



MONASH University

**Adherence to acute hand therapy treatment – application of a
multi-dimensional model**

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“We may be specialists in treating a single limb with a specific instrument, but we must be guided by the whole individual—body, mind, spirit—who has to decide to what extent he or she is prepared to place the whole person at the service of one of the digits and restrict his or her whole freedom and activity to improve a single joint.”

Paul Brand, Hand Surgery Pioneer, 1914-2003

General Declaration

In accordance with Monash University Doctorate Regulation 17/ Doctor of Philosophy and Master of Philosophy (MPhil) regulations the following declarations are made:

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

This thesis includes four original papers published (or in press) in peer reviewed journals and one unpublished publication (which has been submitted to Archives of Physical Medicine and Rehabilitation). The core theme of the thesis is *Adherence to acute hand therapy treatment*. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the candidate, working within the Department of Occupational Therapy, Monash University under the supervision of Associate Professor Ted Brown and Associate Professor Louise Farnworth.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of Chapters 3-7 my contribution to the work involved the following:

Thesis chapter	Publication title	Publication status*	Nature and extent of candidate's contribution
3	Predictors of adherence to therapeutic splint wear in adults with acute upper limb injuries: a systematic review	Published	100%
4	Determinants of compliance with hand splinting in an acute brain injured population	Published	85% - Concept development, literature review, ethics application, data collection, writing and submission of manuscript, amendments to manuscript post peer review
5	Patient experience of distraction splinting for complex intra-articular finger fractures	Published	75% - Concept development, literature review, ethics application, securing of funding, data collection, data analysis, writing and submission of manuscript, amendments to manuscript post peer review
6	Comparison of dynamic digital distraction splinting and no-distraction for complex intra-articular finger fractures: Long-term outcomes	Submitted to journal	70% - Concept development, literature review, ethics application, securing of funding, majority of data collection, data analysis, writing and submission of manuscript, amendments to manuscript post peer review
7	Mallet finger: a single-blind randomized controlled trial of three different splints	Published	85% - Concept development, literature review, ethics application, data collection, writing and submission of manuscript

I have included published papers in the format in which they appeared in their respective journals. Chapter 7 is presented as an uncorrected proof as the final version was not available at time of thesis submission.

Signed:

Date: 9th March 2011

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Summary

This thesis has its foundations in my clinical work as a Senior Hand Therapist in a fast paced acute hospital setting. The literature shows that patient adherence to hand therapy treatment in acute conditions (defined as less than three months post injury) results in superior recovery and prevention of deformities in tendon, nerve, and bony injury and prevention of contractures post burns. Non-adherence with splinting in acute injury can result in increased health system costs by increasing the need for difficult secondary surgical repair procedures, medical, nursing, and allied health support.

In this setting, patients who fail to follow their therapy regime have traditionally been labelled 'non-compliant' by the surgery and therapy team. Hand therapy literature and conference presentations confirm this thesis' contention that most therapists perceive non-compliance as a mostly patient-driven problem, reflecting attitudes of the patient, such as ignorance or forgetfulness. This simplistic view is not supported by evidence, with newer patient health behaviour models encompassing additional influences such as socio-economic, health care system, condition-related, and therapy-related factors. There has also been a shift in conceptualising patient behaviour from *compliance* to that of *adherence*, and the difference between these terms is explained in Chapter 1. A review of the literature on adherence behaviour is also presented in this thesis, and the Multi-dimensional Adherence Model (MAM) published by the World Health Organisation in 2003 forms the central reference point for the five publications that comprise Chapters 3 to 7. These publications address five key research questions that arose from my aforementioned clinical work.

A variety of methodologies have been employed to answer the clinical questions, including a systematic review, qualitative methodology (phenomenological analysis and grounded theory design), a cohort study, and a randomised controlled trial. All provide support for this thesis' contention that ability to follow treatment for acute injury is impacted by more than one factor, and interventions to improve adherence need to address all relevant factors. The discussion chapter provides examples of interventions, with a summary of the current evidence for each.

Thesis Publications

	Journal Impact Factor	Page
O'Brien, L (2010) Adherence to therapeutic splint wear in adults with acute upper limb injuries: a systematic review. <i>Hand Therapy</i> , 15(1): 3-12	N/A	66
O'Brien, L and Bailey, M (2008) Determinants of compliance with hand splinting in an acute brain injured population. <i>Brain Injury</i> , 22(5) 411-18	1.533	83
O'Brien, L and Presnell, S (2010) Patient experience of distraction splinting for complex intra-articular finger fractures. <i>Journal of Hand Therapy</i> , 23(3):249-59	0.612	98
O'Brien, L Simm, A, Loh, I and Griffiths, K (in peer review) Comparison of dynamic digital distraction splinting and no-distraction for complex intra-articular finger fractures: Long term outcomes. Submitted to <i>Archives of Physical Medicine and Rehabilitation</i> December 2010	To be confirmed	117
O'Brien, L and Bailey, M (2011) Single blind, prospective Randomized Controlled Trial comparing dorsal aluminium and custom thermoplastic splints to Stack splint for acute mallet finger. Accepted for publication in <i>Archives of Physical Medicine and Rehabilitation</i> , 92(2):191-8	2.184	156

Chapter 1 - General Introduction and Literature Review

Chapter 1

General Introduction and Literature Review

In this chapter, I will:

- describe the background to this collection of research publications and how I came to be interested in exploring the issue of treatment adherence in adults with acute hand injury;
- give an outline of the structure of this thesis;
- define the terms compliance, adherence, and concordance, and describe the scope of the problem in the hand therapy context;
- discuss the methodological barriers to the study of adherence; and
- review the literature on models of adherence, justify my selection of the Multi-dimensional Adherence Model (MAM) as the key model in this thesis, and discuss how it relates to current Occupational Therapy theory.

1.1 General Introduction

The motivation for this thesis arose from my clinical practice as a Senior Hand Therapist at the Alfred Hospital in Melbourne, Victoria, Australia. This is a public hospital specialising in

adult acute trauma and burns. Ensuring patient adherence with hand therapy, particularly wearing splints in the crucial early weeks post-injury, was identified as a major challenge by the Hand Therapy team. This challenge was perceived by therapists to be magnified in the following instances:

1. When the patient has altered cognition as well as a hand injury (for example, those patients who had sustained an acute brain injury in the same incident that caused their hand injury);
2. When the treatment is experienced by the patient as painful or confronting (for example, when external traction and mobilisation is required for complex finger fracture/dislocations);
3. When the treatment is experienced by the patient as being restrictive and of long duration (for example, the eight weeks of immobilisation required to heal a finger-tip extensor tendon injury).

As practitioners, we observed that patients with acute injuries who adhered to their hand therapy treatment were more likely to experience superior recovery and less likely to develop complications. Those that did not were labelled 'non-compliant' by the surgical and therapy teams, with the underlying assumption that any negative consequences were likely to be the patient's own fault. This is reflective of the prevailing medical and health-care ideology, in which health care practitioners assume the role of experts and patients the role of passive recipients of treatment, who are expected to 'comply' with or 'obey' the experts'

recommendations.¹ A review of the medical, nursing, and therapy literature of the twentieth century concluded that the term 'compliance' used in this context was synonymous with physician 'control'.¹ This ideology did not sit comfortably with my Occupational Therapy (OT) education and my profession's commitment to client-centred practice. This discomfort with the therapist role of 'controller' (and my belief that the ability of patients to adhere to their hand therapy program was a complex multi-faceted phenomenon) thus became the spur for the research studies that comprise this thesis. I believed that, whilst it was important that the patient wore their splint and completed graded exercises, we as therapists needed to consider how the individual would complete their necessary occupations (self-care, work, and leisure) during this recovery phase. We also needed to establish an agreement with our patients so that they understood *how* they could complete their necessary activities whilst still avoiding potential risks.

As part of the background reading, I was encouraged to note that newer health-care models defined the patient* role as more active and involved, and the term 'compliance' was replaced in many instances with the terms 'adherence' and, occasionally, 'concordance'. In this chapter, I will define and delineate the terms compliance, adherence, and concordance. I will also explore the major patient behaviour models in relation to general health interventions and expand on the hand therapy context of this thesis.

*Although the term *patient* is not consistent with OT philosophy, where the preferred term is *client*, I have used it throughout this thesis, as it is the term most commonly used in the hand therapy and adherence literature.

1.2 Overview of thesis structure

As this is a “Thesis by Publications” it is formatted, in the main, as a series of five research papers. Four of these are published, and one is currently under review, in a range of journals. Each publication is linked using the Multi-dimensional Adherence Model (MAM), and is published in full (with additional commentary) in Chapters 3 to 7.

Chapter 1 (this chapter) provides an overview of the inspiration for this thesis, and defines the scope of the problem in the hand therapy context. It also reviews the literature on the causes of non-adherence, outlines the methodological challenges faced in its research, and describes the model that will underpin the rest of this thesis. Chapter 2 details the separate methodologies chosen for each study that forms this thesis.

The first of the five publications, Chapter 3, is a systematic review of the determinants of adherence to therapeutic splint wear in adults with upper limb injury, mapping the findings to the constructs of the MAM. It provides support for this thesis’ contention that patient adherence is not simply a patient-related issue, and that there are many factors which can act in concert to influence adherence behaviour.

Chapters 4 to 7 are individual publications relating to separate studies conducted with participants from the Alfred and Dandenong Hospitals. Chapter 4 specifically sought to identify factors associated with splint non-compliance in a retrospective file audit of people admitted to the Alfred trauma service with concurrent brain and upper limb injuries (N.B. The term *compliance* was used in this instance as patients were not always able to give their

informed agreement to treatment due to cognitive problems associated with their brain injury). This study found that socio-economic factors and most patient-related factors (such as psychiatric illness, alcohol or substance abuse) exerted no significant influence on compliance in this group, thus supporting the stance of WHO that it is a misconception that adherence is a patient-driven problem.² The factors that were most strongly associated with non-adherence were presence and duration of agitation.

Chapter 5 is the first of two papers on distraction treatment for complex finger joint fractures, and specifically examines the patients' experience of this somewhat confronting treatment using qualitative methodology. Factors that influenced adherence were the complexity and duration of treatment, the immediacy of benefit, interference with lifestyle, and the availability of support. Patient-related factors, such as lack of understanding of the condition and need for treatment, and beliefs about the injury and treatment required also exerted an influence.

Chapter 6, the second involving distraction treatment, is a cohort study comparing long term outcomes for complex finger joint fractures in a group who had distraction treatment compared to a group who had static splinting. This study was unable to establish a significant relationship between the variables studied and adherence, with no differences found between the groups on the adherence measure. There were no statistically significant differences between the two treatment groups, although a clinically significant difference in arc of motion was found, favouring those who had distraction.

The final paper, Chapter 7, is a randomised controlled trial comparing three different splint types for mallet finger. This treatment demands a very high level of patient adherence, as they must wear their splint continuously for the first 8 weeks. We found no difference in the primary outcome (extensor lag) between groups, however two of the splints trialed had significant rates of treatment failure, meaning the patient could not tolerate them due to skin breakdown, poor fit or impracticality. We also found a medium negative correlation between patient adherence and degree of extensor lag. If we expect our patients to wear a splint for 8 weeks, we must ensure the splint provided is robust enough for daily living requirements and does not cause complications which are intolerable to the patient.

Chapter 8 presents an integrated discussion drawn from all the research projects as well as evidence-based recommendations for interventions to improve adherence across all dimensions of the MAM. Finally, Chapter 9 (Conclusions) summarises the original contribution this work has made to the knowledge and understanding of adherence in the hand therapy field and provides suggestions for future research directions.

The appendices contain several documents important to this research, including ethics certificates from all involved agencies and a summary of conference participation, competitive grants and awards received during the period of candidature. It also includes tables summarizing the extensive review of the evidence on distraction splinting undertaken by myself in preparation for the research undertaken into this particular treatment.

1.3 Literature review

1.3.1 Background

The concept of 'compliance' with treatment has dominated the medical and therapy literature since the 1950's, with over 60,000 citations since 1980 relating to compliance.³ These have mostly been in the domains of health, behavioural and social science, with a focus on determining the prevalence of poor adherence, its determinants and interventions to address it.^{1, 2, 4-6} However, the following warning to Physicians - attributed to Hippocrates, the father of Western medicine - suggests that compliance has been a concern of physicians for millennia: "keep aware of the fact that patients often lie when they state that they have taken certain medicines".^{7p2}

Non-compliance with treatment has traditionally been viewed by health care practitioners as reflective of the patient's attributes, such as ignorance about the condition, low motivation, or forgetfulness.⁸⁻¹⁰ Interestingly, these views are still currently held by many health care practitioners including Hand Therapists, as illustrated in an Australian study published in 2002, which surveyed 69 Hand Therapists and 41 patients.¹¹ This study found that the therapists generally viewed their patients as being less motivated and committed to their therapy programs than the patients viewed themselves, and tended to attribute this to patient variables (such as forgetfulness or lack of understanding of the treatment) rather than treatment variables (such as pain caused by movement), therapist-patient relationship variables (such as therapist giving positive feedback) or organisational variables (such as financial costs of treatment).

It is well accepted that consumer non-compliance or non-adherence with medical or therapeutic treatment can reduce treatment benefits, affect recovery, increase the risk of disability, and bias assessment of treatment efficacy.^{7, 11, 12} A meta-analysis found the odds of a favourable outcome in a variety of medical conditions, both acute and chronic, are trebled in patients who adhere to treatment recommendations when compared to those who do not.¹³

Myriad treatment interventions to address the problem of low adherence have been studied in the medical literature, with a particular focus on prescribed medication. A systematic review of interventions for enhancing medication adherence¹⁴ found that, for short-term treatments (for infections or transient allergies), several simple interventions improved adherence but did not enhance the clinical outcome. These included counselling patients about the importance of adherence, dispensing medication in dose-dispensing units, providing written instructions and/or medications charts, and follow-up phone calls. For long-term treatments (for asthma, chronic obstructive pulmonary disease, diabetes mellitus, hypertension, Human Immunodeficiency virus (HIV), Rheumatoid Arthritis, Dyslipidemia, and mental illness) simplifying the dose regimen and using more complex strategies had limited effectiveness, but needed to be balanced with the considerable amount of effort and resources they consumed. The complex strategies studied included combinations of more thorough patient instructions and counselling, reminders, close follow-up, supervised self-monitoring, rewards for success, family therapy, couple-focused therapy, psychological therapy, crisis intervention, and manual telephone follow-up. The authors concluded that “If there is a common thread to these at all, it is more frequent interaction with patients with

attention to adherence....There is no evidence that low adherence can be 'cured'. Thus, efforts to improve adherence must be maintained for as long as treatment is needed".^{14p19}

For overall medical intervention, a recent meta-review by van Dulmen et al.⁵ provided a synthesis of 38 systematic reviews of the effectiveness of adherence interventions published between 1990 and 2005. They grouped interventions by the theoretical approach to adherence interventions, and described four main categories: technical, behavioural, educational, and multi-faceted or complex interventions. They found that there were effective adherence interventions within each category, but pointed out the lack of comparative studies explicitly contrasting theoretical models or their components.

In the nursing literature, much of the patient adherence literature relates to chronic conditions such as mental illness, diabetes, cardiac pathology, organ transplant and obesity.¹⁵⁻¹⁹ A review of models and interventions for improving patient adherence with health behaviours such as physical activity, dietary modification, medication management, and blood glucose monitoring found that there are only a few effective strategies for promoting and sustaining behaviour change in people with chronic conditions.²⁰ Dr Jacqueline Dunbar-Jacob, who has published extensively on adherence in the nursing literature, concluded that "All successful models begin with clearly defining the desired change in behavior, establishing a baseline, and encouraging the patient to self-monitor her or his progress. In most cases multiple interventions are necessary, and only modest changes in behavior can be expected".^{20p20} Although this conclusion is drawn from the evidence on chronic conditions, it is likely that multiple interventions are also necessary for improving

adherence in acute hand injuries, given the complexity of treatment and interference with daily living activities.

1.3.2 Defining the terms: compliance, adherence, and concordance

The terms 'adherence' and 'compliance' are often used interchangeably in the medical and therapeutic literature, but have different connotations and inferences, mainly in the role the patient adopts. Compliance places the patient in a passive role of treatment recipient who takes instruction from the doctor or treating health practitioner. The power balance in the practitioner-patient relationship is heavily slanted toward the practitioner in this instance. In contrast, the patient's role in adherence is that of an informed consentor, in that they understand and agree to follow the chosen intervention or advice in order to achieve optimum clinical benefit.^{3, 16} The power relationship shifts toward the patient in this instance²¹, but the balance of power is still with the health practitioner.^{3, 7, 22}

A detailed description of the differences is discussed in Meichenbaum and Turk, 1987¹⁰ and can be summarised as:

Compliance is the "extent to which patients obey and follow instructions, prescriptions and proscriptions outlined by their treating health practitioner";^{10p20}

Adherence implies an "active, voluntary and collaborative involvement by the patient in a mutually acceptable course of behaviour to produce a preventative or therapeutic result".^{10p20}

The World Health Organisation's adherence project defines adherence as "the extent to which a person's behaviour - taking medication, following a diet and/or executing lifestyle changes -corresponds with agreed recommendations from a health provider".^{2p3} The word **agreed** is the keystone of this statement, as adherence requires the patient to agree with the recommendations, and to stick to the agreed regimen to achieve optimum clinical benefit.³ The term 'adherence' is intended to be non-judgemental, and does not imply blame on the part of the patient, prescriber or treatment.⁷

A further term, introduced in 1997 by The Royal Pharmaceutical Society of Great Britain²³ to describe a new approach to prescribing and taking medicine, is 'concordance':

Concordance is "an agreement reached after negotiation between a patient and a health care professional that respects the beliefs and wishes of the patient in determining whether, when, and how medicines are to be taken. Although reciprocal, this is an alliance in which the health care professionals recognize the primacy of the patient's decisions about taking the recommended medications" (Medicines Partnership, 2001, as quoted in Horne et al.^{24p33}).

The key difference between *concordance* and *adherence* is that concordance focuses on the consultation process rather than on the outcome of the consultation.²³ The term *concordance* is becoming more widely used in health promotion,²⁵ chronic disease management, particularly the use of medications,²⁶ and government health policy.²⁷ It is, however, not used commonly in therapy research, and does not apply easily to acute injury

management; I will therefore not be using the term further in this thesis. The term *adherence* is more appropriate to the field of hand therapy and will be used in the following chapters.

1.3.3 Defining non-adherence

Despite the evidence of the economic and human costs of patient non-adherence, there are several problems relating to the body of research which have led to a lack of consistent findings. Firstly, there is little consensus on its definition and, therefore, how it is measured. Some researchers treat adherence as a dichotomous variable²⁸⁻³⁰ (i.e. a specific patient is rated as either adherent or non-adherent) and others describe varying levels of non-adherence³¹⁻³³ which may span from a) never-adhered to any aspect of treatment; b) adhered with some but not other aspects; c) initially adhered but relapsed over time; to d) inappropriate or over-adherence. Non-adherence can also be context-dependent.^{34, 35} A person may manage well when surrounded by cues and reminders (for example, during their in-patient hospital stay), but may forget to adhere to their therapy program when they return home, or it may become a lower priority. A study of adults aged over 55 found that those who received help at home with daily living activities were significantly more likely to adhere to medication than those who did not.³⁶ One definition of non-adherence that may be useful clinically and in research is “the point at which the desired preventive or desired therapeutic result is unlikely to be achieved”.^{12p31}

1.3.4 The hand therapy context

The problem of non-adherence applies to all medical and therapeutic interventions, and although it is a topic of concern for hand therapists, it is surprisingly under-researched “given the degree to which hand therapists rely on patients to follow strict exercise and splint regimens”.^{11p31} Hand therapy is “the art and science of rehabilitation of the upper quarter of the human body. Hand therapy is a merging of occupational therapy and physical therapy theory and practice that combines comprehensive knowledge of the upper quarter, body function, and activity”.^{37p1} Hand Therapists are certified or registered Occupational Therapists or Physiotherapists, who have developed expertise in the assessment and treatment of upper quarter conditions through clinical experience, advanced continuing education / postgraduate study, and independent learning. Conditions treated by Hand Therapists may be the result of congenital or acquired deformity, trauma, or disease.

A 2008 Practice Analysis by Dimick et al.³⁸ of more than 768 Hand Therapists in the United States, Canada, Australia, and New Zealand conducted via on-line survey found that 46% worked in hospital-based practices, 15% in physician-owned practices, and 8% in corporate-owned practices. The authors did not elaborate on the remaining 31%, but noted that only one (0.001%) characterised him/herself as a researcher. The same study found that the major conditions treated include oedema (57% of respondents), fractures (47%), adhesions or tightness (38%), wounds and scars (36%), cumulative trauma disorders (26%), tendon injuries and conditions including lacerations, transfers, tendonitis, ruptures (22%), muscular strains, tears, avulsions (19%), nerve injuries and conditions such as neuropathies, palsies,

nerve repairs (14%), ligamentous injury and instability (14%), crush injuries/mutilating trauma (12%), dislocations and subluxations (7%), pain (7%), and arthritis / rheumatic diseases (7%).³⁸

The four domains of hand therapy were updated in 2008 by the Practice Analysis Task Force appointed by the Hand Therapy Certification Commission (Sacramento, California).³⁷ These are summarised in Table 1.

Table 1: Domains of Hand Therapy (adapted from Dimick et al³⁸ p 363)

Basic science and fundamental knowledge	Understand and apply knowledge of the theory and principles of anatomy, physiology, kinesiology, and biomechanics as they relate to the upper extremity; understand physical properties and expected outcomes of treatment interventions; Understand the aetiology, pathology, and surgical and medical treatments of conditions affecting the upper extremity.
Evaluate upper extremity and relevant patient characteristics	Perform and document all aspects of patient evaluation, including interviews and assessments.
Determine prognosis and plan of care	Based on the results of the evaluation, determine treatment interventions and expected outcomes. Plan discharge based on progress toward goals. Implement therapeutic interventions Apply and modify therapeutic interventions, including patient education and home programs.
Professional practice	Provide ethical, safe, and fiscally responsible practice; manage human resources; use evidence-based practice; interpret and apply research; promote ongoing professional development for self and others; and advocate for patients and the profession.

For the third domain, which incorporates the plan of care, Hand Therapists are particularly reliant on patient adherence in achieving desired outcomes after acute musculoskeletal injuries. In this case, adherence covers a variety of behaviours including:

- Entering and continuing a therapy program;
- Attending assessment and follow-up appointments;
- Correct wear of prescribed and fitted splints, braces, or orthoses (defined as custom-made or prefabricated devices applied to any part of the body to relieve pain, stabilise body joints or tendons, protect against (re)injury, promote healing, prevent or correct deformity, and assist or increase occupational performance);³⁹
- Correct performance of home-based therapy programs (which may include exercise, rest, oedema management strategies); and
- Avoidance of risk behaviours (e.g., overuse of the injured limb during recovery stages).

In the hand therapy literature, many studies have found a link between patient adherence to splint/orthosis wear and/or prescribed exercises and positive functional outcome post acute injury. These include:

- improved wrist extension, and functional activity status in patients with distal radius fractures;⁴⁰
- prevention of contractures in axillary burns;^{41, 42}
- prevention of secondary defects such as joint deformities, and enhancement of functional hand use in peripheral nerve injuries;^{32, 43, 44}

- Improved function in potentially unstable extra-articular hand fractures;⁴⁵⁻⁴⁷ and
- Increased tendon tensile strength and total active range of movement in tendon repairs.⁴⁸⁻⁵⁰

In summary, ensuring patient adherence with hand therapy is extremely important in achieving superior functional outcomes and avoiding costly secondary surgery for preventable deformities, contractures and re-injury of tissues.

1.3.5 Exploration of splint adherence in the hand therapy literature

The hand therapy literature on splinting or orthotic interventions tends to be dominated by discussions of the underlying anatomical or biological disorder, reflecting a biomechanical or medical model with a clear focus on the client's diagnosis or disability.³⁹ Up until recently, very few authors have acknowledged or articulated the importance of considering the patient's occupational performance, defined as "the ability to choose, organize, and satisfactorily perform meaningful occupations, that are culturally defined and age appropriate, for looking after oneself, enjoying life, and contributing to the social and economic fabric of a community,"^{51p181} when designing or fabricating the splint. There is, however, an encouraging trend toward integrating occupational therapy (OT) and hand therapy theory, which is best encapsulated by the following quote by Stier in 2004: "significant attention to the client's meaningful occupations, whatever they may be, is required to design a splint that will enable individuals to do what they want to, need to and are expected to do."^{52p21} In the soon to be published 6th edition of *Rehabilitation of the*

Hand and Upper Extremity, McKee and Rivard describe a client-centred Bio-Occupational approach to splint (or orthotic) intervention which focuses on enabling occupational performance.³⁹ This approach explicitly addresses both the client's biological needs and occupational performance issues with consideration of the individual's unique circumstances. It involves firstly identifying and addressing the biological factors that are barriers to optimal occupational participation and, secondly, designing splints using an occupational perspective. This approach "ensures that the central therapeutic aim of orthotic intervention remains that of enabling current or future occupational performance, rather than simply providing a splint".^{39,Ch122,no page ref available as not in print until 2011.}

A review of the literature on predictors of adherence with splinting of acute hand injuries was published as part of this candidature, and is reprinted in Chapter 3 of this thesis.

1.3.6 Methodological Barriers to the study of adherence

The study of patient adherence (or compliance) faces many challenges. The two major ones are participant selection and subjective measures of adherence. These are discussed below.

1.3.6.1 Participant selection

There is a selection bias in many studies of adherence, as people who have consented to research participation are, by definition, compliant with requests for information and may be unrepresentative of the typical patient population. This is referred to as *Non-response Bias*,

and occurs when there is a systematic difference between the characteristics of those included in a study and those who are not.⁵³ It occurs because individuals who do not respond to a call to participate in research studies are generally different from those who do respond on several important factors. Responders tend to have healthier lifestyle habits, be less likely to smoke, and have lower morbidity and mortality rates. People with poor literacy or from culturally and linguistically diverse backgrounds are also likely to be excluded, and those with complex health, social, economic and family contexts may become lost to follow up in longitudinal studies.⁵⁴⁻⁵⁶ The impact of selection bias on studies of non-adherence can include errors in estimation of the magnitude of non-adherence, and inaccurate conclusions based on data which may not necessarily reflect the population being studied.

1.3.6.2 Subjective measures of adherence

Many studies of adherence are reliant on the patient's self-report but patients may be unwilling to admit to non-adherence⁵⁷ or may over-estimate their adherence rates to treatment regimens. One study of brace-wear time in an adolescent population (comprised of 40 females aged between 10 and 16)⁵⁸ compared self-report (via a questionnaire) to data recorded by a 'compli-o-meter' (an instrument attached to the brace which accurately recorded wear time). Interestingly, patient self-reports of brace wear (88% of the prescribed length of time) differed significantly to those measured using the compli-o-meter (33%). Poor correlations between these measures is a common finding in the spinal brace literature⁵⁹ but may be partially explained by the adolescent population being studied who may be struggling

with self image issues and feel that wearing a brace has unacceptable impacts on their quality of life.⁶⁰

The use of electronic devices to measure exercise activity in people wearing hand splints is rare. It is, however, likely that people required to wear hand splints may similarly overstate or overestimate their wear time or the number of exercises performed. An early study of six patients post tendon surgery using a splint with a built-in exercise counter⁶¹ could only report the results for four participants, as one refused to be re-tested and the equipment failed in the other. Of these, they found that all recorded lower exercise counts than prescribed or self-reported. A more recent study of five patients who underwent tendon repair found a similar trend⁶² although when they repeated the study with a larger group (N=15) who were unaware of the counting facility of the splint, they found the opposite: participants exercised almost seven times more often than they were instructed.⁶³

Studies that rely on treatment providers' subjective ratings of adherence may also be inaccurate. A study comparing therapists' and patients' perception of adherence with hand therapy programs found significant differences in perception of adherence rates. Therapists generally rated patients as being "less motivated and committed than the patients viewed themselves".^{11p37}

1.3.7 Prevalence of Non-Adherence – How big is the problem?

Most estimates of non-adherence with medical or therapeutic treatments range from 30-60%⁶⁴ with an average of around 40%.¹³ In other words, two out of every five patients fail to adhere to the point at which they are likely to achieve the desired therapeutic result.

Published prevalence percentages must be interpreted with caution, however, for reasons previously mentioned in this chapter, including inconsistent definitions of non-adherence, selection bias, and subjective measurement instruments.^{65, 66} There is also a high degree of variability depending on the type of treatment. Non-adherence is reportedly rare in treatments for acute-onset conditions requiring direct medication with high supervision and monitoring (e.g., chemotherapy for cancer)¹⁰ and higher in chronic disorders where there is little discomfort or risk apparent to the patient, or where lifestyle changes are required. For example, non-adherence with medication in people with schizophrenia measured at one year after hospital discharge was estimated to be 50%⁶⁷ possibly due to unpleasant side-effects, and limited patient insight into the effects of the illness.

Similar trends are found in therapies requiring patients to wear an orthosis, splint, or brace. Non-adherence rates for acute injuries (defined as those resulting from direct trauma to the limb) were generally low: 25% in mallet finger injuries³¹ and 19% in acute Achilles tendon injuries⁶⁸. In chronic conditions (defined as those resulting from a disease process or cumulative strain) non-adherence appeared much more prevalent. Feinberg's⁶⁹ systematic review of treatment adherence in people with Rheumatoid Arthritis found an average splint non-adherence rate of 52.8% (range: 35-75%) across five studies, with data mostly based on

patient report. Vandal et al's⁵⁸ study of adolescents wearing orthopaedic braces for scoliosis found that 67% of participants did not wear their brace for the prescribed time, most likely for reasons mentioned in section 1.3.6.2.

1.3.8 Variables influencing non-adherence

In 1979, Haynes and Sackett⁷ published a comprehensive review of the literature, focusing on the understanding, measurement and resolution of non-compliance. They identified more than 200 factors which have a relationship with and potential impact on patient adherence. These can be grouped into five overlapping categories:

1. Patient/client variables (e.g., age, sex, socio-economic status, family support, cognition);
2. Disease features (e.g., acute injury versus chronic disease);
3. Treatment regimen characteristics (e.g., complexity, timing, duration);
4. Therapy source / clinical setting (e.g., clinic or hospital); and
5. Relationship between the health care provider and the patient/client.

Most well-known adherence models have, however, attempted to explain the phenomenon from the patient perspective only, and have not allowed for the effects of the environment (social and physical) in which treatment is delivered, nor the impact on the individual's

participation in occupations such as self care, productivity (e.g., work or study) and leisure.

The next section will briefly discuss the key adherence models and will introduce an evidence-based multi-dimensional model which will form the basis for this thesis. The multi-dimensional model's commonalities with current OT theory will also be explored.

1.3.9 Explaining Adherence: Conceptual models of patient adherence behaviour

In a recent review of theory use in health behavior research published between 2000 and 2005, the most often used theories were the Health Belief Model, Social Cognitive Theory, and the Trans Theoretical Model of Change.⁷⁰ All of these models contend that sustainable health-related actions are influenced by the individual's knowledge, attitudes,⁷¹⁻⁷⁶ and beliefs.⁷⁷⁻⁸¹ These key models will be discussed in this section, as well as some of the emerging models from the nursing and allied health literature.

1.3.9.1 Health Belief Model (HBM)

The Health-Belief Model (HBM)⁸² was developed in the 1950s and 1960s by Hochbaum, Rosenstock, and Kegels who were American public health service researchers working to explain and predict health behaviours. It was developed from studies of healthy individuals, with researchers focusing on disease-avoidance behaviours and increasing the use of then-available preventive services, such as chest x-rays for tuberculosis screening and immunizations such as flu vaccines. The first version of the model contained four key

concepts: Perceived Susceptibility, Perceived Severity, Perceived Benefits, and Perceived Barriers.⁸² The concept of Cues for Action was added later to stimulate behaviour.⁸³ The model was extended by Becker and colleagues in the 1970s and 1980s⁸⁴, with amendments encompassing the growing evidence on the impact of knowledge and perceptions on self efficacy.

The HBM can be applied to different populations and health behaviours.⁸¹ The three main areas described by Conner and Norman⁷⁷ are:

- Preventive health behaviours, which include health-promoting (e.g., diet, exercise) and health-risk (e.g., smoking) behaviours as well as vaccination and contraceptive practices;
- Sick role behaviours, which refer to compliance with recommended medical regimens, usually following professional diagnosis of illness; and
- Clinic attendance, which includes doctor or therapist visits for a variety of reasons.

The HBM describes some of the factors required in the process of achieving positive changes in health related behaviour, but is mostly concerned with the subjective state of the individual, and why the patient does not change his/her behaviour. Its strength relates to the concept of personal vulnerability: patients who do not recognise health risk, either because of lack of information or having an optimistic bias, have been shown to not engage with health behaviour change.³ The focus on the individual, however, potentially overlooks important influences of

the environment (social or physical) and the individual's own experiences (e.g., with other health professionals). Another limitation of this model is the description of the process being that of a linear progression from start to end point which may over-simplify the sometimes cyclic progression of patients.

Research using this model has demonstrated modest relationships between concepts in this model and preventative health behaviours, although a systematic review of studies that had used the HBM found it lacking in consistent predictive power, possibly because it focuses purely on predisposing factors.⁸⁵ The evidence is also weak for predicting adherence with prescribed medication⁸⁶ diet, exercise, and smoking reduction behaviours.⁸⁷

1.3.9.2 Social Cognitive theory (SCT)

This theory, developed by Bandura in the 1970's,⁷¹ contends that people's attitudes are learned from the observation of others by direct modelling (observing people engaged in particular behaviours) or symbolic modelling (observing people portrayed in the media).⁸⁸ Attitudes can lead to behaviours when combined with the person's beliefs about their ability to engage and their beliefs about the likely consequences of engaging. These two components are referred to as *self-efficacy* and *outcome expectancies*. Other key constructs of this model include self-control and reinforcement, and these can be incorporated into behaviour modification interventions using goal-setting, self-monitoring, and behavioural contracting. Goal-setting and self-monitoring have been found to be particularly useful components of effective interventions.^{89, 90}

Because of its complex structure, SCT has been criticised for being difficult to implement in total,⁹¹ with only the most easily implemented aspects of the theory, such as self-efficacy, actually used in practice. Self efficacy has been shown to be a good predictor of adherence with health behaviours such as smoking cessation, healthy eating, tooth brushing, and exercising⁸⁸ as well as self management of chronic illnesses such as AIDS, cancer, cardiac disease, depression, and diabetes.⁹² A review of theory-based interventions for contraception published in the Cochrane Library⁹³ included 12 trials with interventions based on SCT, with 10 of these showing some positive results for the experimental group. They did not, however, find that SCT had a greater effect than other models (such as the Trans-theoretical model of change, AIDS Risk Reduction Model, or other social cognition models) on any specific outcome or group.

1.3.9.3 Trans-Theoretical model of change

The Trans-Theoretical Model (TTM, also known as the “stage model”) has become a popular model in health behaviour change. It was first used to address alcohol abuse and other addictive behaviours with some evidence of success.^{74, 76, 94} TTM describes change as progress, over time, through a series of stages: Precontemplation, Contemplation, Preparation, Action, and Maintenance.⁷⁵ For most people, the change process is not linear, but spiral, with several relapses to earlier stages before they attain permanent behaviour change. The characteristics of each stage are summarised in Table 2.

Table 2: Stages of Change (Adapted from Mannoock⁹⁵)

Stage	Characteristics
Precontemplation	Denial of problem; Resistant to making change May have given up the thought of changing because they are demoralised
Contemplation	Can see the benefits of changing Over-estimate costs of changing; are ambivalent and not quite ready to change Seriously considering action in next 6 months
Preparation	Have decided to make a change in the next month Have already started to take small steps toward goal
Action	Engaged in changing behaviours and are acquiring new, healthy behaviours
Maintenance	Have been able to sustain change for at least 6 months Actively striving to prevent relapse

This model contends that interventions must be carefully matched to the person's stage of change.⁷⁶ One of its key interventions is Motivational Interviewing, which is described as a client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence.⁹⁶ In addition to the early studies in drug and alcohol dependence, the TTM has also been applied to chronic health conditions, including asthma, chronic pain, depression, and multiple sclerosis,⁹² and vocational rehabilitation⁹⁵ with promising results, although the depth of empirical evidence is lacking. A review of its use in exercise program adherence⁹⁷ showed evidence for initiating a new behaviour, but long-term adherence was not maintained. In a recently published review of the evidence into health and food

behaviour change, Motivational Interviewing was shown to be a highly effective counselling strategy, particularly when combined with Cognitive Behavioural Therapy.⁹⁸

1.3.9.4 Common Sense model

The Common Sense (or Self-regulatory, or Illness Perceptions/Representations) Model (CSM) was developed at Rutgers University in the United States (US) in the 1970's by Howard Leventhal and colleagues.⁷⁹ It is another model based on the individual's beliefs about illness, and its central contention is that a person's ability to adhere to treatment is shaped by how he or she processes illness-related events. For example, a person with a chronic asymptomatic condition such as hypertension may feel well and therefore not adhere to their treatment regimen, whereas someone with underlying beliefs that they have cancer may become hyper-vigilant about symptoms and will seek assistance sooner.

In their studies of individuals with chronic illness, Leventhal and Nerenz⁹⁹ expanded the model to include a description of an adaptive system based on the following three hierarchically linked constructs as depicted in Figure 1:

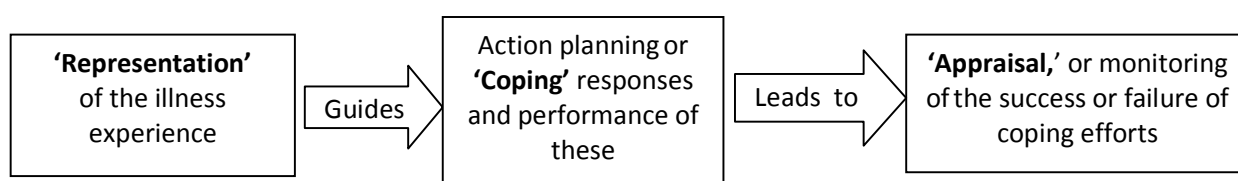


Figure 1 The Common Sense Model (Adapted from Sanderson 2004⁸⁸)

Research in this field has supported the model by demonstrating that individuals consistently look for symptoms which match their view of the illness⁹² and different types of information are needed to elicit action and a change in attitude to a perceived threat to health. Even if a change is made, however, often these responses tend to be short-lived, thus compromising adherence to treatment in chronic conditions.⁷⁸

Interestingly, a meta-analysis of the CSM research¹⁰⁰ found that illness representations may be associated with outcomes relatively independent of the coping strategies used. This conclusion must be treated with caution, however, as the direction of the relationship might not be linear. Coping responses could influence illness representations which may then feed back to influence choice of coping strategy.⁷⁸ A further criticism of this model is that it does not make specific predictions about the role of and interaction with significant others.¹⁰¹

1.3.9.5 Self Determination theory

Self Determination Theory (SDT) emerged in the 1970's and 80's and posits that behaviour is motivated by internal and external regulators, which are defined according to the level of autonomy experienced by the person.⁷³ This can be represented on a continuum (see Figure 2) with the most autonomous pole representing intrinsic motivation (e.g., the individual takes action/adheres with treatment due to interest and/or enjoyment) and the opposite end representing extrinsic motivation (e.g., the individual fears negative consequences if they do not adhere). SDT has been applied to studies of adherence with post-surgery exercise recommendations in patients after knee reconstructions⁷² and exercise for weight loss in obese women¹⁰² with promising results, but has shown little impact on treatment

adherence in people with mental health conditions.¹⁰³ For SDT to work well, both patient and practitioner need to be inclined to share the decision. One possible reason for poor results in the mental illness population is that SDM is only beneficial to patients who want a higher degree of involvement in decision making, and some patients often do not know what it means to be involved until this has been explained to them. Another study found that medical practitioners find it hard to identify patients who would like to participate in SDM.¹⁰⁴

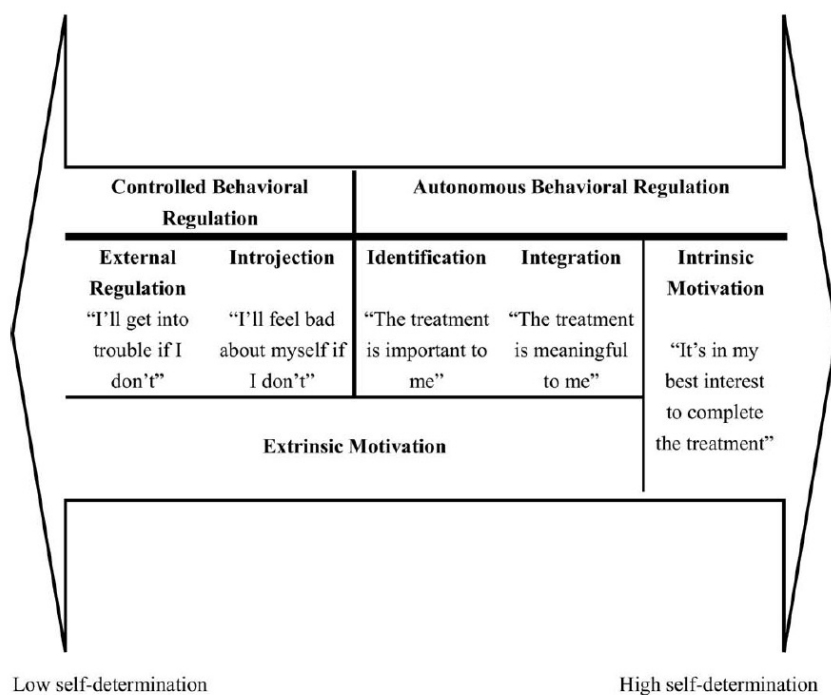


Figure 2: The self determination continuum (Source: Chan, Lonsdale, Ho, Yung and Chan, 2009⁷²)

1.3.9.6 Health Promotion model

This nursing model arose from the Health Belief Model in the 1990's and contends that the likelihood of engaging in health promoting behaviours is determined by the individual's cognitive / perceptual factors (e.g., perceived self efficacy, health status, barriers, and benefits of health promoting behaviours) modified by demographic, biological, interpersonal, situational, and behavioural factors.¹⁰⁵ Concepts are incorporated into a framework with the categories: Individual Characteristics and experiences, Behaviour-specific cognitions and affect, and Behavioural outcomes.⁸⁸

The HPM is widely represented in the nursing literature and is the underpinning framework for over 100 research studies.¹⁰⁶ These have spanned health-promoting strategies in the workplace¹⁰⁷, mammography participation¹⁰⁸, and exercise participation in adults with chronic disease.¹⁰⁹ While there is some evidence of its predictive power for preventative health behaviours, such as use of hearing protection in construction workers¹¹⁰ and exercise behaviour in adolescents,¹¹¹ an evaluation of the application of this model called for studies with greater design rigor, including random sampling techniques, power analysis, and increased psychometric quality of the research measures.¹¹²

One criticism of the model is that it does not reflect interpersonal/situational influences as a source of self-efficacy.¹¹² The HPM is also open to criticism that its linear nature presents limitations in terms of understanding the complexities of the triadic reciprocal relationship (reciprocal determinism) described by Bandura.⁷¹ This theory states that a person's behavior

both *influences* and *is influenced by* personal factors (including cognitive, affective and biological events) and the environment.

1.3.9.7 The Multi-dimensional Adherence Model (MAM)

This model was published by the World Health Organization in 2003 following a major critical review of the evidence on adherence to long term therapies, and identifies five dimensions that influence adherence.² These are represented in Figure 3:

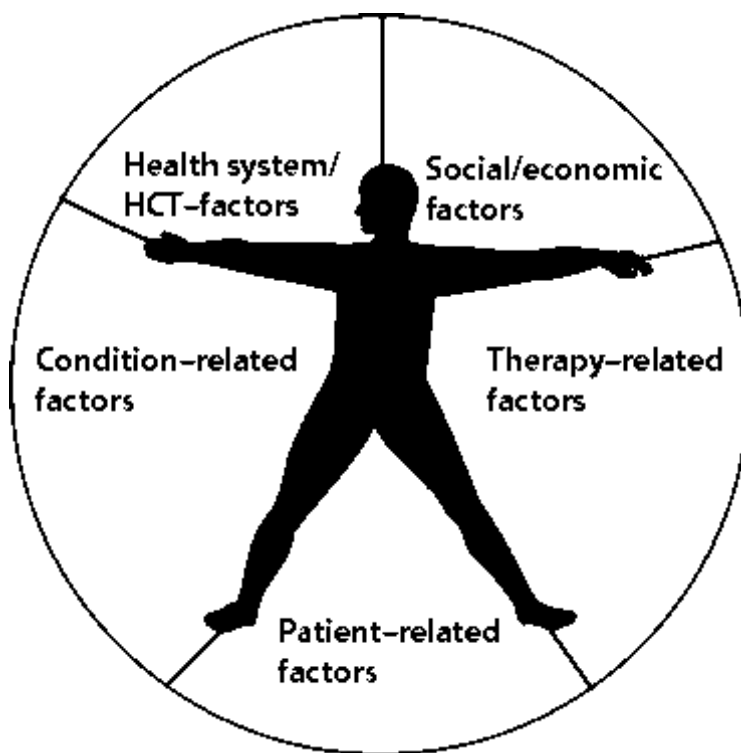


Figure 3: The Five Dimensions of Adherence. (Source: World Health Organization, 2003)

This model differs from those previously discussed by removing the traditional emphasis on patient-related factors, as it is a “misconception that adherence is a patient-driven problem”.^{2p26} This model states that the ability to follow treatment is impacted by more than one barrier, and interventions to improve adherence need to address all relevant factors. Due to its holistic conceptualisation of adherence, sound evidence base, and parallels with current Occupational Therapy theory (see section 1.10) this model has been chosen as the cornerstone for this thesis.

The five key dimensions of the MAM are:

Social and economic

Although not a consistent independent predictor, some factors such as race (and cultural beliefs) poverty, illiteracy, unemployment, lack of social supports, distance from treatment outlet, family dysfunction, and cost of travel / treatment, and age¹¹³⁻¹¹⁷ have shown relationship with adherence to treatment.

Health-care team and system

Although there is some evidence that a good patient-provider relationship and prolonged follow-up can improve adherence,¹¹⁵ there is relatively little research into factors that can have a negative effect, such as poorly developed services, overworked, and poorly trained health care providers, and lack of continuity of care.

Condition-related

These factors include severity of symptoms, level of disability, prognosis, rate of progression and the availability of effective treatment. They also extend to co-morbidities such as depression and substance abuse, as these play an important role in modifying the individual's ability to adhere to treatment^{118, 119}.

Therapy-related

These include complexity, duration, immediacy of benefit, interference with lifestyle, side effects, and frequent changes to treatment pathways. It also encompasses the availability of support to deal with the above factors.

Patient-related

Up until recently, this factor dominated the research output into adherence, and there is an abundance of literature focusing on this topic. Factors reported to affect adherence are physical factors (such as vision hearing or mobility impairment) cognitive impairment (e.g., forgetfulness) psychological factors, such as low motivation, lack of understanding of the condition (and need for treatment), beliefs about side-effects, stress, and negative views about medicine.^{35, 86, 120}

As this is a relatively new model, there is a need for testing in future studies to strengthen its evidence-base, particularly in acute conditions. It does, however, encompass areas that have been shown to directly impact on adherence¹⁷ and it provides clinically useful guidelines (referred to as "lessons learned") that may be readily applied to the field of hand therapy, including:

- The consequences of poor adherence are poor health outcomes and increased health care costs;
- Improving adherence also enhances patient safety;
- Adherence is an important modifier of health system effectiveness;
- Health systems must evolve to meet new challenges;
- A multidisciplinary approach towards adherence is needed; and
- Patients need to be supported, not blamed.

The first three of these points summarise the impact of non-adherence, and the final three guide interventions to address it. Strategies for the field of hand therapy will be explored in more depth in Chapter 8 (Discussion).

1.3.10 Relating the Multi-dimensional Adherence Model to current Occupational Therapy theory

All modern OT theory has “occupation” as the central construct; this is defined as “all activities of daily living that contribute to health and fulfilment for an individual”.^{121p 1} The period between 1975 and 2000 was a particularly productive era in the development and articulation of OT theory, with several key models published, supported by research, and

accepted by the OT community. These include the Person Environment Occupation Model (PEO)¹²², the Model of Human Occupation (MOHO)¹²³ and the Canadian Model of Occupational Performance and Engagement (CMOP-E)¹²⁴.

By including and acknowledging the impact of the social and physical environment in the person's occupational performance, the MAM parallels the PEO model¹²² which acknowledges the dynamic relationship between the Person (comprised of the following aspects of the person: physical, cognitive, spiritual and affective), their Occupations (self-care, productivity and leisure) and their Environments (that include the following aspects: physical, social, cultural, and institutional)- see figure 4.

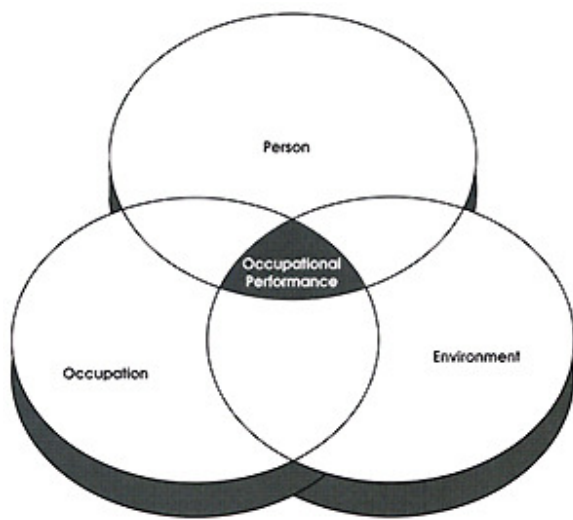


Figure 4 The person-environment-occupation relationship (Source: Law et al, 1996)

This model was further expanded in the Model of Human Occupation (MOHO) which was first published in 1980. This model's assessments and tools have been widely researched and published in the OT literature, with 605 publications listed on its website as of December 2010¹²⁵. It seeks to explain how human occupation is motivated, patterned, and performed in a broad and integrated way, and explains human behaviour in terms of three interrelated components: volition, habituation, and performance capacity. Volition refers to the motivation for occupation, habituation refers to the process by which occupation is organised into patterns or routines, and performance capacity refers to the physical and mental abilities that underlie skilled occupational performance.¹²³ The MOHO also emphasises that, to understand human occupation, we must take into account the physical and social environments in which it takes place. The holistic nature of this model is congruent with the MAM, with the individual's abilities and limitations seen as only one component of their ability to perform an occupation (in this case, completing necessary self care, work, leisure and agreed exercise activities whilst wearing a splint and avoiding potential risks). The social and physical environments in which therapy takes place (e.g., whether the patient has continuity of care, appropriate support, and readily available and accessible transport to the treatment centre) are given equal consideration in both models, and the patient (or client) is not blamed for problems in therapy adherence.

The Canadian Model of Occupational Performance and Engagement (CMOP-E)^{51, 124} was first published in 1997 by the Canadian Association of Occupational Therapists, and builds upon the 1983 publication 'Client-Centred Guidelines for the Practice of Occupational Therapy'.¹²⁶ Building on the PEO, this model includes the relationship between person, occupation and

environment, but adds spirituality as a fourth dimension, placed in the centre of the model to highlight its fundamental importance (see figure 5).

Figure 1.3 The CMOP-E¹: Specifying our domain of concern

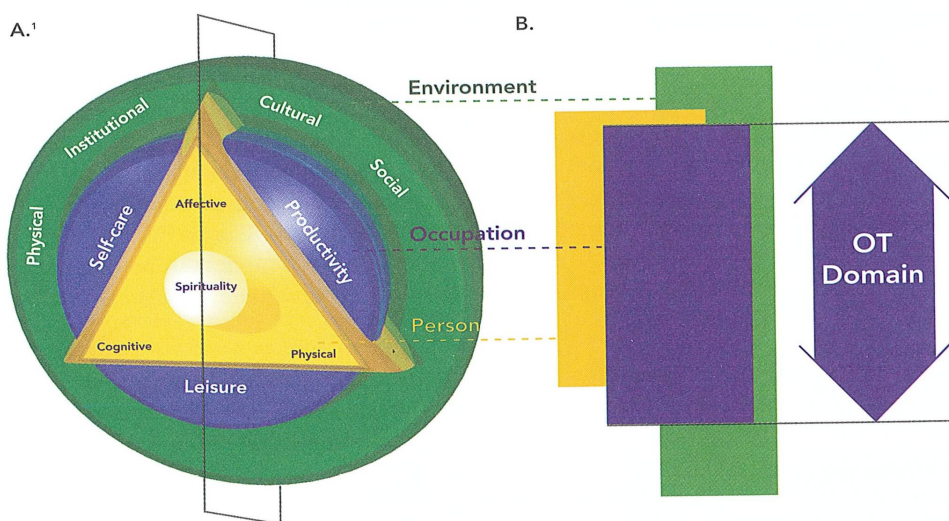


Figure 5 CMOP-E (Source: Townsend and Polatajko 2007)

Again, this is consistent with the holistic, interactive philosophy underpinning the MAM, as it acknowledges and describes the transactions and mutual influences between the dimensions on the individual's occupational performance, in this instance the ability to follow a therapy program.

1.3.11 Summary and Conclusions

Over the previous century, there has been a shift in conceptualising and measuring patient involvement and responsibility in health programs or treatment. The term most commonly

used until the 1980's (and still in use in many health publications) was *compliance* which implied a passive role for the patient as an obedient follower of instructions, prescriptions and proscriptions outlined by their "expert" treating health practitioner. Meichenbaum and Turk¹⁰ made the important distinction between *compliance* and *adherence* articulating the active, voluntary, and collaborative involvement by the patient in a mutually agreed and accepted course of behaviour for the desired health result.

The literature shows that patient adherence to hand therapy treatment in acute conditions (defined as less than 3 months post injury) results in superior recovery and prevention of deformities in tendon^{31, 48-50, 63}, nerve^{32, 43, 44}, and bony injury^{29, 45-47}, and the prevention of contractures post burns.^{41, 42} Non-adherence with splinting in acute injury can result in increased health system costs by increasing the need for difficult secondary surgical procedures,^{29, 127} medical, nursing, and allied health support.^{10, 11, 128}

Research into the predictors and determinants of adherence has resulted in the development of several key models, including the Health Belief, Common Sense, and Health Promotion models, the Trans-theoretical Model of Change, and Social Cognitive Theory. All of these focus on patient-related factors, especially how the individual processes and understands their own health condition and required treatment, and how this translates into motivation and action.

The Multi-dimensional Adherence Model (MAM)² takes a more global view, positioning the patient-related factors within a five-dimensional construct which also acknowledges the

effects on adherence of socio-economic, health care system, condition-related, and therapy-related factors. It was developed following a major critical review of the evidence on adherence and builds on the five overlapping categories of variables described by Haynes.⁷ The Multi-dimensional Adherence Model has been chosen as the theme for this thesis, as it provides a holistic view of the individual in context which is consistent with current OT theory, such as PEO, MOHO, and CMOP-E.

In the next chapter, I will explain the origin of the five key research questions that are answered in the thesis publications, Chapters 3 to 7. I will also outline and justify the aims and methodology chosen for each separate study.

Chapter 2 – Methodology

Chapter 2

Methodology *Introduction*

In the previous chapter, it was established that patient adherence to hand therapy, particularly in acute conditions (defined as less than 3 months post injury), results in superior recovery and prevention of ongoing post-injury deformities. Non-adherence with therapy in the acute hand injury recovery phase can result in long term or permanent disability, lost productivity and increased health system costs. The Multi-dimensional Adherence Model (MAM) was selected as the cornerstone for this thesis, as it provides a holistic view of the individual in context which is consistent with current Occupational Therapy theory.¹²²⁻¹²⁴

In this chapter, I will list the five key research questions that drove this thesis and which are addressed in the publications that form Chapters 3 to 7. The separate methodologies for each of the publications will be described and justified, and the aims, data collection, and data analysis will be outlined.

This chapter highlights the breadth of methodologies used in publications from this thesis, which include a randomized controlled trial, a qualitative (phenomenological and grounded theory) study, a cohort study, a retrospective file audit, and a systematic review.

2.2 The research questions

Following a major review of treatment protocols for common hand conditions treated at the Alfred Hospital Hand Clinic in 2006, several practice challenges were identified and prioritised by the team. This led to the identification of the following five key research questions:

1. What factors are associated with adherence to therapeutic splint or brace wear in adults presenting with acute upper limb injuries?
2. What are the predictors of splint non-compliance for in-patients with acute traumatic brain injury (TBI) and hand injuries? (as noted previously, in this instance, the term *compliance* is appropriate, as patients in post traumatic amnesia are incapable of active and voluntary collaboration with treatment)
3. How does the patient's experience of distraction splinting for intra-articular fractures influence adherence with treatment?
4. Does distraction splinting for intra-articular fractures result in better long-term outcomes for patients when compared with alternative management regimens (that require less of the patient in terms of splint wear and exercise)?
5. Is there a relationship between splint type, compliance, and outcome in the treatment of mallet finger injuries? (again, the term *compliance* is appropriate, as patients in this trial were randomised to treatment – they did not get the opportunity to choose the splint to which they were allocated due to the strict methodology).

As each of these questions approaches the issue of adherence (or compliance in some instances) from a different perspective, the methodologies required to answer them are different and will be detailed separately.

2.3 Materials and Methods

2.3.1 Research Question 1: Which factors are associated with adherence to therapeutic splint or brace wear in adults presenting with acute upper limb injuries?

AIM:

- To identify key factors that could influence patient adherence with splint wear in acute upper limb injuries

METHODOLOGY CHOSEN: SYSTEMATIC REVIEW (SR)

LEVEL OF EVIDENCE = 2A (SR with homogeneity of 2B (Cohort) and better studies)¹²⁹

A systematic review of the literature on the management of acute upper limb injuries was used to answer this question, as it required the gathering, appraising, and synthesising of as much evidence on splint wear in acute injury as possible. The advantage of this method is the ability to assess the consistency of findings across many studies, thus presenting an increased chance of detecting a trend or effect.

Although two systematic reviews of compliance/adherence studies in chronic conditions were found (splint wear in patients with rheumatoid arthritis),^{69, 130} there were no published systematic reviews addressing splint adherence in acute hand injuries.

Search strategy

Relevant articles were identified from a search of Ovid MEDLINE (1970 to June 2009) Ovid CINAHL (1970 to June 2009) and EMBASE (1970 to June 2009) – encompassing Cochrane database of systematic reviews and conference papers. The search strategy (including inclusion/exclusion criteria) is detailed further in the publication (Chapter 3).

Methods of review

The title and abstracts of potentially relevant papers were reviewed by the author, and full text of articles that specifically addressed factors associated with non-adherence with splinting or bracing for acute upper limb injuries were obtained by the author, and were then evaluated for quality using the *Critical Review Form for Quantitative Studies* published by McMaster University, Hamilton, Ontario, Canada.¹³¹

For all included studies, relevant data were extracted by the author into standardised forms to capture the following information: 1) study design, 2) number of participants and their associated injury / condition, 3) adherence measure used, 4) presence of explicit definitions for adherence, 5) whether a statistical comparison was done between adherent and non-adherent participant groups, and 6) study results.

Data synthesis

Due to the differences in methodologies in studies (differing adherence measures and variables used in the study analyses), synthesis was narrative rather than quantitative.

Statistics were therefore reported as published in the original studies. When reported, the 95% CI was used; if it was not available, a *p*-value was reported.

2.3.2 Research Question 2: What are the predictors of splint non-compliance for in-patients with acute traumatic brain injury (TBI) and hand injuries?

AIMS:

- To identify key predictors of non-compliance with hand splints (or other protective removable braces) in patients with acute brain injury; and
- To determine whether the *Westmead Post Traumatic Amnesia* (PTA) scale¹³² is a suitable tool for predicting compliance with splinting (or bracing) in this population.

METHODOLOGY CHOSEN: RETROSPECTIVE FILE AUDIT

LEVEL OF EVIDENCE = 2C (Audit or outcomes research)¹²⁹

The retrospective file audit was chosen as it is a relatively inexpensive and efficient way to investigate a number of potential predictors of non-compliance across a large sample. It also has the advantages of no loss to follow-up or selection bias, thus providing data for the full range of patients meeting the study's inclusion criteria. It enabled the authors to estimate the proportion of people who did not comply with their splint regimen, and to explore hypotheses regarding potential risk factors for non-compliance. It also enabled the authors to assess the usefulness of the Westmead PTA scale in predicting compliance with splinting.

Participants

The sample included the full medical records of all patients who were (1) admitted to the Alfred Hospital (Melbourne) via the Trauma unit in 2005 and 2006, and (2) who were recorded as having concurrent head and upper limb injuries. The medical records for all cases identified by the trauma unit database for that period (N=117) were examined and 71 were eligible for inclusion in this study. Of the 46 excluded, there were 7 deaths, 10 with only superficial injuries to the upper limb and/or the head or face, and 29 with injuries that did not require the fitting of a removable splint or brace (e.g., wrist fractures where standard treatment was a plaster cast).

Data Collection

Full medical records were ordered and baseline information was extracted, including:

- Demographics (age, sex, marital status, place of residence – coded as rural, urban, or inner urban);
- Occupation, coded using the Australian and New Zealand Standard Classification of Occupations (ANZSCO);¹³³
- the presence of other health variables (such as psychiatric co-morbidity, previous brain injury, history of alcohol/substance abuse) as indicated by notes completed by the admitting medical officer;
- mechanism of injury, coded as either motor vehicle, motorcycle, push-bike or pedestrian accident, fall, or 'other' including assault, horse-riding and work accidents, and explosions;
- severity of brain injury using lowest *Glasgow Coma Scale* (GCS)¹³⁴ score in the first 24 hours post injury;
- lobe(s) of the brain that were injured; and
- type of hand injury sustained (e.g., bony, ligamentous, tendon, nerve, skin or soft tissue loss).

Retrospective data for every day of the hospital admission was also extracted from each patient's medical chart on the following items:

- If Plaster of Paris (POP) cast/backslab was applied;
- Days (post injury) POP removed, and thermoplastic splint fitted;
- Post Traumatic Amnesia (PTA) status at time of commencement of splinting;

- Number of days the patient displayed two or more signs of agitation in the one day according to notes in the medical file. Terms used were confined to the list of behaviours used for data collection in Nott et al. (2006),¹³⁵ including restless/excessive movement, pulling at tubes or restraints, and irritability - see publication (Chapter 4) for a full list of terms;
- Whether or not the patient complied with their splinting treatment. Non-compliance was defined as one or more episodes noted in the medical file of self-removal, loss, or incorrect wear of splint, or unprotected hand movement. For patients who were left in their POP cast and did not receive a splint, self-removal of neck or back braces or bandages was considered an incidence of non-compliance.

Statistical Analysis

Descriptive analysis was used to measure the incidence of non-compliance and describe the frequency of non-compliant behaviours. Comparisons between compliant and non-compliant groups were made using chi-square tests for equal proportion, Student *t*-tests for normally distributed data and Wilcoxon rank sum tests for non-parametric data.¹³⁶ In addition, all variables were further compared using logistic regression, allowing for results to be reported as odds ratios (OR) with a 95% confidence interval (CI). A two-sided *p*-value of 0.05 was considered to be statistically significant.

2.3.3 Research Question 3: How does the patient's experience of distraction splinting for intra-articular fractures influence adherence with treatment?

AIMS:

- to describe patients' experiences of distraction splinting; and
- to identify key issues in patient adherence to their splint-wear and exercise program.

METHODOLOGY CHOSEN: Qualitative (phenomenological and grounded theory)

A qualitative methodology (phenomenological analysis for the first part and grounded theory design for the second) was selected as first person accounts provide clinicians with a richer understanding of the patient experience of the treatment we provide.

Participants

Selection criteria for the study included adults who could speak English, were able to give informed consent, and who had sustained an intra-articular finger fracture within the previous eight years that was treated with distraction splinting at the Alfred Hospital. All patients who met these criteria (N=18) were identified from the hospital database, contacted by mail, and invited to participate. Follow-up telephone calls were made to discuss the aims of the study and to schedule interview times. Data collection commenced in April 2009 and

was finished in July 2009, when data saturation of thematic content had been achieved according to consensus agreement by the researchers involved in the data analysis.

Data collection

Twelve (12) participants were interviewed by the first author (LOB), using a semi-structured interview schedule developed for this study. Questions were designed to elicit responses that explored the participants' thoughts and feelings about their injury, their experience of distraction treatment, including their preparedness for it, and the reactions of their friends, family, and colleagues to the physical appearance of the splint. Interview questions are listed in the publication (Chapter 5).

All but two interviews were completed in the hand therapy department of the hospital; one was completed via phone as the participant had moved interstate, and the other was completed in the participant's home. Interviews were recorded using a digital voice recorder, and transcribed verbatim for analysis by an individual who was blinded to the participant's identity. All transcriptions were checked for accuracy by the first author (LOB).

Data Analysis

Two parallel analytical strategies were used for all analysis of interview transcripts, both modelled on the methodology detailed by Starks and Brown Trinidad.¹³⁷ The first author conducted a manual analysis and developed preliminary findings. Transcripts were also entered into a computer data management program (*nVIVO Version 2.0, QSR International*)

and were independently analysed by the second author. For the phenomenological component of this study, a systematic process for coding data (as described by Starks and Brown Trinidad)¹³⁷ was used in which specific statements were analysed and categorised into clusters of meaning that represented a phenomenon of interest.

To develop an explanatory framework for predicting treatment adherence, grounded theory's method of comparison using three stages of coding was used.¹³⁸ The first stage involved open coding: examining and comparing data, then developing coding categories that reflected the content of the data collected. The data was then re-assembled into groupings based on patterns and relationships between the categories and patient report of adherence to treatment (axial coding). Finally the central or core category was identified and described. The themes, patterns, categories, descriptive examples and quotations identified through the analysis formed the basis of the interpretation of the findings.

For both analyses, the authors compared emergent themes and categories to review thematic and conceptual consistency, and any disagreements were resolved by consensus moderation. In order to ensure trustworthiness of the results, the researchers also 'member checked' the emerging themes and categories with two of the interviewees to ensure that the interpretation of the findings were an accurate representation of the participants accounts of their experience.

2.3.4 Research Question 4: Does distraction splinting for intra-articular fractures result in better long-term outcomes for patients when compared with alternative management (that requires less of the patient in terms of splint wear and exercise)?

AIM:

- to compare long-term functional outcomes achieved in both groups of patients in terms of active movement, pain, and independence in daily living activities.

METHODOLOGY CHOSEN:

LEVEL OF EVIDENCE = 2B (Cohort study)¹²⁹

A cohort study approach is the most rigorous epidemiological design, with the main advantages of being well suited to rare exposures (in this case, distraction splinting, which is not widely used in Victoria, Australia), ethically safe, and administratively easier and less costly than a randomized controlled trial. In this study design, participants were selected using pre-treatment x-rays (to ensure comparability of groups). Eligibility criteria and outcome assessments were standardised to enhance rigor. The disadvantages are that blinding was not achieved (due to unexpected delays in recruiting one of the cohorts), treatment exposure may have been linked to a hidden or unknown confounder, and participants and controls may have differed on important predictors of outcome (e.g., key socio-economic criteria, such as literacy or access to public transport to attend appointments).

Participants

Selection criteria for the study included adults who could speak English, were able to give informed consent, and had treatment for a comminuted intra-articular fracture of the proximal or distal interphalangeal joint of the finger in the previous eight years at either of the two participating centres (the Alfred Hospital or Dandenong Hospital). All patients who fit these criteria were identified by a search of the hospital databases, contacted by mail and telephone, and invited to participate.

Participants from the Alfred Hospital formed the Distraction Splinting Group (Group A). For details of the treatment/therapy received, see the full manuscript (Chapter 6). Group A participants were similar to participants from Dandenong Hospital (Group B) on variables such as age, gender, time since injury, and occupation.

Data collection

Participants completed a one-page form that included information on hand dominance, finger injured, satisfaction with result, pain (using the 10cm Visual Analogue Scale),¹³⁹ complications (such as further procedures required) and current employment status. They also completed the *Disabilities of the Arm Shoulder and Hand* (DASH)¹⁴⁰ self-report functional outcome scale. Impairment measurement was completed by a research assistant, and included total active range of motion (using 15 cm steel finger/toe goniometer) following a standardised protocol with a dorsal placement approach.¹⁴¹ Information regarding complications (i.e. malunions, non-unions, infections), and further surgery was extracted

from patients' medical records and checked with participants, in the event that treatment was sought elsewhere.

Data Analysis

Assuming a minimum of 16 per group, it was calculated that the study would have 80% power to detect a difference in continuous variables equivalent to one standard deviation with a 2-sided p -value of 0.05. All data were analysed using SPSS version 18.0 (SPSS Inc, Chicago, IL, USA). Group comparisons were made using student t -tests for normally distributed variables, chi-square tests or Fishers Exact tests for categorical variables, and Wilcoxon rank-sum tests otherwise.¹³⁶ Correlations between primary outcome (combined range of motion at the proximal and distal interphalangeal joints) and continuous data were investigated using Pearson product-moment correlation coefficient (after checking for normality) and non-parametric data were tested using Spearman rank correlation coefficients. A two sided p -value of 0.05 was considered to be statistically significant.

2.3.5 Research Question 5: Is there a relationship between splint type, compliance and outcome in the treatment of mallet finger injury?

AIMS:

- to compare outcomes, compliance, and patient satisfaction in people with mallet finger injuries by splint type, of which there were three:

- the perforated thermoplastic splint;
- the dorsal aluminium-foam “Mexican hat” splint; or
- a control splint (the off-the-shelf “Stack splint”).

METHODOLOGY CHOSEN: Randomised Controlled Trial (RCT)

LEVEL OF EVIDENCE = 1B Individual RCT (with narrow Confidence Interval)¹²⁹

A recent Cochrane Systematic review¹⁴² found that there was insufficient evidence to establish the comparative effectiveness of different types of finger splints (either custom-made or off-the-shelf) for treating mallet finger injuries. The authors of the Cochrane Systematic review commented that there were only 4 trials that met the inclusion criteria, and all of these were “small, heterogeneous, inadequately described and reported....and had methodological flaws”.^{143p6} We therefore chose a randomised controlled trial, as we believed we could incorporate this design to eliminate methodological weaknesses noted in previous trials (e.g., we achieved assessor blinding, allocation concealment, and 20-week follow-up in most cases). We also anticipated that we could find a suitable number of participants as these injuries present relatively frequently to public hospitals. Other advantages of RCT’s include the unbiased distribution of confounding variables, and the facilitation of statistical analysis.⁵⁴ Disadvantages of RCT’s include the expense involved, in both time and money.⁵⁵ This trial recruited patients over a four year period, which is significantly longer than was first estimated. To address this, we widened our catchment to include two other hospitals as

recruitment sites. One hospital, however, did not recruit any participants suggesting staff were either unclear as to who/how to enroll, or unwilling to change current routine treatment practices. The other hospital recruited a further five participants in the final six months of the trial, and reported no difficulty adhering to the trial protocol.

Participants

Referrals to the trial were sourced through the Alfred and Dandenong Hospitals' Emergency Departments and Plastics streams, a Melbourne private hand therapy clinic, and local medical practitioners between May 2006 and 2010. Assuming a minimum of 16 participants per group, it was calculated that this study would have an 80% power to detect a difference in continuous variables equivalent to one standard deviation with a 2-sided *p*-value of 0.05. Based on the assumption of normality, a reduction of one standard deviation would be equivalent to about 24%, therefore a reduction of 0.8 of a standard deviation would be approximately equivalent to a 20% reduction. A difference of this size is perceived to be of clinical importance.¹⁴⁴

Patients with mallet injury to the thumb, open fractures, co-existing rheumatologic illness, or those whose time from injury to presentation was greater than 2 weeks were excluded to minimise confounding variables. A diagnosis of mallet finger was made based on X-rays and clinical finding of extensor lag at the Distal Inter Phalangeal joint (DIPJ).

Participants were allocated via a computer generated randomised sequence to one of three groups: a) custom-made thermoplastic thimble splint constructed from 1.6 mm Orfit Classic

Soft micro-perforated (Orfit Industries, Belgium); b) custom-made dorsal aluminium (Mexican hat) splint made from 13mm width aluminium padded splint (Smith and Nephew, USA); or c) control (off-the-shelf Stack splint). All splints allowed for full Proximal Inter Phalangeal joint (PIPJ) motion.

Data collection

Each participant was seen by a Hand Therapist with at least 3 years' experience who collected baseline data, measured the finger's degree of extensor lag with a standardised finger goniometer, and noted other relevant health information such as the presence of other hand injuries on injured hand, smoking status, and medication. The therapist then provided and fitted the splint according to the randomised sequence. Allocation concealment was achieved by having treatment group information contained in sealed opaque envelopes. Participants were given the same information regarding hygiene procedures (adapted from Richards et al.)¹⁴⁵ and a diary to complete regarding instances (and reasons for) splint removal, modification, or accidental dislodgement. All were provided with a review appointment at one week to check splint fit, and further reviews at six, eight, 10, 12, and 20 weeks were scheduled.

Patients were instructed to contact the clinic immediately if their splint became damaged or was lost so that it could be replaced as soon as possible. Splints were checked at each appointment and remoulded, repaired, or replaced if required. The treating therapists saw

the patients up until the 8 week review, then a blinded assessor completed the following measurements at 10, 12, and 20 weeks:

- degree of extensor lag (measured with a standardised goniometer);
- development of complications;
- splint failure (i.e. a change in splint type was required due to splint breakage, poor fit, participant report of either splint impracticality or inability to manage splint application/removal);
- patient compliance to the treatment protocol measured on a 3 point scale, based on that used by Groth et al. (1994)¹⁴⁶ which uses self-report, therapist observation, and attendance at therapy appointments to determine whether the patient is compliant, secondarily non-compliant, or non-compliant;
- patient satisfaction with result on 5-point Likert scale, ranging from 1 = very dissatisfied to 5 = very satisfied;
- pain 'on a typical day during the last week', measured by 10 cm Visual Analogue Scale (VAS). There is evidence that the VAS is a reliable (test-retest 0.99) and valid ($r=0.6$ correlation between VAS and descriptive pain scale) measure of subjective pain experience.¹³⁹

To ensure blinding, splints were removed prior to the assessment and re-applied afterwards by another therapist using a standard donning/doffing technique.

Data Analysis

With a minimum of 16 per group, it was calculated that this study would have 80% power to detect a difference in continuous variables between any two groups equivalent to 1 standard deviation with a 2-sided p -value of 0.05. All data were analysed using SAS version 9.2 (SAS Institute, Cary, NC, USA). Baseline participant characteristics in the three groups were compared using one-way analysis of variance for continuous variables and chi-square tests for categorical variables. For the primary analysis, extensor lag data from the 12 and 20 week reviews were compared using Analysis of Variance.

The secondary measure (complications causing treatment failure) was compared using chi-square test for equal proportion. Analysis of variance (for measures of satisfaction and pain) and Kruskal Wallis tests (for compliance) were used where required. A two sided p -value of 0.05 was considered to be statistically significant, and, where an overall group difference was found, pair-wise comparisons were made to establish the specific reason behind the statistical significance. All analyses were performed on an "Intention To Treat" (ITT) basis, but given the sample size and the significant incidence of treatment failure in two of the splint groups, it was considered appropriate to also perform a 'Per Protocol' analysis for the primary outcome (degree of extensor lag). Per-protocol groups were defined as the final

splint groups if participants did not tolerate the original randomly allocated splint, and were changed to a different splint.

2.4 Chapter Summary

This chapter lists five key research questions that arose from the author's clinical practice as a hand therapist and describes and justifies the separate methodologies used to answer each of these. As each question approaches the issue of patient compliance or adherence with hand therapy from a different perspective, this thesis encompasses a variety of methodologies. To further explore the background for this thesis, the next chapter is a systematic review of factors have been shown to have reliable correlations with adherence to therapeutic splint or brace wear in adults presenting with acute upper limb injuries.

Chapter 3 – Adherence to therapeutic splint wear in adults with acute upper limb injuries: A Systematic Review

Chapter 3

Adherence to therapeutic splint wear in adults with acute upper limb injuries: A Systematic Review *Introduction*

Chapter 2 outlined the methodology for each of the studies included in this thesis. This chapter is the first of five publication chapters, and presents a systematic review of the published evidence on adherence with splinting in acute hand injury. This paper highlights the lack of publications and overall poor standard of evidence in this field.

3.2 Chapter Contents

O'Brien, L (2010) Adherence to therapeutic splint wear in adults with acute upper limb injuries: a systematic review, *Hand Therapy*, 15(1):3-12.

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This study aimed to identify and describe the body of knowledge on factors that could affect patient adherence with splint wear in acute upper limb injury. Outcomes other than splint adherence were not examined as part of this review. In this paper, the terms *compliance* and *adherence* were described and applied to the hand therapy context. Factors examined in the included studies were grouped and discussed using the Multi-dimensional Adherence Model (MAM).

Review

Adherence to therapeutic splint wear in adults with acute upper limb injuries: a systematic review

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Abstract

Introduction. Non-adherence with therapeutic splinting in acute hand injury can reduce treatment benefits, increase risk of disability and bias assessment of treatment efficacy. This systematic review aims to critically analyse the literature on splinting of acute upper limb injuries to identify key factors that could influence patient adherence with splint wear.

Methods. Trials were identified from searches of EMBASE, MEDLINE, CINAHL (to June 2009) and reference lists of articles and relevant reviews. Search terms used were patient compliance/adherence behaviour, splint/s, orthosis/es and brace. Where possible, randomized controlled trials or prospective cohort studies were sought, and then cross-sectional and retrospective studies if the former were not available. Studies specifically addressing chronic conditions were excluded. All relevant trials were assessed for methodological quality by the author using explicit criteria. Data were extracted using a standardized form designed by the author.

Results. Six studies (one randomized controlled trial, two cross-sectional analytic surveys and three retrospective file reviews) involving 490 people were included. Owing to the heterogeneity of studies synthesis is narrative rather than quantitative. There was no consistent correlation between adherence and age or gender. One study found a correlation with patient perception of positive effect, and one found negative correlations with agitation and brain injury severity.

Discussion. Studies found were generally of varied quality and may be susceptible to bias. This is a field with little published scientific evidence, and future research should measure adherence relationships with socioeconomic, health-care system, therapy- and patient-related characteristics.

Keywords: Adherence behaviour, patient compliance, hand injuries, splints, review

Introduction

The terms 'adherence' and 'compliance' are often used interchangeably in medical and therapeutic literature, but have different connotations and inferences. A detailed description of the differences is discussed by Meichenbaum and Turk¹ and can be summarized as follows:

Compliance is the extent to which patients obey and follow instructions, prescriptions and proscriptions outlined by their treating health practitioner; Adherence implies an 'active, voluntary and collaborative involvement by the patient in a mutually acceptable course of behaviour to produce a preventative or therapeutic result'. (p. 20)¹

The term 'adherence' is intended to be non-judgemental, and does not imply blame on the part of the patient, health-care practitioner or treatment.²

Adherence is the 'most unpredictable, least controllable variable in medical intervention [and] can strongly sway the outcome of any treatment'³ (p. 31).

It is well accepted that consumer non-adherence with medical or therapeutic treatment can reduce treatment benefits, affect recovery, increase the risk of disability and bias assessment of treatment efficacy.^{2,4}

The literature on the determinants of adherence with health-care interventions is extensive. The multi-dimensional adherence model (MAM) published by the World Health Organization in 2003 following a major critical review of the evidence identifies five dimensions that influence adherence.⁵ The five dimensions of the MAM are (1) socioeconomic, (2) health-care system-related, (3) condition-related, (4) treatment-related and (5) patient-related factors (Figure 1). It differs from many preceding models by removing the focus on patient-related

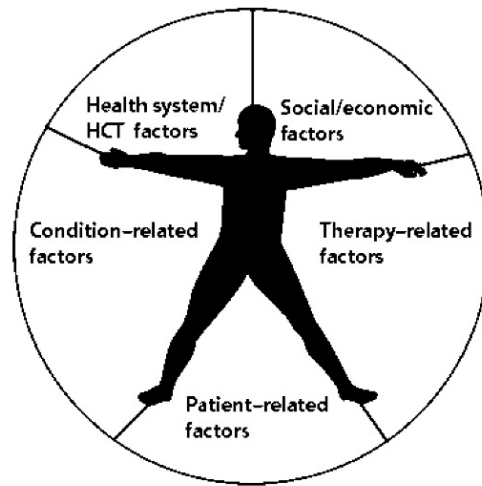


Figure 1 The five dimensions of adherence. Source: World Health Organization (WHO), 2003 (reproduced with permission from WHO, Geneva)

factors, stating that it is a 'misconception that adherence is a patient-driven problem' (p. 26). This model contends that ability to follow treatment is impacted by more than one factor, and interventions to improve adherence need to address all relevant factors. Although this model was designed for long-term therapies, its key concepts apply equally to acute conditions and it provides clinically useful guidelines (referred to as 'lessons learned') that are readily applied to the field of hand therapy.

Practitioners (for example, occupational therapists, physiotherapists and orthotists) who prescribe and fit splints, braces or orthotics are particularly reliant on patient adherence in achieving desired outcomes after acute musculoskeletal injuries. In their case, adherence covers a variety of behaviours including:

- (1) entering and continuing a therapy programme
- (2) attending assessment and follow-up appointments
- (3) correct wear of prescribed and fitted splints, braces or orthoses
- (4) correct performance of home-based therapy programmes (which may include exercise, rest, oedema management strategies)
- (5) avoidance of risk behaviours (e.g. overuse of the injured limb during recovery stages).

This review is focused on point 3 above, as there is evidence to support that adherence to prescribed splint wear in acute conditions results in superior recovery and prevention of deformities in tendon,⁶⁻¹⁰ nerve¹¹⁻¹³ and bony injury,¹⁴⁻¹⁷ and prevention of contractures post burns.^{18,19}

Non-adherence with splinting in acute injury can result in increased health system costs by increasing the need for difficult secondary surgical procedures,^{14,20} medical, nursing and allied health support.^{1,21,22}

Although there are several systematic reviews of compliance/adherence studies in chronic conditions, including examining splint wear in patients with rheumatoid arthritis,^{23,24} there are no systematic reviews addressing splint adherence in acute injuries.

Objective

The objective of this review is to identify key factors that could influence patient adherence with splint wear in acute upper limb injury. Factors will be grouped and discussed using the MAM. Outcomes other than splint adherence were not examined as part of this review.

Methods

Search strategy

Relevant articles were identified from a search of Ovid MEDLINE (1970 to June 2009), Ovid CINAHL (1970 to June 2009) and EMBASE (1970 to June 2009) – encompassing Cochrane database of systematic reviews and conference papers.

The following search strategy was used by the author to search CINAHL and was modified as necessary for MEDLINE and EMBASE:

- (1) compliance.mp. (mp = title, subject heading word, abstract, instrumentation)
- (2) patient compliance/or patient adherence or 'ADHERENCE BEHAVIOR (IOWA NOC)'/
- (3) splint*.mp. or exp Splints/
- (4) orthosis.mp. or exp Orthoses/
- (5) brac*.mp
- (6) hand*mp or wrist* or finger* or thumb* or elbow*mp
- (7) 1 or 2
- (8) 3 or 4 or 5
- (9) 6 and 7 and 8.

The search was restricted by age (adults: aged 18 years plus) and date (1970 to June 2009), and publication in English. The reference lists of relevant review articles and all included studies were examined to identify further studies.

Inclusion criteria

Types of studies

Where possible, randomized, quasi-randomized or clinically controlled trials or prospective cohort studies were sought, and then cross-sectional and retrospective studies if the former were not available.

Types of participants

People aged 18 years and over with acute (i.e. <3 months post injury) bone, tendon or nerve injury, including symptoms of newly diagnosed nerve compression injury, of the hand, wrist or forearm.

Types of intervention

All studies that measured adherence with splint or orthosis wear were included. Co-interventions (such as exercise programmes) were allowed.

Exclusion criteria

Studies specifically addressing chronic conditions (such as rheumatoid or osteoarthritis, osteoporosis or chronic tendonitis) were excluded. Case studies were also excluded, as were studies that did not examine reasons for non-adherence. A list of excluded studies is available on request.

Methods of review

After excluding all articles not relating to upper limb injuries in adults, 38 articles were identified by the search strategy, and the title and abstracts of potentially relevant papers were reviewed by the author.

Full text of articles that specifically addressed factors associated with non-adherence with splinting or bracing for acute injuries (i.e. bone, tendon or nerve injury of <3 months since onset) were obtained by the author, and were then evaluated for quality using explicit criteria.

For all included studies, relevant data were extracted by the author into standardized forms to capture the following information: (1) study design, (2) number of subjects and their associated injury/condition, (3) adherence measure used, (4) presence of explicit definitions for adherence, (5) whether a statistical comparison was done between adherent and non-adherent groups and (6) study results.

Data synthesis

Owing to the heterogeneity of studies (differing adherence measures and variables used in analysis), synthesis is narrative rather than quantitative. Statistics are therefore reported as published in the original studies. When reported, the 95% CI is used; if it was not available, a *P* value is reported.

Results

Description of included studies

Six studies involving 490 people and published over a 19-year period (1987–2008) were deemed suitable for inclusion in this review (see Figure 2 for flow diagram of inclusion/exclusion of studies). All papers addressed upper limb splinting. One was a quasi-randomized controlled trial (with participants allocated to groups depending on the last digit of their Social Security number), two were cross-sectional analytic surveys and three were retrospective file reviews. Settings included the USA,^{7,14,25} Europe,¹³ UK²⁶ and Australia.²⁷

Most studies involved people with acute hand injuries or nerve compressions who were living at home and

returning to normal daily living and work; however, data for one study²⁷ was drawn from inpatients with coexisting acute brain injury. Duration of observation varied from 15.4 days (average length of hospital stay in O'Brien and Bailey²⁷) to 12 months¹³ with most being between four and nine weeks. One study did not indicate the duration of observation.¹⁴

The mean age for most participant groups was in the fifth decade, with one study conducted in a veteran's centre having an older group (mean age 60 years),²⁵ another with a mean age of 30 years²⁶ and one failing to describe the total group adequately.¹⁴ Interestingly, most participants were men (234 in total compared with 56 women, or 80% of sample). While this generally reflects the gender split in acute trauma-related hand injuries (68% men in reference²⁸), the study examining adherence in people with carpal tunnel syndrome had a men:women ratio of 16:1, which conflicts with the usual gender pattern of 1:3²⁹ suggesting an unrepresentative sample.

All had reasonably clear criteria for determining adherence with splinting, with half electing a dichotomous (i.e. yes/no) measure and half including grades of adherence (complete, partial, non-adherence).

While most studies conducted a comparative analysis of factors associated with adherent and non-adherent groups, two^{14,25} did not, and one made only passing reference to factors found to be statistically unrelated.⁷ Only two studies used multivariate analysis to examine relationships between adherence and other variables.^{13,27}

Table 1 summarizes the included studies as well as their findings.

Methodological quality

Studies were assessed for quality using the Critical Review Form for Quantitative studies published by McMaster University, Canada.³⁰ This tool was used as it allowed for the differing methodological designs of studies included in this review and it has been used in several allied health evidence reviews.^{31–33} Studies were evaluated using the form, which incorporated the headings shown in Table 2.

Each included study was assessed on whether it met the requirements listed under each criterion. Those requirements that were met were rated as 'yes' and awarded one point. If the requirement was inadequately addressed or completely overlooked, it was given a rating of 'no' and received no points. For headings that were inappropriate for a particular research design and did not reflect the quality of the article, the 'not applicable (n/a)' option was checked.

The total number of points received by a study (out of a maximum of 15) was then calculated and is represented in Figure 3.

Adherence rates

Most studies found high adherence rates (i.e. 75% or more; mean = 85.17%) with splint wear instructions, with the obvious exception of the study focusing on those with concurrent acute brain injury,²⁷ which found an adherence rate of 60.5%. Sandford *et al.*²⁶ initially reported a very low adherence rate (33%) but this reflected

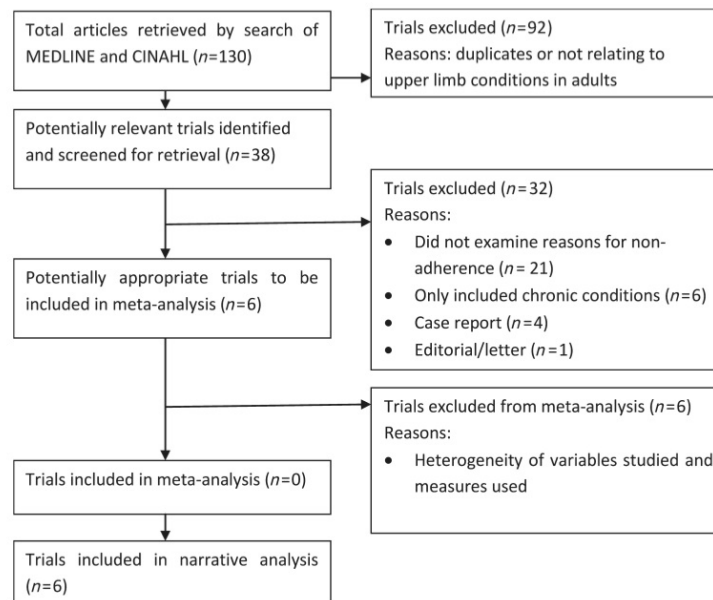


Figure 2 Review flowchart

a very stringent definition (any instance of splint removal over the first 4 weeks counted as non-adherence, whether it be for hygiene, to get dressed or because of discomfort). This was acknowledged in their paper, and using Groth's⁷ definition of 'secondary compliance', they adjusted the figure to 83%.

Factors associated with adherence

Results are presented using the five dimensions of the MAM and are summarized in Table 3.

Social and economic

While Hall¹⁴ concluded that age <27 years, male gender, unemployment, injury sustained in a fight and alcohol consumption at time of injury were significantly associated with non-adherence with splinting in acute hand fractures, no statistics were presented, and there appears to be no between-group comparison for adherent versus non-adherent groups. Numbers were also low in the non-adherent group (only 12 out of 200 participants) so results should be interpreted with caution. Sandford *et al.*²⁶ found a significant correlation for male gender, but results are possibly explained by low numbers of women enrolled in the study (11% of sample).

O'Brien and Bailey²⁷ found no significant correlation for age (OR 1.0 [0.98, 1.03], $P = 0.95$), gender (OR 0.62 [0.14, 2.62], $P = 0.51$), occupation type (OR 0.87 [0.63, 1.21], $P = 0.41$) or race/cultural factors (OR 0.99 [0.31, 3.14], $P = 0.99$). Groth *et al.*⁷ and Sandford *et al.*²⁶ also

found no correlation for age, but neither published their statistical analyses.

Health care and system

This factor was not examined by any of the studies included in this review.

Condition related

Sandford *et al.*²⁶ found no correlation with adherence and injury type (flexor versus extensor tendon) or dominant versus non-dominant-hand injuries. Paternostro-Sluga *et al.*¹³ completed a logistic regression and also found no significant relationship between adherence and diagnosis (type of peripheral nerve injury) or hand dominance. Neither study published specific statistics for non-significant results. No other studies explored the relationship between injury type and severity with adherence.

Treatment related

One study found evidence of a strong association between patient perception of positive effect and adherence with a day-time functional splint²⁵ (OR 54.1 [2.106, ∞]), but this factor was not measured in any other included studies. Sandford *et al.*²⁶ found splint discomfort to be the fourth most common reason for splint removal, and Walker²⁵ noted that one participant did not wear their splint due to interference with work, but neither paper reported specific statistics for these findings.

Table 1 Included studies

Reference	n	Study design	Population	Hand condition	Adherence measure	Adherence definition	Adherence reported	Adherence versus non-adherence analysis	Determinants of non-adherence
Groth <i>et al.</i> ⁷	44	Retrospective file review	Outpatients (age range not stated; mean age 41.7 years). Men: women ratio = 31:13	Mallet finger injury	FTA hand therapy appts, patient self-report of splint wear	Y	75% (including those partially compliant)	Y	None reported (although authors state that age was not significantly related). No statistics on adherence correlates reported
Hall ¹⁴	200	Retrospective file review	Outpatients (age not stated for total group; in non-compliant group: 18–27). Men:women ratio not stated	Metacarpal and phalangeal fractures	Removal of cast or splint prior to physician's decision for discontinuance FTA outpatient/hand therapy appts	Y	94%	N	Sex (men more likely to be non-compliant), age <27 years old, unemployment, injury sustained during a fight, drinking alcohol at the time of injury, no statistics on adherence correlates reported
O'Brien and Bailey ²⁷	71	Retrospective file review	Hospital inpatients with acute TBI (age 20–89; mean 41.1; SD 18.2). Men: women ratio = 61:10	Traumatic upper limb injury	1 or more instances of patient removing splint, or loss/incorrect splint wear	Y	60.5%	Y	Agitation (presence) (OR 0.15 [0.05, 0.44], $P = 0.001$). Agitation (duration) (OR 0.73 [0.6, 0.9], $P = 0.003$). Brain injury severity (PTA duration) (OR 0.94 [0.89, 0.99], $P = 0.04$). PTA status at time of splint application (OR 0.3 [0.09, 0.99], $P = 0.05$)
Paternostro-Sluga (2003) ¹³	78	Cross-sectional analytic survey	Outpatients (age 21–76; mean 48; SD 14.76). Men: women ratio = 55:23	Peripheral nerve injury	Patient report of splint wear via phone questionnaire	Y	85% (day splints). 84% (night splints)	Y	Patient perception of positive effect (OR 54.1 [2.106, ∞], $P < 0.016$)

(Continued)

Table 1 (Continued)

Reference	n	Study design	Population	Hand condition	Adherence measure	Adherence definition	Adherence reported	Adherence versus non-adherence analysis	Determinants of non-adherence
Sandford <i>et al.</i> ²⁶	76	Cross-sectional analytic survey	Outpatients (age range 17–66; mean age 30 years; SD 11.5). Men: women ratio = 67:9	Surgically repaired tendon injury	Patient report of splint removal via written questionnaire	Y	83% (including those partially compliant)	Y	Gender (men more likely to be non-compliant), $P = 0.002$ Reasons for splint removal: 1. Wash hand 2. Dressing 3. Have bath/shower 4. Discomfort
Walker <i>et al.</i> ²⁵	21	Quasi-randomized controlled trial (group 1: full time splint wear, group 2: night-time splint wear)	Outpatients (age range 44–81; mean age 60; SD 11.20). Men: women ratio = 20:1	Untreated newly diagnosed carpal tunnel syndrome	Patient report of splint wear via written questionnaire	Y	Group 1: night adherence: 100%; day adherence: 100% (including those partially compliant). Group 2: night adherence: 85%	N	Interference with job performance in one participant. No statistics on adherence correlates reported

FTA, failure to attend; appts, appointments; TBI, traumatic brain injury; OR, odds ratio; PTA, post-traumatic amnesia; ∞, infinity

Table 2 McMaster critical appraisal scoring system

	Maximum score
Study purpose	1
Literature	1
Design	1
Sample	2
Outcomes	2
Interventions	3
Results	4
Conclusions	1
Total	15

Patient-related

This dimension includes such factors as physical sensory or cognitive impairment, psychological factors, such as low motivation, lack of understanding of the condition (and/or the need for treatment), beliefs about side-effects, stress and negative views about medicine. Only one study²⁷ collected data on patient factors, finding that duration of post-traumatic amnesia (an index of brain injury severity) (OR 0.94 [0.89, 0.99], $P = 0.04$) and the presence (OR 0.15 [0.05, 0.44], $P = 0.001$) and duration of agitation (OR 0.73 [0.60, 0.90], $P = 0.003$) were significantly associated with non-adherence.

Discussion

Although the literature shows that social and economic factors in general are not consistently associated with adherence rates, some such as race (and cultural beliefs), poverty, illiteracy, unemployment, lack of social supports, distance from treatment outlet, family dysfunction, cost of travel/treatment and age have shown relationship with adherence to long-term therapies.⁵ While age was found to be a significant factor in one study in this review,¹⁴ it was considered to be of poor quality and highly susceptible to bias. Three other studies found no relationship with age^{7,26,27} suggesting that this is unlikely to be a predictive factor.

In this review, only one study²⁷ included education and occupation type in their analysis, but found no significant correlation. The literature on the impact of the person's level of education on therapy adherence in general is equivocal; Groth *et al.*³⁴ stated that more literate people were more likely to understand their condition and hence

comply with treatment,³⁴ whereas Sluijs *et al.*³⁵ found highly educated patients to be more likely to be non-compliant with home exercise programmes, but did not speculate on why this was so.

One study in this review¹⁴ found a link between unemployment and non-adherence but, as stated previously, concerns about quality make it a poor source of evidence.

No studies in this review examined factors related to the health-care team and system. This may be an important gap, as there is some evidence that a good patient-provider relationship can improve splint adherence in chronic conditions,^{24,36} and positive feedback from the therapist can improve exercise adherence in acute conditions.³⁵ There is relatively little research into factors that can have a negative effect, such as poorly developed services, overworked and poorly trained health-care providers and lack of continuity of care.⁵

Condition-related factors include severity of symptoms, level of disability, prognosis, rate of progression and the availability of effective treatment. This review found similar adherence rates in patients with acute tendon and bony injury. This is not surprising given that these conditions will result in similar levels of short-term disability and overall would have the expectation of a good return to function. Interestingly, the study that focused on nerve repairs (which have a longer recovery time and a lower likelihood of a full recovery) also had a similar adherence rate.

The treatment-related dimension includes complexity, duration, immediacy of benefit, interference with lifestyle, side-effects and frequent changes to treatment pathways. It also encompasses the availability of support to deal with the above factors.

One study¹³ found that immediate benefit from wearing the splint was the only factor significantly associated with splint adherence, concluding that this highlights the need for good patient education: 'the better an individual is informed of the potential positive effect, the better it will be realized' (p. 93).

Ensuring splints are comfortable and aesthetically acceptable to the patient is also a key issue, but was examined by only one of the included studies²⁶ who found 'discomfort' was one of the four most common reasons for splint removal. Previous research has found that splint comfort^{37,38} and the visual appearance (and visibility to others) of the splint is important to the wearer and can influence adherence.^{19,39,40} For example, a

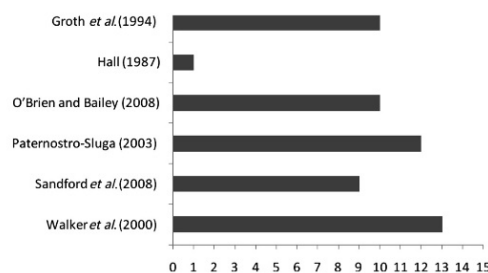
**Figure 3** Quality appraisal scores for included studies (maximum = 15)

Table 3 Overview of factors associated with non-adherence to therapeutic splint wear in adults with acute upper limb injuries using World Health Organization's Multidimensional Adherence Model

Dimension	Variable	Associated with non-adherence	Associated with adherence	No association
Social and economic	• Age	Hall ¹⁴		O'Brien and Bailey, ²⁷ Groth <i>et al.</i> , ⁷ Sandford ²⁶
	• Male gender	Hall ¹⁴ Sandford ²⁶		O'Brien and Bailey ²⁷
	• Ethnicity			O'Brien and Bailey ²⁷
	• Employment status	Hall ¹⁴		O'Brien and Bailey ²⁷
	• Family/social dysfunction	Hall ¹⁴		O'Brien and Bailey ²⁷
	• Drug/alcohol issues	Hall ¹⁴		O'Brien and Bailey ²⁷
	• Education level			O'Brien and Bailey ²⁷
Health-care team and system	• Patient-provider relationship	No studies examined this dimension		
	• Follow-up length			
Condition related	• Type of injury			Sandford ²⁶ (flexor versus extensor tendon)
	• Prognosis	No studies examined this variable		
	• Co-morbidities (psychiatric illness, previous brain injury)			
Therapy related	• Complexity, duration of treatment	No studies examined these variables Walker ²⁵ Sandford ²⁶		
	• Interference with lifestyle/activities of daily living/work			
	• Immediacy of benefit		Paternostro-Sluga ¹³	
	• Discomfort	Sandford ²⁶		
Patient related	• Physical factors	No studies examined these variables O'Brien and Bailey ²⁷		
	• Cognitive impairment (including agitation, presence and duration of post-traumatic amnesia)			
	• Psychological factors (e.g. low motivation, lack of understanding of the condition)	No studies examined these variables		

modified splint for axilla burns in Indian population claimed that it had greater patient acceptance due to 'aesthetic appeal over the currently available aeroplane splints, as this could be worn comfortably within one's garment'¹⁹ (p. 502).

The patient-related dimension includes physical, sensory and psychological aspects of the patient. In this review, one study of people postbrain injury²⁷ showed lower rates of adherence with splinting than all other studies (60.5% compared with overall mean of 85.17%). Even in the absence of an identified cognitive impairment, however, it is important to recognize the patient's ability to understand and remember hand therapy instructions.⁴¹⁻⁴³ One study (not included in this review) followed 28 unimpaired patients postflexor-tendon repair⁴² and found that only 42.5% recalled instructions (including 'do not remove your splint') without the need for a cue. Another author (an experienced hand therapy practitioner) recommends the use of the mini-mental status examination with elderly clients to determine if memory problems exist so that the therapeutic approach can be amended as necessary.⁴¹

Patient beliefs and attitudes about their condition (particularly their own power to influence the outcome) have been found to have an effect on adherence in chronic conditions,^{35,44} but were not examined by any studies in this review.

Prevalence of non-adherence

Most estimates of non-adherence with medical or therapeutic treatment range from 30% to 60%⁴⁵ with a high degree of variability depending on the type of treatment. Non-adherence is reportedly rare in treatments for acute-onset conditions requiring direct medication, high supervision and monitoring (e.g. chemotherapy for cancer)¹ and higher in chronic disorders where there is little discomfort or perceived risk from the disorder, and where lifestyle changes are required.

Acute versus chronic condition adherence rates

This review found higher overall rates of splint adherence in acute injuries ($\geq 75\%$) than the comparable literature for chronic conditions such as rheumatoid arthritis (rates of 25-65%),^{23,24} which parallels the evidence on adherence with prescription medicine in acute versus chronic illness.^{1,5} The difference may be partly explained by the fact that splinting for chronic conditions is mainly for palliative purposes, so there are no immediate perceived dangers associated with non-adherence as there are in acute injuries.

This is also consistent with findings in adherence studies examining other aspects of therapy. For example, a study examining a multidisciplinary pain management programme for people with chronic pain found that only 12% adhered to the full programme.⁴⁶ Chronic conditions may also be often associated with co-morbidities such as depression and substance abuse, and these play an important role in modifying the individual's ability to adhere to treatment.

Limitations of this review

This review was completed by a sole author, so there is the possibility of bias in the inclusion and exclusion of studies, and in the quality ratings given to studies. In addition, grey literature sources such as registers of clinical trials and dissertations were not searched. Finally, the included studies did not use comparable adherence measures or variables, limiting the possibilities for pooling data.

Methodological barriers to the study of adherence

Published prevalence figures must be interpreted with caution as adherence is a construct that is difficult to measure for several reasons. Firstly, many studies of adherence are reliant on the patient's self-report and patients may be unwilling to admit non-adherence.¹ There may be selection bias in many studies of adherence, as respondents are by definition compliant with requests for information and may be unrepresentative of the typical patient population. There is also the potential for performance bias; patients' behaviour may change if they know their adherence is being monitored. One way researchers are attempting to limit the reliance on patient report is to embed sensors in the splint or brace that can accurately calculate hours of wear and/or exercises performed while wearing the splint^{6,47} although this method is still rarely used in hand splinting.

Secondly, adherence is conceptualized, defined and measured differently by researchers. Adherence tends to be treated as a dichotomous variable when there are, in effect, varying levels of non-adherence which may span from (a) never-adhered to any aspect of treatment; (b) adhered to some but not to other aspects; to (c) initially adhered but relapsed over time. One definition of non-adherence that may be clinically useful is 'The point at which the desired preventive or desired therapeutic result is unlikely to be achieved' (Gordis, 1976 in reference¹, p. 31).

Finally, adherence can be context-dependent. A person may manage well when surrounded by cues and reminders (for example, during their inpatient hospital stay) but may lose motivation or forget to adhere to their therapy programme when they return home.

Conclusions

It is established that poor adherence to splinting leads to worse outcomes for the patient and increasing costs to the

health-care system.^{2,4} We also know that adherence is an important modifier of treatment effectiveness.⁵

Implications for research

Many studies of splinting adherence in people with musculoskeletal injuries have a number of limitations that reduce the usefulness of their findings. These limitations include the failure to use multivariate analytic methods to study factors associated with adherence and the failure to use a theoretical model to select the variables measured. Future research should be designed according to an established and validated adherence model and analysed using multivariate analysis.

To be of best value to practitioners, it is recommended that specific data be collected on socioeconomic variables (see Table 3), distance from treatment centre, length of follow-up, continuity of care (e.g. did the same therapist provide treatment or were there multiple therapists involved?) and patient ratings of complexity of treatment regimen, patient-therapist relationship and interference with lifestyle/activities of daily living/work. Measures of adherence should include length of time the splint was worn (as a percentage of recommended wear time) as well as number of therapy sessions attended (as percentage of number scheduled). Options for recording splint wear time objectively include embedded sensors. Where this is impractical, separate splint wear diaries completed by the patient and their partner/carer may yield a more accurate measure of splint adherence.

Implications for practice

This review found no consistent relationship between splint adherence and socioeconomic and condition-related factors, suggesting that there is little to be gained from adapting treatment based on these variables in isolation. It is vital that patients are supported throughout their therapy, and not blamed for fluctuating or poor adherence.⁵

There was some evidence that treatment/therapy-related factors such as immediacy of benefit, splint comfort, and minimizing interference with lifestyle and daily living activities can improve splint adherence.

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Competing interests: None declared.

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3.3 Impact of the study

Journal Metrics: None listed

As a result of this study, the hand therapy team have increased the emphasis on minimising impact on lifestyle and daily living. For example, materials such as neoprene, which is softer and more comfortable than thermoplastic, are used more frequently when total immobilisation is not required. Also, additional written resources for patients have been produced which give examples of how daily living tasks can be modified or made easier with commonly available items, such as well designed kitchen implements with ergonomic grips.

3.4 Chapter Summary

In the previous chapter, the literature on adherence models was discussed, and the MAM was chosen as a key framework for this thesis. This paper specifically applies the model to published studies of adults with acute hand injuries that include a measure of treatment adherence. Six eligible trials were identified from searches of MEDLINE, CINAHL (to October 2008), reference lists of articles, and relevant reviews.

As studies varied widely in measurement of adherence, a quantitative synthesis with pooling of results was not possible. Most studies were also of limited methodological quality.

Key findings were:

- Overall rates of splint adherence in acute injuries ($\geq 75\%$) were higher than the comparable literature for chronic conditions such as rheumatoid arthritis (25-65%);
- There was no consistent correlation between adherence and social and economic factors such as age, gender, ethnicity and employment status;
- No studies examined the influence of health care system factors on adherence;
- For condition-related factors, no correlation was found with adherence and injury type, although studies measuring these variables were limited;
- There was some evidence that treatment/therapy-related factors such as immediacy of benefit, splint comfort, and minimising interference with lifestyle and daily living activities can improve splint adherence; and
- For patient-related factors, one study found a correlation with patient perception of positive effect, and one found negative correlations with agitation and brain injury severity (N.B. this paper was completed as part of this candidacy, and is presented in Chapter 4).

In summary, this is a field with little published high quality evidence, and future research should measure adherence relationships with socio-economic, health care system, therapy-related, condition-related, and patient-related characteristics.

The following chapters seek to apply specific components of this model to several patient groups who have been identified by hand therapy colleagues at the Alfred Hospital as particularly challenging to treat due to issues of splint and/or therapy non-adherence. The first of these will examine hand therapy compliance in people with co-existing acute traumatic brain injuries.

Chapter 4 – Determinants of Compliance with Hand Splinting In an Acute Brain Injured Population

Chapter 4

Determinants of Compliance with Hand Splinting In an Acute Brain

Injured Population

4.1 Introduction

Chapter three systematically reviewed the existing acute hand therapy literature to identify key factors that could influence patient adherence with splint wear in acute upper limb injury. It built on Chapter 2 by grouping and discussing these factors using the MAM. This and subsequent chapters aim to apply specific components of this model to several patient groups who have been identified by hand therapy colleagues at The Alfred Hospital as particularly challenging to treat due to issues of non-adherence.

This chapter specifically explores the incidence, and predictors of, splint non-compliance in people with concurrent acute brain injuries. In this instance, the term *compliance* is used as it cannot be assumed that individuals had the capacity to understand and agree to their treatment regimen during the acute phase of their brain injury.

4.2 Chapter Contents

O'Brien, L and Bailey, M (2008) Determinants Of Compliance With Hand Splinting In An Acute Brain Injured Population. *Brain Injury*, 22(5): 411-18

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Date of publication in hard copy: May 2008

This paper aimed to identify key predictors of splint non-compliance in people who had acute Traumatic Brain Injury (TBI) as well as hand injuries. Prior to this study, Occupational Therapists (OT's) working in neuro-trauma at The Alfred Hospital used Post Traumatic Amnesia (PTA) status to determine when to remove the plaster cast and commence active hand therapy (including the removable splints) for patients with TBI and concomitant hand injuries. They expressed concern that they might be impeding patient recovery by delaying splinting and mobilisation until patients had emerged from PTA, but needed to balance this with managing the risk of the patient removing the splint and potentially injuring their hand further.

Monash University

Declaration for Thesis Chapter Four

Declaration by candidate

In the case of Chapter Four, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Concept development, literature review, ethics application, data collection, writing and submission of manuscript	85%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	Nature of contribution	Extent of contribution (%) for student co-authors only
Michael Bailey	Statistical analysis	15%

Candidate's
Signature

	Date
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Declaration by co-authors

The undersigned hereby certify that:

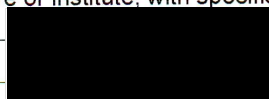
- (1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
- (2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
- (3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
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- (5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
- (6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)

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Determinants of compliance with hand splinting in an acute brain injured population

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Abstract

Purpose: Poor compliance with hand splinting treatment in the acute injury stage increases the risk of ongoing disability by affecting recovery and functioning. The aims of this study were to identify key predictors of splinting non-compliance in acute traumatic brain injury (TBI) patients and to determine the suitability of the Westmead PTA scale for predicting splinting compliance in TBI.

Method: Retrospective medical record review of all patients who were (1) admitted to a major adult trauma hospital in 2005–2006 and (2) flagged as having concurrent brain and upper limb injuries. Data extracted included demographic information, co-morbidity, injury mechanism, TBI severity, incidence and duration of agitation. Compliance data included loss, removal or agitation with the splint or brace.

Results: Of the 71 subjects, 39.5% ($n=28$) were non-compliant with their splint or brace; 60.5% ($n=43$) were compliant. The presence and duration of agitation were the strongest predictors of non-compliance with splinting ($p=0.001$ and $p=0.003$, respectively).

Conclusion: PTA status at splint application does not accurately predict compliance with splinting. This highlights a specific clinical gap in the management of hand injuries against a background of agitation and cognitive impairment.

Keywords: Traumatic brain injury, therapy, compliance, acute care, agitation, post traumatic amnesia, Westmead PTA scale

Introduction

In acute health-care settings, poor compliance of consumers with treatment and therapy can increase the costs of hospitalization by increasing the need for medical services, nursing and allied health support and extending the length of stay [1–3]. Poor compliance (or adherence) can have longer term effects on recovery and functioning, unnecessarily increasing the risk of ongoing disability and decreased labour productivity [2].

The patient's cognitive status is a key determinant of compliance with treatment [4] and is of particular interest in an acute treatment setting, where patients may sustain multiple injuries, including traumatic

brain injury (TBI). Most commonly this is the result of road, workplace or home accidents and assaults. Brain injury is often associated with neurobehavioural and cognitive sequelae which can impact on the person's ability to engage in their therapy programme [5, 6].

In larger acute hospitals, patients with TBI who also sustain upper limb injuries are referred to a Hand Therapist (usually a specialist Occupational Therapist or Physiotherapist) for management of the injury in the acute stage. In this institution, as probably in many others, it is accepted practice to remove the plaster of paris (POP) casts or backslabs and fabricate a thermoplastic hand splint. These are

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custom made to protect healing structures and promote early mobilization (within safe limits), which in turn prevents disuse, tissue wasting, scar adhesions, stiffness and disability [7, 8] whilst allowing the carer to provide basic hand hygiene. Hand therapists therefore rely heavily on the ability of the patient to follow treatment protocols that include strict splint wear and exercise regimes.

There is significant evidence to support early splinting and therapy intervention in traumatic hand injuries [9–11], but commencement for those with co-existing brain injury may be delayed due to concern regarding the patient's cognitive status, agitation and the need to manage risks associated with this. This can lead to poorer long-term functional outcomes and a possible need for secondary surgical procedures to release scar tissue or repair structures that become damaged by unprotected early movement [12–14].

A clear understanding of the factors affecting a person with TBI's readiness to adhere to their hand therapy treatment plan is therefore key to improving the clarity of the clinician's decision-making regarding timing of treatment and thus the quality and effectiveness of care provided.

Determining cognitive readiness for hand splinting

A search of the literature conducted in August 2007 revealed a dearth of publications on the issue of compliance with hand therapy (and splinting in particular) for people with brain injury and subsequent cognitive impairment. There were no journal articles specifically addressing the issue of TBI and hand therapy, although there was one paper on cognitive impairment in the elderly [15] which advocated the use of the Mini-Mental State Examination (MMSE) [16] for assessing this population's ability to remember and follow therapy instructions, which could then guide the style of instruction, intensity of monitoring and clinical decision-making around suitability for elective surgery.

Currently, Occupational Therapists (OT's) working in neuro-trauma at one of the major acute adult trauma hospitals in Australia (The Alfred Hospital, Melbourne) use Post-Traumatic Amnesia (PTA) status to inform clinical decision-making around timing of removal of plaster and commencement of active hand therapy (including removable splints) for patients with TBI and concomitant hand injuries. PTA is defined as 'a general defect of cerebral function after consciousness has been regained' ([17], p. 77) and is usually manifested in patient disorientation and inability to record new memories reliably, but may also appear as impaired attention, slowed information processing and agitation [18]. A patient is deemed to have emerged from PTA when he/she

is fully oriented and displays the capacity to store and retrieve new information.

Assessment of PTA can be difficult [19] and there are few published, standardized tools designed for this purpose, the most commonly used being the Westmead Post-Traumatic Amnesia (PTA) Scale [20] and the Galveston Orientation and Amnesia Test (GOAT) [21]. At The Alfred Hospital, the Westmead scale has been selected as the screening tool for determining PTA status as it has high inter-rater reliability, can be used with minimal training of medical, nursing and therapy staff, is suitable for use in people aged over 7 years [20] and is a valid measure of PTA in severe [22] and mild TBI [18]. It does, however, comprise only orientation and memory items, when a more comprehensive test of PTA should include additional measures of reaction time, visual recognition and speed of information processing [19].

Hand splinting and active mobilization are usually delayed until a patient is deemed to be out of PTA (i.e. scores 12/12 on the Westmead PTA scale for 3 successive days), however plaster casts are sometimes removed by medical staff without consulting the Occupational Therapist, and a splint is required immediately whether or not (in the therapist's judgement) the person is able to inhibit the impulse to remove it. It is worth noting that while the Westmead PTA scale is not designed for the purpose of predicting compliance with therapy, it is seen as the 'best fit' option in the absence of a more specific tool.

Objective

This retrospective study aims to (a) identify key predictors of non-compliance with hand splints (or other protective removable braces) in patients with acute brain injury; and (b) determine whether the Westmead PTA scale is a suitable tool for predicting compliance with splinting (or bracing) in this population.

Method

Participants

The sample included the full medical records of all patients who were (1) admitted to The Alfred hospital (Melbourne) via the Trauma unit in 2005 and 2006 and (2) recorded as having concurrent head and upper limb injuries. No potentially identifying data was extracted and the study was approved by The Alfred Hospital's Human Research and Ethics Committee. The medical records for all cases identified by the trauma unit database for that period ($n=117$) were examined and 71 were eligible for

Table I. Pre-morbid and injury related characteristics of sample.

	Male (<i>n</i> = 61)	Female (<i>n</i> = 10)	Total (<i>n</i> = 71)
Age in years, <i>M</i> (SD)	40.91 (16.8)	54.7 (28.2)	41.1 (18.2)
Marital status			
• Single	14	1	15
• Married/defacto	25	4	29
• Living with parents	14	2	16
• Divorced/widowed	8	3	11
Place of residence			
• Rural	21	6	27
• Urban	34	4	38
• Inner urban	6	0	6
Occupation (ANZSCO skill level)			
• Level 1 (manager/professional)	13	0	13
• Level 2 (manager, technician or health/welfare support worker with diploma or assoc degree)	4	1	5
• Level 3 (trades/technician)	20	0	20
• Level 4 (semi-skilled labourers/machinery operator/driver/shop assistant)	14	3	17
• Level 5 (labourer)	4	0	4
• Unemployed	1	1	2
• Pensioner/retired	4	3	7
• Not recorded	1	2	3
Pre-morbid health			
• Previous ABI	4	0	4
• History of alcohol and/or substance abuse	20	3	23
• History of psychiatric illness	9	5	14
Ethnicity			
• Australian	44	9	53
• European	5	1	6
• Asian	9	0	9
• Not recorded	3	0	3
Mechanism of injury			
• Motor car accident	17	6	23
• Motorcycle accident	18	0	18
• Pedestrian	7	1	8
• Cyclist	6	0	6
• Fall	6	3	9
• Other (assault, explosion, work accident)	7	0	7
TBI severity (GCS score)			
• Severe (3–8)	13	2	15
• Moderate (9–12)	4	0	4
• Mild (13–15)	44	8	52

inclusion in this study. Of the 46 excluded, there were seven deaths, 10 with only superficial injury to the upper limb and/or the head or face and 29 with injuries that did not require the fitting of a removable splint or brace (for example, wrist fractures where standard treatment was a plaster cast).

Summary statistics for the final sample (*n* = 71) are included in Table I.

Data collection

Full medical records were ordered and the lead researcher extracted baseline information, including:

- Demographics (age, sex, marital status, place of residence—coded as rural, urban or inner urban);
- Occupation (coded using the ANZSCO—Australian and New Zealand Standard Classification of Occupations [23]);
- the presence of other health variables (such as psychiatric co-morbidity, previous brain injury, alcohol/substance abuse) as indicated by notes completed by the medical officer;
- mechanism of injury (accidents involving motor vehicle, motorcycle accident or push-bike, pedestrian accident, fall or ‘other’ including assault, horseriding and work accidents and explosions);
- severity of brain injury using lowest Glasgow Coma Scale (GCS) score in the first 24 hours post-injury;
- lobe of the brain injured; and

Table II. Terms used in data collection process [24].

<ul style="list-style-type: none"> • Restless/excessive movement • Pulls at tubes or restraints • Thrashing in bed • Rocking/rubbing/moaning • Wanders • General agitation • Disinhibition • Impulsive/impatient 	<ul style="list-style-type: none"> • Low tolerance to pain/frustration • Irritable • Combative • Uncooperative resistant to care • Verbally aggressive/screams • Aggressive towards others/property • Explosive and/or unpredictable anger • Self abusive, verbal and/or physical 	<ul style="list-style-type: none"> • Sudden changes in mood • Emotional lability • Rapid, loud or excessive talking • Makes unusual noises • Inappropriate verbalizations • Inappropriate gestures • Bizarre behaviour/delusions • Perseveration—motor or verbal
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Table III. Descriptive statistics: differences between compliant and non-compliant groups.

	Compliant (<i>n</i> = 43)	Non-compliant (<i>n</i> = 28)	Odds ratio (95% CI)	<i>p</i>
Agitation noted on record (total/%)	15 (34.8%)	22 (78.5%)	0.15 [0.05, 0.44]	0.001*
Agitation in days (mean/SE)	3.98/0.68	1.18/0.399	0.73 [0.60, 0.90]	0.003*
PTA duration in days (mean/SE)	3.70/1.27	9.25/2.27	0.94 [0.89, 0.99]	0.04*
In PTA at splint application (total/%)	11/22 (50%)	7/30 (23.3%)	0.30 [0.09, 0.99]	0.05*
GCS (mean/SE)	12.53/0.5	10.78/0.8	1.13 [0.94, 1.29]	0.06
Frontal lobe injury (total/%)	9 (20%)	10 (35.7%)	0.48 [0.16, 1.38]	0.17
Gender (M/F)	36 (83.7%)	25 (89.2%)	0.62 [1.14, 2.62]	0.51
Psychiatric History (total/%)	10 (23.2%)	4 (14.2%)	1.82 [0.51, 6.49]	0.36
Alcohol/Substance abuse (total/%)	15 (34.8%)	8 (28.56%)	1.34 [1.48, 3.76]	0.58
Previous ABI (total/%)	2 (4.6%)	2 (7.1%)	0.63 [0.08, 4.78]	0.66
Age (years) (mean/SE)	43.79/2.97	42.78/3.82	1.0 [0.98, 1.03]	0.95

Notes: *Difference between groups is significant at the $p \leq 0.05$ level.

SE = Standard Error; OR = Odds Ratio; CI = Confidence Interval; GCS = Glasgow Coma Scale; PTA = Post-Traumatic Amnesia.

- type of hand injury (e.g. bony, ligamentous, tendon, nerve, skin or soft tissue loss).

Retrospective data for every day of the hospital admission was also extracted on the following items:

- If Plaster of Paris (POP) cast/backslab was applied;
- Days (post-injury) POP removed and thermo-plastic splint fitted;
- PTA status at time of commencement of splinting;
- Number of days the patient displayed two or more signs of agitation in the one day according to notes in the medical file. Terms used were confined to the list of behaviours used for data collection in [24]—see Table II; and
- Whether or not the patient complied with their splinting treatment. Non-compliance was defined as one or more episodes noted in the medical file of self-removal, loss or incorrect wear of splint or unprotected hand movement. For patients who were left in their POP cast and did not receive a splint, self-removal of neck or back braces or bandages was considered an incidence of non-compliance.

Statistical analysis

Descriptive analysis was used to measure the incidence of non-compliance and describe frequency of non-compliant behaviours. Comparisons between

compliant and non-compliant groups were made using chi-square tests for equal proportion, student *t*-tests for normally distributed data and Wilcoxon rank sum tests for non-parametric data. In addition, all variables were further compared using logistic regression, allowing for results to be reported as odds ratios (OR) with a 95% confidence interval (CI). A two-sided *p*-value of 0.05 was considered to be statistically significant.

Results

Descriptive statistics for compliant and non-compliant groups on items agitation (incidence and duration) PTA (duration and status at splint application) GCS, frontal lobe injury and other health variables are presented in Table III.

Incidence of non-compliance

Of the 71 subjects included, 39.5% (*n* = 28) were non-compliant with either their hand splint, back brace or neck brace and 60.5% (*n* = 43) were compliant. Twenty-five of the non-compliant group removed or lost their splint or brace, with 15 of these having multiple occasions of splint/brace removal noted in their files (with seven of these observed to have moved the injured hand without protection of the splint) and 10 patients were agitated by wearing their splint and attempted to remove it. In the latter

instance, the splint was usually bandaged on by the therapist to minimize chances of the patient removing it.

Relationship between non-compliance and other variables

Differences between compliant and non-compliant groups on key variables are shown in Table III. Univariate analysis shows that the presence of agitation is the strongest predictor of non-compliance with splinting ($p=0.001$) with number of days of agitation being the second strongest ($p=0.003$). Accepted indicators of brain injury severity (PTA duration and GCS) had slightly differing results, with PTA duration being a significant predictor ($p=0.04$) and GCS marginally not significant statistically ($p=0.06$). Those patients deemed to be in PTA at the time they received their splint were significantly more likely to be non-compliant ($p=0.05$), although only 50% of those in PTA were non-compliant.

Age, gender, frontal lobe injury and pre-morbid history of psychiatric illness, prior brain injury and alcohol or substance abuse showed no relation to compliance. Urbanicity, ethnicity and occupational category were also not related to compliance.

Multivariate analysis using logistic regression showed that the presence of agitation (OR [95%CI] = 0.153 [0.04; 0.48]; $p=0.001$) and length of stay (0.95 [0.91; 0.99]; $p=0.035$) were the two major predictors of non-compliance.

Incidence and duration of agitation and PTA

Incidence of agitation was 52.1% (37/71) of the total sample which included 78.5% (22/28) of the non-compliant group and 34.8% (15/43) of the compliant group. Duration of agitation was up to 13 days (mean = 3.92 days) in the non-compliant group and 15 days (mean = 1.18 days) in the compliant group.

Thirty-eight of 71 (53.5%) of the total sample had PTA recorded, including 67.8% (19/28) of the non-compliant group and 44.1% (19/43) of the compliant group. Duration of PTA was up to 47 days (mean = 9.25 days) in the non-compliant group and 45 days in the compliant group (mean = 3.7 days).

Overall, where either agitation or PTA were present ($n=48$) PTA outlasted agitation in 29 (60.4%) cases, agitation outlasted PTA in 17 (35.4%) cases and duration of both was equal in two cases.

Relationship between agitation and other variables

Spearman correlation for length of agitation with other variables is shown in Table IV. There was a significant positive relationship with duration of

Table IV. Pearson's correlation between length of agitation and other variables.

	<i>n</i>	<i>r</i>	<i>p</i>
LOC duration (where recorded)	19	0.8	0.0001*
GCS	71	-0.6	0.0001*
PTA duration in days	71	0.48	0.0001*
Compliance with splint	71	-0.4	0.0004*
ANZSCO skill level 5: Labourer	69	0.31	0.0076*
Length of stay	71	0.31	0.0077*
Frontal lobe injury	71	0.3	0.0089*
Australian ethnicity	69	-0.25	0.0364*
Male gender	71	-0.04	0.7
Psychiatric history	71	0.04	0.7
Alcohol/substance abuse	71	-0.07	0.536
Previous ABI	71	-0.03	0.75

Notes: * Correlation is significant at the $p \leq 0.05$ level.

LOC = Loss of Consciousness; GCS = Glasgow Coma Scale score; PTA = Post-Traumatic Amnesia; ANZSCO = Australian and New Zealand Standard Classification of Occupations [15].

loss of consciousness and PTA duration ($p < 0.0001$ for both), compliance with treatment ($p = 0.0004$), belonging to the occupational group of 'labourer' (defined as workers who perform 'a variety of routine and repetitive physical tasks using hand and power tools and machines either as an individual or as part of a team assisting more skilled workers' [23, p. 13]) ($p = 0.0076$), length of stay ($p = 0.007$) and frontal lobe injury ($p = 0.0089$). There were significant negative relationships with GCS ($p < 0.0001$) and being of Australian ethnicity ($p = 0.0364$). This means that the higher the GCS score, the less likely the person was to be agitated, and people who were not of Australian origin were more likely to be agitated. There was no significant relationship with any of the other variables including gender (50% of males and 60% of females in this sample were agitated) age, other co-morbidities, marital status or urbanicity.

Discussion

This study showed that the two most important predictors of non-compliance with hand splinting were the *presence* and *duration* of agitation. This is supported by recent literature [5, 24] which both contend that even sub-clinical agitation (as defined by a cut-off score < 22 in the Agitated Behaviour Scale [25]) has 'a strong inverse relation with the brain-injured patient's engagement in physical and occupational therapies, beyond that accounted for by injury severity' ([5], p. 181). This study also confirmed findings by Lequerica et al. [5] that agitation *can* outlast PTA (or acute period of confusion [APOC]) in contrast to the prior

contention that agitation only occurs during the PTA phase [25, 26].

The incidence of agitation in this sample was 52.1%, which is similar to the 50% found in a similar population [27], but significantly less than another recent Australian sample where the figure for acute patients was 86.3% [24]. This is a large difference, given that this study used the same criteria to code agitation, but is possibly explained by the differences in the sample (Nott et al.'s [24] study was conducted at a specialist brain injury rehabilitation facility and the sample comprised people referred for short- and long-term rehabilitation programmes, whereas this study included ALL people hospitalized with TBI and hand injuries, 44% of whom were discharged home after their acute stay). The figures for agitation sorted by gender (50% of males and 60% of females) were slightly higher than that found in a similar population (41% and 42%, respectively [27]), but this study agreed with their finding of no significant sex difference in incidence of agitation.

The finding on logistic regression that agitation was positively correlated with length of stay is also not unexpected, as agitation has been found in previous research to be associated with increased length of stay as well as reduced cognitive and physical capacity at discharge [28].

While one might expect a pre-morbid history of psychiatric illness or drug and/or alcohol abuse to be positively related to agitation, this study found no significant link. This contrasts with the contention by Fleminger [29, p. 5] that 'alcohol and drug misuse, with craving, intoxication, or a withdrawal syndrome may all exacerbate agitation and aggression'. Interestingly, other studies have also found a relationship between these factors and aggressive behaviour [30], but 'a relationship with agitation is not evident' [24, p. 1176]. It is worth noting that aggression differs from agitation in that 'it is generally observed after brain injury, usually during the later stages of recovery, when the patient is no longer suffering from PTA and has regained cognitive awareness' [31, p. 2], whereas agitation is usually noted in the acute phase of recovery, where it is usually related to PTA [32].

The finding of a significant relationship between length of agitation and frontal lobe injury is supported by studies linking frontal and fronto-temporal lesions to disinhibition, impulsivity, aggression, restlessness and agitation [26, 33]. These are clearly important factors in relation to a person's ability to adhere with their treatment plan and suppress the impulse to remove or tamper with their splint. Interestingly, though, no significant relationship was

found directly between frontal lobe injury and non-compliance ($p=0.17$). This could possibly be explained by the small numbers in this study, as only 19 of the total sample had a frontal lobe injury noted on their file. It is also worth noting that 11 of the frontal lobe group were agitated and eight of this 11 were non-compliant. It thus appears that the combination of frontal lobe injury and agitation increases the likelihood of non-compliance.

In terms of the accepted measures of brain injury severity, stronger support was found for PTA duration as a predictor of non-compliance, with GCS being marginally non-significant statistically. This has parallels with PTA duration's stronger association with radiological measures of brain injury severity and neurobehavioural symptoms than the GCS [34, 35].

Finally, it was found that PTA status at the time of splint application was a statistically *but not clinically* significant predictor of compliance with splinting, as it failed to predict non-compliance in 50% (11/22) of those cases. In addition, 23.3% (7/30) of the compliant group were in PTA at the time they received their splint, so total incorrect predictions made using this tool as a predictor was 34.6% (18/52). It is therefore possible that many patients are not receiving optimal care by either commencing splinting therapy before they are cognitively ready or being unnecessarily held back when they are capable of complying with splinting.

Limitations of this study

As this is a relatively modest sample size ($n=71$) and all subjects were drawn from one urban Australian hospital, results may not necessarily be applicable in other settings. Also, the study design was a retrospective file audit and was thus reliant on accurate and comprehensive note taking by nursing, medical and allied health staff rather than objective measures or scales. Finally, medication to decrease the expression of agitated behaviours was administered in some cases, which may affect the accuracy of the agitation duration scores.

Conclusion

Incidence and duration of agitation were the two strongest predictors of compliance with splinting in this sample. Co-morbidities (such as psychiatric illness, alcohol or substance abuse) exerted no significant influence on compliance in this instance.

The PTA status of the patient at splint application, as assessed using the Westmead PTA scale, had limited utility in predicting compliance with

splinting as only 50% of the non-compliant group were deemed to be in PTA. This is not surprising, given that this scale is not designed for this purpose, but it highlights a specific clinical gap in the management of hand injuries against a background of agitation and reduced cognition.

The identification of reliable predictive criteria which can be considered alongside PTA assessment may lead to the prevention of unnecessary secondary surgical procedures, improved hand function and productivity for the patients, reduction in patient care health-care costs and better continuity of care from the acute phase to the rehabilitation settings. Since bone and joint injuries co-occur frequently with TBI, this may have application to the management of other orthopaedic injuries.

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4.3 Impact of the Study

Journal Metrics:

- Thomson Scientific ISI Web of Knowledge Journal impact factor: 1.533
- Thomson Scientific ISI Web of Knowledge Journal rank:
 - Neurosciences: Q4 (182nd of 231)
 - Rehabilitation: Q2 (16th of 33)
- SCImago Journal Ranking: 0.089
- H Index: 47
- Source Normalized Impact per Paper (SNIP): 0.82

This paper showed that the presence and duration of agitation (even in the absence of PTA) was a stronger predictor of non-adherence than PTA status of the patient at the time of splint application (as assessed using the Westmead PTA scale). We found this scale had

limited utility in predicting compliance with splinting as only 50% of our non-compliant group were deemed to be in PTA. A sensitivity analysis was not done as part of this paper, but is calculated at 23.33% meaning that this test only picks up 23.33% of patients that became non-compliant. This is not surprising, given that the PTA scale was not designed for this purpose, but it highlights a specific clinical gap in the management of hand injuries when patients are agitated or have reduced cognition.

As a result of this study's findings, the Westmead PTA scale is no longer used when determining whether to remove a plaster cast in order to allow controlled mobilisation. Patients' agitation levels over the preceding days are monitored instead, and the hand therapy and trauma clinicians use this to guide clinical reasoning and provision of appropriate treatment intervention.

4.4 Chapter Summary

In the previous chapter, the literature on splinting for acute hand injuries was systematically reviewed, and the MAM was used to group the factors examined in each paper. This retrospective file audit specifically extracted data on 28 factors can be grouped under three of the dimensions of the MAM. These included:

- socio-economic (age, gender, occupation, education, ethnicity, place of residence, family/social dysfunction);

- patient-related (presence and duration of agitation, presence and duration of PTA, cognitive impairment); and
- condition-related (severity of brain injury, lobe of brain injured, type of hand injury, psychiatric co-morbidity, previous brain injury, alcohol/substance abuse).

It concluded that socio-economic factors and most patient-related factors (such as psychiatric illness, alcohol or substance abuse) exerted no significant influence on compliance in this group, thus supporting the WHO's stance that it is a "misconception that adherence is a patient-driven problem".^{2p26} This study provides support for this thesis' contention that ability to follow treatment is impacted by more than one factor, and interventions to improve adherence need to address all relevant factors.

The next chapters continue to explore the particular groups who have been identified by hand therapy colleagues at The Alfred Hospital as particularly challenging to treat due to difficulties in achieving splint and therapy adherence. The first of these examines distraction splinting for intra-articular fractures of the fingers from the patients' point of view. In the following study, the focus is on the "therapy related" dimension of the MAM, i.e. the specific splint and exercise therapy regimen.

Chapter 5 – Patient experience of distraction splinting for complex finger fracture dislocations

Chapter 5

Patient experience of distraction splinting for complex finger fracture dislocations

5.1 Introduction

Chapter 4 aimed to identify key predictive factors that could affect adherence in people with acute brain injury and concurrent hand injuries. It built on Chapter 3 by focusing on a patient group identified by hand therapy colleagues at the Alfred Hospital as being a particularly challenging group to treat due to non-adherence issues.

Complex finger fracture dislocations can severely impact on hand function and are often sustained by young, healthy individuals (in our study the average age was 31.83 years) during participation in sporting activity. Since 2001, the Hand Surgery / Therapy team at the Alfred Hospital has treated these injuries with a swing design dynamic distraction splint (see description in the following journal article) however therapy staff have noted the following challenges to patient adherence:

- Initial application of the rubber bands to the outrigger can be painful, with patient records revealing one person fainted and three became distressed and nauseous subsequent to splint application;

- Some patients have reported difficulty adhering to the required splint wear regimen and hourly mobilisation required of them due to discomfort or difficulty fitting in around daily living activities; and
- Many patients have described the splint as confronting in appearance and some have commented that their families, friends and employers have found the visual appearance of the splint (and visible k-wire/traction) distressing.

5.2 Chapter Contents

O'Brien, L and Presnell, S (2010) Patient experience of distraction splinting for complex finger fracture dislocations. *Journal of Hand Therapy*, 23(3):249-59

Date submitted: 9 November 2009

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Date of acceptance: 25 January 2010

Date of publication in hard copy: July 2010

This study aimed to a) describe patients' own experiences of distraction splinting, and b) identify key issues in patient adherence to their splint-wear and exercise program. To achieve these aims, a qualitative methodology incorporating a phenomenological analysis for the first part and grounded theory design for the second was selected. Semi-structured interviews were conducted as first person accounts can provide the clinician with a richer understanding of the patients' experience of the treatment we provide.

Monash University

Declaration for Thesis Chapter Five

Declaration by candidate

In the case of Chapter Five, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Concept development, literature review, ethics application, securing of funding, data collection, data analysis, writing and submission of manuscript, amendments to manuscript post peer review	75%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	Nature of contribution	Extent of contribution (%) for student co-authors only
Dr Scott Presnell	Data analysis	25%

Candidate's
Signature

	Date 2/2/10
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Declaration by co-authors

The undersigned hereby certify that:

- (1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
- (2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
- (3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (4) there are no other authors of the publication according to these criteria;
- (5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
- (6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s) **La Trobe University, The Alfred Hospital**

[Please note that the location(s) must be institutional in nature, and should be indicated here as a department, centre or institute, with specific campus identification where relevant.]

Signature 1

	Date 2/2/10
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Patient Experience of Distraction Splinting for Complex Finger Fracture Dislocations

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ABSTRACT: The study design is qualitative phenomenological and grounded theory. Intraarticular fractures of the finger joints can severely limit function due to stiffness and pain. Distraction with early movement is thought to deliver the best results and this has been used to treat these types of injuries at The Alfred Hospital for eight years. Qualitative data from patient interviews were used to describe patients' own experiences of treatment with distraction splinting and identify key issues in patient adherence. The key finding was a disconnect between perceived complexity of injury and treatment. Those who adhered with the treatment regime felt that they were well informed of the reasoning behind it. The hand surgery and therapy team must be aware of the patient experience of complex finger injuries and should ensure patients are well supported with education about their injury and treatment. Early preemptive pain control may help optimize adherence to the splint and exercise regime. Findings can be applied to other acute conditions requiring cumbersome splinting and potentially uncomfortable early exercise routines.

J HAND THER. 2010;23:249–60.

The terms “adherence” and “compliance” are often used interchangeably in the medical and therapeutic literature but have different connotations and inferences, mainly in the patient's role. *Compliance* is the “extent to which patients obey and follow instructions, prescriptions, and proscriptions outlined by their treating health practitioner;”^{1p20} *Adherence* implies an “active, voluntary, and collaborative involvement by the patient in a mutually acceptable course of behavior to produce a preventative or therapeutic result.”^{1p20} The problem of nonadherence applies to all medical and therapeutic interventions, and although it is a topic of concern for hand therapists, it is surprisingly underresearched “given the degree to which

hand therapists rely on patients to follow strict exercise and splint regimens.”^{2p31}

Research on adherence from the patient's perspective is particularly lacking in the hand therapy literature, despite the fact that a 2002 study of therapist and patient perceptions of compliance with hand therapy² found that most therapists perceived noncompliance as a mostly patient-driven problem, drawing parallels with a study of physicians in 1966,³ who viewed it as “reflecting attitudes of the patient, such as ignorance or forgetfulness.”^{2p37} This simplistic view is not supported by evidence,⁴ with newer models of adherence encompassing additional influences, such as socioeconomic, health care system, and condition- and therapy-related factors.^{1,4} For example, splint comfort and aesthetics are clearly important to patients, with one recent study⁵ finding that discomfort was one of the four most common reasons for splint removal, and previous research demonstrating that splint comfort^{6,7} and the visual appearance (and visibility to others) have a direct influence on adherence.^{8–10}

This study focuses on the patient experience of distraction splinting for intraarticular finger fractures and the factors that influence treatment adherence to add to the body of knowledge and to maximize patient outcomes. The findings, however, can be

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I certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on myself or on any organization with which I am associated.

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applied more widely to adherence with any cumbersome splint and early mobilization program, especially in the case of painful acute injuries.

Aims of this study are:

1. to describe patients' experiences of distraction splinting; and
2. to identify key issues in patient adherence to their splint wear and exercise program.

To achieve this, we chose a qualitative methodology (phenomenological analysis for the first part and grounded theory design for the second) as first person accounts can provide the clinician with a richer understanding of the patient experience of the treatment we provide.

BACKGROUND

Intraarticular fracture dislocations of the finger are potentially the most severe injuries to the finger.¹¹ They can severely impact on hand function due to stiffness, pain, and traumatic arthritis,^{12,13} and there is no consensus regarding optimal treatment.^{14,15} These injuries are usually caused by a direct blow applied to the fingertip (e.g., in falls onto the finger or when trying to catch a fast-moving ball) resulting in hyperextension and axial loading of the proximal interphalangeal joint.¹⁶ Unstable finger joint dislocations, and those with significant comminution or fragment displacement, are very difficult to treat and usually require surgery.¹³ Surgical options include internal fixation (e.g., screws into fracture fragments, with or without bone grafts); percutaneous Kirschner wire (K-wire) fixation;¹⁷ or external fixation and traction.^{14,15} Traction works to reduce the fracture by capsuloligamentotaxis and prevents shortening of collateral ligaments. Movement minimizes adhesions in and around the joint and promotes cartilage healing.¹⁵

Since 2001, a dorsally based swing design dynamic distraction splint has been used to treat these types of injuries at The Alfred Hospital in Melbourne, Australia (see Figure 1). This splint has a thermoplastic forearm/hand component with a movable hinged outrigger attached at the level of the injured joint. The outrigger is covered at the distal end with thermoplastic material in which two dressmaker's hooks are embedded. After surgical placement of a K-wire transversely through the bone distal to the injured joint, the splint is applied to the forearm and hand, with rubber bands attaching the K-wire to the hooks in the outrigger, thus providing a distraction force. The splint is worn continuously by the patient for up to six weeks, and patients are instructed to commence hourly passive mobilization of the injured joint (10 repetitions of up to 45 degrees of motion in the first week) immediately postsurgery.

Anecdotally, hand therapy staff at The Alfred Hospital have noted that most patients have found



FIGURE 1. Patient with dorsal swing design dynamic distraction splint for PIP joint injury. PIP = proximal interphalangeal joint.

the initial application of the rubber bands to the outrigger to be painful, with reports of one person fainting and three becoming distressed and nauseous after splint application. Five patients have also reported difficulty adhering to the required splint regimen and hourly mobilization required of them. Almost all patients have described the splint as confronting in appearance and some have commented that their families, friends, and employers have found the visual appearance of the splint (and visible K-wire/traction) distressing.

LITERATURE REVIEW

Distraction Splints

Several different types of distraction devices that allow movement at the affected finger joint have been described in the literature. As this article is particularly interested in those designs that include a forearm component, we will limit our discussion to these. Traction fixation was pioneered by Robertson et al. in 1946¹⁸ with the "banjo" splint. This was a static

traction device with three points of axial traction around a circular frame attached to a plaster forearm/hand splint. This design was modified by Schenck¹⁹ in 1987. Morgan et al.,²⁰ in a series of 14 cases using this system, found that most of the patients were "very compliant" and achieved good results but stated that "the majority of patients were inconvenienced by the device, felt it to be awkward, and had some difficulties with their usual activities of daily living" (p 569). They also noted that patients found the exercise regime to be quite painful initially.

In 1992, Dennys et al.²¹ described a dorsal approach splint that allowed the patient to *actively* bend the affected finger. They compared the splint to the Banjo splint, describing theirs as more compact and interfering less with patients' activities of daily living (ADL). Murray and McIntyre¹² used a similar dorsal design incorporating active mobilization, stating that it differed from the Schenck design by allowing "active joint mobilization by the patient in a technique that we believe leads to improved patient compliance" (p 17). They stated that their splint was "very small," thus minimally impacting on daily routine, allowing for "easy compliance and pain-free rehabilitation" (p 17). This design is the most similar to the one used by participants in the present study.

Emotional Impact of Hand Injuries

Several recent studies have focused on the emotional impact of acute hand injuries. Although many of these studies have focused on severe or mutilating injuries (such as amputations) there are nonetheless some findings that are relevant to the present investigation.

A longitudinal qualitative study of people with work-related hand injuries²² found that traumatic stress symptoms and anxiety were most common in the early stage of recovery, suggesting that the time immediately after injury is when the patient's need for support is highest. A qualitative study of 20 patients in Sweden who had acute traumatic hand injuries²³ aimed to identify stress factors in the very early stages postinjury (i.e., from the day of injury to the first follow-up visit) via semi-structured interviews. Stress factors, defined as "circumstances that the ... patients experienced as problems in the actual situation" (p 1334), included problems with ADL, uncertainty about future function, being dependent on others, pain, the trauma experience itself, and the appearance of the injured hand at the time of the accident or when it was being treated in the emergency department.

A further descriptive cross-sectional study of 112 Swedish adults with acute hand trauma was reported by Gustafsson et al. in 2003.²⁴ Using a logistic regression analysis, the factors most closely associated with emotional distress in the early stages after hand injury

were negative reactions to the sight of the hand, the need for help with ADL, and "troublesome" pain.

A holistic conceptual pain model was proposed by Dr. Paul Brand, a leading orthopedic hand surgeon and published in 1993 with Paul Yancey.²⁵ This model identifies three levels of pain experience: signal (detection of danger by the nerve endings), message (coding of signals by the spinal cord and brainstem as a message to the brain), and responses (where pain is experienced on a cognitive and emotional level by the individual). The individual's responses are influenced by past experiences and cultural factors, which shape the meaning of pain.²⁶ Brand argued that documentation at each of these levels of pain requires a different method. For example, a Visual Analog Scale (VAS) measures the pain experience at the *signal* level, and the Disabilities of Arm, Shoulder, and Hand (DASH²⁷) questionnaire measures the *message* level, but the *response* level, incorporating personal and cultural meanings, is best described using qualitative sources. A mixed-methods (i.e., incorporating qualitative and quantitative data) study of people with acute hand injuries²⁶ drew on this model to explain patient progress postinjury and to correlate pain intensity (measured by VAS) with function (measured by DASH, grip strength, Short Form-36 [SF-36] physical health scores and mental health scores) for more than six months. They found strong correlations between pain and functioning measures at one month, with fewer at three months. At six months, the only statistically significant correlation was between pain and the social functioning scale of the SF-36. Qualitative interviews of adaptation to pain found that people who had a complicated progression postinjury and reported ongoing pain and disability tended to be more reliant on "formal external services, including both medical and benefit systems" (p 434) than those who progressed in a more straightforward manner.

METHODOLOGY

Participants and Design

As we were seeking to capture the meaning and common features of the patients' experience of distraction splinting, and to identify key predictors of adherence with this treatment, we used a qualitative design using phenomenological and grounded theory's content analysis methods.²⁸ Participants were recruited from a larger study examining long-term outcomes from intraarticular injuries of the finger. Selection criteria for the study included adults who could speak English, were able to give informed consent, and who had sustained an intraarticular finger fracture within the previous eight years that was treated with distraction splinting at The Alfred Hospital. All patients who met these criteria

TABLE 1. Participant Demographics

Patient	Gender	Age	Injury to Dominant Hand	Finger	Joint	Years postinjury	Mechanism	Occupation
A	F	39	No	5	PIP	2.2	Fall	Professional
B	F	28	No	4	DIP	2.7	Crush	Community/personal service
C	F	24	Yes	5	DIP	3.0	Bicycle accident	University student
D	M	24	Yes	5	PIP	2.7	Ball sport	Sales
E	M	50	No	4	PIP	2.4	Fall	Manager
F	M	26	No	2	PIP	2.5	Ball sport	Professional
G	M	32	No	5	PIP	1.7	Ball sport	Manager
H	F	30	No	4	PIP	7.8	Ball sport	Clerical
I	M	42	Yes	4	PIP	2.6	Ball sport	Trade
J	F	32	Yes	5	PIP	3.7	Stub	Clerical
K	M	27	No	4	PIP	2.6	Fall	Professional
L	F	28	Yes	3	PIP	0.2	Bicycle accident	Sales

M = male; F = female; Finger: 2 = index, 3 = middle, 4 = ring, 5 = little, PIP = proximal interphalangeal joint; DIP = distal interphalangeal joint.

($N = 18$) were identified from the hospital database, contacted by mail, and invited to participate. Follow-up telephone calls were made to discuss the aims of the study and to schedule interview times. Data collection commenced in April 2009 and was finished in July 2009, when data saturation of thematic content had been achieved according to consensus agreement by the researchers involved in the data analysis.²⁹ Descriptions of participant demographics, injury mechanism, time since injury, and current work status are summarized in Table 1. To maintain participant anonymity, each person is denoted by a letter from A to L.

Data Collection

Twelve participants were interviewed by the first author (L.O.B.), using a semi-structured interview schedule developed for this study. Questions were designed to elicit responses that explored the participants' thoughts and feelings about their injury, their experience of distraction treatment, including their preparedness for it, and the reactions of their friends, family, and colleagues to the physical appearance of the splint. Interview questions are summarized in Table 2.

All but two interviews were completed in the hand therapy department of the hospital; one was completed via phone as the participant had moved interstate, and the other was completed in the participant's home. Interviews were recorded using a digital voice recorder and transcribed verbatim for analysis by a transcriber who was blinded to the participant's identity. All transcriptions were checked for accuracy by the first author (LOB).

Ethical Considerations

Informed consent was obtained in writing before the interview was conducted. Participants were informed before the interview about how data would be analyzed and were assured of its confidentiality. The study was approved by the Human Research and

Ethics Committees of Monash University and The Alfred Hospital.

Data Analysis

Two parallel analytical strategies were used for all analysis of interview transcripts, both modeled on the methodology detailed by Starks and Trinidad.²⁸ The first author (LOB) conducted a manual analysis and developed preliminary findings. Transcripts were also entered into a computer data management program (*nVIVO Version 2.0*; QSR International, Melbourne, VIC, Australia) and were independently analyzed by the second author (S.P.).

For the phenomenological component of this study, a systematic process for coding data (as described by Starks and Trinidad²⁸) was used in which specific statements were analyzed and categorized into clusters of meaning that represented a phenomenon of interest. To develop an explanatory framework for predicting treatment adherence, grounded theory's method of comparison using three stages of coding was used.³⁰ The first stage involved open coding: examining and comparing data, then developing coding categories that reflected the content of the data collected. The data were then reassembled into groupings based on patterns and relationships between the categories and patient report of adherence to treatment (axial coding). Finally, the central or core category was identified and described. The themes, patterns, categories, descriptive examples, and quotations identified through the analysis formed the basis of the interpretation of the findings. An example of the coding process is shown in Figure 2.

For both analyses, the authors compared emergent themes and categories to review thematic and conceptual consistency, and any disagreements were resolved by consensus moderation. To ensure trustworthiness of the results, the researchers also "member checked" the emerging themes and categories with two of the interviewees to ensure that the interpretation of the findings were an accurate

TABLE 2. Semi-structured Interview Questions

Question	
1	Tell me about your finger injury and your initial thoughts when it happened
2	What were you expecting in terms of treatment? (e.g., medical, therapy, surgery, cast/splint)
3	How/when was distraction treatment (splint and exercises) explained to you, and did you find the explanation understandable and clear?
4	Tell me about your first impressions/feelings regarding the splint
5	How did your family/friends/colleagues react to your splint?
6	How well prepared were you for the splint and exercise program?
7	Were you able to do the exercises given to you?
8	Were there some things that helped you get used to wearing the splint/doing the exercises?
9	Were there any things that you found did NOT help?
10	Overall, what are your thoughts regarding this treatment now?
11	Are there any other comments you would like to make?

representation of the participants' accounts of their experience.

RESULTS

Twelve participants (six male; six female) with an average age of 31.83 years and an average time since injury of 2.84 years took part in this study. The most common mechanism of injury was trauma associated with participation in ball sports. All participants had returned to either full-time work or study at the time of interview.

During the analysis process and the search for essential meaning, several key phenomena were

found across the 12 interviews, and these are both summarized in Table 3 and discussed below.

The Major theme identified from the data was *Disconnect between perceived complexity of injury and treatment*. Three further subthemes were also identified—*Unexpected levels of pain, self efficacy and Outcome expectancies*, and *Splint discomfort: aesthetic, physical, and functional*.

In this section, the themes are described and further illustrated by participant quotations selected to describe the shared experiences of the respondents.

Major Theme: Disconnect between Perceived Complexity of Injury and Treatment

Half of the sample described their initial impression of the injury in terms such as "it didn't look that bad" or "I didn't think [the injury] was very much" and half were somewhat distressed at the appearance of the injured finger immediately postinjury, for example, "it was poking, like sticking up funny," "it was really excruciating and I didn't even want to look at it," and "it looked horrible." All the participants in this study, however, stated that they had initially expected that their injury would be quickly managed by the hospital staff, with a simple surgical procedure, manipulation, or a period of immobilization. Those who initially didn't regard their injury as being severe appeared to be more likely to subsequently interpret the prescribed distraction treatment as being overly complex for their injury.

Given the patients' understanding of their injury (that it only involved a small body part, therefore treatment should be relatively contained and simple) and their expectation of treatment that would be

TRANSCRIPT OF INTERVIEW	OPEN CODING	AXIAL CODING
<p>Interviewer: Tell me about your first impressions and feelings when you first saw that splint.</p> <p>Interviewee: Um full on, because it's gone from "it's just a broken finger" to "they are just going to strap it up" to wearing this splint that was like all the way up to my arm. I was actually thinking this is overkill...but everyone kept saying well ... "you really ruined the middle part of your finger so this is the best option". So I was [saying] "OK" but it was really kind of like "Oh my God" because I went into work with the splint on and people were like... "but you just broke your finger", so it was a bit overkill. But I see why they did it now.</p>	<p>Small injury → small scale treatment expected</p> <p>Splint seems out of proportion to injury</p> <p>Explanation of injury by hospital staff accepted by patient, but not fully understood</p> <p>Colleagues' comments undermined patient's acceptance of explanation</p>	<p>DISCONNECT between patient's perception of injury complexity and the expected vs actual treatment</p> <p>Patient's understanding can be undermined by others in between clinic appointments</p>

FIGURE 2. Example of coding of interview transcript.

TABLE 3. Distribution of Responses in 12 Participants

	Patient											
Issues raised	A	B	C	D	E	F	G	H	I	J	K	L
Found initial injury appearance distressing	×			×				×		×	×	×
Dissonance between perceived injury and treatment complexity	×	×	×		×	×	×	×	×	×	×	×
Severe pain on commencement of splinting/exercise		×	×	×	×	×	×	×		×		×
Confronting appearance of splint and exposed K-wire	×	×	×	×	×	×	×	×	×	×	×	×
Impact on ADLs/work		×	×	×	×	×	×	×		×	×	×
Belief that would get poor outcome if fails to adhere to splint/exercise regime/good outcome if adheres	×		×		×	×	×	×		×	×	×
Discomfort/difficulty maintaining skin hygiene	×		×		×	×		×		×	×	
Admitted nonadherence with exercises		×	×			×	×		×			

ADL = activities of daily living.

simple and quick, the distraction splint and treatment regime seemed out of proportion.

I understand I had to be operated (sic), the pin inside my bone [but] I didn't [understand how] ... the splint and all this structure on my arm would work for me, because it turned out I had a big, big splint up to my elbow; it was huge, and I had to wear it for seven weeks ... the splint was that big that it created an impression I had broken all of my, half of my arm or something (E)
It kind looked really to me like I was a car accident victim or something. All of a sudden I had this pin and I had this hinge ... and it stuck out a good kind of two inches further than my finger so ... it was probably a little bit more cumbersome than I imagined. I was a bit overwhelmed ... [I thought] 'Oh, it's kind of THIS big' (H)
It looked like a bit of an over extravagance for the injury (K)
It was hard for me to understand why for such a small joint that there was so much time and energy that went into it. That kind of made me feel a bit ... silly because I just felt like it was a lot of time for other people to put into my little tiny joint (B)
I hadn't really thought about hand therapy. I think mostly because it was a little finger and how hard can it be? (A)

This understanding was relative, although, to what they (or other people they knew) had experienced for previous injuries or what participants had researched about their condition. One participant was relieved to find that her splint was not as big as the “banjo” style splint that she was expecting:

I was told that I would have a distraction splint. I didn't really understand what that involved so I looked it up online and the picture was some huge enormous thing and my big concern was how on earth would I manage with that, and when I learned that the splint I was going to have was a lot more compact I was relieved (A)

Although most found the explanation of the treatment and its rationale clear and logical at the time it was given, it is worth noting how easily the individual's belief in the legitimacy of the treatment approach could be undermined by the contrary opinions of others. For some respondents, the comments of others had a strong influence in shaping their beliefs about the type of treatment that they felt they *should* be receiving, acting to reinforce, and validate the perceived sense of *disconnect* where the actual treatment offered was very different to that which was expected:

Wearing this splint that was ... all the way up to my arm. I was actually thinking this [is] like overkill ... but everyone [at the

hospital] kept saying, 'well ... you really ruined the middle part of your finger so this is the best option'. ... I went into work with the splint on and people were like 'but you just broke your finger' so it WAS a bit of overkill. ... But I see why they did it now (J)
A very successful dentist and a friend of my good doctor ... he had ... the same fracture the same finger He showed me his finger ... [when] I was wearing this splint. I was trying so hard through the summer, through the heat ... a tremendous effort, and he told me "Look, I didn't do anything at all" and he [could straighten it further].... He just told me, "What's the point, you know? You just try to exercise and resolve any pain and try to do as much as you can and try to massage and warm up your finger" ... And I was very upset about that ... I wasn't about to tell you about that but if you didn't ask me this question, I probably wouldn't raise it (E)

There were also some patients who believed that their treatment was “experimental” and that they were not given any other option. This appeared to be underpinned by the belief that they should have received a much simpler treatment, such as an operation to pin the fracture.

I was expecting that firstly they would put some plaster on it.... They didn't explain anything [in the Emergency Department] ... they were experimenting, I believe, on that day (F)
I [was expecting] an internal plate or something ... and it will slowly and surely unionize It seemed like quite a new thing that they were going through, and I didn't really know what the reason was and why they were doing it and all that. That said, obviously they explained to an extent, but I didn't really know the technicalities of this and what other options are available and that sort of thing ... I've shown it to some other doctors ... around here [and overseas] ... and my parents as well, and none of them were very ... they didn't really know [about] this 'new thing' (D)

The perceived “over-sized” splint, however, had unexpected benefits for some. Several participants stated that the size (and perceived complexity) of their splint gave their injury credibility at work or helped explain and validate the extent of the injury to employers, work colleagues, or friends:

My unit manager was in the middle of a meeting with his boss and they were actually talking about why I needed to be off work for six weeks so when I walked in [and they saw the splint] they said 'Oh yes, fair enough, no work for you' and pretty much everyone else, my family, my colleagues and friends, all said "that looks pretty impressive" (A)
I guess once people kind of saw it they got a bit of an understanding as to why I was complaining about being in pain and things like that so ... I guess just a little bit of surprise most people

haven't seen anything like this before so it is quite interesting to a lot of people, strangers just walk up to you and start asking you about it and asking what you have done and stuff like that (L)
I was going in for special consideration [for University exams] and all that ... they were like ... "this looks really bad, you do whatever you want, take however long you want" and yeah, it kind of scared them (D)

Subtheme 1: Unexpected Levels of Pain (Especially in the Early Stages)

For most participants, any pain they experienced in the finger became worse immediately after splint application, and many had difficulty performing exercises in the first few days after splint application. In some participants, pain appeared to be interpreted as a sign of further damage being done to the tissues. This may have contributed to ambivalence regarding the distraction treatment:

They got me to do these exercises to move it up and down and to be honest it was excruciating pain. It didn't even seem like it was, you know, a proper way of medicating it because it was just excruciation. Because there was like two rubber bands put on to that ... pin ... and every time you just move it up and down, it's just unbelievable pain (D)

First couple of days I was in a bit of a world of pain and yeah and wanting to get it [the splint] off (L)

[After] day surgery ... they had given me morphine ... so when I left here I was in a little bit of pain but not a great deal ... I was due to come back here in the morning and see [the hand therapist] and see how it was going. And by the time I got back in here I hadn't slept much because I was in so much pain ... I was beside myself ... in so much pain. Like, I kid you not, I almost fainted on poor [hand therapist] ... so we took the elastic bands off and had some better pain relief and then put them back on, but put them back on less tight ... But we didn't put them on [full traction] until two days later ... (J)

The first few times made me feel physically sick because it actually hurt so much ... I guess that was my own fault as well because I tried to get off the pain killers as quickly as I could ... I just don't like taking pain killers (G)

Obviously he had to bend my finger, so the pain increased like anything. [That was] the moment I faint[ed] (F)

The ambivalence regarding the treatment appears to have influenced treatment adherence, with some admitting nonadherence with either splint wear or the exercise regime. This was mainly attributed to pain or difficulty fitting in the number of exercises around work or daily living routines.

I mainly probably found them just boring and repetitive and I guess I just I didn't do it as much as I should have and sometimes I guess because it was painful and you sort of, you worry about ... maybe damaging the finger again or something (B)

After two weeks every night I was just taking [it] off ... because I wanted to be able to sleep properly, and the reason was that it was giving more pain when sleeping (F)

I thought the more I exercise, the better ... at one point it gave me uncomfortable pain, that is why I stopped (E)

They were telling me "it's going to be hard for you, but you have got to keep on exercising". Well I did, but not that regular basis, frankly speaking. If I would have done, maybe there would be more improvement. But at the same time I [was] getting hurt, so ... Interviewer: It was very painful? Interviewee: Painful.

Because the thing is I have to go to work, so I don't want to have pain and go home. So I just ... sometimes ... don't exercise ... So, in a day I do two or three times ... maximum, at first. So in the first two weeks I did the exercise ... after that I didn't (F)

Subtheme 2: Self-Efficacy and Outcome Expectancies

Most people expressed the belief that they could influence the outcome of their rehabilitation by adhering to the exercise and splint wear required of them. For some, this was expressed as a fear of a poor outcome if they failed to wear the splint or do their exercises; for others, it was an expectation of a good outcome if they followed therapy instructions:

[The hand therapist] saying to me that if I didn't do the exercises I wouldn't be able to move my finger. I think that was the main thing, the fear of not being able to move my fingers again (C)

I think because [the hand therapist] had really spoke about the importance of ... bending it regularly. I think we even came up with a ten times every hour I had to bend it as much as I could. And in the beginning that was really minimal ... I couldn't really move it but ... I was well informed [as] to what it would take to get mobility back in my finger and I think I was very determined because it was my ring finger ... and I was very determined that this finger was going to not end up like a claw lady (H)

They kept saying the more that you do them, the better off that you would be so ... it was just a case of, well I wanted to be able to move my finger so I'll do them (J)

One did not do his exercises as he believed he was a "good healer"

Was there a reason you weren't doing [the exercises] as frequently as you should? Interviewee: Um ... just my nature basically

Interviewer: Ok, you're the sort of person ... that doesn't follow through with those sort of things, or ... ? Interviewee: Oh ... I just ... I don't generally ... as I say I've hurt myself to varying degrees fairly regularly over my life and I find I heal fairly pretty well (I)

Subtheme 3: Splint Discomfort: Aesthetic, Physical, and Functional

Most described the splint appearance as confronting, using terms such as "freaky," "gruesome," and "horrible." Interestingly, these evaluations did not appear to impact directly on treatment adherence for these respondents.

At Uni my former supervisor was particularly freaked out. ... from the other side of the room she would [say] "I can't look". She didn't want to hear anything about it, the idea of it made her feel squeamish, she had to sit on the other side of me, even if she was not even looking at it, and I had to have my arm hanging down by my side or hidden behind my back if she walked past. Because she was clearly very distressed by the whole notion of it (A)

There was a bit of a running joke going that I should walk around with an oven mitt over my hand because I was scaring little children on trains with it (C)

The girls at work were absolutely grossed out by it. Especially with the wire through the finger and everything else (G)

Some described the splint as a "novelty" and did not find everyone reacted negatively:

Everyone's fascinated with the pin that was going through my bone as well ... some people didn't want to look at it, but there were others that were very curious (H)
 It was a bit of a sideshow for me, it was a bit of fun ... a bit ghoulish, but I like that sort of thing and that's how I sold it to my friends, so it was a bit of a story (I)
 People were curious, if anything. It was more of a talking point, so in that regard I didn't mind (K)
 Having had a contraption on my hand and on my wrist for when I did my tendons [in a childhood accident], it was probably ... three quarters as freaky [or] spooky ... The one I had when I was younger was probably a little bit worse ... freaky looking and because I'd had that and I had wires coming off that and was meant to strain against them to work the muscle and the joints ... the contraption ... didn't bother me (I)

Several participants stated that the splint was hot, uncomfortable, smelly, or itchy:

It was in the middle of summer [and] I was very hot. I was sweating inside the splint and it was itching all the time (E)
 It was the middle of summer when it happened and it was really hot, the splint was really hot. I had tubigrip and changed it every day and I found that my skin got really rough and prickly and damaged (A)
 It got so annoying and ... I had a bit of eczema ... and I was dying to take it off ... and sleeping with it was really annoying (J)
 I took it off every two days or so because it was getting smelly and ... and a bit disgusting under it. So I had to clean it and that sort of thing and then putting myself back into the splint ... That was a bit of an issue (C).

Difficulty with ADL (e.g., wires catching on clothes when dressing, outrigger being longer than the hand, so would bump on things) and work was reported by most participants. Typically, these difficulties were experienced as a need for conscious processing of task performance requirements, rather than an inability to complete tasks—things could be done but not necessarily in the usual way:

The little hooks ... keep getting stuck in my clothes and so I put tape around those (C)
 Going to the bathroom was very, very hard ... to take a shower (E)
 It distracted me a lot, especially while I was sleeping. That [K-wire] would cut into my clothes (F)
 I live on my own so having a little plastic bag on in the shower ... and wearing a suit to work is [difficult] ... but eventually I managed to get the suit across the splint ... The actual little swing was a distraction on the end, because it was so long, it used to cause an issue, because it was longer than what you are used to so you bang it against things and that's when you get a bit of pain and things like that as well (G)
 [Looking after myself was] quite difficult to be honest. I had my parents and people coming over and helping me out but couldn't really do much on my own (D)
 I actually couldn't do my work because at that time I was a [Personal Assistant] to someone so ... I couldn't type one handed and so I wasn't working (H)
 You can't open cans and things like, things that you need two hands to hold on ... You can't peel vegies at home so you've got to basically have someone to look after you or eat takeaway (L)

Others reported little or no difficulty with ADLs:

It was comfortable. I had been concerned at first that I was going to have to make alterations to clothes like you do when you have a cast on your leg or your arm and there wasn't any of that it was fine it was really comfortable it didn't break or crack or anything like that and it was light weight and I got quite used to it (A)

DISCUSSION

The aims of this study were to gain a deeper understanding of the patients' experiences of distraction splinting and to identify key issues that may impact on adherence to splint wear and exercise program.

These aims will be addressed separately in this section.

The Patient's Experience of Distraction Splinting

The common phenomena experienced across our sample include the perception that distraction treatment seemed out of proportion to what they were expecting (based on their understanding of their injury), severe and poorly managed pain was frequently experienced in the early days of the splint regime, a sense that they could influence the outcome by adhering or not adhering to treatment, the confronting appearance of the splint, and difficulties with ADL. Each of these experiences will be discussed in greater detail below.

Disconnect between Perceived Complexity of Injury and Treatment

Often, the patient's simplistic understanding about finger anatomy appeared to be associated with the expectation of a simple treatment, for example, an operation to pin the fracture. The complexity and scale of distraction treatment (which includes surgical placement of a K-wire, four- to six-week wear of a forearm-based splint, hourly exercises) threatens this belief that finger structures are simple; therefore, treatment should be simple.

According to the Health Belief Model,^{31,32} by the time a patient decides to consult a medical professional, they have already formed a unique view of their injury/illness that is shaped by four key factors:

1. his or her health beliefs about what is wrong with them (the explanatory model or attribution of the injury appearance or symptoms to a particular condition like a fracture or dislocation);
2. his or her fears or concerns about the injury (e.g., potential complications if left untreated);
3. the effect of the injury on ADL; and
4. his or her expectation of what should be done to treat the injury.

Our finding that the splint seemed disproportionately large for the condition, directly contradicts Murray and McIntyre's¹² assertion that a splint similar to that used in this study is "very small." Only one person commented that the splint was smaller than expected, and this participant (like Murray and McIntyre¹²) was comparing the splint to the Banjo

design, which they had discovered when researching their injury on the Internet.

Despite the assurances and education provided by the treating team, the individual's beliefs about the nature of the injury (e.g., it's only a small part of body, therefore injuries are unlikely to be serious) can be deeply held and difficult to relinquish. This finding has parallels with Combs¹¹ observation of athletes nonchalant reactions to finger injuries that can seem innocuous but "can cause significant permanent disability" (p 168). The explanation of the injury and recommended treatment, while often accepted by the individual at the time, can be either undermined or reinforced by comparing the injury and treatment to previous injury experiences, with other people with seemingly similar injuries, or with research from other sources. This suggests a need for enhanced patient education regarding the evidence and rationale for distraction treatment.

Unexpected Levels of Pain

According to Brand and Yancey,²⁵ the individual's response to pain, and hence the meanings they attribute to it, are shaped by past experiences, beliefs, and cultural factors. In this sample, pain was interpreted by some as a belief that further damage was occurring to the finger, and this affected adherence to the exercise program.

Our finding of unexpected high levels of pain on exercising in the initial weeks is supported by Morgan et al.²⁰ who noted that patients need to understand that "though these exercises are initially quite painful, they will actually help to reduce the general pain level of this injury" (p 568). This finding contradicts the contention by some researchers that traction allows early pain-free mobilization by the patient.^{12,33} If patients were told to expect pain-free motion, and then went on to experience severe pain, this may have undermined the patient's belief and trust in the treatment, and therefore affected adherence.

Self-efficacy and Outcome Expectancies

In our sample, participants stated that they adhered with the splint and exercise regime because they believed it would give them a good outcome, or they feared a poor result if they did not. This finding fits with the central contention of the Health Belief and Common Sense (or self-regulatory)³⁴ models of patient adherence, that a person's ability to adhere to treatment is shaped by how he or she cognitively processes illness-related events. Social Cognitive Theory³⁵ adds to this by contending that attitudes lead to behaviors when combined with the person's beliefs about their ability to engage and their beliefs about the likely consequences of engaging. The key components *self-efficacy* and *outcome expectancies*

have been shown to be good predictors of adherence with health behaviors, such as following an exercise program.³⁶

Splint Discomfort: Aesthetic, Physical, and Functional

All participants in this study commented that the splint and exposed K-wire looked confronting and drew attention to them. Therapists need to be aware that the splint appearance could possibly affect adherence (although this did not appear to be the case in this sample) and every effort should be made to ensure that splint design is as aesthetically acceptable as possible. The stigma associated with wearing a highly visible splint for a significant period of time warrants further exploration.

Difficulty with ADL and work was reported by most participants. Whilst this was expressed as a frustration, it again did not appear to impact on adherence with treatment. Respondents who coped well with the treatment described successful adaptation of activities, indicating that enabling ADL independence at an early stage may increase self-efficacy, thus promoting adherence.

The evidence shows that splint comfort and aesthetics are key issues in adherence, as illustrated in the Introduction section.

Predictors of Adherence

Our analysis of the data using grounded theory can be summarized into two broad themes:

1. The experience of disconnect between the individual's perception of the severity of the original injury and the complexity of treatment is a negative predictor of adherence.
2. The individual's beliefs regarding the likely outcome of adhering to recommended treatment protocols also predict adherence.

Limitations of the Study

Limitations of this study include the retrospective design and length of time since injury (up to 7.8 years in one case) that may have impacted on participants' recollections of the experience. Also, the interviews were conducted by the lead author who is affiliated with the hospital in which the treatment was provided, which may have impacted on the ability of participants' confidence in speaking freely and critically about treatment they received.

Implications for Hand Therapy Practice

The use of phenomenology as a research methodology fulfilled the aim of gaining a greater understanding of the experiences of patients undergoing distraction treatment for complex finger joint

fractures. It provided valuable insights into how patients viewed and coped with the treatment for the four- to six-week treatment period, which can be applied more broadly to other acute conditions where outcomes are dependent on patient adherence to cumbersome splinting and potentially uncomfortable early exercise routines.

From the findings of this study, the authors believe that the key to ensuring adherence with treatment for acute hand injury is the resolution of the disconnect between the individual's perception of the scale of the injury and complexity of treatment. Patients who perceive the treatment as credible and warranted are more likely to adhere to the treatment regime. This has implications for how treatment is introduced to patients and the need for detailed, appropriately pitched education about the nature of the injury, and what to expect in terms of the splint (size, appearance, and duration of wear) and exercise regime. Information on the injury and the treatment need to be congruent to the patient and supported with current evidence as to the treatment's efficacy.

Participants in this study were, on the whole, not expecting the level of pain they experienced in the early days after commencement of distraction and mobilization. Several described it as much worse than that experienced at the time of the actual injury. The surgeon and therapist need to be aware of the impact of heightened pain on the person's beliefs about their injury, as it could be interpreted as an indicator of further damage to the joint, which could threaten the credibility of the treatment and could potentially result in lack of adherence to treatment in the crucial early days. Patients need to be informed that they may experience pain, particularly in the early stages of rehabilitation, but reassured that this should resolve as the joint heals. Preemptive analgesia is vital during the first week.

Measurement of pain during distraction therapy should go beyond intensity as measured by the VAS and function (measured by instruments, such as the DASH). The treating team needs to attend to the cognitive and emotional response to pain, as they can be predictors of potential development of chronic pain issues.²⁶

In summary, the major recommendations for hand therapists in terms of maximizing patient adherence are:

- Provide detailed, evidence-based, appropriately pitched education about the nature of the injury and your proposed treatment, so that the patient is adequately prepared.
- Be aware that you may need to revisit your explanation of the injury and treatment rationale throughout the course of rehabilitation, as patient

understanding can be eroded by outside influences in between therapy sessions.

- Prepare patient for the fact that exercise can be painful in the early stages, but this does not signify further damage.
- Ensure preemptive analgesia in the first week.
- Go beyond basic pain measures and tune into patient's cognitive and emotional responses to pain, as these can potentially flag chronic problems.
- Reinforce the patient's ability to influence their outcome by following the recommended program.
- Give examples of how other patients have successfully adapted ADL's without compromising splint adherence.

Acknowledgments

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5.3 Impact of the study

Journal Metrics:

- Thomson Scientific ISI Web of Knowledge Journal impact factor: 0.612
- Thomson Scientific ISI Web of Knowledge Journal rank:
 - Orthopedics: Q3 (39th of 56)
 - Surgery: Q4 (133rd of 167)
- SCImago Journal Ranking: 0.071
- H Index: 26
- Source Normalized Impact per Paper (SNIP): 0.43

This study was the first published in the hand therapy literature to focus purely on the patient's experience of acute splinting and the impact this has on adherence.

Results from this study have been presented to all hand surgeons at the Alfred hospital, and pain relief is now ordered routinely prior to applying the traction device. Enhanced patient information booklets are currently in development, with further information on the injury complexity and sections on managing ADL's . A modified splint is now used which is volarly-based and has better proximal control, resulting in less slippage and discomfort.

A presentation on this study was one of only nine selected for the plenary session at the 8th Triennial Congress of the International Federation of Societies for Hand Therapy (IFSHT) in Florida, June 2010. It was very well received, and feedback to the presenter was overwhelmingly positive.

5.4 Chapter Summary

In this qualitative study of patient experience of a challenging hand therapy regimen, the common phenomena experienced by our participants included:

- the perception that distraction treatment seemed out of proportion to what patients were expecting (based on their understanding of their injury);
- severe and poorly managed pain in the early days of the splint regimen;
- a sense that the individual could influence the outcome by adhering or not adhering to treatment;
- the confronting appearance of the splint; and
- difficulties with daily living activities.

In terms of predicting adherence to this treatment, two key themes emerged:

1. The experience of dissonance between the individual's perception of the severity of the original injury and the complexity of treatment was a negative predictor of adherence.
2. The individual's beliefs regarding the likely outcome of adhering to recommended treatment protocols also predicted adherence.

These themes fit within the following dimensions of the MAM:

- Therapy-Related, including the complexity and duration of treatment, the immediacy of benefit, interference with lifestyle, and availability of support;
- Patient-Related, including psychological factors, such as lack of understanding of the condition and need for treatment, and beliefs about the injury and treatment required; and
- Health Care Team, especially the crucial patient-provider relationship, which involves trust, clear and consistent education, and continuity of care.

This study concluded that therapy-related factors, particularly complexity of treatment, interference with daily living activities, and availability of support (i.e. pain relief), exerted the most significant influence on adherence in this group. Interestingly patient-related factors, especially beliefs about the condition and treatment required, also appeared to have a bearing on adherence.

This study provides further support for this thesis' central contention (i.e. that ability to follow treatment is impacted by more than one factor, and interventions to improve adherence need to address all relevant factors).

The next chapter builds on the evidence regarding the different treatment for intra-articular fractures of the fingers, by comparing long term outcomes of these injuries by the treatment received.

Chapter 6 – Efficacy of distraction splinting for complex intra-articular finger fractures

Chapter 6

Efficacy of distraction splinting for complex intra-articular finger fractures

6.1 Introduction

The previous chapter explored the patient's experience of distraction splinting which can, for some, be painful, confronting, and a hindrance to daily occupations. Many stated that they adhered with this treatment regimen as they believed the health team's assertion that to do so would result in a significantly better outcome. This raises an interesting issue, however, as the evidence to support distraction for intra-articular finger fractures to date is drawn purely from case series, or Level 4 evidence. Appendix 4 tables summarise the published evidence on the different distraction methods, and highlight the need for rigorous research that compares distraction with other methods of management.

While intra-articular fractures are estimated to account for 19% of phalangeal fractures, only 20 cases at The Alfred Hospital, and 23 at Dandenong Hospital between January 2005 and May 2009 fit within the eligibility criteria for this study, which focused on complex, comminuted, and unstable fractures. Given the relative rarity of these injuries, it is not practical or cost-effective to conduct a randomised controlled trial, and a cohort study was chosen as it is well suited to rare exposures (in this case, distraction splinting, which is not widely used in Victoria, Australia), ethically safe, administratively easier, and less costly.

6.2 Chapter Contents

O'Brien, L, Simm, A, Loh, I, and Griffiths, K (2010) Comparison of distraction splinting and no-distraction for complex intra-articular finger fractures: Long term outcomes.

This article was submitted for consideration for publication in *Archives of Physical Medicine and Rehabilitation* on 11th December 2010. It is presented in the format required by that journal. All sources cited in the article are referenced at the end of the article in numerical order.

This study aimed to compare range of motion at least one year post injury in two groups of patients with complex intra-articular finger fractures, one of whom received a distraction splint, and the other static splinting (with or without surgical fracture fixation). We also aimed to discover whether there were differences between the groups in functional outcome, as measured by the Disabilities of Arm and Shoulder (DASH),¹⁴⁰ complication rates, patient satisfaction, pain, and adherence.

Declaration for Thesis Chapter Six

Declaration by candidate

In the case of Chapter Six, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Concept development, literature review, ethics application, securing of funding, recruiting Alfred participants, data collection, writing and submission of manuscript	70%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	Nature of contribution	Extent of contribution (%) for student co-authors only
Dr Andy Simm	Search of hospital database for eligible participants (Southern Health) grading of x-rays, editing of manuscript	10%
Dr Ian Loh	Search of hospital database for eligible participants (Southern Health) grading of x-rays, editing of manuscript	10%
Kim Griffiths	Recruiting participants, data collection (Southern Health) editing of manuscript	10%

Candidate's Signature		Date 9/12/10
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Declaration by co-authors

The undersigned hereby certify that:

- (1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
- (2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
- (3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (4) there are no other authors of the publication according to these criteria;
- (5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
- (6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	The Alfred Hospital, Southern Health (Dandenong Hospital)
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Signature 1		Date 9/12/10
Signature 2		Date 03/12/10
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TITLE PAGE

Comparison of dynamic digital distraction splinting and no-distraction for complex intra-articular finger fractures: Long-term outcomes

(Short title: distraction splinting for finger fractures)

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ABSTRACT

Objective: To compare arc of motion in the injured finger at least one year post injury in two groups of patients with complex intra-articular finger fractures. One group had distraction splinting, the other had static splinting with or without fracture fixation.

Design: Two-centre Cohort Study

Setting: Outpatient hand therapy clinics (two public hospitals)

Participants: Patients (N=25) at least one year since injury

Interventions: Either thermoplastic distraction splint with a movable hinged outrigger attached at the level of the injured joint worn for 6 weeks continuously (distraction) or static splint, with or without surgical fracture fixation (no-distraction). The distraction group commenced immediate passive joint mobilisation, and the no-distraction group (except for those with crossed k-wires) commenced gentle active mobilisation at two weeks.

Main outcome measures: The primary outcome was combined range of motion of the PIP and DIP joints. Secondary outcomes were functional outcome as measured by the Disabilities of Arm and Shoulder (DASH), patient satisfaction, pain, complication rates, and patient adherence with treatment.

Results: The mean combined range of motion of the PIPJ and DIPJ in the distraction group was 135°; in the no-distraction group it was 113°. This was clinically significant, but not

statistically significant ($p = 0.21$). There was a moderate statistically significant negative correlation between age and total arc of motion ($p=0.02$). No significant differences between groups were observed for DASH scores, patient satisfaction, pain, complication rates or treatment adherence.

Conclusions: This study showed promising results for range of motion in the distraction splinting group, however was unable to show a statistically significant difference between this and static splinting with or without surgical fracture fixation.

Key Words: Finger injuries; fracture; dislocation; splint; orthosis; traction

List of Abbreviations:

PIPJ = Proximal Interphalangeal joint; DIPJ = Distal Interphalangeal joint; MCPJ = metacarpophalangeal joint; VAS = Visual Analogue Scale; DASH = Disabilities of Arm Shoulder and Hand; TAM = Total Active Motion

Introduction

Intra-articular fracture dislocations of the finger most commonly involve the base of the middle phalanx usually in impaction, dislocation, and pilon types of injuries.¹ The typical mechanism of injury is a direct force applied to the fingertip with hyperextension and axial loading of the proximal inter-phalangeal joint (PIPJ) causing impaction of the articular surface of the middle phalanx onto the condyles of the proximal phalanx. The incidence of these injuries is difficult to determine due to under-reporting, however one UK study found that intra-articular fractures represented around 19% of phalangeal fractures in a geographical area, and comminuted or large-fragment PIPJ joint injuries comprised 2.2% of the total.² A US study of 134 consecutive closed articular fractures of the metacarpophalangeal joint (MCPJ) and PIPJ's found only three pilon injuries.³ Despite their relative rarity, these injuries are frequently featured in the hand therapy and surgery literature as they are potentially the most severe of finger injuries¹ and can severely limit hand function due to stiffness, pain and traumatic arthritis^{4,5}.

Unstable finger joint dislocations, and those with significant comminution or fragment displacement, are usually treated surgically.⁵ Surgical options include internal fixation (e.g., screws into fracture fragments, with or without bone grafts) or external fixation and traction.⁶ Internal fixation is technically difficult, time consuming, and can result in significant complications.^{7,8} Traction is thought to work by reducing the fracture by capsulo-ligamentotaxis, and preventing shortening of collateral ligaments. Movement is thought to minimise adhesions in and around the joint, and promote cartilage healing.⁶

Over the previous eight years, the Alfred Hospital's Plastic Surgery and Hand Therapy teams in Melbourne, Australia have used dynamic distraction splinting to treat complex intra-articular finger fractures of the PIPJ joint (see figure 1) whilst patients with the same injury at another hospital in the same city (Dandenong Hospital) have received static splinting, with or without surgical fixation.

Traction fixation was pioneered by Robertson, Cawley, and Farris in 1946⁹ with the 'banjo' splint. This was a static traction device with three wires and three rubber bands providing tri-directional (dorsal, volar, and axial) traction around a circular frame. Quigley and Urist advanced on this in 1947, describing a skeletal traction device for finger joints that allowed early motion.¹⁰ In 1987 Schenck¹¹ detailed a splint similar in shape to the Banjo splint, but which allowed early passive mobilisation between two points on the frame. He also recommended that 300 grams (10.6 ounces) of traction force was necessary to adequately distract the fracture fragments.

Several different types of distraction devices that allow movement at the affected joint have been described in the literature. For ease of discussion these can be classified as either finger-based frames or dynamic splints with a forearm component. The finger-based frames involve two Kirschner (K) wires placed perpendicularly through the bones proximal and distal to the injured joint, with traction force achieved by various methods including rubber bands,¹²⁻¹⁷ springs,^{7, 18} a rigid straight k-wire,^{19, 20} a dorsal parabolic curved k-wire,^{21, 22} a rhomboid-shaped pulley-based frame,²³ and a hinged compass device.²⁴⁻²⁶ Another variation of this is the force couple splint, which links three K-wires (the two mentioned previously,

plus another one that projects dorsally just distal to the one above of the injured joint) using a single rubber band.²⁷ These devices do not have a thermoplastic component, and the wrist and hand are free to mobilise.

The dynamic splints usually involve a single K-wire placed perpendicularly through the bone distal to the injured joint (some designs also have a second k-wire just proximal to the injured joint), a frame onto which rubber bands or springs can be attached from the K-wire to distract the joint, and a forearm or hand component to counterbalance the distraction force and prevent distal slippage of the device. These can be further categorised into two types:

- the 'swing' design, comprised of a thermoplastic forearm based splint which extends to the injured finger (either dorsally or volarly) and has a compact hinged outrigger to which the k-wire is attached using rubber bands;^{4, 28-30} and
- the 'arcuate' designs (similar in shape to the original Banjo splint), which usually have a forearm piece made of thermoplastic or casting material. The one exception to this is the Hand Arc design³¹ which is a hand-based splint with the wrist free to mobilise. All arcuate splints have a circular (or semi-circular) hoop attached. In these splints, the traction system (attached to the k-wires by rubber bands or springs) glides along the hoop on an arc of motion between two set points. The earliest of these designed by Schenck in 1986¹¹ was known as the 'pizza pan' splint as the hoop was moulded around the diameter of a pizza pan. Several modifications have since been made to this design, and promising results have been achieved in case series studies.^{8, 32-35}

The traction splint used in this study is the swing design, specifically the dorsally applied splint described by Murray and McIntyre.⁴ The benefits of this design, according to its creators, is that it is smaller than the Schenck design, thus minimally impacting on daily routine, allowing for easy compliance and pain-free rehabilitation. All of the publications for swing design splints, apart from a case series of 14 patients,²⁹ are practice forum articles which describe the design and fabrication of the splint, but do not present any data from actual cases.

Apart from a small study in 1991⁸ comparing open reduction (N=9), banjo traction (N=6), Schenck splint (N=1), and static splinting (N=4) at an average of 25 months post injury, there are also no published clinical trials comparing any of the skeletal traction treatments with a control treatment. Also, with the notable exception of one study that reviewed patients at an average of 56 months post injury,¹² none of these included the long term follow up of patients necessary to identify the incidence of post-traumatic arthritis. This study aims to address these obvious gaps in the evidence.

This study aimed to compare range of motion in the injured finger at least one year post injury in two groups of patients with complex intra-articular finger fractures. One group were treated at a hospital routinely managing these injuries using distraction splinting; the other at a hospital that routinely used static splinting (with or without surgical fixation). We also aimed to discover whether there were differences between the groups' functional outcomes (as measured by the Disabilities of Arm and Shoulder (DASH)³⁶ patient satisfaction and pain), complication rates, and patient adherence with treatment. We hypothesised that distraction

splinting would achieve better motion and functional outcomes for patients than static splinting (in fingers with or without surgical fracture fixation).

Methods

This cohort study involved patients who presented to one of two urban public hospitals located in Melbourne, Australia. The study was conducted between March 2009 and October 2010 and was approved by the Ethics Committees of Monash University, the Alfred Hospital, and Southern Health. Potentially eligible participants were identified by searches of both hospitals' hand surgery databases, and were contacted by mail and telephone (where possible) and invited to participate. Informed consent was obtained in writing and patients were informed prior to data collection about how data would be analysed, stored, and treated confidentiality.

Inclusion Criteria

Patients eligible for this trial had a diagnosis of complex, comminuted, or unstable intra-articular fracture of an interphalangeal finger joint sustained between 2001 and 2009. They also needed to be able to give informed written consent in English.

Exclusion Criteria

Those with co-existing rheumatologic illness were excluded.

Interventions

A. Distraction splinting group

The hand therapist fabricated a dorsally applied thermoplastic forearm/hand component with a movable hinged outrigger attached at the level of the injured joint. The outrigger was covered at the distal end with thermoplastic material in which two dressmaker's hooks were embedded. After surgical placement of a K-wire through the bone distal to the injured joint, the splint was applied to the forearm and hand, with rubber bands attaching the K-wire to the hooks in the outrigger, thus providing a distraction force (see figure 1). Reduction was checked radiographically, with different sized rubber bands trialled until the traction was deemed sufficient to restore normal joint space. Distraction forces were not routinely measured, as this would not be considered reliable due to the tendency for rubber bands to lose tension after prolonged stretch. X-rays were repeated weekly, and traction adjusted by changing the size and number of rubber bands required to maintain joint space. The hand therapist instructed the patient to complete 10 passive flexion / extension exercises of the injured joint each hour, and this was commenced immediately post-surgery. At the end of the first week the aim was to produce 45° of motion, with incremental increases of 5° per week for the next five weeks. The patient was instructed to wear the splint continuously until the k-wire was removed by the surgeon. Total splint wear time varied between 30 and 55 days (mean=40.7 days). After splint removal, patients commenced a graded strengthening program using exercise putty. If an extensor lag was present, static progressive night splinting was introduced, with low profile spring-loaded extensor splints used during the day. If the

patient had a flexor deficit, static progressive flexion splints or gloves were used. All attended hand therapy treatment at least once per week up to 10 weeks post injury, with some requiring additional treatment beyond this.

B. No distraction group

This group were seen by a hand therapist who fabricated a static thermoplastic hand-based splint (i.e. the wrist was free to mobilise) which was volarly applied. Six participants underwent open reduction and internal fixation (2 had a single lag-screw inserted, 1 had 2 lag screws, 1 had a plate and 4 lag screws, 1 had a volar plate repair and k-wire fixation, and 1 had k-wire, bone graft, and extensor tendon repair). 3 had closed reduction with 2 crossed k-wires and 2 were managed conservatively. All were splinted as close to the safe position of immobilisation as possible (i.e. MCPJ's at 70-90° flexion, and IPJ's fully extended) and those without k-wire fixation commenced gentle active mobilisation at 2 weeks, light strengthening at 4 weeks, and passive stretching at 8 weeks. Those with k-wire fixation had the wires removed between 4 and 6.4 weeks post operatively and commenced the mobilisation and strengthening program at that point.

Data collection

Participants consenting to this study had their x-rays independently graded by the second and third authors, both hand surgery registrars, according to the fracture/dislocation classification system described by Schenck.³⁷ In this system, fractures involving <10% of articular surface are graded 1; 11-20% are graded 2; 21-40% are graded 3; and >40% are

graded 4. Dislocations <25% are graded A; 25-50% are graded B; >50% are graded C; and total dislocations are graded D. Where gradings differed, results were discussed and a consensus reached. On attendance at the clinic, the participant completed a one-page form that included information on hand dominance, finger injured, pain (using the 10cm Visual Analogue Scale³⁸), complications (such as further procedures required), satisfaction with result, and current employment status (which were categorised using Australian and New Zealand Standard Classification of Occupations codes).³⁹ They also completed the DASH, which is a 30 item self-report functional outcome and symptom scale with a maximum score of 100 indicating an extreme impairment. A 10 point difference in mean score is considered the minimum important difference.⁴⁰ For pain, a 13mm difference in pain scores on the VAS (100mm) is considered the minimum important difference.⁴¹

Active range of motion of MCPJ, PIPJ, and distal interphalangeal joint (DIPJ) was measured by a senior hand therapist using 15 cm steel finger/toe goniometer) following a standardised protocol with a dorsal placement approach.⁴² Raw scores for total arc of motion were calculated by summing total flexion at PIPJ and DIPJ, with extension deficits at both joints subtracted from this figure. A difference of 20° combined range of motion of the PIPJ and DIPJ joints was perceived to be of clinical importance.⁴³ Strickland's original system for classifying finger movement was then used to categorize range of movement outcome.⁴⁴ This is essentially a simplification of the Total Active Motion (TAM) system and was originally designed to evaluate outcomes post flexor tendon injuries, but has been used for intra-articular PIPJ fractures.¹² It does not include motion of the MCPJ, as this is usually not affected in PIPJ or DIPJ fractures and could therefore bias the measurement of the functional

result. In this system, the total flexion minus the extension deficit (calculated as above) is then compared with a theoretical finger in which this value would be 175 degrees. Results are classified (as a percentage score compared with 175 degrees) into four categories: excellent (85-100%) good (70-84%) fair (50-69%) and poor ($\leq 49\%$)⁴⁵. Strickland's system is preferable as it provides comparison with a norm, and the availability of a normal contralateral finger is not a prerequisite for the measurement.⁴⁵ Information regarding complications and further surgery was extracted from the patient's medical record, and verified with the patient in case treatment was sought outside the original treating hospital. The therapist rated overall patient adherence with the treatment protocol, using a three-point scale, based on that used by Groth et al (1994)⁴⁶ which uses self-report, therapist observation, and attendance at therapy appointments to determine whether the patient is adherent, secondarily non-adherent, or non-adherent.

Participants

43 potentially eligible patients were identified from the database search. We were unable to establish contact with 10 potentially eligible individuals, 3 were unable to consent (due to cognitive or language barriers) and 5 declined to be involved. 25 participants underwent evaluations by the researchers: 19 men and 6 women. The mean age (at review) for the distraction group was 36.4 years; for the no-distraction group it was 44.4 years. This difference was not statistically significant ($p=0.10$). Mean time since injury was 34.8 months in the distraction group and 42.2 months in the non distraction group (also not significant: $p=0.36$). The distraction group was comprised of 50% complex intra-articular fractures (CIF)

and 50% fracture dislocations (FD); the no-distraction group had 27.3% CIF's and 72.7% FD's. The difference in proportions was not significant ($p = 0.46$). The mean percentage of joint surface involved was 40.4% in the distraction group, and 45% in the no- distraction group, also not significant ($p = 0.44$). The dominant hand was injured in 9 cases (5 in the distraction group; 4 in the no-distraction group) and the most common causes of injury were sporting accidents (10 cases) falls (6 cases) and cycling/motorcycle accidents (5 cases). Descriptions of participant demographics, injury type, joint, time since injury, complications, and occupation are summarised in Table 1. All enrolled had returned to full time work, study, or home duties at the time of review.

Statistical Methods

With a minimum of 16 per group, we calculated that this study would have an 80% power to detect a difference in continuous variables equivalent to one standard deviation with a 2-sided p-value of 0.05. All data was analysed using SPSS version 18.0 (SPSS Inc, Chicago, IL, USA). Group comparisons were made using student t-tests for normally distributed variables, chi-square tests or Fishers Exact tests for categorical variables, and Wilcoxon rank-sum tests otherwise. Correlations between primary outcome and continuous data were investigated using Pearson product-moment correlation coefficient (after checking for normality) and non-parametric data were tested using Spearman rank correlation coefficients. For complications, the number of participants in each group experiencing problems was expressed as a proportion. Data were then analysed as the difference in proportions

between the two groups, and are presented as odds ratios with 95% confidence intervals. A two sided p-value of 0.05 was considered to be statistically significant.

Results

All results for key measures are presented in Table 2.

Primary Outcome: Range of Motion

The mean combined range of motion of the PIPJ and DIPJ in the distraction group was 135°; in the no-distraction group it was 113°. This mean difference of >20° was clinically significant but not statistically significant ($p=0.21$). Strickland score means were 77.3% (categorised as a good result) for the distraction group and 64.5% (categorised as fair) for the no-distraction group; this was also not statistically significant ($p = 0.21$).

Primary outcome was also analyzed by age, sex, occupation type and injured finger.

Continuous data were investigated using Pearson product-moment correlation coefficient (after checking for normality) and non-parametric data were tested using Spearman rank correlation coefficients. There was a moderate negative correlation between age and total arc of motion which was statistically significant ($r=-0.46$, $p=0.02$) with increasing age associated with less range of motion. For sex, no significant difference was found ($\rho=-0.05$; $p = 0.82$). The relationship between arc of motion (PIPJ and DIPJ) and occupation type was

not significant ($\rho=-0.15$, $p=0.48$). There was also no significant relationship between the specific finger injured and range of motion ($\rho=-0.19$, $p=0.36$).

Secondary outcomes

DASH Scores

The mean DASH scores were 11.3 in the distraction group and 7.5 in the no-distraction group indicating a slightly higher level of self-rated symptoms and impact on daily living tasks in the distraction group, but this was not clinically or statistically significant ($p=0.46$) .

Patient satisfaction

Mean patient satisfaction scores were similar in both groups (3.9 and 3.7 out of a best possible score of 5 respectively; $p= 0.73$) indicating that most participants were reasonably satisfied with the outcome.

Pain

Overall, pain levels were low, with mean scores on the 10 cm Visual Analogue Scale (VAS) pain measure below 1.5 for both groups. There were no significant differences between groups ($p= 0.71$).

Complications

Seven of the 14 participants in the distraction group experienced one or more complications, two of them severe enough to require corrective surgery (one had malunion and collapse of fracture requiring open reduction and internal fixation, the other required tenolysis to release adhesions). Other complications in this group include: pin track infection successfully managed by oral antibiotics (N=2), swan-neck deformity (N=2), cold sensitivity (N=2), mallet deformity (N=1) and stiffness/adhesions (N=1). Seven of the 10 participants in the no-traction group experienced complications, one of whom underwent further surgery (tenolysis for adhesions). The other five experienced clinodactyly (N=2), stiffness/ adhesions (N=2), cold sensitivity (N=1), and subchondral sclerosis/cyst formation (N=1) pin dislodgement (N=1). The difference in incidence of complications between the two groups, expressed as a percentage of sample, was not significant (Odds Ratio: 13.6; 95% CI [-33.13, 60.41]; $p=0.78$).

Patient adherence with treatment

Twenty of 24 (83.3%) patients were rated as adherent (i.e. did not remove splint/only removed with extreme care; missed two or less appointments but followed the treatment plan), 2 (8%) secondarily non-adherent (splint loose or accidentally dislodged and instantly replaced; missed > two appointments, but otherwise followed treatment plan), and 3 (12%) were non-adherent (splint not worn properly/taken off several times; did not follow treatment plan). A Mann-Whitney U test revealed no significant difference in adherence between the 2 treatment groups ($p = 0.32$). The relationship between adherence and arc of motion was investigated using Spearman rank correlation coefficients. There was no statistically significant relationship between the two variables ($p=0.94$).

Discussion

Given the relative rarity of this injury and resulting difficulty recruiting adequate sample sizes, it is not surprising that there are no prospective clinical trials into the efficacy of distraction treatment. The evidence to date is mainly level 4 or 5 evidence, consisting of case series (evaluating outcomes of one particular type of traction treatment), or practice articles (explaining how to fabricate and fit the splint). The only exceptions found were one small study published nearly 20 years ago⁸ (describing individual outcomes for open reduction, two types of traction splint, and static splinting) and a conference abstract for a single-centre retrospective analysis of 41 patients treated with either a Suzuki frame or a modified Banjo splint.⁴⁷ Neither paper described how participants were allocated to treatment, nor did they provide statistical analyses between groups.

This retrospective cohort study aimed to add to the evidence by comparing two groups with similar characteristics and injury types who were allocated differing treatments based on the hospital at which they were treated.

Combined PIPJ and DIPJ motion was rarely reported in the traction literature, however our result (135°) was similar to that achieved with the Banjo or Schenck (130° in⁸ and 143° in³³) but superior to that achieved in a similar long-term study of people treated with the Suzuki pins and rubber traction (95.5° in¹²). The results achieved in our no-distraction group (68° PIPJ and 113° combined PIPJ/DIPJ) were similar to those reported in the only other study to

include an ORIF group (70° and 120° respectively).⁸ Although our analysis found the difference between groups to be clinically significant, we did not achieve statistical significance, and this is possibly explained by the low numbers enrolled in this study. Our finding of a moderate statistically significant negative correlation between age and total arc of motion was surprising given the relatively young sample (overall mean age at injury 39.96 years) but could indicate reduced articular remodelling and the early onset of osteo-arthritis in the older individuals in our sample.

Our mean range of motion at the PIPJ for the distraction group (78°) was comparable to that achieved in the only other published results for this type of splint (81° reported in Dennys in 1992²⁹) and to results achieved with arcuate splints such as the Banjo or Schenck (70° in⁴⁷, 80° in⁸, and 89° in³³).

No other published studies into distraction splints for finger fractures included DASH scores, and all used different methods to classify pain so it is not possible to compare results for these measures. In terms of complications, our finding of complications in 50% of the distraction group is similar to that reported in the other study using this style of splint (42%), with pin track infection, stiffness, flexion contracture, and mallet deformity being the key issues reported.²⁹

Limitations of this study

Unfortunately, numbers enrolled were lower than expected, which may have limited our power to detect a difference between groups. Also, treatment was provided by different

hand surgeons and therapists in the respective hospitals, introducing potentially confounding variables. Finally, our no-distraction group were on average 8 years older than our distraction group, which could account for the clinically significant difference in range of motion.

Conclusions

There are many different methods for treating complex intra-articular finger fractures, and in the absence of strong evidence from comparative studies, treatment is still based on the experience, skill, and personal preference of individual surgeons and hand therapists.⁶

Research into this area has been difficult for this reason, as well as the challenges involved in long-term follow-up of potential participants. Future research may need to be multi-centre to enable an adequate sample size, and should aim for consistent treatment protocols within and across comparison groups.

This study showed promising results for range of motion in the distraction splinting group, however was unable to show a statistically significant difference between this and static splinting with or without surgical fracture fixation.

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Figure 1 Patient with dorsal swing design dynamic distraction splint for PIP joint injury



Table 1 Demographic, injury, and treatment details of participants

case	age	sex	Injury type	Grade if FD	Joint	% joint surface	dominant hand	finger	follow up (months)	Delay to surgery (days)	Treatment received	Removal of distraction device or k-wire (weeks)	Complications	Further surgery	Occupation
1	39	F	CIF		PIP	50	No	5	27	10	Distraction splint	5.0	pin track infection		professional
2	60	M	CIF		PIP	40	No	3	44	4	" " "	6.7	-		professional
3	24	F	FD	4B	DIP	50	Yes	5	36	5	" " "	6.3	-		university student
4	25	M	CIF		PIP	40	Yes	5	33	6	" " "	5.1	swan neck, collapse of #, adhesions, malunion	ORIF	sales
5	50	M	FD	3A	PIP	25	No	4	29	9	" " "	7.1	-		manager
6	27	M	CIF		PIP	50	No	2	30	1	" " "	7.9	pin track infection		professional
7	32	M	FD	3B	PIP	40	No	5	21	12	" " "	6.1	-		manager
8	30	F	FD	4B	PIP	50	No	4	95	10	" " "	5.9	swan neck		clerical
9	42	M	FD	3A	PIP	25	Yes	4	32	12	" " "	5.9	-		technician/ trades-person
10	32	F	CIF		PIP	50	Yes	5	45	8	" " "	4.3	Mallet finger cold sensitivity		clerical
11	27	M	FD	3A	PIP	25	No	4	31	7	" " "	4.7	-		professional

12	32	M	CIF		PIP	40	No		4	36	7	"	"	"	4.9	-		technician/ trades-person
13	39	M	FD	3B	PIP	40	Yes		5	15	7	"	"	"	4.9	cold sensitivity		technician/ trades-person
14	51	M	CIF		PIP	40	No		3	12	2	"	"	"	6.9	stiffness, adhesions	Tenolysis	professional
15	59	M	FD	4B	PIP	50	Yes		2	53	17	open reduction VP repair k-wire			2.1	clinodactyly, subchondral sclerosis / cyst		technician/ trades-person
16	51	M	FD	3A	PIP	40	No		5	49	6	open reduction 2 lag screw			N/A	adhesions		professional
17	22	F	FD	3B	PIP	30	Yes		5	35	28	open reduction 1 lag screw			N/A	-		university student
18	32	M	FD	4B	PIP	60	No		5	19	2	closed reduction 2 k-wires			6.4	cold sensitivity		technician/ trades-person
19	25	M	CIF		DIP	60	Yes		4	10	2	closed reduction 2 k-wires			6.0	-		professional
20	50	F	FD	3*	PIP	40	No		5	69	13	open reduction 1 lag screw			N/A	adhesions		community/personal service
21	55	M	FD	4D	PIP	80	Yes		5	73	0	open reduction k-wire, bone graft			4.0	adhesions	Tenolysis	labourer
22	45	M	CIF		PIP	30	No		5	34	2	open reduction 4 screws & plate			N/A	clinodactyly		manager
23	51	M	FD	4B	PIP	50	No		5	12	N/A	conservative			N/A	-		professional
24	46	M	FD	1C	PIP	5	No		2	91	N/A	conservative			N/A	-		sales
25	53	M	CIF		PIP	50	No		5	40	14	closed reduction 2 k-wires			4.0	-		Home duties

M=male; F=female; CIF=complex intra-articular fracture; FD = Fracture Dislocation; Finger: 2=index, 3=middle, 4=ring, 5=little; N/A=Not Applicable; VP = Volar Plate, ORIF= Open

Reduction Internal Fixation, * = severity of dislocation unknown as reduced before x-ray

Table 2: Comparison of Results for digits treated with distraction vs no-distraction splinting

		Distraction Group (N=14)	No traction group (N=11)	<i>p</i> value
Range of Motion * (PIP+DIP)		135°± 34.0	113°± 53.4	0.21
Strickland Score		77.3% ± 19.4	64.5% ± 30.5	0.21
Strickland Classification: Excellent/Good/Fair/Poor		5/5/2/2	3/3/1/4	N/A
Range of motion at injured joint	PIP	78°±18.1	72°±34.7	0.56
	DIP	52°	75°	N/A (N=1 in both groups)
DASH		11.3 ± 13.5	7.5 ± 11.5	0.46
Patient satisfaction (5 point scale (5= very satisfied))		3.9 ± 1.4	3.7 ± 1.3	0.73
Pain VAS (0= no pain)		1.3 ± 2.2	1.1 ± 1.2	0.71
Complication incidence		7/14 (50%)	7/11 (64%)	0.78

*The values are given as the mean (and the standard deviation) for the combined range of motion for the proximal interphalangeal and distal interphalangeal joints. N/A = Not applicable; DASH = Disabilities of the Arm, Shoulder and Hand outcome questionnaire; VAS = Visual Analogue Scale.

6.3 Impact of the study

Journal Metrics: to be confirmed (pending acceptance by journal)

Although results are promising for distraction treatment, it is not possible to strongly recommend one treatment over another. Patients are given information about the potential benefits and risks of the different treatment options, and are consulted about their preferences prior to commencing a course of treatment. Hand therapy staff are currently collecting data for future research into the newer (volar approach) splint design¹⁴⁷ which may yield better results as it is more stable and more comfortable for patients, and therefore may lead to improved adherence with splint wear and exercise.

6.4 Chapter Summary

This study showed promising results for range of motion in the distraction splinting group, however was unable to show a statistically significant difference between this and static splinting with or without surgical fracture fixation.

This has interesting implications for how we present this treatment to our patients, as many of those interviewed for the qualitative study (Chapter 5) stated that they went along with treatment as the health care team strongly espoused the benefits of distraction, and did not offer them an alternative, as illustrated in the following excerpt from one interview:

Interviewer: So the explanation that you got wasn't very clear to you?

Interviewee: Not really.

Interviewer: And you weren't told about the other options?

Interviewee: Not really given the other options, kind of thing.

One patient declined distraction treatment and presented as quite defensive in his first hand therapy appointment after the clinic in which he communicated his decision. After reassuring him that his decision was respected, he confided that he felt that he was "treated like an idiot" by the doctor and told that he would have an inferior outcome. Eight months after completing treatment, he emailed me the following statement:

Hi Lisa

Please find below my brief Patient Statement. Best of luck with your research and I would be very interested to see your final conclusions.

PATIENT STATEMENT

Early in 2010 I fell backwards off a treadmill at the gym. I used my left hand to break my fall and in the process broke the little finger on that hand. With my doctors referral I presented to plastic surgery outpatients at the Alfred Hospital in Melbourne. The consulting specialist told me that X rays revealed that the fracture in the joint of my finger was complex and unlikely to heal cleanly.

The specialist strongly recommended corrective surgery that would have involved use over many weeks of a large splint covering most of my left arm. After consideration I rejected his recommendation because I was about to get married and have my honeymoon and I did not want the huge inconvenience that such a large splint would have created.

Instead I kept the finger in a much smaller finger splint and allowed the fracture to heal naturally. In addition I used a series of finger manipulation exercises recommended to me by my occupational therapist whom I saw on a regular basis at the Alfred Hospital in the months after the accident.

It is now about 8 months since the accident. My finger causes me virtually no inconvenience. I experience no pain in the finger except when I jar or twist it. It certainly looks irregular but my understanding is that I have regained about 70% of its former flexibility.

I am very thankful that my impending wedding motivated me to reject the recommendation of surgery and allow my finger to heal naturally. This is especially so as I understand that surgery could well have been very painful, highly inconvenient and would have had no certainty of delivering an outcome significantly better than the one I have achieved.

Sincerely,

B

The following dimensions of the MAM were examined in this study:

- Therapy-Related, specifically the splint design (distraction vs no-distraction) and therapy program (immediate hourly passive mobilisation vs gentle active mobilisation at 2 weeks);
- Patient-Related, specifically gender; and
- Socio-economic, specifically age and occupation category.

This study was unable to establish a significant relationship between the variables studied and adherence.

The following chapter is the last of the publications in this thesis and deals with a treatment that is difficult to adhere to for very different reasons. In this instance, the injury is generally

not painful during treatment and the splint is small and relatively unobtrusive. The period of splinting is eight weeks and the injured joint must remain completely immobile during that time, leading to completely different challenges for the patient.

**Chapter 7 – Mallet finger: a single-blind randomized controlled trial
of three different splints**

Chapter 7

Mallet finger: a single-blind randomized controlled trial of three different splints

7.1 Introduction

The previous chapters have examined patient adherence in cases where the splinting and rehabilitation can be experienced by the patient as painful or confronting. This chapter explores a treatment which is often experienced as dull, restrictive, and of long duration. Both treatments require high levels of adherence from patients in order to achieve a favourable outcome, but the challenges to adherence are different due to the nature of the injury and the vastly different pain levels experienced. As for the previous studies, this chapter arises from the author's clinical work at the Alfred Hospital.

Mallet finger, also known as drop or baseball finger, occurs when the tip of the finger is suddenly forced into flexion, causing a tear of the extensor tendon or a small fracture of the distal phalanx where the tendon inserts. This results in the patient being unable to actively straighten the end of the finger and if not managed correctly, the patient can be left with a persistent extension lag (loss of voluntary straightening) and swan neck deformity (a flexion deformity of the distal finger joint with a secondary hyperextension deformity of the proximal joint resulting from an imbalance in the extensor mechanism). Other persistent problems associated with mallet finger include cold intolerance^{148, 149} and chronic pain.¹⁴⁸⁻¹⁵⁰

The most common presentation of this injury is the type 1, which is a closed injury (i.e. the skin is intact) resulting from blunt trauma such as trying to catch a fast moving ball, or falling onto the fingertip. For definitions of the injury types, see table 1 in the following journal article. Treatment for type 1 mallet injuries commonly involves immobilising the distal finger joint in extension (or slight hyper-extension) in a splint for six to eight weeks, usually followed by overnight splinting for a further four weeks¹⁴³. Positioning is crucial, as the tendon needs to be relaxed, and the torn ends (or fracture fragments) in close proximity for the best chance to heal¹⁴³.

Splints currently in common use include the pre-fabricated “Stack splint”¹⁵¹ and custom-made splints such as the perforated thermoplastic thimble-shaped splint and variations on padded aluminium (or Zimmer) splints fixed with adhesive tape. The advantages of the Stack splint include low cost and ease of application, however complications associated with its use include skin maceration and difficulty achieving adequate fit for all fingers^{145, 152} leading to imperfect immobilisation and treatment failure in some cases.

The perforated thermoplastic splint has the advantage of perfect fit as it is moulded directly on the patient, but its circumferential shape can lead to difficulty removing and reapplying, and some patients have skin irritation or maceration due to difficulty keeping the skin dry¹⁵³.

The padded aluminium splint is usually applied dorsally, is adaptable to a wide variety of finger shapes and sizes¹⁵² and also allows pinch and other grips¹⁵⁴. One trial¹⁵² reported significantly less skin irritation than with a Stack splint, although placement of the splint appears to be an issue, with another trial¹⁵⁵ reporting that those splints placed on the dorsal

surface of the digit were associated with the highest number of skin problems. A retrospective file audit of patients with either type 1a or 1b injuries treated with dorsal aluminium splints¹⁵⁶ found that most patients achieved an excellent (51% of type 1a and 73% of type 1b) or good (31% of type 1a and 20% of type 1b) outcome as assessed using the Crawford Scale¹⁵⁷ (see Table 2 in the following journal article). It is worth noting, however, that the authors were only able to report the 12 week outcome data for 54 of the 155 patients treated over the study period (35% of sample), meaning that this study is highly susceptible to bias.

An adapted version of the padded aluminium splint is the “Mexican hat” splint¹⁵⁸. This splint is manually moulded to “produce a “buckle” over the DIP in order to prevent direct pressure at this point. The side view resembles a Mexican Hat...hence its name”(158 p 489). Similarly, the Kleinert modified dorsal finger splint¹⁵⁹, also fabricated from padded aluminium, has a dip cut out of the padding in its middle third to prevent sustained pressure over the DIP joint. There are, however, no published clinical trials for either of these splints to test the contention that the shape is any more effective than standard dorsal aluminium splinting.

The Hand Therapy team at the Alfred Hospital has tended to use the thermoplastic splint due to the ability to achieve a close fit and, therefore, immobilisation of the tendon ends in the healing phase. They had, however, noted the following challenges to patient adherence:

- Poor understanding of the injury and the treatment time required for it to heal. Many patients at first believed they had dislocated the distal joint, and thought that treatment would only require a short period of immobilisation. They were not

expecting to wear a splint for eight weeks, and some commented that this seemed excessive for what appeared to be a very small injury. This has parallels with the findings from the qualitative study of patient experience of distraction treatment (see Chapter 5);

- difficulty keeping the finger dry, particularly those who work in hospitality or health care sectors, where they need to wash their hands frequently; and
- difficulty keeping the splint intact and in place at all times for the first eight weeks, especially during occupations such as sports, playing a musical instrument, or using a computer keyboard.

7.2 Chapter Contents

O'Brien, L and Bailey, M (2011) Single blind, prospective randomized controlled trial comparing dorsal aluminium and custom thermoplastic splints to stack splint for acute mallet finger. Archives of Physical Medicine and Rehabilitation (scheduled for publication in February issue 2011 Vol. 92(2):191-98

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This study aimed to compare overall outcome (extensor lag at 12 and 20 weeks) with three different types of finger splint in patients with the most common type (type 1a or b) of mallet finger injuries. The splints chosen were the circumferential perforated thermoplastic splint, the dorsally applied aluminium-foam “Mexican hat” splint¹⁵⁸ and the off-the-shelf “Stack splint”¹⁶⁰. We also aimed to discover whether there were differences between groups in complication rates, treatment failure, patient satisfaction, pain, and treatment compliance. The term *compliance* was used in this context, as participants did not get to collaborate with the therapist in choosing their treatment, due to the study design (a randomised controlled trial).

Monash University

Declaration for Thesis Chapter Seven

Declaration by candidate

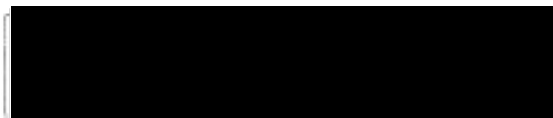
In the case of Chapter Seven, the nature and extent of my contribution to the work was the following:

Nature of contribution	Extent of contribution (%)
Concept development, literature review, ethics application, data collection, writing and submission of manuscript	85%

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	Nature of contribution	Extent of contribution (%) for student co-authors only
Dr Michael Bailey	Statistical advice on study design, analysis	15%

Candidate's
Signature



Date
1/11/10

Declaration by co-authors

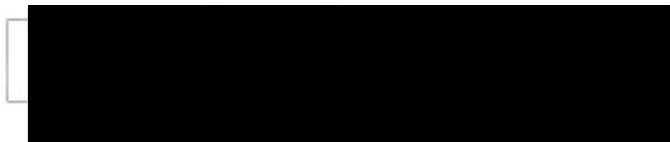
The undersigned hereby certify that:

- (1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
- (2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
- (3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
- (4) there are no other authors of the publication according to these criteria;
- (5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
- (6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s) **Monash University, The Alfred Hospital**

[Please note that the location(s) must be institutional in nature, and should be indicated here as a department, centre or institute, with specific campus identification where relevant.]

Signature 1



Date
1/11/2010

ORIGINAL ARTICLE

Single Blind, Prospective, Randomized Controlled Trial Comparing Dorsal Aluminum and Custom Thermoplastic Splints to Stack Splint for Acute Mallet Finger

Lisa J. O'Brien, MCLinSc, BAppSc(OT), Michael J. Bailey, PhD, MSc

ABSTRACT. O'Brien LJ, Bailey MJ. Single blind prospective, randomized controlled trial comparing dorsal aluminum and custom thermoplastic splints to stack splint for acute mallet finger. *Arch Phys Med Rehabil* 2011;92:191-8.

Objective: To compare Stack, dorsal, and custom splinting techniques in people with acute type 1a or b mallet finger.

Design: Multi-center randomized controlled trial.

Setting: Outpatient hand therapy clinics (2 public hospitals and 1 private clinic).

Participants: Patients (N=64) with acute type 1a or b mallet finger.

Interventions: Prefabricated Stack splint (control), dorsal padded aluminum splint, or custom-made thermoplastic thumb splint. All were worn for 8 weeks continuously, with a 4 week graduated withdrawal and exercise program.

Main Outcome Measures: The primary outcome was extensor lag at 12 and 20 weeks. Secondary outcomes were incidence of treatment failure, complications, range of motion of the distal interphalangeal joint, pain (visual analog scale) patient compliance, and patient satisfaction.

Results: There was no difference in the primary outcome between groups at 12 or 20 weeks; however, the Stack and dorsal splints had significant rates of treatment failure (23.8% in both groups, compared to none in the thermoplastic group; $P=.04$). There was a medium negative correlation between patient compliance and degree of extensor lag. No significant differences between groups were observed for patient satisfaction or pain.

Conclusions: As splints for mallet finger must be worn continuously for 6 to 8 weeks, and compliance correlates with favorable outcomes, treating practitioners must ensure the splint provided is robust enough for daily living requirements and does not cause complications, which are intolerable to the patient. In this study, no extensor lag difference was found between the 3 splint types, but custom-made thermoplastic splints were significantly less likely to result in treatment failure.

Key Words: Finger injuries; Orthotic devices; Rehabilitation; Splints; Tendons.

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MALLET FINGER, A LOSS OF continuity of the distal insertion of the extensor tendon at the finger tip, is a common hand injury in ball sports,¹ but can also occur from minor incidents such as bed-making and trips/falls.² If not managed correctly, the patient can be left with a persistent extension lag and swan neck deformity (flexion deformity of DIPJ with a secondary hyperextension deformity of the proximal joint resulting from an imbalance in the extensor mechanism). Other persistent problems associated with mallet finger include cold sensitivity^{3,4} and chronic pain,^{3,5} although these are relatively uncommon. Conservative treatment is the primary choice for a typical mallet finger injury,⁶ which is a closed injury with or without a small (<20% of joint surface) bony avulsion fragment. These injuries are classified as Doyle type 1a (no bone injury, but loss of extensor tendon continuity) or 1b (small bony avulsion of terminal extensor tendon without DIPJ subluxation).⁷ Treatment involves static splinting in full extension to slight hyperextension to allow relaxation of the tendon and encourage healing by bringing the torn ends or fracture fragments closer together during the healing phase. The technique adopted during splinting is regarded as very important because over-zealous hyperextension can lead to restriction of circulation and impaired healing or even skin necrosis.^{8,9}

Identifying a superior splint would improve the management of these injuries, and a recently published well designed RCT found a trend in favor of the custom thermoplastic splint (compared to dorsal or volar padded aluminum splints) for resolving extensor lag, although this was not statistically significant.¹⁰ A Cochrane review (updated in 2008)⁶ also found insufficient evidence to establish the comparative effectiveness of different types of finger splints (either custom-made or off-the-shelf) concluding that "until there is reliable evidence to the contrary, the continued use of the off-the-shelf but suitably fitted Stack mallet splint, or equivalent, for the majority of patients (ie, those with acute closed soft-tissue or bony mallet finger injury) seems appropriate."^(p8) It is worth noting that only 4 trials met the review's inclusion criteria for research design, and all of these were "small, heterogeneous, inadequately described and reported... and had methodological

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The trial was registered with the U.S. National Library of Medicine and the Australian Clinical Trials Registry (trial nos. NCT00310570 and N012606000123549, respectively).

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List of Abbreviations

ANOVA	analysis of variance
DIPJ	distal interphalangeal joint
ITT	intention-to-treat
RCT	randomized controlled trial
VAS	visual analog scale

flaws."^(p9) They recommended that future research include measures of treatment failure, as well as patient satisfaction, preference, and treatment adherence.

This study aimed to compare outcomes achieved with 2 different types of finger splint to the Stack splint for patients with acute Doyle 1a or 1b mallet finger injuries. This trial differs from those previously published in that it also includes measures of patient physical activity levels, satisfaction, pain, and treatment compliance. We hypothesized that the custom-made thermoplastic splint would demonstrate superior results to the noncustom splints.

METHODS

This study was a prospective, multi-center, single blind RCT of patients presenting to 1 of 2 urban public hospitals and a private hand therapy clinic all located in Melbourne, Australia. The study was conducted between May 2006 and March 2010 and was approved by the Ethics Committees of Monash University, The Alfred Hospital, and Southern Health. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and the National Statement on Ethical Conduct in Human Research (2007) of the Australian National Health & Medical Research Council. The trial was registered with the U.S. National Library of Medicine and the Australian Clinical Trials Registry (trial nos. NCT00310570 and NO12606000123549, respectively).

Hand surgeons, general practitioners, and emergency department doctors referred participants for this trial to the hand therapy departments of 2 urban public hospitals (The Alfred and Dandenong hospitals) and 1 private hand therapy practice (Resolve Hand Therapy) in Melbourne, Australia. Participants who gave informed written consent were seen by an experienced hand therapist who collected baseline data, including days postinjury, whether a bony injury had occurred (according to radiographs sent with referral), and the category of current activity levels (including work, home duties, and recreation) according to Ludlow's¹¹ definition of work demands. The therapist measured the injured finger's degree of extensor lag with a standardized steel finger goniometer with 1 degree increments using a dorsal approach. Other relevant health information such as the presence of other hand injuries on injured hand, smoking status, and medication were noted. Participants were then allocated via a computer-generated randomized sequence to 1 of 3 groups: Stack splint (control), dorsal aluminum, or custom thermoplastic. The therapist then provided and fitted the splint according to the randomized sequence. Allocation concealment was achieved by having treatment group information contained in consecutively numbered, sealed opaque envelopes which were prepared by the lead agency

(The Alfred Hospital). Blocks of consecutively numbered envelopes were distributed to the different centers and participants were allocated in strict numerical sequence.

Inclusion Criteria

Patients eligible for this trial had a diagnosis of type 1a or 1b closed mallet finger (based on radiographs and clinical finding of extensor lag at the DIPJ) with the injury occurring within the previous 2 weeks. They also needed to be able to give informed written consent in English.

Exclusion Criteria

Those with open injuries, mallet thumb, or coexisting rheumatologic illness were excluded.

Interventions

The 3 splints in this trial were selected on the basis of research or anecdotal evidence in support of each. These were the prefabricated Stack splint,¹² the dorsal aluminum (made from 13-mm width padded aluminum), and the custom-made circumferential thermoplastic splint constructed from 1.6mm Orfit Classic Soft micro-perforated.^a Splints are pictured in figure 1. The dorsal aluminum splint was manually molded to produce a buckle over the DIPJ in order to prevent direct pressure at this point. This splint is also known as a Mexican Hat splint due to its side-on profile.⁹ The Stack splints varied in size from 1 (smallest) to 7 (largest). The appropriate size was selected for each participant with the aim of achieving the firmest fit without compromising circulation. This was assessed at each review and changed if necessary. The dorsal aluminum and Stack splints were fixed to the finger with Durapore 12.5 mm skin tape^b or Elastoplast 13mm strapping tape^c; the custom thermoplastic splint did not require tape. All splints were to be worn continuously for 8 weeks, and all allowed full proximal interphalangeal joint motion. Participants were given the same information regarding hygiene procedures (adapted from Richards et al¹³) and a diary to complete regarding instances of (and reasons for) splint removal, modification, or accidental dislodgement. Participants were also provided with a review appointment at 1 week to check splint fit, and further reviews at 6, 8, 10, 12, and 20 weeks. Patients were instructed to contact the clinic immediately if their splint became damaged or was lost so that it could be replaced as soon as possible. Splints were checked at each appointment and remolded, repaired, or replaced if required. The treating therapist noted any complications and recorded instances of treatment failure, defined as significant problems requiring a change to a different splint type. Examples of reasons for treatment failure were partici-

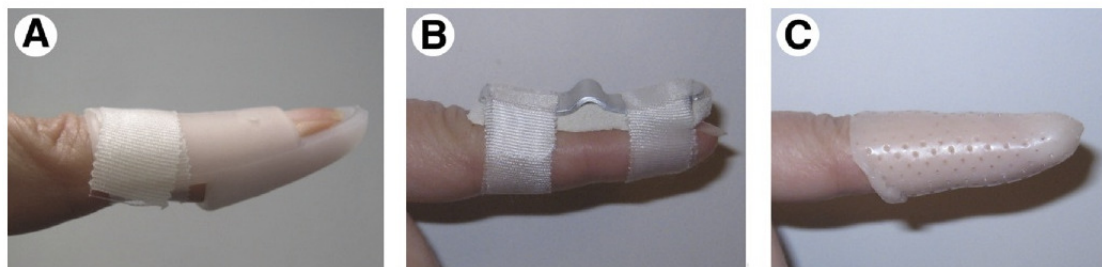


Fig 1. (A) Stack splint; (B) Dorsal aluminum; (C) Custom thermoplastic.

pant report of significant splint discomfort or impracticality, skin necrosis or severe maceration, or poor fit causing inadequate immobilization. The therapist rated patient compliance with the treatment protocol at 6 and 8 weeks, using a 3-point scale designed by Groth et al¹² which uses self-report, therapist observation, and attendance at therapy appointments to rate the patient as (3) Compliant (splint never removed or removed only with extreme care, missed 2 or less appointments, and followed treatment plan); (2) Secondly noncompliant (splint loose or accidentally dislodged and instantly replaced and/or missed more than 2 appointments but otherwise followed treatment plan); or (1) Noncompliant (splint not worn properly or taken off several times; did not follow treatment plan). All therapists/assessors were trained at the respective sites by the lead author at the commencement of recruitment to ensure consistency of splint fabrication, and measurement of extensor lag, pain, compliance, and patient satisfaction.

The treating therapist saw the patient up until the 8-week review, and a graduated splint withdrawal and exercise program commenced at this point if there was no evidence of extensor lag. If there was extensor lag greater than 10°, the patient was advised to wear the splint continuously for a further 2 weeks. The program comprised overnight splint wear until 12 weeks, with removal of splint for brief exercise periods during the day (10 repetitions of loose fist then full finger extension, 5 times/day) for the first week postimmobilization, removal for light activities only for the second week, and splint wear only for contact sports or heavy activity in the third week.

A blinded assessor (another hand therapist who was not aware of the splint allocated to the patient) completed the following measurements at 12 and 20 weeks: degree of extensor lag and total active range of motion at the DIPJ (measured with a standardized steel finger goniometer with 1 degree increments using a dorsal approach); patient satisfaction with result on 5-point Likert scale, ranging from 1 (very dissatisfied) to 5 (very satisfied); and pain on a typical day during the last week, measured by 10-cm VAS. There is evidence that the VAS is a reliable (test-retest 0.99) and valid ($r=0.6$ correlation between VAS and descriptive pain scale) measure of subjective pain experience.¹⁴ To ensure blinding, splints were removed

prior to the assessment and reapplied afterwards by another therapist or assistant using a standard technique.

Participants

Eighty-five patients were assessed for eligibility into the trial, and 21 of these were excluded due to not fitting eligibility criteria, refusal to participate, or logistical reasons (eg, inability to attend all follow-up appointments due to travel plans in the next 5mo). Participants ($N=64$) with an age range of 11 to 86 years were enrolled during the study period (May 2006–March 2010). Participants included 42 men (65.62%) and 22 women (34.4%). Just over half sustained the injury to a finger on the dominant hand, and 28 (43.7%) sustained a bony (Doyle 1b) injury with the rest sustaining a tendon rupture (Doyle 1a) only. The index finger was involved in 7 cases (10.9%), the middle finger in 13 cases (20.3%), the ring finger in 22 cases (34.4%), and the little finger in 22 cases (34.4%). Groups were similar at baseline on all characteristics except sex (the thermoplastic splint group had a statistically significant higher proportion of women; $P=.05$). The thermoplastic group also had a lower proportion of smokers, but this was not statistically significant ($P=.10$). Table 1 summarizes participant details at baseline.

Figure 2—Consolidated Standards of Reporting Trials flow chart—illustrates movement through the trial for each participant group. At the week 1 review, 10 participants (5 each in the Stack and dorsal aluminum groups) were classified as splint failure (defined as a need to change splint type) as decided by the treating therapist and patient. In the Stack group, 4 were changed to circumferential thermoplastic splints, and 1 was changed to the dorsal aluminum splint. In the dorsal aluminum group, 4 were changed to circumferential thermoplastic splints, and 1 was changed to a volar aluminum splint. The decision regarding the type of replacement splint was made by the treating therapist, and was based on patient preference, site of skin breakdown, patient activity levels, and occupational demands. There were 14 participants lost to follow-up at 20 weeks (21% of sample) with comparable dropout figures in each group.

Table 1: Participant Details at Baseline (ITT)

Group	Control (Stack) (n=21)	Dorsal Aluminum (n=21)	Thermoplastic (n=22)	Total (N=64)
Sex: men/women	16/5	16/5	10/12*	42/22
Age: mean \pm SE (range) in years	39.6 \pm 3.2 (14-69)	33.1 \pm 3.4 (11-86)	39.9 \pm 3.0 (16-76)	37.6 \pm 1.9 (11-86)
Occupation:				
Sedentary	7	10	10	27
Light	5	2	5	12
Medium	6	5	4	15
Heavy	3	3	2	8
Very heavy	0	1	1	2
% Injury to dominant hand	42.9%	57.1%	59.1%	53.1%
Finger injured				
Index	0	1	6	7
Middle	4	3	6	13
Ring	11	9	2	22
Little	6	8	8	22
Mean days postinjury \pm SE	5.0 \pm 1.0	4.2 \pm 0.7	4.8 \pm 0.7	4.6 \pm 0.4
Mean extensor lag (in degrees) \pm SE	25.5 \pm 2.8	21.6 \pm 2.6	22.0 \pm 2.7	23.0 \pm 1.6
Bony injury (Doyle 1b)/tendon only (Doyle 1a)	7/14	9/12	11/11	27/37
% Smoker	28.6%	23.8%	4.5%	18.8%

*Significant at $P<.05$.

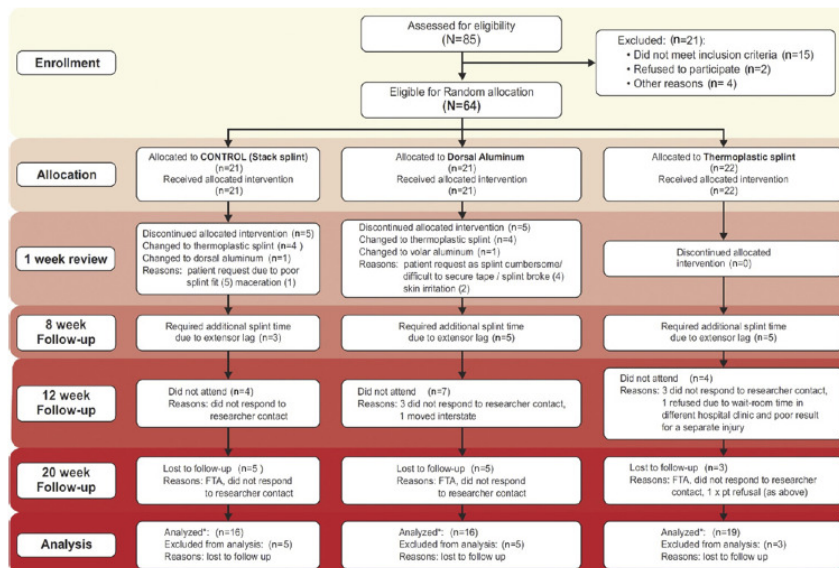


Fig 2. Consolidated Standards of Reporting Trials flow chart.
Abbreviation: FTA, Failed To Attend.
*Intention to Treat Analysis.

Statistical Methods

With a minimum of 16 per group, we calculated that this study would have an 80% power to detect a difference in continuous variables between any 2 groups equivalent to 1 SD with a 2-sided P value of .05. All data was analyzed using SAS version 9.2.⁴ Baseline participant characteristics in the 3 groups were compared using 1-way ANOVA for continuous variables and chi-square tests for categorical variables. For the primary analysis, data from the 12- and 20-week reviews were compared using ANOVA. The secondary measure of complications causing treatment failure was compared using chi-square test for equal proportion. ANOVA (for measures of satisfaction and pain) and Kruskal-Wallis tests (for compliance) were used where required. A 2-sided P value of .05 was considered to be statistically significant, and, where an overall group difference was found, pair-wise comparisons were made to establish the specific reason behind the statistical significance. All analyses were performed on an ITT basis, but given the sample size and the nature of this study, it was considered appropriate to also perform a per protocol analysis for the primary outcome. Per-protocol groups were defined as the final splint groups if participants did not tolerate the original randomly allocated splint, and were changed to a different splint.

RESULTS

Primary Outcomes

Extension lag. At 10 weeks, the average change in extensor lag (from baseline) was 19.7°; at 20 weeks it was 20.5°. Results for extension lag at different time-points are summarized by allocated treatment group (ITT) and actual treatment received (per protocol) in table 2. In both the ITT analysis, and the per protocol analysis, differences between groups were also not significant at 8, 10, 12, or 20 weeks.

Primary outcome was also analyzed by sex, smoking status, Doyle type 1a/1b injury, and injured finger. For sex, no signif-

icant difference was found at 8, 10, and 12 weeks; however, there was a significant difference at 20 weeks in favor of women (difference in means=4.9°; 95% confidence interval, 0.2–9.7; $P=.04$). For both smoking status and injury type (Doyle 1a vs 1b), there were no significant differences between groups at any time point. A 1-way between-groups ANOVA was conducted to explore the impact of injured finger on extensor lag. There was a statistically significant difference in extensor lag at 10 weeks between the little and ring fingers, with the little finger having 11.5° greater lag ($P=.002$), but this improved by 12 weeks and continued to improve at 20 weeks (mean difference=3.5° and 1.4°; $P=0.60$ and 0.92, respectively). For full results, see table 3.

Correlations with age and occupation level. Age was strongly correlated with extensor lag at 12 weeks ($r=0.55$, $P<0.001$) and moderately correlated at 20 weeks ($r=0.44$, $P=0.001$) with increasing age associated with worse extensor lag. Occupation level (as measured on the Ludlow scale) was not significantly correlated with extensor lag at either 12 or 20 weeks ($\rho=-0.08$, $P=0.58$; $\rho=0.06$, $P=0.68$ respectively).

Secondary Outcomes

Treatment failure and complications. Participants ($n=23$) experienced complications, mainly transient skin maceration or irritation (12 instances), poor splint fit with inadequate immobilization (9 instances), splint breakage/splitting (4 instances), and pain/splint discomfort (3 instances). There were 4 instances of patients expressing dissatisfaction with the splint appearance, cumbersome nature, or constant need for repair/replacement. Results are presented in table 4. Most complications were found in the Stack splint group (19 instances, compared to 8 in the dorsal aluminum group and 5 in the thermoplastic group). The thermoplastic splints were more likely to split or crack down the seam (3 instances), but all participants who experienced this were able to secure the splint

Table 2: Outcome at 8, 10, 12, and 20 Weeks by Mean Extension Lag in Degrees (95% Confidence Intervals)

Analysis/Time Point	Splint Type			P
	Control (Stack)	Dorsal Aluminum	Thermoplastic	
ITT (ie, originally allocated group)				
Week 8	(n=18) -0.4 (-3.0 to 2.2)	(n=16) 4.9 (0.7 to 9.0)	(n=20) 3.5 (-0.9 to 7.9)	0.12
Week 10	(n=18) 2.4 (-2.8 to 7.7)	(n=17) 6.2 (1.1 to 11.4)	(n=18) 4.9 (0.9 to 9.0)	0.49
Week 12	(n=17) 0.9 (-1.1 to 3.0)	(n=14) 5.2 (-.70 to 11.1)	(n=18) 4.7 (1.0 to 8.5)	0.21
Week 20	(n=16) 1.5 (-0.5 to 3.5)	(n=16) 3.1 (-1.6 to 7.9)	(n=19) 5.0 (1.6 to 8.5)	0.33
Per Protocol (ie, treatment actually received)				
Week 8	(n=15) -0.5 (-3.7 to 2.7)	(n=12) 2.5 (0.0 to 5.0)	(n=27) 4.4 (0.5 to 8.2)	0.16
Week 10	(n=15) 2.9 (-3.4 to 9.3)	(n=13) 4.2 (-1.5 to 10.0)	(n=25) 5.6 (2.1 to 9.1)	0.69
Week 12	(n=14) 0.4 (-1.9 to 2.8)	(n=11) 2.7 (-1.4 to 6.8)	(n=23) 5.7 (1.8 to 9.5)	0.11
Week 20	(n=13) 1.5 (-0.9 to 3.8)	(n=12) 1.2 (-0.7 to 3.2)	(n=26) 5.2 (1.6 to 8.8)	0.14

with tape and attend clinic for repairs, and did not request a change to a different splint type. Ten cases (5 each in the Stack and dorsal aluminum groups) were classified as splint failure. This was statistically significant ($P=.04$) with post hoc analysis between groups using Fisher's exact test finding greater differences in dorsal aluminum versus thermoplastic ($P=.01$) than Stack versus thermoplastic ($P=.04$).

Thirteen (20.3%) of the total sample required an additional 2 weeks of splinting due to presence of extensor lag after 8 weeks of splinting. This was evenly spread between groups, with no significant differences ($P=.45$). Three of these had a bony injury (Doyle type 1b), and 10 had a tendon rupture only (type 1a), but again this was not significant ($P=.14$).

Range of Motion

One-way ANOVA showed no significant differences between groups at 20 weeks on range of motion at the DIPJ ($P=.72$). The mean \pm SD for each group were: Stack splint 64.4 ± 4.7 , dorsal aluminum 59.1 ± 5.2 , and thermoplastic 62.7 ± 4.0 .

Patient Compliance With Treatment

At 6 weeks, 48 (82.8%) of 58 patients were rated as compliant (ie, did not remove splint/only removed with extreme care; missed 2 or less appointments but followed the treatment plan), 9 (15.5%) were secondarily noncompliant (splint loose

Table 3: Outcome at Each Time-Point by Sex, Smoking Status, Type of Injury, and Finger Injured

Variables	Mean Extension Lag in Degrees \pm SE			
	Week 8	Week 10	Week 12	Week 20
Sex				
Men	3.7 \pm 2.3	4.7 \pm 1.8	6.5 \pm 2.5	6.4 \pm 2.2
Women	2.0 \pm 1.1	4.4 \pm 1.8	1.8 \pm 0.8	1.5 \pm 0.7
Mean difference (95% CI)	1.6 (-2.9 to 6.2)	0.3 (-5.3 to 5.9)	4.7 (-0.8 to 10.1)	4.9 (0.2 to 9.7)*
Smoking status				
Smoker	2.6 \pm 1.1	4.4 \pm 1.3	3.8 \pm 1.3	3.5 \pm 1.2
Nonsmoker	2.7 \pm 3.6	4.8 \pm 4.4	2.1 \pm 1.4	2.7 \pm 1.5
Mean difference (95% CI)	-0.7 (-5.9 to 5.8)	-0.3 (-7.1 to 6.4)	1.6 (-4.2 to 7.6)	0.8 (-4.4 to 6.0)
Type of injury				
Doyle 1a	2.4 \pm 1.7	5.1 \pm 1.9	2.8 \pm 1.3	2.7 \pm 1.3
Doyle 1b	2.9 \pm 1.2	3.5 \pm 1.6	4.7 \pm 1.8	4.3 \pm 1.4
Mean difference (95% CI)	-0.4 (-4.9 to 4.0)	1.5 (-3.9 to 7.0)	-1.9 (-6.4 to 2.5)	-1.6 (-5.6 to 2.4)
Finger injured				
Index	2.7 \pm 1.7	3.0 \pm 1.8	3.0 \pm 3.0	4.2 \pm 2.4
Middle	0.3 \pm 1.0	3.0 \pm 2.0	3.1 \pm 1.8	2.8 \pm 1.6
Ring	0.2 \pm 1.5	-0.3 \pm 1.3	2.1 \pm 2.2	2.7 \pm 2.1
Little	6.6 \pm 2.6	11.2 \pm 3.0*	5.6 \pm 1.8	4.1 \pm 1.6

Abbreviation: CI, confidence interval.

*Significant at $P<.05$.

Table 4: Complications by Allocated Splint Group

Complication	Splint Type		
	Control (Stack)	Dorsal Aluminum	Thermoplastic
Skin irritation/maceration	8	3	1
Poor splint fit	8	0	1
Splint discomfort/pain	2	1	0
Patient dissatisfaction with splint	1	3	0
Splint breakage/cracking	0	1	3
TOTALS	19	8	5
TREATMENT FAILURE ($P=.04$)* Post Hoc Analysis - Fisher exact test (compared thermoplastic)	5/21 ($P=.04$)*	5/21 ($P=.01$)*	0/22

*Statistically significant.

or accidentally dislodged and instantly replaced; missed more than 2 appointments, but otherwise followed treatment plan), and 1 (1.7%) was noncompliant (splint not worn properly/taken off several times; did not follow treatment plan). At 8 weeks, compliance levels had dropped slightly: 41 (70.6%) of 58 patients were compliant, 14 (24.1%) were secondarily noncompliant, and 3 (5.2%) were rated as noncompliant. There were no significant differences between the 3 splint groups on the compliance measure at either time point ($P=.53$ and 0.67 , respectively). Interestingly, the presence of pain during the splinting period ($n=3$) did not affect compliance—all 3 participants reporting pain during this phase were rated as fully compliant.

The relationship between compliance and extensor lag at 20 weeks was investigated using Pearson's correlation coefficients. There were medium negative correlations between compliance at 6 weeks ($r=-.47$) and 8 weeks ($r=-.40$) with outcome at 20 weeks. Both were statistically significant ($P=.001$ and $.003$, respectively) with high levels of compliance associated with lower degrees of extensor lag. Results are presented in table 5.

Patient Satisfaction

Mean patient satisfaction at 12 and 20 weeks are summarized per protocol in table 6. One-way ANOVA showed no significant differences between groups at either time point ($P=.29$ and $.16$, respectively).

Pain

Overall, pain levels were low, with mean scores on the 10-cm VAS pain measure below 2 for all groups at 12 weeks, and below 1 at 20 weeks (see table 6). One-way ANOVA showed no significant differences between groups at either time point ($P=.67$ and $.83$, respectively).

DISCUSSION

Few prospective trials have compared different splints for acute mallet injury. Pike et al¹⁰ compared 3 splints (volar, dorsal, and thermoplastic) in a RCT ($N=87$) and found no lag difference between groups at week 12, but noted a trend suggesting superiority in the custom thermoplastic group. Maitra and Dorani,¹⁵ who compared a combined volar and dorsal aluminum splint with the Stack splint in an RCT ($N=60$), also found no significant difference in extensor lag between groups. Warren et al⁴ compared the Abouna splint (made of rubber coated wire) with the Stack splint in a quasi-RCT ($N=117$) and again found no difference in extensor lag. Kinninmonth and Holburn¹⁶ compared the Stack with custom thermoplastic ($N=54$), but did not report their criteria for grading lag deformity nor their measurement instrumentation. Our finding of no difference between groups on the primary outcome is consistent with the available evidence.

Our actual extensor lag results are also comparable to those achieved at the similar time points in studies of mallet fingers treated with volar static splints¹² and dorsal aluminum splints,¹⁷ but better for both dorsal aluminum and thermoplastic splints in the study by Pike et al¹⁰ which only immobilized participants for 6 weeks. One prospective noncomparative cohort study of custom made thermoplastic splints¹³ used the Abouna and Brown classification system² of success, improved, and failure to rate results at 12 weeks and reported a success and improved rate of 88.2%. Using these criteria, participants in our trial achieved similar results (81% success, 12.2% improved). Using the Crawford scale¹⁸ (which classifies full DIP extension/flexion and absence of pain as excellent; 0° – 10° extensor lag, full flexion and absence of pain as good; 10° – 25° extensor lag, any loss of flexion and absence of pain as fair; and $>25^{\circ}$ extensor lag and/or persistent pain as poor) our

Table 5: Extensor Lag at 20 Weeks by Treatment Compliance

Degree of Extensor Lag at 20 Weeks	$>25^{\circ}$	10° – 25°	1° – 9°	0°
Week 6 $P=.001$ *				
Noncompliant	1 (100%)	0	0	0
Secondarily noncompliant	0	2 (25%)	1 (12.5%)	5 (62.5%)
Compliant	0	6 (15%)	8 (20%)	26 (65%)
Week 8 $P=.003$ *				
Noncompliant	1 (50%)	1 (50%)	0	0
Secondarily noncompliant	0	2 (18%)	1 (9%)	8 (73%)
Compliant	0	5 (13%)	8 (21%)	25 (66%)

*Result statistically significant.

Table 6: Patient Satisfaction and Pain (Per Protocol)

Measure/Time Point	Splint Type		
	Control (Stack)	Dorsal Aluminum	Thermoplastic
Satisfaction 5-point scale (5=very satisfied)			
Week 12 $P=.29$	4.5 \pm 0.2	3.8 \pm 0.4	3.9 \pm 0.3
Week 20 $P=.16$	4.6 \pm 0.2	4.5 \pm 0.2	4.1 \pm 0.2
Pain VAS (0=no pain)			
Week 12 $P=.67$	0.6 \pm 0.3	1.1 \pm 0.7	1.2 \pm 0.4
Week 20 $P=.83$	0.3 \pm 0.2	0.5 \pm 0.3	0.5 \pm 0.2

NOTE. Values are mean \pm SE.

results are 64.7% excellent, 17.6% good, 15.7% fair, and 2% poor.

Our study had relatively high rates of treatment failure in both the Stack and Dorsal aluminum splint groups (23.8% in both groups) and no instances in the thermoplastic splint group. The rate of treatment failure in our Stack splint group was similar to that in other studies of 9 (33.3%) of 27 patients,¹⁶ 28 (48.3%) of 58 patients,⁴ and 10 (33.3%) of 30 patients.¹⁵ For dorsally applied padded aluminum splints, no studies published treatment failure rates, although 1 published a complication rate of 20 (52.6%) out of 38,¹⁹ which was higher than our findings of 8 (38%) out of 21. In the study in which the aluminum splint was applied to both dorsal and volar surfaces, there was a complication rate of 2 (6.6%) out of 30,¹⁵ suggesting that those splints placed on the dorsal surface only were associated with higher numbers of skin problems. Our finding of no treatment failures in the thermoplastic group is consistent with the findings in a study of 42 consecutive patients using a similar splint made of the same material.¹³

Given that the patient needs to wear the mallet splint continuously for 6 to 8 weeks, compliance with the splinting regime plays a crucial role in the outcome. Our finding of a statistically significant correlation between compliance and outcome is supported by another study into the effect of compliance on outcome following mallet finger,¹² which found that compliant patients were significantly more likely to have an excellent or good outcome than noncompliant patients. Our findings for compliance rates at 8 weeks (70.6% compliant, 24.1% secondarily noncompliant, and 5.2% noncompliant) were higher than those in the aforementioned study (59.1% compliant, 15.9% secondarily noncompliant, 25% noncompliant), but may be explained by our participants having consented to be part of a prospective trial, and therefore more likely to be compliant. Unfortunately, we do not have outcome measures for those lost to follow up at 12 weeks. This may be important, as a higher percentage of this group (53%) were secondarily noncompliant or noncompliant. Our finding of a significant difference in extensor lag at 20 weeks in favor of women is interesting; unfortunately, no other studies have reported results separately for men and women. We also found a moderate correlation with age and extensor lag, which is consistent with findings by Pike et al.¹⁰

Study Limitations

Unfortunately, numbers enrolled were lower than expected, which may have limited our power to detect a difference between groups. We did, however, meet the minimum figures in our power analysis recommendation. Interrater reliability for the therapy staff assessing patients at baseline and at key reviews was not specifically measured at

each site, and it is possible that the assessors varied in their measurement technique. For those patients who experienced treatment failure, the replacement splint was thermoplastic in 80% of cases, and may indicate a bias toward this type of splint in the therapists engaged in this trial. It is worth noting that patient preference was always sought when choosing a new type of splint.

CONCLUSIONS

Our findings demonstrate that the majority of mallet finger injuries treated with 8 weeks of immobilization and graded exercise thereafter achieve excellent or good results, adding weight to the argument that these injuries can be managed independently in hand therapist-led clinics.¹⁷ To enable patients to comply with this protocol, the splint provided must be robust enough for daily living requirements and must not cause complications which are intolerable to the patient. In this study, there was no significant difference in the outcomes achieved in the 3 trial splints; however, the custom-made thermoplastic splint was significantly less likely to result in complications that lead to treatment failure thus supporting its use in the treatment of mallet finger.

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Suppliers

- a. Orfit Industries, Vosveld 9A, B-2110 Wijnegem, Belgium.
- b. 3M, 3M Corporate Headquarters, 3M Center, St. Paul, MN 55144-1000.
- c. Beiersdorf, Head Office Unnastraße 48, 20245 Hamburg, Germany.
- d. SAS Institute, 100 SAS Campus Dr, Cary, NC 27513.

7.3 Impact of the study

Journal Metrics:

- Thomson Scientific ISI Web of Knowledge Journal impact factor: 2.184
- Thomson Scientific ISI Web of Knowledge Journal rank:
 - Rehabilitation: Q1 (6th of 33)
 - Sport Sciences Q1 (13th of 73)
- SCImago Journal Ranking: 0.155
- H Index: 84
- Source Normalized Impact per Paper (SNIP): 1.72

Patients with mallet finger at the Alfred are now consulted about their splint preference and occupational participation (e.g., self care, work, hobbies/sports, life roles, time use, habits, values) to determine the most suitable splint for them. Stack splints are rarely used due to difficulty achieving good fit.

7.4 Chapter Summary

In this study comparing patient outcomes for mallet finger using three different splints, we found no difference in the primary outcome between groups at 12 and 20 weeks, however the Stack and Mexican Hat splints had significant rates of treatment failure (23.8% in both these groups, compared to none in the thermoplastic group; $p=.04$). Treatment failure was defined as significant problems requiring a change to a different splint type. Examples of reasons for treatment failure are poor fit (and inadequate immobilisation), skin necrosis, and participant report of significant splint discomfort or impracticality.

Compliance rates were very high across all treatment groups at eight weeks (the end of the continuous splinting phase of the treatment) when compared to a retrospective study for the same injury (70.6% compliant compared to 59.1%). This is probably explained by our participants being more likely to be compliant having consented to be part of a prospective trial (the phenomenon of altered behaviour or performance resulting from awareness of being a part of an experimental study, also known as the “Hawthorne effect”¹⁶¹). We also found a medium negative correlation between patient compliance and degree of extensor lag.

A limitation of this study is that we measured extensor lag using goniometry, which may lack accuracy. A recent study found that, in comparison to radiographs, goniometry tended to over-estimate extensor lag in mallet injuries.¹⁶²

In addition to the data published in the journal article, Ordinal Logistic Regression was performed to assess the impact of a number of socio-economic (age, occupation category) and patient factors (gender, smoking status) on the level of compliance at eight weeks. The full model containing all predictor variables was not significant ($p= 0.73$), and none of the individual variables was found to have a significant relationship with compliance levels.

The following dimensions of the MAM were examined in this study:

- Therapy-Related, specifically the splint material and design;
- Patient-Related, specifically gender and smoking status; and
- Socio-economic, specifically age and occupation category.

This study was unable to establish a significant relationship between the variables studied and compliance, possibly due to the high compliance levels of participants.

The next chapter draws together the findings from the previous five chapters, and discusses these in further depth using the MAM as the central framework.

Chapter 8 – Integrated Discussion

Chapter 8

Integrated Discussion

In this chapter the original research questions are revisited, and the overall findings from the research projects that comprise this thesis are discussed. Interventions for improving patient adherence are discussed in terms of the five dimensions of the MAM, and limitations of this thesis are described.

8.1 Revisiting the research questions

The research questions posed in Chapter 2 are presented in Table 3 along with the individual findings and the impact this has had on practice at the Alfred hospital (the author's hand therapy workplace). Common themes are explored further in section 8.2.

Table 3: Research questions, findings, and impact on practice at the author's place of work

RESEARCH QUESTION	FINDINGS	IMPACT ON PRACTICE
1. Which factors have been shown to have reliable correlations with adherence to therapeutic splint or brace wear in adults presenting with acute upper limb injuries?	<p>From a systematic review of the hand therapy literature in acute injuries, it was found that:</p> <ul style="list-style-type: none"> • Socio-economic factors such as age, education, occupation had no reliable correlation or association with adherence; and • There was some evidence that treatment/therapy-related factors such as immediacy of benefit, splint comfort, and minimising interference with lifestyle and daily living activities can improve splint adherence on the part of the patient. <p>No studies examined factors related to the Health-care team and system, and this may be an important gap to investigate in the future</p>	<p>The hand therapy team have increased the emphasis on minimising impact on lifestyle and daily living. For example, materials such as neoprene, which is softer and more comfortable than thermoplastic, are used more frequently when total immobilisation is not required.</p> <p>Also, additional written resources for patients have been produced which give examples of how daily living tasks can be modified or made easier with commonly available items, such as well designed kitchen implements with ergonomic grips.</p>
2. What are the predictors of splint non-compliance for in-patients with acute TBI and hand injuries?	<p>From a retrospective review of full medical records of 71 patients who were (1) admitted to the Alfred hospital (Melbourne) via the Trauma unit in 2005 and 2006, and (2) who were recorded as having concurrent head and upper limb injuries, it was found that:</p> <ul style="list-style-type: none"> • The presence of agitation is the strongest predictor of non-compliance with splinting, with number of days of agitation being the second strongest; • Those patients deemed to be in PTA at the time they received their splint were significantly more likely to be non-compliant ($p=0.05$), although only 50% of those in PTA were non-compliant; • Age, gender, frontal lobe injury, and 	<p>The patient's performance on the Westmead PTA scale is no longer used when determining whether to remove a plaster cast in order to allow controlled mobilisation.</p> <p>Patients' agitation levels over the preceding days are monitored instead, and the hand therapy and trauma clinicians use this to guide clinical reasoning and provision of appropriate treatment intervention.</p> <p>TBI = Traumatic Brain injury PTA=Post Traumatic Amnesia</p>

	<p>pre-morbid history of psychiatric illness, prior brain injury, and alcohol or substance abuse showed no relation to compliance; and</p> <ul style="list-style-type: none"> Urbanicity, ethnicity and occupational category were also not related to compliance. 	
<p>3. How does the patient's experience of distraction splinting for intra-articular fractures influence adherence with treatment?</p>	<p>This qualitative study of twelve patients who had undergone distraction splinting for intra-articular fractures, found the following:</p> <ul style="list-style-type: none"> The major theme identified from the data was <i>Dissonance or Disconnect between the patient's perception of the complexity of the injury and treatment</i>. This had direct impacts on treatment adherence. Three further sub-themes were also identified— i) Unexpected levels of pain, ii) Self efficacy and Outcome expectancies, and iii) Splint discomfort: aesthetic, physical, and functional. 	<p>Results have been presented to all hand surgeons at the Alfred hospital, and pain relief is now ordered routinely prior to applying the traction device.</p> <p>Enhanced patient information booklets are currently in development, with further information on the injury complexity and sections on managing ADL's .</p> <p>A modified splint is now used which is volarly-based and has better proximal control, resulting in less slippage and discomfort.</p>
<p>4. Does distraction splinting for intra-articular fractures result in better long-term outcomes for patients when compared with alternative management regimens (that require less of the patient in terms of splint wear and exercise)?</p>	<p>This cohort study compared long-term functional outcomes achieved in two groups of patients with the same injury but different treatment (distraction versus static splinting with or without surgical fixation) in terms of active movement, pain, and independence in daily living activities. We found the following:</p> <ul style="list-style-type: none"> The mean combined range of motion of the PIP and DIP joints in the distraction group was 135°; in the no-distraction group it was 113°. This was clinically significant, but not statistically significant ($p = 0.21$); There was a moderate statistically significant negative correlation between age and total arc of motion ($p=0.02$); and 	<p>Results are promising, but most likely did not achieve statistical significance due to small sample sizes.</p> <p>Hand therapy staff are currently collecting data for future research into the newer splint design which may yield better results as it is more comfortable for patients, and therefore may lead to improved adherence with splint wear and exercise.</p>

	<ul style="list-style-type: none"> No significant differences between groups were observed for DASH scores, patient satisfaction, pain, complication rates or treatment adherence. 	
5. Is there a relationship between splint type, compliance, and outcome in the treatment of mallet finger injuries?	<p>This randomised controlled trial of 64 patients with mallet finger injury found the following:</p> <ul style="list-style-type: none"> There were no significant differences between the three splint types (pre-fabricated Stack splint, dorsal aluminium, and custom-made thermoplastic) on the compliance measure; The relationship between compliance and degree of extensor lag (i.e. inability to actively straighten the finger-tip) at 20 weeks revealed medium negative correlations between compliance at 6 weeks ($r = -0.465$) and 8 weeks ($r = -0.402$) with outcome at 20 weeks (i.e. high levels of compliance were associated with lower degrees of extensor lag); and The stack and aluminium splints were associated with significantly higher rates of treatment failure (defined as a need to change splint type, as decided by the treating therapist and patient). 	<p>Patients are consulted about their splint preference and occupational participation (e.g., self care, work, hobbies/sports, life roles, time use, habits, values) to determine the most suitable splint for them. Stack splints are rarely used due to difficulty achieving good fit.</p>

8.2 Overall findings

Non-adherence with health interventions is recognised as a major problem worldwide. In the US for example, it is estimated that 49% of people diagnosed with hypertension do not adhere to prescribed treatment,¹⁶³ and in Australia, 57% of people with asthma do not

consistently take their medication as prescribed.¹⁶⁴ This thesis has established that although non-adherence rates are relatively low in people with acute hand injuries ($\leq 25\%$), there is a high risk associated with non-adherence in this group, as it is more likely to result in the need for difficult secondary surgical procedures,^{29, 127} increased disability, longer recovery times, and an increased burden on health care resources.^{10, 11, 128}

When applying the MAM to people with acute injuries, the evidence shows that socio-economic factors (including age, ethnicity, occupation, level of education, place of residence, family/social dysfunction) and most condition-related factors (including co-morbidities) exert little or no influence on adherence. Patient factors such as cognitive impairment, lack of understanding of the medical condition and the treatment rationale have some impact on adherence, but therapy-related (especially impact on daily living activities, lifestyle and work, immediacy of benefit, complexity and duration of treatment) and Health Care Team factors (patient-provider relationship, clear and consistent education, continuity of care) appear to have consistent impacts (see Table 4, p.174).

Most of the research undertaken as part of this thesis demonstrated that the ability of patients to optimally follow through on their hand therapy program is influenced by more than one *barrier* from more than one *dimension* of the MAM. It logically follows that strategies put in place to enhance adherence need to target multiple dimensions and their sub-components in order to have a significant impact on adherence rates of patients. This is supported by the global health-care evidence, which has shown that uni-dimensional interventions for enhancing treatment adherence (e.g., self-management education)^{165, 166}

tend to have modest impacts at best, whilst multi-level, multi-targeted approaches that focus on several factors with multiple interventions are more effective.^{167, 168}

Table 4: Summary of adherence associations by Multi-dimensional Adherence Model factors

	Socio-Economic	Health Care Team / System	Therapy-related	Condition-related	Patient related
Systematic review	(0)		(-) impact on ADL's (+) immediacy of benefit (-) discomfort	(0)	(-) cognitive impairment
TBI study	(0)			(0)	(-) agitation (-) cognitive impairment
Qualitative distraction study	(0)	(+) patient-provider relationship (+) clear and consistent education (+) continuity of care	(-) complexity and duration of treatment (+) immediacy of benefit, (-) interference with lifestyle (-) impact on ADL's (+) availability of support		(-) lack of understanding of the condition and need for treatment, (+) beliefs about the individual's ability to influence their own outcome
Quantitative distraction study	(0)		(0)		(0)
Mallet trial	(0)		(0)		(0)

(-) negative impact on adherence; (+) positive impact on adherence; (0) no impact on adherence; ADL's = Activities of Daily Living; TBI = Traumatic Brain Injury. Shaded areas indicate that this dimension was not examined in this study

8.3 Interventions for improving adherence

Evidence-based suggestions for improving adherence are arranged according to the five dimensions of the MAM. It is important to remember that a combination of strategies across

several dimensions is more likely to improve the chances of success of interventions used with clients.

8.3.1 Social and economic interventions

Although none of the studies in this thesis found a consistent relationship between socio-economic factors and adherence, it is reasonable to assume that factors such as access to services in the local community, lack of family support, and cost of treatment (and travel to clinics) could have an impact on some individuals. Examples of interventions that have been shown to work in chronic hand conditions are peer support groups, for example those for people with arthritis.¹⁶⁹ These group programs usually aim to provide comprehensive information, promote sharing of experiences regarding management of the condition/disease, and engender the patient's sense of responsibility and self efficacy. There is substantial evidence that peer support among patients can improve adherence to therapy in chronic conditions such as Asthma, Diabetes, HIV/AIDS, and Tuberculosis, with the added benefits of reducing the burden on health care providers, improving patient self-management skills, and integrating overall care provision.²

In summary, social and economic interventions for maximising patient adherence are:

- Using/developing peer support groups;
- Building the patient's own self-management skills, and ensuring they are confident in using these; and

- Capacity building in the patient's local community (for example coaching staff at the local community health centre in monitoring the patient's progress and engaging them in suitable activities).

8.3.2 Health care team and health system interventions

In Chapter 5, which explored the patient experience of distraction splinting, one of the themes to emerge was that patients who trusted their treatment providers (most importantly the hand therapist, but also the surgeon) and were provided with clear and consistent education, were more likely to follow the splint and exercise program.

Unfortunately, this dimension of adherence has not been widely investigated in the acute hand therapy literature (none of the studies included in Chapter 3's systematic review included any Health Care Team/System factors), adding support for this thesis' contention that hand therapists tend to view adherence as a patient-driven problem.

This is a missed opportunity, as many of the factors that can play a significant role in promoting adherence are within our control. For example, one study of 40 people in the US with rheumatoid arthritis²⁸ randomly assigned people to two groups: one group had 'standard treatment approach' from the therapist and receptionist; the other group had 'compliance enhancement approach' from both staff. The compliance enhancement approach first involved the receptionist setting up favourable expectations by telling patients that the splints were very comfortable and useful and that the therapist was highly skilled and a specialist in arthritis. The therapist would then use learning principles associated with effective patient education to assess the patient expectations, and address any

dissatisfaction or unmet expectations. The therapist would also use an affective tone that conveyed positive regard for the patient, genuineness, trustworthiness, and confidence in the patient's own ability to assume responsibility for the treatment program. The therapist also made reference to the patient's rheumatologist (indicating continuity of care between all involved health team members) and made a follow-up call in two weeks to check whether the patient was finding the splint comfortable and useful. The control group were greeted by the receptionist but not engaged in conversation. The therapist assessed the patient, fabricated the splints, educated them on correct wear, answered any questions, but did not actively elicit patient participation in the treatment session. Patients were instructed to phone if there were any problems with the splint.

The results showed that patients in the 'compliance enhancement approach' group were significantly more likely to wear their splints, and that knowledge of splint use correlated with actual use regardless of group. The same researcher, in a systematic review of the literature on the effect of patient-practitioner interaction on compliance in people with arthritis,⁶⁹ found evidence that affective tone (including the patient's perception of the practitioner's attitude, and whether adequate time was spent with them) and the patient's belief in the benefit of a particular treatment, had a significant influence on compliance. Another study from the Physiotherapy literature found that positive feedback from the therapist can improve exercise adherence in acute conditions.⁵⁷

Outside of the hand therapy literature, positive patient-practitioner communication has been shown to improve treatment adherence in HIV/AIDS¹⁷⁰ diabetes¹⁶⁶ and mental illness.¹⁷¹

There is also modest evidence to support the use of modified health care system teams in cardiac rehabilitation and diabetes. One large multi-centre study in the US found a case-management system was considerably more effective than usual medical care for modification of coronary risk factors after myocardial infarction,¹⁷² and a 4-year study of 244 diabetic outpatients found that the use of diabetes nurse specialists significantly enhanced compliance and management of blood sugar levels.¹⁷³

Although there have been some hand therapy research efforts in this area it is possible that these efforts have had little impact as practitioners either lack the necessary skills or do not consistently enact these skills in practice. Apart from a general lack of awareness and knowledge about patient adherence, there are no clinical tools to assist therapists in evaluating and intervening where a problem is identified. In practice, it comes down to the therapist's own training and experience, with those skilled in facilitating adaptive health behaviours the most likely to be aware of and manage this issue best.

To give an example, I came to hand therapy after 15 years' experience in field of Vocational Rehabilitation with research, training, and practice in Motivational Interviewing,⁷⁵ a client-centred method for enhancing intrinsic motivation by surfacing and resolving ambivalence to change (see 1.3.9.3 on page 26 for a brief description). I therefore brought a set of skills to the field that are different to those developed by practitioners who have only worked as hand therapists. An example of how I used this approach in my hand therapy work is given in section 8.3.5, Patient-related interventions on page 184.

My clinical supervisor, a highly skilled practitioner with encyclopaedic technical knowledge, observed that I had more success with patients he considered “difficult” and was happy to refer these cases to me, as he found them frustrating to work with. He perceived this to be a personality issue but, having explored and reflected on this issue further while working on this thesis, I now view it as a possible gap in his otherwise extensive practical and clinical skill-set, and an opportunity for him to further complement these skills.

In summary, health care team and health system interventions for maximising patient adherence are:

- Ensuring continuity of care – the entire health care team should be giving the same messages, delivered in the same way;
- Encouraging the patient’s own sense of self efficacy;
- Eliciting the patient’s perceptions, expectations, wants, and needs in the early stages of the therapeutic relationship so that these can be addressed and incorporated into the treatment plan;
- Specific skill development in adherence management to enable practitioners to better design and implement interventions to improve adherence of patients to treatment regimens. This should aim to achieve a clinically useful understanding of the factors that have been shown to affect adherence; and

- Development of clinical tools for assessing and addressing the potential for non-adherence in each patient. It should also address how to assess and to address it if it is occurring.

8.3.3 Therapy-related interventions

The therapy-related dimension includes complexity, duration, immediacy of benefit, interference with lifestyle, side effects, and frequent changes to treatment pathways. It also encompasses the availability of support to deal with the above factors. These factors, especially the perceived complexity of treatment, interference with the completion of daily occupations (productivity, self-care and leisure), and availability of support (especially pain relief) exerted the most significant influence on adherence in the group undergoing distraction treatment (see Chapter 5). One of the papers reviewed in Chapter 3 also found that immediate benefit from wearing the splint was the only factor significantly associated with splint adherence, highlighting the need for good patient education: “the better an individual is informed of the potential positive effect, the better it will be realised”.^{32p93}

Previous research has found that splint comfort^{174, 175} and the visual appearance (and visibility to others) of the splint are important factors to the wearer and can influence adherence.^{42, 176, 177} For example, a modified splint for axilla burns in an Indian population concluded that it had greater patient acceptance due to “aesthetic appeal over the currently available aeroplane splints, as this could be worn comfortably within one’s garment”.^{42p502}

Although there are few studies that have examined the impact of including meaningful, occupation-based activity (also known as Occupationally Embedded Exercise) into hand therapy programs, positive results on measures of range of motion, strength and patient rating of functional abilities have been found in one small randomized controlled trial in a military setting in Turkey.¹⁷⁸ Meaningful activities can also improve treatment adherence¹⁷⁹ with participants in one randomized controlled trial recording higher number of repetitions of an exercise when their device was connected to a computer game compared to participants given the exercise device and told to use it at a comfortable pace.¹⁸⁰ This is consistent with the work of David Nelson, a US researcher who has studied the impact of Occupationally Embedded Exercise in elderly, stroke, and brain-injured populations.¹⁸¹⁻¹⁸⁵ For example, a multi-site randomized controlled trial compared rote exercise to a simple dice game for people with pronator spasticity post-stroke and found improved supination in the game group.¹⁸¹

In terms of the broader health care literature, there is evidence that the following strategies are consistently associated with higher rates of treatment adherence in chronic conditions such as asthma, HIV/AIDS, depression, smoking and diabetes: simplifying treatment regimens, clear instructions to patients, continuous monitoring and reassessment of treatment, patient self-management, education on use of medicines, and teaching desired health behaviours (e.g., suitable physical activity).²

In summary, therapy-related interventions for maximising patient adherence in hand therapy include:

- Ensuring splints are comfortable and aesthetically acceptable to the patient;
- Incorporating meaningful activity into therapy programmes wherever possible;
- Preparing patients for the fact that exercise may be painful or uncomfortable in the early stages after an acute injury, but this does not signify further damage;
- Liaising with the medical staff to ensure pre-emptive analgesia in the early stages post injury; and
- Giving examples of how other patients have successfully adapted ADL's without compromising splint adherence.

8.3.4 Condition-related interventions

Condition-related factors include severity of symptoms, level of disability, prognosis, rate of progression, co-morbidities and the availability of effective treatment. There are few studies in the acute hand therapy literature that have explicitly studied this dimension, apart from one that compared flexor with extensor tendon injuries³⁰ and one that compared injuries to different peripheral nerves in the arm.³² Not surprisingly, given that comparison groups within these studies had similar rates of progression, level of disability and prognosis, both investigations found no significant differences in adherence levels between groups. In fact, all of the conditions studied as part of this thesis generally have good prognoses and, while the level of disability may be high in the early stages, the rate of progress is usually relatively

rapid with most people discharged from therapy and returning to full occupational participation within three months. Interestingly, although we know that adherence rates in long-term degenerative conditions such as rheumatoid arthritis are significantly lower (between 25 and 65%) similar patterns have emerged from a systematic review of compliance studies,¹³⁰ which found no relationship between disease severity / level of disability and compliance.

Few studies of acute hand injuries have examined the impact of co-morbidities and adherence. Chapter 4 in this thesis examined the impact of drug and alcohol abuse, psychiatric illness, and previous brain injury on compliance with splinting in an acutely brain-injured population and found no significant relationship.¹⁸⁶ In contrast, the literature on adults with acute burns has found a strong association between pre-injury alcohol intake, drug dependency, and psychiatric illness and compliance with therapy.^{187, 188} Furthermore, burns patients with a prior psychiatric history were likely to have greater depression and blame themselves for the accident, thus resulting in lower compliance with therapy regimens.¹⁸⁹

In summary, condition-related interventions for maximising patient adherence are:

- Ensuring that therapists are able to identify the signs and symptoms of co-morbidities that may affect adherence, such as depression or anxiety disorders;

- Ensuring that support or treatment for co-morbidities is in place. This may involve contact with the treating doctor, referral to counselling services, or mobilising the patient's own support systems (i.e. friends and family, peer support groups); and
- Providing clear education about the expected prognosis and rate of progress for the specific condition and a clear rationale for treatment at each stage.

8.3.5 Patient-related interventions

The patient-related dimension includes the resources (physical, sensory and psychological), knowledge, attitudes, motivation, beliefs, perceptions and expectations of the patient. As hand therapist we often assume that the patient is (or should be) motivated to follow their treatment protocol, and that educating them about their injury should be sufficient for ensuring adherence.¹¹ Both are questionable assumptions.

To examine the issue of motivation first, the evidence from the behavioural sciences shows that patients vary in their level of readiness to follow treatment plans.^{75, 94} These levels of readiness are explained briefly in Chapter 1 (see Trans-Theoretical model of change on page 26) and therapists need to adjust their approach to the stage the person is in to influence the ability of the patient to take action. For example, one of my patients was an Electrician who sustained a deep flexor tendon laceration to his index finger. At his first appointment after surgery to repair the tendon, his plaster was removed and a thermoplastic dorsal blocking splint (which went along the back of his forearm all the way to the fingertips) was made for him. He was taken aback at the size of the splint and requested it be cut down to include only

the repaired finger, and allow unrestricted wrist movement so that he could remain at work on full duties. Despite our best efforts to educate him about the rates of tendon healing and the anatomical reasons for protecting the entire affected muscle group, he was clearly upset and had difficulty accepting this. This man appeared to be in the pre-contemplation phase, where he was over-estimating costs of adhering to his treatment plan and not quite ready to make any changes to his work routine for the crucial first six weeks of recovery. Two of the strategies for dealing with people in this stage include resolving ambivalence and taking small steps. To address the former, we discussed the pro's and con's of following the treatment plan, and made the pro's (e.g., I will get a good recovery which will affect the ability to use the hand long-term) outweigh the con's (e.g., I will have to wear an uncomfortable splint and not use my hand for the next 6 weeks). For the small steps, we looked at how he could re-structure his workload over the next months, by cancelling some jobs or employing someone to help him in the short term.

The second assumption, that "an informed patient is a compliant patient" is potentially a dangerous one, as information alone has been shown to be not enough for creating or maintaining good adherence habits. In the example above, the patient was an intelligent man who understood our explanations, but simply perceived the cost of adhering as being too great. In other cases, patients may doubt the seriousness of their injury or lack confidence in their own ability to follow the treatment. In each of these instances, the risk of non-adherence is high.

Patient beliefs and attitudes about their condition, expected treatment, and their own power to influence the outcome were shown to be important factors in the qualitative study (Chapter 5) and have been found to have an effect on adherence in chronic hand conditions.^{57, 190} The therapist has an important role in promoting optimism, providing enthusiasm, providing a 'reality check' and reinforcing the patient's power to influence their own outcome by engaging in adherence behaviours throughout the therapy program.² It is important to also activate the patient's own resources, such as family members, friends, and co-workers to reinforce therapy goals. For example, one of the participants in this study stated that her partner became involved in treatment by setting up reminders for her:

He helped with the routine and exercise that I needed to do regularly and so I was very diligent to the point where I would set the alarm on my phone ... every hour my alarm would go off and I would stop what I was doing and bend this finger ten times and then set my alarm again... We would even be driving and the alarm would go off and we would pull over and do the exercises.

Patients may also fail to benefit from education due to being distracted or overwhelmed at the time information is given to them (e.g., in the hours post surgery or in a busy outpatient clinic) thus struggling to retain the information given. A study of 28 cognitively unimpaired patients post flexor-tendon repair¹⁹¹ found that only 42.5% recalled instructions (including "do not remove your splint") without the need for a cue. Some therapists and surgeons suggest that this is best addressed using written instructions. One letter to the *British Journal of Plastic Surgery* recommended an adhesive label be applied to the splint (similar to the

instructions on a medicine bottle) detailing splint wear and exercise routines, stating that “many patients fail to progress as they should because of confusion, ignorance or forgetfulness”.^{192p537} Another author (an experienced hand therapy practitioner) recommends the use of the *Mini-Mental Status Examination* with elderly clients who appear to have memory problems so that the therapeutic approach can be amended as necessary.¹⁹³ In both examples there is potential for the patient to feel patronised, insulted, and alienated by the health practitioner’s approach. It is my recommendation that these interventions should only be used in cases where a cognitive disability is strongly suspected or if the splint application is the responsibility of carers.

In summary, patient related interventions for maximising patient adherence are:

- Ensuring that interventions go beyond the provision of advice and prescriptions². It is well established that education alone is a weak intervention;²
- Promoting optimism, providing enthusiasm, providing a ‘reality check’ and reinforcing the patient’s power to influence their own outcome;
- Activating the patient’s own resources, such as family members, carers, friends, and co-workers to reinforce therapy goals; and
- Specific skill development for therapists in behaviourally-based interventions that can be incorporated into daily practice.

8.4 Limitations of this thesis

This thesis employed a variety of methodologies to answer clinically relevant questions about patient adherence in acute hand injuries from varying perspectives. Some of these methodologies have inherent limitations. The systematic review for example (Chapter 3) was limited by the small number and varying quality of the adherence literature in hand therapy, and the lack of comparable adherence measures or variables, limiting the possibilities for pooling data. The retrospective file review (Chapter 4) completed on trauma patients admitted to the Alfred hospital was dependent on the quality and accuracy of the file notes, and this can vary enormously between all involved nursing, medical and allied health staff. It was also impossible to control for confounding variables, such as medication given to patients. The qualitative study of patient experience of distraction treatment was possibly limited by recall bias; participants that had a particular result may have been more inclined to remember (and associate this result with) factors that others with different results did not recall. For example, one of the participants who had a poor result recalled that the surgical staff did not appear experienced in or confident about the treatment. No other participants mentioned this. The time elapsed since injury (up to 7.8 years in one case) may also have affected memory of the experience. The randomised controlled trial (Chapter 7) was particularly challenging to oversee, with at least 12 different therapists (each with their own treatment preference and experience with this particular injury) involved in recruitment, treatment, and measurement of participants over its 4 year enrolment period. It is possible

that this may have affected their communication of the treatment given, and thus the patient's perception of outcome. In this trial, numbers enrolled were lower than expected, which may have limited our power to detect a difference between groups.

Limitations with relation to each individual study are discussed in more detail in the respective refereed publications.

This chapter has summarised the results of the publications that make up this thesis. It has also discussed the evidence for (and provided recommendations regarding) specific interventions for improving adherence. Chapter 9 (Conclusions) summarises the original contribution this research has made to the knowledge and understanding of adherence in acute hand injuries, and also makes recommendations for future hand therapy research.

Chapter 9 - Conclusions

Chapter 9

Conclusions

The previous chapters have demonstrated that the ability of patients to adhere to their hand therapy program is usually affected by more than one barrier, often in interaction with other barriers. Although non-adherence is a behaviour observed in an individual patient, it is important to recognise that the causes are not just patient-related. “[Non-adherence] occurs in the context of treatment-related demands that the patient must attempt to cope with. These demands are characterized by the requirement to learn new behaviours, alter daily routines, tolerate discomforts and inconveniences, and persist in doing so while trying to function effectively in their various life-roles”.^{2p145}

9.1 Original contribution this work has made to the knowledge and understanding of adherence in the hand therapy field

Conceptualising patient adherence in a Multi-dimensional way represents a significant advance for the hand therapy field, which tends to be dominated by medical and biomechanical models.¹⁷⁹ As stated previously, a 2002 study of therapist and patient perceptions of compliance with hand therapy¹¹ found that most therapists perceived non-

compliance as mostly a patient-driven problem, drawing parallels with a study of physicians in 1966⁹, who viewed it as “reflecting attitudes of the patient, such as ignorance or forgetfulness”.^{11p37} This study also found that therapists generally rated their patients as being less motivated and committed than the patients rated themselves.

Research on adherence from the patient’s perspective is particularly lacking in the hand therapy literature, despite the fact that Hand Therapists rely heavily on the ability of the patient to follow treatment protocols that include strict splint wear and exercise regimens. Interestingly Chapter 5, a qualitative study of the patient’s experience of distraction splinting, met with very mixed feedback when submitted to the *Journal of Hand Therapy* (US). One reviewer in particular could not see the relevance of the study:

“....this study is focussed on a specific and small population of injuries, making it more difficult, per se, to draw a strong direct impact on most clinician’s day to day clinical practice....I really am having a hard time seeing the need for a body of work that realistically, we as therapists perform each day with the education and follow up of our patients with any diagnosis or post-operative diagnosis.” (Reviewer 1)

Another reviewer commented:

*“The word ADHERENCE works however consider the word COMPLIANCE”
(Reviewer 2)*

Thankfully the editor gave me the opportunity to respond to this feedback, and arranged another reviewer. In my response I pointed out that:

I have used the term adherence, as it implies more patient agreement in the chosen intervention or advice implementation and an active effort on the patient's part to stick to the agreed regimen to achieve optimum clinical benefit. Compliance connotes a more passive role for the patient. I have included a paragraph in the intro section outlining the key differences.

The evidence indicates that many therapists see adherence as the patient's problem when there are endless opportunities for therapists to have an influence. This paper gives the reader an insight into the patient's perspective (hugely under-researched in hand therapy literature) and makes specific recommendations for how we can adjust our approach to improve the chances of adherence.

This study focuses on the patient experience of distraction splinting for intra-articular finger fractures, and the factors that influence treatment adherence, in order to add to the body of knowledge and to maximise patient outcomes. The findings, however, can be applied more widely to

*adherence with ANY cumbersome splint and early mobilisation program,
especially in the case of painful acute injuries.*

The paper was accepted after this, with the following encouraging words from the editor:

Congratulations!

*The review of your revised manuscript has been completed and I am
pleased to inform you that your paper, "Patient experience of distraction
splinting for complex finger fracture dislocations", has been accepted for
publication in the Journal of Hand Therapy (JHT). You have made a very
good case that adherence to splinting is a problem and can be a major
barrier.*

Thank you for submitting your work to Journal of Hand Therapy.

Yours sincerely,

Paul LaStayo, PhD, PT, CHT

Editor-in-Chief

Journal of Hand Therapy

and 4th reviewer:

Good content related to factors that can influence the healing process that are more patient centred. Since the patient is the one dealing with this 24/7, I think excellent things were discovered in a researched manner that previously were only anecdotal.

Good use of methodology—very appropriate to this study and content area

The results have the potential of helping the health providers better educate the patients so that they can achieve better compliance—or at least break down some of the barriers to compliance (Reviewer 4)

There is clearly a lot of work to be done before many hand therapy practitioners widen their focus when considering adherence. This is reflected in the published literature in our field (which was reviewed in Chapter 3) which tends to measure mostly socio-economic variables. More encouraging was the reviewer response for this review in *Hand Therapy* (formerly known as *British Journal of Hand Therapy*) – the international journal of the British Association of Hand Therapists Ltd and official journal of the European Federation of Societies for Hand Therapy:

A strong component of this manuscript is that it is clearly grounded in theory and tries to draw implications for practice as it relates to this theory of 'splint wear' adherence behaviour in people with acute hand injuries. (Reviewer A)

A very nice review which is thorough and informs both practice and research – excellent section on implications. (Reviewer B)

and this from the reviewers at *BRAIN INJURY*, the official journal of the International Brain Injury Association:

Patients' compliance with treatment is a critical factor for the success of any disease therapy regimes. Therefore it is quite important for clinical therapist to identify and prevent the probable reasons leading to non-compliance with treatment. (Reviewer 1)

Overall I enjoyed reading this paper and I believe that it has some pertinent points to make. It has particular merit for a number of reasons, the main ones probably being that:

- 1. We need to be able to make better predictions in this respect*
- 2. There is still rather limited literature on the usefulness of the*

9.2 Future Research Directions

Many studies of splinting adherence in people with musculoskeletal injuries have a number of limitations that reduce the usefulness of their findings. The key limitation is the failure to use an established and validated theoretical adherence model to select the variables measured. The *Multi-dimensional Adherence* model published by the WHO² was designed to explain patient adherence with long term therapies, but has been shown throughout this research to be equally applicable in the acute hand therapy context.

Adherence is a complex phenomenon influenced by the interplay of the five previously discussed dimensions. Attributing the sole responsibility to the patient is unhelpful and reflects a “misunderstanding of how other factors affect people’s behaviour and capacity to adhere to their treatment”.^{2p27} To be of best value to practitioners, it is recommended that specific data is collected beyond the standard patient-related and socio-economic variables. These should ideally include factors that can be addressed and modified by practitioners such as continuity of care (e.g., did the same therapist provide treatment or were there multiple therapists involved?; were the surgical and therapy staff giving the same messages to the patient?), patient ratings of complexity of treatment regimen, patient-therapist relationship, length of follow up, splint comfort, pain management, and interference with lifestyle/ activities of daily living/ work. In order to improve service planning, researchers should also

consider collecting data on distance from treatment centre to the patients home or workplace, availability of public transport / car parking facilities, and availability of local community support.

Measures of adherence should include length of time the splint was worn (as a percentage of recommended wear time) as well as number of therapy sessions attended (as percentage of number scheduled). Options for recording splint wear time objectively could include embedded sensors. Where this is impractical, separate splint wear diaries completed by the patient and their partner / carer may yield a more accurate measure of splint adherence.

Researchers also need to use multivariate analysis methods to study factors associated with adherence, so that contributing factors (and combinations of these) can be identified with scientific rigor. This enables practitioners to solve the problems related to each of these factors in order to improve adherence. Finally, a commitment to a multidisciplinary coordinated approach from health professionals, researchers, and health planners is needed to make progress in our understanding of, and response to, this issue.

Appendices

Appendix 1: Ethics Approvals

Project	Approval date, number, and page reference			
	Monash SCERH	Alfred Hospital Ethics Committee	Southern Health Human Research Ethics Committee B	Eastern Health (Box Hill)
Predictors of splint non-compliance for in-patients with acute traumatic brain injury (TBI) and hand injuries (part 1 of project “Development of an assessment tool to determine readiness of people with TBI to engage in hand therapy treatment”	19/12/06 2006/1085MC (p. 203)	30/11/06 217/06 (p. 204)	N/A	N/A
Patient acceptance of distraction splinting for complex intra-articular finger fractures	12/11/08 CF08/3232 – 2008001583 (p. 203)	2/10/08 260/08 (p.206)	N/A	N/A
Efficacy of distraction splinting for complex intra-articular finger fractures	12/11/08 CF08/3232 - 2008001583 (p. 203)	2/10/08 260/08 (p.206)	30/7/09 09107B (p. 207)	N/A
Comparison of Splinting Interventions for treating mallet finger injuries	1/3/10 CF10/0456 – 2010000218 (p. 208)	2/5/06 58/06 (p. 209)	31/7/09 09110B (p. 210)	26/9/08 E11/0809 (p. 211)

Ethics Certificate 2006/1085MC (Monash University)

MONASH University



Standing Committee on Ethics in Research Involving Humans (SCERH)
Research Office

Ms Lisa O'Brien
Department of Occupational Therapy
Faculty of Medicine, Nursing and Health Sciences
Peninsula Campus

19 December 2006

2006/1085MC - Development of an assessment tool to determine readiness of people with acute traumatic brain injury (TBI) to engage in hand therapy treatment

Dear Researchers,

The above research project has been considered by the Standing Committee on Ethics in Research Involving Humans and approval has been given. This approval will be ratified at meeting A1/2007 on 6 February 2007. It is possible that issues may be raised by the Committee at that meeting. If you do not hear anything further you may assume that approval for the project is confirmed.

Terms of approval

1. This project is approved from 19 December 2006 to 30 November 2008 and this approval is only valid whilst you hold a position at Monash University.
2. It is the responsibility of the Chief Investigator to ensure that, if relevant, all information that is pending is forwarded to SCERH. You will then receive a letter from SCERH confirming that we have received the information.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by SCERH.
4. You should notify SCERH immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. **Amendments to the approved project:** Changes to any aspect of the project require the submission of a Request for Amendment form to SCERH and must not begin without written approval from SCERH. Substantial variations may require a new application.
6. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
7. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. Please provide the Committee with an Annual Report determined by the date of your letter of approval.
8. **Final report:** A Final Report should be provided at the conclusion of the project. SCERH should be notified if the project is discontinued before the expected date of completion.
9. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by SCERH at any time.
10. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

All forms can be accessed at our website www.monash.edu.au/resgrant/human-ethics

We wish you well with your research.

[Redacted Signature]

Mrs Lyn Johannessen
Acting Human Ethics Officer (on behalf of SCERH)

Cc: Jacqui Morarty

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CRICOS Provider No. 00008C ABN 12 377 614 012

Ethics Certificate 217/06 (The Alfred)



ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 217/06

Project Title Development of an assessment tool to determine readiness of people with acute traumatic brain injury (TBI) to engage in hand therapy treatment

Principal Researcher: Ms Lisa O'Brien

Protocol No: 217/06

Participant Information and Consent Form version 3 dated: 27-Oct-2006

Participant Information and Consent Form (Retrospective) v. 2 dated: 27-Oct-2006

*was considered by the Ethics Committee on 23-Nov-2006 and is **APPROVED**.*

Approval date: 30-Nov-2006 **Expiry date:** 30-Nov-2008

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report every 12 months for the duration of the project (*forms to be provided*);
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

SPECIAL CONDITIONS

None

SIGNED

Chair, Ethics Committee (or delegate)

Please quote Project No and Title in all correspondence

**R. FREW
SECRETARY
ETHICS COMMITTEE**

Ethics Certificate CF08/3232 - 2008001583 (Monash University)



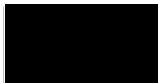
Standing Committee on Ethics in Research Involving Humans (SCERH)
Research Office

Human Ethics Certificate of Approval

Date: 12 November 2008
Project Number: CF08/3232 - 2008001583
Project Title: Efficacy and patient acceptance of distraction splinting for complex intra-articular finger fractures
Chief Investigator: Lisa O'Brien
Approved: From: 12 November 2008 to 12 November 2013

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained and a copy forwarded to SCERH before any data collection can occur at the specified organisation. **Failure to provide permission letters to SCERH before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by SCERH.
4. You should notify SCERH immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to SCERH and must not begin without written approval from SCERH. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. SCERH should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by SCERH at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Ben Canny
Chair, SCERH

Cc: Ben Cunningham,

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ABN 12 377 614 012 CRICOS Provider #00008C



ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 260/08

Project Title Efficacy and patient acceptance of distraction splinting for complex intra-articular finger fractures

Principal Researcher: Ms Lisa O'Brien

Project Proposal: Version 1 **dated:** 13-Aug-2008

Participant Information and Consent Form version 2 dated: 1-Oct-2008

Participant Information and Consent Form (parent/guardian) version 2 dated: 1-Oct-2008

*was considered by the Ethics Committee on 25-Sep-2008 and **APPROVED** on 02-Oct-2008*

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report on the anniversary of approval and on completion of the project (*forms to be provided*);

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

SPECIAL CONDITIONS

None

SIGNED: _____

Chair, Ethics Committee (or delegate)

Please quote Project No and Title in all correspondence

**R. FREW
SECRETARY
ETHICS COMMITTEE**

Ethics Certificate 09107B (Southern Health)

Southern Health

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Australia

tel 03 9594 6666
fax 03 9594 6111

HUMAN RESEARCH ETHICS COMMITTEE B CERTIFICATE OF APPROVAL

DATE 30 July 2009
PROJECT NO. 09107B
PROJECT TITLE **Efficacy of Distraction Splinting for Complex Intra-articular Finger Fractures**

Participant Information & Consent Form Version No. 2 dated 29 May 2009

INVESTIGATOR(S) Ms Lisa O'Brien

HREC MEETING DATE 21 May 2009

APPROVAL 30 July 2009 to 30 July 2012

The Principal Investigator is required to notify the Administrative Officer, Research Directorate of:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any)
2. Serious or unexpected adverse effects of project on subjects and steps taken to deal with them
3. Any unforeseen events that might affect continued ethical acceptability of the project
4. Any expiry of the insurance coverage provided in respect of sponsored trials
5. Discontinuation of the project before the expected date of completion, giving reasons
6. Any change in personnel involved in the research project including any study member resigning from Southern Health &/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual report to the Committee.

Annual report forms will be forwarded to the researcher.

SIGNED **DATE** 30 July 2009
Committee Representative

Please quote Project No. and Title for all correspondence

Southern Health

ABN 82 142 080 338

Dandenong Hospital
Kingston Centre
Cranbourne Integrated
Care Centre

Monash Medical Centre - Clayton
Monash Medical Centre - Moorabbin
Casey Hospital
www.southernhealth.org.au

Community Health
Services across the
South East

Ethics Certificate CF10/0456 – 2010000218 (Monash University)



MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date: 1 March 2010
Project Number: CF10/0456 - 2010000218
Project Title: Comparison of splinting interventions for treating mallet finger injuries
Chief Investigator: Ms Lisa O'Brien
Approved: From: 1 March 2010 to 1 March 2015

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.



Professor Ben Canny
Chair, MUHREC

Cc: Mr Ben Cunningham; Ms Emmeline Fooks;

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ABN 12 377 614 012 CRICOS Provider #00008C

Ethics Certificate 58/06 (Alfred Hospital)



ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 58/06

Project Title Comparison of splinting interventions for treating mallet finger injuries

Principal Researcher: Ms Lisa O'Brien

Protocol No: 58/06

Participant Information and Consent Form version 3 dated: 2-May-2006

*has been considered by the Ethics Committee on 27-Apr-2006 and is **APPROVED**.*

Approval date: 02-May-2006 **Expiry date:** 02-May-2008

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report every 12 months for the duration of the project (*forms to be provided*);
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to The Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Research Involving Humans (1999).

SPECIAL CONDITIONS

None

**R. FREW
SECRETARY
ETHICS COMMITTEE**

SIGNED:

Chair, Ethics Committee (or delegate)

Please quote Project No and Title in all correspondence

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fax 03 9594 6727

HUMAN RESEARCH ETHICS COMMITTEE B CERTIFICATE OF APPROVAL

DATE 31 July 2009
PROJECT NO. 09110B
PROJECT TITLE **Comparison of splinting interventions for treating
mallet finger injuries**

Participant Information and Consent Form Version No. 3 dated 31 July 2009.
Parent/Guardian Information and Consent Form Version No. 1 dated 31 July 2009.

INVESTIGATOR(S) Ms Lisa O'Brien

HREC MEETING DATE 21 May 2009

APPROVAL 31 July 2009 to 31 July 2012

The Principal Investigator is required to notify the Administrative Officer, Research Directorate
of:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any)
2. Serious or unexpected adverse effects of project on subjects and steps taken to deal with them
3. Any unforeseen events that might affect continued ethical acceptability of the project
4. Any expiry of the insurance coverage provided in respect of sponsored trials
5. Discontinuation of the project before the expected date of completion, giving reasons
6. Any change in personnel involved in the research project including any study member resigning from Southern Health &/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual report to the Committee.

Annual report forms will be forwarded to the researcher.

SIGNED
2009

.....
Committee Representative

DATE 31 July 2009 01 August

Please quote Project No. and Title for all correspondence

Southern Health

ABN 82 142 080 338

Dandenong Hospital
Kingsdon Centre
Cranbourne Integrated
Care Centre

Monash Medical Centre
Casey Hospital

www.southernhealth.org.au

Community Health
Services across the
South East

Ethics Certificate E11/0809 (Eastern Health)


easternhealth

26 Septemeber 2008

Dr Lisa O'Brien
Principal Investigator
The Alfred Hospital
Commercial Road
Melbourne Vic 3000

Dear Dr O'Brien

E11/0809 Comparison of splinting interventions for treating mallet finger injuries

The above study was considered by the Eastern Health Research and Ethics Committee to be conducted at Box Hill Hospital at its meeting on 17 July 2008 and was approved subject to the amendments and clarifications. Following receipt of your email clarification dated 18 September 2008, final approval can now be given for the study to proceed.

The following documents have been approved:

- Module 1
- Participant Information and Consent Form Version 5 dated 12 September 2008.

The Third Party Acknowledgement Form was inadvertently resubmitted with email sent on 18 September 2008. **Please note** this form has **not** been approved as part of PI&CF.

Please note, an annual progress report is due in September 2009 - **continuing approval is subject to the timely submission of a satisfactory progress report.**

The Eastern Health Research and Ethics Committee is constituted and functions in accordance with the National Health and Medical Research Council Guidelines (National Statement on Ethical Conduct in Human Research 2007). No member of the Committee adjudicates on research in which that member has any conflict of interest including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.

N:\02-03¤t\Ethics - Eastern Health\All Correspondence\E11-0809 final approval 26Sept08.doc

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Ethics Committee
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Email:
ethics@easternhealth.org.au
Website:
www.easternhealth.org.au/ethi

Other Members of Eastern Health

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Forest Hill Victoria 3131 Australia
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Community Health Service
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Clive Ward Centre
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PO Box 94, Box Hill 3128
Tel (03) 9895 3259
Fax (03) 9895 3176
info@easternhealth.org.au
ABN 68 223 819 017
www.easternhealth.org.au

Please refer to the National Statement on Ethical Conduct in Human Research (2007) <http://www.nhmrc.gov.au/publications/synopses/e35syn.htm> and Module 1.38 for researchers' obligations. **Continuing approval is subject to the adherence of these guidelines and the fulfilment of researchers' obligations.**

Please quote our reference number **E11/0809** in all future correspondence.

Yours sincerely



Dr Patricia Molloy
Chair
Eastern Health Research and Ethics

Encl: Committee Composition letter

)

Appendix 2: Conference participation

Abstracts – Peer Reviewed Journal

O'Brien, L and Bailey, M (2008) Determinants Of Compliance With Hand Splinting In An Acute Brain Injured population, 7th World Congress on Brain Injury; *Brain Injury*, 22 (Supplement 1) p 4

Awards

Alfred Health Professor of Medicine Poster Prize for Patient Safety and Quality Improvement (for poster: **O'Brien, L** and Bailey, M Single blind, prospective randomized controlled trial comparing dorsal aluminium and custom thermoplastic splints to stack splint for acute mallet finger. Presented at Alfred Week, October 2010)

Alfred Health Professor of Medicine Poster Prize for Patient Safety and Quality Improvement (for poster: **O'Brien, L** and Presnell, S Patient experience of distraction splinting for complex finger fracture dislocations, presented at Alfred Week, October 2009)

Victorian Neurotrauma Initiative Skills Development Award (2008) \$2000 (for project: Predictors of splint non-compliance for in-patients with acute traumatic brain injury (TBI) and hand injuries.

Henrietta Law Memorial Prize for Allied Health Research (for poster: Salway, J and **O'Brien, L** Factors associated with non-adherence to hand splinting regimens in an acute inpatient burns population, presented at Alfred Week , 2008)

Conference Presentations

O'Brien, L Adherence to therapeutic splint wear in adults with acute upper limb injuries: a systematic review. Presented at the 8th Triennial Congress of the International Federation of Societies for Hand Therapy (IFSHT) June 2010; Orlando, Florida, USA

O'Brien, L and Presnell, S Patient experience of distraction splinting for complex finger fracture dislocations. Presented at the 8th Triennial Congress of the International Federation of Societies for Hand Therapy (IFSHT) June 2010; Orlando, Florida, USA

O'Brien, L and Bailey, M Determinants Of Compliance With Hand Splinting In An Acute Brain Injured Population. Presented at the 7th World Congress on Brain Injury, April 2008; Lisbon, Portugal

O'Brien, L and Bailey, M Determinants Of Compliance With Hand Splinting In An Acute Brain Injured Population NTRI Allied health Trauma Symposium; Nov 2007 Melbourne

O'Brien, L Custom-Made vs Off-The-Shelf Splinting for Mallet Finger Injuries – Which Is Best? Presented at 7th Triennial Congress of the International Federation of Societies for Hand Therapists (IFSHT) March 2007; Sydney

Conference Posters

O'Brien, L and Bailey, M Single blind, prospective randomized controlled trial comparing dorsal aluminium and custom thermoplastic splints to stack splint for acute mallet finger. Presented at Alfred Week, October 2010; The Alfred Hospital Melbourne

O'Brien, L Why our clients do or don't stick with their program – a new way of looking at adherence. Presented at 15th World Federation of Occupational Therapists (WFOT) Congress, May 2010, Santiago Chile

O'Brien, L Why our clients do or don't stick with their program – a new way of looking at adherence. Presented at Alfred Week, October 2009; The Alfred Hospital Melbourne

O'Brien, L and Presnell, S Patient experience of distraction splinting for complex finger fracture dislocations. Presented at Alfred Week, October 2009; The Alfred Hospital Melbourne

Salway, J and **O'Brien, L** Factors associated with non-adherence to hand splinting regimens in an acute inpatient burns population. Presented at 23rd National Conference and Exhibition of OT Australia September 2008; Melbourne

Appendix 3: Successful Competitive Grant Applications

O'Brien, L Victorian Occupational Therapy Trust Grant (2008) \$4000 for Impact of distraction splinting for complex intra-articular finger fractures

O'Brien, L The Alfred Allied Health Research Grant (2006) \$20,000 for Comparison of splinting interventions in the treatment of mallet finger injuries (1 year grant)

***Appendix 4: Summary tables of published evidence on traction devices
for intra articular fractures***

Group 1: Finger-Based Frames

Table A4.1 Traction device = Rubber band/s

Table A4.2 Traction device = Spring or S-quattro

Table A4.3 Traction device = Rigid straight K-wire

Table A4.4 Traction device = Rhomboid Frame

Table A4.5 Traction device = Dorsal parabolic wire

Table A4.6 Traction device = hinged compass device

Group 2: Dynamic traction splints

Table A4.7 Swing designs

Table A4.8 Arcuate designs

Abbreviations for appendix tables:

m= male; f= female; PRTS Pins and Rubbers traction system; DDEF Dynamic Distraction

External Fixation RTW return to work; AROM = active range of motion; TAM= total active

movement; PIP = proximal; DIP= distal interphalangeal joint; IP = interphalangeal joint of the

thumb; Pt = patient; Artic = articular

Group 1: Finger-Based Frames

A4.1: Traction device = Rubber band/s

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTROL	MEASURES	FINDINGS
Debus (2010)	15	Retrospective cross sectional	56	11m:4f age 21-63	Complex # of PIP	Modified Suzuki PRTS – no control (see figure A1)	AROM PIP and DIP Grip/key and tip pinch strength (% of uninjured hand) Pt satisfaction Complications	average range: PIP 56.6° DIP 39.6° Grip 80%, Key pinch 84%, tip 89% 35% satisfied Pin track infection (N=3), residual joint oedema (N=7) Clinodactyly (N=7) Cold sensitivity (N=8) Persistent pain (N=8)
Deshmukh (2004)	14	Retrospective cross sectional	34	11m:3f age 18-57	#/disloc of PIP (N=13) #/disloc of thumb IP (N=1)	Modified Suzuki PRTS – no control (see figure A1)	Michigan hand outcome Questionnaire AROM PIP and DIP Grip strength RTW Complications	Mean score: 84 average range: PIP 85° DIP 48° Average of 92% of uninjured hand 12 out of 14 pin track infection(N=2) cold intolerance (N=2) fixed deformities: 10° valgus (N=2) 10° hyperextension (N=1)
Duteille (2003)	20	Case series	18	18m:2f age 12-74	Complex # of PIP (N=9) #/disloc of PIP (N=11)	Suzuki PRTS – no control (see figure A1)	Treatment failure AROM PIP	Patient unable to tolerate (N=1) Pin track infection (N=1) average range: PIP 85.9°

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTROL	MEASURES	FINDINGS
							Joint pain	No pain (N=15) pain (N=1)
							Complications	Joint space narrowing (N=7) malunion (N=1) Clinodactyly (N=1)
Majumder (2003)	14	Case series	20	12m:2f age 5-46	Complex # of PIP	Suzuki PRTS – no control (see figure A1)	AROM PIP/TAM	average range: PIP 74°/average TAM 196°
							Grip strength	Not reported
							Sensation	Normal in all pts
							Pt satisfaction	95% satisfied
							Pain	Mean = 2 (on 10-point scale)
							Complications	Pin track infection (N=3) Flexion contractures (n=13) Subluxation (N=6)
Ruland (2008)	34	Retrospective file review	16	27m:7f age mean 30	#/disloc of PIP	DDEF (lever assisted reduction technique) - no control (see figure A2)	AROM PIP and DIP	average range: PIP 88° DIP 60°
							Complications	Pin track infection (N=8) Extensor adhesions (N=1) Swan neck deformity (N=1)
Suzuki (1994)	7	Case series	13	5m:2f age 16-61	#/disloc of PIP (N=4) Complex # PIP (N=1) Complex # DIP (N=1) Complex # trapezium (N=1)	Suzuki PRTS - no control (see figure A1)	AROM at affected joint	#/disloc PIP average range 80°
							Pain	No pain (N=6) Pain (N=1)
Agee (1987)	16	Case series	20.4	10m:6f age 15-51	#/disloc of PIP	Force Couple splint (3 k-wires and rubber band) (see figure A3)	AROM PIP	average range: PIP 83°
							Complications	Recurrent subluxation (N=3) Adhesions causing loss of DIP flexion (N=1)

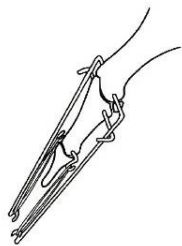


Figure A1: Suzuki frame, copyright © 1994¹⁹⁴



Figure A2: DDEF (lever assisted reduction technique), 2008¹⁹⁶

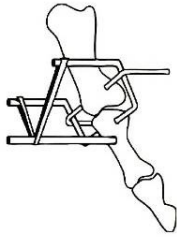


Figure A3: Force couple splint, copyright © 2000¹⁹⁵ copyright ©

A 4.2: Traction device = Spring or S-quattro

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/ CONTROL	MEASURES	FINDINGS
Allison (1996)	14	Case series	10.2	12m:2f age16-61	#/disloc of PIP (dorsal, N=11; pilon N=3)	Springs mounted between K-wires – no control (see figure A4)	AROM PIP Pain Complications	average range: PIP 76.6° No significant pain Dislocation (N=1) degenerative change (N=1)
Khan (2006)	100	Case series	PIP: 10.7 DIP: 9.7 MCP: 11.3 Thumb: 8	71m:29f age18-94	Complex # of PIP (N=81) Complex # of DIP (N=10) Complex # of MCP (N=6) Complex # of thumb IP (N=3)	S-quattro– no control (see figure A5)	AROM affected joint Pain	Average range: PIP: 92° DIP: 82° MCP: 91° Thumb: 80° PIP: mild (N=6) moderate (N=2) DIP: moderate(N=1) MCP: 91° Thumb: 80° PIP: 97% satisfied Patient satisfaction Complications
								Device dislodged and required reapplication (N=2) Degenerative changes requiring silastic joint replacement (N=1)

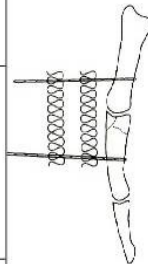


Figure A4: The Allison device, copyright© 1996¹⁹⁷

Figure A5: S-quattro, copyright© 1990¹⁹⁸

A 4.3 Traction device = Rigid straight K-wire

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTROL	MEASURES	FINDINGS
Badia (2005)	6	Case series	24	4m:2f age 21-42	#/disloc of PIP	Modified Gaul & Rosenberg skeletal traction frame – no control (see figure A6)	AROM PIP and DIP Complications	Average range: PIP: 84° DIP: 78° Pin track infection (N=2) Fixed flexion deformity (N=4)
Hynes (2001)	9	Case series	12	7m:2f age 16-57	Pilon # PIP (N=8); Thumb IP # (N=1)	Skeletal traction frame using rigid wires – no control (see figure A7)	AROM affected joint Pain Complications	Average range: PIP: 76° Thumb IP: 70° Occasional pain (N=3) Pin track infection (N=2) Fixed flexion deformity (N=7) Cold sensitivity (N=1)

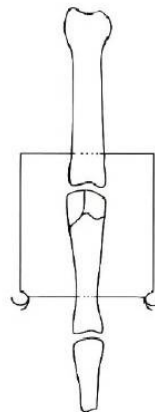
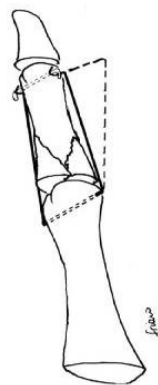


Figure A6: Modified Gaul & Rosenberg traction, copyright© 2005¹⁹⁹ Figure A7: Hynes and Giddins device, copyright© 2001²⁰⁰

A 4.4: Traction device = Rhomboid Frame

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTROL	MEASURES	FINDINGS
Inanami et al (1993)	7	Case series	17	7m:0 f Age 18-44 in acute cases; 34-44 in malunited cases	Acute #/disloc of PIP (N=4) Malunited #/disloc of PIP (20-118 days post injury) (N=3)	Dynamic external fixator (3 k-wires and 2 rhomboid apparatuses with 2 pulleys at each end; 2 arm apparatuses with one pulley in the middle) - no control (see figure A8)	AROM PIP Pt satisfaction with result Pain Complications	average range: 95 80 All satisfied Persistent pain N=1 subluxed jt (n=1)

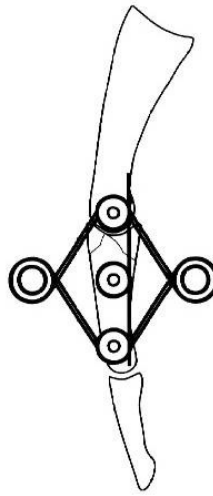
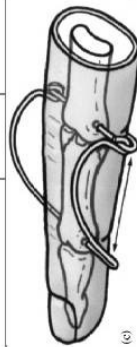


Figure A8: Inanami fixator copyright© 1993²⁰¹

A 4.5: Traction device = Dorsal parabolic wire

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTROL	MEASURES	FINDINGS
Syed (2003)	8	Case series	26	6m:2f age 19-72	Pilon # PIP	Skeletal traction frame using dorsal parabolic wires – no control (see figure A9)	AROM PIP Pt satisfaction Pain Complications	Average range: PIP: 79° Excellent (N=1) Good (N=6) Fair (N=1) Occasional pain (N=1) Disassembly during motion (N=2)
Theivendran (2007)	12	Case series	6	10m:2f age 18-60	#/disloc of PIP (N=11) #/disloc of thumb IP (N=1)	Skeletal traction frame using dorsal parabolic wires – no control (see figure A9)	AROM PIP and DIP Michigan hand outcome Questionnaire Grip strength Pain Complications	Average range: PIP 64° DIP 52° Mean score: 90 Average of 86% of uninjured hand All pts pain-free Pin track infection (N=2) Device dislodged and required reapplication (N=1) Extensor lag average 11°

Figure A9: Dorsal Parabolic wire, copyright© 2003²⁰²

A 4.6: Traction device = Hinged compass device

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTROL	MEASURES	FINDINGS
Bain (1998)	20	Case series	8	18m:2f age 13-55	#/disloc of PIP (N=10) Dorsal disloc PIP (N=2) PIP contracture (N=2) # base middle phalanx (N=1) Swan neck deformity due to VP avulsion (N=4)	Compass PIP Hinge (Smith & Nephew) – no control (see figure A10)	AROM PIP Complications	Average range: PIP 74° Pin track infection (N=4) Breakage of pin block (N=2) Redislocation (N=1) Septic arthritis (N=1) Extensor lag average 12°
Krakauer (1996)	20	Case series	11 (Group 1) 14 (Group 2)	Group 1: 9m:3f age 17-42 Group 2: 5m:3f age 16-45	Group 1: < 2 weeks post injury Dorsal # disloc (N=10) Volar #/disloc (N=2) Group 2: >4 weeks post injury dorsal #/disloc (N=6) prox phalanx unicondylar malunion (N=1) degenerative arthritis (N=1)	Compass PIP Hinge (Smith & Nephew) – no control (see figure A10)	AROM PIP and DIP Pain Complications	Group 1: average range: PIP 73° DIP 47° Group 2: average range: PIP 56° DIP 44° Group 1: Pain on heavy activity (N=3) Group 2: Pain on heavy activity (N=3) Mod-severe pain (N=2) Group 1: Pin track infection (N=1) Device dislodged – not reapplied (N=1) PIP extensor lag average 12° Group 2: Deep infection (N=1) superficial infection (N=1) Recurrent subluxation (N=1) Recurrent angular deformity – required silastic joint replacement (N=1)

Group 2: Dynamic traction splints

A 4.7: Swing Design

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/CONTR OL	MEASURES	FINDINGS
Murray (1995)	N/A	Practice article				Swing with dorsal block		
Byrne (1995)	N/A	Practice article				Swing design - volar splint (similar to figure A11)		
Kadelbach (2006)	N/A	Practice Article				Swing design - volar splint (see figure A11)		
Dennys (1992)	14	Case series	6.1	8m:6f age 13-55	Complex # of PIP (N=13) thumb IP (N=1)	Lateral hinge traction - dorsal splint (see figure A12)	AROM PIP Complications Pain	Average range: PIP 81° Pin track infection (N=1) Flexion contracture (N=10) PIP extensor lag (N=1) Minor discomfort (N=3) ache after activity (N=1)

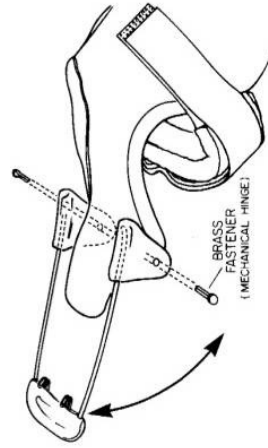
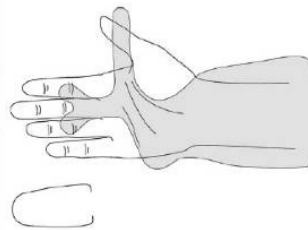


Figure A 11: Lateral hinge traction splint, copyright© 2006¹⁴⁷

Figure A 12: Lateral hinge traction splint, copyright© 1992²⁰⁴

A 4.8: Arcuate design

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/ CONTROL	MEASURES	FINDINGS
Baier (2010)	N/A	Practice article				Hand-Arc splint (see figure A13)		
Sarris (2004)	6	Case series	29	4m:2f age 18-36	Pilon # PIP (N=4) Pilon # base prox phalanx thumb (N=2)	Schenck dynamic traction splint – no control (see figure A14)	AROM Pain Pt satisfaction Complications	Average range: PIP 94° MCP thumb 63° Pain free (N=3) Pain after prolonged activity (N=1) Pain on ADL's (N=1) All satisfied Pin track infection (N=1) Asymptomatic swelling (N=2)
Stern (1991)	20	Retrospective cross sectional	25	16m:4f age 17-44	Pilon # PIP	Group 1: Open reduction (N=9) Group 2: Banjo splint/traction (N=6) (see figure A15) & Schenck dynamic traction splint (N=1) (see figure A14) Group 3: Static splint (N=4)	AROM Grip strength(% of uninjured hand) Pain	Average range: Gp 1: PIP 70°, DIP 50° Gp 2: PIP 80°, DIP 50° Gp 3: PIP 65°, DIP 50° Gp1: 87.3% Gp 2: 94.1% Gp 3: 104% Gp 1: Pain free (N=2) pain on axial loading (N=4) pain on heavy activity (N=1) Continuous pain (N=2) Gp 2: Pain free (N=4) pain on axial loading (N=2) pain on heavy activity (N=1) Gp 3: 2 required arthodesis. Of remaining 2: pain on heavy activity (N=1) Continuous pain (N=1)

STUDY	N	STUDY DESIGN	MEAN FOLLOW-UP (MONTHS)	POPULATION	INJURY	INTERVENTION/ CONTROL	MEASURES	FINDINGS
							Radiographic appearance	Gp1: Lack of anatomic articular restoration, significant articular remodelling Gp 2:remodeling & varying degrees of splay base of middle phalanx Gp3: articular remodeling, central depression, splaying
							Complications	Gp 1: deep infection requiring drainage, skin graft (N=1) Fall onto finger, broken k-wire, required later arthrodesis (N=1) Gp 2: nil Gp 3:symptomatic arthritis requiring arthrodesis (N=2)
Haines (1991)	N/A	Practice article						
Morgan (1995)	14	Retrospective cross sectional	23.8	8m:6f age 18-63	Pilon #PIP (N=5) dorsal #/disloc PIP (N=6) palmar #/disloc PIP (N=2) open intra-articular comminuted #PIP (N=1)	Schenck dynamic traction splint - no control (see figure A14)	AROM PIP & DIP	Average range: PIP 89° DIP 54°
							Grip strength(% of uninjured hand)	Dominant hand injured: 102% Non-dominant hand injured: 77%
							Pain	Pain free (N=7) rare/occasional mild pain (N=5) frequent mild pain (N=1) pain n cold (N=1)
							Complications	Pin track infection (N=6)



Figure A13: Hand Arc traction splint, copyright©2010²⁰⁵

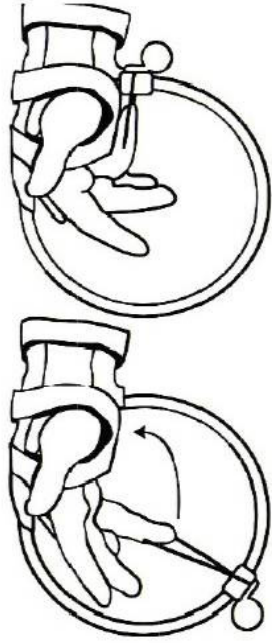


Figure A14: Schenck dynamic traction splint, copyright©2000²⁰⁶

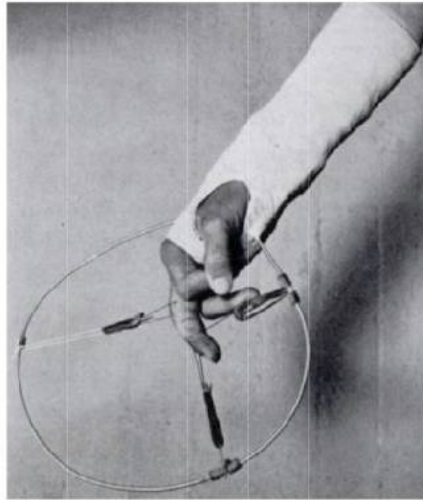


Figure A15: The Robertson Banjo splint, copyright© 1946²⁰⁷

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