect (Lannin et al., 2003). One important clinical issue arising from these findings is that how patients spend the rest of their day may have an effect on contracture development rates. Given earlier animal studies on the impact of stretch on muscles, Study 2 findings suggested one of two possibilities: either that the high-load weightbearing stretch may have been enough to prevent or reduce contracture across both groups on its own; or alternatively, that the degree of stretch provided by the splint was not clinically sufficient when the wrist was positioned in a ‘neutral’ position. Prior to the first randomised controlled trial, splints could be provided in good faith on the basis of both practice tradition and theoretical assumptions relating to the effect on muscles of neutral splints. Following dissemination of the results of study 2, this practice is no longer tenable (‘Journal review’, 2003; Walker, 2003). Study 2 was the first to rigorously demonstrate the effect of splinting in a neutral position.

The third study (Chapter 5), a randomised controlled trial, investigated the question arising from Study 2 regarding intensity of stretch by comparing the effects of no splint, with a functional or neutral splint position and an extension splint position. Findings of this study also revealed no significant effect from either splint condition at four or six weeks on degree of contracture compared to no splint (Lannin et al., 2005). Given previous findings,
it suggests that where contracture prevention is the short-term goal (a four to six week time frame), splinting is not an effective intervention.

Study 3 thus has three clinical implications. First, the intensity or duration of stretch may not the critical factor in contracture prevention, as the rate of contracture in Study 3 did not differ between groups. This finding is counter-intuitive given previous animal studies and trials and suggests that either stretch is indeed not a factor of importance, or that other factors impacted on the finding. If this latter proposition is correct, the second clinical issue is that although stretch may be important, splints may not be able to provide the intensity or duration of stretch that is required to achieve significant differences in contracture prevention or reduction. Therefore other intervention methods to achieve the necessary stretch intensity and duration should be explored. One possibility is that low-load long-duration stretches (as used in Study 2) may be capable of providing the necessary stretch intensity. The third clinical issue arising from Study 3 findings is that there is no benefit gained from having any splint for the purposes of increasing function, decreasing pain, or reducing spasticity.

In summary, the two randomised controlled trials (Chapters 4 and 5) confirm that splinting does not prevent or reduce contracture rate in the short-term after brain impairment. The findings lead to provocative questions regarding the role of stretch in contracture prevention, and the role that other factors play in relation to stretching. The findings highlight areas of need for further research on contracture prevention, including: (1) mechanisms of stretch and contracture, (2) alternative forms of stretch intervention, and (3) other factors that may potentially affect stretch conditions when wearing splints.
Both studies found that splinting does not decrease perceived pain. This finding is surprising, given that upper limb pain is believed to be due to immobilisation, muscle shortening and stiffness (Atwood, 1999; Waters, 1978), and current practice aims to manage pain with splinting (e.g. Milazzo & Gillen, 1998). The finding suggests that other mechanisms may be contributing to/producing the pain experienced by people post-acquired brain impairment, particularly as rating of self-perceived pain were similar across all groups at all data points.

6.3 Strengths and Limitations

6.3.1 Study Design

The randomised controlled trial is considered the best study design for measuring the efficacy of an intervention because of its ability to minimise bias (Barton, 2000; Jadad, 1989). The randomised controlled trial design includes a control group to account for rival hypotheses that could explain changes in the dependent variable (i.e. the presence of contracture) other than those related to the intervention (hand splinting). Random assignment of individuals to the different groups in both trials ensured a balance between groups for the known and unknown factors that might have influenced outcomes. The use of a randomised controlled trial design in both studies 2 and 3 was a strength.

6.3.2 Recruitment and selection biases

Random allocation reduced the threat of selection bias (Pocock, 1983) in both trials presented in this program of research. Randomisation alone is not sufficient, however, to protect against selection bias. The effects of an intervention can be exaggerated if the randomisation sequence is not concealed from the investigators during trial consent (Chalmers, Celano, Sacks, & Smith, 1983). Thus, concealed allocation is a hallmark of a high quality randomised controlled trial. To guard against inflation of effect sizes, both
trials reported in this program of research used concealed allocation during randomisation (Jadad, 1998). In other words, when participants were randomised to groups, the investigator had no knowledge of what the next treatment allocation was going to be (Lewis & Warlow, 2004). This process reduces the likelihood that participants will be selected in a biased way.

Selection bias can also be introduced with convenience sampling of the population. That is, sites may be selected based on convenience rather than random selection. Further, people who give informed consent to enter trials may differ from those who are eligible but decline or are not invited. In Studies 2 and 3, study sites were chosen based on convenience. Such selection biases may have allowed more highly motivated sites to be overrepresented in the studies. The extent of selection bias remains unknown in both Studies 2 and 3 as randomised controlled trials as no baseline data were collected from non-participants.

Recruitment fractions for both studies two and three, which represent the proportion of potential participants who actually enrolled in each study (53% and 66% respectively) were equivalent or higher than the average rate reported in the literature (Gross, Mallory, Heiat, & Krumholz, 2002). These recruitment fractions indicate that participants in the trials were less ‘highly selected’ than participants in other medical clinical trials. Inclusion and exclusion criteria deliberately made studies as ‘inclusive’ as possible to allow for comparisons between groups to be representative of a broad population. Taken together the unrestricted participation criteria and high participation fraction suggest that participants are unlikely to be highly selected.
6.3.3 Attrition

A limitation of many randomised controlled trials conducted in rehabilitation is an inadequate sample size. The potential for bias in underpowered clinical trials is commonly accepted (Halpern, Karlawish, & Berlin, 2002; Pocock, 1983). The sample size calculations for both randomised trials presented in this thesis were deliberately inflated to account for potential non-compliance and attrition of participants in line with recommendations by Kirby and colleagues (2002). The low attrition rates for both studies 2 and 3 (11% and 4% respectively) are less than the average loss to follow-up of 19% found in trials with a similar population (Dickinson, Bunn, Wentz, Edwards, & Roberts, 2000). These low attrition rates suggest that it was unlikely Studies 2 and 3 were biased by differential loss to follow-up.

To handle missing data in both Studies 2 and 3, the intention-to-treat strategy (Lachin, 2000; Hollis & Campbell, 1999) was used during data analysis. Using the intention-to-treat strategy, participants in a randomised controlled trial were analysed as part of the treatment group to which they were assigned regardless of whether they received the intended treatment. Thus, all participants who enrol in a study with the intention of receiving the treatment are analysed as if they received the full treatment. The intention-to-treat approach preserves randomisation and has a robust pragmatic interpretation of results of a study even where there are high levels of non-compliance. However one caution is that because some participants in the experimental group may never fully receive the planned treatment the intention-to-treat strategy can minimise the reported effects of a treatment (Fogg & Gross, 2000).
6.3.4 Outcome Measures

Another potential threat to the validity of results in randomised controlled trials is the assessment of meaningful change. Meaningful change is defined as the difference that is observable and relevant to study participants (Hollon & Flick, 1988). Selecting outcome measures that are sensitive to difference between experimental and control groups is essential for estimating intervention efficacy (Wade, 2003; Whyte, 2003). In both RCTs, a strength was that measures used had strong reliability, validity and evidence of sensitivity to change.

A further potential limitation of studies is the presence of measurement bias. Bias can occur when the therapist measuring outcomes influences the results to favour one group (intentionally or otherwise) to confirm the hypothesis. Measurement bias can be minimised by blinding the assessors and/or the participants, so that they are unaware of group assignment. Although it was not possible in either Study 2 or 3 to blind participants for practical reasons (i.e. all participants were aware of the study question and whether or not they were wearing a splint), assessors were blinded. Unblinded participants may introduce bias through a number of mechanisms, including placebo effects, the differential use of other effective interventions (contamination), differential reporting of symptoms (Altman et al., 2001), or differential loss to follow-up. Placebo effects are unlikely to have occurred in the current studies because we did not observe effects of splinting on most variables. (It is, however, possible that the observed effect of splinting on pain at six weeks was a placebo effect.) Use of inpatient populations in both Studies 2 and 3 provided the opportunity to monitor and control co-interventions to avoid contamination. Attrition rates between groups in studies 2 and 3 did not vary, suggesting that the threat of this bias was minimised. While it is not possible to influence differential reporting of symptoms, the person who assesses the primary outcome can be blinded to treatment allocation, thereby helping to reduce bias.
In both studies the primary outcome, presence of contracture, was assessed by a clinician who was unaware of group assignment; participant self-report was not used as a primary outcome measure in either trial.

### 6.3.5 Intervention Biases

Contamination and study limitations also arise when members of the control group unintentionally receive the intervention. This occurred once only in Study 2, with the incorrect random allocation of one participant to the control group. Contamination was managed using intention-to-treat analysis. Nonetheless, the potential for bias is acknowledged.

A methodological strength of the studies presented in this thesis is that co-interventions were anticipated and managed proactively. Inpatient rehabilitation is multidisciplinary by nature, therefore participants and therapists were asked to refrain from using other interventions that might result in stretch of the target muscles and to record other interventions received (for example acupuncture).

Study 3 was conducted at multiple sites leading to a greater threat of contamination and co-intervention. If different therapists were involved in the provision of splints to the different groups of clients, results may have been influenced. To avoid bias induced by different levels of education and skill among therapists, the primary investigator fabricated hand splints in Studies 2 and 3. Additionally, sites were monitored for adherence to study protocol and to prevent unintentional contamination.

Even when participants are highly motivated, clinical practice and anecdotal report indicates that it is unlikely all will adhere precisely to the intervention protocol (Fogg & Gross,
The variability in frequency and amount of splinting was monitored in both Studies 2 and 3 using time on-time off log sheets completed by nursing staff. To guard against possible threats that non-adherence might present to power, sample size calculations were inflated to allow for 20% non-compliance/los to follow-up by participants.

6.4 Recommendations and Implications

A number of recommendations and implications flow from the program of research presented in this thesis. First recommendations for clinical practice are presented. Second, policy initiatives that have the potential to enhance the connection between the current research and clinical practice are addressed. Third, a broad perspective of future directions for contracture research is proposed. Finally, suggestions are provided for clinicians and policy makers keep up with important contracture research findings related to contracture prevention and management.

6.4.1 Implications for clinical practice and policy

There is a need for allied health staff to be informed about the effectiveness of commonly used interventions in rehabilitation. Tate and Douglas (2002) encourage clinicians to move away from their reliance on consensus opinion (the lowest level of evidence) and move towards integrating high level evidence into treatment decisions. Therapists can use results presented in this thesis to inform their treatment decisions with regard to splinting. In order to further advance evidence-based practice which has so far lagged behind research practice, therapists may benefit from exploring their own beliefs about the usefulness of hand splinting. The value therapists place on stretch as an intervention is worthy of consideration in light of the new evidence the present series of studies provides.
Therapists can access and apply this evidence using clinical guidelines. Recent guidelines have incorporated results from the presented program of research (Intercollegiate Stroke Working Party, 2004; Teasell et al., 2003). Clinical practice guidelines aim to promote the delivery of evidence-based health care by appraising and summarising best evidence (Thomas et al., 1999). The impact of studies presented in this thesis can be seen by comparing guidelines published prior to, and following dissemination of results. In contrast to clinical guidelines published prior to 2003, hand splinting is now no longer recommended for people following stroke. For example, in 1995, the post-stroke clinical practice guideline recommended that “spasticity and contracture should be treated/prevented by splinting” (Gresham, Duncan, Stason, Adams, Adelman, Alexander et al., 1995) whereas a recent set of guidelines concludes that “Hand splinting does not improve motor function or reduce contracture in the upper extremity” (Teasell et al., 2003, p. 31). None of the recent guidelines recommend hand splinting for contracture management (National Stroke Foundation, 2005; Teasell et al., 2003). In this day of computers, electronic searches and databases, therapists can now access clinical guidelines online. Relevant sites include the National Guideline Clearinghouse18 and the Physiotherapy Evidence Database.19 Both websites enable therapists with the ability to search across a number of guidelines, and provide links to each guideline.

There are many challenges to disseminating this new knowledge on splinting to therapists, educators and researchers. There are, however, even more challenges to changing splinting practice traditions. Integrating evidence into practice is one of the challenges of evidence-based practice. A recent discussion paper addressed this issue (Dean-Baar & Pakieser-Reed, 2004), and suggested ways of supporting rehabilitation staff who wish to change their practice behaviour. The first step in overcoming resistance to change is to acknowledge that

18 http://www.guideline.gov
19 http://www.pedro.fhs.usyd.edu.au
change takes time and energy. The use of clinical practice guidelines reduces the demand on time, since research evidence has already been integrated into recommendations for clinicians. The approach required to change practice behaviours will differ according to the research, practice area and disciplines involved. In line with recommendations for using a multi-targeted approach to facilitate change (Clifford & Clark, 2004), the candidate has disseminated findings using scientific publications as well as conference presentations to local and international colleagues, with a view to lobbying for change in practice.

A key finding of the thesis, that splinting in the neutral or maximum-tolerated extension position was not clinically worthwhile, suggests that splinting should no longer be used when the goal of treatment is contracture prevention or reduction over 4 to 6 weeks during early rehabilitation. Results from Studies 2 and 3 demonstrate the lack of effect of splinting under these conditions, both when used in conjunction with prolonged low load stretch and when alone as the sole treatment.

Prolonged low load stretching may have some effect on contracture prevention. The absence of a control group in Study 2 that did not receive splinting or stretching meant that this thesis was unable to determine the effect of positioning ‘stretches’. However the provision of a prolonged, low-load stretch by means other than a hand splint needs more investigation, especially given the conflicting results on the effects of stretches in the upper limb post-stroke. A recent randomised controlled trial (Ada et al., 2005) reported that positioning in a prolonged low-load stretch for 30 minutes prevented contracture of shoulder external rotation muscles. These results are in contrast with the findings to those reported by Turton and Britton (2005). In that randomised controlled study of stretches to the upper limb post-stroke, no significant effects were reported following stretch positioning for contracture prevention following stroke. Until more definitive research provides
guidance to therapists, providing this type of stretch using different modalities other than splinting may be worthwhile continuing as this intervention is low-cost and does not appear to cause any harm.

With particular reference to the wrist extension splint used in Study 3, results were contrary to expectations based on animal models. Results showed that positioning the wrist in maximum achievable extension in a hand splint for up to 12 hours did not produce greater wrist range of movement than a control group that received no positioning from a stretch or splinting. Such results bring into question mechanisms of contracture development, and point to other factors that may affect the ability of the splint to provide adequate stretch to the appropriate muscles. Results indicate that if therapists aim to prevent contracture in the wrist and fingers of a person in early rehabilitation, clinical practice should no longer be to provide a hand splint.

With regard to health policy and health funding, resources should be allocated to those interventions which are effective, and withdrawn from those which are ineffective (Black, 2004; Klein, 2000; Wooldridge, 1998). Policy makers should therefore refer to the evidence generated by the two randomised controlled studies presented in this thesis when making decisions about the funding of treatments for adults following acquired brain impairment. Results have already been incorporated into national clinical guidelines in Australia and overseas (National Stroke Foundation, 2005; Teasell et al., 2003; Intercollegiate Stroke Working Party, 2004). Evidence from this thesis will have benefits for policy beyond allocation of resources, including reduction of risk of legal liability due to negligent care. Despite the potential benefits of evidence-based policy, the translation of policy into practice continues to be a challenge.
Therapists should use suitable standard measures as part of their practice to evaluate clinical outcomes and make decisions about whether an intervention is of value for a patient. It is widely accepted that outcome measures should be convenient for use by clinicians, and acceptable to the patient, in addition to being reliable, valid and sensitive to change (Cole, Finch, Gowland, & Mayo, 1994). The extensibility measurement procedure, upper limb subscales of the Motor Assessment Scale, and rating scales used in this study were practical, efficient and psychometrically sound. They are therefore ideal for implementation in clinical settings.

In summary, practice and policy changes emerging from this study include amendments to clinical practice guidelines and what has previously been considered evidence-based practice, specific client decisions regarding splint use, and appropriate use of evaluation measures.

### 6.4.2 Implications for education

Education of undergraduate and graduate therapists should include research presented in this thesis as best evidence. Course materials should reflect the finding that the application of stretch using hand splints is not effective for adults with recently acquired brain impairment. The testing of a long-held consensus opinion, and the finding that data do not support clinical practice, is also important for therapists undergoing professional preparation. Informed, critical discussion of evidence-based practice will provide an opportunity to demonstrate to students the importance of life-long learning with respect to clinical skills.
**Professional development/Continuing education**

Evidence-based practice does not come without some cost. Current therapy practices in neurological rehabilitation are not, in many cases, evidence-based. Ongoing evaluation of an individual’s own clinical practice is an essential component of being an evidence-based practitioner, yet it can be professionally demanding for some clinicians. Previous authors have already highlighted the difficulties health professionals experience when trying to alter the way they have always practiced (Buchan, Sewell, & Sweet, 2004; Cockburn, 2004; Grol & Wensing, 2004). In this way, recommendations for clinical practice and for education are closely related, since use of best research evidence and the ensuing change in clinical practice will require substantial education within the clinical setting.

The goal of disseminating the findings of this thesis not only includes wide dissemination but also understanding and action by clinicians. In general, results have been, and continue to be, disseminated as broadly as possible, but in ways that respect the concerns and sensitivities of therapists, patients and other key stakeholders. Target audiences include not only occupational therapists and physiotherapists, but also other rehabilitation stakeholders such as consultant physicians, nursing staff, and more importantly, support groups and advocates for people with acquired brain impairment. Internet technology gives people with acquired brain impairment and their advocates access to a wealth of knowledge and information (Eysenbach & Jadad, 2001), including best-practice guidelines and results of the candidate’s collective research. Informed advocates are able to participate more actively in healthcare decisions (Fox, Ward, & O’Rourke, 2005; Hittner, 1997). Online information shows that results from the candidate’s systematic review and first randomised controlled trial are freely available to consumers through PEDro, the Physiotherapy Evidence Database, and OTseeker, a database of trials and systematic reviews relevant to occupational therapy, as well as via clinical guidelines in various countries. Publication of the results of Study 3 and its appraisal and inclusion on evidence websites and in clinical
guidelines will inform not only the practice of clinicians but also assist with goal setting and treatment planning by family members.

While improved information sharing among therapists will help to disseminate research results, professional associations must play a role in facilitating this. For example, the mission statement of OT-Australia (the peak representative body in Australia) states that they are committed to enabling members to become evidence-based practitioners. It is hoped that such a commitment will extend beyond providing education in the skills of evidence-based practice, and also develop a mechanism to examine assumptions in professional practices, and mechanisms for dissemination of research results to all members.

6.4.3 Implications for future research

This thesis has provided answers to important clinical questions regarding the treatment of adults following acquired brain impairment who are at risk of developing contractures. However, many important contracture-related issues still need to be researched.

No statistical difference in passive range of movement to standardised force was found between the splinted and control groups in either clinical trial. Considering the excellent compliance to the splinting regimes and the adequate statistical power of both Studies 2 and 3, the results are conclusive. Research which has measured the effects of four weeks of wrist stretches in acute stroke patients (Turton & Britton, 2005), eight weeks of thumb web-space stretches in acute neurology patients (Harvey, Simpson, Pironello, Glinsky, Baillie, & Ritchie, 2006), and four weeks of lower limb stretches of spinal cord injured patients...
(Harvey, Batty, Crosbie, Poulter, & Herbert, 2000; Harvey et al., 2003) also found no significant effects on muscle extensibility. Given the amount of research funding and resources allocated to this topic already, further investigation of the effect of hand splinting on wrist and finger flexor muscle extensibility in patients with an acute acquired brain impairment is not warranted.

Studies 2 and 3 did show that patients who cannot move their hand and wrist after acquired brain impairment lose considerable range of movement. This finding is consistent with those of a study of the time course of development of contractures at the wrist (Pandyan, Cameron, Powell, Stott, & Greanat, 2003) and with the results from a study of the effect of stretch positioning to prevent contractures post stroke (Turton & Britton, 2005). Therefore, it remains important that an effective treatment to prevent contractures is found and empirically tested through future research studies. Further research investigating the effectiveness of other modalities that can provide stretch to the wrist and finger flexor muscles following acquired brain impairment may be worthwhile. Modalities which remain inconclusive include positioning a muscle on stretch (Ada et al., 2005; Turton & Britton, 2005) and casting a joint so that muscles are placed on stretch (Gossman et al., 1982). Positioning a muscle on stretch using casting provides the opportunity to deliver a low-load long duration stretch with greater intensity (that is, greater range of movement) than can be applied using a hand splint. Casting a joint at its end of range provides the opportunity for clinicians to deliver a low-load long duration stretch with greater compliance (since the cast is not easily removed) and with longer durations. With evident differences between these modalities and the hand splint, further research investigating their effectiveness is may be worthwhile.
The mechanism of contracture development and prevention following acquired brain impairment remains unknown. There is a developing body of evidence across a number of populations (including populations with acquired brain impairment) that stretching as it is usually applied in the clinical setting is not effective. This represents a clear disparity between animal model behaviour and that measured in this thesis. The influence of other factors with relation to contracture formation and prevention in human muscles therefore warrants investigation. To this end, subgroup analyses from Study 3 may have provided information about factors which influenced the time-course development of contractures. Subgroup analyses are, however, prone to serious bias, particularly when subgroup hypotheses are not specified, a priori, and when the study is not adequately powered to investigate effect modifiers (Herbert, Jamtvedt, Mead & Hagen, 2005). For this reason subgroup analyses were not performed. The importance of clear differentiation between prevention and reduction of contracture is acknowledged. Future studies should determine whether the duration of stretch differs for prevention of contracture versus reduction of contracture, since studies to date have investigated the issue of prevention and treatment as a single concept.

Further development and evaluation of the self-report style of upper limb assessment for use with people following acquired brain impairment would also be a valuable contribution to both rehabilitation and research. Examination of sensitivity data from the Disabilities of Arm Shoulder and Hand Questionnaire (Solway, Beaton, McConnell, & Bombardier, 2002) used in study 3 may provide insight into its relevance and usefulness for clinicians. Consumer perspectives gained from self-report assessments would fill important gaps in the information needed to make evidence-based decisions and allow healthcare decisions to incorporate consumer priorities.
In addition to areas of research evident from the findings of these studies, much can also be learnt from the challenges faced during the conduct of the randomised controlled trials. During rehabilitation many individuals receive a combination of therapies and often treatments are highly individualised and poorly documented (Whyte, 2003a; Whyte & Hart, 2003b). Rehabilitation as a setting for research requires an understanding of the range of co-interventions, and substantial monitoring to facilitate compliance. Moreover, because of the interest in outcomes at various levels of analysis, rehabilitation research is at risk of statistical problems associated with multiple testing (Fuhrer, 2003; Pocock, 1983; Whyte, 2003a). Finally, randomised controlled trials require sufficient numbers of suitable participants for statistical analyses. In Australian settings the required sample size often exceeds the capacity of a single setting and multicentre clinical trials become a necessity (as in Study 3). Recruiting for multicentre clinical trials present their own challenges (Lannin & Cusick, 2006), however this approach is unavoidable in many instances to ensure sufficient participant enrolment (Fuhrer, 2003).

Research carried out in this thesis makes a substantial contribution to the development of evidence-based rehabilitation practice. It is acknowledged, however, that the translation of findings of research into clinical practice is poor (Mccluskey & Cusick, 2002; Tse, Lloyd, Penman, King, & Bassett, 2004). The opportunity to implement research-based practice is great, but requires attention, resources, education and support. A clear next-step in this project is the application of evidence-based practice – focussing on knowledge transfer and supporting behaviour change in clinicians. Arising from this logical next step is an opportunity to research how well recommendations from this research and clinical guidelines are adopted by clinicians for the benefit of people following acquired brain impairment.
6.5 Conclusion

Investigating the effectiveness of hand splinting in the prevention of wrist and finger flexor muscle contracture following acquired brain impairment involved conducting a systematic review and two randomised controlled trials. Overall, the findings indicate that neither the traditional position for hand splinting, nor one of greater wrist extension, prevented or reversed contracture following acquired brain impairment. With increasing numbers of people experiencing acquired brain impairment each year, these findings represent an important contribution to rehabilitation literature and practice.

“Rehabilitation stakeholders are in accord in demanding scientifically credible evidence that interventions are safe, effective, and worthwhile.”

(Fuhrer, 2003:S10).

The results of this thesis provide evidence that overnight splinting of the hand and wrist for periods of up to 12 hours is neither effective nor worthwhile for adults who have acquired brain impairment.
References


*Paraplegia*, 3, 221–225.

and Rehabilitation*, 82, S8–S15.

practical management of spasticity in children and adults* (pp. 1–7). Philadelphia: 
Lea & Febiger.

changes following cerebrovascular accident. *Australian Journal of Physiotherapy*, 
42, 139–147.

*Current Contents*, 18, 3–6.


computer-aided goniometry versus standard goniometry for recording finger joint 

Louis: Mosby.

with occupational therapy outpatient attendance: a quality assurance study. 


Harvey, L., Simpson, D., Pironello, D., Glinsky, J., Baillie, R., Ritchie, B. (under review, 2006). Does three months of nightly splinting reduce the extensibility of the flexor
pollicus longus muscle in people with tetraplegia?


Behavioral Assessment, 10, 197–206.


MacDermid, J.C., & Tottenham, V. (2004). Responsiveness of the disability of the arm, shoulder, and hand (DASH) and patient-rated wrist/hand evaluation (PRWE) in evaluating change after hand therapy. *Journal of Hand Therapy*, 17, 18–23.


Ottenbacher, K. J. (1995). Why rehabilitation research does not work (as well as we think it should). *Archives of Physical Medicine and Rehabilitation, 76*, 123–129.


# List of Appendices

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix A</td>
<td>Publications</td>
<td>222</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Study 2 ethics approval</td>
<td>253</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Study 3 ethics approval</td>
<td>256</td>
</tr>
</tbody>
</table>
Appendix A

Publications by the candidate relevant to the thesis.
Candidate’s statement of contribution to jointly published work

Three studies forming part of this thesis have been published (or are in press) in peer-reviewed journals and were jointly authored. A further two related publications are also included in the Appendices and one of these was jointly authored. For each publication, the first-listed author was principally responsible for the concept, design, conduct and write-up and acted as guarantor, with decreasing contributions by subsequent authors in order of listing. Therefore the candidate has provided the lead for the four jointly authored publications and was sole author for the remaining publication. A copy of all publications and a manuscript under review are presented in Appendix A.

Publications relevant to the thesis with details of contributions by the candidate


   Lannin initiated and coordinated this review, was jointly involved in the systematic review and analysis, and was responsible for the study design, comparison of searches and content, majority of the write up and responses to reviewers.


   Lannin initiated and coordinated this trial, participated in design and statistical analysis, and was responsible for the hand splinting intervention, majority of the write up and responses to reviewers.

Lannin coordinated this trial, substantially contributed to design and statistical analysis, and was responsible for the majority of the write up.

**Publications in the appendices only**


Is hand splinting effective for adults following stroke? A systematic review and methodological critique of published research

NA Lennin School of Exercise and Health Sciences, University of Western Sydney and RD Herbert School of Physiotherapy, University of Sydney, Australia

Received 13th February 2003; returned for revisions 17th June 2003; accepted after review.

Background: Upper limb hemiplegia after stroke is common and disabling. Hand splints are widely used to prevent contracture and reduce spasticity.

Objective: To assess the effectiveness of hand splinting on the hemiplegic upper extremity following stroke.

Search strategy: A search was conducted of the Cochrane Central Register of Controlled Trials; the electronic databases MEDLINE, EMBASE, CINAHL, PEDro, SCI, SSCI; websites of professional associations; reference lists in trial reports and other relevant articles.

Selection criteria: Studies of the effect of upper extremity splinting on motor control, functional abilities, contracture, spasticity, or pain in the hand or wrist.

Data collection and analysis: Validity of studies was assessed systematically and a content analysis was conducted of the methodologies used. Methodological quality of randomized trials was rated by two independent assessors using the PEDro scale.

Results: Nineteen studies were appraised for content. Of these, most (63%) were reports of case series. Four studies (21%) were randomized controlled trials. Methodological scores of trials ranged from 2 to 8 (maximum possible score 10). One trial of nominally ‘medium’ quality reported that inflatable arm splinting makes no difference to hand function (mean difference on Fugl-Meyer Assessment −0.12, 95% confidence interval CI −8.8 to 8.6). The remaining trials investigated effects of thermoplastic splints; one trial of ‘high quality’ reported no difference in contracture formation in the wrist and finger flexor muscles after wearing a hand splint which positioned the wrist in the traditional functional position for 12 hours each night for four weeks (mean difference in range of movement after four weeks was 1°, 95% CI −3.7° to 6.1°; power >80%). All remaining trials were of poor methodological quality. Limited research and lack of a no-splint control group in all trials to date limit the usefulness of these results.

Reviewer’s conclusion: There is insufficient evidence to either support or refute the effectiveness of hand splinting for adults following stroke.

Address for correspondence: Natasha Lennin, School of Exercise and Health Sciences, University of Western Sydney (Campbelltown Campus), Locked Bag 1797, Parramatta NSW 1797, Australia. e-mail: Lennin@bigpond.com
Introduction

After stroke, patients often experience motor deficits that interrupt normal upper extremity function. Hand splints are a common component of rehabilitation programmes for addressing such deficits.\textsuperscript{1-5} Splinting within this population has historically been controversial\textsuperscript{6-10} and there are respected leaders within rehabilitation professions who advocate and oppose the use of hand splints. Such controversy has continued unabated largely as a result of the lack of scientific evidence to document the effectiveness of splinting.\textsuperscript{8,10-12} Despite the controversies associated with splinting the hemiplegic upper extremity, splints continue to be used in the clinical setting.\textsuperscript{3}

A survey of upper extremity splinting following stroke reveals a range of design principles, wearing schedules, splinting materials and clinical aims.\textsuperscript{3} The clinical aims for splinting adults following stroke include reduction in spasticity,\textsuperscript{1,2,5,10} reduction in pain,\textsuperscript{8,10} improvement of functional movement,\textsuperscript{1,9,10} prevention of contracture,\textsuperscript{1,2,9,10} prevention of overstretching\textsuperscript{5,9} and oedema.\textsuperscript{2,10} Despite the variety of aims, there are only two theoretical rationales for splinting in this population: the biomechanical\textsuperscript{5,7,10} and the neurophysiological.\textsuperscript{5,7,10} Therapists and physicians who apply the biomechanical rationale recommend splinting to prevent as well as manage length-associated changes in muscles and connective tissue, whereas those who apply the neurophysiological rationale recommend splinting to inhibit reflexive contraction of muscle. Such opposing views on a theoretical rationale for splinting continue to fuel the existing controversies surrounding whether or not to prescribe hand splints for adults following stroke.

With varied clinical aims, splint designs and materials, and opposing theoretical rationales, it is understandable that there is much controversy surrounding this common rehabilitation practice. The research literature on splinting to date has not resolved such controversies, and knowledge on the absolute and relative efficacy of splinting is incomplete.\textsuperscript{14} Published research was systematically reviewed to understand the range and quality of evidence available on the topic of hand splinting for adults following stroke, and randomized controlled trials (RCTs) of any hand or wrist splint for hemiplegia were further appraised to assess the evidence of efficacy.

Method

The aim of the review was to critically appraise research into effects of hand splinting for adults following stroke. The two specific objectives were to:

- identify research methodologies used, and
- determine whether hand splinting improves clinical outcomes.

These objectives led to a content analysis of published literature, and a systematic review of the evidence obtained from randomized trials.

Search strategy

This review used the search strategy developed by the Cochrane Stroke Review Group to identify studies involving people who have experienced a stroke. This search strategy was combined with keywords specific to the topic (splint*, cast*, ortho*, orthotic*, brace*, bracing, and thermoplastic*). Terms were exploded where possible then combined. The Cochrane Central Register of Controlled Trials (www.cochrane.org) was used to identify any controlled trials not published on this topic. In addition, the author searched electronic databases and hand-searched specific journals. Studies undertaken to evaluate the effect of hand splinting were identified by searching:

1) bibliographical databases: MEDLINE, EMBASE, CINAHL, PEDro (www.pedro.com.au) and OTSeeker (www.otseeker.com)
2) citation index databases: Science Citation Index (SCI), and Social Sciences Citation Index (SSCI)
3) websites of 15 relevant professional organizations
4) citation-tracking of primary studies, review articles and books.

Databases were searched up to 26 May 2003.
Refinements, searching and reporting constraints

Inclusion criteria: English language studies of the effects of splinting that fulfilled the following criteria were included in the review:

1) **Type of study**: studies which generated level 4 evidence or higher (Table 1). The author accepts that the best available evidence is that which is least susceptible to bias, such as that provided by levels 1a and 1b of the Oxford Centre for Evidence-based Medicine levels of evidence (Table 1). However a broader search strategy included studies more prone to bias (levels 2, 3 and 4) for content analysis.

2) **Type of intervention**: studies that involved the administration of upper extremity splinting programmes for adults following stroke. For the purpose of this review, splints are 'any external, removable device designed to apply, distribute or remove forces to or from the body in a controlled manner, to control body motion and alteration or prevention in the shape of body tissue'.

3) **Types of subjects**: studies that explicitly involved human subjects in which more than 50% of the participants were adults who had experienced a stroke.

4) **Types of outcome measures**: studies that included a measure of functional hand use, joint range of motion, tone, spasticity, oedema, or pain.

Studies were excluded from the review if:

- less than 50% of the splints were applied to the wrist or hand,
- a second publication of the same study presented the same results.

A single reviewer applied these criteria.

Data collection and analysis

A content analysis of published research located through the search strategy that quantitatively examined hand splinting using prospective, retrospective or comparative methodologies was made. Studies that produced similar levels of evidence were grouped into common categories by reported splint design and appraised for their level of evidence using the system developed by the Oxford Centre for Evidence-based Medicine (Table 1). Further, each study was evaluated for its internal and external validity and rated according to criteria developed by the American Occupational Therapy Association's Evidence-Based Literature Review Project as 'high' (no threats present), 'moderate' (one or two threats exist), or 'low' (more than two threats to validity exist) validity. Systematic reviews were not appraised for included study validity. Each study was only counted and coded once to ensure robust findings and minimal interpretation by one investigator (NL).

Randomized controlled trials identified in the search strategy were also included in the systematic review, and the remainder of studies (level 2, 3 and 4) were characterized as 'low-quality' evidence (Table 1). Data extracted from all studies included: authors and date of study; description of hand splint; number of participants; setting; study design and outcomes; and description of findings. Data synthesis for content analysis was restricted to presenting studies together in tables. This method is designed to facilitate appropriate understanding of the current literature and provide methodological focus for planning future studies.

In line with published recommendations for reviews of treatment efficacy, the systematic review excluded nonrandomized trials. The

---

**Table 1** Oxford Centre for Evidence-based Medicine levels of evidence (abbreviated)

<table>
<thead>
<tr>
<th>Level 1a evidence</th>
<th>Systematic reviews and meta-analyses of randomized controlled trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1b evidence</td>
<td>Randomized controlled trials (RCTs)</td>
</tr>
<tr>
<td>Level 2a evidence</td>
<td>Systematic reviews and meta-analyses of randomized and nonrandomized controlled trials</td>
</tr>
<tr>
<td>Level 2b evidence</td>
<td>Controlled trials, cohort and poor quality RCTs</td>
</tr>
<tr>
<td>Level 3 evidence</td>
<td>Case-control studies</td>
</tr>
<tr>
<td>Level 4 evidence</td>
<td>Case series</td>
</tr>
<tr>
<td>Level 5 evidence</td>
<td>Expert opinion including literature/narrative reviews, consensus statements, descriptive studies and individual case studies</td>
</tr>
</tbody>
</table>

---

**Abbreviated from ref. 15 and used with permission.**
methodological quality of included trials was assessed by two raters using the PEDro scale (www.pedro.fhs.usyd.edu.au/FAQs/Scale/ scaleitems.htm). The PEDro scale has established reliability and provides a score out of 10. It was established a priori that studies that attained a PEDro score of 7 or greater would be considered ‘high quality’, those with a PEDro score of 5 or 6 would be considered ‘moderate quality’ and those with a PEDro score of 4 or less would be considered ‘poor quality’.

The intention was to conduct a meta-analysis if there was sufficient clinical and statistical homogeneity.

Results

Of the 108 papers retrieved using the above search strategy, 21 studies met the criteria for appraisal. Reasons for exclusion of papers were: less than 50% or nondescribed proportion of population were adults who had experienced a stroke (n = 17; 20%); splint applied to body part other than hand/wrist (n = 9; 10%); study did not investigate effectiveness of splinting (n = 15; 17%); and paper was narrative opinion/literature review without explicit appraisal (n = 38; 44%). Eight papers (9%) were excluded because the purpose of the splint was to provide functional electrical stimulation and not to apply forces to the musculature of the hand/wrist. (References to excluded papers are available from the first author on request.)

Twenty-one studies were included in the content analysis (Tables 2 and 3, see also Appendix). Evidence from these studies was generally weak, largely because of a scarcity of randomized controlled trials. Overall, 1 study provided level 5 evidence (5%), 12 studies (57%) provided level 4 evidence, 2 (9%) provided level 3 evidence, 1 study (5%) provided 2a evidence (systematic review of randomized and nonrandomized studies), 4 (19%) provided level 2b evidence (RCTs with methodological limitations), and 1 study (5%) provided level 1 evidence (high-quality RCT) (Table 1 outlines levels of evidence).

All studies were further appraised for quality (systematic review not included in appraisal). All but one study were found to have threats to internal validity present on appraisal: 17 (85%) were rated as low internal validity, 2 (10%) were rated as moderate internal validity, and 1 (5%) was rated as high internal validity. A common threat to statistical conclusion validity was small sample size (Table 2). Appraisal of external validity provided better results, with 6 (34%) rated as high, 13 (65%) rated as moderate, and 1 (5%) rated as low.

Five randomized controlled trials were included in the systematic review. The included trials differed in design (independent and dependent variables, splint designs, wearing regimes, outcome measures, and study periods different across studies) (Table 2). This heterogeneity precluded meta-analysis.

Methodological quality of included studies

Table 4 presents the PEDro score for each RCT. There was mixed quality in the papers, most were of either ‘moderate’ or ‘poor’ quality and only one RCT met the criteria for a rating of ‘high’ quality. PEDro scores ranged from 2 to 8 (median score = 3.5). Whilst all studies used random allocation, only two studies used blinded assessors, and only one study used concealed allocation and intention to treat analysis.

The data from the one ‘moderate’ quality study25 showed no difference in motor function in the wrist and hand after wearing an inflatable pressure splint which positions the shoulder in 90 degrees of flexion and maximum external rotation with full elbow extension (hand and wrist not enclosed in splint) for 30 minutes/day (mean difference on the 57-point Fugl-Meyer Assessment −0.12, 95% confidence interval (CI) −9.8 to 9.6, where a negative difference indicates a beneficial effect).

Remaining studies investigated the effect of thermoplastic hand splints. The data from the one ‘high-quality’ study25 showed no difference in contracture formation in the wrist and finger flexor muscles after wearing a hand splint which positioned the wrist in the traditional functional position for 12 hours each night for four weeks (mean difference in range of movement after four weeks was 1°, 95% CI −3.7° to 6.1° mean difference after six weeks (follow-up) was −2°, 95% CI −7.2° to 3.2°; power >80%). The control group
Table 2: Summary of studies—interventions and participants

<table>
<thead>
<tr>
<th>Study</th>
<th>Defining intervention</th>
<th>Control intervention</th>
<th>Outcomes</th>
<th>Total n</th>
<th>Mean age (years)</th>
<th>Time post stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard split (Unilateral)</td>
<td>Stroke lesion to keep joint fully extended</td>
<td>Corresponding muscles with tendon stretching and joint unopposed</td>
<td>Stroke</td>
<td>14</td>
<td>64 years</td>
<td>6-12 months</td>
</tr>
<tr>
<td>Brother et al., 1980</td>
<td>Posture exercise without sensory discrimination</td>
<td>Bobath therapy</td>
<td>Stroke</td>
<td>8</td>
<td>64 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>FAIR trial</td>
<td>Direct split with 60° of extension</td>
<td>None</td>
<td>Stroke</td>
<td>20</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Thomas et al., 2000</td>
<td>Direct split with maximal leg length &amp; maximal passive stretch plus 40° of internal rotation</td>
<td>None</td>
<td>Stroke</td>
<td>18</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Direct split</td>
<td>With skirt split</td>
<td>None</td>
<td>Stroke</td>
<td>16</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Elia et al., 2000</td>
<td>Strengthening exercises with gait training</td>
<td>None</td>
<td>Stroke</td>
<td>16</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Comparison tests versus split</td>
<td>None</td>
<td>None</td>
<td>Stroke</td>
<td>1</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Chino, 1994</td>
<td>Direct split, with 60° of extension</td>
<td>None</td>
<td>Stroke</td>
<td>10</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Intra-articular splinting</td>
<td>None</td>
<td>None</td>
<td>Stroke</td>
<td>20</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Medrici et al., 1997</td>
<td>Direct split, split 10°C, Splint extension 5°</td>
<td>None</td>
<td>Stroke</td>
<td>16</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Haddad et al., 1997</td>
<td>Direct split, higher 0°, higher 0°, higher 0°, and higher 0°</td>
<td>None</td>
<td>Stroke</td>
<td>16</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
<tr>
<td>Comparison tests versus intra-articular splinting</td>
<td>None</td>
<td>None</td>
<td>Stroke</td>
<td>16</td>
<td>66 years</td>
<td>6 months-1 year</td>
</tr>
</tbody>
</table>

1See Appendix for list of studies.
<table>
<thead>
<tr>
<th>Study</th>
<th>Research Design</th>
<th>Land of Study</th>
<th>Measurable Variable</th>
<th>Internal Validity</th>
<th>External Validity</th>
<th>Treatment Duration</th>
<th>Spacing</th>
<th>Control Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hall et al. 1990</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1991</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1992</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1993</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1994</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1995</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1996</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1997</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1998</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 1999</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
<tr>
<td>Bland et al. 2000</td>
<td>Case series</td>
<td>UK</td>
<td>k at 12 months</td>
<td>Moderate ***</td>
<td>Not applicable</td>
<td>6 weeks</td>
<td>2</td>
<td>Control group</td>
</tr>
</tbody>
</table>
Table 4: Methodological rating of randomized controlled trials

<table>
<thead>
<tr>
<th>Study</th>
<th>PEDro criterion score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>McPherson et al., 1982</td>
<td>Y</td>
</tr>
<tr>
<td>Rose et al., 1987</td>
<td>Y</td>
</tr>
<tr>
<td>Pico et al., 1987</td>
<td>N</td>
</tr>
<tr>
<td>Langlois et al., 1991</td>
<td>Y</td>
</tr>
<tr>
<td>Linnin et al., 2003</td>
<td>Y</td>
</tr>
</tbody>
</table>

Explanation of score items: Item score 0=absent or not clearly present, 1=present. The PEDro scale criteria are:
1. Specification of eligibility criteria;
2. Random allocation; 3. Concealed allocation; 4. Prognostic similarity at baseline;
5. Subject blinding; 6. Therapist blinding; 7. Assessor blinding; 8. >65% follow-up of at least one key outcome;
9. Intention-to-treat analysis; 10. Between-group statistical comparison for at least one key outcome; and (11) point estimates of variability provided for at least one key outcome. Only items 2-11 are summed to provide total score.

Note: Item 1 is not included in the calculation of PEDro score.

In this study received two prolonged stretches to their wrist and finger flexor musculature (30 minutes in duration) five days a week for the study period, and so while the study provides an estimate of the effectiveness of hand splinting whilst patients are receiving a daily prolonged stretching programme, it does not permit inference about the effectiveness of hand splinting with patients who are not receiving prolonged stretches.

Another study reported that hand splinting in the functional position for 2 hours (total time to outcome) using either volar or dorsal splints results in a statistically significant increase in passive range of wrist extension and a decrease in hypertonus (point measures and measures of variability were not reported). A different trial reported no significant difference between dorsal and volar splints in decreasing hypertonus (mean difference = 0.11b, 95% CI -1.4 to 1.5). In that study the splints were worn for 2 hours/day for five weeks. The methodological limitations of these two studies (threats to internal validity, short follow-up and lack of non-splint comparison) limit the usefulness of these results.

In the remaining study, Langlois et al. report no difference in wearing a finger-spreader splint for 6 hours compared to longer wearing times of 12 hours or 22 hours with regard to wrist stiffness (hypertonicity) at two weeks (mean difference between groups = 0.001 Nm/rads, 95% CI: −0.424 to 0.414), but again usefulness is limited by the lack of a no-splint control group.

Discussion

As the rehabilitation of adults following stroke consumes substantial health resources, it is crucial that an evidence-based approach be adopted in response to controversies and clinical uncertainties, such as those found abundant in the debate about hand splinting. Unfortunately, the present effort to systematically review the international literature found an inadequate evidence base from which to inform clinical decision-making. Despite the widespread use of hand splints for adults stroke patients, surprisingly few studies (n = 18), and even fewer randomized controlled trials (n = 5), have examined the effect of splinting in this population. Studies of thermoplastic hand splinting for adults following stroke were nearly all of low methodological quality. Heterogeneity of study design, methods, splint design and regime, and outcomes hindered the pooling of data.

The majority of published papers are based on opinion without explicit appraisal (44%). Of the quantitative studies which met the criteria for inclusion in the content analysis, the most popular approach is the use of case series. Few investigators have employed more rigorous designs such randomized n-of-one studies (single case experimental designs) or randomized trials. Overall, only 26% of the included studies were based on true-experimental designs.

Only one systematic review was located using the search strategy, which reported that there is insufficient evidence that splinting is effective for decreasing muscle tone in adults following...
stroke. The usefulness of this study was limited by the inclusion of non-randomized trials in their review and the limited search strategy reported (review located only five of the published 19 studies, and only two of the four RCTs published that would have met inclusion criteria). Despite these limitations, it is of interest to note that the authors’ conclusions concerning splinting were similar to those of this review (where the conclusion is based on a greater number of studies).

This review was limited by the inclusion and exclusion criteria. Only trials in which more than 50% of the participants were adults who had experienced a stroke were included in the review. Furthermore, non-English language reports were excluded. In addition to this methodological limitation, the lack of published research, the small number of randomized controlled trials, and the overall poor methodological quality also reduces the strength of findings.

Reviewer’s conclusions

There is good evidence (level 1) to refute the effectiveness of volar hand splinting for the treatment of contracture management in stroke patients who are receiving upper limb stretching programme five days a week. There is, however, insufficient evidence to either support or refute the effectiveness of dorsal or volar hand splinting in the treatment of adults following stroke who are not receiving upper limb stretching programme. There is no evidence of long-term benefits or adverse effects.

Implications for research

Assigning levels of evidence to the existing studies identified within the content analysis guides future researchers to areas of research requiring further empirical evaluation. The efficacy of hand splinting will not be fully understood until well-designed randomized controlled trials have compared hand splinting with a control condition which does not involve hand splinting or upper limb stretching. Such trials should adhere to recommendations made by Pocock including clear eligibility criteria, a priori calculation of sample size and specification of primary and secondary outcomes, randomization, allocation concealment and blinding.

Most of the existing studies have focused on which splint design is most efficacious. As well as considering the effects of different splint designs it may be important to consider the effects of the amount of time the splint is worn and the position of the hand in the splint. There is still much that is not well understood about the effect of hand splinting in this population and it is only through research that the ongoing controversies will finally be put to rest.

References


Clinical messages

- There is level 1 evidence to refute the effectiveness of hand splinting in the functional position for the management of contractures in adults following stroke who are receiving a daily stretching programme.
- There is insufficient evidence to either support or refute the effectiveness of hand splinting for adults following stroke who are not receiving prolonged stretches to their upper limb.
Appendix A 230

Hand splinting 815

Appendix – References to included studies


Gracies JM, Marochniak K, Renton P, Sarnat J, Gandevia SC, Burke D. Short-term effects of

Appendix A

1. Appendix A 230

2. Hand splinting 815

3. Appendix – References to included studies


9. Gracies JM, Marochniak K, Renton P, Sarnat J, Gandevia SC, Burke D. Short-term effects of

Appendix A

1. Appendix A 230

2. Hand splinting 815

3. Appendix – References to included studies


9. Gracies JM, Marochniak K, Renton P, Sarnat J, Gandevia SC, Burke D. Short-term effects of


Splinting the Hand in the Functional Position After Brain Impairment: A Randomized, Controlled Trial

Natasha A. Lunnin, BSc, GradDip, Sally A. Horsley, BAppSc, Robert Herbert, PhD, Anne McCluskey, MA, Anne Cusick, PhD


Objective: To evaluate the effects of 4 weeks of hand splinting on the length of finger and wrist flexor muscles, hand function, and pain in people with acquired brain impairment.

Design: Randomized, assessor-blinded trial.

Setting: Rehabilitation center in Australia.

Participants: Twenty-eight adults with acquired brain impairment, all within 6 months of the first injury. There were 1 withdrawal.

Interventions: Subjects in both experimental (n=17) and control (n=11) groups participated in routine therapy—motor training for upper-limb use and upper-limb stretches—5 days a week. The experimental group also wore an immobilizing hand splint in the functional position (0°-30° wrist extension) for a maximum of 12 hours each night for the duration of the 4-week intervention period.

Main Outcome Measures: The length of the wrist and extrinsic finger flexor muscles was evaluated by measuring the torque-controlled range of wrist extension with the fingers extended. Functional hand use was evaluated with the Motor Assessment Scale. Pain was evaluated with a visual analog scale.

Results: The effects of splinting were statistically nonsignificant and clinically unimportant. At follow-up, estimates of treatment effects slightly favored the control group: range of motion at the wrist favored controls by 3° (95% confidence interval [CI], −0.2° to 3.2°); function favored controls by 0.2 points (95% CI, −2.7 to 3.3), and pain favored the experimental group by 1.0 cm (95% CI, −4.6 to 2.2).

Conclusions: An overnight splint-wearing regimen with the affected hand in the functional position does not produce clinically beneficial effects in adults with acquired brain impairment.

Key Words: Contracture, Hemiplegia, Occupational therapy, Rehabilitation, Spasticity.

© 2003 by the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation

PEOPLE WITH acquired brain impairment, such as stroke or traumatic brain injury (TBI), commonly experience loss of movement and strength in the upper limb.1,2 Subsequently, secondary complications, such as contracture, often occur.3-5 Contracture, or loss of joint range of motion (ROM), may be due to changes in the passive mechanical properties of muscles (perhaps consequent to a reduction in serial sarcomere numbers)6 or may be associated with spasticity.7-9 Contracture is common after both stroke and TBI.9-12 Contractures are associated with poor functional recovery8,9,13-15 because they restrict ROM and interfere with the performance of many everyday tasks.9,13 Pain is also widely reported to be a secondary complication of acquired brain impairment.9,11,16,17

In some clinics, patients who experience a loss of movement after acquired brain impairment are routinely16 provided with hand splints.16,17 There are discrepancies in splinting practices, and the use of hand splints with this population is controversial.18,19,20 The aims of splinting include reductions in spasticity,18,21-23 pain,19 improvement of function,19 compensation for protective sensation,6,24,25 and prevention of deformity.19,26-28 Overstretching,29-31 and edema.11,32-34 Of these, the most common aim,15 and the one used as a basis for our study, is the prevention of contracture.30 Despite the variety of aims, there are only 2 basic theoretical rationales for splinting in this population. These are the biomechanical18,19,21,22,23,26,27 and the neurophysiological19,19,20,25,26 rationales. Therapists who apply the biomechanical rationale recommend splinting to prevent length-associated changes in muscles and connective tissue. Therapists who apply the neurophysiological rationale recommend splinting to inhibit reflexive contraction of muscle.

Regardless of the rationale used, few therapists use splints on patients who have active movement.19 Typically, therapists recommend a static (resting) splint for patients without active movement.30 This splint positions the wrist and fingers in the functional position.15 A major controversy arising from the neurophysiological rationale is whether to place this splint on the palm or dorsal surface of the hand. The controversy is due to the belief that a splint placed on the palmar surface of the hand will stimulate the flexor muscles and therefore increase spasticity.18-22,23,30 The research literature to date does not, however, resolve this or other controversies.

The efficacy of splinting after acquired brain impairment is yet to be established.19,21,23 Most published studies18,19,20 have not used true experimental designs,19,24 and most have measured the effect of splinting on spasticity. The clinical relevance of spasticity as an outcome is questionable because recent research suggests that spasticity is unrelated, or only weakly related, to functional ability after stroke.25 The efficacy of splinting, therefore, needs to be addressed by using randomized, controlled trials (RCTs) that investigate the effect on clinically relevant variables, such as joint ROM, hand function, and pain.

The primary aim of this study was to determine the effect of 4 weeks of splint wearing on the length of the wrist and finger flexor muscles in patients who were in the early stages of...
rehabilitation after acquired brain impairment. Secondary aims were to determine whether splinting affected the recovery of hand function and pain in the upper limb.

METHODS

Participants

The trial included 28 subjects who were recruited on their admission to the Townsville Hospital Rehabilitation Unit, Queensland, Australia. Subjects were required to meet the following criteria for inclusion in the study: (1) have a history of a single stroke or brain injury resulting in upper-limb hemiplegia of no more than 6 months in duration, (2) be unable to actively extend the affected wrist, and (3) be between 18 and 80 years old. Subjects were excluded if they had language comprehension, perceptual, or cognitive deficits that would prevent written, informed consent or participation in the program. Because it is not customary in clinical practice to provide a wrist splint to patients with active movement, subjects with active wrist extension were excluded from participating in the study. Of 53 consecutive patients admitted to the unit with acquired brain impairment, 23 patients were excluded because they did not meet the inclusion criteria. Reasons for exclusion included active wrist extension (n=19), concurrent fracture of the hemiplegic arm (n=2), and decreased ability to provide informed consent (n=2). Two patients who were eligible elected not to participate in the study. The protocol was approved by hospital and university ethics committees.

Sample Size

The required sample size was determined by using the pooled estimate of within-group standard deviations (SDs) obtained from pilot data. A 5% change in mean muscle extensibility was selected as the smallest clinical change that would be considered worthwhile after the extensive period of splint wearing. Power calculations indicated that a sample of 28 subjects would provide an 80% probability of detecting a 5% effect on wrist and finger flexor length, with a power of 0.6, loss to follow-up of 10%, and a set at 0.5.

Design

An assessor-blinded, randomized design was used. A random number table was used to generate the random number sequence. Subjects were randomly allocated to control and experimental groups by using a simple randomization process. Random allocation occurred after baseline measurements. The investigator contacted an independent person to obtain group allocation for each subject. This ensured concealed randomization. Both groups received routine therapy. In addition, the experimental group wore a hand splint for up to 12 hours a night for 4 weeks.

Intervention

Subjects in both groups participated in routine therapy for individual motor training and upper-limb stretches 4 days a week. This routine therapy was provided as follows.

Upper-limb motor training. An individually designed motor training program designed to improve performance in upper-limb tasks was conducted with each subject for approximately 30 minutes a day, 5 days a week.

Stretching. Two 30-minute stretches were applied to the subject's upper limbs 5 days a week for the duration of the study and follow-up period (5 wk in total). These stretches provided a prolonged low-load stretch to muscles at risk of developing contracture. The upper-limb stretches used in the study included the following: first, a seated weight-bearing stretch of the upper limb with (1) the shoulder joint positioned in external rotation, abduction, and slight extension; (2) the elbow in extension; (3) the forearm in supination; and (4) the wrist and fingers in extension. Second, a seated stretch of the upper limb involving use of an inflatable long-arm air splint with (1) the shoulder joint positioned in external rotation and abduction, (2) the elbow positioned in extension, (3) the wrist positioned in extension, and (4) the thumb positioned in abduction.

In addition to the routine motor training and stretching described previously, subjects in the experimental group wore a static, palmar resting wrist splint on a daily basis, for a maximum of 2 hours each night, for the duration of the 4-week intervention period. The splint was worn at night partly to keep treating physiotherapists blinded to subject allocation. One of the investigators (SAL) and the nursing staff on the hospital ward were responsible for ensuring that the splints were applied and fitted correctly for the duration of the study. The splint held the hand in the functional resting position: wrist positioned between 10° and 30° extension, thumb in opposition and abduction, and semiflexion of the fingers (fig 1).

No adjustments to the splints were required during the study period to maintain the functional resting position.

Measurement Procedures

Outcome measures were obtained on 3 occasions: before random allocation (baseline), at the end of the 4-week experimental period on the 30th day (postintervention), and 1 week after the experimental intervention was ceased on the 38th day (follow-up). Measurements on day 30 were taken at least 3 hours after the splint had been removed. Measurements were conducted by one of the investigators (SAL), who was assisted by a second clinical physiotherapist. Both assessors were blinded to allocation.

Outcomes Measures

Three outcomes were recorded. These were length of wrist and finger flexor muscles, hand and arm function, and pain levels.

The length of the wrist and finger flexor muscles was obtained by using a standard procedure, which provided a torque-controlled measurement of wrist extension with the fingers extended. Good reliability of this procedure has been
established, and it has been shown to be sensitive within 5.20
Using a spring balance, the assessor applies a known torque to the wrist to produce passive wrist extension. Wrist angle is then measured with skin-surface markers and a goniometer, which is attached to the instrument. Three consecutive measurements were taken on each occasion. The mean of the three readings was used for subsequent analysis. A brief stretch into wrist extension was provided to all participants before each measurement. This brief stretch was conducted to reduce potential pain on measurement.31 The measurement procedure used does not distinguish between the resistance caused by biomechanical and neural factors (i.e., soft-tissue length changes and spasticity, respectively). Spasticity was not measured in isolation for a number of reasons. First, the main reason cited by therapists for making hand splints for this population is the prevention of contractures, not spasticity.2 Second, traditional tools believed to measure spasticity (e.g., the Ashworth or Modified Ashworth Scales) are also unable to distinguish between neural and biomechanical factors.23,24 Third, there are also concerns about the validity, accuracy, and reliability of such measures.25,26

Upper-limb function was measured using components 6 (upper-limb function), 7 (hand movements), and 8 (advanced hand activities) of the Motor Assessment Scale25,27 (MAS). Psychometric properties of this scale have been investigated, and good reliability and validity have been established.26-28 As required in the standardised procedure, 3 consecutive measurements were taken on each occasion, and the best performance was used in analysis. Each scale component was rated on a 0- to 6-point scale of increasing ability. Summed scores were then used to provide an indicator of overall upper-limb function.

Upper-limb pain was measured with a visual analog scale (VAS), which is a sensitive, reliable, valid, and reliable method of collecting subjective pain intensity. This was recorded before measuring the wrist and finger flexor muscle length.

In addition to these clinical outcome measures, compliance with the splint-wearing schedule was recorded. Splint-wearing duration was logged daily on time-on/time-off recording charts by nursing staff on the hospital ward and was monitored by an investigator (NAL).

**Data Analysis**

Changes in the length of wrist and finger flexor muscles, upper-limb function scores, and pain scores in control and experimental groups were compared by using 2-tailed independent sample t-tests. We also performed a secondary analysis of the differences between the 2 groups on the upper-limb function scores using nonparametric Mann-Whitney test. Significance levels were pre-established at the P<.05 level. The size of the treatment effect was estimated by differences in group means and their 95% confidence intervals (CIs). Where possible, outcome measures were obtained for all subjects who participated in the trial. Each subject's data were analyzed in the group to which the subject was allocated, in accordance with the principle of intention to treat.4,24

**RESULTS**

Subjects in the 2 groups, on average, had similar characteristics at the time of recruitment to the study (table 1). Of the 28 subjects randomized, 25 (44 from the experimental group, 11 from the control group) participated in all interventions and assessments as allocated (fig 2). Outcome measures were obtained from 26 subjects after intervention and from 27 subjects at follow-up. One subject in the experimental group withdrew from the study during the intervention period as a result of self-discharge from the rehabilitation unit. Two additional subjects in the splint group refused postintervention measurement but participated in follow-up measurements (1 subject continued to receive interventions as allocated). One subject in the control group reported a pain rating of 0 at baseline and of 0 at postintervention and increased her rating by 100% (maximum score, 10) at the follow-up measure 1 week later. The follow-up value for pain differed so greatly that it was omitted from all analyses. The effects of splinting (the difference between the experimental and control groups) were not clinically important or statistically significant.

**Effect of Splinting on Contractures**

Splinting increased wrist extension by a mean of 1° after the intervention (95% CI, 3.7° to 6.1°), and it reduced wrist extension by a mean of 2° at follow-up (95% CI, −7.2° to 3.2°).

**Effect of Splinting on Function**

Splinting decreased upper-limb function (MAS component 6) by a mean of 0.3 points after the intervention (95% CI, −1.5 to 0.9) and decreased upper-limb function by 0.8 points at follow-up (95% CI, −2.0 to 0.3). Splinting decreased performance of hand movements (MAS component 7) by 0.4 points after the intervention (95% CI, −1.4 to 0.6) and by 0.5 points at follow-up (95% CI, −1.5 to 0.6). Splinting decreased the performance of advanced hand activities (MAS component 8) by 0 points after the intervention (95% CI, −0.5 to 0.4) and by 0.1 point at follow-up (95% CI, −0.8 to 0.5). Splinting decreased overall upper-limb function, measured by the summed scores of MAS, by 0.1 points after the inter-

<table>
<thead>
<tr>
<th>Table 1: Characteristics of Subjects in the Control and Experimental Groups at Study Commencement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>Gender (males/females)</td>
</tr>
<tr>
<td>Mean age ± SD (y)</td>
</tr>
<tr>
<td>Mean days postinjury ± SD</td>
</tr>
<tr>
<td>Dominant upper limb (left/right)</td>
</tr>
<tr>
<td>Affected upper limb (left/right)</td>
</tr>
<tr>
<td>Location of lesion</td>
</tr>
<tr>
<td>Forearm proximal area</td>
</tr>
<tr>
<td>Forearm midproximal area</td>
</tr>
<tr>
<td>Parastial lobe</td>
</tr>
<tr>
<td>Palmarocciptal area</td>
</tr>
<tr>
<td>Temporal lobe</td>
</tr>
<tr>
<td>Temporoparastial area</td>
</tr>
<tr>
<td>Internal capsule</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td>Mean extension range ± SD (deg)</td>
</tr>
<tr>
<td>MAS* ± SD</td>
</tr>
<tr>
<td>Mean pain intensity ± SD</td>
</tr>
</tbody>
</table>

NOTE: There were no significant differences between groups for any baseline variables.
* Cumulative score (maximum, 18).
+ Centimeters on a 10-cm VAS.
Appendix A

**DISCUSSION**

The major finding of this RCT was that subjects with acquired brain impairment who were participating in routine motor training and upper-limb stretches did not show detectable or important changes in wrist and finger flexor extensibility after wearing a splint daily for 4 weeks. Contrary to expectations, subjects in the control group did not lose wrist and finger flexor extensibility (i.e., acquire a contracture) in this 4-week period if they did not wear a hand splint. The literature recommends that splints be worn for 2 to 6 hours a day in this population.¹⁸ Splints were worn for up to 12 hours a day in this study (daily mean ± SD, 11 ± 5.9 h, range, 0–12 h). Despite this intensive regimen of splinting, no significant differences between the control and experimental groups were detected.

Findings related to secondary study outcomes also indicated no effect. First, there was no evidence of clinically significant effects of splinting on upper-limb function, as measured by individual component or summed MAS scores. Second, the 4-week splint-wearing program did not significantly reduce upper-limb pain levels. It is acknowledged that the pain scores were low at baseline, which may have made reduction in pain difficult to detect. These 2 findings do suggest, however, that the practice of splinting to improve function¹⁰,¹¹,¹³,¹⁴,¹⁵ and to reduce pain levels¹⁰,¹²,¹³ after acquired brain impairment should be questioned if patients are already receiving motor training and upper-limb stretches as part of their rehabilitation.

The absence of an effect after splint wearing on wrist and finger flexor extensibility may have been because the routine motor training and upper-limb stretches were already maintaining the length of the wrist and finger flexor muscles. These therapies may have rendered the additional stretch (the stretch provided by the hand splints) redundant. There is, however, no clear evidence that prolonged stretches prevent or reverse contracture of the wrist and finger flexor muscles after acquired brain impairment. Although a number of animal studies have found that short periods of daily stretching can prevent the development of muscle contracture,⁴⁶–⁴⁸ clinical studies on human muscles have yet to show the same benefits. Further research is needed to determine whether prolonged stretching

---

**Table 2: Experimental Group Participation in Splint Wearing**

<table>
<thead>
<tr>
<th>Wear Time (Target Duration)</th>
<th>Mean Participation (h)</th>
<th>Mean ± SD</th>
<th>Median (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nightly (12h)</td>
<td>11±3</td>
<td>12 (9.5)</td>
<td></td>
</tr>
<tr>
<td>Weekly (15h)</td>
<td>74±14</td>
<td>81 (44–85)</td>
<td></td>
</tr>
<tr>
<td>Total (236h)</td>
<td>260±7.9</td>
<td>268 (44–336)</td>
<td></td>
</tr>
</tbody>
</table>

Arch Phys Med Rehabil Vol 86, February 2003
at maximal wrist extension prevents or reduces contrac- ture at the wrist in adults after acquired brain impairment.

There was a considerable range in time since impairment in the subjects recruited for this study, particularly in the control group. Nonetheless, the admission criteria ensured that all subjects were of similar upper-limb motor ability, with none having active wrist extension. The finding that splinting was not effective for increasing ROM when provided in addition to routine therapy specifically relates to the study population—patients with acquired brain injury without active wrist extension. This result does not suggest patient subgroups that may benefit from splinting. In addition to analyses of change scores, a priori covariate analysis of future studies may provide guidance relating to the effect of subject age and lesion type.

The results of this study suggest that splinting in the functional resting position does not produce clinically useful effects in adults with acquired brain impairment. However, it could be that hand splinting in other positions that administer greater torque at the wrist may be beneficial. Further research studies should continue to use simple, accurate, and reliable assessment measures of torque-controlled ROM, motor function, and pain. Finally, the importance of replication of research findings is acknowledged, given the statistically non-significant results.

CONCLUSION

This RCT showed that 4 weeks of hand splinting in the functional resting position does not improve contracture, hand function, or pain in adults with acquired brain impairment who are already participating in routine motor training and upper-limb stretch exercises.

Acknowledgments: Appreciation is extended to the therapists and nursing staff at the Townsville Hospital Rehabilitation Unit, Queensland, for their cooperation and assistance with this study.

References


Supplier

a. URIAS® Pressure Splint; Smed Andersson Plastic Industri, Maersk Medical A/S, Engroven I, 3540 Lyngby, Denmark.
Reliability, validity and factor structure of the upper limb subscale of the Motor Assessment Scale (UL-MAS) in adults following stroke

NATASHA A. LANNIN*

School of Exercise Health Sciences, University of Western Sydney, Australia

Abstract

Purpose: The upper limb items of the Motor Assessment Scale (MAS) have been shown to be a sensitive, valid and reliable measure of upper limb function for adults following stroke; however, the validity and reliability of summing these items into an independent subscale has not yet been evaluated. The stability, internal consistency and construct validity of the upper limb MAS subscale (UL-MAS) was assessed in this study.

Method: Twenty-seven inpatients following stroke (mean age = 67 years, range = 40–80) were sampled from an acute, inpatient rehabilitation setting. Patients were evaluated with 'Upper Arm Function', 'Hand Movements', and 'Advanced Hand Activities' items of the MAS by masked physiotherapists who had received standardized training in administration of the MAS.

Results: All items were explained by one factor on confirmatory factor analysis and correlated significantly with one another and with the composite (summed total) score. Internal consistency analysis produced a Cronbach's alpha of 0.83 which did not benefit from removal of any items.

Conclusions: The acceptable internal consistency score obtained verifies the validity and reliability of using the UL-MAS as an independent scale. This study has also verified the construct validity of the UL-MAS subscale and provides a valuable extension of previous work, which together demonstrate the value of the UL-MAS as a responsive, valid and reliable measure of upper limb function in adults following stroke. The UL-MAS produced a single, composite score that could be interpreted as a total score for upper limb function in this population.

Introduction

Cerebral Vascular Accidents, including hemorrhagic and ischemic stroke, are a leading cause of significant disability within the Western World.1–7 Loss of upper limb movement is a common and undesirable consequence of stroke6 which limits performance of daily activities and consequently increases disability. Recent research has demonstrated that the upper limb paresis following stroke contributes significantly to the prognoses of patients.8 Furthermore, stroke patients identify that functional task performance is of greatest importance to their upper limb rehabilitation following stroke.9 The development of accurate methods to assess upper limb functional ability in order to plan and provide appropriate rehabilitation is, therefore, an important area for therapists.7

For decades, physicians, therapists and researchers have struggled to determine the most appropriate methods to assess the ability of stroke patients to use their upper limbs within functional tasks. These efforts have led to the development of a wide variety of assessment tools.10–21 Such assessments include Assessment of Motor and Process Skills (AMPS),11 Frenchay Arm Test,12 National Institute of Health Stroke Scale,13 Rivermead Motor Assessment,14 and Fugl-Meyer Assessment Scale (FMA).15 Although each tool may have strengths relative to their intended use, overall, each of these assessments has been criticized for not adequately addressing the current need for efficient functional assessment tools that are applicable to individuals following stroke who display a wide range of abilities as a direct result of differing levels of stroke severity.22 Indeed, Owton and Cull22 identified that each of these assessments lacks sensitivity at the upper and lower ends of skill, limiting their usefulness as both clinical and research tools. Another assessment commonly used is the Action Research Arm Test

* Author for correspondence; School of Exercise Health Sciences, University of Western Sydney (Building 26) Campbelltown Campus, Locked Bag 1977, Penrith South DC, NSW 1797, Australia e-mail LANNIN@bigpond.com
Appendix A

N. A. Laurin

(ARA).\(^\text{14}\) The ARA, along with the Frenchay Arm Test, Arm Function Test, Rivermead Motor Assessment, and FMA have been further criticized for using simulations of tasks and as such are not true functional assessments.\(^\text{14}\) A true functional assessment of the upper limb is one which records the patient's capacity to perform real life activities using their upper limb,\(^\text{15, 16}\) and that are relevant to the client.\(^\text{17}\)

Within research settings, rehabilitation therapists administer a number of these 'pseudo-functional' assessments to the study population to ensure sensitivity to varying levels of ability, and thus overcoming one of the main criticisms of these assessments (for example, in a study evaluating the effectiveness of forced use, both the FMA and the Rivermead Motor Assessment were used together to evaluate upper limb 'Functional use').\(^\text{18}\) In fact, a recent review of outcome measures in rehabilitation research found that the typical paper uses three outcome measures (although this range extended up to 14).\(^\text{18}\) This practice poses a threat to statistical conclusion validity and predisposes a study to error rate problems.\(^\text{19}\) A further problem associated with the use of multiple assessments is the time required to administer within the clinical setting which may subsequently reduce the clinical utility of a study's findings. In Australian clinics and some recent research papers,\(^\text{16}\) one solution to the problems associated with currently available assessment tools, has been to use relevant test items of the Motor Assessment Scale\(^\text{20}\) to provide data relating to functional upper limb use.

**THE MOTOR ASSESSMENT SCALE**

The Motor Assessment Scale (MAS) is an assessment tool designed to measure the functional movement of adult patients following upper motor neuron dysfunction.\(^\text{20}\) The MAS was developed in an effort to provide a measure of motor function that has validity, reliability, and is responsive for individuals with a broad spectrum of abilities, such as those adults frequently encountered within stroke rehabilitation. It has been shown to be the only upper limb assessment recommended by the Post-Stroke Rehabilitation Clinical Practice Guidelines which contains true functional test items, that is, to use real functional activities as opposed to simulated tasks.\(^\text{1}\)

The MAS consists of nine items, of which three relate to upper limb movements (Item 5: Upper Arm Function, Item 7: Hand Movements, and Item 8: Advanced Hand Activities). Each upper limb item contains six tasks, with hierarchical scoring for each item ranging from 0 (unable to perform task 1) to 6 (optimal performance as patient can perform all six tasks). These upper limb items, the UL-MAS subscale, incorporate common, everyday movements associated with the performance of basic activities of daily living and instrumental activities of daily living, such as shoulder protraction, external rotation, forward flexion, elbow flexion and extension, forearm supination, and wrist extension and radial deviation.\(^\text{20}\) In addition to demonstrating ability to perform such upper limb movements, actual functional performance of common upper limb tasks is also evaluated,\(^\text{20}\) such as grasping of a cup, fine motor pinch grasp of a small bean, picking up and using a pen, cutting a slice of bread, and combing one's hair. Inspection of such items assures face validity of the UL-MAS subscale: these items appear to have been designed to measure what it is supposed to measure, and, for our purposes, that is functional movement of the upper limb. Since the UL-MAS incorporates active movement, speed of performance and functional ability components, it is able to provide a thorough assessment of the hemiplegic upper limb following stroke.\(^\text{20}\)

The UL-MAS subscale takes only 5-15 min to administer (dependent on the skills of the patient). In line with published MAS scoring guidelines each task is attempted three times, with the best performance recorded for scoring. A full description of test items and scoring criteria for the upper limb components of the MAS is published elsewhere by the scale's authors.\(^\text{20}\)

**RESPONSIVITIES**

Previous testing of the MAS has demonstrated that the scale is sensitive to measuring change in motor function post-stroke\(^\text{21}\) and that has been confirmed by its use as an outcome measure for research purposes\(^\text{22, 23}\) and its recommendation of use for clinical purposes.\(^\text{24}\) Publications also confirm the ability of the UL-MAS subscale items to discriminate between varying abilities of stroke patients,\(^\text{13, 14}\) demonstrating the ability of the UL-MAS subscale to provide clinical outcome data for a range of ability levels,\(^\text{13, 14}\) and its ability to discriminate between patients for research purposes.\(^\text{17}\)

Whilst the individual items have been shown to be responsive to change in upper limb function of adults following stroke,\(^\text{22}\) no probability testing of the UL-MAS as a subscale has been conducted. Before any such sensitivity and specificity testing can occur, it is important to determine the validity of using MAS items that correspond to upper limb function as a separate subscale (the UL-MAS), and whether a composite score of such a scale is reliable. Whilst this is not yet known,
UL subscale of the MAS in adults after stroke

Previous research on the MAS does provide useful information regarding the UL-MAS.

**VALIDITY**

**Content validity**

Content validity of the UL-MAS is supported by the fact that items for the composite score were based on an extensive literature review of issues relating to motor function for stroke patients and on the reports and clinical experience of expert physiotherapists.

**Predictive validity**

Both the individual items from the UL-MAS and the composite score have been shown to be a good predictor of stroke outcome. The UL-MAS composite score was shown to be a good predictor of stroke outcome (arm function) at 1 week ($r = 0.86$) and 1 month ($r = 0.94$) (this study used the Spearman correlation coefficient calculated using results of performance on the UL-MAS from 50 adults following stroke). In fact, the outcome measure that Loewen and Anderson found to demonstrate the greatest predictive validity across a number of measures and items was the composite (summed) score from the UL-MAS ($r^2 = 0.95$) which was able to accurately predict discharge arm function at 1 month.

**Concurrent validity**

Two studies have examined the concurrent validity of the UL-MAS subscale using the upper limb section of the Fugl-Meyer Assessment (FMA) as the criterion test. The FMA is a commonly used assessment of upper limb movement for stroke patients with recognized validity and reliability. Both studies computed the correlations between the individual items of the UL-MAS subscale and the corresponding items of the FMA (using spearman’s rho), and found that they ranged from 0.89 to 0.92 with a median correlation of 0.90. The correlation (spearman’s rho) between the composite score of the UL-MAS subscale and the FMA (upper limb items) was 0.91 ($p < 0.001$) in chronic stroke patients and 0.93 ($p < 0.001$) in acute stroke patients.

**Construct validity**

Previous testing of the UL-MAS indicates that the subscale adequately measures the underlying construct of upper limb motor function. Convergent validity of the UL-MAS was supported by the strong correlations between the composite (summed total) score of the UL-MAS and the FMA, and between individual items of each sub-scale. This construct validity demonstrates that the UL-MAS is concurrently valid with the FMA (previously shown to be a valid assessment). Further evidence of construct validity was investigated in the current study using the factor analysis to determine whether or not all items cluster around the construct of functional upper limb movement.

**RELIABILITY**

**Test-retest reliability**

Test-retest reliability of the MAS was first established using a group of 14 stroke patients rated by one experienced physiotherapist (1 month apart). This testing yielded correlation coefficients (Pearson’s product-moment) for all items ranging from 0.87 to 1.00 with an average correlation of 0.98 (unfortunately which of these correlation scores relates to upper limb items 6,7,8 is not identified). The items of the MAS were then further tested by Loewen and Anderson who tested test-retest reliability using videotaped performances of seven stroke patients (videos re-evaluated after 1 month). Items included in the UL-MAS subscale yielded a mean Kendall’s rank order correlation coefficient of 0.94, 1.0 and 1.0 for items 6, 7, and 8 respectively.

**Inter-rater reliability**

Previous testing of the MAS using five stroke patients and 20 physical therapists and students indicated inter-rater reliability (intraclass correlation coefficient (ICC)) of 0.95. In a subsequent study, two therapists assessed 24 chronic stroke patients and yielded an interrater reliability coefficient (Spearman’s Rho) of 0.99 for the total MAS, and 1.00 ($p < 0.001$) for each upper limb item. This high interrater reliability result was replicated in another study, which tested interrater reliability using the Kappa coefficient (seven cases rated by 14 physical therapists) and report high agreement between raters for each upper limb item ranging from 0.93 (item 6) to 1.0 items 7 and 8.

While the temporal stability reliability of the UL-MAS items has been demonstrated in previous research, the internal consistency of a composite (summed total) score of the three upper limb items has not. Although the upper limb component of the MAS contains three test items, use of a single, composite score
is preferred. In traditional test theory, the summed score has been the principal statistic used for scoring or as an estimate of proficiency \(^\text{46}\) and is more useful than individual item scores to both clinicians and researchers. \(^\text{46}\) Initially, the MAS instrument was designed to produce a summed total score, and since the upper limb items produce rank-ordinal data, it is proposed that calculating a summed total score for the UL-MAS subscale would be reasonable. The production of a summed score for the UL-MAS would have greater clinical utility, allowing a single score to indicate upper limb functional movement. Use of a single score to represent upper limb function (rather than three separate item scores) would address the concern of researchers about multiple testing of \(p\)-values and their effect upon power and sample size. \(^\text{46-48}\) A single score from the UL-MAS in analyses would overcome the current issue of using multiple endpoints, addressing the use of a number of outcome measures to measure a single construct \(^\text{48}\), as well as the use of three separate items of the UL-MAS individually in analyses.

The authors of the MAS created it to assess functional motor skills across the whole person, using three items to evaluate upper limb function. But for the purposes of future research and clinical utility, it needs to be determined if it is valid and reliable for the scores on the upper limb items of the MAS to be summed to form one total score, a composite score for the UL-MAS. Following this ascertainment, it would then be appropriate to undertake further testing of the sensitivity and specificity of the UL-MAS scale.

The purpose of this study, therefore, was to evaluate the internal consistency of a composite score for the UL-MAS subscale to determine the reliability of using the UL-MAS subscale as an independent assessment scale. The second purpose of this study was to extend existing work that has investigated the validity of the UL-MAS subscale items. Such information is important if UL-MAS is to be used for both clinical and research purposes, especially as the UL-MAS subscale has already been shown to be one of only two true functional assessments of the upper limb \(^\text{28}\) and that it takes less time to administer than other assessments commonly used for this purpose. \(^\text{28}\)

**Method**

**SUBJECTS**

Twenty-seven participants from an acute hemiplegic population at a rehabilitation centre in Australia took part in this study. All participants had a history of a single stroke resulting in upper limb hemiplegia of no greater than 6 months duration and were aged between 40 and 80 years (mean = 67). Of the 27 subjects, 12 were male and 15 were female. There were 13 right hemiplegic subjects and 14 left. The length of time since impairment ranged from 2 weeks to 27 weeks (average of 7 weeks).

Demographic details of participants are outlined in Table 1. Ethical approval and informed consent was obtained prior to testing.

**DESIGN**

All subjects were evaluated with the upper limb items (6, 7, and 8) of the Motor Assessment Scale. UL-MAS scores obtained during a randomized controlled trial of hand splinting and stretching were used for this study (results of the trial are published elsewhere). \(^\text{16}\) Inclusion criteria for the larger trial were that all participants were to have no active movement of their wrist at time of recruitment; upper arm function and function of the hand at the completion of the study varied across participants.

Three experienced physiotherapists who had undertaken training in administration of the MAS were used as the assessors in this study. All assessors conformed to a standardized inter-rater reliability evaluation prior to involvement [assessment of each physiotherapists’ rating to conform to standard rating of test-cases was]

<table>
<thead>
<tr>
<th>Table 1 Subject demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
</tr>
<tr>
<td>Gender Male: Female</td>
</tr>
<tr>
<td>Age Mean (SD)</td>
</tr>
<tr>
<td>Days post-impairment</td>
</tr>
<tr>
<td>Dominant upper limb</td>
</tr>
<tr>
<td>Affected upper limb</td>
</tr>
<tr>
<td>Lesion location</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Passive wrist extension (range in degrees)</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
conducted through University of Sydney, School of Physiotherapy, Sydney, Australia]. This ensured interrater reliability across assessors. All assessors were masked to treatment group allocation for the administration of the UL-MAS.

**ANALYSIS**

A total of 27 UL-MAS scores were used in the analysis. UL-MAS scores were considered scale level data. There was no missing data in analyses. The level of statistical significance was pre-determined at 0.05.

Whilst previous testing of the individual upper limb items of the MAS has been shown to have face and concurrent validity, for the UL-MAS items to be used as a stand-alone scale it is important to test the interrelationships among each item. Therefore, the validity of the UL-MAS subscale was further examined by estimating the construct validity using factor analysis. In this case, factor analysis (unrotated) was used to test the assumption that whilst each item contributes to the composite score, only one factor is present (since all items measure the single construct of upper limb function). Principle components method of extraction was used to reduce the UL-MAS scale to the minimum number of variables required.

Reliability comes to the forefront when variables developed from summated scales are used as independent components to test the outcomes of therapy, such as has been the practice with the UL-MAS items. Since the UL-MAS is an assembly of interrelated items designed to measure the underlying construct of upper limb function, it is important to know whether all three scale items are measuring the same construct (upper limb function) consistently. Reliability of the UL-MAS was determined by estimating the construct validity and unidimensionality of the three items of the UL-MAS using Cronbach’s alpha coefficient. Cronbach’s alpha measures how well a set of items measures a single unidimensional latent construct. When data have a multidimensional structure, Cronbach’s alpha will usually be low; for the purposes of this study alpha > 0.6 was considered as evidence of an acceptable internal consistency for the composite (total) score. Unidimensionality of the data was tested using correlations (Spearman’s rho) between items and the composite (summed total) score. Previous studies suggest an expectation for positive correlation between scores, and so one-tailed tests were used.

**Results**

**Validity:** Factor analysis undertaken within this study revealed only one dimension underlying the UL-MAS, explaining 81% of the total variance (extraction method: principle component analysis). This produced a single, composite score that could be interpreted as a total score for upper limb function.

**Reliability:** The internal consistency for the three items of the UL-MAS subscale provided an acceptable Cronbach’s Alpha of 0.83. Alpha coefficients were calculated for the UL-MAS subscale following removal of items: only removal of item 8 resulted in a higher alpha (0.94); however this improvement was not statistically significant (p = 0.388). Correlations between the summed (total) score and individual item scores UL-MAS confirmed that all correlations were positive and statistically significant at 0.01 level or higher (one-tailed) (table 2). These high inter-item correlations and the acceptable alpha coefficient for UL-MAS provides evidence that the items are measuring the same underlying construct, thus that the UL-MAS subscale is a reliable measure of upper limb function. These results confirm the use of a single, composite score instead of reporting the three subscale item scores separately.

**Discussion**

The results of this study estimated the construct validity and internal consistency reliability of the UL-MAS subscale and provide further support for its use as an instrument to measure upper limb motor function in stroke patients.

With previous studies confirming the face validity, predictive validity, construct validity, and interrater and test-retest reliability of the items included in the UL-MAS subscale, this study provides important data to demonstrate the acceptability of using the three upper limb items of the original MAS as an independent subscale. The composite score of the single scale provided an acceptable overall alpha of 0.83. Since this result indicates that the data is unidimensional, all three

<table>
<thead>
<tr>
<th>Item 6</th>
<th>Item 7</th>
<th>Item 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spearman’s rho</td>
<td>Item 7 Correlation coefficient</td>
<td>0.767*</td>
</tr>
<tr>
<td></td>
<td>Item 6 Correlation coefficient</td>
<td>0.461*</td>
</tr>
<tr>
<td></td>
<td>Item 8 Correlation coefficient</td>
<td>0.576*</td>
</tr>
<tr>
<td></td>
<td>Summed score correlation coefficient</td>
<td>0.095*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.793*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.482*</td>
</tr>
</tbody>
</table>

*Correlations were all significant at the .01 level (1-tailed).
items can statistically be combined to create one single scale, thus verifying the use of a single, composite score from the UL-MAS subscale as an indicator of upper limb functional ability.

This study was completed through the analysis of baseline data from a trial published elsewhere. The inclusion criteria for the prospective trial therefore impacted on the data used in this study: it is acknowledged that the UL-MAS scores used in this study did not represent the range of possible scores which may impact on the external validity of the findings and is likely to be the reason why item 8 did not contribute as much to the composite score as items 6 or 7 (functionally easier task items). Therefore further investigation of the UL-MAS may be warranted for stroke patients who possess greater functional hand use following admission. A further methodological limitation may have been sample size (n = 27), however since factor analysis showed the presence of only one factor for the UL-MAS, literature would support that the sample size (n = 27) was adequate to demonstrate the reliability and validity of using a composite score for the UL-MAS. It should also be noted that when using summed scores, omitted responses/test items may affect interpretation of results.

Literature shows that in contrast to more commonly used upper limb assessments (such as the ARA), the UL-MAS subscale contains true functional test items and as a result the UL-MAS possesses greater face validity than these other assessments. This, in addition to the predictive, convergent and concurrent validity discussed, suggests that the UL-MAS subscale may provide a more valid and reliable representation of upper limb function. It should be noted that the concurrent validity of the upper limb subscale of the MAS has only been validated in previous studies using the FMA and further testing of its validity against other assessments of upper limb motor function is therefore recommended. Since results indicate that the use of a single, composite score from the UL-MAS does represent upper limb function for adults following stroke, it is recommended that further studies also investigate the sensitivity and specificity of the UL-MAS.

The results of this study, when taken with previous testing, shows that the upper limb motor recovery of patients with stroke can be assessed quantitatively using the UL-MAS. The subscale has already shown to provide an objective measure of patient's progress and to be able to study the effects of a treatment programme, and the present study has provided justification for using the UL-MAS subscale as an independent scale for evaluating the upper limb function of adult stroke patients. Further, results of the internal consistency evaluation demonstrated that items all measure the same phenomenon, and thus that it is reliable to use the composite score (summed total of these items) from the UL-MAS as a unidimensional index of upper limb function. Construct validity results provide further evidence to support the validity of the UL-MAS as a single, independent scale to measure the construct of functional motor skill in stroke patients.

Acknowledgements

I would like to thank Sally Horsley for management of all clinical assessments, Dr Beatrice Webber for advice on statistical analyses, and Dr Anne van Dijk for study and manuscript advice.

References


Appendix A

UL subscale of the MAS in adults after stroke


Factors Affecting Patient Recruitment in an Acute Rehabilitation Randomized Controlled Trial

Natasha Lannin, Anne Cusick

OBJECTIVE. To evaluate factors associated with randomized controlled trial patient recruitment by therapists.

METHOD. Survey of 18 (of a possible 25) therapists who had agreed to recruit patients for a randomized controlled trial (76% response rate).

RESULTS. Sixteen respondents had enrolled at least one patient. The site at which the therapist worked neither influenced the likelihood that a therapist would contact the researcher nor influenced the recruitment rate. Seventeen respondents reported that they contacted the researcher to discuss one or more of their patients for potential inclusion in the trial. Factors reported by therapists as reasons why they did not recommend the trial to eligible patients were not specific to study inclusion or exclusion criteria, rather were linked to personal judgments about patient suitability for the study. Regression analysis indicated that being enrolled in or having completed master's level postgraduate studies, and choosing not to refer patients because of concerns for their poor medical prognosis were the only factors that significantly influenced recruitment rate (p < 0.001).

CONCLUSION. Recruitment practices vary amongst therapists. Selection of therapists with postgraduate qualifications as recruiters may be an effective way to enhance recruitment rate.


Introduction

There is an urgent need to carry out randomized controlled trials to provide evidence of occupational therapy intervention effectiveness. The success of trials depends on the ability to recruit patients to become research subjects. Most existing surveys of recruitment issues and strategies provide guidance for drug or surgical trials (Visanji & Oldham, 2001). This study investigated factors associated with patient recruitment by occupational therapists for a randomized controlled trial conducted in multisite acute rehabilitation settings. To date there have been few randomized controlled trials in such settings and no studies investigating patient recruitment by occupational therapists. There are no studies dedicated to investigating recruitment rates or factors in other therapy fields (such as physical therapy). Most recruitment studies have instead been conducted in medicine, primarily cancer and primary care trials (Ach, Connor, Hamilton, & Fox, 2000; Benson et al., 1991; de Wit, Queroz, Zuirhoff & Numans, 2001; Petro, Coudner, & Bond, 1993; Taylor, Margolese, & Sokolne, 1984).

The trial linked to the present study investigated the effect of adding contract management hand splinting to rehabilitation following stroke (Lannin, Cusick, Herbert, & McCluskey, in progress). It followed an earlier trial investigating hand splinting only (Lannin, Howley, Herbert, McCluskey, & Cusick, 2003). Eligible patients were from six consenting acute rehabilitation hospitals. Evidence-based strategies were used to enhance referral by therapists at participating sites (Cavaliere, 2003; Visanji & Oldham, 2001). Information presentations, regular face-to-face, telephone and e-mail contacts, study and recruitment reminders, newsletters, and information about recruitment progress were used. In addition to these study-linked strategies, therapists were eligible to register their study participation for continuing
professional development credits, and they had access to free continuing education sessions. It was intended that 63 patients would be recruited over 18 months (this target was based on previous randomized control trial recruitment patterns in a similar setting [Lannin et al., 2003]). Although 25 therapists across six sites had agreed to recruit patients, after 18 months only 50 had been enrolled.

Recruitment of patients for hospital-based research can be difficult (Benson et al., 1991). Barriers to trial recruitment that have been identified in physician studies include: attitudes such as accepting the uncertainty involved in many treatment decisions, which make professionals uncomfortable about referring patients to trials where usual treatments are not performed (Benson et al.; Taylor et al., 1984); concern about informed consent (Taylor et al.); possible effects of the trial on patient prognosis with physicians more likely to refer those patients with a poor prognosis for trial participation (Benson et al.); and forgetfulness by recruiting personnel (Bell-Sayer & Klabor Moffett, 2000; de Wit et al., 2001; Petro et al., 1993). There are also investigator-related barriers to recruitment, such as lack of time, heavy caseloads, or time spent in other research activities (Asch et al., 2000; Petro et al.). Design and resource issues such as the availability of dedicated and experienced recruiters have also been suggested to affect trial recruitment (Lovato, Hill, Hertott, Hunninghake, & Proberfield, 1997).

Aim
To identify factors associated with occupational therapist patient recruitment rates for a multisite randomized controlled trial conducted in an acute rehabilitation setting.

Method
Participants
Twenty-six occupational therapists who participated in the trial were targeted.

Instrument
An author-designed survey was used. Questions were initially developed on the basis of recruitment studies literature (Asch et al., 2000; Benson et al., 1991; de Wit et al., 2001; Petro et al., 1993; Taylor et al., 1984), refined following feedback by occupational therapy researchers involved in the conduct of randomized controlled trials. The 20-item questionnaire used a combination of multiple-choice and open-ended questions. There were four sections seeking (a) demographic information (e.g., for example their qualifications) (7 items); (b) information about their recruitment behavior (e.g., whether all, some, or none of eligible patients were entered) (5 items); (c) their views on the scientific design of the trial, including their own beliefs about the effectiveness of interventions under study (e.g., whether or not they believed splints were essential) (5 items); and finally (d) their views about obstacles to recruitment inherent in randomized controlled trials (Benson et al., 1991) (e.g., whether there were problems telling patients that they would be randomly assigned to groups, or problems explaining that as therapists they did not know which treatment was best) (2 items).

Procedure
The survey was mailed to the 26 occupational therapists. Because of the known low response rates of mailed surveys (Blumberg, Fuller, & Hare, 1974; Krysan, Schuman, Scott, & Beatty, 1994; Shostek & Fairweather, 1979) and the need for a good response rate (Asch, Jedrziewski, & Christakis, 1997), a research assistant followed up written reminders with another copy of the instrument and telephone reminders in which participants could choose to respond to the questionnaire with data de-identified via telephone. These techniques have been shown elsewhere to improve response rates among health professionals (Asch et al.).

Data Analysis
Because of the sample size and descriptive intent of the survey, raw frequencies and percentages were used. Linear regression was used to examine hypotheses of independence between recruitment rate and factors that may have had an influence on it. Associations between recruitment in the trial and the responses to the questionnaire were examined. The results of the ordinary least-squares (OLS) regression analysis of recruitment rate are presented in Table 6 (decision factors where responses greater than .8 = .2 were entered into the model). Regression coefficients and their associated standard errors are reported. In addition, the relevant probabilities for testing the hypothesis that the regression coefficient is statistically significantly different from zero (no effect) are also reported. The levels of statistical significance used in analysis was p < .05.

Results
Participants
Eighteen surveys were completed giving a response rate of 78% (16 by post and 2 by telephone). Characteristics of respondents are shown in Table 1.

March/April 2006, Volume 60, Number 2
Table 1. Characteristics of Respondents

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5.5 (1)</td>
</tr>
<tr>
<td>Female</td>
<td>94.4 (17)</td>
</tr>
<tr>
<td>Qualification</td>
<td></td>
</tr>
<tr>
<td>Bachelor's degree</td>
<td>83.8 (16)</td>
</tr>
<tr>
<td>Bachelor's degree (with dedicated</td>
<td></td>
</tr>
<tr>
<td>research training known as “honors”)</td>
<td>14.4 (2)</td>
</tr>
<tr>
<td>Master's degree</td>
<td>5.5 (1)</td>
</tr>
<tr>
<td>Enrolled in postgraduate study</td>
<td>16.6 (3)</td>
</tr>
<tr>
<td>Years of practice</td>
<td></td>
</tr>
<tr>
<td>Less than 1</td>
<td>5.5 (1)</td>
</tr>
<tr>
<td>1–&lt;3</td>
<td>16.6 (3)</td>
</tr>
<tr>
<td>3–&lt;5</td>
<td>33.3 (6)</td>
</tr>
<tr>
<td>5–&lt;10</td>
<td>44.4 (9)</td>
</tr>
<tr>
<td>Primary Work Site</td>
<td></td>
</tr>
<tr>
<td>Private (for profit) Hospital</td>
<td>16.6 (3)</td>
</tr>
<tr>
<td>Public Hospital–Rehabilitation Unit</td>
<td>22.2 (4)</td>
</tr>
<tr>
<td>Public Hospital–Stroke Unit</td>
<td>61.1 (11)</td>
</tr>
<tr>
<td>Primary Work Role</td>
<td></td>
</tr>
<tr>
<td>Clinician</td>
<td>83.8 (16)</td>
</tr>
<tr>
<td>Manager</td>
<td>16.6 (3)</td>
</tr>
<tr>
<td>Previous Research Involvement</td>
<td>16.6 (3)</td>
</tr>
</tbody>
</table>

Reruitment Rate

Recruitment was initially categorized into “1 or more patients enrolled” and “no patients enrolled.” Of the 18 occupational therapists who responded, 16 (89%) recruited 1 or more of their patients to the splinting trial, and 2 (11%) recruited no patients. Most respondents (n = 9) had referred between 2 and 5 patients, and only 1 therapist referred more than 10 patients (mean 3.8, mode 4). There was no evidence that site affected referral rate (chi-square = 21.47, p = 0.60).

Recruitment Plan Implementation

All respondents received the same recruitment strategies: information presentations, site visits, e-mail contact, newsletters, access to free continuing education, and use of study involvement for continuing professional development accreditation. Therapists were also invited to contact the researcher to discuss eligible patients at any time. There was variation in the extent to which the researcher was sought out by therapists to discuss eligible patients (Table 2). There was no evidence that site affected the likelihood that therapists would contact the researcher (chi-square = 9.14, p = 0.52), nor that contacting the researcher to discuss eligible patients was correlated to recruitment rate (r = -0.09, p > 0.05).

Recruitment Behavior

No therapist reported actively discouraging patients from taking part in the trial (i.e., no therapist told eligible patients not to participate or told them that the trial might have adverse outcomes). Six factors were reported as reasons why therapists chose not to present the trial to eligible patients (Table 3). None of these reasons were specific to the inclusion or exclusion criteria, and must therefore be considered independent therapist judgments about study suitability. Four therapists identified that they did not recommend the trial to eligible patients.

Reasons for Recruitment Decisions

Over half the respondents declared a preferred treatment and one indicated a concern with the use of a randomized control trial design. Other design issues that were negatively viewed and underpinned decisions by therapists not to recruit included: random assignment, being unable to make an individualized decision about treatment, and patient discussions of treatment uncertainty. All three factors are integral parts of randomized controlled trials (Taylor, 1984). One respondent said, “The main reason I consider not entering patients on the trial is that I have my own thoughts on how I think a patient would best improve.” Table 4 presents the perceived barriers to recruitment.

Table 2. Implementation of Study Recruitment Strategy by Therapists

<table>
<thead>
<tr>
<th>Percentage (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher contacted about</td>
</tr>
<tr>
<td>all eligible patients</td>
</tr>
<tr>
<td>most of the eligible patients</td>
</tr>
<tr>
<td>none of the eligible patients</td>
</tr>
<tr>
<td>Number of eligible patients recruited to the trial</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2–5</td>
</tr>
<tr>
<td>6–10</td>
</tr>
<tr>
<td>&gt;10</td>
</tr>
</tbody>
</table>

Table 3. Recruitment Behaviors

<table>
<thead>
<tr>
<th>Percentage (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of therapists who reported that they had actively discouraged patients from taking part in the trial</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>Reasons trial not recommended to eligible patients*</td>
</tr>
<tr>
<td>Consent that patient unlikely to understand what is likely to be involved</td>
</tr>
<tr>
<td>Patient's or family perceptions of study treatments</td>
</tr>
<tr>
<td>Patient's or family perceptions of use of a control group</td>
</tr>
<tr>
<td>Social/geographical problems with patient</td>
</tr>
<tr>
<td>Clinical work and practice (time constraints)</td>
</tr>
<tr>
<td>Therapist beliefs about the splinting treatments</td>
</tr>
</tbody>
</table>

Note: *Categories were not exclusive.
Table 4. Randomized Controlled Trial Recruitment Barriers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Percentage (No.) (N = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preference for one treatment</td>
<td>55 (10)</td>
</tr>
<tr>
<td>Anticipated compliance of eligible patients</td>
<td>35 (6)</td>
</tr>
<tr>
<td>Rigid eligibility criteria</td>
<td>35 (6)</td>
</tr>
<tr>
<td>Protocol controls concomitants</td>
<td>22 (4)</td>
</tr>
<tr>
<td>Medical condition of eligible patients</td>
<td>22 (4)</td>
</tr>
<tr>
<td>Protocol does not allow individualized therapy</td>
<td>17 (3)</td>
</tr>
<tr>
<td>Acceptance of treatment uncertainty</td>
<td>5 (1)</td>
</tr>
<tr>
<td>Age of eligible patients</td>
<td>5 (1)</td>
</tr>
<tr>
<td>Concern about scientific design</td>
<td>5 (1)</td>
</tr>
<tr>
<td>Randomization</td>
<td>5 (1)</td>
</tr>
</tbody>
</table>

Suggestions for Enhanced Recruitment

A few suggestions for enhanced recruitment were made (Table 5). All suggestions were already employed within the trial, although citing them may indicate that more frequent reminders about the study may have improved recruitment rate. One respondent provides insight into this when in response to the question, Do you have any suggestions about how recruitment to the trial or our management style could be improved? She wrote, "No. Reminder e-mails, signs, regular contact from researchers was great, problem is with us clinicians."

Recruitment Rate and Association With Demographic and Decision-Making Factors

The OLS results indicate that having completed a master's level postgraduate degree (or being enrolled in a master's program) and choosing not to refer patients because of concern for their medical prognosis were the only independent variables in the model that exceed the conventional benchmarks for statistical significance. All other demographic factors and decision factors identified in the survey fall considerably short of that benchmark. The overall goodness of fit for the model is high ($R^2 = .822$); however, caution in interpreting the results is warranted because of the small sample size ($N = 18$).

Discussion

The key finding of this study is that therapists who have attained research qualifications (or are getting them) are more effective recruiting patients for a randomized controlled trial than other therapists. This factor is more important than other factors, and has not previously been identified as an attribute related to recruitment success in any field. Judgments about likely patient compliance and being able to satisfactorily obtain informed consent were identified as reasons for recruiting decisions, but they were not related to rates of recruitment. Choosing not to refer patients because of concern for their medical prognosis was the only patient-related factor that was significantly related to recruitment rate. Although the finding that therapists are concerned about informed consent is consistent with results of physician studies (Taylor et al., 1984), excluding eligible patients with poor medical prognosis is not. In fact, Benson and colleagues (1991) found that surgeons were more likely to refer patients who were considered "a hopeless case."

Half the therapists expressed concern regarding the study protocol that controlled potential cointerventions.

Table 5. Subject Recommended Strategies To Improve Recruitment Rate

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Percentage (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of eligibility checklist to screen all new admissions</td>
<td>11.1 (2)</td>
</tr>
<tr>
<td>Telephone reminders</td>
<td>11.1 (2)</td>
</tr>
<tr>
<td>E-mail reminders</td>
<td>5.5 (1)</td>
</tr>
<tr>
<td>Use of senior therapist to assist new therapists to assess potential patients</td>
<td>5.5 (1)</td>
</tr>
</tbody>
</table>

Table 6. Regression Analysis of Recruitment (N = 18)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Regression Coefficient</th>
<th>Standard Error</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic Factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years of practice</td>
<td>0.01</td>
<td>0.301</td>
<td>0.754</td>
</tr>
<tr>
<td>Master's degree (completed or enrolled)</td>
<td>0.006</td>
<td>0.232</td>
<td>0.621</td>
</tr>
<tr>
<td>Honors' degree</td>
<td>-0.145</td>
<td>0.233</td>
<td>0.559</td>
</tr>
<tr>
<td>Previous involvement in research</td>
<td>0.221</td>
<td>0.275</td>
<td>0.464</td>
</tr>
<tr>
<td>Decision Factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient related—Poor medical prognosis</td>
<td>0.791</td>
<td>0.204</td>
<td>0.021*</td>
</tr>
<tr>
<td>Patient related—Capacity for informed consent</td>
<td>0.010</td>
<td>0.285</td>
<td>0.972</td>
</tr>
<tr>
<td>Patient related—Potential patient compliance</td>
<td>0.032</td>
<td>0.224</td>
<td>0.227</td>
</tr>
<tr>
<td>Patient related—Potential family issues</td>
<td>-0.011</td>
<td>0.026</td>
<td>0.509</td>
</tr>
<tr>
<td>Therapist related—Preference for one arm of study</td>
<td>0.027</td>
<td>0.311</td>
<td>0.463</td>
</tr>
<tr>
<td>RCT design—Need to control cointerventions</td>
<td>0.048</td>
<td>0.267</td>
<td>0.867</td>
</tr>
<tr>
<td>RCT design—Unable to make individualized decisions</td>
<td>-0.026</td>
<td>0.216</td>
<td>0.901</td>
</tr>
</tbody>
</table>

*significant at $p = 0.05$

$R^2 = .822$; adjusted $R^2 = .497$

Standard error of the estimate (SEE) = 2.109.
Because all controlled interventions lacked evidence of treatment effect, this finding may suggest difficulty on the part of therapists to accept the uncertainty within usually prescribed interventions and reluctance to admit the lack of evidence for them. This is consistent with previous literature (Benson et al., 1991; Taylor et al., 1984).

Many factors cited in the literature as investigator-related barriers to recruitment were investigated in the survey but were not found. Lack of time, for example, was not a barrier to recruitment (Asch et al., 2000; Peto et al., 1993); heavy caseloads or time spent in other research activities were also not identified as barriers (Asch et al., 2000). The latter may be a reflection of the pragmatic trial protocol used in the study that mimicked clinical practice and did not impose separate trial demands. The pragmatic trial protocol may also explain why three eligible patients were treated according to the protocol but not enrolled. The protocol may have been thoroughly integrated into practice.

Forgottenness by recruiters, although a common factor in literature for poor recruitment (Bell-Sayer & Klaber Moffett, 2000; de Wit et al., 2001; Peto et al., 1993), was found in this study by only one person. It may be that the recruitment support strategies of the trial were successful; only 2 therapists identified the need for more reminders. The lack of dedicated recruiters for this study may have affected the speed of recruitment as this has been suggested as an important aspect of successful recruitment (Lovato et al., 1997). Even though no therapists reported heavy caseloads as a barrier and few admitted forgottenness, day-to-day clinical practice may have preempted recruitment to the trial.

This study provides further suggestions for enhancing the conduct of randomized clinical trials by identifying the potential impact of therapist attributes on recruiting behavior. Reasons for recruitment decisions are also presented. Selection of therapists with research qualifications as recruiters may be an effective way to enhance recruitment rates. ▲

Acknowledgment

Project funding was provided by the School of Exercise and Health Sciences, University of Western Sydney, Sydney, Australia.

References


Appendix B

Study 2 Ethics Approval

Copies of letters from:

- Townsville General Hospital Ethics Committee for Protocol Number: 64/98
  University of Western Sydney Ethics Review Committee (Human Subjects) for Protocol Number: 2000/054.
12 February 1999

Ms N Lannin
Occupational Therapist
TOWNSVILLE GENERAL HOSPITAL

Dear Natasha

Re: 64/98 Does thermoplastic splinting prevent the progression of contracture of the wrist flexor muscles in people following CVA

I refer to your letter dated 7 February 1999 regarding the above protocol. Thank you for providing the information regarding randomising of patients. I have reviewed the documentation and you may now commence the study.

Yours sincerely

[Signature]

Dr Trevor Wood
Secretary
TDHS Institutional Ethics Committee
UNIVERSITY OF WESTERN SYDNEY MACARTHUR RESEARCH OFFICE

ETHICS REVIEW COMMITTEE (HUMAN SUBJECTS)

Phone: 4620 3641
Fax: 4627 2406

Memorandum

TO: Ms Natasha Lannin, Dr Anne Cusick, Ms Annie McCluskey, Dr Robert Herbert Faculty of Health

FROM: Claire Kaspura, Research Office

DATE: 1 September 2000

PROTOCOL NO: 2000/054

PROTOCOL TITLE: The effects of splinting on muscle contracture of the wrist following brain impairment

At its meeting on 24 August 2000, the UWSM Ethics Review Committee (Human Subjects) noted Professor Cusick's correspondence and agreed to approve the application subject to:

1. inclusion of a statement in the participant information letter and consent form as appropriate for gaining the patient's consent to access medical records.
2. clarification of Clause 5 of the consent form relating to freedom to withdraw from the study. Is the taking of final measurements part of the normal treatment process?
3. the committee noted its preference for the use of the word "participant" rather than "subject".

The Committee commended the researchers for their response to Question 18 of the application and their thoughtful approach to the recruitment of participants.

A Certificate of Approval for the commencement of the research will be issued when these concerns have been addressed to the satisfaction of the Committee.

Please do not hesitate to contact me should you wish to discuss this matter further.

Claire Kaspura
Executive Officer
Appendix C

Study 3 Ethics Approval

Copies of letters from:

- University of Western Sydney Ethics Review Committee (Human Subjects) – Protocol Number: 01/166,
- Sydney Adventist Hospital Ethics Committee (letter of approval 12 July 2002),
- St Joseph’s Hospital Quality Care Committee (letter of approval 13 June 2002),
- South Eastern Sydney Area Health Service Human Research Ethics Committee Eastern Section – Protocol Number: 02/152,
- South Western Sydney Area Health Service Research Ethics Committee – Protocol Number: 02/113,
- St Vincent’s Hospital Sydney Human Research Ethics Committee – Protocol Number: Q02/128, and
- Western Sydney Area Health Service Human Research Ethics Committee – Protocol Number: HREC2003/12/4.18(1737).
8 August 2002

Natasha Lannin
Unit 40
22 Ridge Street
North Sydney NSW 2060

Dear Natasha

Re: Research Project: *Does splinting prevent contractures following stroke?* Registration Number HEC 01/166

The Committee has reviewed the responses to the outstanding issues and has agreed to grant an ethics approval for the above research project.

You are advised that the Committee should be notified of any further change/s to the research methodology should there be any in the future. You will be required to provide a report on the ethical aspects of your project at the completion of this project. The form is attached and also located on the Research Services Web Page.

The Protocol No. HEC 01/166 should be quoted in all future correspondence about this project. Your approval will expire 30 December 2005. Please contact the Human Ethics Officer, Kay Buckley on tel: 4570 1136 if you require any further information.

The Committee wishes you well with your research.

Yours sincerely

[Signature]

Professor Elizabeth Deane
Chairperson
UWS Human Research Ethics Committee

Cc Dr Anne Cusick
12 July 2002

Mr Natasha Lannin
40/22 Ridge Street
NORTH SYDNEY NSW 2060

Dear Natasha,

DOES SPLINTING PREVENT CONTRACTURE FOLLOWING STROKE?

It is a pleasure to share with you the minutes of our recent Ethics Committee:

Dr Anne Cusick (supervisor for PhD student, Natasha Lannin, University of Western Sydney) presented a proposal for a study entitled Does splinting prevent contracture following stroke? The project is planned as a multi-centre trial involving patients at Mt Wilga Private Hospital.

Despite the wide use of splints, there has been no research, either in Australia or overseas, to investigate whether or not splinting actually does help to prevent hand contractures following stroke. This randomised controlled trial will investigate the effect of hand-splinting in two positions on the prevention of contracture.

The main ethical issue of the study relates to the phase of withholding treatment (i.e. no splinting group), but after careful review it was concluded that since there is presently no evidence that splinting helps, harms or has any effect, it is not ethically wrong to withhold it. However, to compensate for any concerns that may be felt by participants, the offer is made to provide free treatment at the conclusion of the trial. Advice has been obtained that there should not be any irreversible muscle shortening within the six-week timeframe of the study.

VOTED: to approve the above study for implementation at Mt Wilga Private Hospital on condition that a report is submitted on the progress of and at the conclusion of the study, and that the Committee is informed of any significant changes to the protocol, or any significant complaints or problems encountered.

We trust the study goes well and with best wishes.

Sincerely

[Signature]

Dr Thomas Lubowici
Secretary, Hospital Ethics Committee
toml@sah.org.au

cc: Dr Anne Cusick, Dr Robert Herbert, Ms Annie McCluskey, Dr Helen Mackie
Dear Ms Lannin,

Re: Research Proposal entitled
Does Splinting Prevent Contracture Following Stroke?

The above mentioned Research Proposal submitted by you was considered at the Quality Care Committee Meeting held on 30th May 2002.

It was resolved by the Committee to approve St Joseph’s Hospital Involvement in this research subject to the following inclusions to the consent form:

1. Explain that a control group would use a non-splinting technique and that the patient may be allocated to that group.

2. Explain that splinting may be the normal treatment in certain hospitals of the multi-centre trial.

An initial progress report on your research should be forwarded to the Quality Care Committee three months after the project has commenced.

We would appreciate being informed if we have not subsequently been included in your research, and would also appreciate St Joseph’s Hospital being notified of any publication of this research in the future.

Yours sincerely,

Dr D Popovic AM
MD MB BS MRACMA
Director of Clinical Services

Copy to:
Mr J Anderson, Executive Director St Joseph’s Hospital
Mrs Sharon Smith, Occupational Therapy Head of Department, St Joseph’s Hospital
RESEARCH ETHICS COMMITTEE - Eastern Section

Room G71, EBB
Corner High & Avoca Sts
RANDWICK NSW 2031
Tel: 9382 3587
Fax: 9382 2813

28th August 2002

Ms Natasha Lannin
College of Social and Health Services,
University of Western Sydney
Bldg 24, Campbelltown Campus
Locked Bag 1797
PENRITH SOUTH DC NSW 1797

Dear Lannin

Re: Does Splinting Prevent Contracture Following Stroke? REF: 02/152

The Research Ethics Committee at its meeting of 27th August 2002 considered the Ethics Approval given on 12th August 2002 for the following for the above study, and this decision was ratified.

- Clarification about the competency of participants in providing informed consent.
- Clarification that participants will not be at risk of significant adverse consequences as a result of controlling finger stretching.
- Inclusion in the Patient Information Sheet and Consent Form that participants understand that they will be closely monitored and if indicated, the research treatment will be altered.
- Correction of the ‘type’ in the Patient Information Sheet and Consent Form.

In accordance with the National Health and Medical Research Council Guidelines, the Committee requires you to furnish it with a progress report every 12 months until and on completion of the study.

The Committee wish you well with the continuation of your study.

Yours sincerely

Kim Breheny
Executive Officer
Human Research Ethics Committee - Eastern Section

190 Russell Avenue Derris Point NSW 2219 PO Box 430 Kogarah NSW 1485 Telephone 61 2 9947 9898 Facsimile 61 2 9947 9891

Incorporating: The Prince of Wales & Prince Henry Hospitals • Sydney Children's Hospital • Royal South Sydney • Royal Hospital for Women • St George Hospital • Suburban Hospital • Sydney and Sydney Eye Hospitals • Community Health Services

Genevan House • Associated • Colley • D二氧化碳 • Harwood Membership Hospitals • Special Needs Hospitals • Stretton Family Centre • Administration Responsibility: The Queen Elizabeth Hospital
Ms Natasha Lannin  
School of Exercise and Health Science  
University of Western Sydney  
Building 24, Campbelltown Campus  
PENRITH SOUTH 1797

November 19, 2002

Dear Ms Lannin,

Project No: 02/113 - Does Splinting Prevent Contracture following Stroke

The SWSAHS Research Ethics Committee wishes to acknowledge receipt of your correspondence with regards to the above project.

As all of the issues raised by the Committee have now been satisfactorily addressed, formal approval is hereby granted for this study to proceed as a Category A Project.

Ethics clearance is granted for periods of up to twelve months. This project will be due for renewal on 30th September, 2003 and you must provide a Progress Report (attached) or final report by this date. If no report is supplied, ethics clearance for this project may be cancelled.

Your attention is drawn to the attached document Guidelines for Investigators which sets out not only the principles under which research should be conducted, but also the conditions under which Ethics approval is granted by the Committee. Also enclosed for your information, is a copy of the document Guidelines for Responsible Practice in Research and Dealing with Problems of Research Misconduct.

Please note that the Committee must be notified IMMEDIATELY of any untoward or unexpected complications or side affects arising during the project or of any ethical or medico-legal problems that may arise. Also, any changes to the original protocol must be submitted to the Committee for approval.

Would you please quote the above project number in all future correspondence relating to this project.

Yours sincerely,

PROFESSOR HUGH DICKSON  
Chairperson  
SWSAHS Research Ethics Committee

For: Mr Ian Southwell  
Chief Executive Officer

Category A: Projects with limited risk potential, including quality assurance surveys.
Category B: Projects with significant patient risks.
Category C: Drug trials (international/national) sponsored by drug companies and already covered for risk evaluation and monitoring of adverse reactions.
January 7th 2003

Natasha Lannin  
College of Health Sciences  
University of Western Sydney  
Campbelltown Campus (Bldg 24.0 Locked Bag 1797)  
Penrith South DC NSW 1797

Dear Natasha

Re: Does splinting prevent contracture following stroke. 
SVH Ref No. Q02/128

Your application was considered at the last meeting of the Human Research Ethics Committee executive.

I am pleased to inform you that approval has been given to commence this study. The St Vincent’s Hospital Human Research Ethics Committee is constituted and operates in accordance with current NHMRC guidelines. The approved consent form is that dated November 20th 2002.

Under NO circumstances may you or your co-investigators depart from the approved protocol without the prior consent of the Committee.

Would you inform the Committee of any adverse effects or events occurring in association with your study.

Would you inform the Committee when the research is completed.

If you have any queries relating to the above, please contact me on 8382 2075.

Yours sincerely

Kay Blackwell

Rodney Eccleston  
Executive Officer  
Human Research Ethics Committee

cc Dr Steven Faux, SHH Rehabilitation Services
2 March, 2004

Ms Natasha Lannin
School of Exercise & Health Science
UWS Building 24
Campbelltown Campus
Locked Bag 1797
Penrith South DC  NSW  1797

Dear Ms Lannin

Research Proposal: "Does splinting prevent contracture following stroke?"

Thank you for your letter dated 20 February 2004 enclosing revised Participant Information and Consent Forms (Version 2 dated 20 February 2004), in accordance with the requests of the Human Research Ethics Committee. These forms are approved.

As the Committee's ethical concerns have now been satisfied, approval of the study is confirmed and it may now begin.

The Committee wishes you well with the study and looks forward to receiving progress reports in due course.

Yours sincerely

[Signature]

Dr Howard Smith
Secretary
Western Sydney Area Health Service
Human Research Ethics Committee