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A COMPARISON OF THE OUTCOMES OF TWO REHABILITATION PROTOCOLS AFTER FLEXOR TENDON REPAIR OF THE HAND AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

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ABSTRACT

Flexor tendon repair of the hand and rehabilitation are frequently discussed between hand surgeons and therapists. This is mainly due to the poor outcomes commonly achieved after this type of surgery. There are many patients in public hospitals in South Africa who require flexor tendon repair surgery. They are regularly sent to therapists for rehabilitation, where the early passive motion protocol is commonly implemented. Although the early active motion protocol has yielded improved results globally, there is limited evidence on the comparison of the outcomes of these two protocols in the South African context. The aim of the study was to compare the outcomes of an early active motion protocol to the outcomes of an early passive motion protocol in patients with zone II to IV flexor tendon repairs of the hand, attending rehabilitation at Chris Hani Baragwanath Academic Hospital. The study was a quantitative single-blinded comparative controlled trial. Forty-six patients who sustained a zone II-IV flexor tendon injury were recruited for the study and equally distributed between the two groups (early active motion and early passive motion). Out of these participants, 11 did not return for the initial assessment at four weeks post-surgery and were therefore excluded. There were 19 participants in the early active motion group and 16 participants in the early passive motion group. Results were collected and classified at 4, 8 and 12 weeks post-surgery. Data collection took place from December 2014 to January 2016 in the Chris Hani Baragwanath Academic Hospital Hand Unit. At 12 weeks post-surgery, the total active motion, fingertip to table, and distal palmar crease measurements were similar between the two groups. Tendon rupture occurred in 8.57% (n=3, early active motion = 5.71%, early passive motion = 2.86%) of patients. This study found that there was no difference in outcomes between the two groups. Therefore, either protocol could be implemented in South African public hospitals. However, since the early active motion protocol takes less time to implement, this protocol is recommended. A study with a greater magnitude would be necessary to determine a significant comparison between the two groups; however, this is challenging due to poor patient compliance.

Keywords: outcomes; flexor tendon repair; rehabilitation; early active motion; early passive motion

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TABLE OF CONTENTS

Declaration of originality ii

Abstract iii

Acknowledgements iv

List of tables viii

List of figures ix

1 Introduction 1
- **1.1 Background** 1
- **1.2 Problem statement** 3
- **1.3 Research question** 4
- **1.4 Aim** 4
- **1.5 Objectives** 4
- **1.6 Hypothesis** 5
- **1.7 Significance of study** 5
  - 1.7.1 Outcomes of flexor tendon repair 5
  - 1.7.2 Patient compliance and protocol selection 5
- **1.8 Delineations and assumptions** 6
  - 1.8.1 Delineations 6
  - 1.8.2 Assumptions 6
- **1.9 Definition of key terms** 6
- **1.10 Overview of the chapters** 8
- **1.11 Conclusion** 8

2 Literature review 9
- **2.1 Introduction** 9
- **2.2 Flexor tendon anatomy** 10
  - 2.2.1 Flexor tendons of the extrinsic muscles of the hand 10
  - 2.2.2 Zones of the flexor tendons 11
  - 2.2.3 Digital flexor tendon sheath 12
  - 2.2.4 Flexor tendon nutrition 14
- **2.3 Flexor tendon biomechanics** 14
  - 2.3.1 Tendon tension 15
  - 2.3.2 Tendon excursion 16
  - 2.3.3 Tendon friction and force 18
- **2.4 Flexor tendon injuries** 18
  - 2.4.1 Mechanism of injury 19
- **2.5 Flexor tendon healing** 20
  - 2.5.1 Stages of tendon healing 20
  - 2.5.2 Extrinsic vs. intrinsic flexor tendon healing 21
  - 2.5.3 Patient factors that influence tendon healing 22
- **2.6 Surgical management of flexor tendon injuries** 24
  - 2.6.1 Timing of repair 24
  - 2.6.2 Type of injury 25
  - 2.6.3 Type of surgical tendon repair 26
- **2.7 Rehabilitation of flexor tendon repairs** 27

2.7.1 Factors to consider in the rehabilitation of flexor tendon repairs 27
2.7.2 Rehabilitation protocols 30
2.7.3 Immobilisation protocol 31
2.7.4 Early passive motion protocol 32
2.7.5 Early active motion protocol 35
2.8 Evaluation of outcomes after flexor tendon repair 40
2.8.1 Time intervals for outcome measurements 40
2.8.2 Goniometric measurement 40
2.8.3 Total active motion 41
2.8.4 Strickland's method 42
2.8.5 Fingertip to distal palmar crease and table measurements 43
2.9 Review of results from EAM and EPM protocol studies 43
2.9.1 Similar outcomes between the EAM and EPM protocols 44
2.9.2 Different outcomes between the EAM and EPM protocols 44
2.9.3 Outcomes of an EAM study 45
2.9.4 Outcomes of an EPM study 46
2.10 Complications post flexor tendon surgery and rehabilitation 48
2.10.1 Tendon adhesions 48
2.10.2 Tendon gapping 49
2.10.3 Tendon rupture 49
2.11 Conclusion 50

3 Research methodology 51
3.1 Introduction 51
3.2 Research design 51
3.3 Research setting 52
3.4 Research population 52
3.5 Inclusion and exclusion criteria 52
3.5.1 Inclusion criteria 52
3.5.2 Exclusion criteria 53
3.6 Selection of subjects 53
3.6.1 Process of selection 53
3.6.2 Process of random assignment 53
3.7 Sample size 54
3.8 Implementation of study 54
3.9 Data collection 58
3.9.1 Measurement tools and methods 58
3.10 Ethical considerations 58
3.10.1 Autonomy 59
3.10.2 Non-maleficence 59
3.10.3 Beneficence 59
3.10.4 Justice 59
3.10.5 Informed consent 60
3.11 Variables 60
3.12 Control of variables 60
3.13 Data analysis 62
3.14 Conclusion 63

4 Results 64

4.1 Introduction **64**
4.2 Outcomes post flexor tendon repair **64**
4.2.1 Total active motion 66
4.2.2 Fingertip to distal palmar crease 69
4.2.3 Fingertip to table 70
4.2.4 Multi tendon versus single tendon injury 72
4.3 Participant demographics **72**
4.3.1 Recruitment and follow-up 73
4.3.2 Participant details 73
4.3.3 Flexor tendon injury details 75
4.3.4 Timing to surgical repair and rehabilitation 77
4.3.5 Participant compliance 78
4.3.6 Socio-economic factors 79
4.4 Complications post-surgery and rehabilitation **82**
4.5 Conclusion **83**

5 Discussion **84**
5.1 Introduction **84**
5.2 Outcomes post flexor tendon repair **85**
5.2.1 Total active motion 86
5.2.2 Fingertip to distal palmar crease 88
5.2.3 Fingertip to table 88
5.2.4 The effect of the degree of injury on outcomes 89
5.3 Participant demographics **89**
5.3.1 Participant details 89
5.3.2 Flexor tendon injury 90
5.3.3 Timing to surgical repair and rehabilitation 92
5.3.4 Participant compliance 93
5.3.5 Socio-economic factors 96
5.4 Complications post-surgery and rehabilitation **98**
5.4.1 Adhesions 98
5.4.2 Infection 98
5.4.3 Tendon rupture 99
5.5 Selection of a rehabilitation protocol **99**
5.5.1 Surgical considerations 100
5.5.2 Rehabilitation protocols 100
5.5.3 Participant compliance 101
5.6 Conclusions and recommendations **101**
5.7 Study limitations **105**
5.8 Indications for further research **106**

6 References **107**

7 Appendices **112**
7.1 Appendix A **113**
7.2 Appendix B **115**
7.3 Appendix C **121**
7.4 Appendix D **128**
7.5 Appendix E **130**
7.6 Appendix F **134**

LIST OF TABLES

Table 1: Key terms used in this document 7
Table 2: Tendon excursion per 10 degrees of DIP or PIP joint flexion[4] 18
Table 3: Classification of timing of tendon repair[18] 25
Table 4: Summary of the immobilisation protocol 31
Table 5: Summary of published early passive motion protocols 34
Table 6: Summary of published early active motion protocols 39
Table 7: Total active motion categories in relation to the percentage of function of the corresponding digit on the uninjured hand[10] 42
Table 8: Flexor tendon rehabilitation studies 47
Table 9: Compiled data at the 4, 8 and 12-week time period for the EAM and EPM groups 66
Table 10: Number of injured fingers in total active motion categories at 12 weeks post-surgery 68
Table 11: Number of participants in total active motion categories at week 12 68
Table 12: Total active motion mean percentage of function categories of injured fingers 69
Table 13: Total active motion mean percentage of function categories of injured hand.. 69
Table 14: Fingertip to distal palmar crease measurement (injured fingers) 70
Table 15: Fingertip to table measurement (injured fingers) 71
Table 16: Multi tendon versus single tendon injuries in the EAM group 72
Table 17: Multi tendon versus single tendon injuries in the EPM group 72
Table 18: Participant details in the two rehabilitation groups 74
Table 19: Clinical details of participants' injuries 75
Table 20: Associated injuries across the sample 76
Table 21: Associated injury between the EAM and EPM groups 76
Table 22: Mechanism of injury between the EAM and EPM groups 77
Table 23: Education across the sample 80
Table 24: Category of employment across the sample 80
Table 25: Monthly income across the sample 81
Table 26: Type of transport taken to the hospital 81
Table 27: Cost of transport to and from the hospital 81
Table 28: Tendon rupture characteristics 83
Table 29: Complications post-surgery and rehabilitation according to the rehabilitation protocol and zone of injury 83
Table 30: Comparison of participants in total active motion categories between the study by Frueh et al[8] and this study between the two groups 87

LIST OF FIGURES

Figure 1: View of the volar aspect of the hand[2] 11
Figure 2: Anatomical zones of the flexor tendons[2] 12
Figure 3: View of the tendon synovial sheath[2] 13
Figure 4: Lateral view of the annular and cruciate pulleys[2] 14
Figure 5: Bowstringing of the middle finger flexor tendons due to absent pulleys[2] 17
Figure 6 Two-strand Modified Kessler tendon repair[3] 26
Figure 7 Four-strand cruciate tendon repair[2] 27
Figure 8: The strength of tendon repairs against the forces exerted by different motion types[2] 29
Figure 9: EPM protocol dorsal blocking splint with finger loops and elastic 56
Figure 10: EAM protocol dorsal blocking splint 56
Figure 11: Position of participants' wrist in measurement of the outcomes 62
Figure 12: Total active motion percentages of the whole hand and injured fingers between the two groups 67
Figure 13: Fingertip to distal palmar crease 70
Figure 14: Fingertip to table 71
Figure 15: Participants follow-up at each time period in the EAM and EPM groups 73
Figure 16: Mechanism of injury 77
Figure 17: Participants lost to follow-up 78
Figure 18: Participant compliance portraying participants lost to follow-up and those who completed the study 82

1 INTRODUCTION

1.1 BACKGROUND

The hand is a highly complex prehensile organ, with important functions such as touch and fine movement, allowing engagement in a range of multifaceted activities throughout life.[1] To enable these functions to be effective, the balance of the hand is important, which is reliant on the various tissues involved and the way in which they work together.[1] It has been stated that traumatic injuries comprise approximately one-third of upper limb injuries, one of the most severe being tendon injuries.[2] These injuries often result in the impairment of optimal hand function and have a direct impact on daily activities. Tendon rehabilitation has been documented to take between three to four months during which the patient has limited use of the hand.[2]

Amadio[3] states, "it became clear that tendon rehabilitation is a critical factor determining the quality of the result after finger flexor tendon repair". Flexor tendon rehabilitation has been a topic of discussion between hand therapists and surgeons for many years. The discussions have developed due to the abundance of research conducted on the biomechanics and structure of tendons, the reaction of tendons to injury and surgery, tendon strength, and the effect of post-surgical motion on tendon healing and strength.[4] Khanna et al[5] are of the opinion that flexor tendon rehabilitation is the only clinically significant intervention that decreases adhesion formation. The topic that causes much debate is regarding the type of rehabilitation protocol which should be implemented. The two main types of protocols that are debated in many centres in South Africa are the early active motion (EAM) and early passive motion (EPM) protocols.

The outcome of rehabilitation following flexor tendon repair is dependent on the close interaction between the surgeon, the therapist, and the patient.[6] The past few years have seen an overwhelming trend towards the use of early active motion in the treatment of flexor tendon repairs internationally.[6] Advances in tendon surgery, improved insight into the process of tendon healing, as well as the value of proximal tendon excursion to functional recovery, have directed and guided this trend.[6,7]

Globally, many studies have been carried out to ensure that protocols are kept current and in line with new developments in the treatment of flexor tendon injuries.[7-15] These studies originated in Switzerland,[8] the United States of America,[9,11] the United Kingdom,[10,14,15] Turkey,[12] and Hong Kong.[7,13] In the literature reviewed, minimal research could be found on this topic in South Africa.

Flexor tendon repairs are commonly seen in South African hospitals. The rehabilitation of patients who undergo these repairs has remained the same over many years, and global trends in rehabilitation after flexor tendon repair have not been adopted locally.

Based on a telephonic survey (Appendix A) conducted with six of the larger public hospitals in Gauteng, it was found that most of these public hospitals still make use of EPM rehabilitation protocols as the treatment of choice. These hospitals were chosen for the survey because they carry out surgery and rehabilitation of flexor tendon repairs on a regular basis. The results of the survey portrayed that five out of the six hospitals still make use of EPM protocols in the rehabilitation of flexor tendon repairs. The reasons stated for implementing this protocol included:

- The protocol had been implemented in the past.
- The EPM protocol seemed effective.
- The surgeons requested the protocol to be carried out.

The only hospital which implements an EAM protocol stated that they changed their rehabilitation protocol due to post-surgical and rehabilitation complications such as adhesions. There were varied responses in terms of the surgical technique implemented by the surgeons, which included 2 or 4-strand repairs. Alternatively, the surgeons did not report on the number of strands used to carry out the repair.

Based on this telephonic survey, it was revealed that several factors contribute to the continued use of the EPM protocol. This appears to centre largely on socio-economic challenges associated with the South African population. Lack of education and poor understanding by patients are regarded as contributing factors to non-compliance

and loss of patients to follow-up. Financial constraints also play a significant role,[16] with many patients lacking the financial resources to attend therapy regularly.

The aforementioned factors have guided South African therapists and surgeons towards the selection of protocols, which limit the degree of responsibility placed on the patient. Globally, therapy is focused on establishing and maintaining the balance between tendon tension and adequate tendon excursion of a repaired tendon.[16] However, in the developing world, it is largely preferred to protect the tendon repair than achieving adequate tendon excursion.

1.2 PROBLEM STATEMENT

Patients who have undergone flexor tendon repair often experience complications such as decreased range of movement, tendon adhesions, and tendon rupture. These factors have a negative impact on the patients' ability to perform activities of daily living and work. One of the factors which could contribute to the reduction of complications is the rehabilitation protocol implemented post-surgery.

In 2013, an audit was conducted at Chris Hani Baragwanath Academic Hospital (CHBAH) on the outcomes of flexor tendon repair using an EPM protocol. The results of this audit indicated poor outcomes, identifying the need to explore the implementation of a different rehabilitation protocol. Literature has shown that the use of an EAM protocol in the rehabilitation of flexor tendon repair yields more favourable outcomes.[7,9,11,13,15] To ensure that a tendon repair is strong enough to withstand an EAM protocol, a 4-strand repair of the flexor tendon is required.[4] Before the EAM protocol could be scientifically studied, the hand surgeons at CHBAH had to change their surgical technique. The surgeons at CHBAH were approached with this information, and they agreed to adjust their suture technique in support of this study. This enabled the researcher to conduct the study to determine if this protocol could work in this environment and if it would yield more favourable outcomes. Minimal literature could be found on studies conducted within the South African context regarding the implementation of the EAM protocol. A study to determine the outcomes of an EAM protocol compared to the outcomes of an EPM protocol in the rehabilitation of flexor tendon repair patients was thus required.

1.3 RESEARCH QUESTION

How do the outcomes of an EAM protocol compare to the outcomes of an EPM protocol in patients with zone II to IV flexor tendon repairs attending rehabilitation at CHBAH?

1.4 AIM

The aim of this study was to compare the outcomes of an EAM protocol to the outcomes of an EPM protocol in patients with zone II to IV flexor tendon repairs of the hand attending rehabilitation at CHBAH.

1.5 OBJECTIVES

The following were the objectives of the study:

1. To implement the EAM or EPM protocols during the first four weeks of rehabilitation of patients with zone II to IV flexor tendon repairs
2. To determine the outcomes of patients with zone II to IV flexor tendon repairs during rehabilitation following an EAM protocol based on the following measurements:
    a. Total active motion of the affected and unaffected fingers
    b. Fingertip to distal palmar crease measurements of the affected fingers
    c. Fingertip to table measurements of the affected fingers
3. To determine the outcomes of patients with zone II to IV flexor tendon repairs during rehabilitation following an EPM protocol regarding:
    a. Total active motion of the affected and unaffected fingers
    b. Fingertip to distal palmar crease measurements of the affected fingers
    c. Fingertip to table measurements of the affected fingers
4. To compare the results of objectives 2 and 3
5. To evaluate the effect of the degree of injury on the outcomes, such as multi tendon injury versus single tendon injury
6. To determine if there is a relationship between patient compliance and socio-economic factors

The collection of relevant data assisted the researcher to investigate the above objectives and to study other factors which may influence the final outcome of flexor tendon repairs. These included participant demographics, complications post-surgery and rehabilitation, and factors to consider when selecting a rehabilitation protocol.

1.6 HYPOTHESIS

The hypotheses that follow were used in connection with this study.

Null hypothesis: There is no difference in the outcomes for the EAM protocol compared to the outcomes for the EPM protocol in the rehabilitation of zone II to IV flexor tendon repairs of the hand.

Alternative hypothesis: There is a difference in the outcomes for the EAM protocol compared to the outcomes for the EPM protocol in the rehabilitation of zone II to IV flexor tendon repairs of the hand.

1.7 SIGNIFICANCE OF STUDY

The significance of the study will be discussed according to the outcomes of flexor tendon repair, patient compliance, and protocol selection.

1.7.1 Outcomes of flexor tendon repair

The findings of this study could be used to reconsider the protocol being implemented post flexor tendon repair at CHBAH. This may influence the outcomes currently experienced post flexor tendon repair at CHBAH. The method used in this study could also be used to replicate this study in a different setting.

1.7.2 Patient compliance and protocol selection

Patient compliance should be determined prior to the selection of the rehabilitation protocol. This is difficult to gauge during the first session with a patient. However, since socio-economic factors could have an influence on patient compliance, the therapist could collect information regarding a patient's socio-economic factors and

then tentatively predict the potential patient compliance. This would influence the selection of the appropriate rehabilitation protocol.

1.8 DELINEATIONS AND ASSUMPTIONS

1.8.1 Delineations

Participants who had a zone I or V flexor tendon repair of the hand were not included in the study, as these zones cannot be compared to zone II to IV due to the anatomy and different treatment protocols necessary in these zones.

1.8.2 Assumptions

The following assumptions were made in this study:

- It was assumed that the participant would carry out the prescribed exercise programme explained to them during their treatment sessions.
- It was assumed that the participant would be compliant with instructions regarding the precautions they must follow when wearing the splint and following the exercise programme.
- It was assumed that the range of motion measurements would provide an adequate reflection of the function that the participant would have post-surgery and rehabilitation.

1.9 DEFINITION OF KEY TERMS

The key terms that are used in this dissertation are highlighted in Table 1. The term, abbreviation, and meaning are summarised.

Table 1: Key terms used in this document

Term	Abbreviation	Meaning
Adhesion	N/A	The formation of scar tissue between the connective tissue
Distal interphalangeal joint	DIP Joint	The articulation between the middle phalanx and the distal phalanx[2]
Early active motion	EAM	Early active motion is the active flexion and extension of the fingers by the patient (See Section 0)
Early passive motion	EPM	Early passive motion is the passive flexion of the fingers by an external force with active or passive extension by the patient (See Section 2.7.4)
Flexor digitorum profundus	FDP	Tendon forming the deep forearm muscle compartment, originating from the ulna and interosseous membrane and inserting into the distal phalanx of the finger[2] (See Section 2.2.1)
Flexor digitorum superficialis	FDS	Tendon forming the intermediate forearm muscle compartment, originating from the ulna, humerus and radius and inserting into the middle phalanx of the finger[2] (See Section 2.2.1)
Flexor tendon repair	N/A	The surgical repair of a flexor tendon post tendon injury (See Section 2.6)
Metacarpophalangeal Joint	MCP Joint	The articulation between the metacarpal and proximal phalanx[2]
Outcomes	N/A	Measurements of range of movement (total active motion, fingertip to table and palm) taken at different points in time (See Section 2.8)
Proximal interphalangeal Joint	PIP Joint	The articulation of the proximal phalanx and middle phalanx[2]
Tendon excursion	N/A	The distance that the tendon moves in relation to muscle contraction
Tendon gapping	N/A	Gap formation between the tendon repair ends
Tendon rupture	N/A	Complete break of the repaired tendon
Two rehabilitation protocols	N/A	EAM and EPM protocols used in the rehabilitation of flexor tendon repairs (See Section 2.7)

1.10 OVERVIEW OF THE CHAPTERS

The next chapter includes the literature review where the flexor tendon anatomy, biomechanics, injury, healing, surgery, and rehabilitation are discussed. Chapter 3, which focuses on the research methodology, will discuss the technical aspects of the study in terms of how it was conducted. In the fourth chapter, the results of the study are then displayed and analysed. Finally, Chapter 5 is a discussion of the results, including the selection of a rehabilitation protocol, conclusions and recommendations, study limitations, and indications for further research.

1.11 CONCLUSION

The rehabilitation of flexor tendon repairs remains an important variable in the outcome of flexor tendon surgery. Many studies have been carried out internationally to determine which rehabilitation protocol is the most effective in producing acceptable outcomes.[7-15] The global trend is moving towards the implementation of EAM protocols.[6] No research was found on the implementation of EAM protocols in the South African context.

Gauteng public hospitals still implement EPM protocols. This is largely due to patient-related factors which have guided therapists to implement this protocol. An audit conducted on the outcomes of the EPM protocol at CHBAH produced poor results, therefore highlighting the need for a change in rehabilitation. A study comparing the outcomes of an EAM protocol compared to an EPM protocol was therefore necessary to determine which protocol produces more favourable outcomes in patients post flexor tendon repair.

2 LITERATURE REVIEW

2.1 INTRODUCTION

Amadio[2] states that tendon injuries are one of the most severe upper limb injuries which often lead to significant disability. In the past three decades, there have been developments in surgery techniques and rehabilitation of flexor tendon repairs of the hand worldwide.[17] One of the main developments in surgery was the implementation of stronger primary flexor tendon repairs by hand surgeons. Stronger repairs have meant that more stress can be applied to the healing tendon without the danger of rupture. This has prompted the need for a change in flexor tendon rehabilitation.[17]

Hand therapists make use of rehabilitation programmes which will ultimately have a positive effect on their patients' functioning in daily life. According to Amadio,[2] rehabilitation post flexor tendon repair is one of the main determinants of the outcome. Common poor outcomes post flexor tendon rehabilitation include adhesion formation, rupture of repairs, and decreased range of movement of the finger joints.[16] These factors have a significant impact on the ability to use the hand in activities which promote functional use of the hand. Work and home life may be severely impacted due to the complications post flexor tendon repair.

The previous chapter provided an introduction and background to the study. In this chapter, the following will be described:

- flexor tendon anatomy and biomechanics
- flexor tendon injuries and healing
- surgical management of flexor tendon injuries
- rehabilitation of flexor tendon repairs
- outcomes post flexor tendon repair
- review of studies comparing rehabilitation protocols
- complications post flexor tendon repair surgery and rehabilitation

2.2 FLEXOR TENDON ANATOMY

To rehabilitate a repaired flexor tendon, it is vital for the therapist and surgeon to have a comprehensive understanding of the flexor tendon anatomy. This section will describe the flexor tendons of the extrinsic muscles of the hand, the anatomical zones of the flexor tendons, the digital flexor tendon sheath, and flexor tendon nutrition.

2.2.1 Flexor tendons of the extrinsic muscles of the hand

A tendon connects the muscle to the bone, forming a musculotendinous unit, which allows the transmission of forces between the muscle and bones in order to move and stabilise joints in the body.[18] A tendon is made up of soft connective tissue consisting of collagen fibres, proteoglycans, and elastin.[18,19] Tendons found in the hand consist of four layers, namely, the tendon fascicles, covered by the endotenon; the septa of the endotenon; the paratenon; and lastly the epitenon.[4]

The muscles that originate in the forearm and insert into the hand are called the extrinsic muscles of the hand.[2] The extrinsic hand muscles on the posterior aspect of the forearm are the extrinsic extensor tendons of the hand. The extrinsic hand muscles on the anterior aspect of the forearm are the extrinsic flexor tendons of the hand. Only the flexor tendon anatomy will be discussed.

The extrinsic flexors of the hand consist of two groups of muscles, namely, the flexor digitorum profundus (FDP) and the flexor digitorum superficialis (FDS). The FDP originates from the medial surface of the ulna and the interosseous membrane within the forearm. The median and ulnar nerves innervate the FDP.[2,20] The FDP forms part of the deep compartment layer of the forearm muscles, passing through the carpal tunnel of the wrist and into the hand.[2] At the level of the metacarpophalangeal joint (MCP), the FDP passes deep to the FDS into the flexor tendon sheath.[2] The FDP becomes more volar over the middle phalanx, where it continues to insert into the volar base of the distal phalanx.[2,21]

The FDS muscle originates from the humeral epicondyle of the upper arm and coronoid process of the ulna (humeroulnar head), as well as from the proximal shaft of the radius (radial head) within the forearm.[2,21] The FDS is innervated by the median nerve.[20] The FDS forms part of the intermediate compartment of the forearm muscles, lying superficial to the FDP muscle belly. The FDS passes through the carpal tunnel into the hand, where it enters the flexor tendon sheath superficial to FDP.[2,21] At the level of the proximal third of the proximal phalanx, the FDS bifurcates into two slips which insert into the proximal lateral areas of the middle phalanx.[2,21] The FDP and FDS insertions can be seen in Figure 1.

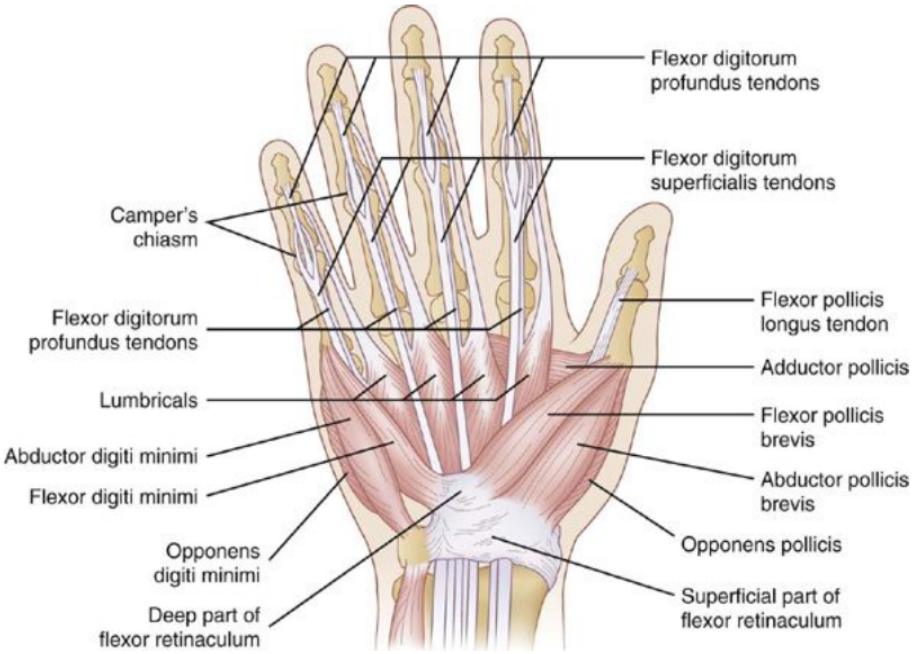


Figure 1: View of the volar aspect of the hand[2]

2.2.2 Zones of the flexor tendons

The zones of the flexor tendons are important to know, as the surgery and rehabilitation protocols will be adjusted according to this. Each zone has specific anatomical structures and biomechanical aspects to consider,[2] assisting the surgeon and therapist in selecting the appropriate treatment protocols. Therefore, the zone of injury should be documented according to the location of the tendon laceration with the finger in extension.[2]

According to Verdan's description, the flexor tendons are divided anatomically into five zones.[2] Flexor tendon injuries may fall into one or more of these zones.[2] The demarcation of the zones is illustrated in Figure 2. Zone I extends from the insertion of the FDS tendon into the middle phalanx to the insertion of the FDP into the distal phalanx; zone II extends from the A1 pulley to the insertion of the FDS; zone III extends from the distal border of the transverse carpal ligament to the A1 pulley; zone IV encompasses the segment of flexors covered by the transverse carpal ligament; and zone V extends from the musculotendinous junction in the forearm to the proximal border of the transverse carpal ligament.[2]

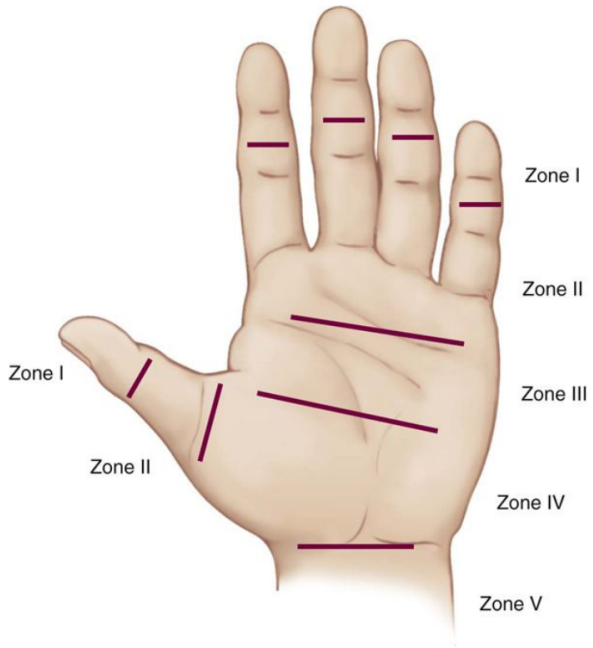


Figure 2: Anatomical zones of the flexor tendons[2]

2.2.3 Digital flexor tendon sheath

The FDP and FDS tendons are enclosed in a digital flexor tendon sheath superficial to the phalanges of the digits.[2,21] The digital flexor tendon sheath begins at the level of the metacarpal neck, which has synovial and retinacular tissue components, ensuring efficient tendon gliding.[2,20] There are two layers to the synovial component of the sheath, namely, the visceral layer that surrounds the flexor tendons and a parietal layer which lines the wall of the sheath. The sheath contains synovial fluid

between these two layers, ensuring that there is nutrition to the tendon as well as efficient gliding.[2,18] The flexor tendon sheath is illustrated in Figure 3.

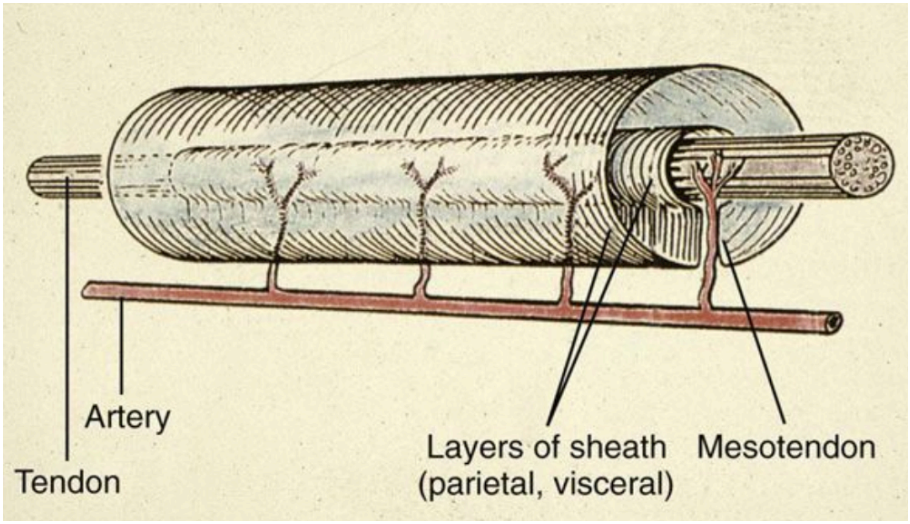


Figure 3: View of the tendon synovial sheath[2]

The retinacular tissue components consist of annular pulleys as well as cruciate pulleys which envelop the synovial tendon sheath and prevent bowstringing of the tendon. There are five thickened transverse annular pulleys. The first annular pulley (A1) attaches to the volar plate of the MCP joint. The second annular pulley (A2) attaches to the volar aspect of the proximal phalanx. Further, the third annular pulley (A3) attaches to the volar plate of the proximal interphalangeal (PIP) joint. The fourth annular pulley (A4) connects to the volar aspect of the middle phalanx. Finally, the fifth annular pulley (A5) joins to the volar plate of the distal interphalangeal (DIP) joint.[2,21] Three thin flexible cruciate pulleys are situated in between the annular pulleys. These pulleys are depicted in Figure 4.

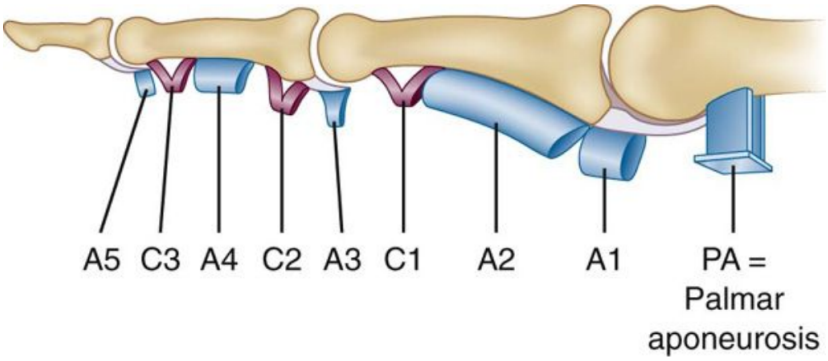


Figure 4: Lateral view of the annular and cruciate pulleys[2]

2.2.4 Flexor tendon nutrition

The flexor tendons receive nutrition via two pathways, namely, a direct vascular supply and by synovial diffusion.[2] The transverse branches of the digital arteries carry nutrition to the tendon via the palmar vincula, which supply both the FDP and FDS tendons. In addition, the tendons receive blood supply from their distal bony insertions and from dorsal vessels. It is believed that the tendons also receive nutrition via synovial diffusion.[2]

2.3 FLEXOR TENDON BIOMECHANICS

Biomechanics of the flexor tendons play a pivotal role in the choice of surgical technique and post-surgical rehabilitation protocol. It is important that the biomechanics are thoroughly understood by both the surgeon and the therapist. For movement to take place, the muscle has to shorten, which generates force through the tendons to the bone. The tension in the tendon increases and the tendon glides through its sheath. For the glide to take place, there should be relatively low or no friction. In this section, tendon tension, tendon excursion, and tendon friction and force will be discussed.

2.3.1 Tendon tension

Tendon tension occurs when the muscle shortens, which generates force through the tendons to the bones, thereby increasing the tension in the tendon. Muscle contraction is a complex process of events which will not be described in detail here. What is important is that the tension generated by the muscle is related to its length.[22] The tendons of the extrinsic flexors muscles of the hand cross over the wrist joint, MCP joints, PIP joints, and DIP joints. Therefore, when the muscle contracts, there is increased tendon tension leading to a chain reaction of movement of multiple joints.

A muscle tendon unit can have insufficient tension, more specifically termed active and passive insufficiency. Active insufficiency occurs when a muscle tendon unit crossing many joints is required to perform movement in the same direction over all those joints, for example, joint flexion. The forearm flexor muscles contract to produce this movement; however, the potential tension and excursion are limited by the ability of the muscle to contract. Passive insufficiency occurs when a tendon of a muscle crossing many joints is required to perform movement in the same direction over all those joints. The forearm extensor muscles are similar to the flexor muscles in that the extensor tendons cross multiple joints; therefore, at the maximal stretch in simultaneous wrist and finger flexion, the ability of the flexor muscles to contract further is limited.[22] Simultaneous wrist and finger flexion is thus difficult to achieve due to the combination of active insufficiency of the forearm flexor muscles and passive insufficiency of the forearm extensor muscles.[22]

As the extrinsic flexor tendons of the hand cross multiple joints, the position of the wrist will influence the tension in the flexor tendons.[23] Position of the wrist is therefore an important factor to consider in rehabilitation, since the newly repaired tendon should be placed under the least tension possible. When the wrist is in flexion, the passive flexor tendon tension is the lowest, which is good for tendon healing, as the tendon is not put under too much strain. However, if the tendon is required to contract with the wrist in flexion, it has to overcome the passive tension of the extrinsic extensors to move the fingers. Therefore, tendon tension of the flexor tendons is

decreased in a neutral wrist position. This is more advantageous than maintaining the wrist in flexion.[24] Therapists need to be cautious of placing the wrist in too much flexion or extension when fabricating a splint post flexor tendon repair, as this may increase the tension placed on the repair site and thus have a negative impact on the outcomes.

2.3.2 Tendon excursion

The pulley system and tendon sheath described in Section 2.2.3 are responsible for ensuring efficient flexor tendon excursion and joint rotation.[4] The tendon sheath reduces the friction. Tendon excursion occurs when the FDS or FDP muscle contracts or relaxes, thereby actively moving the tendon proximally or distally within the hand and forearm. This then causes the joint to rotate,[23] allowing finger flexion or extension. The distance between the axis of joint rotation and the flexor tendon is called the moment arm.[4] The pulleys in the fingers ensure that there is minimal distance between the axis of joint rotation and the tendon, thus ensuring a greater amount of joint rotation for a given tendon excursion. The larger the distance between the axis of joint rotation and the tendon, the greater the moment arm. This will result in decreased joint rotation using the same amount of tendon excursion.[4]

Any disruption in the pulley system will result in decreased efficiency of tendon excursion. Disruption in the pulley system could lead to tendon bowstringing, hence increasing the moment arm, which may result in flexion contractures of the joint.[2] The tendon excursion required for the same degree of motion is also increased, resulting in a lack of full flexion. Figure 5 illustrates bowstringing of the flexor tendons when the pulleys are absent. The flexor tendons are further from the axis of joint rotation, therefore increasing the moment arm and amount of tendon excursion required.

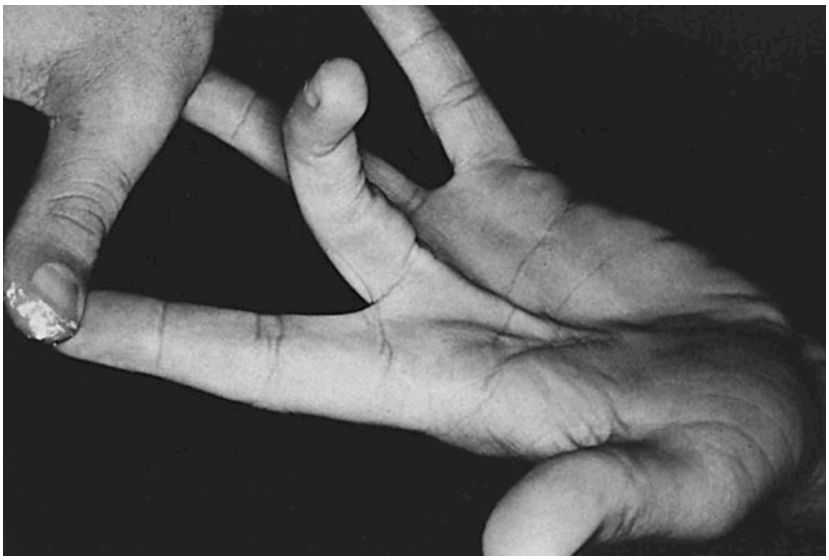


Figure 5: Bowstringing of the middle finger flexor tendons due to absent pulleys[2]

To achieve full wrist and finger flexion or extension simultaneously, as much as 9 centimetres of flexor tendon excursion may be required.[4] However, with the wrist in a neutral position, only 2.5 centimetres of flexor tendon excursion is necessary to produce full finger flexion.[4] This is therefore important in the rehabilitation of flexor tendon repairs, as the wrist position will have an impact on the amount of tendon excursion produced.

In an uninjured finger, 1-2 millimetres of FDP tendon excursion is produced per 10 degrees of DIP joint flexion.[2,4] Strickland[4] states that 1.5mm of FDP and FDS tendon excursion is produced per 10 degrees of PIP joint flexion. In a finger post flexor tendon repair, 0.3mm of FDP tendon excursion is produced per 10 degrees of DIP joint flexion and 1.3mm of FDP and FDS tendon excursion is produced per 10 degrees of PIP joint flexion.[2,4] This is indicated in Table 2. Pretorius et al[1] state that 3-5mm of tendon excursion post tendon repair is necessary to prevent adhesions from forming. However, Evans[24] points out that recent evidence reports that 1.7-2mm of tendon excursion is adequate to prevent adhesion formation.

Table 2: Tendon excursion per 10 degrees of DIP or PIP joint flexion[4]

	Joint flexion (degrees)	Uninjured tendon (mm)	Repaired tendon (mm)
DIP joint (FDP)	10	1-2	0.3
PIP joint (FDP and FDS)	10	1.5	1.3

2.3.3 Tendon friction and force

During excursion of the tendon, there is friction between the normal finger flexor tendon and its tendon sheath.[3] The frictional force of a tendon is measured by adding the load placed on the finger and the friction of the tendon moving beneath the pulley.[3] In a normal finger, there is a very low frictional force between the tendon and tendon sheath at rest, approximately 10 grams (g) or 0.1 newtons (N). In active PIP joint flexion to 90 degrees, the frictional force is greater than that of a PIP joint flexed to 30 degrees.[3]

After flexor tendon repair, approximately 600g or 6N of force is necessary to overcome tendon friction to move the tendon.[3] It is therefore essential that the tendon repair should cause the least amount of friction possible so that the load required to achieve movement is decreased.[2] If the surgical repair is bulky, there will also be increased friction between the repair and the pulleys.

2.4 FLEXOR TENDON INJURIES

MacDermid[25] states that, “a tendon injury impairs physiological functioning of the affected musculotendinous unit in the hand”. The reason for this is that there is loss of motion of the joints and decreased strength of the muscles, thereby affecting the functional use of the hand. A patient who sustains a tendon injury should undergo surgery to repair the musculotendinous unit and also requires about three to four months of intensive rehabilitation.[2] This type of injury can result in significant disability and commonly occurs in the young, working population.[2] This section will discuss the mechanism of flexor tendon injury.

2.4.1 Mechanism of injury

Flexor tendon injuries may occur from a number of causes, such as lacerations, gunshot wounds, infections, and de-gloving injuries. The extent and mechanism of the injury may have a significant impact on functional recovery, especially when there are associated injuries.[26] Associated injuries complicate the surgical repair as well as the rehabilitation. For example, if a tendon injury, as well as fracture of the bone, is sustained, then the surgical and rehabilitation protocols will need to be adjusted to also take the bone healing into consideration. There is usually increased scarring with associated injuries,[2] which then decreases the ability of the repaired tendon to glide.

Lin et al[18] classify tendon injuries in direct acute injuries, such as lacerations, contusions, non-penetrating blunt injuries, and indirect tendon injuries. Indirect tendon injuries result from overuse of the hand, causing micro trauma and tensile overload to the tendon. Only direct acute injuries will be discussed.

There are two types of acute injuries: clean-cut wounds and crush injuries. Tang[27] highlights that clean-cut wounds have the least contamination, are simple in terms of the tendon repair, and are usually caused by a knife or glass. Crush injuries are said to have a higher contamination rate and are more complicated to manage, as tissues need to be debrided prior to the repair.[27]

In a study determining whether mechanism of injury affects the clinical outcomes of tendon repair, it was determined that crush tendon injuries have poorer outcomes compared to clean or sharp lacerations.[26] Pettengill and Van Strien[2] further clarify this as they state that a crushing or blunt injury usually causes more scar formation due to the associated injuries of surrounding tissues, thereby impacting on tendon healing.

2.5 FLEXOR TENDON HEALING

The mechanism of flexor tendon healing is important, as it guides rehabilitation in the different time frames. This section will describe the stages of tendon healing, extrinsic versus intrinsic tendon healing, and patient factors that influence tendon healing.

2.5.1 Stages of tendon healing

When a tendon is repaired, there is a sequence of events that take place to ensure tendon healing. There are three main phases of tendon healing which are distinguished by the cellular events that take place during each phase.[2,6,18] These are the inflammatory phase, the proliferation or fibroplasia phase, and lastly the remodelling or maturation phase. It is important to note that all the injured tissues, including the tendon, follow these stages of healing.[2]

Inflammatory phase

The first phase is the inflammatory phase (0 to 5 days), which begins when the tendon is injured, and a haematoma forms in response.[2,6,18] The clot then enables the cascade of vasodilators and platelets, which, in turn, causes inflammatory cells to move to the injury site. Phagocytosis of the necrotic tissue and debris occurs as well as the breakdown of the blood clot, and there is an increase of factors (DNA, fibronectin, glycosaminoglycan, water, collagen type III) which all work to stabilise the extracellular matrix.[18] The extracellular matrix is the principle component of tendon tissue containing collagen, proteoglycans, fibronectin, and elastin.[2]

Proliferation or fibroplasia phase

The next phase is the proliferation or fibroplasia phase (3 to 21 days).[2,6,18] In this phase, there is disorganised granulation tissue at the injury site, with the dominant cells being fibroblasts. This is a process of converting collagen type III into collagen type I.[18] From days 5 to 21 in an immobilised tendon, the tensile strength of the tendon is increased as the collagen matures. However, in a mobilised tendon, the tensile strength of the tendon increases earlier in the healing process.[2]

Remodelling or maturation phase

The third phase is the remodelling or maturation phase (21 days onwards). In this phase, there needs to be a balance of collagen formation as well as collagen breakdown.[2] At the tendon repair site, the random alignment of collagen is replaced by collagen, which is aligned along the longitudinal axis of the tendon, by placing stress on the repair site.[2,18] This increases the strength of the tendon. However, Lin et al[18] state that the repaired tendon will never reach the tensile strength of an uninjured tendon.

The surrounding tissues also follow the aforementioned stages of tissue healing. There is no differentiation of the tissues at the site of healing, thus limited organisation of the collagen. Adhesions can form between the tendon and surrounding tissues, therefore decreasing the ability of the tendon to glide. One of the most prominent complications post tendon repair is adhesion formation.[2] The remodelling phase is an important stage of healing, as it allows for the surrounding tissues to be manipulated in order to enable efficient tendon gliding.[2]

2.5.2 Extrinsic vs. intrinsic flexor tendon healing

In literature, two theories regarding flexor tendon healing are described, namely, extrinsic and intrinsic healing.[2,7,18] These will be discussed after which the current understanding of tendon healing will be considered.

Extrinsic flexor tendon healing

In extrinsic flexor tendon healing, the cells that are extrinsic to the tendon enable the healing process to take place. It is believed that adhesion formation and extratendinous blood supply possibly allow the extrinsic healing process to occur. This theory led to the proposal of immobilisation of a flexor tendon repair to allow for extrinsic healing.[2] The sequence of events in this type of healing takes place according to the phases of tissue healing described in Section 2.5.1.

Intrinsic flexor tendon healing

The intrinsic healing theory proposes that healing is possible without the tissues and cells extrinsic to the tendon; therefore, the healing takes place between the tendon ends only.[2,7] In-vitro studies to support this theory have demonstrated that tendon healing can take place in an isolated cell-free environment.[2] Taras[2] articulates that in theory, an increase in the intrinsic healing process should result in decreased adhesion formation.

This process advocates for the use of a controlled motion protocol post tendon repair. The controlled motion is said to increase intrinsic tendon healing, thereby decreasing adhesions and resulting in a stronger tendon repair.[2] The sequence of events for this theory are different to the sequence described when the tendon is immobilised. The sequence is as follows: the inflammatory phase (0 to 3 days) with proliferation and thickening of the epitenon cell layers, collagen formation and vascular ingrowth (from 5 to 7 days), fibrous callus formation (at 10 days), and proliferation ingrowth of endotenon tenocytes (at 2 to 3 weeks).[2,18]

Current understanding of tendon healing

In the past 30 years, there have been many studies conducted to determine the processes of tendon healing.[4] It is now believed that tendon healing occurs through a combination of the two theories discussed above and is dependent on a variety of factors, including blood supply, availability of synovial fluid, degree of tendon trauma, as well as the location of the injury.[2,4,7,18]

2.5.3 Patient factors that influence tendon healing

There are a number of patient factors that may limit the ability of the tendon to heal.[2,18] These include a patient's age, health, quality of scar formation, motivation, and socio-economic factors.[11,28]

Age

Pettengill and Van Strien[2] declare that with increased age, there is aging of the body cells, which could lead to decreased capacity of the tenocytes. They also state that the number of vincula, which enable tendon nutrition, may decrease as the patient gets older; thus, certain areas of a healing tendon may lack blood supply. This then leads to a decrease in the tendon healing potential. Age has influenced a number of research designs where outcomes after tendon repair were researched. In a study conducted by Trumble et al,[11] participants below the age of 15 years were excluded, as they have been found to have an increased tendon rupture rate. Participants above age 75 years were also excluded, as they portrayed lower hand function results.[11] Two studies that also had an age exclusion criterion were Yen et al[13] at 19 to 84 years and Starnes et al[26] at 18 to 75 years. Neither reported a reason for the exclusion. Kitis et al[12] reported an age range of 18 to 57 years, while Hung et al[7] reported an age range of 12 to 61 years in their studies. They also did not indicate why they excluded these ages.

Health

A patient's health may also affect the healing capacity of the tendon. One of the main health-related factors which influence tissue healing is smoking. Trumble et al[11] portrayed results which showed that smoking significantly affected range of movement. Patients who smoke demonstrated a lesser range of movement of digits, greater joint contractures, and lower satisfaction scores.

Quality of scar formation

Furthermore, scar formation also has a significant effect on tendon healing. Some patients may develop firm, thick, rapidly developing scars, which will make mobilising the tendon very difficult. On the other hand, other patients may develop a scar slowly, producing a light scar. These patients may run the risk of tendon rupture.[2]

Motivation

Patient motivation is an important consideration, as it will have an overall effect on the outcome of rehabilitation,[2] consequently impacting the tendon healing process. The therapist must always take the patients' goals into consideration and formulate a rehabilitation plan in accordance with this. A patient needs to understand their role within the rehabilitation programme to ensure success.[2] This will assist in improving the patients' motivation to complete the rehabilitation correctly. Therefore, comprehensive education on the injury, surgery, rehabilitation, and the importance thereof is necessary. This will aid in the protection of the tendon repair, allowing efficient tendon healing to take place and the adherence to the rehabilitation protocol.

Socio-economic factors

Socio-economic factors should be taken into account, as these may have a positive or negative impact on rehabilitation and tendon healing.[2] The patients' ability to afford medical insurance, transport to health facilities and employment will influence the outcome of rehabilitation.[2] If a patient is the sole breadwinner in the family and sustains such an injury, the whole family will be affected negatively. If the patient lives alone, they will need to adapt their activities of daily living in order to protect the tendon repair and carry out the rehabilitation programme effectively. The therapist needs to take these factors into account when planning a rehabilitation protocol.[2]

2.6 SURGICAL MANAGEMENT OF FLEXOR TENDON INJURIES

It is important for therapists to understand the surgical management of flexor tendon injuries, since this will influence the selection of a specific rehabilitation protocol post flexor tendon repair. This section will discuss the timing of repair, type of injury, and the type of surgical repair.

2.6.1 Timing of repair

The timing of the tendon repair is a vital factor to consider, as this may influence tendon healing. Poor outcomes are generally associated when there is a long delay period between the tendon injury and repair. The timing of the repair can be classified

as primary repair, delayed primary repair, secondary repair, and late secondary repair.[18] Table 3 depicts the classifications and specific timing of tendon repair.

Table 3: Classification of timing of tendon repair[18]

Classification	Time
Primary repair	<12 hours
Delayed primary repair	Within 14 days
Secondary repair	2-4 weeks
Late secondary repair	4 weeks

According to Lin et al,[18] repair of the injured tendon should be carried out as early as possible.[2] Lutsky et al[20] state that the primary repair should be carried out during the period prior to six weeks post-injury, stating that the ideal time frame is within zero to ten days post-injury. The longer the delay between injury and repair, the more challenging the rehabilitation of the repaired tendon is.[21] The reason for this is that there is a shortening of the musculotendinous unit and increased scarring of the tendon ends, which increases the potential for adhesion formation. Additionally, the tendon ends may need to be dissected from the surrounding tissues, therefore creating more tissue damage, causing adhesions once tissue healing takes place.[2]

2.6.2 Type of injury

Another important aspect to consider is whether both the FDP and the FDS should be repaired when they have both been injured at the same site, or whether only the FDP should be repaired. According to Lutsky et al,[20] both the FDP and FDS should be repaired if possible. They found that when both the FDP and FDS tendons were repaired, there was an increased return of grip strength.[21] Taras et al[2] point out that there are advantages of repairing both the FDP and FDS, as there will be maintenance of the blood supply to the FDP, increased strength of the finger, and a smooth gliding surface for the FDP. However, Tang[16] found that if both tendons are repaired, there is an increased probability of adhesion formation.

2.6.3 Type of surgical tendon repair

Amadio[2] indicates, "the ideal tendon repair is strong, easy to perform, and does not interfere with either tendon healing or gliding". It is necessary for the repair to be strong enough in order to tolerate light motion force and have fewer suture loops or knots on the surface of the tendon to reduce friction.[2]

Historically, the most widely accepted tendon repair technique has been the 2-strand repair. [4] Figure 6 demonstrates the Modified Kessler repair, which is a 2-strand tendon repair. Tang[16] and Strickland[4] reveal that tendon repair methods have evolved from 2-strand repairs to multi-strand repairs in order to ensure a stronger repair. The most important factor determining the strength of the tendon repair is the number of suture strands that cross the repair site.[20] The tendon repair strength has been shown to be directly proportional to the number of strands crossing the repair site.[2,4,18,20,29,30]

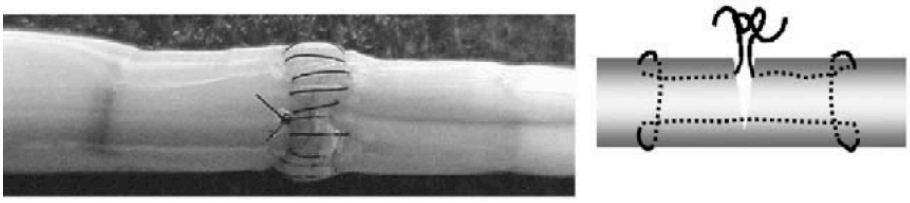


Figure 6 Two-strand Modified Kessler tendon repair[3]

The 4-strand tendon repair has been reported to be superior to that of the 2-strand tendon repair[20]; therefore, many authors advocate the use of the 4-strand tendon repair. [3,4,16,20,21,31] There are many 4-strand repairs which have been described. However, the double-modified Kessler and cruciate repairs are most commonly implemented.[21] Figure 7 depicts a cruciate tendon repair, which is a type of 4-strand tendon repair. According to Strickland,[4] the cruciate repair was found to be superior, as it is stronger and easier to execute, compared to the double-modified Kessler repair.[4,21]

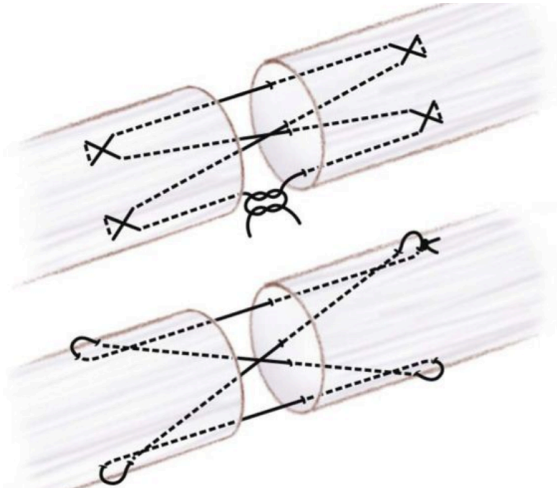


Figure 7 Four-strand cruciate tendon repair[2]

Tendon repairs using more than four strands have increased complications due to the suture bulk at the repair site.[20,31] This increased suture bulk has a negative effect on tendon gliding and may increase friction at the repair site, which increases the potential for tendon rupture.

2.7 REHABILITATION OF FLEXOR TENDON REPAIRS

The surgical management of flexor tendon injuries alone will not ensure an adequate outcome. All patients who have undergone surgical repair of a flexor tendon require rehabilitation. The reason for this is that the tendon repair needs to be protected while ensuring efficient tendon gliding, to assist the patient in achieving adequate hand function. This section will discuss the factors to consider in the rehabilitation of flexor tendon repairs as well as three different types of post-surgical rehabilitation protocols.

2.7.1 Factors to consider in the rehabilitation of flexor tendon repairs

Timing of rehabilitation

It is imperative to consider the timing of rehabilitation, as this will have an influence on tendon healing. Early mobilisation of the repaired flexor tendons is vitally important, as this improves tendon healing, ensures fewer adhesions, and improves excursion of the tendon. [4] Should a tendon be immobilised for more than one week,

the tendon will weaken, increasing the risk of rupture and development of adhesions.[2] However, in order to achieve some tendon healing and allow the inflammation to decrease, the tendon should be immobilised for part of the inflammatory phase as discussed in Section 2.5.1.

Amadio[3] and Torrie[21] highlight that rehabilitation should commence between three to five days post-surgery, but not longer than five days post-surgery.[3,21,24] Evans[24] suggests that the patient should be seen 24 hours post-surgery. At this time, a thermoplastic splint is fitted, oedema is managed, and the patient is educated about the condition and the rehabilitation. Exercise only commences three days post-surgery.

Surgical considerations in selection of rehabilitation protocol

A significant factor to consider in the selection of a rehabilitation protocol is the type of surgery which was carried out. There are three types of rehabilitation protocols which are available for selection post tendon repair. These are immobilisation, where the hand and wrist are immobilised completely; EPM, which includes passive finger flexion; and active or passive finger extension and EAM, which includes active finger flexion and extension.[30] These rehabilitation protocols will be discussed in more detail in Section 2.7.2.

It is accepted that the rehabilitation of flexor tendon repairs depends on the strength of the repair.[2] Strickland[4] completed a study which resulted in a graph wherein he plotted force (grams) against tendon repair strength, taking into consideration all the factors that may influence repair strength. These factors include oedema, suture bulk, and excursion force. This graph is portrayed in Figure 8. It can be seen from the figure that the 2-strand repair is only able to withstand EPM, which generates less than 2000g of force. It can also be observed that a 4-strand and a 6-strand flexor tendon repair are able to withstand EAM, which generates a maximum force slightly greater than 2000g. A 2-strand repair therefore would not be able to withstand EAM. Many authors now recommend the use of a 4-strand repair to allow EAM post flexor tendon repair.[2,16,21,31]

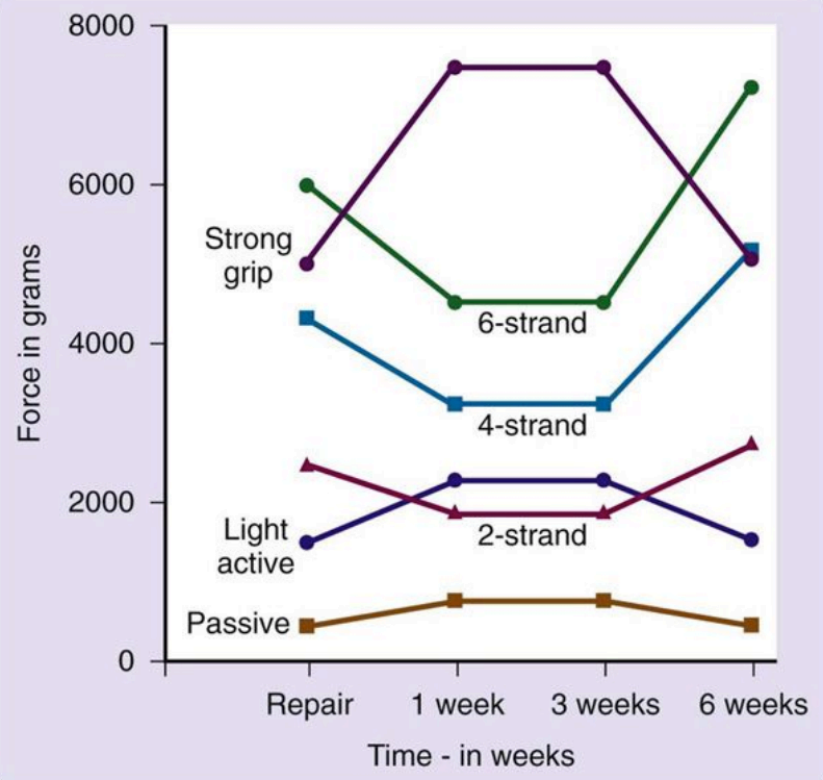


Figure 8: The strength of tendon repairs against the forces exerted by different motion types[2]

Patient compliance

Patient compliance is a critical factor to consider when selecting a rehabilitation protocol. Peck et al[14] state that the participants in their study were partially accountable for the high tendon rupture (46%). In the results of this study, the reasons for tendon rupture were due to patient activities such as being involved in a fight, opening a door with the injured hand, or during an arrest by police.[14] Harris et al[32] also stated that the participants' behaviour was strongly linked to tendon rupture in the early stages post-surgery. In their study, half of the participants who experienced tendon ruptures had used their injured hand inappropriately, with their splint on or off, despite being cautioned not to do so.

There is also the issue of patient follow-up. Patients are seen post-surgery and then booked with the therapist as necessary. Occasionally, patients do not come back for follow-up appointments as they should, and some disappear altogether. Peck[14] points out that their study only followed up with participants until 12 weeks post-surgery, as

in their unit, participants rarely attend follow-up appointments after this point. As seen in Table 8, three of the studies portrayed participant loss to follow-up of 7.7-15%.[11,12,15] Other studies with a different focus other than type of protocol indicate that there was a participant loss to follow-up of 25% and 35%.[32,33]

Sandford et al[34] conducted a study to determine the compliance of patients who were required to wear a forearm-based splint post tendon repair consistently for four weeks. It was found that 67% of the participants removed their splint in the four-week period. They also found that 76% of this group removed their splint between one and six times, for less than one hour, in the four-week period. The remainder removed their splint daily for more than one hour.

Should a patient remove their splint during the aforementioned period, there is a risk of tendon rupture, infection, or stiffness. Patient compliance is a complicated variable in rehabilitation, as it is not within therapists' control.

2.7.2 Rehabilitation protocols

As stated previously, the selection of a flexor tendon rehabilitation protocol requires the surgeon and therapist to communicate regarding details of the injury, the tendon repair strength,[24] and maintaining safe parameters within rehabilitation.[11]

There are three main approaches to the rehabilitation of flexor tendon repairs. These are immobilisation, EPM and EAM.[2] The therapist selects one of these protocols and implements this during the early stage of rehabilitation. However, during the intermediate and late stages of rehabilitation, therapy is similar for all patients depending on their individual needs.[2] All three protocols make use of a forearm-based dorsal blocking splint, as there is no available evidence supporting mobilisation post flexor tendon repair without a splint.[13] All tendon repairs require protection in the form of a splint, especially in the first four to eight weeks post-surgery. This will prevent tendon ruptures or gapping, which may be caused by incorrect use of the hand or poor positioning of the hand and wrist. This poor position would be that of simultaneous wrist and finger extension, placing excessive tension at the tendon repair site, which may result in tendon rupture.

Each protocol agreed to by the therapist and surgeon is divided into three stages: early stage, intermediate stage, and late stage. These stages are timed from day 1 post-surgery. The early stage is from zero to three or four weeks, the intermediate stage from four to six weeks, and lastly the late stage begins at six to eight weeks post-surgery up until the end of therapy.[2] The three rehabilitation protocols are discussed next in detail.

2.7.3 Immobilisation protocol

Immobilisation refers to no active or passive movement of the fingers during the four-week period post-surgery.[2] When this protocol is followed, the patient is fitted with a forearm-based dorsal blocking splint, with the wrist in 20 to 30 degrees of flexion, MCP joints in 40 to 60 degrees of flexion, and the interphalangeal joints in full extension.[2] The exercise protocol in the first month of rehabilitation includes range of motion exercises of the elbow and shoulder.

In the intermediate stage of rehabilitation, the splint will be adjusted to bring the wrist into a more neutral position.[2] Tendon gliding exercises may be carried out during the rehabilitation sessions and as part of a home exercise programme.[2] In the late stage of rehabilitation, the splint will be discarded, and isolated blocking exercises of the FDP and FDS tendons are implemented. Should complications such as shortening of the musculotendinous unit or adhesions arise in this late stage of rehabilitation, then the therapist addresses these accordingly.[2] A summary of the immobilisation protocol is indicated in Table 4.

Table 4: Summary of the immobilisation protocol

Protocol	Splint position	Early stage (0-3/4 weeks)	Intermediate stage (4-6 weeks)	Late stage (6-8 weeks)
Immobilisation [2]	Wrist: 20-30° flexion MCP joints: 40-60° flexion IP joints: full extension	ROM of elbow and shoulder	Increase wrist extension within splint Tendon gliding exercises	Discard splint Isolated joint blocking exercises of FDP and FDS

When a tendon is immobilised post flexor tendon repair, there is loss of strength of the repair in comparison to a mobilised flexor tendon repair.[2,24] The historically

accepted method of implementing immobilisation for three weeks post flexor tendon repair has mostly been discontinued due to the high rate of adhesion formation and poor functional outcomes.[3,4,21] However, in the treatment of certain patients, there is a place for immobilisation in the rehabilitation of flexor tendon repairs. These patients include very young patients who cannot understand any of the other protocols, patients who have cognitive deficits, associated injuries such as fractures[20] or are unable or unwilling to participate in a rehabilitation programme. In these cases, an immobilisation protocol is implemented to protect the repair.[2]

2.7.4 Early passive motion protocol

EPM refers to passive finger flexion with active or passive finger extension.[30] The evolution of this protocol came about when it was accepted that the flexor tendons could heal intrinsically.[2] That being the case, the formation of adhesions to surrounding tissues due to immobilisation for four weeks post-surgery was no longer necessary.[30] The EPM protocol historically portrayed a decrease in the risk of adhesion formation, encouraged tendon healing and synovial diffusion, and ensured a stronger tendon repair due to tendon mobilisation.[2] Pettengill[30] stated that Kleinert et al and Duran and Houser reported acceptable results with the use of an EPM protocol.

Work by Verdan and Kleinert in the 1960s portrayed that flexor tendon repair could be a success by means of primary tendon repair and early mobilisation.[21] Since most of the repairs carried out were 2-strand flexor tendon repairs,[4] the EPM protocol was considered a safe method of treatment. Should the surgeon perform a 2-strand flexor tendon repair, it is accepted that the EPM protocol is implemented, to decrease the incidence of tendon rupture.[7,31]

Pettengill and Van Strien[2] state that in using the foregoing type of protocol, the tendon is pushed proximally. This therefore causes the tendon to bunch up, rather than actively glide within the tendon sheath.[2,30] This, in turn, leads to poor tendon excursion, which causes poor differential glide between the FDS and FDP tendons. The result is an increase in adhesion formation and a decrease in function.[7]

Based on work by Kleinert et al and Duran and Houser, at least three published EPM protocols have been described for this type of rehabilitation.[2] These are discussed next and summarised in Table 5.

The protocol developed by Kleinert et al in the 1960s

Kleinert et al developed a protocol using a forearm-based dorsal blocking splint with rubber band traction, as poor results were achieved with immobilisation of the repaired flexor tendon.[11] The patient is fitted with a forearm-based dorsal blocking splint with the wrist in 45 degrees of flexion, 10 to 20 degrees of MCP joint flexion, and full IP joint extension.[2,30] Rubber band traction is then applied to the fingernails, to passively flex the fingers.[2] Passive flexion and active extension of the affected fingers are carried out repetitively 10 times every waking hour. At three to six weeks post-surgery, gentle active flexion is begun, and between six to eight weeks resisted exercises are implemented. Pettengill[30] reports that Kleinert et al reported good results with the 'new' early motion protocol. A disadvantage in the rehabilitation protocol utilising rubber band traction is that this may lead to an increase in PIP joint flexion contractures. This is due to the decreased ability to attain a full active extension of the affected fingers in the splint, as well as the flexed position of the fingers between exercises.[16,21,30] In an attempt to decrease the risk of flexion contractures of the affected fingers, some therapists require patients to strap their fingers into extension against the splint when the hand is at rest.[30]

The protocol developed by Duran and Houser in 1975

In this protocol, the patient is fitted with a forearm-based dorsal blocking splint with the wrist in 20 degrees of flexion, the MCP joints in a relaxed position of flexion, and the IP joints in extension.[2] Exercises consist of first passively flexing the MCP and PIP joints and then passively extending the DIP joint. Secondly, exercises include passively flexing the MCP and DIP joints and passively extending the PIP joints, repeating this six to eight times twice per day.[2,30] The authors maintain that this method allows differential glide of the FDP and FDS tendons.[2] Using intraoperative studies, these authors found that this method of mobilisation produced 3-5

millimetres of passive tendon glide, which was considered sufficient to prevent or decrease adhesions.[21,30]

In the intermediate stage, the splint is replaced with a wristband and traction, which prevents simultaneous wrist and finger extension, thereby further protecting the repair.[2] Resisted active flexion is initiated at seven and a half to eight weeks post-surgery.

The modified Duran protocol

The next EPM protocol to be discussed is the modified Duran protocol. Pettengill and Van Strien[2] state that the Duran protocol is rarely implemented in its standard form, as therapists modify it as needed. It is therefore termed the modified Duran protocol. The protocol described by Pettengill and Van Strien[2] is discussed next.

The patient is fitted with a forearm-based dorsal blocking splint with the wrist between 20 degrees extension and 20 degrees of flexion, the MCP joints in 40 to 50 degrees of flexion, and the IP joints strapped into extension between exercises and when sleeping.[30] The exercises consist of individual finger and composite passive flexion and extension, as well as active composite extension of the IP joints, with the MCP joints blocked manually.[2] Synergistic wrist motion exercises are implemented in therapy sessions with the splint removed. These exercises include assisted or passive wrist flexion with finger extension and wrist extension with finger flexion.[2] It was not stated how often patients attended therapy.

Table 5: Summary of published early passive motion protocols

Protocol	Splint position	Early stage (0-3/4 weeks)	Intermediate stage (4-6 weeks)	Late stage (6-8 weeks)
Kleinert et al[2,11,16,21,30]	Wrist: 45° flexion MCP joints: 10-20° flexion IP joints: full extension Rubber band traction is applied to the fingernails	Passive flexion (by rubber band traction) and active extension of fingers Repetitions: 10x per waking hour	Gentle active finger flexion is initiated	Resisted exercises are initiated
Duran and Houser[2,21,30]	Wrist: 20° flexion MCP joints: relaxed	Passive DIP joint extension, with MCP	Splint is replaced with a wristband and	Resisted active finger flexion

Protocol	Splint position	Early stage (0-3/4 weeks)	Intermediate stage (4-6 weeks)	Late stage (6-8 weeks)
	position of flexion IP joints: full extension	and PIP joints held passively in flexion Passive PIP joint extension, with MCP and DIP joints held passively in flexion Repetitions: 6-8x twice daily	traction to prevent simultaneous wrist and finger extension Gentle active finger flexion is initiated	
Modified Duran[2,30]	Wrist: 20° extension to 20° flexion MCP joints: 40-50° flexion IP joints: full extension	Passive DIP joint extension, with MCP and PIP joints held passively in flexion Passive PIP joint extension, with MCP and DIP joints held passively in flexion Composite passive finger flexion with active finger extension Repetitions: 6-8x twice daily Synergistic wrist and finger motion out of splint (only in therapy)	Gentle active finger flexion is initiated	Resisted active finger flexion

2.7.5 Early active motion protocol

EAM is the process of actively flexing and extending the fingers. In the past 15 years, the EAM protocol has become more popular. Early active motion has been studied by different authors who found that this type of rehabilitation produced fewer adhesions and more effective tendon gliding.[2,11,30]

The process of early active motion ensures that the tendon is actively pulled proximally by means of active muscle contraction, thereby increasing the tendon excursion.[18,35] Studies have shown that the implementation of active tendon gliding enhances differential gliding between the FDP and FDS tendons.[2,7,30] This active contraction of the muscle then ensures that muscle tone and strength are able to

recover at a faster rate. Pettengill and Van Strien[2] highlight that, "some of the best early passive motion results come when patients 'cheat' and add a little active motion". Further, Pettengill[30] indicates that some of the best results are found when patients flex their fingers consciously. One of the most important biomechanical considerations, when this protocol is implemented, is that the repair should be strong enough to tolerate active muscle contraction, which characterises the EAM protocol.[18] The repair strength of a tendon has been shown to be directly proportional to the number of strands crossing the repair site.[2,5,18,29,30] According to Yen et al[13] and Strickland[4], a 4-strand tendon repair is strong enough to withstand early active motion of the repaired tendon. However, despite the stronger suture technique, there is still concern with this type of protocol, as there is an increased probability of tendon ruptures.[11]

The initiation of the EAM protocol usually starts from 24 to 48 hours post-surgery. However, some authors advocate starting the programme five to seven days post-surgery.[2] There is no specific EAM protocol which has been deemed the 'gold standard' of treatment, as all the described protocols have been formulated in a specific clinical setting, with different patient populations and surgical techniques.[2] Four published EAM protocols are discussed next. These are summarised in Table 6.

The EAM protocol described by Gratton

The protocol described by Belfast and Sheffield in 1989 has undergone many changes.[36] Gratton modified this EAM protocol in 1993.[2,30] In this protocol, the patient is fitted with a forearm-based dorsal blocking splint with the wrist in 20 degrees of flexion, the MCP joints at 80 to 90 degrees of flexion, and the IP joints in full extension.[2,30]

The patient has to perform exercises every four hours in the splint.[2] The exercises consist of full composite passive flexion and full active extension of the fingers, active PIP joint flexion to 30 degrees, and active DIP joint flexion to between five to ten degrees during the first week.[2] It is expected that active flexion will increase so that by the fourth week, the PIP joints can flex 80 to 90 degrees and the DIP joints 50 to 60 degrees.[2] In order for the patient to progress gradually, the patient is taught to

place their uninjured hand vertically in relation to the injured hand with the little finger perpendicular across the palm of the injured hand in line with the palmar crease, then to flex their injured fingers until they reach the index finger of the uninjured hand.[2] As the programme progresses, the patient should flex further to the middle, ring and little fingers respectively. At four to six weeks post-surgery, the splint is removed if tendon gliding is poor. If tendon gliding is sufficient, the splint is only removed at five to six weeks.[2] Full function of the affected hand is expected at 12 weeks post-surgery.[2]

The EAM protocol described by Strickland and Cannon

Strickland and Cannon propose an active place-and-hold motion protocol, developed in 1993.[2,30] Place-and-hold motion is the process of passively flexing the finger with the other hand; the patient then sustains this flexed position by active contraction of the involved muscle.[30] Using this protocol, the patient is first fitted with a forearm-based dorsal blocking splint with the wrist in 20 degrees of flexion, the MCP joints in 50 degrees of flexion, and the IP joints in full extension.[2]

The exercises consist of hourly individual finger and composite passive flexion and extension, as well as active composite extension exercises in the splint.[2] The patients have a second splint, which is hinged. This splint allows full wrist flexion and limited wrist extension to 30 degrees.[2] Full IP joint flexion and extension is allowed, but MCP joint extension is limited to 60 degrees. Some authors make use only of the hinged splint, both for constant wear as well as for hourly exercises.[2]

When the patient is not exercising their fingers, a block is placed between the two parts of the splint to maintain the correct wrist position. The patient first does the exercises in the dorsal blocking splint, then the exercise splint is fitted to the hand, and the patient carries out place-and-hold finger flexion in the exercise splint.[2] The patient actively flexes the wrist, allowing the fingers to extend to the limit of the splint, and then they actively extend the wrist, allowing the fingers to move into flexion, where this position is held for five seconds. At four weeks post-surgery, the exercise splint is removed, and only the dorsal blocking splint is worn.[2] The splint is removed for synergistic wrist flexion and extension exercises. Synergistic wrist movement is wrist flexion with simultaneous finger extension and wrist extension with

simultaneous finger flexion. The patient relaxes into the wrist flexion or extension position, causing the fingers to extend or flex due to the insufficient tension of the flexor or extensor muscles. At seven to eight weeks post-surgery, resisted active exercises are performed, and the patient resumes normal functioning in activities of daily living by 14 weeks post-surgery.[2]

The EAM protocol described by Sandow and McMahan

The protocol described by Sandow and McMahan is that of an assisted active protocol which they developed in 1996.[30] The patient is fitted with a forearm-based dorsal blocking splint, with the wrist in 20 degrees of extension, the MCP joints in 90 degrees of flexion, and the IP joints in full extension.[2] The wrist is placed in extension to ensure that passive extensor resistance to active flexion is decreased. Assisted active flexion of all fingers is performed hourly. The splint is removed at six weeks post-surgery. Strengthening exercises are performed from eight weeks post-surgery.[2]

Controlled active motion protocol described by Tang

Tang[27] described an EAM protocol in 1997, in which the patient is fitted with a forearm-based dorsal blocking splint with the wrist in 20 to 30 degrees of wrist flexion, the MCP joints in slight flexion, and the IP joints in full extension. In the first two days, no motion is allowed, to decrease oedema and pain.[21] From day 3, the patient performs assisted finger flexion exercises in order to 'warm up' and follows this by 20 to 30 degrees of gentle active finger flexion exercises, which are performed in the splint for two weeks, three times per day.[21] Full active flexion of the fingers is not encouraged, but it is essential to gain full active extension. At the end of the second week, post-surgery, the splint is adjusted so that the wrist is positioned in 30 degrees of extension.[21] At the end of the fifth week, full active flexion is encouraged, and at the end of the sixth week, the splint should be worn at night time only. At eight weeks post-surgery, the fingers may be used normally.[21]

Table 6: Summary of published early active motion protocols

Protocol	Splint position	Early stage (0-3/4 weeks)	Intermediate stage (4-6 weeks)	Late stage (6-8 weeks)
Gratton[2,30]	Wrist: 20° flexion MCP joints: 80-90° flexion IP joints: full extension	Full passive flexion, full active extension, active flexion of PIP joint to 30° Repetitions: Every 4 hours	PIP joint flexion to 80-90° and DIP joint flexion to 50-60° Splint is removed at 4-6 weeks if tendon gliding is poor If tendon gliding is good, then splint is only removed at 5-6 weeks post-surgery	Resisted exercises are initiated
Strickland and Cannon[2,30]	Splint 1 Wrist: 20° flexion MCP joints: 50° flexion IP joints: full extension Splint 2 Wrist: Hinged wrist allowing full wrist flexion, but extension to 30° MCP joints: 60° flexion IP joints: full extension	Splint 1 exercise: Individual finger and composite finger passive flexion and extension exercises, and composite active extension Repetitions: hourly Splint 2 exercises: Place-and-hold finger flexion exercises. Wrist flexion with finger extension and wrist extension with finger flexion. This is held for 5 seconds	Splint 1 is removed for synergistic wrist and finger exercises Splint 2 is removed and only splint 1 is worn	Resisted active finger flexion
Sandow and McMahan[2,30]	Wrist: 20° extension MCP joints: 90° flexion IP joints: full extension	Assisted active finger flexion and extension Repetitions: hourly	Splint is removed Active finger flexion	Resisted exercises are initiated
Tang[27]	Wrist: 20-30° flexion MCP joints: slight flexion IP joints: extension	Passive finger flexion exercises as a warm-up Followed by 20-30° of active finger flexion at the PIP joint Wrist 20-30° degrees extension Repetitions: 3x per day for the first 2 weeks. 5-6x per day thereafter	Full active flexion and extension of the fingers is encouraged	At 6 weeks post-surgery, the splint can be worn at night time only Fingers can be used normally by 8 weeks post-surgery

2.8 EVALUATION OF OUTCOMES AFTER FLEXOR TENDON REPAIR

Using objective outcome measurements ensures that results are comparable and reproducible. There are various ways to evaluate the outcomes post flexor tendon repair, including a range of movement measurements and classifications, as well as patient-rated evaluations. This section will discuss time intervals for outcome measurement, goniometric measurement, total active motion (TAM), Strickland's method, and fingertip to distal palmar crease and table measurements.

2.8.1 Time intervals for outcome measurements

Most studies regarding rehabilitation post flexor tendon repair report that outcome measures were recorded between four weeks to one year post-surgery.[7,11] In a study reported by Hung et al,[7] the outcomes were measured at 3, 6, 9 and 12 weeks, whereas in a study by Kitis et al,[12] the outcomes were only recorded at 12 weeks post-surgery. In a study by Orkar et al,[33] it was stated that a 12-week post-surgery follow-up is sufficient, as normal activities are resumed then, and that the loss of participants to follow-up is higher due to participants returning to work.

2.8.2 Goniometric measurement

MacDermid[25] highlights that when the outcome of flexor tendon rehabilitation is assessed, the amount of motion achieved by the fingers is the primary physical component to measure. The way in which impaired motion is measured is by using goniometric measurement, which allows one to determine whether the implemented rehabilitation protocol has been effective in improving range of movement or not.[37] Studies which determine the reliability and validity of finger goniometry on patients with tendon injuries could not be found. Published studies on goniometry that were conducted on participants post-dislocation or fracture were used to establish reliability and validity.[37] The reliability of finger goniometry refers to the consistency of measurement, and validity refers to the accuracy of the instrument. Groth et al[37] state that the gold standard of determining a joint angle is by means of radiography. However, this is impractical in a clinical setting, as it would be time-consuming and expensive for the patient to be sent for repeated X-rays before therapy.

There are different ways to place the goniometer on the joint when measuring, either on the dorsum or the lateral aspect of the joint. In the same study conducted by Groth et al,[37] they found that 72% of the raters preferred dorsal placement when measuring joint angles. Other raters preferred placing the goniometer on the lateral aspect of the joint. However, the study concluded that the placement of the goniometer did not significantly affect the mean values of joint motion. The reliability coefficients were 0.99 for dorsal placement and 0.86 for lateral placement, therefore portraying high-reliability coefficients in both cases. In the same study, it was reported that inter-rater reliability was high for the measurement of PIP and DIP joints. However, it was stated that the validity of goniometry needs further research, as this was inconclusive, and that the radiological and goniometric measurements were vastly different from each other.[37]

In another study carried out by Lewis et al,[38] it was reported that intra-rater reliability was high in goniometer use. It was also found that active range of movement was a more reliable measurement compared to a passive range of movement. The reason for this is that the therapist only needs to handle the goniometer as the patient actively moves their finger joints. On the other hand, in passive range of movement of the joint and handling of the goniometer, the pressure applied to the joint introduces another variable. The authors suggested that therapists should be trained in goniometer use to ensure increased inter-rater reliability.

2.8.3 Total active motion

When measuring outcomes post flexor tendon repair, most studies make use of the calculation of TAM of the involved joints.[7,11,12,26,30,39] MacDermid[25] is of the opinion that the value of the scores is more reliable if all the involved joints are used in the calculation.[25] Therefore, in a zone II injury, one would calculate TAM for the PIP and DIP joints, whereas in zone III-V, one would calculate the TAM of the MCP, PIP and DIP joints.[25]

To have an outcome which is comparable internationally, the American Society for Surgery of the Hand (ASSH) introduced the concept of TAM in 1976. This TAM figure is calculated by adding the active flexion of the finger joints minus the extension

deficit of each joint. The extension deficit of a joint is defined as the inability to reach full active joint extension.[35]

Outcomes in many studies are reported in terms of rating scales such as poor, fair, good, and excellent. However, these scales have not been validated and are subjective.[25] A more reliable method is to compare the final TAM score to the uninjured side. Outcomes are then expressed as a percentage of function compared to the uninjured side.[25]

The TAM score for each affected finger is calculated as follows:

$$\frac{\text{(MCP+PIP+DIP joint flexion – extension deficit) of affected finger}}{\text{(MCP+PIP+DIP joint flexion) of unaffected finger}} \times 100$$

As indicated in Table 7, the TAM percentages are then categorised in relation to the percentage of function of the corresponding digit of the uninjured hand.[10,21]

Table 7: TAM categories in relation to the percentage of function of the corresponding digit on the uninjured hand[10]

Category	Percentage (%)
Excellent	100
Good	75-99
Fair	50-74
Poor	<50

2.8.4 Strickland's method

Another popular measurement implemented in many of the studies is Strickland's method. The method was developed to standardise the way in which flexor tendon repair outcomes are reported on.[30,35]

This method uses the following calculation for each affected finger:

$$\frac{\text{(PIP+DIP flexion) – extension deficit}}{175°} \times 100$$

The result provides a percentage of normal function, which is classified in the following categories: excellent, good, fair, and poor. Torrie et al[21] report an acceptable correlation between TAM and Strickland's classification, with a correlation coefficient of 0.85.

2.8.5 Fingertip to distal palmar crease and table measurements

Another reported outcome measure is the distance between the pulp of the fingertip to the distal palmar crease. It is a quick, useful method which gives an estimation of finger function when composite finger flexion is performed.[1] This measurement must be carried out in a standardised fashion in order to prevent measurement error. A normal measurement is 0 centimetres.

Lastly, the distance between the fingertips to the table can also be recorded in assessment. This is the perpendicular distance between the fingernail and the table, with the dorsum of the hand on the table. This is a quick method which will give an estimation of finger function when composite finger extension is performed.[1] A normal measurement is 0 centimetres. If a finger flexion contracture has developed, it will not be possible to achieve full finger extension, and therefore the final outcome will be affected.

All the measurements discussed above assist the therapist to determine whether the specific applied protocol is effective in the treatment of patients after flexor tendon repair. Therapists have the opportunity to choose the measurement tool that suits them best, given their expertise and clinical circumstances.

2.9 REVIEW OF RESULTS FROM EAM AND EPM PROTOCOL STUDIES

There have been many studies conducted to determine the most effective protocol in the rehabilitation of flexor tendon repairs of the hand.[7-15] Table 8 summarises the results from various studies. These results will be discussed according to similar outcomes between the EAM and EPM protocols, different outcomes between the EAM and EPM protocols, outcomes of an EAM study, and outcomes of an EPM study.

2.9.1 Similar outcomes between the EAM and EPM protocols

A number of studies found that there was no difference in the TAM between the EPM and EAM groups.[8,10,14] Prowse et al[10] conducted a retrospective case series comparing the ruptures and range of movement in patients post-zone II flexor tendon repair. They found that the mean TAM percentages were 72% for the EAM group and 70% for the EPM group at 12 weeks post-surgery. These results fell into the fair category of 54-70%. Peck et al[14] compared participants following a zone II flexor tendon repair and matched their participants according to age, gender and injury characteristics. They made use of the Strickland criteria; however, they found no significant differences between the EAM and EPM groups.

Frueh et al[8] carried out a retrospective analysis which compared the EAM and EPM protocols between patients who had undergone flexor tendon repair in zone I and II. At the four-week post-surgical mark, it was found that there was a statistically significant difference in TAM between the two groups in that the EAM group had superior results. However, at 12 weeks post-surgery, it was found that there was no significant difference between the two groups. Sixty-five percent of the participants in the EAM group fell into the good category, and 35% fell into the fair category. In the EPM group, 8% of the participants fell into the excellent category, 45% into the good, 43% into the fair and 4% into the poor categories. Frueh et al[8] state that their unsatisfactory results could be due to the study concluding at 12 weeks post-surgery, where recovery could continue past this point.

2.9.2 Different outcomes between the EAM and EPM protocols

A study conducted by Trumble et al[11] compared the implementation of an EAM to that of an EPM protocol by means of a randomised control trial. The results of this study were that in the EAM group, 94% of the injured fingers attained good to excellent results, compared to the EPM group, where only 62% of the injured fingers attained good to excellent results using Strickland's criteria. The EAM group developed less flexion contractures and achieved an increased range of movement.

In a systematic review by Starr et al,[9] where over 3000 flexor tendon repair outcomes were reported on, it was found that participants who followed the EAM protocol had a 6% decreased range of movement compared to the EPM protocol which had a 9% decreased range of movement. They also found that the EPM protocol had a lower risk of tendon rupture, however, an increased risk of decreased range of movement compared to the EAM protocol. Lastly, the 2-strand tendon repair had higher tendon rupture rates compared to the 4-strand repair; however, this was not statistically significant. Their overall conclusion was that an early active motion protocol could be implemented when a stronger surgical repair is performed.

Yen et al[13] compared clinical results following flexor tendon repair and found that the EAM group returned to work at 2.4 months post-injury compared to the EPM group that returned to work at 3.2 months post-injury. They also found that the EAM group achieved 90%, and the EPM group achieved 40% of TAM percentage of function of the digit on the uninjured side. Grip strength, pinch strength and the Mayo wrist scores were also measured. The EAM group showed superior results in all measurements compared to the EPM group.

Lastly, Bainbridge et al[15] conducted a comparative study of the outcome of flexor tendon repairs when implementing an EAM or EPM protocol. They found that the EAM group achieved good or excellent ratings, while the EPM group achieved only 50% of good or excellent ratings. Bainbridge et al[15] also considered the associated injuries that were split into three groups, namely, the digital nerve injuries with or without arterial injury, bilateral nerve injuries or revascularisations, and volar plate injuries or fractures with an open joint. There was no significant difference between the two groups.

Other relevant studies described by Yalcin et al[31] also exhibit favourable results for an EAM protocol compared to a passive motion protocol.

2.9.3 Outcomes of an EAM study

Hung et al[7] conducted a prospective study to determine the role of active mobilisation post flexor tendon repair in zone II and other zones. This study compared zone II

outcomes to the outcomes of the other zones. It was found that the final results were good to excellent, as the zone II groups achieved 71% and the other zones achieved 77%. Hung et al[7] reveal that the zone II injuries achieved similar results to the other zones, however, with a three-week delay in recovery compared to other zones. They also measured the mass grasp and pinch strength; nevertheless, there was no difference found between zone II and the other zones. It was found that both groups achieved 95% strength compared to the uninjured side.

2.9.4 Outcomes of an EPM study

In a study by Kitis et al,[12] the Washington and Kleinert protocols were compared. These are both EPM protocols. This study found that the Washington group achieved a TAM score of 87%, and the Kleinert group achieved a TAM score of 75%. This study also evaluated grip strength and conducted the self-report questionnaire called the disabilities of arm, shoulder, and hand (DASH). The grip strength was 89% in the Washington group and 81% in the Kleinert group when compared to the uninjured side. The DASH score was higher in the Kleinert group compared to the Washington group.

Table 8: Flexor tendon rehabilitation studies

Author	Year	Protocol	Result	Rupture	Loss to follow-up	Follow-up	Outcome measure used
Frueh et al[8] (Switzerland)	2014	EPM vs. EAM	No difference at 12 weeks	EPM: 7% EAM: 5%	Retros-pective study	4, 12 weeks	TAM
Starr et al[9] (USA)	2013	EPM vs. EAM	EAM greater ROM compared to EPM	EPM: 4% EAM: 5%	Not reported	Not repor-ted	ROM
Prowse et al[10] (UK)	2011	EPM vs. EAM	No difference	EPM: 2% EAM: 11%	Retros-pective	12 weeks	TAM
Trumble et al[11] (USA)	2010	EPM vs. EAM	EAM greater ROM compared to EPM	EPM: 4.3% EAM: 4.3%	7.7%	6, 12, 26, 52 weeks	ROM
Kitis et al[12] (Turkey)	2009	EPM (Kleinert and Washingt on)	Good results (TAM): 10-15%	Not reported	8%	12 weeks	TAM
Yen et al[13] (Hong Kong)	2007	EPM vs. EAM	EAM greater ROM compared to EPM*	EPM: 0% EAM: 0%	None	12 weeks	ROM
Hung et al[7] (Hong Kong)	2005	EAM	Good or excellent results (TAM): 75%	EAM: 6.5%	None	3, 6, 9, 12 weeks	TAM
Peck et al[14] (UK)	1998	EPM vs. EAM	No difference	EPM: 7.7% EAM: 46%*	Not reported	12 weeks	Strickland
Bainbridge et al[15] (UK)	1994	EPM vs. EAM	Good or excellent results (TAM): * EAM=94% EPM=50%	EPM: 3% EAM: 7.5%	15%	16 weeks	TAM

Statistically significant results *
Country where the study was conducted ( )
Early active motion (EAM)
Early passive motion (EPM)
Range of movement (ROM)
Total active motion (TAM)

2.10 COMPLICATIONS POST FLEXOR TENDON SURGERY AND REHABILITATION

Since flexor tendons have such a complicated anatomical structure and rely on perfect biomechanics for optimal functioning, post-operative complications often influence the final outcome of repair and rehabilitation. This means that hand surgeons and therapists continue to ask many questions regarding the most effective surgery and rehabilitation. The following complications will be discussed in this section: tendon adhesions, tendon gapping, and tendon rupture.

2.10.1 Tendon adhesions

Tendon adhesions are one of the most prominent complications post flexor tendon repair. [5,31] Tendon adhesions may be caused by the type of tendon injury, the surgical technique, decreased tendon nutrition, post-operative immobilisation of the tendon, and tendon gapping.[4] As tendons have a decreased healing capability, this results in adhesions forming around the repaired site.[16] This is due to the extrinsic flexor tendon healing concept discussed in Section 2.5.2, where the cells extrinsic to the tendon enable the healing process to take place, therefore resulting in adhesion formation. These adhesions could be both filmy and loose (they have no impact on tendon healing), or dense and restrictive. The latter have a major negative impact on hand function.[16]

A crucial factor that influences adhesion formation is the choice of the rehabilitation protocol and the refinement thereof. The reason for this is that, should a tendon be immobilised for an extended period of time, there will be an increased risk of adhesions. However, when a mobilisation protocol is followed, this risk is decreased.[2,16] Tang[16] reports that the DIP and PIP joints are particularly stiff when the repair has been protected by rubber band traction. He is of the opinion that the disuse of rubber band traction and the use of active motion have decreased the stiffness experienced post flexor tendon repair.

2.10.2 Tendon gapping

Tendon gapping is when the ends of the tendon repair pull apart due to excessive force with movement or a weak surgical repair. The force that is placed on a tendon in rehabilitation programmes is an important factor, as tendon gapping may occur. Should a gap form between the ends of the tendon repair, there will be increased adhesions, decreased tendon glide, poor mechanical functioning of the tendon due to increased length, and poor outcomes post tendon repair.[24,30] Evans[24] and Pettengill[30] state that a gap of 3 millimetres or less does not impair the functioning of the tendon or contribute to adhesion formation.

2.10.3 Tendon rupture

Tendon rupture is a major concern to the therapist, surgeon, and patient, as reoperation will be required. Many factors may cause a tendon to rupture. These include overloading the tendons, using the hand incorrectly, and increased oedema.[16] A repaired tendon can be overloaded by placing too much force on the tendon, such as carrying out full active finger flexion in the early stages of tendon healing.

A number of studies discuss an increased rupture rate in the EAM protocol compared to the EPM protocol.[7,9,10,14,15] Table 8 shows that the EAM group ruptures were reported to be between 5-11%, with the exception of Peck et al,[14] who reported a rupture rate of 46% (12 participants). The reasons for these ruptures were reported as the following:

- 2-strand modified Kessler or horizontal mattress suture tendon repair technique[7]
- failure to comply with splint wear
- accidental fall; spontaneous rupture
- inadvertent clenching of the hand during sleeping or inadvisable activities

Table 8 indicates that ruptures in the EPM groups have been reported to be between 2-7.7%. There are also studies which report no ruptures in either of the two groups[13] or no difference between rupture rates in the two groups.

The treating therapist needs to find a balance between creating enough force for the tendon to actively glide and protecting the tendon repair.[3] Therapy should aim to achieve an adequate result while preventing any of the complications commonly associated with flexor tendon repair.

2.11 CONCLUSION

The literature review has outlined the flexor tendon anatomy and biomechanics, flexor tendon injuries and healing, surgical management of flexor tendon injuries, and rehabilitation of flexor tendon repairs. The treating therapist should have a sound knowledge of the anatomy and biomechanics of the forearm and hand to ensure informed clinical reasoning. Patient factors must always be considered, specifically compliance to therapy and having the resources to attend therapy.[2,40] There are three different protocols for rehabilitation of patients with flexor tendon repairs of the hand. Many factors need to be considered when choosing a rehabilitation protocol after flexor tendon repair. According to literature, over the last 15 years, there has been a trend towards the use of an EAM protocol in the treatment of flexor tendon repair patients, as this protocol has shown superior outcomes to that of EPM and the immobilisation protocols.[7,9,11,13,31,41] There still remains a need for immobilisation or the EPM protocol depending on the patient and depending on the surgery which has taken place.[2,7,31] It is imperative that the therapist, surgeon, and patient all work together in formulating an appropriate rehabilitation protocol.

The next chapter will discuss the research methodology employed in this study.

3 RESEARCH METHODOLOGY

3.1 INTRODUCTION

The purpose of the study was to compare the EAM and EPM protocols in the rehabilitation of patients who have had a flexor tendon repair(s) of the hand. The participant details and outcomes of the rehabilitation protocols were captured and compared to determine which protocol produced the most favourable results. The preceding chapter was a review of literature pertinent to this study. This chapter will discuss the research design, setting and population, the process of subject selection, the implementation of the study, and the data collection and analysis process.

3.2 RESEARCH DESIGN

The research design used was a quantitative single-blinded comparative controlled trial experimental design.[42] Different techniques were adapted to suit the requirements of this study. The techniques used will be discussed according to their relevance, strengths, and weaknesses.

First, the study was a single-blinded controlled trial. The assessors measuring the outcomes of the participants were blinded to the allocation of the EAM or EPM protocols to the participant. Since the assessors were introduced to the participants once their splints had been removed, they did not know which protocol had been implemented. Furthermore, the assessors did not have access to the participants' hospital file. This therefore eliminated subjective bias.[42] Double blinding of both the participants and researcher would have reduced the risk of information bias even more. However, this was not possible in this particular study. The researcher implemented the rehabilitation with the participants in the first four weeks post-surgery and therefore could not be blinded to the allocation of the specific rehabilitation protocol.

As the study was a controlled trial, it does not have external validity in that the results of the study cannot be generalised to the greater population.[42] The reason for this is

that the participants volunteered to be part of the study once screening had taken place, thus eliminating external validity.

The study was comparative and experimental, as the EAM or EPM protocols were allocated by random assignment to the participants after which the outcomes were compared between the two groups. The rehabilitation protocols were assigned by a random technique,[42] giving each participant an equal chance of being allocated to either protocol. By carrying out a comparative and experimental design, the researcher was able to assess possible causal associations and detect the effectiveness of the specific protocols.[42,43] The difficulty with a comparative design is that participants have varied backgrounds which could add to the number of variables.[43] Variables were controlled as far as possible.

This specific research design enabled the researcher to attain reliable results in order to test the hypotheses of the study.

3.3 RESEARCH SETTING

The study took place in the Chris Hani Baragwanath Academic Hospital (CHBAH) Hand Unit situated in Soweto, Johannesburg. The Hand Unit consists of a multidisciplinary team including orthopaedic surgeons, occupational therapists, physiotherapists, nursing staff, and administrative staff.

3.4 RESEARCH POPULATION

The research population consisted of patients who had undergone flexor tendon repair surgery of the hand between December 2014 and October 2015 in the Hand Unit at CHBAH. The sample group was selected from the research population based on the inclusion and exclusion criteria outlined in Section 3.5.

3.5 INCLUSION AND EXCLUSION CRITERIA

3.5.1 Inclusion criteria

The criteria for inclusion in the study included the following:

- age of 18 years and older

- zone II-IV flexor tendon injuries
- 4-strand surgical repair

3.5.2 Exclusion criteria

The exclusion criteria comprised the following:

- all associated conditions, such as traumatic brain injury or psychiatric conditions, reported in the patient's hospital file
- associated injuries, such as fractures, reported in the patient's hospital file
- flexor tendon repair of both hands
- injury to the corresponding finger on uninjured side
- patients who did not understand English, Afrikaans, Zulu or Tswana

3.6 SELECTION OF SUBJECTS

3.6.1 Process of selection

The sampling method was non-randomised, specifically a sample of convenience. This sampling method was used because the researcher was working at CHBAH as an occupational therapist in the Hand Unit. It was therefore convenient to request these patients to volunteer to participate in the research.

The researcher was given a surgery list daily, outlining the surgeries which would take place in the Hand Unit at CHBAH. The research population was then identified from this list. These patients were sent to occupational therapy day 1 post-surgery, where the researcher would select the sample group based on the inclusion and exclusion criteria. The patients were informed of the study and asked to sign a consent form after agreeing to participate in the study. If patients declined participation in the study, they were treated according to the EPM protocol currently in use at CHBAH.

3.6.2 Process of random assignment

Once the patients were recruited, either the EAM or EPM rehabilitation protocols were randomly assigned to them. The process of random assignment occurred by means of numbered and sealed envelopes containing the specific protocols to be

implemented. There were equal numbers of the EAM and EPM protocols sealed in the envelopes.

The physiotherapist in the Hand Unit who was not involved in the study asked the participants to draw sealed envelopes containing the protocol to be used. The participants handed the envelope to the physiotherapist, who then informed the researcher of the specific protocol to be implemented and the participant number.

3.7 SAMPLE SIZE

To obtain significant results for comparison of the two rehabilitation protocols, an appropriate sample size was calculated. The researcher met with the statistician to determine the sample size for this study. Data from an audit conducted by the researcher in 2013 was used to calculate the sample size. This audit collected data on the outcomes of rehabilitation, using the EPM protocol, post flexor tendon repair of the hand. The standard deviation for the audit results was obtained using a mixed model with the maximum likelihood as 8.8% and an intra-class correlation coefficient of 0.29%. The design effect for an expected number of two fingers that would be cut was 1+(2-1)*0.29=1.29 and the sample size estimation employed the inflated between subject sd=8.8*1.29%=11.35%. The statistician calculated that 23 participants per group were necessary to identify a clinically significant difference among participants receiving rehabilitation according to the EAM and EPM protocols. Therefore, a total of 46 participants were recruited for this study.

3.8 IMPLEMENTATION OF STUDY

The implementation of the study is outlined below. The key role players, surgery, rehabilitation, and assessment of the outcomes will be discussed.

The study was implemented by the researcher, who is a qualified occupational therapist and worked in the Hand Unit at CHBAH at the time of the study. Other key role players who assisted the researcher in completing the study included the physiotherapist working in the Hand Unit, two qualified occupational therapists, and the hand surgeons.

Patients who have sustained a flexor tendon injury to their hand are admitted to CHBAH and booked for surgery in the Hand Unit. The surgery is conducted by the head of department of the Hand Unit, the consultants or the registrars working in the Hand Unit. Prior to the commencement of the study, all the surgeons agreed to carry out flexor tendon repairs using a 4-strand surgical technique where possible, thereby adhering to the inclusion criteria of this study. After surgery, the surgeons fit the patients with a plaster of Paris dorsal blocking splint. The position of the dorsal blocking splint places the hand in 20 degrees of wrist flexion, 60 degrees of MCP joint flexion, and 10-20 degrees of IP joint flexion. The researcher would identify these patients on the surgery list and ensure they attended occupational therapy day 1 post-surgery. Should a patient's name not appear on the surgery list due to an emergency surgery being carried out or the replacement of a booked patient who did not arrive for their scheduled surgery, the surgeons would then refer the patient to occupational therapy day 1 post-surgery.

The researcher identified potential participants for the study according to the inclusion and exclusion criteria already outlined. The patients were first educated about the surgery that had taken place and the process of the therapy session to follow. They were then informed of the study and were asked to sign the informed consent (Appendix B) if they agreed to participate in the study. Once the participants were recruited, the process of random assignment occurred as described in Section 3.6.2. The researcher then completed the first two pages of the data capturing form. This form contained the participants' medical and demographic information. The form has been included under Appendix C.

The researcher removed the plaster of Paris dorsal blocking splint and dressed the wound. The participants were then fitted with a thermoplastic dorsal blocking splint with a palmar bar. The position of the splint placed the wrist in a neutral position at 0 degrees, MCP joints at 60 degrees of flexion, and the IP joints in full extension at 0 degrees. The participants in the EAM group received their specific home exercise programme, and the exercises were demonstrated during the session. The participants in the EPM group had leather loops glued onto their fingernails, and the elastic thread was threaded through the loops. The participants were given their

specific home exercise programme, and the exercises were demonstrated during the session. The two different splints are depicted in Figure 9 and Figure 10.

Figure 9: EPM protocol dorsal blocking splint with finger loops and elastic

Figure 10: EAM protocol dorsal blocking splint

The EPM and EAM groups received different home exercise programmes in the first four weeks post-surgery. The EPM protocol ensured that only passive finger flexion and active extension exercises were used, by means of the elastic band and leather finger loops, in the first four weeks. The EAM protocol performed passive finger flexion by using the uninjured hand to passively flex the fingers and active extension in the first week post-surgery, thereafter progressively increasing active finger flexion for the remaining three weeks. The home exercise programmes were given to the

participants in their language of choice. The rehabilitation programmes were translated from English into Afrikaans, Zulu, and Tswana, by people who are fluent in the relevant languages. Where the participant only understood Afrikaans, Zulu or Tswana, a nurse in the Hand Unit at CHBAH assisted the researcher in ensuring that the participant understood the home exercise programme. From four to 12 weeks post-surgery, the participants received the same rehabilitation programmes. From four to eight weeks post-surgery, the participants were sent to physiotherapy for active range of movement exercises. From 8 to 12 weeks post-surgery, a graded muscle strengthening programme was implemented, and the splint was removed completely. The detailed home exercise programmes are outlined in Appendix D, the home exercise programmes given to the participants are outlined in Appendix E.

The participants were followed up weekly for the first four weeks post-surgery by the researcher. After that, the participants attended physiotherapy and occupational therapy once every two weeks. They were discharged when they no longer required therapy. In total, the participants were required to attend a minimum of nine follow-up sessions over the duration of the study. Three of these included rehabilitation and recording of data; the remainder were for rehabilitation only.

Assessment of the participants for data capturing was conducted by two occupational therapists trained by the researcher. These assessments were carried out at 4, 8 and 12 weeks post-surgery. A pilot study was conducted with the first six patients recruited. Three participants of each group (EAM and EPM protocols) were measured by each assessor during the pilot study at four weeks post-surgery. The purpose of the pilot study was to ensure that the process of the study functioned according to the implementation plan. It also ensured inter-rater and intra-rater reliability between the occupational therapists who assessed the participants. On completion of the pilot study, a meeting was held by the researcher with the assessors to discuss areas of concern. It was evident from the pilot study that the implementation plan was complete, and no changes were necessary.

The recruitment and data collection of the 46 participants for the study took place from December 2014 to January 2016.

3.9 DATA COLLECTION

A standard form was used to collect the participants' demographic and medical information as well as assessment outcomes, as reflected in Appendix C. This data was then collated and stored on an Excel spreadsheet.

3.9.1 Measurement tools and methods

The following measurement tools and methods were used:

- A finger goniometer was used to measure the range of movement of the affected and non-affected fingers.[2,37] The assessors placed the goniometer on the dorsal aspect of the joint.
- Total active motion of each affected finger was calculated,[25,39] which provided an overall view of the hand motion in relation to normal total active motion. This method is described in Chapter 2 under Section 2.8.2.
- Fingertip to distal palmar crease[1]: The patient had to make a fist; the distance from the fingertip to the distal palmar crease was measured in centimetres with a standard ruler. A normal measurement is 0 centimetres.
- Fingertip to table[1]: The dorsum of the hand was placed on a table; the patient had to extend their fingers to touch the table. The distance from the fingertip to the table was measured in centimetres with a standard ruler. A normal measurement is 0 centimetres.

3.10 ETHICAL CONSIDERATIONS

Permission to conduct the study was obtained from the relevant boards at CHBAH, and ethical clearance was granted through the University of Pretoria (Protocol number: 314/2014). The study commenced once permission had been granted from all relevant ethical committees.

The ethical principles that follow were adhered to.[44]

3.10.1 Autonomy

The participants were informed that participation in the study was voluntary and that they could withdraw at any time, without any consequence. The human rights of the participants were respected at all times. Participant privacy was protected by ensuring that all the participant details remained confidential by capturing data according to the number allocated to them; this process can be viewed in Section 3.6.2.

3.10.2 Non-maleficence

No known harm was caused to the participants while they participated in this study. All participants were educated on the precautions to follow according to their rehabilitation protocol, as well as taking their prescribed medication according to the surgeons' instructions. This education was provided to attempt to prevent tendon rupture, which could not be controlled by the therapist. Tendon rupture could occur if the participants used their injured hand in any activities except those specified for treatment in the first four weeks post-surgery or if the wound became infected.

3.10.3 Beneficence

Regardless of which rehabilitation protocol was implemented after flexor tendon repair of the hand, the intention of post-surgical occupational therapy is to benefit the participant so that they can use their hand effectively and within their activities of daily living.

3.10.4 Justice

The participants were selected for the study as explained in Section 3.6.1. All flexor tendon repair patients at the CHBAH Hand Unit had the option of being part of this study, provided that they matched the inclusion criteria outlined in Section 3.5.1.

3.10.5 Informed consent

Each participant was given an information sheet regarding the study, shown in Appendix B. If the participant was unable to understand English, the information sheet was provided to them in Zulu, Tswana or Afrikaans. If they were unable to read the information sheet, it was read to them by a person who is fluent in the patients' language of choice and has a medical background, for example, a nurse, physiotherapist or surgeon in the Hand Unit. Once they had read or listened to and understood the information sheet and had agreed to participate, they were asked to sign the consent form in their language of choice.

3.11 VARIABLES

The applicable variables in this study included the following:

- Independent variables
  - The implementation of an EAM protocol
  - The implementation of an EPM protocol
- Dependent variables
  - TAM of the affected fingers
  - Fingertip to distal palmar crease measurements of affected fingers
  - Fingertip to table measurements of the affected fingers
- Extraneous variables
  - Socio-economic factors such as income and transport costs
  - Compliance in attending therapy
  - Demographic information

3.12 CONTROL OF VARIABLES

The variables were controlled where possible. These were outlined by describing the occupational therapists that conducted the assessment, as well as the process of assessment and blinding of both the researcher and assessors.

The assessment of the participants was done by two experienced occupational therapists, who were not involved in the participants' rehabilitation. These

occupational therapists are qualified and have a minimum of four years' work experience. The reason why two therapists were used to assess the participants at week 12 is that CHBAH has limited human resources. This ensured that a contingency plan was in place to ensure that data could still be collected should one of the therapists not be available to assess the participants.

Both assessing occupational therapists were trained by the researcher on the finger goniometer placement on the dorsal aspect of the joint, as well as assessing the hand in the same manner for every participant. The assessors were also given a verbatim explanation of how to conduct the assessment, indicated in Appendix C. The participants were all assessed according to the same method to increase the reliability and consistency of the results. There was a standard verbatim explanation to the participant by the assessor that was used in each assessment session; this can be seen in Appendix C.

This explanation was also translated into Afrikaans, Zulu and Tswana to ensure that the permanent staff member assisting the assessor was consistent in the explanation and instructions given.

The use of a pegboard ensured the exact same placement of the participants' hands and wrists for each measurement. The participants' wrists were placed on a pegboard where the position of the hand was marked at the volar and dorsal wrist, as well as the palm and dorsum of the hand. The exact position of the four pegs was recorded so that measurements could be repeated in the same position each time the participant returned for assessment. The process of using the pegboard is depicted in Figure 11**.** Since the measurements recorded were active motion of the affected and unaffected fingers, no external force was placed on the finger joints of the participant. The same metal goniometer was used to measure all joint motion of all the participants.

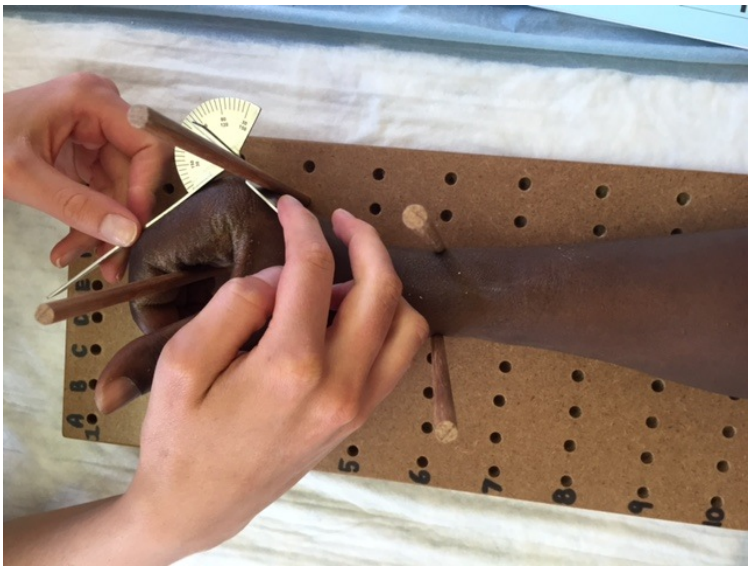


Figure 11: Position of participants' wrist in measurement of the outcomes

The assessors were unaware which protocol had been implemented with each of the participants and were therefore blinded to this. Researcher bias was thus eliminated, as the researcher did not measure any of the outcomes. The researcher only had access to the results of each participant once the 12-week assessment period was completed. This ensured that the rehabilitation of the participants by the researcher was not influenced by the recorded results. The data was captured on an Excel spreadsheet at the end of the 12-week intervention and assessment period.

3.13 DATA ANALYSIS

The data was analysed using Stata Release 14 statistical software. Clinical and demographic variables were assessed in a univariate analysis comparing the EAM and EPM protocols. For discrete variables, Fisher's exact test was used. For continuous variables, Student's two-sample t-test and Wilcoxon's rank sum test were used. The purpose of the above is to summarise the data and to determine the covariates for the main analysis where the EAM and EPM groups were compared with respect to the study outcomes, analysing all fingers of the participants' hand and injured fingers only.

The EAM and EPM groups were compared with respect to study outcome variables where employment and age were identified as potential covariates using an analysis of covariates (ANCOVA) when:

i. Adjusting for age only
ii. Adjusting for employment only
iii. Adjusting for both employment and age

This analysis was done at each time point. Twelve weeks was the most important time point. If the covariates were not significant when included into the ANCOVA individually or simultaneously, then the p-values for the treatment groups from the t-test are reported. If the covariates were significant ($p<0.10$) when included into the ANCOVA individually or simultaneously, then the p-values for the treatment groups from that ANCOVA are reported.

3.14 CONCLUSION

This chapter included a detailed account of how the study was carried out. The research design, setting and population, selection of the subjects, implementation of the study, data collection and analysis, and the ethical considerations were discussed.

The chapter that follows will focus on the results of the study.

4 RESULTS

4.1 INTRODUCTION

The foregoing chapter dealt with the research methodology used in this study. The data collection in this study consisted of two parts; each part was recorded on separate forms. The first form, completed by the researcher, has been included as a document in Appendix C. It included the demographic information of the participants, the injury sustained, and details about the surgery. The second form, which was completed by the assessors, has been included as a document in Appendix C. This form included all the outcome measurements taken at 4, 8 and 12 weeks post-surgery. These outcomes consisted of the total active motion (TAM), fingertip to distal palmar crease, and fingertip to table. Data was analysed with the use of the Fisher's exact test for discrete variables, Student's two-sample t-test, and Wilcoxon's rank sum test for continuous variables. An analysis of covariates (ANCOVA) was used, as age and employment were identified as potential covariates.

Forty-six participants were recruited for the study. Equal random allocation of the participants to the EAM and EPM groups was made. Eighteen (39.13%) participants were lost to follow-up over the duration of the study.

This chapter will present the results of the study based on:

- outcomes post flexor tendon repair
- participant demographics
- complications post-surgery and rehabilitation

4.2 OUTCOMES POST FLEXOR TENDON REPAIR

The outcomes collected included TAM, fingertip to distal palmar crease, and fingertip to table measured at three predetermined time periods. These time periods were 4, 8 and 12 weeks post-surgery. Measurements of the injured and uninjured fingers of each participant's injured hand were taken. The EAM and EPM groups were

compared with respect to study outcome variables. Employment and age were identified as potential covariates using an ANCOVA when:

i. Adjusting for age only
ii. Adjusting for employment only
iii. Adjusting for both employment and age

This analysis was done at each point in time. The 12-week analysis was the most important one. If the covariates were not significant when included into the ANCOVA individually or simultaneously, then the p-value and mean for the EAM and EPM groups from the t-test are reported. Further, if the covariates were significant ($p<0.10$) when included into the ANCOVA individually or simultaneously, then the p-value and adjusted mean for the EAM and EPM groups from that ANCOVA are reported. The p-value of 0.10 was only used when analysing the covariates; it was not used in the remainder of the data analysis.

Table 9 portrays the compiled means, adjusted means, covariate adjusted for and p-values (at a 0.05 significance level) for the injured finger(s) and injured hand over the three time periods, for the EAM and EPM groups. If the actual mean was used, then the p-value from the t-test is reported. However, if the adjusted mean was used, then the p-value from the ANCOVA is reported. These results are separately displayed in Table 9 and in the following subsections of TAM, fingertip to distal palmar crease and fingertip to table.

Table 9: Compiled data at the 4, 8 and 12-week time period for the EAM and EPM groups

Time	Outcome		Protocol	Mean (sd)	Adjusted for covariate	Adjusted mean	p-value (0.05) *
4 weeks	TAM (%)	Hand	EAM (n=19)	42.91 (18.42)	-	-	0.77
		Inj. fingers		26.10 (11.72)	-	-	0.83
	TC (cm)	Hand		5.04 (1.67)	-	-	0.83
		Inj. fingers		6.67 (1.34)	-	-	0.74
	TT (cm)	Hand		2.11 (2.06)	Age	2.02	0.47
		Inj. fingers		2.71 (1.45)	Employment	2.38	0.33
	TAM (%)	Hand	EPM (n=16)	40.99 (21.79)	-	-	0.77
		Inj. fingers		25.18 (13.29)	-	-	0.83
	TC (cm)	Hand		4.91 (2.01)	-	-	0.83
		Inj. fingers		6.80 (0.88)	-	-	0.74
	TT (cm)	Hand		2.38 (1.78)	Age	2.49	0.47
		Inj. fingers		3.71 (1.79)	Employment	2.94	0.33
8 weeks	TAM (%)	Hand	EAM (n=17)	67.24 (20.66)	Age	67.98	0.26
		Inj. fingers		43.98 (13.91)	Age	44.35	0.87
	TC (cm)	Hand		3.23 (1.91)	Age	3.16	0.56
		Inj. fingers		5.76 (2.09)	Employment	5.49	0.23
	TT (cm)	Hand		0.82 (1.13)	Age	0.76	0.13
		Inj. fingers		1.56 (1.33)	Age	1.52	0.43
	TAM (%)	Hand	EPM (n=14)	60.39 (24.98)	Age	59.32	0.26
		Inj. fingers		43.98 (16.53)	Age	43.45	0.87
	TC (cm)	Hand		3.48 (2.37)	Age	3.58	0.56
		Inj. fingers		5.30 (2.43)	Employment	4.43	0.23
	TT (cm)	Hand		1.51 (2.16)	Age	1.60	0.13
		Inj. fingers		1.93 (2.01)	Age	1.99	0.43
12 weeks	TAM (%)	Hand	EAM (n=15)	73.79 (21.12)	Age	75.97	0.48
		Inj. fingers		53.93 (15.75)	Age	55.64	0.99
	TC (cm)	Hand		2.88 (1.71)	Age	2.70	0.41
		Inj. fingers		5.00 (1.98)	Age	4.86	0.73
	TT (cm)	Hand		0.67 (1.20)	Age	0.52	0.22
		Inj. fingers		1.07 (1.37)	Age	0.94	0.46
	TAM (%)	Hand	EPM (n=13)	70.83 (26.59)	Age	70.24	0.48
		Inj. fingers		56.20 (19.91)	Age	55.74	0.99
	TC (cm)	Hand		3.23 (2.32)	Age	3.28	0.41
		Inj. fingers		4.57 (2.16)	Age	4.61	0.73
	TT (cm)	Hand		1.12 (1.89)	Age	1.16	0.22
		Inj. fingers		1.33 (1.89)	Age	1.36	0.46

TAM = total active motion
TC = tip to crease
TT = tip to table
% = percentage
cm = centimetres
sd = standard deviation
p-value = significance (0.05)
* = if mean was unadjusted, then p-value from the t-test; if mean was adjusted, then p-value from ANCOVA

4.2.1 Total active motion

TAM was calculated as a percentage of function compared to the uninjured side. The average TAM percentage over the three time periods, between the two rehabilitation

groups, is illustrated in Figure 12. The mean TAM percentage at four weeks post-surgery for the injured hand was 42.91% for the EAM group and 40.99% for the EPM group, at eight weeks, the EAM group was 67.98% and EPM was 59.32%; and at 12 weeks, the EAM was 75.97% and 70.24% for the EPM groups.

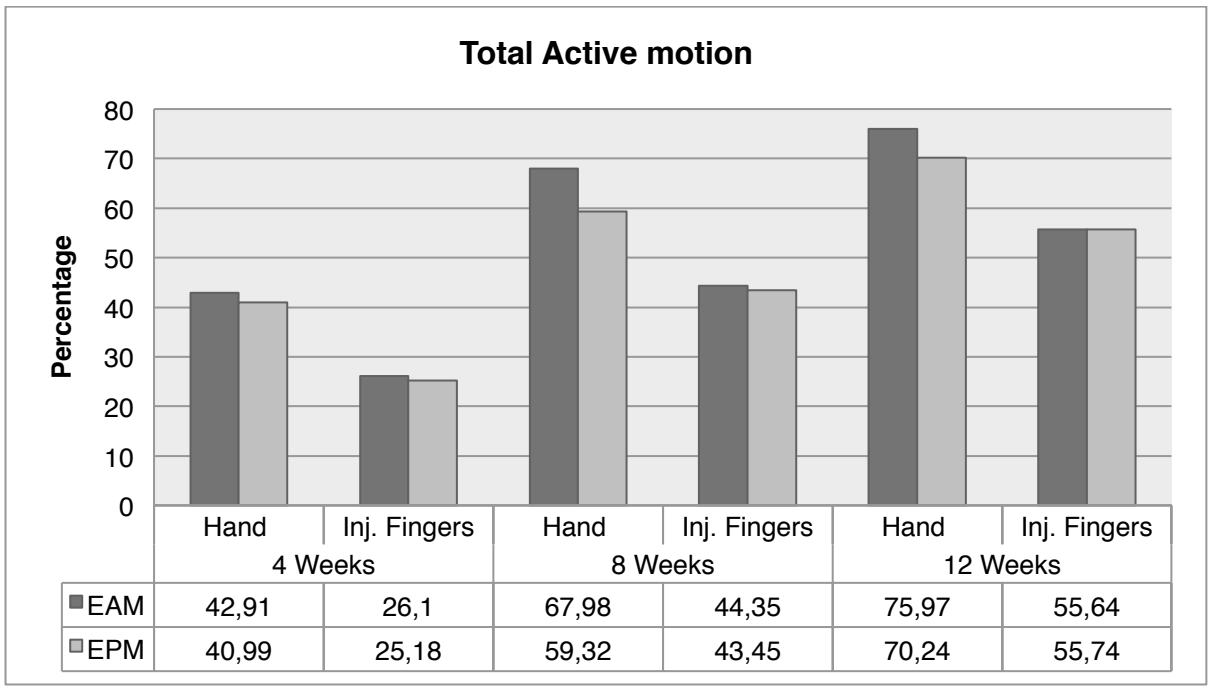


Figure 12: Total active motion percentages of the whole hand and injured fingers between the two groups

At 12 weeks post-surgery, the EAM group had 30 injured fingers. These were categorised in relation to the percentage of function compared to the uninjured side. These categories are ‘excellent’, ‘good’, ‘fair’ and ‘poor’. Two (6.67%) fingers were graded as good, 17 (56.67%) as fair and 11 (36.66%) as poor. The EPM group had 18 injured fingers. Five (27.78%) fingers were graded as good, eight (44.44%) as fair and five (27.78%) as poor. This can be seen in Table 10.

Table 10: Number of injured fingers in total active motion categories at 12 weeks post-surgery

	EAM		EPM	
	Fingers (n)	Percentage (%)	Fingers (n)	Percentage (%)
Excellent (100%)	0	0	0	0
Good (75-99%)	2	6.67	5	27.78
Fair (50-74%)	17	56.67	8	44.44
Poor (<50%)	11	36.66	5	27.78
Total	30	100	18	100

The mean TAM percentages were then categorised in relation to the percentage of function compared to the uninjured side. The number of participants in the EAM and EPM groups in the TAM categories at 12 weeks is indicated in Table 11.

Table 11: Number of participants in total active motion categories at week 12

	EAM		EPM	
	Participants (n)	Percentage (%)	Participants (n)	Percentage (%)
Excellent (100%)	0	0	0	0
Good (75-99%)	1	6.67	3	23.08
Fair (50-74%)	10	66.67	7	53.85
Poor (<50%)	4	26.66	3	23.07
Total	15	100	13	100

TAM categories for the injured fingers and injured hand are portrayed in Table 12 and Table 13. Table 12 shows that between the EAM and EPM groups, the highest category achieved for the **injured fingers** was fair.

Table 12: Total active motion mean percentage of function categories of injured fingers

Time	Protocol	Excellent (100%)		Good (75-99%)		Fair (50-74%)		Poor (<50%)	
		n	%	n	%	n	%	n	%
4 weeks	EAM	0		0		0		**19**	**26.10**
	EPM	0		0		0		**16**	**25.18**
8 weeks	EAM	0		0		0		**17**	**44.35**
	EPM	0		0		0		**14**	**43.45**
12 weeks	EAM	0		0		**15**	**55.64**	0	
	EPM	0		0		**13**	**55.74**	0	

In Table 13, where TAM is viewed and categorised for the **injured hand,** the highest category achieved by the EAM group at the 12-week assessment was good.

Table 13: Total active motion mean percentage of function categories of injured hand

Time	Protocol	Excellent (100%)		Good (75-99%)		Fair (50-74%)		Poor (<50%)	
		n	%	n	%	n	%	n	%
4 weeks	EAM	0		0		0		**19**	**42.91**
	EPM	0		0		0		**16**	**40.99**
8 weeks	EAM	0		0		**17**	**67.98**	0	
	EPM	0		0		**14**	**59.32**	0	
12 weeks	EAM	0		**15**	**75.97**	0		0	
	EPM	0		0		**13**	**70.24**	0	

4.2.2 Fingertip to distal palmar crease

Fingertip to distal palmar crease measurements are depicted in Figure 13. A measurement of 0 centimetres is normal; therefore, the lower the measurement, the better the outcome. This measurement improved slightly over time for both groups; however, the results are viewed as poor, as the injured fingers measured approximately 4-5 centimetres distance between the fingertip and distal palmar crease. There was no significant difference in measurements between the two groups. Table 14 reveals the means and p-values for fingertip to distal palmar crease over the three points in time.

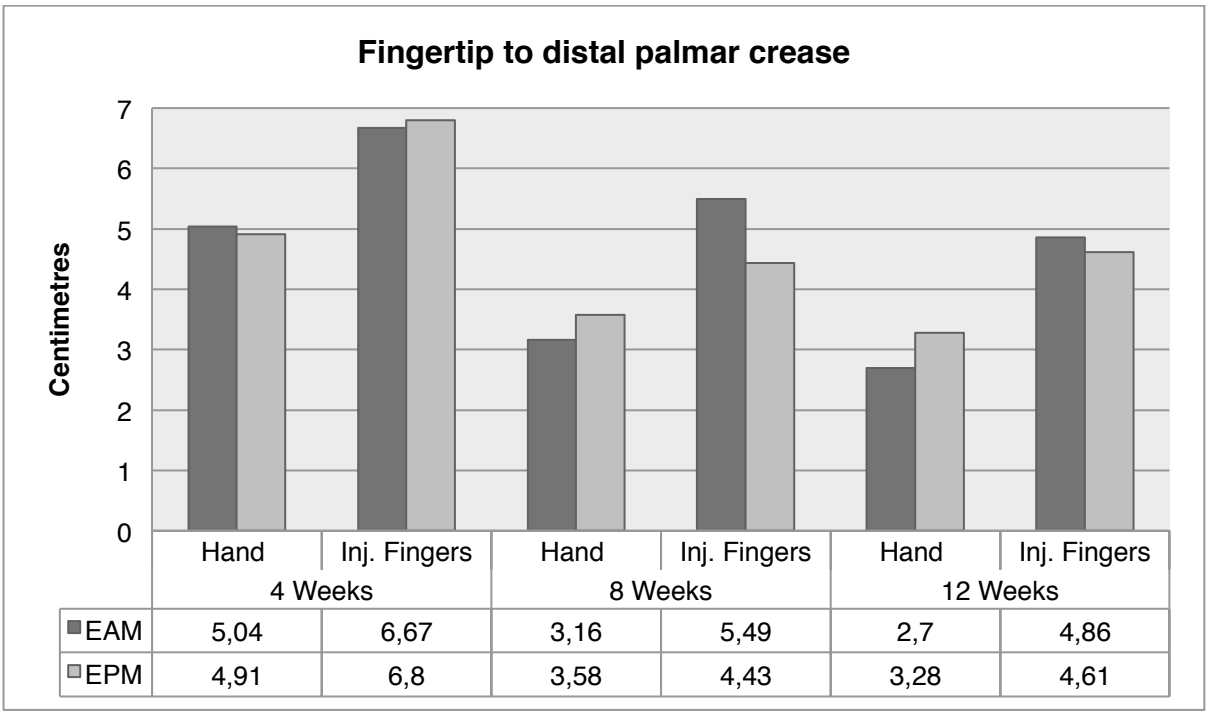


Figure 13: Fingertip to distal palmar crease

Table 14: Fingertip to distal palmar crease measurement (injured fingers)

Time	Protocol	Mean (cm)	p-value (0.05)
4 weeks	EAM	6.67	0.74
	EPM	6.80	
8 weeks	EAM	5.49	0.23
	EPM	4.43	
12 weeks	EAM	4.86	0.73
	EPM	4.61	

p-value = significance (0.05)
cm = centimetres

4.2.3 Fingertip to table

The fingertip to table measurements are shown in Figure 14. A measurement of 0 centimetres is normal; thus, the lower the measurement, the better the outcome. Overall, the measurement of fingertip to table improved over time. At four weeks post-surgery, the EAM average fingertip to table measurement for the injured fingers was 2.38 centimetres and the EPM 2.94 centimetres; at eight weeks post-surgery,

the EAM average was 1.52 centimetres and the EPM 1.99 centimetres; and at 12 weeks, the EAM average was 0.94 centimetres and EPM 1.36 centimetres.

Table 15 highlights the adjusted means and p-values for fingertip to table measurements over the three points in time.

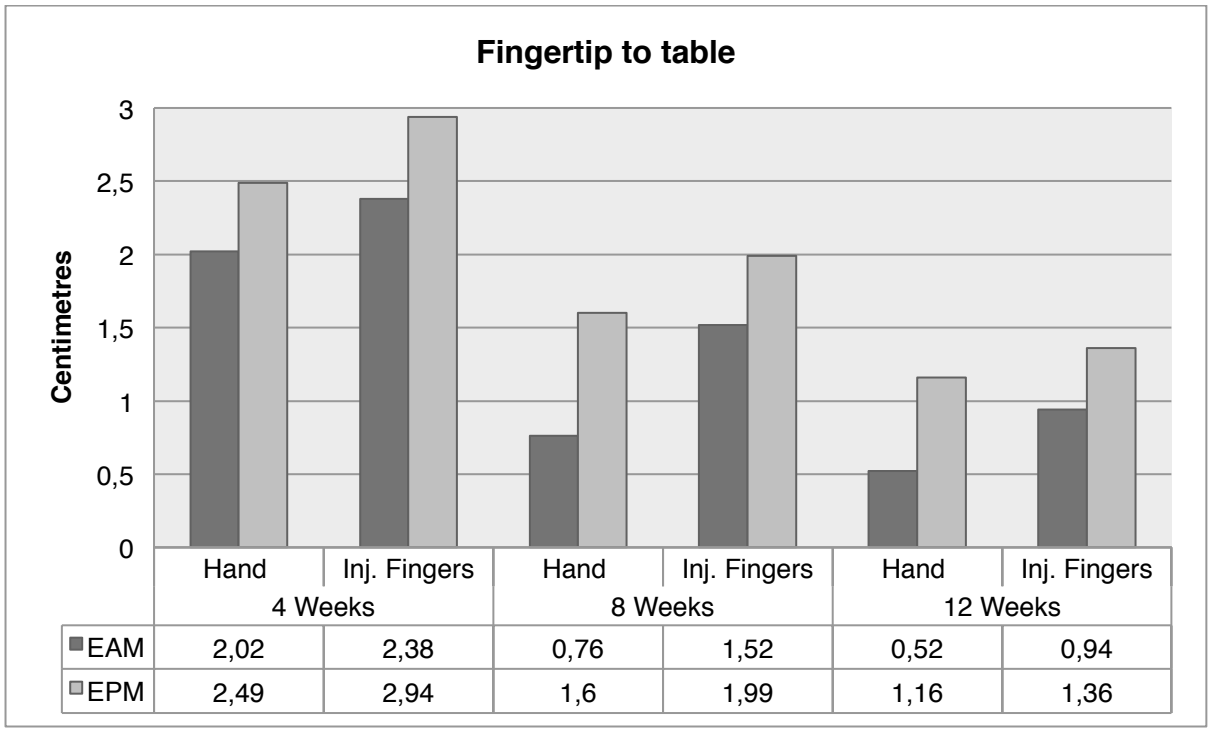


Figure 14: Fingertip to table

Table 15: Fingertip to table measurement (injured fingers)

Time	Protocol	Mean (cm)	p-value (0.05)
4 weeks	EAM	2.38	0.33
	EPM	2.94	
8 weeks	EAM	1.52	0.43
	EPM	1.99	
12 weeks	EAM	0.94	0.46
	EPM	1.36	

p-value = significance (0.05)
cm = centimetres

4.2.4 Multi tendon versus single tendon injury

Multi tendon versus single tendon injuries were then analysed in accordance with TAM. In Table 16, it can be seen that there is equal distribution between the multi tendon injury and single tendon injury in the EAM group. Most of the participants who sustained a multi tendon injury in the EAM group fell into the fair category.

Table 16: Multi tendon versus single tendon injuries in the EAM group

	EAM multi tendon injury		**EAM single tendon injury**	
	Participants (n)	Percentage (%)	Participants (n)	Percentage (%)
Excellent (100%)	0	0	0	0
Good (75-99%)	1	12.50	0	0
Fair (50-74%)	4	50.00	5	71.43
Poor (<50%)	3	37.50	2	28.57
Total	8	100	7	100

According to Table 17, there were slightly more participants who sustained single tendon versus multi tendon injuries in the EPM group. Again, most of the participants fell into the fair category, and only three participants with single tendon injuries fell into the good category.

Table 17: Multi tendon versus single tendon injuries in the EPM group

	EPM multi tendon injury		**EPM single tendon injury**	
	Participants (n)	Percentage (%)	Participants (n)	Percentage (%)
Excellent (100%)	0	0	0	0
Good (75-99%)	0	0	3	37.50
Fair (50-74%)	5	100	4	50.00
Poor (<50%)	0	0	1	12.50
Total	5	100	8	100

4.3 PARTICIPANT DEMOGRAPHICS

Participant demographics will be described under various headings. These include recruitment and follow-up of participants; participant details; flexor tendon injury details; timing to surgical repair and rehabilitation; participant compliance; and the participants' socio-economic factors.

4.3.1 Recruitment and follow-up

Forty-six participants were recruited for the study. Equal random allocation of the participants to the EAM and EPM groups was conducted. Eighteen (39.13%) participants were lost to follow-up over the duration of the study. Seventeen participants did not return for therapy, and one participant passed away in a motor vehicle accident. Eleven of the eighteen participants did not attend the first assessment at four weeks post-surgery. Of these 11 participants, one did not return for therapy after the first session. The remaining six participants lost to follow-up, did not return at the eight or 12-week post-surgery assessment. The number of participants within each group and at each time period can be seen in Figure 15.

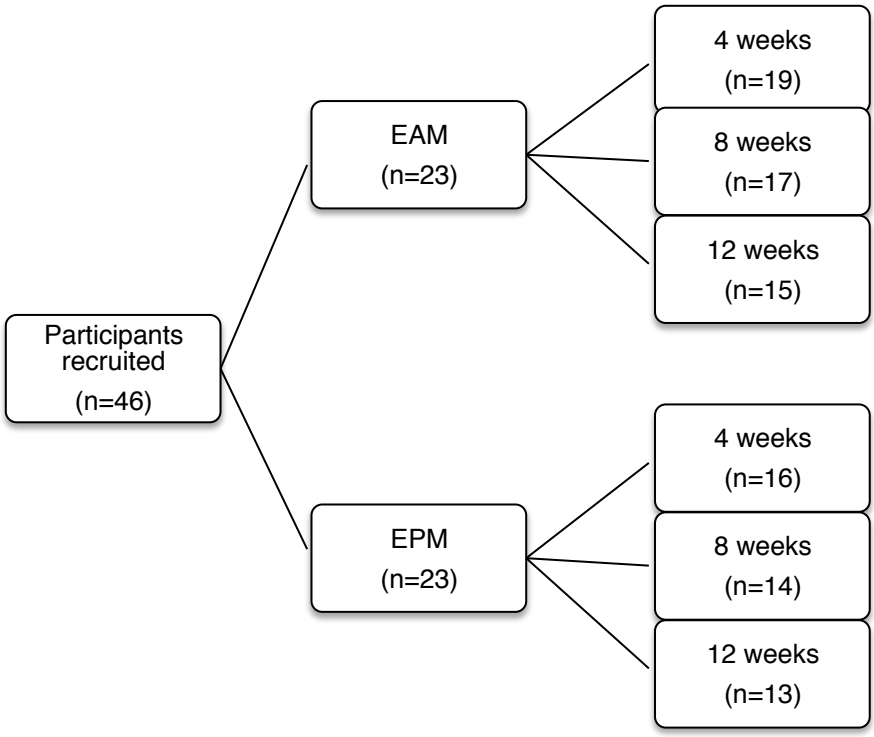


Figure 15: Participants follow-up at each time period in the EAM and EPM groups

4.3.2 Participant details

Table 18 summarises all the participant details in the EAM and EPM groups. The p-value reported in Table 18 was used to determine if there were significant differences

in the variables between the two groups. The participant details regarding age, gender, and smoking are discussed next.

Table 18: Participant details in the two rehabilitation groups

	EAM	EPM	p-value (0.05)
Participants (n=35)	19	16	
Age (mean, range)	36.32 (21-62)	31.56 (19-75)	0.09
Males (n=18)	9	9	0.74
Females (n=17)	10	7	0.74
Dominant hand injured	18 (51.43%)	14 (40.00%)	0.58
Smoking (n=12)	8	4	0.48
Translator required (n=5)	3	2	
Tendons injured (n=102)	61	41	0.58
FDP (n=57)	35	22	
FDS (n=45)	26	19	
Digits injured (n=59)	36 (61.02%)	23 (38.98%)	0.53
Index finger (n=16)	10 (27.78%)	6 (26.09%)	
Middle finger (n=14)	8 (22.22%)	6 (26.09%)	
Ring finger (n=18)	10 (27.78%)	8 (34.78%)	
Little finger (n=11)	8 (22.22%)	3 (13.04%)	
Days to surgery (mean)	7.84	9.38	0.68
Referral days to OT (mean)	1.42	1.38	

p-value = significance (0.05)

Gender and age

More males (n=18, 51.43%) than females (n=17, 48.57%) were recruited for the study. The average age of the participants was 34.14 years, ranging from 19-75 years. The EAM group had a mean age of 36.32 years, and the EPM group had a mean age of 31.56 years. There was a marginally significant difference in the mean age between the EAM and EPM groups, which is why age was identified as a potential covariate. Therefore, the ANCOVA test was performed to adjust for age. By

adjusting for age, all the participants of both groups were adjusted to the same age (34.14 years). When comparing the EAM and EPM protocols with respect to the study outcomes, if age was significant ($p<0.1$) when included into the ANCOVA for the EAM and EPM groups, then the adjusted mean and p-value for that ANCOVA are reported, while if age was not significant when included into the ANCOVA, then the actual mean and t-test p-value are reported.

Smoking

There were 12 (34.29%) participants who were smokers. Eight of these participants were in the EAM group and four in the EPM group.

4.3.3 Flexor tendon injury details

The sample group consisted of 35 participants who presented a total of 59 injured fingers and 102 injured tendons. It was found that 65.63% of the participants injured their dominant hand, and 91.43% of the participants were right-hand dominant.

Zones of injury

The majority of injuries occurred in zone II (65.71%), followed by zone III (31.43%) and zone IV (2.86%) of the hand. Table 19 illustrates the zones of injury, detailing the number of participants, injured fingers and tendons according to the rehabilitation protocol applied.

Table 19: Clinical details of participants' injuries

	Early active motion (EAM)			**Early passive motion (EPM)**		
	Participants	Fingers	Tendons	Participants	Fingers	Tendons
Zone II	13	26	41	10	15	26
Zone III	6	10	20	5	6	12
Zone IV	0	0	0	1	2	3
Total	19	36	61	16	23	41

Associated injuries

Twenty-one of the participants did not sustain associated injuries. The remaining 14 sustained the following associated injuries: digital nerve (28.57%), median nerve (8.57%), and dislocation (2.86%). This is highlighted in Table 20.

Table 20: Associated injuries across the sample

Associated injury	Number of participants (n)	Percentage (%)
Digital nerve	10	28.57
Median nerve	3	8.57
Dislocation	1	2.86
None	21	60.00
Total	35	100.00

Table 21 portrays the associated injuries between the EAM and EPM groups.

Table 21: Associated injury between the EAM and EPM groups

Associated injury	EAM		EPM	
	Participants (n)	Percentage (%)	Participants (n)	Percentage (%)
Digital nerve	5	26.31	5	31.25
Median nerve	2	10.53	1	6.25
Dislocation	0	0	1	6.25
None	12	63.16	9	56.25
Total	19	100	16	100

Mechanism of injury

The most common mechanism of injury was a knife (54.29%), then in descending order: accidental glass injury (22.86%), assault by glass (8.57%), panga (2.86%), other (5.71%), and lastly motor vehicle accident (MVA) (5.71%). Assaults accounted for 65.72% of the mechanisms of injury. A breakdown of the mechanism of injury can be seen in Table 22 and Figure 16.

Table 22: Mechanism of injury between the EAM and EPM groups

Mechanism of injury	EAM		EPM	
	Participants (n)	Percentage (%)	Participants (n)	Percentage (%)
Knife	13	68.42	6	37.50
Glass (accident)	4	21.05	4	25.00
Glass (assault)	2	10.53	1	6.25
Panga	0	0	1	6.25
MVA	0	0	2	12.50
Other	0	0	2	12.50
Total	19	100	16	100

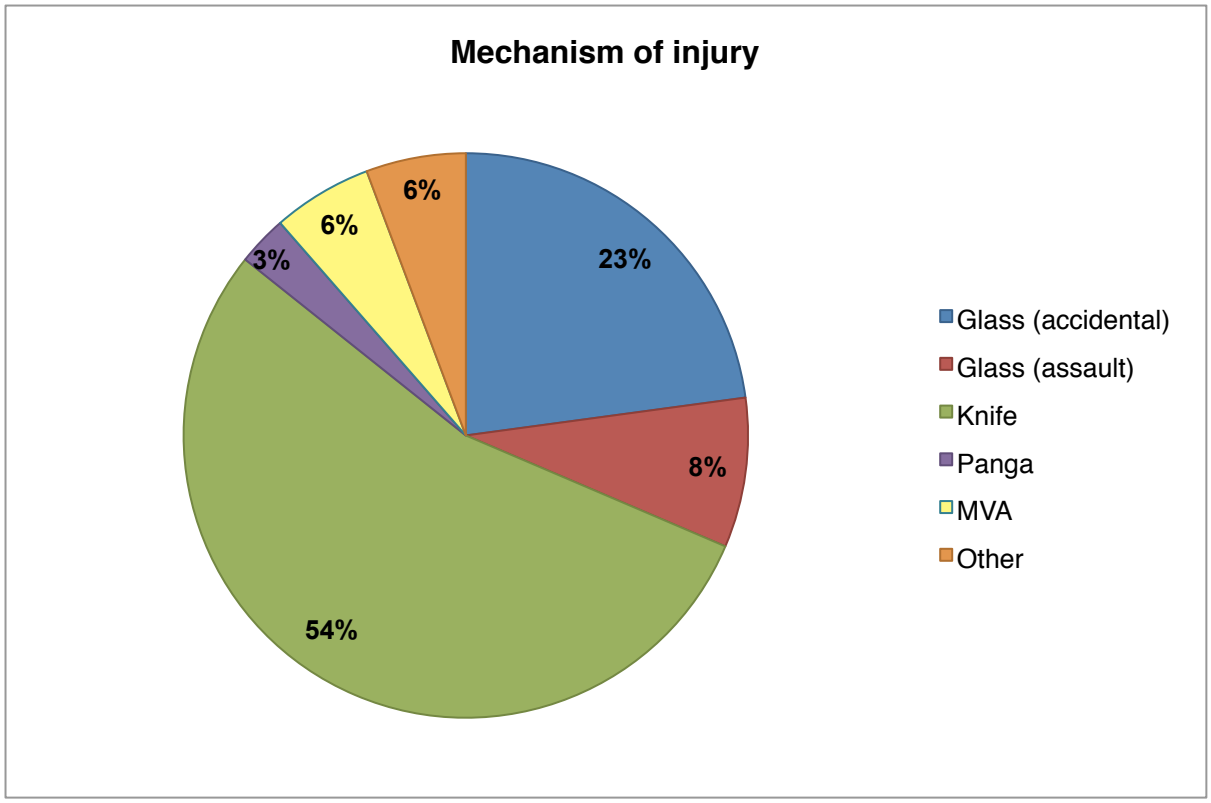


Figure 16: Mechanism of injury

4.3.4 Timing to surgical repair and rehabilitation

Timing to surgical repair

All the tendons were repaired using a 4-strand repair. The average number of days between injury and surgery was 8.54, with the minimum being one and maximum being 60 days. Twenty-eight participants had surgery between one to nine days post-

injury; four participants had surgery between 10 to 14 days post-injury; one participant had surgery at 22 days post-injury; one participant had surgery 32 days post-injury; and lastly one participant had surgery at 60 days post-injury.

Timing to rehabilitation

The participants were referred to occupational therapy on average 1.40 days post-surgery, with the minimum being zero days and maximum being four days.

4.3.5 Participant compliance

Participant compliance was determined based on adherence to appointments, the removal of the splint during the first four weeks post-surgery, and carrying out exercises correctly as prescribed by the researcher for the duration of the 12 weeks.

Loss to follow-up

As indicated in Section 4.3.1, 11 participants were lost to follow-up prior to the first evaluation, with only 28 participants completing the 12-week assessment. Figure 17 portrays the percentage of participants lost to follow-up, which was 39%.

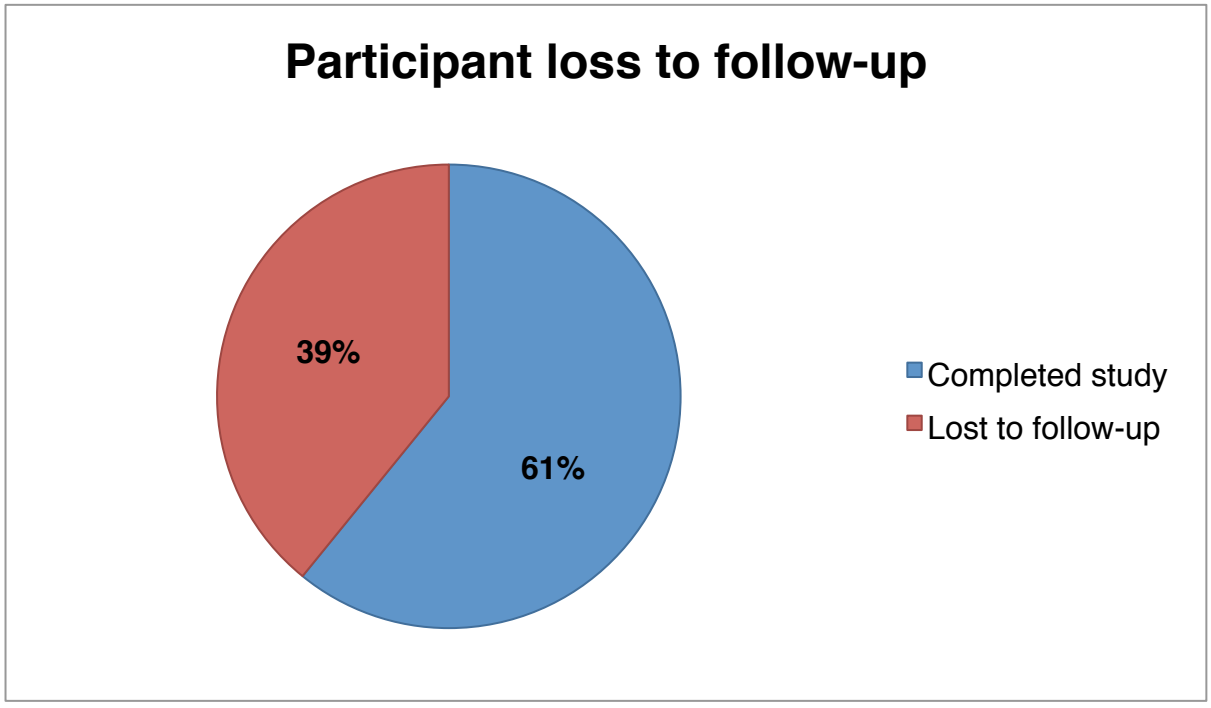


Figure 17: Participants lost to follow-up

Attendance of therapy sessions

The average attendance of participants for appointments was 73.19%, with only 34.78% attending all of the nine appointments throughout the study.

Removal of splint and correct exercise

In terms of the 35 participants removing their splint, 45.71% of the participants removed their splint in order to carry out activities of daily living during the initial four-week period. In the whole sample excluding one participant who did not return at all after the first session (n=45), 23 (51.11%) participants removed their splints in the first four weeks post-surgery. In the EAM group, 60.87% (n=14) of these participants removed their splints and in the EPM group, 39.13% (n=9) of these participants removed their splints. The prescribed exercises were adhered to by 71.43% of the participants.

4.3.6 Socio-economic factors

The socio-economic status of the participants was determined according to the information gathered from answers regarding education, employment, monthly income, and transport type and costs. The socio-economic status in relation to participant compliance is also portrayed.

Education

Of all the participants, 51.42% of the participants completed matric, 42.86% did not finish high school, 2.86% completed primary school only, and 2.86% did not go to school at all. Table 23 depicts education across the sample. Only 20% of the participants completed tertiary education.

Table 23: Education across the sample

Education	Number of participants (n)	Percentage (%)
High school complete	18	51.42
High school incomplete	15	42.86
Primary school only	1	2.86
Did not attend school	1	2.86
Total	35	100.00

Employment

In terms of employment, 27 (57.14%) participants were employed. Of these employed participants, 37.14% earned below R4500 per month, and 20% earned above R4500 per month. The EAM group had 73.68% (n=14) employed participants, and the EPM group had 37.50% (n=6) employed participants. Because of the high discrepancy of employed participants between the two groups, employment was identified as a potential covariate, whereby the ANCOVA test was performed to adjust for employment. By adjusting for employment, all the participants were placed at a reference point of 0.43, meaning that they were put on the same level of employment. When comparing the EAM and EPM protocols with respect to the study outcomes, if employment was significant ($p<0.1$) when included into the ANCOVA for the EAM and EPM groups, then the adjusted mean and p-value for that ANCOVA are reported, whereas if employment was not significant when included into the ANCOVA, then the actual mean and t-test p-value are reported.

A breakdown of employment and monthly income can be seen in Table 24 and Table 25.

Table 24: Category of employment across the sample

Type of employment	Number of participants (n)	Percentage (%)
Manual labour	3	8.56
Teller	1	2.86
Businessman/woman	1	2.86
Other	15	42.86
Unemployed	15	42.86
Total	35	100.00

Table 25: Monthly income across the sample

Income	Number of participants (n)	Percentage (%)
R500-R1500	4	11.43
R1500-R3000	2	5.71
R3000-R4500	7	20.00
R4500-R5500	2	5.71
>R5500	5	14.29
No income	15	42.86
Total	35	100.00

Transport

The majority of the participants made use of public transport to attend appointments at the hospital. Taxi use was the highest at 88.57%. Of these participants, 80.00% paid between R10 and R40 for a return trip, and a further 8.57% paid over R40 to attend appointments at the hospital. The remainder of participants stated that they did not pay for transport, as they walked or a family member or friend drove them to hospital. The type of transport and transport costs are shown in Table 26 and Table 27 respectively.

Table 26: Type of transport taken to the hospital

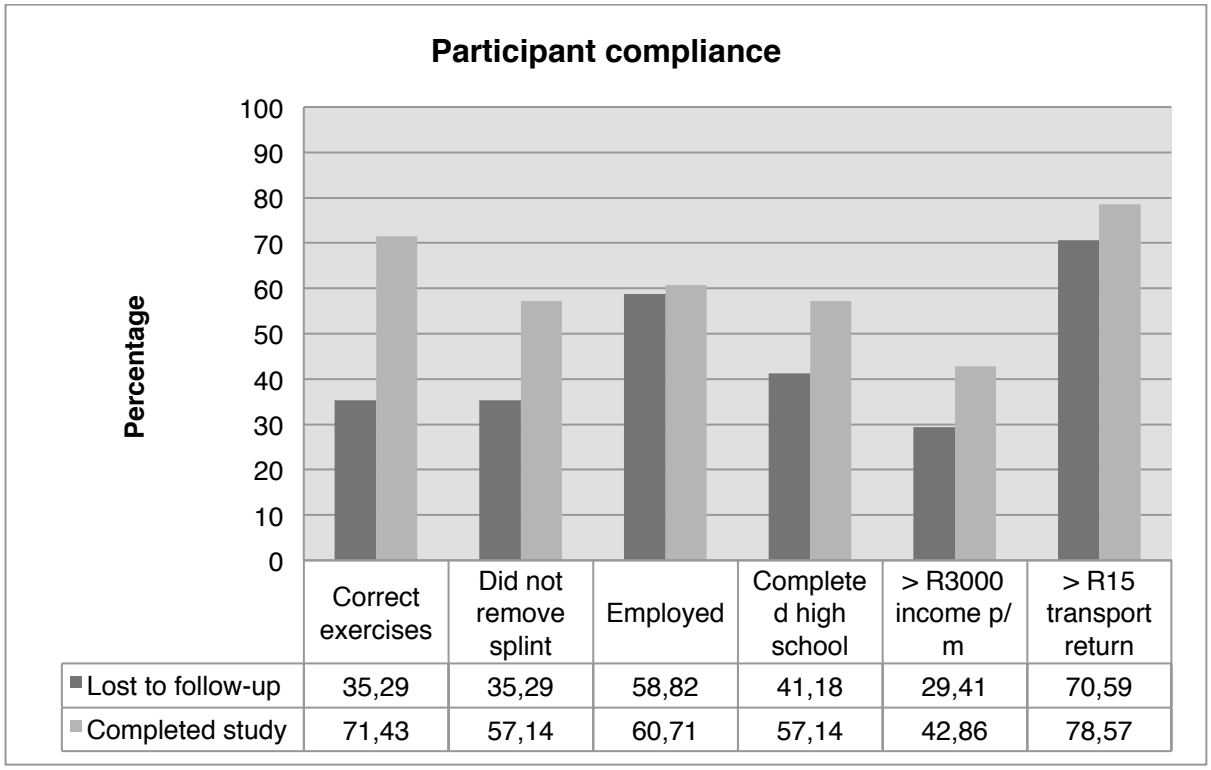
Transport type	Number of participants (n)	Percentage (%)
Taxi	31	88.57
Own car	4	11.43
Total	35	100.00

Table 27: Cost of transport to and from the hospital

Transport cost	Number of participants (n)	Percentage (%)
Free	4	11.43
R10-R15	5	14.29
R15-R20	11	31.43
R20-R30	7	20.00
R30-R40	5	14.29
>R40	3	8.57
Total	35	100.00

Socio-economic factors in relation to compliance

Figure 18 shows participant compliance by portraying specific socio-economic details related to participant compliance in those participants who were lost to follow-up over the duration of the study (n=17) and those who completed the study (n=28). There were 18 participants lost to follow-up during the duration of the study; however, one participant did not follow up for any sessions, and therefore the researcher did not have information regarding removal of splint and correct exercises. This participant was thus left out of the analysis that follows.



	Correct exercises	Did not remove splint	Employed	Completed high school	> R3000 income p/m	> R15 transport return
Lost to follow-up	35,29	35,29	58,82	41,18	29,41	70,59
Completed study	71,43	57,14	60,71	57,14	42,86	78,57

Figure 18: Participant compliance portraying participants lost to follow-up and those who completed the study

4.4 COMPLICATIONS POST-SURGERY AND REHABILITATION

There were some complications post-surgery and rehabilitation. For example, adhesions and infection were the most common complications, making up 31.43% (n=11) and 20% (n=7) respectively. Three (8.57%) participants sustained tendon ruptures, and two (5.71%) participants had contractures. Of the three participants who sustained tendon ruptures, two removed their splints in the first four-week period

post-surgery, and one participant that removed the splint also carried out incorrect exercises. Specific details of the participants who sustained tendon ruptures are indicated in Table 28.

Table 28: Tendon rupture characteristics

Ruptures	Protocol	Removal of splint	Correct exercises	Infection
1	EAM	Yes	Yes	No
2	EAM	No	Yes	No
3	EPM	Yes	No	No

Seven (20%) of the participants required repeat surgery to clean the infection or repair the ruptured tendon. Table 29 outlines the complications post-surgery and rehabilitation according to the rehabilitation protocol and zone of injury. Out of the 35 participants, 16 did not have any complications.

Table 29: Complications post-surgery and rehabilitation according to the rehabilitation protocol and zone of injury

Protocol	Zone	Rupture	Infection	Adhesions	Contracture	Reoperation
EAM	II	2	3	4	1	4
	III	0	1	1	0	0
	IV	0	0	0	0	0
EPM	II	1	2	4	0	2
	III	0	1	2	1	1
	IV	0	0	0	0	0
Total		3 (8.57%)	7 (20.00%)	11 (31.43%)	2 (5.71%)	7 (20.00%)

4.5 CONCLUSION

This chapter described the results of the study in terms of outcomes post flexor tendon repair, participant demographics, and complications post-surgery and rehabilitation. As indicated, 46 participants were recruited for the study.

The factors affecting the outcome of the results will be discussed in Chapter 5.

5 DISCUSSION

5.1 INTRODUCTION

Research on flexor tendon repair and rehabilitation of the hand is ongoing due to the poor outcomes frequently experienced. These outcomes include adhesion formation, rupture of tendon repairs, and decreased range of movement of the finger joints.[16,17] Research over the past three decades has resulted in changes in the techniques used in surgery and rehabilitation of flexor tendon repairs.[17] Although surgical techniques are extremely important in ensuring improved outcomes, rehabilitation has been shown to be vital in improving the long-term outcome of flexor tendon repair of the hand.[2] Many studies have been conducted to determine the most effective rehabilitation protocol post flexor tendon repair of the hand.[7-11,13-15] There has been a global move towards the use of an EAM protocol post flexor tendon repair.[6]

The aim of this study was to compare the outcomes of an EAM protocol to the outcomes of an EPM protocol in the rehabilitation of patients with zone II-IV flexor tendon repairs of the hand. Forty-six participants were recruited for the study. They were randomly allocated to the EAM or EPM groups. A total of 18 participants were lost to follow-up over the duration of the study. Eleven of the eighteen participants did not return for the first evaluation at four weeks post-surgery. These 11 participants were therefore excluded from the data analysis. The study yielded many results for analysis and discussion.

The results of the study will be discussed in relation to the objectives. The first objective of the study was to implement the EAM or EPM protocols during the first four weeks of rehabilitation of patients with zone II to IV flexor tendon repairs. This objective was achieved for all the participants who were referred, recruited and followed up for the study. Objectives 2 to 5 encompassed the main study objectives where the two protocols were compared. The comparison of the outcomes of the two protocols will be discussed in Section 5.2. The last objective of the study was to determine if there is a relationship between patient compliance and socio-economic factors. This will be discussed in Section 5.3.5.

The penultimate chapter focused on the results of the study. This chapter provides a discussion of the study and has been divided into the following sections:

- outcomes post flexor tendon repair
- participant demographics
- complications post-surgery and rehabilitation
- selection of a rehabilitation protocol
- conclusions and recommendations
- study limitations
- indications for further research

5.2 OUTCOMES POST FLEXOR TENDON REPAIR

The main objective of the study was to determine if there is a difference between the outcomes after the EAM and EPM protocols had been followed during the first four weeks. This was established by the collection of the total active motion (TAM), fingertip to distal palmar crease, and fingertip to table measurements. The results of this study will be discussed in relation to the objectives of the study. The objectives that will be discussed in this section are as follows:

Objective 2: To determine the outcomes of patients with zone II to IV flexor tendon repairs during rehabilitation following an EAM protocol based on the following measurements:

- total active motion of the affected and unaffected fingers
- fingertip to distal palmar crease measurements of the affected fingers
- fingertip to table measurements of the affected fingers

Objective 3: To determine the outcomes of patients with zone II to IV flexor tendon repairs during rehabilitation following an EPM protocol regarding:

- total active motion of the affected and unaffected fingers
- fingertip to distal palmar crease measurements of the affected fingers
- fingertip to table measurements of the affected fingers

Objective 4: To compare the results of objectives 2 and 3

Objective 5: To evaluate the effect of the degree of injury on outcomes such as multi tendon versus single tendon injury

Objectives 2, 3 and 4 will be discussed in the sections on TAM, fingertip to distal palmar crease and fingertip to table, where the EAM and EPM results are compared. The fifth objective, pertaining to the degree of injury on outcomes, will be discussed at the end of this section.

5.2.1 Total active motion

The TAM results were calculated for the injured finger(s) and for the injured hand as seen in Section 4.2.1, Figure 12. The TAM measurements were similar for both groups during each of the measurement periods, at 4, 8 and 12 weeks post-surgery. The TAM percentages of the injured fingers showed poorer results compared to that of the whole hand. The injured hand TAM results were 20% better than that of the injured fingers. This therefore emphasises the importance of calculating the specific injured finger TAM, to portray how poor the range of movement of the injured finger actually is.

The mean TAM percentages, for the injured fingers only, in the EAM and EPM group at the 12-week time period were 55.64% and 55.74% respectively. In a study conducted by Prowse et al,[10] it was found that the mean TAM percentages were 72% for the EAM group and 70% for the EPM group at 12 weeks post-surgery. Both this study and the study by Prowse et al[10] show that there was no difference in the TAM results between the EAM and EPM groups. Furthermore, the TAM results fell into the 'fair' category. Peck et al[14] also found that there was no difference between the EAM and EPM groups; however, they made use of the Strickland criteria[30,35] to classify their results and did not use TAM measurements.

Table 12 in Section 4.2.1 depicts the mean TAM percentages of the injured fingers. According to the TAM classification, the results fell into the 'poor' category for both groups at four and eight weeks post-surgery. The highest category achieved was fair

at 12 weeks post-surgery. Table 13 in Section 4.2.1 illustrates that the EAM group achieved a 'good' mean TAM percentage and the EPM a fair mean TAM percentage for the injured hand by 12 weeks post-surgery.

Frueh et al[8] found no significant difference in TAM measurements between the EAM and EPM groups by 12 weeks post-surgery. This is similar to this study where no significant differences between the two protocols were found. The comparison between the study by Frueh[8] and this study can be viewed in Table 30. In the study by Frueh et al,[8] 65% of the EAM protocol participants fell into the good category and 35% into the fair category. Eight percent of their EPM participants fell in the 'excellent' category, 45% into good, 43% into fair, and 4% into the poor categories. They stated that their inadequate results could be attributed to the opinion that 12 weeks is not the end point of recovery.[8] The results of this study can be seen in Table 11, Section 4.2.1. The table shows that 6.67% of the EAM participants fell into the good, 66.67% into the fair, and 26.66% into the poor categories. The EPM participants fell into the good category at 23.08%, 53.85% into the fair category, and 23.07% into the poor category. These results indicate that the TAM results from this study are not as good as compared to the study conducted by Frueh et al.[8]

Table 30: Comparison of participants in total active motion categories between the study by Frueh et al[8] and this study between the two groups

	Frueh et al[8]		**This study**	
	EAM (%)	**EPM (%)**	**EAM (%)**	**EPM (%)**
Excellent (100%)	0	8	0	0
Good (75-99%)	65	45	6.67	23.08
Fair (50-74%)	35	43	66.67	53.85
Poor (<50%)	0	4	26.66	23.07
Total	**100**	**100**	**100**	**100**

The results of this study were therefore different to that of Hung et al,[7] Bainbridge et al,[15] Trumble et al,[11] and Yen et al[13] who all found that the EAM protocol yielded superior results. Both Yen et al[13] and Bainbridge et al[15] produced statistically significant results, showing that the EAM protocol produced improved outcomes compared to EPM protocol. Kitis et al[12] found good TAM results when two EPM

protocols were compared. These results are different to the results of this study. As indicated in Table 8, Section 2.9, these studies were conducted in different contexts compared to South Africa.

The null hypothesis for the outcome of TAM can therefore be accepted, as there was no difference between the two protocols.

5.2.2 Fingertip to distal palmar crease

This quick and useful measurement portrays the composite active finger flexion that one is able to achieve, allowing for an estimation of finger function.[1] It is the measurement between the fingertip and the distal palmar crease.

The fingertip to distal palmar crease results did not portray any significant difference between the EAM and EPM groups. The null hypothesis can therefore be accepted for the outcome of fingertip to distal palmar crease. Figure 13 and Table 14 in Section 4.2.2 present these results. When looking at the injured finger measurement, at eight and twelve weeks post-surgery, the EPM group had slightly better results compared to the EAM group. When looking at the injured hand measurements at eight and twelve weeks post-surgery, the EAM group had slightly better results compared to the EPM group. All these results progressively improved over the three measurement periods. However, these results are still regarded as poor, as the mean 12-week measurement for the injured fingers was 4.86 centimetres for the EAM group and 4.61 centimetres for the EPM group. An uninjured finger should have a fingertip to distal palmar crease measurement of 0 centimetres.

5.2.3 Fingertip to table

Fingertip to table is the perpendicular measurement between the fingertip and table. This is an efficient method which portrays finger function when composite finger extension is performed.[1] A normal measurement is 0 centimetres.

There was no significant difference between the fingertip to table measurement between the EAM and EPM groups. The null hypothesis can therefore be accepted. Figure 12 and Table 15 in Section 4.2.3 show these results. It can be seen that the

results improved over the three time periods, for both the injured finger(s) and injured hand. Between the EAM and EPM groups, the EAM group indicated slightly better results compared to that of the EPM group. At the 12-week measurement, the mean EAM group measurement was 0.94 centimetres, compared to the EPM group, which was 1.36 centimetres. These results can be regarded as acceptable. An uninjured finger should have a fingertip to table measurement of 0 centimetres.

5.2.4 The effect of the degree of injury on outcomes

Objective 5 was to determine the effect of the degree of injury on the outcomes, such as multi tendon versus single tendon injury. As stated earlier, there was no significant difference in the outcomes between the EAM and EPM groups. When looking at TAM and the multi versus single tendon injuries, there were no significant differences in the results. Table 16 and Table 17 in Section 4.2.4 highlight these results. The results show a relatively even division over the TAM categories, thus showing that in this study, the number of tendons injured did not have an effect on the outcomes.

5.3 PARTICIPANT DEMOGRAPHICS

Even though the main purpose of the study was to compare the outcomes between the EAM and EPM groups, the study provided data on other variables that may have influenced the outcomes of the study. These will be discussed in the sections that will follow, which describe participant demographics and complications post-surgery and rehabilitation.

This section gives an overview of the participant demographics according to the participant details, flexor tendon injury, timing to surgical repair and rehabilitation, participant compliance, and socio-economic factors.

5.3.1 Participant details

Forty-six participants were recruited for the study, with equal random allocation to the EAM and EPM groups. Figure 15, Section 4.3.1 shows the number of participants followed up at each time period in the EAM and EPM groups. Eleven of these participants did not arrive for their first assessment session at four weeks post-

surgery; they were therefore excluded from the data analysis. Data from 35 participants was analysed. The participant details discussed in this section are gender, age, and smoking. A summary of the participant details can be seen in Table 18, Section 4.3.2.

Gender and age

Table 18 reveals that there were slightly more males than females recruited for the study. The average age was 34.14 years. The age range was between 19 and 75 years. This complied with the inclusion criteria of the study that stated that participants had to be 18 years or older. The age distribution of this study was thus similar in terms of recruitment ages to Trumble et al[11] and Starnes et al,[26] who recruited participants up to the age of 75 years. Gender across the two groups did not have an effect on the outcomes.

The average age of the participants in the EAM group was 36.32 years, and in the EPM group, it was 31.56 years. Because of the marginal discrepancy in age between the two groups, age was identified as a potential covariate. This therefore influenced the method used to analyse the data, as discussed in Chapter 4.

Smoking

The distribution of smokers between the EAM and EPM groups was fairly similar. Twelve of the participants in this study were smokers: eight in the EAM group and four in the EPM group. Results did not indicate that smoking had an influence on the study outcomes. This was different to the findings of Trumble et al,[11] who found that those who smoked during the study showed a significantly lower range of movement results.

5.3.2 Flexor tendon injury

The 35 participants presented a total of 59 injured fingers and 102 injured tendons. Flexor tendon injuries among the participants will be discussed according to zones of injury, associated injuries, and mechanism of injury.

Zones of injury

The injuries mostly occurred in zone II (65.71%). In both of the groups, 35.43% of the injuries occurred in zone III, and 2.86% occurred in zone IV. The zone of injury distribution between the two groups was similar. Because of the high number of zone II injuries in this study, future research may consider comparing only this zone of injury between the EAM and EPM groups.

Associated injuries

There were 14 (40.00%) participants who sustained associated injuries. These consisted of injury to the digital nerve (28.57%), median nerve (8.57%), and dislocation of a joint (2.86%). Associated injuries complicate the surgical repair, as not only the tendon but also other structures need to be repaired, potentially causing more complications. There is usually increased scarring with the associated injuries,[27] resulting in adhesion formation which will affect the ability of the tendon to glide. Associated injuries could therefore have resulted in decreased range of movement due to the increased formation of adhesions. As seen in Table 21, the associated injuries were equal across the EAM and EPM groups, and hence did not have an effect on the outcomes. The EAM group had seven associated injuries, five to the digital nerve, and two to the median nerve. The EPM group had seven associated injuries, five to the digital nerve, one to the median nerve, and one dislocation.

Mechanism of injury

Mechanism of injury is important to note, as this will have an effect on the extent of the injury. The extent of the injury may have an effect on the outcome of the flexor tendon repair.[2] Acute clean-cut injuries have less contamination and are simple in terms of the repair.[27] Acute crush injuries usually result in associated injuries and higher contamination, making the tendon more difficult to repair. The most common mechanism of injury among the participants was injury by knife (54.29%). Other mechanisms of injury in this study were assault by glass, panga, accidental glass injury, other, and motor vehicle accident.

Table 22 revealed that the EAM group had double the amount of knife injuries compared to the EPM group. The EPM group had injury by panga, motor vehicle accident, and other, which the EAM group did not have. According to the data analysis, mechanism of injury was evenly divided between the two groups. These knife injuries may be classified as acute clean-cut wounds, which are said to have the least contamination and improved outcomes compared to crush injuries.[2,27]

5.3.3 Timing to surgical repair and rehabilitation

Timing to surgical repair

Tendon repair should ideally be carried out as early as possible.[18] Torrie et al[21] state that the longer the delay between the tendon injury and repair, the more challenging the surgery and rehabilitation of the repaired tendon is. Lutsky et al[20] point out that the tendon should be repaired up until six weeks post tendon injury. In this study, the timing to surgical repair of the tendon showed a minimum of one day and a maximum of 60 days, with the mean at 8.54 days. According to Lin et al,[18] a primary repair is classified as less than 12 hours post-injury, with a delayed secondary repair being done at four weeks post-injury. This was not the case with one of the participants in this study who underwent primary flexor tendon repair at 60 days post-surgery. In South African public hospitals, flexor tendon injuries are occasionally missed in casualty or at the smaller clinics. Accordingly, patients may have to undergo a delayed primary repair or even a secondary repair depending on the case.

The participant that had surgery 60 days post-injury was in the EPM group, injured one finger and was non-compliant in terms of carrying out the correct exercises and not removing the splint. No associated injuries or complications were present. At 12 weeks post-surgery, the TAM result for the injured finger fell into the fair category at 45.39%, the fingertip to distal palmar crease measurement was 7.5 centimetres, and fingertip to table measurement was 0 centimetres. This particular patient sustained a tendon rupture and required reoperation. It is difficult to say whether the delay in surgery might have influenced this participant's outcomes, due to the other variables such as non-compliance and tendon rupture. Twenty-eight of the remaining participants had surgery between one to nine days post-injury, four participants had

surgery between 10 to 14 days post-injury, one participant had surgery at 22 days post-injury, and another participant had surgery 32 days post-injury.

Timing to rehabilitation

Post-surgery, a tendon should be mobilised early, as this improves tendon healing, ensures fewer adhesions, and improves excursion of the tendon.[4] In this study, the timing of referral to occupational therapy was between one to four days. The average days to referral were 1.40 days. Amadio[3] and Torrie[21] state that the ideal time to initiate rehabilitation is between three to five days post-surgery. At Chris Hani Baragwanath Academic Hospital (CHBAH), the patients are usually referred to occupational therapy one to four days post-surgery, depending on whether the repair was conducted during the week or over the weekend. There are limited hospital beds at CHBAH, and therefore patients need to be discharged as soon as possible post-surgery. Rehabilitation is therefore started prior to the end of the inflammatory phase of tissue healing.

Ideally, rehabilitation should begin in the proliferation phase of tissue healing, which is from approximately three days post-surgery.[7,18,27] Evans[24] suggests that the patient be fitted with a dorsal blocking splint 24 hours post-surgery. The patient is then educated on the condition and then rehabilitation commences. Exercises can then be started three days post-surgery. It has been suggested that this sequence is implemented at CHBAH to allow the inflammatory phase to subside. However, the patients are only seen weekly due to the lack of resources, which may affect the correct implementation of the protocol by the patient.

5.3.4 Participant compliance

It is generally accepted by therapists working in a clinical environment that patient compliance to therapy is a significant variable in the outcome of rehabilitation. A patient needs to understand the extent of their injury and the importance of rehabilitation after surgery to ensure that there is carry-over in the home environment. It is essential for the patient to understand their role in the rehabilitation programme in order to ensure success.[2] In this section, participant compliance is discussed by

looking at loss to follow-up, attendance of therapy sessions, removal of splint, and correct exercises performed.

Loss to follow-up

One of the main factors affecting the results of this study was the loss of participants to follow-up. Over the duration of the study, 39.13% of the participants were lost to follow-up. As discussed previously, out of the 46 participants that were recruited, 11 (23.91%) did not follow up at the four-week session. The participant loss to follow-up in this study is higher than reported in most other studies.

In literature, a participant loss to follow-up of between 7.7% and 15% was reported.[11,12,15] The highest participant loss to follow-up was 25% and 35%.[32,33] Although these numbers were similar to the participant loss to follow-up of 23.91% in this study, they were still lower than the participant loss to follow-up in this study.

One of the predetermined limitations for this study was based on Orkar et al[33] and Peck et al,[14] who highlight that patients usually return to normal activities at 12 weeks post-surgery. Orkar et al[33] also reveals that the loss of participants to follow-up is higher after 12 weeks, since many patients return to work from 12 weeks onwards. However, in this study, it can be seen that most of the loss to follow-up occurred prior to the 4-week post-surgery time period. Therefore, it is suggested that the reasons for loss to follow-up of patients in this environment be further investigated.

Frueh et al[8] maintain that recovery may still take place after the 12-week period. A study conducted for longer than 12 weeks might have enabled the researcher to draw additional conclusions about the difference between the two rehabilitation protocols. However, due to the large number of participants lost to follow-up prior to the 12-week time period, it is not viable to continue with the study for longer than the 12-week post-surgery time period.

The high participant loss to follow-up therefore produced fewer results for analysis. Therefore, fewer conclusions could be drawn from the results. At CHBAH, patients

are often lost to follow-up in the Hand Unit. Some come back years later with functional loss as a result of minimal to no rehabilitation.

The following assumptions may be made regarding the reason for participant loss to follow-up:

- access to resources such as transport money
- return to work
- moving to a province or country where family can look after the participant, where rehabilitation may not be available
- lack of understanding of the importance of rehabilitation

Attendance of therapy sessions

Of the 35 participants, only 34.78% attended all nine therapy sessions over the duration of the study. The remainder missed appointments, requiring the researcher to make phone calls or send a message to remind them to attend therapy. Despite being reminded to attend therapy, many participants failed to come back for follow-up treatment. It is important for patients to take responsibility for their own health and follow up with all the relevant appointments. In typical therapy situations, it is not always possible for the therapist to remind patients to attend therapy. In this environment where there is minimal administrative support compared to other more sophisticated health care systems, it becomes even more of a challenge.

Removal of splint and correct exercises

Out of the 35 participants, 45.71% removed their splints during the first four weeks post-surgery, and 71.43% of the participants adhered to the prescribed exercises. This occurred even after extensive education in the first treatment session, specifically on anatomy, surgery, and rehabilitation. When viewing the complete sample, including those who did not follow up at the first evaluation session but excluding one participant who did not return at all after the first session (n=45), 23 participants removed their splints in the first four weeks post-surgery. Fourteen (60.87%) participants were from the EAM group and nine (39.13%) were from the

EPM group. This could be because the EAM splint was easier to remove than the EPM splint.

In the first four weeks post-surgery, 45.71% of the participants removed their splints. This was less than what was reported by Sandford et al.[34] They found that 67% of their participants removed their splints during the first four weeks post-surgery. The reasons for removal of splint by the participants in this study included washing the hand and carrying out other activities of daily living. A patient risks rupture of the tendon, infection, and stiffness, should they remove their splint and use their hand in the first four weeks post-surgery.

The prevalence of tendon rupture post flexor tendon repair may be linked to participant compliance. Peck et al[14] and Harris et al[32] attribute the reported rupture rates of their study to the participant's behaviour. Peck et al[14] had a high rupture rate of 46%. They reported that one of the reasons for rupture was participant activities during the rehabilitation. This study had a rupture rate of 8.57%. Rupture rate will be discussed comprehensively in Section 5.4.3.

5.3.5 Socio-economic factors

Education, employment and transport

In this study, 51.42% of the participants completed matric, 42.86% did not finish high school, 2.86% completed primary school only, and 2.86% did not go to school at all. Regarding employment, 57.14% of the participants were employed. Of the participants, there were 73.68% in the EAM and 37.50% in the EPM group who were employed. Because of the high discrepancy of employment between the two groups, employment was identified as a potential covariate. This therefore influenced the method that was used to analyse the data, as discussed in Chapter 4.

Of the employed participants, 37.14% earned below R4500 per month, and 20% earned above R4500 per month. Transport was also investigated, and it was found that most of the participants (88.56%) make use of public transport (taxis). Eighty per cent of these participants paid between R10 and R40 for a return trip to attend therapy.

Relationship between participant compliance and socio-economic factors

The sixth objective of this study was to determine whether there was a relationship between participant compliance and socio-economic factors. Socio-economic factors are an important consideration, as these could impact on the ability of the participant to attend therapy or carry out their prescribed home programme. Patients attending therapy at CHBAH would often tell the therapists that they did not have money for transport to attend weekly therapy sessions. In some case, they would disclose that they were unable to follow the prescribed home exercise programme, as they were living by themselves or they were looking after children by themselves and therefore had to cook or clean.

Pettengill and Van Strien[2] acknowledge that socio-economic status can have a positive or negative effect on the outcome of rehabilitation due to access to resources, transport to the hospital, and income. A positive effect could be that the patient has family or friends to assist them in carrying out their daily roles, which would allow the patient to focus on their prescribed therapy programme. It could also be that they are able to afford therapy, as they may still be receiving an income while they are unable to use their hand for work purposes. A negative effect would be that the patient cannot afford transport to and from the hospital or that they are unable to carry out their roles, as they do not have the necessary support from family or friends. If patients are living by themselves, they are more likely to use their injured hand to carry out their activities of daily living. This means that it is more difficult for the patients to follow their prescribed therapy programme and adhere to rehabilitation precautions.

Socio-economic status was established by analysing data regarding education, employment, monthly income, and transport costs. This was then compared to participant compliance. Participant compliance was determined based on adherence to appointments, removal of splint during the first four weeks post-surgery, and carrying out the exercises correctly as prescribed by the researcher.

The participants who were lost to follow-up and the participants who completed the study were compared; this is illustrated in Figure 18. The participants who completed

the study showed improved compliance in terms of carrying out the exercises correctly and not removing their splint in the four weeks post-surgery. They also had a higher socio-economic status, as they had a slightly higher employment rate, mostly completed high school, earned a higher income, and could afford the transport costs. The decreased socio-economic status could thus have had an impact on the poor compliance seen in this study. For example, if participants were unemployed, they did not receive an income. Therefore, they would struggle to pay for the transport costs. Also, if participants completed high school, they could have an increased probability of being employed and therefore be able to afford to come for therapy sessions.

5.4 COMPLICATIONS POST-SURGERY AND REHABILITATION

The complications post-surgery and rehabilitation will be discussed by looking at adhesions, infection, and tendon rupture.

5.4.1 Adhesions

Tendon adhesions are the most common complications post flexor tendon repair.[29,31] This was confirmed by the results of this study, as adhesions were the most common complication, with 31.43% of the participants presenting with adhesions. Adhesions affect the ability of the tendon to glide efficiently. Therefore, the fingers cannot be flexed or extended fully. This has a negative impact on hand function.[16] Adhesions may have contributed to the poor range of movement results, which can be seen in Section 5.2, where the outcomes post flexor tendon repair are discussed.

5.4.2 Infection

Infection was the second most common complication in this study, at 20%. Infection may result from wound contamination resulting from the mechanism of injury. It may also arise from non-compliance of the patient, for example, removing the splint and exposing the new surgical wound to an unsterile environment. In this study, the participants who had an infection had either removed their splint or got the hand wet.

5.4.3 Tendon rupture

Tendon rupture causes an inability to flex the finger. If a tendon has ruptured, secondary repair will be necessary. There was a similar division of tendon ruptures between the EAM (n=2) and EPM (n=1) groups.

In this study, three (8.57%) of the participants sustained tendon rupture. Two (5.71%) of these participants were from the EAM group, and one (2.86%) was from the EPM group. One participant from the EAM group and one from the EPM group removed their splints during the four weeks post-surgery. Additionally, the participant from the EPM group carried out incorrect exercises.

From reviewed studies, it was found that there was an increased rupture rate in the EAM group participants.[7,9,10,14,15] The rupture rate in these studies was between 5% and 11%. This study is therefore in line with the reviewed studies in terms of the rupture rate. The rupture rate for the EPM groups in various studies was found to be between 2% and 7.7%.[8-11,14,15] Peck et al[14] reported a rupture rate of 46% in the EAM group.[14] Most of the reasons for rupture were due to participant behaviour. However, it must be noted that in the study by Peck et al,[14] a 2-strand modified Kessler repair and a horizontal mattress suture were used. They also stated that participants may have been reluctant to use their injured hand in the EPM group due to the rubber band traction, and that EAM participants may have taken advantage of being able to move freely.

5.5 SELECTION OF A REHABILITATION PROTOCOL

As discussed in Chapter 3, the EPM protocol is currently in use at CHBAH. There are certain factors that need to be taken into consideration in the selection of a rehabilitation protocol. The factors that had an impact on this study included the type of surgery carried out and patient compliance.

There are many factors to consider in the selection of a rehabilitation protocol. These include the type of surgery performed, knowledge about rehabilitation protocols, and patient compliance. It is critical for the therapist and surgeon to communicate about

the injury and surgery details in order to maintain safe parameters in rehabilitation.[11,24]

5.5.1 Surgical considerations

Prior to this study, the surgeons in the Hand Unit at CHBAH were using a 2-strand surgical technique in the repair of flexor tendons. This limited the therapists to the use of an EPM protocol in the rehabilitation of flexor tendon repairs. Strickland[4] asserts that a 2-strand flexor tendon repair can only withstand the force of an EPM protocol. Because of the busy work environment at CHBAH, the surgical technique and specific patient population, the rehabilitation of these patients has remained the same for many years. For this study, the surgeons in the CHBAH Hand Unit agreed to implement a 4-strand surgical repair where possible. This therefore allowed the researcher to conduct this study, comparing the EAM and EPM protocols. The surgeons in the Hand Unit at CHBAH are still using a 4-strand flexor tendon repair.

5.5.2 Rehabilitation protocols

In CHBAH, there is a high turnover of staff, and therefore the clinical experience varies. A therapist needs to have a sound knowledge of the flexor tendon anatomy, biomechanics, surgery, and rehabilitation protocols when rehabilitating patients post flexor tendon repair. This knowledge therefore will enable the therapist to effectively select an appropriate protocol. The use of protocols is important in this environment, as this provides definite guidelines for therapists with limited experience, thus creating safer parameters in the rehabilitation of patients with a flexor tendon repair. However, it is important to note that patients should be viewed as individuals and their hand deficits treated accordingly.

There are three main protocols in the rehabilitation of flexor tendon repairs, which are immobilisation, EPM, and EAM.[2] Each type of protocol has a place in rehabilitation, and it is therefore important for the therapist to know these. Globally, there has been a move towards the implementation of an EAM protocol, which can be implemented, provided a 4-strand repair has been used.[4]

5.5.3 Participant compliance

Participant compliance has been discussed in detail in Section 5.3.4. This is an important consideration, as it will have a significant effect on the outcome of rehabilitation. However, this is a complicated variable in the selection of the rehabilitation protocol, as it is not within the therapists' control.

At the initial session, it is difficult to know what the compliance of the patient might be. However, there are some factors which have been identified in this study that could assist the less experienced therapist at CHBAH in choosing the EAM versus the EPM protocol. The factors that were identified are related to the participants' socio-economic status, specifically: employment; completion of high school; increased income; and ability to afford transport costs. The therapist could ask questions relating to these factors and make an informed decision about the potential compliance of the patient. They could then decide which protocol to implement in accordance with the other factors necessary to select a rehabilitation protocol.

Should a patient be susceptible to decreased compliance, then the EPM protocol could be implemented. This would ensure safer parameters in which to carry out the prescribed home programme. Peck et al[14] emphasise this, as they state that the elastic band traction used in the EPM protocol in their study could have made the patients more reluctant to use their hand. With the EAM protocol, patients may have felt they could use their hand more freely at home, as there was no elastic band traction barrier. However, if the therapist deems the patient to be compliant, then the EAM protocol could be implemented.

5.6 CONCLUSIONS AND RECOMMENDATIONS

Although this study indicates that the outcomes are similar when implementing an EAM or EPM protocol, it is recommended that an EAM protocol be implemented at the CHBAH Hand Unit. The reasons for this are as follows:

- **Time efficiency:** Improving time efficiency is really important, as there are limited human resources and many patients with flexor tendon repair, and

other conditions, need to be seen in the CHBAH Hand Unit. At CHBAH, one of the most common hand injuries is flexor tendon injury. Patients with this injury are sent to occupational therapy one day post-surgery. The EPM protocol requires the therapist to fabricate the dorsal blocking splint and apply the leather loops and elastic. The EAM protocol only requires the splint to be fabricated. By implementing the EAM protocol, a shorter session will be required, hence allowing the therapist to see more patients.

- **Decreased use of material resources:** The EPM protocol requires thermoplastic material, velcro, leather, superglue, and elastic. The superglue, leather, and elastic required for the EPM protocol are not easily available to the therapists at CHBAH, as they are not on the government tender. The EAM protocol only requires the thermoplastic material and velcro, which is easily accessible when ordering from the government tender.
- **Surgical tendon repair:** The hand surgeons in the CHBAH Hand Unit are now making use of a 4-strand surgical tendon repair where possible. This therefore allows the therapists to implement an EAM protocol, as it is safe to do so. This study confirmed that the outcomes of the EAM protocol are similar to that of the EPM protocol and will therefore not cause harm to the patient. It is thus safe to recommend that the EAM protocol be implemented provided that a 4-strand tendon repair has been reported in the post-surgical notes. If there is no record of the surgical repair and the surgeon is unavailable for discussion, or if a 2-strand surgical repair has been used, then the EPM protocol should be implemented.

It is important to note that there is still place for both the immobilisation and EPM protocols at CHBAH. The reasons for this are as follows:

- Patient compliance. Although it is difficult to gauge the compliance level of the patient in the first therapy session, there are a number of questions that the therapist can ask to determine the patients' socio-economic status. As discussed in Section 5.5.3, this study showed that a patient's socio-economic factors might influence their compliance. The therapist should therefore ask questions about the patient's socio-economic status and home environment to

determine the patient's potential compliance. Should a patient show signs of potential decreased compliance, the EPM protocol should be implemented in order to protect the repair. Should a patient show signs of being compliant, then an EAM protocol should be considered in conjunction with the other factors necessary to select a protocol, as discussed in Section 5.5.

- Surgery is often conducted in the main theatres by the orthopaedic surgeons on call. This may result in a 2-strand flexor tendon repair. It often happens that there is very little detail recorded about the surgery in the file. In this case, the therapists should implement an EPM protocol to ensure that the repair is protected.
- Young children or patients with cognitive deficits are often referred to the CHBAH Hand Unit for flexor tendon repair surgery. If the patient is very young or has limited understanding of the protocol, surgery, and injury, then they should be immobilised in order to protect the repair.
- Complicated injuries, which involve flexor tendon repair and the management of associated injuries, should be comprehensively discussed with the surgeon who performed the surgery. The protocol can then be selected and individualised for the patient. Occasionally, the surgeon will request an immobilisation or EPM protocol, depending on the situation.
- Therapist expertise will also determine which protocol is selected. The treating therapist needs to have a sound knowledge of the flexor tendon anatomy, biomechanics, surgery, and possible protocols before treating the patient. This is not always possible in a government institution because the therapist may be newly qualified. In this case, the therapist should make use of the protocol that they are most comfortable with, in order to protect the repair. As EAM is a fairly new concept in South Africa, EPM is usually the protocol of choice, as this has been used in the past.

Overall, the outcomes of the EAM and EPM protocols were poor to fair over the three measurement periods. This could be due to a number of reasons:

- **Number of therapy appointments:** Patients at CHBAH who have had a tendon repair are only seen once a week. The main reasons for this are the

limited number of occupational therapists to attend to the patients and also the cost for the patient to attend therapy. In an ideal situation, it would be beneficial for the patient to attend therapy twice a week. This would ensure that the home programmes are being followed correctly and would allow the therapist to adjust the home programme as necessary and according to the patients' range of motion deficits. It often happens that patients come for their one-week or two-week follow-up, and they have either been performing the exercises incorrectly or not at all. At this stage, the hand may already be very stiff.

- **Type of EAM protocol:** The first week of the EAM protocol implemented in this study entailed passive flexion and active extension in the splint. The reason for this was to ensure that full passive finger flexion was achieved prior to starting active motion. Another reason for the first week of passive motion was that the researcher chose to be more cautious in the development of the protocol to prevent complications such as tendon ruptures. Based on the results of this study, the researcher is of the opinion that active motion could have been started during the first therapy session. This would have ensured that the tendon was gliding smoothly, and therefore adhesions may have been prevented. However, this would be challenging in the CHBAH environment, especially since the patients are usually seen day 1 post-surgery, and they are still in the inflammatory stage of tissue healing. Another factor to consider is the pain that is experienced by the patient so early on in their rehabilitation. Ideally, the patients should be seen approximately three or four days post-surgery, as this would allow active motion to be implemented earlier.
- **Patient responsibility:** In CHBAH, the main goal post tendon repair is to protect the repair. The reason for this is to decrease the probability of the patient requiring further surgery, as there are minimal resources for this. It is also the therapists' goal to ensure that the patient regains optimal function of their hand so that they can return to their activities of daily living.

  However, in this environment, the responsibility is often taken away from the patient and taken over by the health care professional. The reason for this is to prevent potential complications. The researcher is of the opinion that the

therapists and surgeons need to give more responsibility to the patient and therefore allow them to do more at home regarding rehabilitation. The patients are usually not allowed to remove their splints at all during the first four weeks post-surgery. On that account, they are unable to wash their hand once the wound has healed or perform rehabilitation out of the splint until it is safe to do so. This could have also contributed to the poor outcomes of this study. However, the therapist is faced with a challenge in giving more responsibility to the patient because of reduced patient compliance, which was evident in this study.

The outcomes of flexor tendon repair, especially in this context, need to be improved to ensure that patients attain optimal hand function post-surgery. It is recommended that the outcomes be improved through the following suggestions:

- Emphasis should be placed on occupational therapy training and education in evidenced-based rehabilitation of flexor tendon repairs in post-graduate hand therapy qualifications or courses.
- Increased investigation by hand surgeons and hand therapists combined into the reasons for poor outcomes following flexor tendon repair.
- Further research is necessary to determine the most suitable and effective rehabilitation protocol post flexor tendon repair. Indications for further research are discussed in Section 5.8.

5.7 STUDY LIMITATIONS

The following limitations applied to this study:

- The results of this study are only valid for patients attending CHBAH and are not applicable to patients attending other hospitals.
- The participant follow-up to therapy was poor, and therefore the final participant number was decreased, thereby limiting the conclusions made by the researcher.

- All attempts were made to standardise the study; however, there was more than one evaluator collecting the participant outcomes due to the high turnover of staff, sick leave, and availability of staff.
- There were many variables in the study which were out of the researcher's control; this therefore may have influenced the results obtained.

5.8 INDICATIONS FOR FURTHER RESEARCH

It would be worthwhile for future research to pay attention to the following:

- This study was only conducted at CHBAH, and therefore the results are only applicable to this environment. If this type of study was implemented across different institutions, the results could be generalised to a larger population.
- A study using the same methods could be conducted with a larger sample size. This would make provision for the high loss to follow-up rate and produce more results, from which conclusions could be drawn.
- Compliance of participants was not formally assessed; nonetheless, conclusions were drawn from a combination of the socio-economic factors and loss to follow-up data. It would be worthwhile to conduct a study which formally assesses patient compliance and the reasons for not returning for therapy. This could potentially assist the multidisciplinary team in increasing patient attendance and decrease the amount of patients who return to hospital years later with hand deficits.

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7 APPENDICES

7.1 APPENDIX A

- **Telephonic survey to six large Gauteng public hospitals**

Telephonic survey

The aim of the survey was to determine the flexor tendon repair rehabilitation protocols used at other large Gauteng public hospitals. The hospitals targeted included those who have orthopaedic departments where flexor tendon repair surgery is carried out.

Hospital	**Which rehabilitation protocol is used post flexor tendon repair?**	**Why is this protocol used?**	**What suture technique is used in the repair of flexor tendons?**	**Why is this suture technique used?**
Hospital Number One	The modified Kleinert protocol (EPM)	The hand surgeons request this protocol to be used.	The surgeons do not usually comment on the tendon repair. Generally a 2-strand repair.	Unable to comment on this.
Hospital Number Two	Adapted Kleinert protocol (EPM)	It works the best with patients as patients are seen once every 2 weeks.	Surgeons do not report on this.	Unable to comment on this.
Hospital Number Three	Kleinert protocol (EPM)	Has been used in the past and therefore has not been changed.	The surgeons do not regularly report on this. Generally a 2-strand repair is carried.	Unable to comment on this.
Hospital Number Four	Synergistic wrist motion splint (EAM)	This has been carried out for 1-2 years as the therapist found poor outcomes with the EPM protocols. A poor outcome mentioned was adhesions.	4-strand repair or more.	The surgeons want the strongest repair possible.
Hospital Number Five	Dorsal blocking splint with passive flexion, active extension of the fingers. (EPM)	The protocol was started in the past 3 years and carried on with.	Modified Kessler. 4-strand repair	The occupational therapists requested a 4-strand repair.
Hospital Number Six	Duran or Kleinert protocol (EPM)	Seems to be effective	Does not know what surgeons do in terms of technique.	Unable to comment on this.

7.2 APPENDIX B

- **Informed Consent**

PATIENT / PARTICIPANT'S INFORMATION LEAFLET & INFORMED CONSENT FORM FOR INTERVENTION RESEARCH

STUDY TITLE: A COMPARISON OF THE OUTCOMES OF TWO REHABILITATION PROTOCOLS AFTER FLEXOR TENDON REPAIR OF THE HAND AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Principal Investigators: Roxanne Wentzel

Institution: University of Pretoria

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):

Daytime numbers: 011-933-9953

Afterhours: 072-380-6492

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

				:
Day	**Month**	**Year**		**TIME**

Dear Patient

INTRODUCTION

You are **invited** to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. The doctor that operated on your hand is fully aware that we are conducting the study. He is happy for you to be part of the study and will see you at your next follow up appointment at the hand clinic.

WHAT IS THE PURPOSE OF THE RESEARCH STUDY?

You have had flexor tendon repair and the investigator would like you to consider taking part in the research that will determine the best of two splints and exercise programs. All patients who have had an operation such as yours will be asked to take part in this study. This study will determine which type of exercise is better to use after this type of operation.

If you participate in the study you will receive either the active motion protocol or the passive motion protocol. This means that you will either receive a splint with elastic bands attached to it or you will receive one that does not have elastic bands. If you have a splint with elastic bands, you will be taught how to do your exercises in the splint. If you receive the splint without elastic bands, you will be taught different exercises.

WHAT IS THE DURATION OF THIS RESEARCH STUDY?

If you decide to take part in the study you will be one of approximately 46 patients. The study will last for up to 4 months. You will be asked to visit the investigator 7 times as per the following schedule: day 1(today), week 1, week 2, week 3, week 4, week 8 and week 12 after surgery. Each time that you come for a visit, you will receive your usual therapy. If you are not part of this study, you will still have to come for therapy at these times after surgery.

DESCRIPTION OF PROCEDURES

At the assessment sessions you will be asked questions about your injury, your work, how well you can use your hand and the movement in your hand will be measured. Each assessment session will take 20 minutes, thereafter you will have a treatment session which will help you to recover as much hand function as possible. All efforts will be made to ensure your assessment session is on the same day as your regular doctor or therapy appointment.

HAS THE RESEARCH STUDY RECEIVED ETHICAL APPROVAL?

This research study Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 3541677 / 012 3541330 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors and healthcare professionals in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT IN THIS RESEARCH STUDY?

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to therapy or other medical care. The investigator retains the right to withdraw you from the study if it is considered to be in your best interest. If it is detected that you did not give an accurate history or did nor follow the guidelines of the trial and the regulations of the trial facility, you may be withdrawn from the trial at any time.

IS ALTERNATIVE TREATMENT AVAILABLE?

If you decide not to take part in this study your therapist will provide you with the standard rehabilitation protocol used at Chris Hani Baragwanath Academic Hospital for patients who have had your type of surgery.

MAY ANY OF THESE RESEARCH STUDY PROCEDURES RESULT IN DISCOMFORT?

You may experience the normal discomfort associated with your injury during the measurement of the movement of your hand.

WHAT ARE THE BENEFITS TO YOU?

As a participant in this research study, there may be no direct benefit for you; however, information from this study may benefit other people now or in the future.

WHAT ARE THE RISKS INVOLVED IN THIS RESEARCH STUDY?

There are known risks at this time to participate in the study.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS RESEARCH STUDY?

None.

INSURANCE AND FINANCIAL ARRANGEMENTS

There will be no payments made to you for participating in this study.

SOURCE OF ADDITIONAL INFORMATION

For the duration of the trial, you will be under the care of Roxanne Wentzel. If at any time between your visits you have any questions during the trial, please do not hesitate to contact her. The 24-hour telephone number is 0723806492/0119339953, through which you can reach her or another authorised person.

CONFIDENTIALITY

All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information which identifies you as a patient in this trial.

INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, Roxanne Wentzel about the nature, conduct, benefits and risks of clinical study. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the clinical study.

I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

I may, at any stage, without prejudice, withdraw my consent and participation in the study. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Patient's name _____
(Please print)
Patient's signature _____ Date _____

I, Roxanne Wentzel herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above study.

Investigator's name _____
(Please print)
Investigator's signature _____ Date _____

Witness's name* _____Witness's signature _____ Date _____
(Please print)

VERBAL PATIENT INFORMED CONSENT (applicable when patients cannot read or write)

I, the undersigned, Roxanne Wentzel, have read and have explained fully to the patient, named …….. and/or is/her relative, the patient information leaflet, which has indicated the nature and purpose of the study in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the study and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing his/her subsequent injury attributable to the drug(s) used in the clinical study, to which he/she agrees.

I hereby certify that the patient has agreed to participate in this study.

Patient's Name _____
(Please print)
Investigator's Name _____
(Please print)
Investigator's Signature _____ Date _____

Witness's Name _____Witness's Signature _____ Date _____
(Please print)

(Witness - sign that he/she has witnessed the process of informed consent)

7.3 APPENDIX C

- **Data collection form, verbatim explanation to participant by assessor and verbatim explanation to the assessors by researcher**

RESEARCHERS PARTICIPANT EVALUATION SHEET (Page 1 of 2)

Patient evaluation form

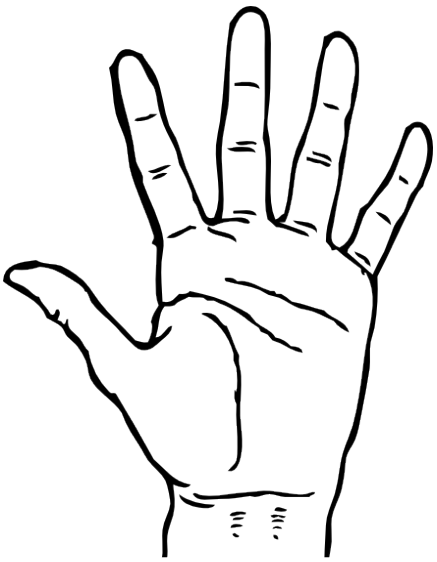
Respondent number | | |

Age | | |

Gender

Female	Male

Home language _____
Date of injury _____
Date of surgery _____
Type of repair _____
Date of referral to OT _____
Mechanism of Injury _____



Position and state of injury
Notes:_____

Hand injured

Right	Left

Dominance

Right	Left	Ambidextrous

Smoker

Yes	No

Tendons injured

	FDS	FDP	Zone
IF			
MF			
RF			
LF			

Associated Injury

FCU	FCR	FPL	Median Nerve	Ulnar Nerve	Digital Nerve	Fracture	Vascular
						_____	_____

RESEARCHERS PARTICIPANT EVALUATION SHEET (Page 2 of 2)

Therapy:

Protocol

Passive mobilisation protocol	Active mobilisation protocol

Self-removal of splint

Yes	No

Adherence to appointments

Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 10	Week 12

Post-operative complications:

Rupture	Infection	Adhesions	Contracture	Re-operation

Demographics

Employment

Manual labour	Domestic worker	Desk Job	Teller	Packer	Business women/man	Other (specify)	N/A

Income per month

<R500	R500-R1500	R1500-R3000	R3000-R4500	R4500-R5500	>R5500	N/A

Education

Primary school	High school – not complete (state grade)	High school complete	Tertiary education

Transport type

Taxi	Bus	Own car	Walk	Other

Transport cost to and from the hospital in total

Free	<R10	R10-R15	R15-20	R20-30	R30-R40	>R40

Language

	English	Afrikaans	Zulu	Tswana	Other
Read					
Write					

ASSESSORS PARTICIPANT EVALUATION SHEET (Page 1 of 2)

Week 4: Post-surgery
Respondent number: | | |

1. Position of hand and wrist on peg board (Record right/left hand next to affected/unaffected hand)

UNAFFECTED HAND (_____)		**AFFECTED HAND (_____)**	
Position of peg	**Peg hole number**	**Position of peg**	**Peg hole number**
Dorsal aspect of wrist		Dorsal aspect of wrist	
Volar aspect of wrist		Volar aspect of wrist	
Dorsal aspect of hand		Dorsal aspect of hand	
Palmar aspect of hand		Palmar aspect of hand	

2. Active range of motion of the affected hand

	IF			MF			RF			LF		
	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total
MP joint												
IP joint												
DP joint												
TAM (flex-ext)												
Tip to palm												
Tip to table												

3. Active range of motion of the unaffected hand

	IF			MF			RF			LF		
	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total
MP joint												
PIP joint												
DIP joint												
TAM (flex-ext)												
Tip to crease												
Tip to table												

ASSESSORS PARTICIPANT EVALUATION SHEET (Page 2 of 2)

Week 8: Post-surgery

1. Active range of motion of affected hand

	IF			MF			RF			LF		
	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total
MP joint												
IP joint												
DP joint												
TAM (flex-ext)												
Tip to palm												
Tip to table												

Week 12: Post-surgery

1. Active range of motion of affected hand

	IF			MF			RF			LF		
	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total	Ext	Flex	Total
MP joint												
IP joint												
DP joint												
TAM (flex-ext)												
Tip to palm												
Tip to table												

Verbatim explanation of assessment provided to assessors to use during data capturing sessions to the participant

(Assessors actions are in brackets and italics)

I am going to measure how much movement is in your hand. The reason for doing this is for the research which you have agreed to participate in. If you have any questions while I am measuring your hand then please stop me.

ONLY AT WEEK 4: First, I am going to measure the movement of your uninjured hand. I would like you to place your uninjured hand on its side on this pegboard.
(Assessor to then correctly place the uninjured hand on the pegboard and record the position of hand on the data collection sheet)
Please bend your fingers to close the hand as much as possible.
(Assessor to use the finger goniometer to measure flexion of all the fingers of all the joints)
Now, open your hand and make the fingers as straight as possible.
(Assessor to use the finger goniometer to measure extension of all the fingers of all the joints)

WEEK 4, 8, 12: I am now going to measure the movement of your injured hand. I would like you to place your injured hand on its side on this pegboard. I am going to position your hand and put these pegs in place so that each time you come back, we can put the hand in the same position.
(Assessor to then correctly place the injured hand on the peg board and record the position of hand on the data collection sheet)
Please bend your fingers to close the hand as much as possible. If you are getting tired at anytime then please tell me so that you can take a break.
(Assessor to use the finger goniometer to measure flexion of all the fingers of all the joints)
Now, open your hand and make the fingers as straight as possible. If you are getting tired at anytime then please tell me so that you can take a break.
(Assessor to use the finger goniometer to measure extension of all the fingers of all the joints)

WEEK 4, 8, 12: I am now going to measure how much your fingers close with this ruler. Close your hand as much as possible. If you are getting tired at anytime then please tell me so that you can take a break.
(Assessor to use ruler to measure pulp to palm)

WEEK 4, 8, 12: We are finished with that assessment. Please place the back of your injured hand on the table like this.
(Assessor to demonstrate)
Straighten your fingers as much as possible to touch the table with your fingernails. If you are getting tired at anytime then please tell me so that you can take a break. I am going to measure the distance between your fingernail and the table.
(Assessor to stabilise the patients' wrist and use the ruler to measure from fingertip to table)

The assessment is now finished. Thank you.

Verbatim explanation of assessment to the assessors by the researcher

You have been given a sheet containing the verbatim explanation of assessment to the participant. Please use this each time that you assess a participant. You need to complete the assessment with each participant at week 4, 8 and 12 post-surgery. Please place the data collected on the data collection form. You will keep this data collection form until week 12, thereafter you can give this form to me.

When assessing the participant:

Place the participants' uninjured hand onto the pegboard, on the ulnar aspect of the hand. Take the four pegs, and place one at the dorsum of the wrist, the volar aspect of the wrist, the dorsum of the hand and the palmar aspect of the hand. Record the peg placement on the data collection sheet. Then ask the patient to flex their fingers, place the metal goniometer on the dorsum of the MCP joint and record the measurement. Repeat this for the MCP, PIP and DIP joints. The goniometer must be placed on the dorsum of the joint for every measurement. Then ask the patient to extend their fingers, place the metal goniometer on the dorsum of the MCP joint and record the measurement. Repeat this for the MCP, PIP and DIP joints. You will only measure the uninjured hand at the 4 week assessment.

Then place the participants' injured hand onto the pegboard, on the ulnar aspect of the hand. Take the four pegs, and place one at the dorsum of the wrist, the volar aspect of the wrist, the dorsum of the hand and the palmar aspect of the hand. Record the peg placement on the data collection sheet. Each time that the patient returns, you will place their hand in the same position on the peg board. Then ask the patient to flex their fingers, place the metal goniometer on the dorsum of the MCP joint and record the measurement. Repeat this for the MCP, PIP and DIP joints. The goniometer must be placed on the dorsum of the joint for every measurement. Then ask the patient to extend their fingers, place the metal goniometer on the dorsum of the MCP joint and record the measurement. Repeat this for the MCP, PIP and DIP joints, with. This measurement will be carried out for the injured hand at 4, 8 and 12 weeks post-surgery.

With the participants' hand on the pegboard, ask them to make a fist. You will then take the ruler and measure the distance from the pulp of the finger to the distal palmar crease for each finger. Place these measurements on the data collection sheet. This measurement will be carried out for the injured hand at 4, 8 and 12 weeks post-surgery.

Then ask the participant to move their hand off the peg board and to place the back of their injured hand onto the table. The participant must try to make their fingers straight to touch the table. You must stabilise the participants' wrist on the table with your hand and then take the measurement from the fingernail to the table, using a ruler. Place these measurements on the data collection sheet. This measurement will be carried out for the injured hand at 4, 8 and 12 weeks post-surgery.

7.4 APPENDIX D

- **Detailed rehabilitation protocols**

Early active mobilisation protocol:

Period post-surgery	Splint	Splint Wearing Schedule	Exercise
Day 1	Dorsal blocking splint Wrist: neutral (0°) MCP joints: 60° flexion IP joints: full extension	Full time wear	Passive PIP and DIP joint flexion, active PIP and DIP joint extension within splint.
Week 1	As above	As above	Active PIP joint flexion to 30°, active PIP joint extension within splint. Synergistic wrist and finger motion during therapy sessions.
Week 2-3	As above	As above	Active PIP joint flexion and extension within splint. Synergistic movement within splint, removing palmar block.
Week 4-6	As above	Night time wear and for protection in busy places	Protected active motion out of splint.
Week 6-8	As above		Isometric strengthening
Week 8-12	N/A	Remove splint	Concentric strengthening

Early passive mobilisation protocol:

Period post-surgery	Splint	Splint Regimen	Exercise
Day 1	Dorsal blocking splint Wrist: 0-10° flexion MCP joints: 60° flexion IP joints: full extension A rubber band traction will be attached to the fingernails.	All time wear	Passive PIP and DIP joint flexion by means of the rubber band traction, active PIP and DIP joint extension. All exercise within splint.
Week 1	As above	As above	
Week 2-3	As above	As above	Passive PIP and DIP joint flexion by means of the rubber band traction, active PIP and DIP joint extension. All exercise within splint. Synergistic wrist and finger mobilisation during therapy sessions.
Week 4-6	As above	Night time wear and for protection in busy places	Protected active mobilisation out of splint.
Week 6-8	As above	As above	Isometric strengthening
Week 8-12	N/A	Remove splint	Concentric strengthening

7.5 APPENDIX E

- **Home exercise programmes for both rehabilitation protocols**

Flexor tendon repair home exercise programme

Early active motion protocol (Page 1 of 2)

Patient Name: _____

Date: _____

Your injury:

You have had a flexor tendon repair. The flexor tendons are part of the muscle which bends the fingers and allows you to close your hand. Before the operation, you could not close some of the fingers as the tendons were broken. The doctor has now fixed the tendon BUT it is not strong. There are rules to follow to make sure that the tendon can heal and your hand can get stronger. It is very important to follow these rules carefully while you are at home.

Rules to follow at home:

X DO NOT remove your splint

X DO NOT pick up anything with your injured hand

X DO NOT get your splint or injured hand wet

X DO NOT place your splint near the fire, stove, heater or hot water

✓ DO your exercises every hour that you are awake

✓ ALWAYS have the strap around your fingers unless you are exercising

✓ Come to every appointment that your therapist gives you

Exercises to follow:

In the FIRST week

- Remove the strap that goes around your fingers
- Use your other hand to bend the fingers of your injured hand
- Then take your other hand away, and make your fingers straight to touch the inside of the splint
- Repeat this 10 times EVERY hour

Flexor tendon repair home exercise programme

Early active motion protocol (Page 2 of 2)

In the SECOND week

- Remove the strap that goes around your fingers
- Place your other hand in your palm of your injured hand, with the little finger on the plastic bar.
- Bend your injured fingers to touch the first finger of your other hand, then make the fingers straight to touch the inside of the splint.
- Repeat this 10 times EVERY hour
- When you are finished, put the strap back on around your fingers.

In the THIRD week

- Remove the strap that goes around your fingers
- Place your other hand in your palm of your injured hand, with the little finger on the plastic bar.
- Bend your injured fingers to touch the second finger of the other hand, then make the fingers straight to touch the inside of the splint
- Repeat this 10 times EVERY hour
- After that exercise, remove the plastic bar from the splint. Move your wrist down and relax the fingers so that they are straight. THEN move the wrist up and relax the fingers so that they bend.
- Repeat this 10 times every hour. When you are finished, put the plastic bar back on and place the strap around your fingers.

Flexor tendon repair home exercise programme

Early passive motion protocol (Page 1 of 1)

Patient Name: _____

Date: _____

Your injury:

You have had a flexor tendon repair. The flexor tendons are part of the muscle which bends the fingers and allows you to close your hand. Before the operation, you could not close some of the fingers as the tendons were broken. The doctor has now fixed the tendon BUT it is not strong. There are rules to follow to make sure that the tendon can heal and your hand can get stronger. It is very important to follow these rules carefully while you are at home.

Rules to follow at home:

X DO NOT remove your splint

X DO NOT pick up anything with your injured hand

X DO NOT get your splint or injured hand wet

X DO NOT place your splint near the fire, stove, heater or hot water

✓ DO your exercises every hour that you are awake

✓ ALWAYS have the strap around your fingers unless you are exercising

✓ Come to every appointment that your therapist gives you

Exercises to follow:

- Remove the strap that goes around your fingers
- Pull the elastic around the back of your hand and put it behind the safety pin
- Your fingers should be in a bent position
- Make the fingers straight to touch the inside of then splint, then relax
- Repeat this 10 times EVERY hour

7.6 APPENDIX F

- **Declaration for the storage of information, the declaration of Helsinki and the ethics clearance certificate**

Protocol No. 314/2014

Principal Investigator(s) Declaration for the storage of research data and/or documents

I, the Principal Investigator(s), Roxanne Wentzel

of the following study titled: A comparison of the outcomes of two rehabilitation protocols after flexor tendon repair of the hand at Chris Hani Baragwanath Academic Hospital

will be storing all the research data and/or documents referring to the above mentioned study at the following address: 24 22nd Street, Parkhurst, Johannesburg, 2193.

I understand that the storage for the above mentioned data and/or documents must be maintained for a minimum of 15 years from the commencement of this study.

START DATE OF STUDY: 01/01/2014

END DATE OF TRIAL/STUDY: 31/12/2015

UNTIL WHICH YEAR WILL DATA WILL BE STORED: 2030

Name Roxanne Wentzel

Signature 

Date 31 July 2014

Special Communication

World Medical Association Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington, DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

    Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

    Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

    When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

    All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

    The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

    In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

    The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it

may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

    After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

    All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

    Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

    Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

    and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

    Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

ARTICLE INFORMATION

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Online-Only Content: Audio podcast is available at www.jama.com.

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314/2014 Wentzel	*Initial Application*
Protocol Number	314/2014
Protocol Title	A COMPARISON OF THE OUTCOMES OF TWO REHABILITATION PROTOCOLS AFTER FLEXOR TENDON REPAIR OF THE HAND AT CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL. (
Principal Investigator	Miss Roxane Wentzel **Tel:** 723806492 **Email:** roxanne@wentzel.co.za **Dept:** Occupational Therapy
Sub Investigators	Wentzel, Roxane R~Rudman, Elsje EMP~
Study Degree	Masters in Occupational Therapy
Sponsor/Company	N/A
Contact Details of Sponsor	**Contact Person:** None **Email:** None **Tel:** None **Cell:** None
Postal Address of Sponsor	None
Meeting Date	20-Aug-2014
Duration of Study	**Start Date:** 01-Jan-2014 **End Date:** 31-Dec-2015 **Duration:** 2 years
Documents submitted electronically	04-Aug-2014

Recommendations of Prelim meeting 22 August 2014

- The researcher need not attend the meeting.
- Recommend approval at the Main Committee meeting, on condition that permission be obtained from Baragwanath Academic Hospital.

Minutes of meeting 27 August 2014

- Provisionally approved, pending permission be obtained from Baragwanath Academic Hospital.
- Approval can then be given for 2 years.
- Votes 15/15

Send to Researcher √

Do not send to Researcher ✖