Early Active Mobilization of Tendon Transfers

Santosh Rath

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Back cover	:	File photograph of Minati Mishra, 14 year old girl with severe deformities due to childhood Leprosy. More than 2 years of her youth she spent in the hospital for multiple operations and physical rehabilitation. Minati along with many other patients who had to stay away from home, family, school and work for prolonged periods of time were the inspiration for this research to reduce morbidity and earlier return home. Printed with permission.
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Early Active Mobilization of Tendon Transfers

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For Alison my wife, Ritu and Nita my daughters

For their encouragement and

For tolerating long period of my absence each month for 12 years

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CHAPTER 1

General Introduction

Introduction

Leprosy, also known as Hansen's Disease, has been known since biblical times.. The causative organism Mycobacterium leprae is unique among bacteria in that it has an affinity to involve, infect and destroy peripheral nerves, especially those of the limbs. The disability problems in Leprosy are mainly due to the nerve trunks affected by the disease resulting in diminution or loss of sensation, paralysis of muscles producing deformities and autonomic nerve function impairment leading to loss of sweating, dryness and cracks in the hands and feet. The affected nerve from the initial stage of involvement advances to the stage of damage and finally to a stage of destruction. In the stage of initial involvement, the nerves are thickened, tender, and painful but have no loss of function. In the subsequent stage of damage there is loss of sweating and sensibility, muscle weakness or complete paralysis. These two stages of nerve involvement and damage are amenable to prompt and adequate treatment by multi drug therapy (MDT) and steroids and recovery of lost nerve functions in possible. In the subsequent stage of nerve destruction, the involved nerve is completely damaged and cannot recover function to any useful level with all available treatment. This stage is diagnosed when the nerve has been completely paralyzed for at least one year.

Leprosy involves three kinds of peripheral nerves. They are (1) dermal nerves, which are fine nerves in the skin; (2) cutaneous nerves, which are thicker nerves that are palpable under the skin and (3) major nerve trunk, which are large nerves of the limbs. From the point of view of disability and deformity, damage to the nerve trunks is far more important than damage to dermal or cutaneous nerves.[1] The nerve trunks commonly involved in Leprosy are the ulnar, median and occasionally the radial nerve in the upper extremity, the common peroneal and the posterior tibial nerve in the lower extremity. The ulnar nerve damage results in claw finger deformity, median nerve damage produces a claw thumb deformity and radial nerve paralysis leads to a drop wrist. The common peroneal paralysis produces a drop foot and the claw toes are produced by posterior tibial nerve damage. Loss of sensation, dryness of the palm and sole and deformities are the primary impairments of nerve damage. Secondary impairments are those that occur as a consequence of primary impairments. The Secondary impairments commonly seen in the hands and feet are cracks, ulcers, infection, joint stiffness, contractures, shortening of toes or fingers, mutilation and amputations of the hand or foot.[1]

The devastation to the limbs in Leprosy is a result of nerve damage, irreversible paralysis, loss of sensation and sweating. Poor care of these insensate paralyzed parts lead to repeated physical insult, worsening of the deformity, festering ulceration and amputations. These grotesque physical deformities are one of the main cause of stigma and ostracization of the people affected with Leprosy. Early diagnosis of disease, identification of nerve function impairment and prompt administration of MDT and steroids along with disability prevention programme to avoid secondary impairment can limit and reverse events that lead to irreversible limb mutilation.

In countries where this disease is endemic, Leprosy is the most common cause of peripheral neuritis[2] and a major source of paralytic deformities. World Health Organization (WHO) classified disability due to nerve involvement in Leprosy into three grades.[3] Grade 0 : the nerves are thickened/tender but has no motor or sensory deficit; Grade 1: Loss of sweating and sensibility but no visible deformity; Grade 2 : visible deformities of hands, feet or face. At present in spite of early diagnosis, MDT and adequate management of nerve function impairment with steroids, nearly 3% of new cases still progress to nerve destruction and Grade 2 deformities.[4,5] It is estimated that there are to be around 3 million persons in the world with Grade 2 deformities due to Leprosy and that about 60% of them live in India.[6] Prevention of secondary impairment and deformity correction by reconstructive surgery can restore form and function and erase the stigma of the disease.

Historically, patients with Leprosy were isolated and segregated in colonies. These persons lived as social outcasts in these communities which were financially supported by charities and government. Most others survived by begging and charity. They had limited or no economic activity and earning. The situation was hopeless as the disease was incurable and lead to grotesque deformities. The situation changed with the advent of dapsone as an effective drug against Leprosy in the late 1940s and then MDT ushered the concept of complete cure of Leprosy for the first time in the history of mankind. The deformities however persist for the rest of the patient's life. Soon after widespread introduction of dapsone therapy, Brand in the early 1950s tried established tendon transfer techniques for correction of deformities of hands and feet in Leprosy and demonstrated that they were equally effective, ushering a new era of corrective surgery in Leprosy and hopes of effective rehabilitation of these unfortunate victims of this fell disease.

The evolution of tendon transfer techniques for limb deformities was one of the remarkable advances in reconstructive surgery of the extremities and the principles were developed over 200 years along with those for flexor tendon grafting. Adamson & Wilson[7] in a historical review of flexor tendon grafting record that one of the earliest tendon transfers was described by Velpeau in 1839 and Malgaigne in 1845 for reconstruction of severed tendons. They transferred adjacent intact functioning tendons to restore functions to the severed tendons. In 1882, Nicoladoni applied the principle of transfer of a tendon of an intact muscle to compensate for the loss of function due to paralysis of one or more paralytic muscles in the lower leg. These principles were subsequently applied for treatment of paralysis of a radial nerve paralysis in 1898. In 1911, Lange reported his experience of more than 1000 tendon transfers in the arm and leg. In a landmark article, Bunnell[8] described his principles of tendon surgery which included tendon transfer to the hand. Kirschner and Stoeffel in Germany, Thomas and Jones in England, and Mayers in the United States of America utilized and improved on these early principles of tendon transfer for treating motor loss due to poliomyelitis. These pioneers expanded on the application of these techniques for deformity correction and restoration of function for other paralytic conditions, such as nerve injuries, muscle loss and for patients with central nervous system disorders. With the control of poliomyelitis in the developed world, the most common indication for tendon transfers was for correction of residual deformities following peripheral nerve injuries.

Brand in Christian Medical College, Vellore, India, applied the principles of tendon transfers for surgical correction of Leprosy deformities and performed the first claw hand correction in 1948.[9] Riordan in 1953[10] published a detailed paper on surgical correction of hand deformities in Leprosy and pioneers like Fritschi, Antia, Srinivasan and Palande in India carried out thousands of tendon transfers for Leprosy deformities in the past following decades. These outstanding surgeons demonstrated the long term reliability of tendon transfer for Leprosy deformities and the added benefit of reducing hand and foot ulcerations following deformity correction.

This thesis focuses on tendon transfers for claw finger hand, foot drop and thumb paralysis in Leprosy. Tendon transfer is done most commonly in Leprosy patients for claw-finger correction. The standard donor tendons for claw deformity correction usually transferred for this purpose are those of the extensor carpi radialis longus (ECRL), the flexor digitorum sublimis (FDS), or the palmaris longus. The transferred tendon is inserted to one of the following sites; the lateral band of the dorsal extensor expansion, the proximal phalanx, the proximal annular pulleys of the flexor sheath and the interosseous tendons. Insertion of transfer to the proximal annular pulley for claw deformity correction is known as the lasso procedure and was first described by Zancolli.[11] The annular pulley insertion avoids post-operative proximal interphalangeal joint hyper-extension which is a problem with lateral band insertion. The FDS donor tendon split into 4 slips (for 4 digit correction) has ample length for a lasso procedure and a Pulvertaft weave[12] for a strong insertion.

Foot drop deformity is the second most common deformity in Leprosy. The standard procedure for foot drop correction is to transfer the tibialis posterior tendon routing it to the dorsum of the foot passing anterior to the ankle joint either by a circumtibial or by interosseous route. The transfer is inserted either to the tarsal bones[13], or split into two slips for insertion to the tendon of extensor hallucis longus and extensor digitorum longus.[14]

Loss of abduction-opposition of the thumb due to lower median nerve paralysis is the third most common condition in Leprosy requiring a tendon transfer. The tendon of extensor indicis or one of the tendons of FDS is used as the donor. The FDS of ring finger is a long and stout tendon and considered better suited for attachment compared to that of the extensor indicis proprius. The tendon transfer is routed around the pisiform and inserted to the abductor pollicis brevis tendon and the ulnar aspect of the metacarpophalangeal joint capsule to enhance the strength of attachment.

It is the usual practice after tendon transfer surgery to immobilize the part with a plaster of Paris cast for 3 weeks for the hand and 4-6 weeks for the feet[14-17] to allow firm union of the transferred tendon attachment at its new site of insertion. Subsequent to removal of cast, the postoperative therapy is needed for 4 to 6 weeks. The rehabilitation time for each procedure is the time from surgery till the part is allowed unrestricted use and this usually extends from 2 to 3 months. The period of postoperative immobilization of tendon transfer usually contributes to 40- 50% of the rehabilitation time.

The scientific basis of immobilizing tendon transfers was debated and the possibility of early mobilization of tendon transfer was considered. The concept of early active mobilization following primary flexor tendon repair was reviewed and the principles were adopted for trial of early active mobilization following tendon transfer surgery. We proposed and tested the hypothesis "that immediate active motion protocol after tendon transfer would achieve outcomes similar to those of the standard practice of immobilization, provided the tendon insertion is protected during mobilization".

Definition

For our purposes "early active mobilization" is defined as: starting post-operative therapy for re-education of the transfer in the first week of surgery.

Principles of early postoperative active mobilization

The principle of early active mobilization of tendon transfers is inspired by the experience of early active mobilization of flexor tendon repairs in the hand, which has been proven to be safe and to significantly improve the outcomes when certain specific conditions are met. For example, flexor tendon repairs in the hand were traditionally immobilized postoperatively for 3 -4 weeks to allow for sound healing of the repair site. Such immobilization was associated with slower return of strength, adhesion formation[18] and a poor tendon glide. This led to the development of early mobilization programs that allows healing but decrease adhesion formation.[18,19] Laboratory studies demonstrated that tendon repairs followed by early mobilization programme healed faster, gained tensile strength quicker, and had better excursion because of less adhesion formation than unstressed repairs.[20,21] Immobilized tendons heal by extrinsic mechanism and the strength of the repair decreases as early as 5th post operative day as tendon ends soften with the inflammatory reaction. In contrast, tendons repairs mobilized early heal through an intrinsic mechanism and steadily gains strength following repair.[22] It is even recommended that repairs be mobilized as early as possible within a day or two of repair.[23]

The strength of the tendon repair is enhanced by sutures of higher tensile strength and multiple strand suture technique making early mobilization relatively safe in compliant patients. Various early mobilization protocols have been described:

(a) Kleinert dynamic flexion using rubber band[20-21] and active extension;

(b) Combination of passive and active flexion[23-24] and finally

(c) Early active mobilization protocols 48 hours after surgery.[25]

All these protocols share the same common principles of mobilization in a restricted range and protection of the site of tendon repair from stretch or dehiscence by the use of a dorsal splint. The main difference is the amount of tension on the sutured tendons which is low in (a) and (b) and much higher in (c).[26,27] The post-operative therapy principles for flexor tendon repair enumerated above were incorporated for early active mobilization of tendon transfers.

Research location and background

The research presented in the thesis was performed in Orissa; an eastern state in India, with a population of 38 million. The state had a very high prevalence rate of Leprosy in 1990.[28] Intensive state wide case detection and treatment with MDT carried out under the auspices of National Leprosy Eradication Programme and supported by organizations like LEPRA, DANIDA etc. achieved dramatic results and elimination of Leprosy as a public health problem achieving prevalence of less than 1 in 10 000 by in June 2006.[29] The estimated number of Leprosy-affected persons with visible Grade 2 deformities in Orissa in mid 1990 was about 42,000.[28] This included the population of old and new cases of deformities, ulcers and lagophthalmos. In 1994, the LEPRA Society, a British non-governmental organization (NGO), set up a Leprosy reconstructive surgery unit in Muniguda, South Orissa in association with HOINA, a NGO to offer corrective surgery. This is a tribal and extremely poor rural area with hardly any civic amenities or health facilities. The reconstructive surgery services were provided free of cost to the Leprosy affected people and the patients stayed in the institution for the entire period from preoperative care till discharge form postoperative rehabilitation therapy. This was deemed necessary due to the vast distances they had to travel from their homes for the treatment and a lack of physiotherapy facilities nearer their homes for postoperative care. In spite of the facilities offered, not all affected persons were willing to avail the opportunity of surgical correction of their deformities and improvement of their disabilities because of the prolonged period of hospital stay and the resulting loss of earnings. Further, the prolonged period of stay in the institution escalated the costs of running the programme considerably. The loss of earning to the patient and the costs to the provider became a major hindrance to the success of the surgical program warranting a review of the protocols in use with an attempt to reduce rehabilitation time and thus the costs to the patients and the health care provider.

In the pre-MDT era, a good proportion of persons with Leprosy-related deformities and disabilities were living on institutional or individual charity and had no gainful economic activities and earnings. In that period, the loss of work following tendon transfer surgery for deformity correction was therefore not a major issue for these individuals. Secondly, the institutions offering corrective surgery were leprasaria committed to keep patients for a long time, if not for the rest of their lives, and patient turn over was not a major concern. With the intensified Leprosy programme and universal use of MDT, very large numbers of Leprosy patients were cured of their disease in a comparatively short period of six months to one year and they continued to be gainfully employed. For them the long duration of rehabilitation time associated with tendon transfer and loss of earning became a major deterrent for accepting surgery, even though when offered free of cost. Lack of social security or loss of work compensation imposed a great financial burden to the individual to undergo Leprosy deformity correction.

Aim of this project

The aim of this project was to test the safety, efficacy and reliability of early postoperative active mobilization after tendon transfers surgery and compare the outcomes with those after conventional post-operative immobilization in Leprosy patients. Treatment for paralysis of abductor pollicis brevis in isolated median nerve paralysis provided a clinical setting where one tendon of flexor digitorum sublimis, was transferred to replace a single lost function: abduction of the thumb at the basal joint. Encouraged by the good results and assured by the safety of early mobilization of opposition tendon transfer, a protocol was developed for early active mobilization following correction of claw finger deformity of digits and then for tendon transfer to correct foot drop. These three deformities patterns constitute to over 90% of Grade 2 deformities in Leprosy requiring a tendon transfer. After establishing the therapy protocols for each tendon transfer, randomized clinical trials were conducted with the two most commonly performed tendon transfers, claw fingers deformity of the hand and foot drop deformity. In these trials outcomes of early mobilization versus immobilization of tendon transfers were compared.

In chapter 2, the findings of a prospective cohort study on an early active motion protocol for opposition transfer using flexor digitorum sublimis of the ring finger is reported. This initial study investigated the safety of early mobilization in 5 hands with meticulous daily assessment and documentation for tendon insertion pullout. The results of the opposition transfer with early mobilization were compared with those of a historical cohort of similar transfers with 3 weeks of postoperative immobilization.

Encouraged by the results reported in Chapter 2, the concept was applied to correction of claw finger deformity of digits. In Chapter 3, the results of a prospective cohort study of 32 hands with early active motion protocol for claw deformity correction with the lasso procedure using flexor digitorum sublimis of the middle finger is presented. Outcomes of this study are compared with a historical cohort of similar transfers immobilized for 3 weeks in regard to safety and functional results. The benefits of early active mobilization are discussed.

The same concepts of early active mobilization were then applied in a prospective cohort study on 21 consecutive patients with tibialis posterior transfer for foot drop correction. Early active mobilization was begun on the 5th postoperative day and outcomes were compared to those obtained in a historical cohort using postoperative immobilization for 4 weeks. The findings of early active mobilization for foot drop are presented in Chapter 4.

Based on the positive results from the prospective cohort studies, in Chapter 5, a randomized clinical trial was conducted in 50 claws finger hands to examine the hypothesis of early active mobilization vs. immobilization. This allowed comparison of post-operative pain, swelling, patients' related outcomes, and restoration of grip and pinch power.

Finally, in Chapter 6, a randomized clinical trial of early mobilization vs. immobilization following tibialis posterior transfer was carried out in 24 patients. This study allowed detailed comparison of the outcomes of early mobilization vs. immobilization for foot drop correction with tibialis posterior transfer.

In Chapter 7, the Discussion, the overall findings of early postoperative active mobilization of tendon transfer to the hand and foot is summarized. The inherent risks and benefits of the new technique are discussed along with the limitations of the technique and areas of further research are introduced.

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CHAPTER 2
Immediate Active Mobilization versus Immobilization for Opposition Tendon Transfer in the Hand

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Abstract

Purpose : To test the hypothesis that immediate post-operative active mobilization of the hand following opposition tendon transfer will achieve similar outcomes to the standard practice of immobilization in a cast.

Method : Prospectively, 5 hands with isolated lower median nerve paralysis underwent opposition tendon transfer followed by immediate post-operative active mobilization for rehabilitation of the transfer. Historical records of 7 identical paralyses with opposition tendon transfers post-operatively immobilized in a cast for 3 weeks were used for comparison. Outcomes were assessed by (i) the status of tendon anchorage to the thumb during immediate mobilization to detect tendon pullout (ii) Results of opposition transfer for both groups using outcomes measures of (a) Range of post-operative active abduction of the thumb (b) pattern of pinch (c) pinch strength and (iii) by comparing the results of both groups.

Results : There were no incidences of tendon pullout during immediate active mobilization of opposition tendon transfer. There were no differences in outcome between the 2 groups at late followup with all opposition transfers achieving good results. Immediate post-operative active mobilization reduced rehabilitation time by an average 19 days and earlier returns to activities of daily living were a further benefit to the patient.

Conclusions : This study supports the hypothesis and suggests similar outcomes can be achieved in reduced time by immediate active mobilization of opposition tendon transfer.

Introduction

Immobilization of the part following tendon transfer surgery is the standard protocol in clinical practice. Hands are usually immobilized for a period of 3 to 4 weeks after opposition tendon transfer[1,2,3,4,5] and require further 4 weeks for post-operative re-education. The prolonged period of morbidity results in loss of workdays for patients and increases cost to the programme providing surgical reconstruction for a large number of Leprosy deformities. It has been our endeavour to find ways to reduce costs, whilst maintaining high quality outcomes to enable greater uptake of reconstructive surgery for paralyzed hands.

Immediate active mobilization following tendon transfer has not been previously reported. Controlled active mobilization protocols for flexor tendon repairs[6,7] have significantly improved outcomes. These principles were applied to the post operative rehabilitation programme following opposition tendon transfer for median nerve paralysis. The hypothesis was that immediate active motion protocol (IAMP) following opposition transfer will achieve similar outcome to the standard practice of immobilization, provided the tendon insertion is protected during mobilization. A prospective trial of immediate active mobilization after opposition tendon transfer in thumb with only lower median nerve paralysis was designed and compared with the historical results of opposition transfer with post-operative immobilization for an identical group of paralyzed thumbs.

Material and Methods

To test the above hypothesis it was necessary to select patients requiring single tendon transfer to restore one lost function in an isolated digit so that the impact could be analysed without confounders. Thumbs with lower median nerve paralysis where the flexor pollicis brevis is supplied by the ulnar nerve was the ideal clinical situation. These thumbs require a single tendon transfer to restore opposition, as the metacarpo-phalangeal (MCP) joints are stable during pinch. Thumbs in combined median-ulnar paralysis and lower median paralysis with weak flexor pollicis brevis requires 2 procedures to restore opposition of thumb and stabilization of the MCP joint to prevent the 'Z' deformity during pinch. During the period 1994–2004 only 12 of 200 hands (6%) required opposition tendon transfer which fulfilled the above criteria. Adequate first web space of a minimum of 40-50^0 measured between the palpable subcutaneous surface of first & second metacarpal with a hand held goniometer was a pre-requisite.

Five consecutive patients, with only lower median nerve paralysis underwent opposition tendon transfer followed by IAMP in a prospective trial (Group A). Historical records of 7 consecutive patients with identical paralysis treated prior to the IAMP trial with opposition tendon transfer followed by 3 weeks of immobilization in a cast formed the comparison (Group B). The entrance criteria were identical with each group consisting of consecutive patients referred to this regional surgical unit from the same geographical area and patient population. All patients were young adults in the age group of 16 to 22 years and had completed multi-drug therapy for treatment of Leprosy. The duration of paralysis in Group A was 3 to 6 years (median 3.5years) and 1 to 7 years (median of 2 years) in Group B.

The flexor digitorum sublimis of ring finger (FDS4) were the donor in all patients in Group A. In Group B the donor tendons were extensor indicis proprius (EIP) in 5 hands and FDS4 for the remaining 2. Patients in Group A were explained the proposed change in the post-operative protocol, including the chance of discomfort in the early mobilization phase and complications of tendon pullout. The possibilities of failure requiring re-exploration or revision surgery were clearly mentioned along with the potential benefits of early rehabilitation.

Surgical Procedure

Standard opposition transfer procedure was followed using the FDS4 or EIP. Route of transfer and pulley was around the pisiform in all 5 Group A hands and 5 Group B hands. In the remaining 2 Group B hands the transfer was routed through the Guyons' canal. The tension of the transfer was adjusted to 10^0 less than the passive abduction of the thumb. The transferred tendon was sutured to the tendon of abductor pollicis brevis and then to the radial capsule of MCP joint with commercially available size '1' monofilament nylon suture with a tensile strength of 4 kilogram. The resting abduction angle of the thumb (RAA) was recorded at the end of the procedure in all hands. All Group B patients had plaster of Paris cast applied with thumb in full abduction.

Modification of technique in Group A : To increase the strength of tendon attachment, the tendon stump was passed under the extensor pollicis longus tendon and sutured to the ulnar capsule of MCP joint by size '1' monofilament nylon suture. Prior to wound closure the transferred tendon was pulled with force at the forearm incision to subjectively ascertain the security of the tendon insertion. A tuck-in plaster of paris splint was moulded into the first web to keep the thumb in maximum abduction / rotation and a dorsal splint applied to the wrist in neutral position for pain relief.

Postoperative Rehabilitation Protocol

The post operative rehabilitation protocol was identical for both groups except for the fact that in Group A the transfer was actively mobilized at 48 hours after surgery and in Group B at the beginning of 4^{th} week after surgery. Group A patients had twice a day therapy for the first 2 weeks and thereafter therapy was given once a day similar to Group B patients. The rehabilitation procedures in 1^{st}, 2^{nd}, 3^{rd} and 4^{th} post operative weeks in Group A corresponds to 4^{th}, 5^{th}, 6^{th} and 7^{th} post -operative weeks in Group B.

First week: Isolation exercises: Ten cycles of isolated contraction of the transferred tendon was begun eliminating gravity with wrist in neutral and then in 30^0 flexion. The RAA was recorded daily to detect any loss of tension of the tendon transfer. The Active Abduction Angle (AAA) was recorded at the end of each week.

Second week: Integration exercises: The thumb was incorporated in function of pinch with opposing digits. The RAA of the operated thumb was in the range of 40-50^0 and this facilitated tripod pinch by the index & middle finger without the need for significant range of abduction of the thumb. Patients with earlier pain relief and quicker integration progressed to activities like picking up small light objects i.e. plastic balls & wooden pegs weighing < 100gms.

Third week: Strengthening and co-ordination exercises: Underwater exercise was begun to improve the glide & strength of the tendon transfer. Adduction of thumb was avoided till the end of third week and tuck-in first web splint inserted daily after therapy. Activity of daily living requiring limited range of abduction of thumb was introduced in the therapy department like holding an empty glass with a maximum weight limit of 250 gms.

Fourth week: Adduction of the thumb was allowed and daytime splintage discontinued only if the AAA was maintained. The difference between AAA and RAA is the Active Range of Abduction (ARA) of the thumb. With increasing ARA, activities of daily living like eating, grooming, and leisure was introduced. Holding a glass full of drinking water (400-500gms.) was the maximum weight allowance. In the event ARA did not increase with reduction of RAA, adduction of thumb was restricted and splintage continued. Patients were discharge from hospital as soon as they were confident in the use of the hand for self care. Group A patients completed their post operative rehabilitation 4 weeks after surgery. In Group B patients the 3 weeks of immobilization increased rehabilitation time to 7 weeks after surgery. Individuals with sedentary occupation were encouraged to return to work with strict instruction to avoid lifting weights more than 500 gms. using the operated hand and to continue night splintage for 3 months. In Group A patients the early outcome assessments were performed at 16 weeks and late assessments at 7 months after surgery by a supervising therapist not directly involved in the care of the patients. For Group B patients, the corresponding time for early assessment were at 19 weeks and late assessment at or

> 8 months after surgery. Unrestricted use of the operated hands were allowed after the early assessment provided the opposition transfer had good pinch strength i.e. > 50% of normal contra lateral hand.

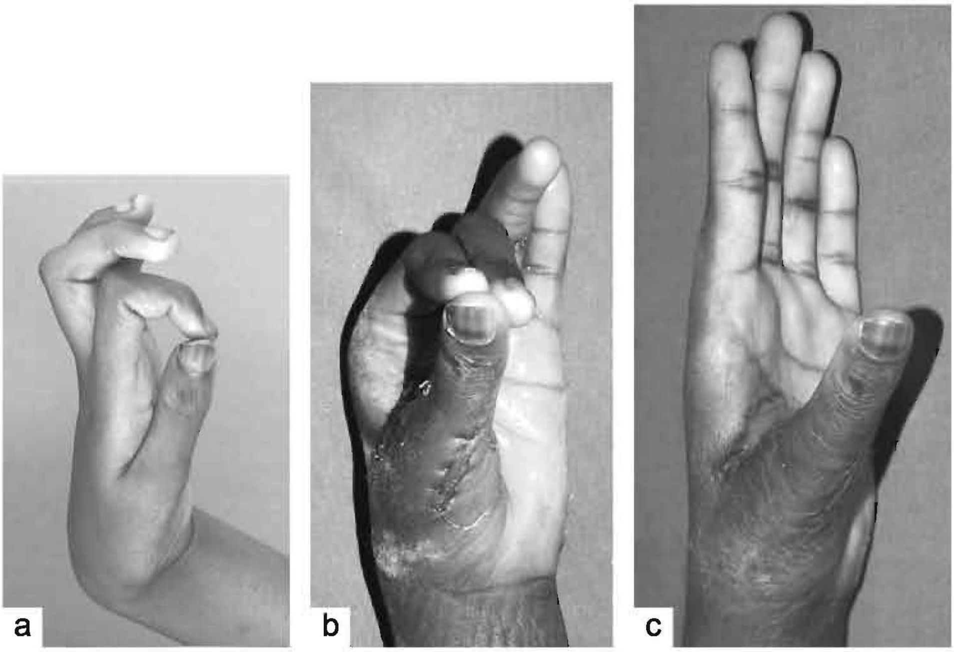

Figure 1. Preoperative and postoperative photographs of opposition tendon transfer for lower median nerve paralysis followed by IAMP (group A, patient 5 in Tables 2 and 3). (A) Lower median nerve paralysis with inability to abduct the thumb. (B) Immediate active mobilization after FDSR opposition tendon transfer. At the end of the first postoperative week the resting abduction angle of the thumb was 40° and this position allows tripod pinch. The ARA at this time was only 5°. (C) Active abduction of 50° showing the gain in opposition after FDSR opposition tendon transfer followed by IAMP.

Evaluation of result

These were based on the following parameters

(i) Tendon transfer pullout or rupture during active mobilization

For the first 3 weeks RAA was recorded daily prior to and after exercises in Group A to detect any sudden loss of tension during therapy. A sudden or progressive decrease in RAA and ARA of the thumb would indicate a tendon pullout or rupture.

(ii) Evaluations of results of opposition transfer for median nerve paralysis

These were based on 3 relevant outcome parameters (1) active range of abduction of thumb, (2) the pattern of pinch and (3) pinch strength. These outcome measures were modified from those described by Meheta & Malaviya[8] for evaluating opposition transfer to thumb for median & combined median - ulnar nerve paralysis (Table 1).

(1) *Active range of abduction of the thumb :* The difference between the AAA and RAA is the active range of abduction of the thumb.

(2) *The pattern of pinch :* Opposition tendon transfer restoring adequate abduction & rotation will enable pulp to pulp pinch and those with limitation will achieve only pulp to side or key pinch.

(3) *Pinch strengths* were measured by a hand held pinch gauge (North Coast Medical Inc. Morgan Hill, CA , USA). The averages of 3 consecutive measurements were used to calculate the pinch power as a percentage of the opposite hand with intact median nerve function in all the 12 patients. Pinch strengths were graded Good when > 50%, Fair 21-50% and Poor <20% of the normal opposite hand.

(iii) Comparison of results of Group A & Group B

Data of both groups at early and late assessment were used for comparison.

Table 1: The evaluation system for assessment of results of opponensplasty for isolated median nerve paralysis with normal Flexor Pollicis Brevis

	Criteria	Score
1.	Active range of abduction of thumb	
	>45 ^{0}	5
	41^0 to 45^0	4
	36^0 to 40^0	3
	35^0 or less	0
2.	Pattern of pinch	
	Pulp to pulp	2
	Pulp to side	1
3.	Strength of pinch (Pulp to pulp)	
	Good (>50% of normal)	3
	Fair (21-50% of normal)	2
	Poor (< 20% of normal)	0

Grading of result : Maximum=10

Good : 10-8, Fair : 7-5, Poor : 4 or less

Results

(i) Tendon transfer pullout or rupture during active mobilization

There was no pullout or rupture of FDS4 opposition tendon transfer during immediate active mobilization (Table 2).

(ii) Results of opposition transfer for median nerve paralysis

1. *Active range of abduction:*

Group A: All hands had ARA $>50^0$ (range 50-60^0) at early and late assessment.

Group B: At the early assessment ARA in 5 hands were $>45^0$ and $<40^0$ in 2 hands. All 7 hands had ARA $>50^0$ at the late assessment.

2. *Pattern of pinch* : All hands in both group had tripod pinch at the early and late assessment.

Table 2: Monitoring opposition tendon transfer during post-operative rehabilitation using immediate active mobilization protocol

Time following opposition tendon transfer surgery												
	End of first week			End of second week			End of third week			End of fourth week		
Angles	**RAA**	**AAA**	**ARA**	**RAA**	**AAA**	**ARA**	**RAA**	**AAA**	**ARA**	**RAA**	**AAA**	**ARA**
Case 1	50	55	5	50	55	5	40	55	15	15	55	40
Case 2	45	55	10	45	55	10	40	55	15	15	55	40
Case 3	45	55	10	45	60	15	45	60	15	20	60	40
Case 4	40	45	5	40	55	15	40	60	20	20	60	40
Case 5	40	45	5	40	50	10	40	50	10	25	50	25

RAA : Resting Abduction Angles of thumb
AAA : Active Abduction Angles of thumb and
ARA : Active Range of Abduction of thumb.

These angles were recorded during active mobilization of opposition tendon transfer in the first four weeks to monitor progress or detect tendon pullout.

3. *Pinch Power:* All the hands in both groups had fair pinch power at the early assessment and good pinch power at the late assessment with an average of 68% (range 65-75%) of the unaffected hand.

(iii) Comparison of results

At the early assessment all 5 hands in Group A had good results & in Group B 5 of the 7 hands had good results. Two hands in Group B had fair results due to ARA $<40^0$. At the late assessment all opposition tendon transfers in both groups had good results and overall there was no difference in the final outcome in the two groups (Table 3).

Table 3: Evaluation scores of opposition tendon transfer to thumb at various time intervals following surgery.

Group A	Early follow-up at 16 weeks	Late follow up at 7 months
Case 1	9	10
Case 2	9	10
Case 3	9	10
Case 4	9	10
Case 5	9	10
Average	9	10
Group B	**Early follow-up at 16 weeks**	**Late follow up at 7 months**
Case 1	9	10
Case 2	7	10
Case 3	9	10
Case 4	9	10
Case 5	9	10
Case 6	9	10
Case 7	7	10
Average	8.7	10

Group A : Immediate Active Mobilization of thumb following Opposition tendon transfer.

Group B : Plaster of Paris cast immobilization of thumb for three weeks following opposition tendon transfer.

Discussion

A recent prospective randomised study[9] of early dynamic motion with an extension out-trigger splint versus immobilization following EIP transfer for extensor pollicis longus rupture demonstrated beneficial outcome of hand function without compromising end results. Patients with early mobilization recovered hand function in a shorter rehabilitation time, thus making the procedure cost effective and demonstrating that immobilization following tendon transfer is not absolutely necessary. Taking a cue from the above and the principles of early mobilization for tendon repair, we proposed a hypothesis that post-operative active mobilization following opposition transfer will achieve similar outcome to immobilization, provided the tendon attachment is protected during mobilization. The results of this study support the hypothesis and the new post-operative rehabilitation protocol produced benefits related to reduce time of post-operative rehabilitation. Immediate Active Mobilization Protocol saved an average of 19 days which translates to 40% reduction in the post-operative rehabilitation time. In a regional context where the majority of patients work in the informal sector with no sickness benefits and earn their living on a daily wage basis, this considerably reduces the economic impact of reconstructive surgery on their immediate livelihood and is likely to improve uptake of surgery. The subjective gains to the patient's confidence are added benefits.

The limitations of the study are the small number of patients in the trial and the different donor tendon in Group A and Group B. Isolated median nerve paralysis occurs in 5% or less in Leprosy patients requiring opposition tendon transfer[2] and this restricted the numbers to be enrolled in the trial. There was a selection bias in choosing FDS4 donor for early mobilization as a longer tendon was necessary for additional attachment to the ulnar side of the thumb. The outcome of opposition transfer using EIP or FDS4 are similar with post operative immobilization.[10] EIP due to its short length was not considered a suitable donor for early mobilization. The availability of an adequately long and thick donor tendon as a prerequisite will restrict wider application of early mobilization for tendon transfers.

Active mobilization protocols following primary tendon repairs have significantly improved end results without increasing tendon rupture[6,7]. Early active mobilization of tendon transfers does not alter the end outcome compared to immobilization. The apparent benefits are the reduced time of rehabilitation and opportunity cost to the individual. The potential risk of early mobilization however is a tendon pullout. The individual has to suffer the consequences of this complication as this may require re-exploration or revision with a new donor. The individual has to understand this dilemma and be willing to accept risks although no such complications were observed in this trial.

The successful application of IAMP to tendon transfer requires a team of skilled therapists who understanding the physiology of wound and tendon healing. The team should be able to detect the loss of tension of the transfer and take remedial steps. This restricts the application of IAMP to specialist units and is a constraint for wider use. Similarly twice daily therapy as proposed in the protocol for the first 2 weeks is an additional demand on the therapist's time. With increasing experience the therapist now give adequate cycles of tendon motion in a single session making therapy input similar for both mobilization and immobilization.

Quicker return of active range of abduction in the IAMP group is possibly due to reduced adhesion formation by the active gliding of the transferred tendon and this allows early return of function. The reduced morbidity by IAMP and likely earlier return to work should improve acceptance of tendon transfer for deformity correction irrespective of the cause of paralysis. Prolonged time off work has been a constraint for people requiring tendon transfer to present for surgery and IAMP can address this issue without compromising the final outcome. Findings from this study support the proposed hypothesis and pave the way for a larger randomised prospective trial of early mobilization versus immobilization to fully assess the differences in outcome and the risks of complication for each protocol. Studies are also required to understand the patient's perspective and to further quantify the economic benefits of IAMP. These planned areas of work will help to define indications, techniques and application of immediate active mobilization to various types of tendon transfer.

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CHAPTER 3

Immediate Postoperative Active Mobilization versus Immobilization following Tendon Transfer for Claw Deformity Correction in the Hand

Reprinted from Journal of Hand Surgery, 2008 [American]; 33A : 232-240.
Santosh Rath. Immediate Postoperative Active Mobilization versus Immobilization following Tendon Transfer for Claw Deformity Correction in the Hand.

Abstract

Purpose : To test the hypothesis that immediate post operative active mobilization of tendon transfer following claw correction with Flexor Digitorum Sublimis 4 tail pulley insertion will achieve similar outcomes to immobilization in a cast for 3 weeks.

Methods : In a prospective study 32 hands with complete ulnar nerve paralysis had Flexor Digitorum Sublimis middle finger 4 tail pulley insertions for 4 digit claw deformity correction and mobilization for tendon transfer rehabilitation on 2^{nd} postoperative day. Surgical technique was modified to increase the strength of transfer slip insertion. Historical record of 32 mobile claw deformities treated prior to the prospective trial in the same institution with the similar procedure and immobilized in a cast for 3 weeks was used for comparison. Outcomes were assessed by (1) the status of tendon transfer attachment to flexor pulley during immediate mobilization to detect tendon transfer insertion pullout; (2) results of the claw correction in open hand position; intrinsic plus position and range of digit flexion using identical outcomes measures (3) Morbidity following surgery; and (4) Comparing results of immediate mobilization with immobilization.

Results : There was no incidence of transfer insertion pullout during immediate postoperative mobilization. There was no clinically relevant difference in results of claw correction of both groups in open hand and intrinsic plus position. Total active motion of digit flexion was significantly better with immediate mobilization at late result. Morbidity was reduced by 21 days and earlier return to daily living activities were a benefit to the patient with immediate postoperative mobilization of tendon transfer for claw correction.

Conclusions : This study supports the hypothesis. Immediate postoperative active mobilization is safe and has similar outcomes of deformity correction compared to immobilization. Immediate mobilization has the added benefit of reduced morbidity and improved total active range of digit flexion compared to immobilization.

Introduction

Post operative immobilization of the hand in a cast is the conventional practice following tendon transfer for claw deformity correction.[1,2] The wrist and Metacarpophalanegeal joints (MCPJ) are immobilized for a period 4 weeks following Zancolli's 'lasso'[3] for claw correction. Following cast removal, 4 weeks is required for tendon transfer re-education before the patient is allowed use of the hand for activities.[1] The period of morbidity with post-operative immobilization of the hand extends to 7-8 weeks. Post immobilization stiffness may increase the rehabilitation time and further delay return to activities.

The concept of immediate active mobilization of tendon transfer was reported recently by Rath[4] for Flexor Digitorum Sublimis (FDS) opposition transfer. In a prospective trial Rath[4] demonstrated that immediate active mobilization of opposition transfer produced similar outcomes to immobilization with the added benefit of 40% reduction in rehabilitation time. To test this concept on tendon transfer for claw deformity correction, I proposed a hypothesis that "Immediate Postoperative Active Mobilization (IPAM) following FDS middle finger 4 tail pulley insertions (4TP) for claw correction will produce similar outcomes to immobilization in a cast". A prospective trial of IPAM following claw deformity correction by FDS 4TP was designed and outcomes were compared with the historical results of FDS 4TP and post-operative immobilization for identical deformities treated prior to the IPAM trial.

Material and Methods

In a prospective trial 32 consecutive hands in 31 patients with mobile claw deformities due to complete ulnar nerve paralysis in Hansen's disease were included in the trial (Group A). The following inclusion and exclusion criteria were used for selection.

Inclusion criteria :

1. Ulnar nerve paralysis of more than one year duration
2. Completion of multi-drug therapy for treatment of Hansen's disease.
3. Mobile or simple claw hand deformity at the time of surgery (Figure 2a, b)
4. Good pre-operative isolation of FDS middle finger i.e. voluntary contraction of donor FDS while keeping the proximal interphalangeal joint (PIPJ) of other digits still.

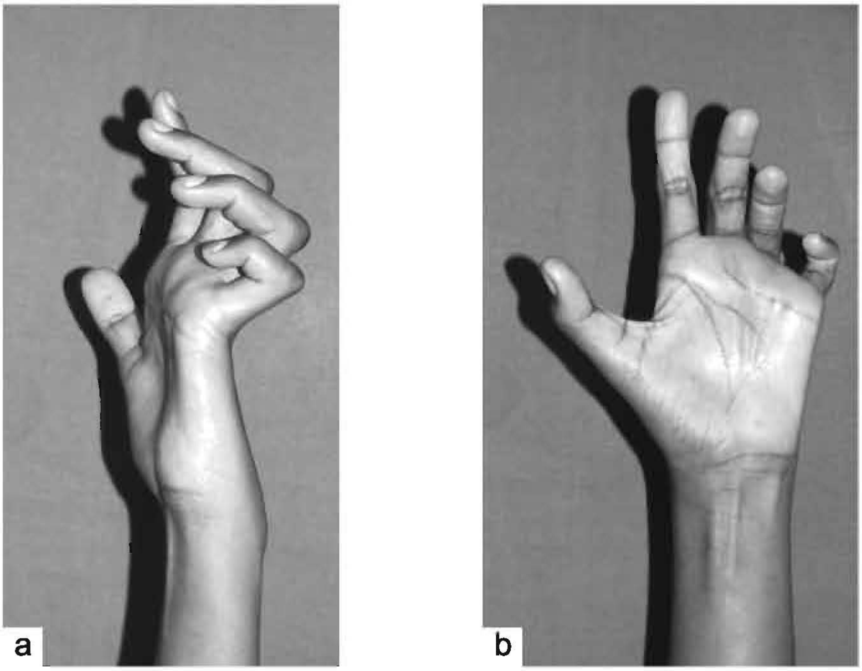


Figure 1 (a, b) : Preoperative photographs of a mobile claw deformity of left hand of 2 years duration.

Exclusion criteria :

1. Digits with persisting PIPJ contracture (Type IV and V hands as per Anderson's classification[1]) and extensor expansion damage (complicated claw hands as per Zancolli[3]).
2. FDS middle finger unsuitable as donor either due to weakness of flexor digitorum profundus or inability to isolate the muscle for transfer.
3. Loss or absorption of digits and neuropathic joints.

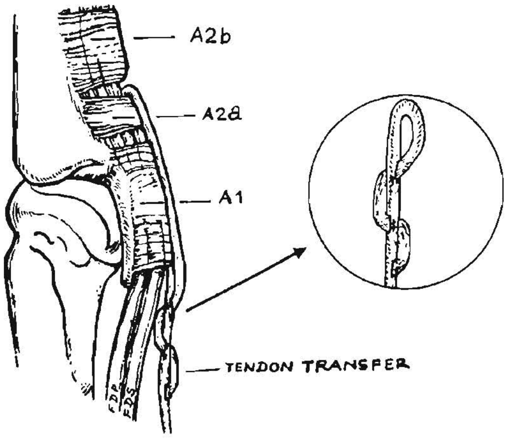
Historical data of 85 hands treated at the surgical centre with FDS 4TP and immobilization prior to the IPAM trial were reviewed. Thirty-two hands with 128 digits fulfilling the above inclusion and exclusion criteria and followup (FU) more than 1 year formed the comparison group (Group B). Fifty-three hands were excluded due to persisting pre-operative PIPJ contractures, extensor expansion damage and FU less than 1 year. The entrance criteria were similar to both groups with patients being referred to the surgical centre from the same geographical area and patient population for deformity correction.

In Group A there were 22 males and 9 females with mean age of 27 years (range 13 to 55 years SD 10.79). In Group B there were 27 males and 5 females with mean age of 31 years (range 14 to 55 years SD 13.14). The mean duration of paralysis in Group A was 5.5 years (range from 1.5 to 15 years SD 3.70) and in Group B the mean of paralysis was 4.2 years (range from 1 to 15 years SD 3.0).

Each individual in Group A was explained the proposed change in post-operative protocol and informed consent obtained. The likelihood of discomfort during early mobilization and possible complications of tendon pullout requiring re-exploration or revision surgery were discussed along with the potential benefits of earlier rehabilitation with IPAM. Institution review board consent for the trial was obtained.

Surgical Procedure

The surgical procedure for FDS 4TP is similar to the direct 'lasso' described by Zancolli[3] and incorporating the extended pulley insertion as described by Anderson.[1] Tendon to tendon anastomosis by Pulvertaft's weave was an additional modification to enhance the strength of tendon transfer insertion in Group A (Figure 1). The FDS middle finger is sectioned between the C1 and A2 pulley through an oblique volar incision in the finger, retrieved though a small incision distal to the carpal tunnel and split lengthwise into 4 equal parts. The tendon slips are routed along the lumbrical canal to each finger and inserted to the A1 and A2a pulleys.[1] With wrist in neutral position the tendon slips are tensioned ideally to produce MCPJ flexion angles of 50^0 to 70^0 with higher flexion in the ulnar digits. The tendon slip is folded back; attached to themselves with a Pulvertaft's weave and sutured using 3-0 non-absorbable suture in Group A (Figure 1). In Group B the tendon slip is folded back and tied to each other with 3-0 non-absorbable suture.



FDP= Flexor Digitorum Profundus
FDS= Flexor Digitorum Sublimis

Figure 2: Diagram to illustrate the insertion of Flexor Digitorum Sublimis slip to A1 and A2a flexor pulley and the Pulvertaft's weave for tendon anastomosis.

For pain relief the hand in Group A is supported with a Plaster of Paris dorsal splint extending to the PIPJ with wrist in neutral and MCPJ in 70^0 flexion. A Plaster of Paris cast is applied in the above position in Group B for 3 weeks.

Postoperative Rehabilitation

The post operative protocol is identical in both groups except that the transfer is actively mobilized on the 2^{nd} post operative day in Group A and at the beginning of 4^{th} postoperative week in Group B. In Group A the treatment protocol in 1^{st}, 2^{nd} ,3^{rd} and 4^{th} post operative weeks corresponds to 4^{th}, 5^{th} 6^{th} and 7^{th} post-operative weeks in Group B. The postoperative rehabilitation is institution based under the supervision of a therapist trained specifically for care of the paralyzed hands and feet.

Therapy Protocol

First and Second week : In Group A the dorsal blocking splint is removed at 48 hours and the patient is encouraged to perform active flexion of the MCPJ while attempting to keep the PIPJ in full extension and then fist closure by active PIPJ flexion. For opening the fist, the PIPJ are actively extended at first keeping the MCPJ flexed and then MCPJ extension for achieving an open hand position. Dorsal MCPJ block at 30^0 is provided by the therapist's hand to avoid over stretching of the transfer. From the position of maximum MCPJ extension in open hand position, the flexion sequence is repeated to fist closure.

In Group B a digital cast with PIPJ in full extension is applied during therapy to assist transfer integration exercises. Digital casting was not required in Group A as all hands had instantaneous integration of transfer. The hand in both groups is supported after therapy with a 70^0 dorsal blocking splint in the 1^{st} week and a 50^0 dorsal blocking splint in the 2^{nd} week.

Third and Fourth Week : Transfer strengthening exercises and light functional activities are begun following integration of the transfer. At the end of 3rd week the patients are sent to occupation therapy for daily living activities restricted to a weight limit of <500 Gms. or 1 pound. The dorsal blocking splint is reduced to 30^0 and used only at night for 3 months. Patients are discharged from rehabilitation after achieving independent ability to perform daily living activities like, dressing, grooming and eating.[5]

Assessments

The MCPJ and PIPJ angles in open hand position provides an objective assessment of deformity correction and intrinsic plus position provides an assessment of tendon transfer integration. The angles are measured using a hand held goniometer over the dorsum. These angles are recorded daily after therapy in Group A and at the end of each week in Group B. The recorded angles are adjusted to the nearest zero or 5^0 ($\leq 2^0$ adjusted to 0 ; $\leq 7^0$ to 5^0 ; $\geq 3^0$ to 5^0 and $\geq 8^0$ to 10^0).

(a) *Open Hand Position* (Figure 3a) : The MCPJ and PIPJ angles are measured with patients actively extending these joints to the maximum possible limit.

(b) *Intrinsic plus Position* (Figure 3b) : Patients actively attempt to achieve full MCPJ flexion keeping the PIPJ extended. In this position the transfer contraction produces MCPJ flexion and extensor digitorum communis extends the PIPJ. The MCPJ and PIPJ angles in intrinsic plus position is a comprehensive measure of tendon transfer activity and integration following claw correction.

(c) *Fist closure* (Figure 3c) : The ability of the finger tips to reach the distal palmar crease, proximal palmar crease or inability to touch the palm with active fist closure is noted. The total active motion (TAM) of the 3 digit joints is recorded.

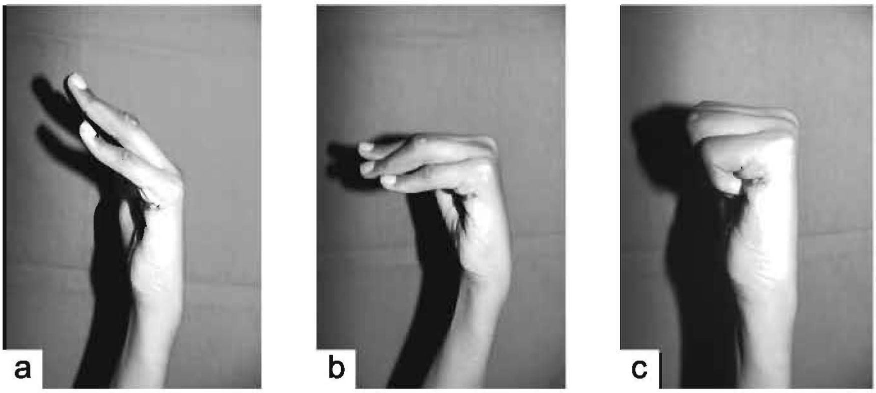


Figure 3(a,b,c) : Post operative photographs of hand (fig2 A,B) at the end of 1st week following Flexor Digitorum Sublimis 4 tail flexor pulley insertion for claw deformity correction and immediate postoperative active mobilization (a) Open Hand Position (b) Intrinsic plus position (c) Full flexion of digits.

followup

Patients are advised FU each month for 3 consecutive months, then at 3 months interval for one year and subsequently once a year. Patients with good transfer integration and strength are allowed to return to sedentary occupation at 8 weeks and unrestricted activities at 12 weeks. The last followup assessment in Group A was done by an independent therapist not involved previously in the care of the patient.

Evaluation of result

The evaluation of results was based on the following parameters:

(I) *Tendon transfer pullout during active mobilization in Group A :* Any sudden or progressive increase in MCPJ extension with loss of active MCPJ flexion indicates tendon transfer insertion pullout. In a successful transfer there is an increase of MCPJ extension; the active MCPJ flexion is retained and the TAM of digit flexion increases. Any change in this relationship should warn the therapist of an impending tendon transfer pull-out .

(II) *Comparison of IPAM with immobilization :* The results at discharge from rehabilitation (discharge result) and the last followup (late result) were compared to asses the difference between the two groups

(a) The MCPJ and PIPJ angles in open hand position, intrinsic plus position and TAM of digital flexion were compared for both groups at discharge and late result. Parametric data analysis with independent sample t- test for equality of means was used to determine the mean, standard deviation, standard error of mean, 95% confidence interval and p value. When the difference of mean angles is less than 5^0 the clinical relevance of the difference is considered trivial. This also rectifies the methodology limitation of adjusting angles to the nearest zero or 5^0.

(b) Results of tendon transfer were categorized for each digit into good, fair and poor as per the criteria of Palande.[6,7]

(i) Deformity correction : The MCPJ and PIPJ angles in the open hand position are correlated to determine grading of deformity correction as

Good: Ability to extend PIPJ to neutral or 20^0 extension lag with MCPJ position between hyperextension 10^0 and 30^0 of flexion.

Fair: PIPJ extension lags of 21 to 30^0 with MCPJ position between hyperextension of 20^0 and 50^0 of flexion.

Poor: PIPJ extension lag $>30^0$ in any position of MCPJ or MCPJ in $>50^0$ of flexion.

(ii) Transfer integration in intrinsic plus position are graded as

Good: PIPJ angles $\leq 30^0$; *Fair:* PIPJ angles 31^0 to 60^0; *Poor:* PIPJ angles $> 60^0$

(iii) Fist closure :

Good : when finger tips touch the distal palmar crease;

Fair : when finger tips touch the palm but fell short of the distal crease and

Poor : when finger tips could not touch the palm.

The statistical significance of difference between Group A and Group B was obtained using non-parametric data for independent samples, the Mann -Whitney U test with p values <0.05 being taken as significant difference. These results were compatible for comparison with published reports in the literature.

(III) *Morbidity :* The time required from the day of surgery till discharge from rehabilitation with adequate hand function to perform daily living activities were used to asses the morbidity of the surgical intervention. Parametric data analysis using t-test for equality of means was used to compare the morbidity in both groups.

All data were analyzed with statistical software SPSS 12.0.1 for windows (SPSS Inc. 233 S Wacker Dr, Chicago, IL 60606) and p values <0.05 being taken as significant difference.

In Group A 32 hands (127 digits) with mean followup of 21 months (range 9 - 30 months SD 6.01 SEM 20.59) and in Group B 32 hands (128 digits at discharge and 127 digits at late followup) with mean followup 56 months (range 9 to 132 months SD 38.58 SEM 6.82) were included in the analysis. One digit in the immobilized group at late followup was excluded from analysis due to neuropathic changes and lateral deviation deformity

Results

(i) Tendon transfer pullout or rupture during immediate active mobilization : There was no incidence of tendon transfer pullout or rupture during immediate post operative active tendon transfer mobilization.

(ii) Comparison of immediate active mobilization versus immobilization :

(a) Details of parametric data analysis for PIPJ angles are presented in Table 1. The intrinsic plus position at discharge (p=0.008) is significantly better in Group A. However the clinical relevance of this difference is trivial as the difference of mean angle is less than 5^0. The mean PIPJ angles deteriorated after discharge in both groups and they were worse off by 8^0 in Group A and 11^0 in Group B at late result. The PIPJ flexion is significantly better in Group A compared to Group B (p=0.016) at late result.

Table 1: Comparison of Proximal Interphalangeal Joint Angles : Immediate Postoperative Active Mobilization (A) with Immobilization (B)							
PIPJ angles	Mean	S.D	SEM	t – test p values	95% C.I (d)		Remark
					Lower	Upper	
OHP (D)							
A (n=127)	4.05	6.478	0.575	0.182	-3.01	0.57	
B (n=128)	5.27	7.970	0.704				
OHP (L)							
A (n=127)	12.36	12.549	1.114	0.068	-7.68	0.28	
B (n=127)	16.06	19.020	1.688				
IPP (D)							
A (n=127)	8.39	9.777	0.868	0.008	-7.02	-1.06	Difference of mean $< 5^0$
B (n=128)	12.42	14.002	1.238				
IPP (L)							
A (n=127)	13.78	13.682	1.214	0.06	-8.09	0.14	
B (n=127)	17.76	19.177	1.702				
ROM (L)							
A (n=127)	92^0	15.3	1.36	0.016*	1.09	10.31	
B (n=127)	86^0	20.4	1.9				

D : Discharge results L : Late followup results PIPJ : Proximal interphalangeal joint
ROM : Range of motion OHP : Open Hand Position IPP : Intrinsic Plus Position
SEM : Standard Error of Mean SD : Standard Deviation
CI : Confidence Interval of the difference (d) * Significantly better in Group A

The parametric data analysis for MCPJ angles are presented in Table 2. Group B has significant better result in intrinsic plus position at discharge (p=0.003). At late result Group A is significantly better for intrinsic plus position (p=0.003) and open hand position (p=0.046). Since the difference of mean angles is less than 5^0 the clinical relevance of these results are insignificant. The MCPJ flexion is significantly better in Group A at late result (p=0.001).

At late result the TAM of digital flexion is higher by a mean of 12^0 with immediate mobilization compared to immobilization with p=0.001 (Table 3). The range of flexion improved consistently in both groups over time with use of the hand.

Table 2 : Comparison of Metacarpophalanegeal Joint Angles : Immediate Postoperative Active Mobilization (A) with Immobilization (B)

MCPJ	Mean	S.D	SEM	t – test p values	95% C.I (d)		Remarks
					Lower	Upper	
OHP D							
A (n=127)	27.87	9.333	.83	0.76	-2.99	2.18	
B (n=128)	28.28	11.492	1.02				
IPP D							
A (n=127)	69.17	6.63	.59	0.003#	-4.60	-0.96	Difference of mean $< 5^0$
B (n=128)	71.95	8.04	.71				
ROM D							
A (n=127)	41.34	12.04	1.07	0.765	-3.77	2.77	
B (n=128)	41.84	14.36	1.27				
OHP L							
A (n=127)	11.85	8.40	.745	0.046*	-5.54	-0.05	Difference of mean $< 5^0$
B (n=127)	14.65	13.28	1.18				
IPP L							
A (n=127)	72.95	7.54	.670	0.003*	1.16	5.53	Difference of mean $< 5^0$
B (n=127)	69.61	9.95	.883				
ROM L							
A (n=127)	64.3	12.18	1.081	0.001*	3.53	10.41	Difference of mean 7^0
B (n=127)	57.3	15.48	1.374				

D : Discharge results L : Late followup results MCPJ : Metacarpophalanegeal Joint
ROM : Range of motion OHP : Open Hand Position IPP : Intrinsic Plus Position
SD : Standard Deviation SEM : Standard Error of Mean
CI(d) : Confidence Interval of the difference
* Significantly better in Group A # Significantly better in Group B

Table 3: Comparison of Total Active Motion of Digit flexion : Immediate Postoperative Active Mobilization (A) with Immobilization (B)

TAM of flexion		Mean In degrees	S.D	SEM	t – test p values	95% C.I (d) Lower	95% C.I (d) Upper
Discharge Results	Group A N=127	227.24	22.40	1.98	0.059	-0.236	11.44
	Group B N=116	221.63	23.82	2.21			
Late Result	Group A N=127	250.07	22.44	1.99	0.001* Difference of mean 12^0	5.31	18.76
	Group B N=112	238.03	30.13	2.84			

TAM : Total Active Motion SD : Standard Deviation SEM : Standard Error of Mean
CI(d) : Confidence Interval of the difference * Significantly better in Group A

Table 4: Comparison of Results of Immediate Postoperative Active Mobilization versus Immobilization

Mann-Whitney U test P<0.05 statistically significant difference	Immediate Postoperative Active Mobilization (n=127 digits)			Immobilization (n=128 digits-Discharge) (n=127 digits-Late followup)		
	Good	Fair	Poor	Good	Fair	Poor
Open Hand Position : Discharge p=0.139	70% (n=89)	30% (n=38)	0	62% (n=79)	36% (n=47)	2% (n=2)
Open Hand Position : Late p<0.001*	84% (n=107)	9% (n=11)	7% (n=9)	63% (n=81)	18.5% (n=23)	18.5% (n=23)
Intrinsic Plus Position : Discharge P<0.001*	100% (n=127)	0	0	91% (n=116)	8% (n=11)	1% (n=1)
Intrinsic Plus Position : Late (P<0.001)*	93% (n=118)	5% (n=7)	2% (n=2)	77% (n=98)	16% (n=20)	7% (n=9)
Fist closure : Discharge(p=0.291)	50% (n=63)	45% (n=58)	5% (n=6)	46% (n=59)	42% (n=54)	12% (n=15)
Fist closure : Late(p=0.606)	82% (n=104)	14% (n=18)	4% (n=5)	79% (n=111)	19% (n=24)	2% (n=2)

*Better result for Immediate Post operative Active Mobilization

(b) Analysis of categorized (good, fair and poor) results of deformity correction, integration in intrinsic plus position and fist closure are presented in Table 4. Significantly better results occurred in Group A for deformity correction at late result ($p<0.001$); intrinsic plus position both at discharge ($p<0.001$) and late result ($p<0.001$). Even though the categorized results have highly significant difference in favor of Group A, the clinical relevance is inconsequential as the difference of mean PIPJ and MCPJ angles for both groups is < 5^0 (Table 5).

Table 5: Interpretation of Statistical Significant Results of Parametric (t-test) and Non-Parametric Analysis (Mann Whitney U test) Comparing Immediate Postoperative Active Mobilization vs. Immobilization

		Statistical Analysis (P<0.05 significant difference)			
Outcome		Mann Whitney U test	t-test		Remark
		Palande[6,7]	PIPJ	MCPJ	
Discharge Result	OHP	p=0.139	P=0.182	P=0.756	No difference
	IPP	P<0.001*	P= 0.008*	P= 0.003#	Clinically insignificant as difference of mean PIPJ & MCPJ angles is < 5^0
	Fist closure	p=0.291			No difference
	Digit flexion		P=0.059		
Late Result	OHP	p<0.001*	P=0.068	P=0.046*	Insignificant as difference of mean is < 5^0
	IPP	P<0.001*	P=0.058	P=0.003*	Insignificant as difference of mean is < 5^0
	Fist closure	p=0.606			Significant difference in TAM of digit flexion (difference of mean =12^0)
	Digit flexion		P= 0.001*		

OHP : Open Hand Position IPP : Intrinsic Plus Position TAM : Total Active Motion
* Better with Immediate Mobilization # Better with Immobilization

Morbidity

Group A : Mean 33 days (range 28 to 37 days) with SD of 2.256 and SEM 0.398.

Group B : Mean 54 days (range 39 to 62 days) with SD of 5.719 and SEM of 1.011.

The morbidity was reduced by 21 days (39%) with immediate postoperative active mobilization compared to immobilization ($p<0.001$ with 95%CI -23.25 to -18.88).

Donor digit deformity :

Group A had 5 (16%) donor digit PIPJ flexion deformity compared to 8 (25%) in Group B at late result. The mean deformity angles in Group A was 9.8^0 compared to 10.2^0 for Group B ($p=0.948$). The donor digit deformity contributed to 4 of the 9 (44%) digits with poor result in Group A compared to 6 of the 23 (26%) digits with poor result in Group B (Table 6).

Table 6: Claw Deformity Correction by Tendon Transfer Insertion to Flexor Pulley : Comparison of Published Reports of Immobilization versus Late FU Results of Immediate Postoperative Active Mobilization

Deformity correction	Patond[14] 99 (H) n=322 (D)	Anderson[1] 20 (H) and Anderson[16] 94(H)	Hasting and McCollam[15] 12 hands (H) n= 23 (D)	Ozkan[13] 9 (H)	Immobilization Group B 32 (H) n=127 (D)	IPAM Group A 32 (H) n=127 (D)
Good	n=262 (D) 81%	92%[1] 86%[16]	n=19 (D) 83%	4 (H) 45%	n=81 (D) 63%	n=107(D) 84%
Fair				3 (H) 33%	n=23 (D) 18%	n=11 (D) 9%
Satisfactory (Good + Fair)	81%	92%[1] 86%[16]	83%	78%	81%	93%
Poor			n=4 (D) 17%	n=2(H) 22%	n=23 (D) 18.5%	n=9 (D) 7%

H : Hands D : Digit

The results of the study support my stated hypothesis. Immediate Postoperative Active Mobilization following FDS middle finger 4 tail pulley insertions for claw correction produces similar outcomes to immobilization in a cast. Immediate mobilization is safe; has the added benefit of reduced morbidity and significantly improved total active range of digit flexion at late followup.

Discussion

A recent prospective study by Rath[4] of immediate active mobilization versus immobilization for opposition tendon transfer in the hand demonstrated that similar outcomes can be achieved with 40% reduction in postoperative rehabilitation time by immediate mobilization. To investigate the above concept on tendon transfer for claw deformity correction, I proposed that immediate postoperative active mobilization following FDS 4TP will produce similar outcomes to conventional management by immobilization in a cast, provided the tendon transfer attachment is protected during mobilization. The objectives were to (1) investigate the feasibility of IPAM following FDS 4TP and determine the risk of tendon transfer insertion pull-out; (2) compare results of IPAM with immobilization; and (3) determine if IPAM reduced morbidity following surgery. There was no incidence of tendon transfer insertion pull-out in the present trial. The new postoperative therapy protocol produced similar deformity correction with higher TAM of digit flexion compared to immobilization. Immediate mobilization has the added benefit of 39% reduction in postoperative rehabilitation time. The reduced morbidity will considerably reduce the loss of income for self-employed patients for undergoing surgery and loss of work compensation payment by the state.

Rath[4] noted that immediate mobilization of opposition tendon transfers does not alter the end outcome compared with immobilization. Silfverskiold and May[8] using reinforced synthetic mesh for tendon transfers concluded that early active mobilization after tendon transfers offers significant advantages in terms of quicker active motion and improved results. Germann et[9] al in a randomized controlled trial demonstrated improved results and earlier return to function with dynamic splint assisted immediate mobilization of extensor indicis transfer for extensor pollicis longus rupture. In the present study immediate mobilization produced better TAM of digit flexion compared to immobilization possibly due to reduced adhesion formation.

Uniformity in assessment of claw correction outcomes are lacking. Categorization of results into good, fair and poor provides a basis for comparison but has significant limitation of accuracy as each category of result has wide range of angles. Comparing parametric data of MCPJ and PIPJ angles has greater accuracy and pertinent clinical interpretation of the difference. Results as per the parametric data analysis were therefore given importance in this study.

Comparing results of immediate active mobilization following FDS 4TP with published reports[1, 13-16] of pulley insertion and immobilization has limitations as the outcomes measures in these reports are not defined[1,14,16] or uniform between the studies.[13,15] The individual components of assessment used in the published reports i.e. deformity correction, integration of transfer and digit flexion have similarities to the assessments as per Palande's criteria[6, 7] used in the present study and can therefore be compared (Table 6). The satisfactory i.e. combined good and fair results of deformity correction with IPAM are similar to those in the published reports.[1,13-16] Integration and digit flexion data on the 9 hands by Ozkan[13] are too small a number for any valuable comparison. In the present study donor digit PIPJ flexion deformity occurred in 16% with immediate mobilization compared to 25% with immobilization. Brandsma[17] reported 26% donor digit PIPJ flexion deformity following FDS donation.

None of the published reports have any information on the morbidity following pulley insertion for claw deformity correction. Anderson[1] allowed use of the hand with a knuckle bender splint 7 weeks after surgery. Klein[5] recommended a period of 12 weeks after surgery to allow splint free hand activities. In the IPAM trial patients used hands for activities of daily living on an average 33 days after surgery.

The therapists observed that integration of transfer in the intrinsic plus position was achieved almost instantaneously in Group A. The pre-operative donor isolation (voluntary contraction of middle finger FDS while keeping the PIPJ of other digits still) is put to use right away during immediate mobilization. Contraction of the transfer produces MCPJ flexion of all 4 digits while the simultaneous relaxation of FDS of little, ring and index finger facilitates PIPJ extension by extensor digitorum communis of these digits to produce the intrinsic plus position.

It is postulated that pre-operative isolation of FDS middle finger improves the 'individuation index' of the little, ring and index finger by establishing new neuronal networks in the brain. Hager-Ross and Schieber[10] described the 'individuation index' to quantify the degree to which non instructed digits move during instructed movement of a given digit. Early post operative mobilization activates the new neuronal networks in the brain as described by Bezuhly[11] whereas immobilization may temporarily erase these neuronal networks. In addition immobilization of the transfer will temporarily erase the cortical representation of FDS middle finger is as demonstrated by de Jong et al[12] with dynamic immobilization of flexor tendons.

The study of de Jong et al[12] demonstrated the impact of a relatively short period of immobilization of digits on the functional organization of the brain. A 6 week period of immobilization induced temporary loss of efficient cerebral control of hand movement. Functional restoration of hand movement occurs in 6-8 weeks time with use of the hand. This may explain the delay in isolation and integration of transfer following immobilization. There is however no difference in isolation and integration at late result and this supports the theory of de Jong et al[12] that immobilization only induces temporary loss of cortical representation.

The major limitation of this study is comparing the results of a prospective trial (IPAM) with retrospective historical data. The IPAM trial included consecutive patients treated by the author in the years 2004-05. The retrospective cohort did not include consecutive patients. The surgical procedure and the donor tendon was decided by surgeons working in the unit between 1994 and 2003 on case to case basis indicating a bias in choice of donor and transfer procedure.

Comparison of results was limited to assessments in open hand position, intrinsic plus position, fist closure and range of flexion since data on pinch, grip and sequence of flexion was not available for Group B. The average followup time of 52 months for Group B compared to 20 months in Group A is skewed. This was however the best available comparison as assessments were done using identical outcomes measures for both groups.

The IPAM trial establishes the efficacy and safety of immediate tendon transfer mobilization with a selected donor with a strong insertion. Increased strength of tendon transfer insertion and protection of the insertion during IPAM are the two essential requirements for this new tendon transfer rehabilitation protocol. Wider application of this principle to other tendon transfer can now be investigated with incorporating the above two principles. Future randomized controlled trials will provide insight into the differences in post operative behavior of tendon transfer with immediate mobilization versus immobilization. In addition the neurophysiologic basis of isolation of donor, integration of tendon transfer and movement restoration can now be tracked in the immediate postoperative period with functional MRI or PET scans.

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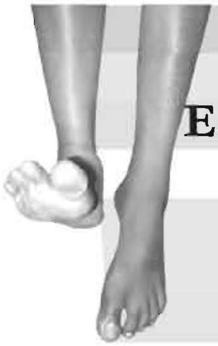

CHAPTER 4
Early Postoperative Active Mobilization versus Immobilization following Tibialis Posterior Tendon Transfer for Foot-drop Correction

Reprinted from Journal of Plastic, Reconstructive & Aesthetic Surgery 2010; 63A : 554-560. Santosh Rath, Ton A.R. Schreuders , Ruud W. Selles. Early Postoperative Active Mobilization versus Immobilization Following Tibialis Posterior Tendon Transfer for Foot-drop Correction.

Abstract

After tibialis posterior tendon transfer surgery for foot-drop correction the patient's foot is traditionally immobilized for several weeks. To test the feasibility of early mobilization in this group, 21 consecutive patients received active mobilization of the transfer starting on the 5th postoperative day. Results were compared with a retrospective cohort of 21 patients receiving 4 weeks immobilization. Average followup was 22 months for both groups. We found no tendon transfer insertion pullout during early active mobilization therapy. In addition, there was no difference in active dorsiflexion, plantar flexion and range of motion between the groups at discharge and followup. The patients in the Mobilization group walked significantly earlier (44 ± 7.9 days compared to 57 ± 2.3 days; p=0.001). This feasibility study indicates that early active mobilization of tibialis posterior transfer is safe and has similar outcomes to immobilization with a reduced time to independent walking.

Introduction

Foot-drop deformity is common in Hansen's disease and is often associated with compromised plantar sensation. Ankle-foot-orthosis (AFO) are often used to treat foot-drop deformity in peripheral nerve injuries and intervertebral disc prolapse but has limited use for foot-drop in Hansen's disease as the majority of patients in endemic countries are manual or agriculture workers habituated to bare feet walking. Anterior transfer of the tibialis posterior tendon therefore is often used for foot-drop correction in Hansen's disease as this allows walking without an orthosis. Patient education for care of the anesthetic foot along with tendon transfer provides appropriate care and rehabilitation for irreversible common peroneal nerve neuritis in Hansen's disease.

Three to four weeks of post-operative immobilization of a tibialis posterior transfer is the conventional practice (Lipscomb and Sanchez[1], Srinivasan et al[2], Warren[3,4], Brandsma and Ebenezer[5], Richards[6], and Soares[7]). The morbidity for foot-drop correction with tibialis posterior transfer then extends to 8-10 weeks.[5, 7] We recently demonstrated the advantages of early post-operative active mobilization following thumb opposition transfer[8] and claw deformity correction.[9] The same concept may also be applicable in tendon transfer for foot-drop correction, although forces at the transfer insertion are higher in this situation. Increasing the strength of insertion by a Pulvertaft weave[10] enabled active tendon transfer mobilization.

In this study, we present data from a prospective trial on early active mobilization after tibialis posterior transfer for foot-drop correction. Results were compared with a retrospective cohort of similar transfers followed by the standard protocol of immobilization in a cast for 4 weeks. The purpose of the study was to assess the safety of early active mobilization for tibialis posterior transfer by an objective method to identify transfer insertion pull-out and compare results with immobilization of the transfer.

Material & Methods

In the prospective trial, 21 consecutive foot-drop deformities (Figure 1a) in Hansen's disease operated by the first author from June 2004 till May 2005 were included in the study. The inclusion criteria for the study were irreversible common peroneal nerve paralysis of more than one year duration and completion of multi-drug therapy for treatment of Hansen's disease. The exclusion criteria were clawed toes requiring additional surgery, neuropathic changes in the foot and active plantar ulcers.

After foot-drop correction using anterior transfer of the tibialis posterior tendon, patients in the Mobilization group received early active mobilization from the 5^{th} postoperative day. Historical records of 81 tibialis posterior transfers with conventional four weeks of post operative immobilization operated by the first author prior to the trial were reviewed. Twenty-one patients with inclusion criteria similar to the Mobilization group and followup of more than one year were used for the Immobilization group. The first author operated all patients at the same institution. The two groups are comparable with regards to age, gender and duration of paralysis (Table 1). Each patient in the Mobilization group was explained the proposed change in post-operative protocol and informed consent was obtained. Institutional review committee approval was obtained for the trial.

Surgical procedure

Patients were operated under sedation using wide local infiltration of 1% lidnocaine with 1:10000 adrenaline and without the use of a tourniquet. The surgical technique for both groups is similar to that described by Srinivasan et al[2] except for the technique of insertion. The tibialis posterior tendon was detached from its insertion to the navicular bone, retrieved in the lower leg and split in the middle up to the musculo-tendinous junction into an anterior and posterior part. Each slip was then transferred to the foot separately along the circumtibial route passing anterior to the ankle and superficial to the extensor retinaculum. Closed tendo-achilles lengthening was performed if passive ankle dorsiflexion was less than 20^0 with extended knee. The limb was put in a prefabricated splint that maintains the knee in 60^0 flexions and ankle in 20^0 dorsiflexion to ensure standardization of tendon transfer tension. One slip of the transferred tendon was inserted into the tendons of extensor digitorum longus with maximum tension and the second slip was inserted into extensor hallucis longus tendon in neutral tension. In the Immobilization group the transfer slip was passed transversely once through the recipient tendon, stitched at the points of entry and exit with monofilament 2-0 nylon and finally tied distally to the recipient tendon. In the Mobilization group the transfer was inserted using a Pulvertaft's weave[10] to increase the strength of attachment. The points of entry and exit were sutured using 2-0 Ethibond (Johnson & Johnson).

For postoperative pain relief, the foot was supported by a below knee posterior splint in full dorsiflexion in the Mobilization group. A below knee cast was applied in full dorsiflexion for four weeks in the Immobilization group. Patients in both groups were allowed non-weight bearing crutch walking from the 2nd postoperative day. A walking heel was applied to the cast in the Immobilization group and patients were allowed partial weight bearing with crutches from the 5th postoperative day. In the Mobilization group the supporting slab was removed for therapy on the 5th postoperative day. The postoperative rehabilitation was institution-based and under supervision of a therapist trained specifically for care of paralyzed hands and feet.

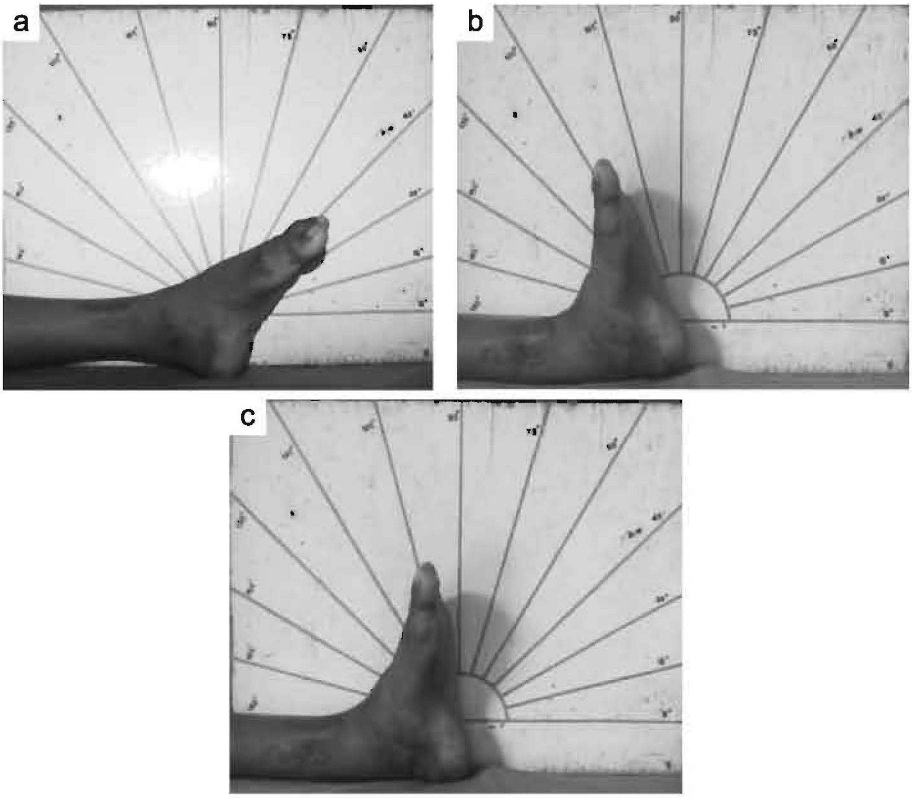

Figure 1: Clinical Photographs of (a) Preoperative Status of Foot-Drop (b & c) Tibialis Posterior transfer for foot drop correction and Early Active Mobilization : Postoperative status at Discharge from Rehabilitation (b) Active Dorsiflexion (c) Plantar Flexion

Rehabilitation protocol

The rehabilitation therapy protocol was similar in both groups except that the transfer was actively mobilized on the 5th postoperative day in the Mobilization group and at the beginning of 5th postoperative week in the Immobilization group. As a result, the treatment protocol in 2nd, 3rd, 4th and 5th postoperative week in the Mobilization group corresponded to the 5th, 6th, 7th and 8th post-operative weeks in the Immobilization group respectively. The therapy programme consists of once a day active dorsiflexion exercises in 1st week of therapy (post-operative week 2 in the

Mobilization group and week 5 in the Immobilization group), gentle active plantar flexion exercises in 2nd week of therapy, partial weight bearing with parallel bars in 3rd week of therapy, full weight bearing and gait training in the 4th week of therapy. The limb was supported after therapy in a posterior splint in full dorsiflexion for three weeks and thereafter only at night for three months. Patients in both groups were discharged from rehabilitation with good transfer contraction and independent walking without any aids. Unrestricted activities were allowed three months after discharge from rehabilitation. Clinical review was recommended once a month for three months; then every three months for a year and then once a year.

Table 1: Descriptive data for the Mobilization and Immobilization Groups at Baseline. Values are Mean ± SD. The p-values indicates the significance level of the t-test comparing both groups

Variables	Mobilization n=21	Immobilization n=21	p value
Age (years)	31.6 ± 11.7	36. 7 ± 11.9	0.174
Gender (Male; Female)	17:4	20:1	-
Duration of Paralysis (years)	4.6 ± 3.3	6.8 ± 4.4	0.070

Outcomes assessment

The primary goal of early active motion is to obtain an earlier discharge from rehabilitation with successful foot-drop correction. The main risk of early mobilization is tendon transfer rupture and insertion pull-out. Therefore, primary outcome measurements are the incidence of transfer pull-out; active ankle dorsiflexion angle of the foot beyond neutral; plantar flexion; ankle range of motion (ROM) from flexion to extension, and time until discharge from rehabilitation with independent walking.

The integrity of tendon transfer insertion in the Mobilization group was monitored by measuring active dorsiflexion, plantar flexion and ROM of the foot on daily basis for the first two weeks of therapy and then at the end of each week. A sudden or progressive reduction of dorsiflexion and ROM would indicate rupture or impending insertion pull-out. The measurement was done using a hand held goniometer with the patient in a sitting position with the knee in 90^0 flexion.

Adverse effects of wound infection, transfer laxity, persisting foot-drop gait and inversion or eversion deformity were recorded. Morbidity was scored, defined as the time required from the day of surgery to discharge from rehabilitation with patient walking independently without any aids.

Data analysis

Outcomes of both groups were compared at discharge from rehabilitation (discharge assessment) and at the last clinical review (followup assessment). The student-t test was used to compare data between the groups to determine the p-value and the 95% confidence interval of the difference between groups. Statistical analysis was performed with SPSS software for Windows (version 12.0.1 SPSS, Chicago, IL). A p-value of 0.05 was considered statistically significant.

To compare the results of the present study with published reports, the outcome measure introduced by Srinivasan et al[2] was used, which also focuses on active dorsiflexion angle and active ankle ROM between dorsiflexion and plantar-flexion. In this measure, results are graded into 3 categories.

For active dorsiflexion, the three different grades are:

Grade 1	(Good)	:	Active dorsiflexion beyond neutral
Grade 2	(Fair)	:	Active dorsiflexion to neutral
Grade 3	(Poor)	:	Unable to achieve active dorsiflexion to neutral

For active ankle ROM, the three different grades are:

Grade 1	(Good)	:	equal or more than 25 °
Grade 2	(Fair)	:	15 ° to 20 °
Grade 3	(Poor)	:	equal or less than 10°

For convenience of comparison the good and fair results were categorized as satisfactory and poor results as failure of foot-drop correction

Results

In each group, 21 patients were available for discharge assessment. Nineteen patients in the Mobilization group (Table 2) and 21 patients in the Immobilization group were available for follow up assessment with mean follow up of 22.2 ± 8.3 and 22.7 ± 8.3 months respectively. The reason for loss-to-followup in the Mobilization group were that one patient died of an unrelated cause six months after operation and one patient could not be traced after the first followup review.

Patients in both groups were able to actively dorsiflex the foot (Figure 1 b) beyond neutral at discharge. At followup, one patient in each group lacked dorsiflexion beyond neutral. There was no difference in the active dorsiflexion angle, plantar flexion angles (Figure 1c) and total active motion between the groups at discharge and final followup assessment (Table 3).

There was no incidence of insertion pullout of the tendon transfer in either group. Patients were discharged from rehabilitation with independent walking at 44 ± 7.9 days (range 37-69) after surgery in the Mobilization group compared to 57 ± 2.3 days (range 53-63) in the Immobilization group. This indicates a significant difference in morbidity (mean difference 13 days, $p > 0.001$; 95% CI -16.8 to 9.5) between both groups. The duration required for therapy in the Mobilization group was 40 ± 7.6days compared to 29 ± 2.3days for the Immobilization group (mean difference 9.8, $p<0.001$, 95% CI 6.3 to 13.3).

Table 2 : Results of 19 patients with early active motion protocol at the last followup assessment

Sl. No.	Hosp. No	Age	Duration of palsy in years	Morbidity in days	FU in months	Dorsi-flexion in degree
1	1939	25	1.6	42	36	25
2	1938	20	2	44	12	25
3	1935	36	2	44	13	20
4	1933	25	12	44	30	20
5	1941	50	2	41	12	25
6	1932	14	5	41	26	20
7	2014	45	4	40	31	15
8	2022	22	1	51	31	20
9	2011	46	8	38	24	20
10	2019	33	7	50	12	5
11	2015	35	1.6	53	22	20
12	2026	15	3	37	26	Nil
13	2030	25	5	37	26	12
14	1949	28	6	40	19	15
15	2037	20	1.6	40	12	10
16	1988	22	5	69	17	5
17	2016	39	3	39	31	30
18	2042	45	5	40	31	2
19	2049	45	1.6	57	30	20

Comparing results of the present study with published reports based on the outcome measure introduced by Srinivasan et al[2] demonstrates that satisfactory active dorsiflexion for the study group is similar to that reported by Richard[6] & Yeap et al.[15] Srinivasan et al[2] reported higher failures in active dorsiflexion but significantly better ROM compared to the study group and those reported by Richard.[6] Early mobilization of tendon transfer for foot-drop correction has results similar to those following immobilization of the transfer (Table 4).

Adverse effects

Two patients in the Mobilization group had deterioration of active dorsiflexion angle following unprotected full weight bearing in the 3rd week of therapy. Daily record of dorsiflexion and ROM enabled detection of the impending tendon insertion pullout. Restricting plantar-flexion for two weeks with continuous use of the posterior supporting slab and isometric exercises restored good dorsiflexion at discharge. One patient in the Mobilization group was lost to followup after discharge and at 26 months followup had recurrence of foot-drop deformity. One patient with irregular followup in the Immobilization group had no active dorsiflexion above neutral and ROM of 10° at 19 months followup. This could either be due to elongation of the muscle-tendon complex as a result of inadequate contraction of the transfer or stretching at the transfer insertion.

Table 3: Comparison of active dorsiflexion, active plantar-flexion and total active motion of the early mobilization and immobilization groups at discharge and last follow-up

		Mean	S.D	SEM	t – test p values	95% C.I (d)	
						Lower	Upper
ADF D	MOB. n=21	5.00	5.36	1.2	0.860	-2.9	2.5
	IMMOB. n=21	5.24	3.02	0.7			
APF D	MOB. n=21	14.90	7.44	1.6	0.220	-5.9	1.4
	IMMOB. n=21	17.14	3.50	0.8			
TAM D	MOB. n=21	9.90	3.73	0.8	0.054	-4.0	0.0
	IMMOB. n=21	11.90	2.72	0.6			
ADF L	MOB. n=19	0.37	7.45	1.7	0.566	-3.2	5.7
	IMMOB. n=21	0.90	6.32	1.4			
APF L	MOB. n=19	15.21	10.61	2.4	0.421	-3.5	8.1
	IMMOB. n=21	12.90	6.59	1.4			
TAM L	MOB. n=19	14.84	5.47	1.3	0.498	-2.0	4.1
	IMMOB. n=21	13.81	3.82	0.8			

Table 4: Comparison of both groups as well as comparison with published reports in the literature using the outcome grading as described by Srinivasan et al [2]

Outcomes		Dorsiflexion			ROM		
Grading		Good	Fair	Poor	Good	Fair	Poor
Mobilization group	(n=19)	18	0	1	2	13	4
Immobilization group	(n=21)	20	0	1	1	13	7
Srinivasan[2]	(n=39)	22	12	5	15	15	4
Yeap[11]	(n=18)	15	3	0	-	-	-
Richard[4]	(n=39)	37	0	2	2	15	22

Discussion

The purpose of the study was to investigate if early post-operative active motion for rehabilitation of tibialis posterior transfer is feasible and will have similar outcomes in reduced time compared to immobilization of the transfer. The results suggest that early active motion following foot drop correction is safe, without the increased risk of tendon insertion pullout and has similar outcomes to immobilization with the added advantage of earlier independent walking compared to immobilization. These findings suggest that the standard practice[1-5] of immobilization following tibialis posterior transfer may not be needed.

In recent years, there has been a move away from the practice of immobilization towards early active motion following tendon transfers.[8, 9, 11-13] Rath demonstrated that early active motion after opposition[8] tendon transfer and after claw hand correction by pulley insertion[9, 11,13] is safe and has no increased incidence of tendon insertion pullout while obtaining similar outcomes compared to immobilization. Silfverskiold and May[14] in a prospective trial using synthetic mesh re-enforcement for early active mobilization for tendon transfer to hand demonstrated significantly improved results along with quicker rehabilitation. This study indicates that the concept of immediate active motion developed for hand tendon transfers can be safely applied to tendon transfers to the foot, provided the insertion is strong enough to tolerate the stress of early weight bearing. A mean reduction of 13 days in morbidity with early mobilization for foot-drop correction is considerably less compared to the reduction of 22 days in morbidity with early mobilization in tendon transfers to the hand.[9,13] This is partly due to beginning of early mobilization for foot drop on 5th postoperative day compared to the 2nd postoperative day for tendon transfers to the hand. The decision was made by the therapist more or less arbitrarily on the presumption that pain threshold and swelling would allow co-operation of the patient to begin movement on the 5th day following foot-drop correction. Future trials may investigate the possibility to even further reduce the morbidity by beginning the mobilization protocol earlier.

It has been suggested in the literature that there are beneficial effects of stress during mobilization on tendon healing [15], suggesting that an early motion protocol for tendon transfer may accelerate healing and improve outcome. In this study, we did not find a difference in outcome between both groups. However, it should be noted that this is a relatively small study with a control group based on historical records. Future randomized controlled clinical trials are warranted to further investigate this.

In addition to the historical control group, we compared the result of foot drop correction with early motion protocol with published reports in the literature.[2, 6, 16] Table 2 shows that the outcome of both Mobilization and Immobilization group included in the in the study protocol of tibialis posterior transfer shows similar results to outcomes reported in the literature. None of the published studies except Soares[7] mention morbidity following foot drop correction. Soares[7] reported that the rehabilitation after tendon transfer for foot drops was completed by ten weeks (70 days). In the present study rehabilitation was completed an average of 57 days after surgery for the Immobilization group compared to 44 days for the Mobilization group. At present, the average time from beginning postoperative therapy until discharge from rehabilitation is 40 days for the Mobilization group compared to 29 days for the Immobilization group. In the future, morbidity may be reduced further as therapist gain experience with early active motion protocol and are able to complete postoperative rehabilitation in similar time to immobilization. Our experience with early mobilization protocol following claw-deformity correction of the hand in large number of patients has demonstrated that after a steep learning curve for the therapists, the average time from beginning postoperative therapy until discharge from rehabilitation is similar to both the mobilization and immobilization group.[9,13]

The present study has a number of limitations. The study is comparison of a prospective trial with a historical control group. Excluding patients with less than 1 year followup in the Immobilization group is likely to filter out failures as patients with unsatisfactory outcomes have higher instances of poor followup. Randomized controlled trials in future can investigate the changes with early mobilization versus immobilization and track their differences over equal period on a more extensive set of outcome measures.

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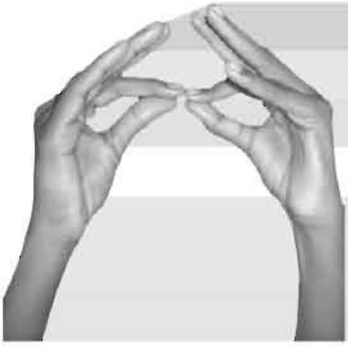

CHAPTER 5

Randomized Clinical Trial comparing Immediate Active Motion with Immobilization following Tendon Transfer for Claw Deformity Correction in the Hand

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Santosh Rath, Ruud W. Selles, Ton A. R. Schreuders, Henk J. Stam, Steven E. R. Hovius. Randomized Clinical Trial comparing Immediate Active Motion with Immobilization following Tendon Transfer for Claw Deformity Correction in the Hand.

Abstract

Background: Immobilization following tendon transfers has been the conventional postoperative management. A recent study indicated beneficial effects of an immediate active motion protocol (IAMP) after tendon transfer for claw deformities correction compared to a historical cohort. In this study, we will further test this hypothesis in a randomized clinical trial comparing the effectiveness of the IAMP with conventional immobilization.

Methods: Fifty mobile claw hand deformities were randomized postoperatively into 2 equal groups for IAMP and immobilization. Therapy began on the 2nd postoperative day for the IAMP group and on the 22nd day for the Immobilization group. The primary outcome measures were deformity correction, active range of motion of digits, tendon insertion pull-out and time until discharge from rehabilitation. Secondary outcome measures were swelling, pain, hand strength and dexterity. Both groups were compared at discharge from rehabilitation at the last clinical followup (at least one year post operatively).

Result: Assessments were available for all 50 patients at discharge and 23 patients in each group at followup. The average followup was 17.9 months for the IAMP group and 16.7 months for the Immobilization group. Deformity correction, range of motion, swelling, dexterity, and hand strength were similar for both groups at discharge and followup. There was no evidence of tendon insertion pullout in any patient both groups. Relief of pain was achieved significantly earlier with IAMP. Morbidity was reduced by, on average, 22 days with IAMP.

Conclusion: We found that the immediate active motion protocol is safe and has similar outcomes compared to immobilization with the added advantage of earlier pain relief and quicker restoration of hand function. Immediate motion following tendon transfer can significantly reduce morbidity, speed up the rehabilitation of paralytic limbs and may save cost for the patients.

Introduction

Immobilization is the conventional post-operative management following tendon transfers in hands and feet. Restoration of function following tendon transfers is usually relatively long due to immobilization and the re-education process. Studies showing improvement in tendon repair outcome after early active motion[1] provided a basis to investigate the feasibility of early mobilization after tendon transfers.

A claw hand due to ulnar nerve neuritis is the commonest deformity in the upper limb in Hansen's disease.[2] Whereas the success rate of tendon transfers for mobile claw hand correction is high,[2,3] acceptance of corrective surgery is low due to morbidity throughout the long rehabilitation time and loss of earning during treatment. Early active mobilization after tendon transfers would accelerate the period of rehabilitation for paralytic limbs and may therefore resolve a major hurdle of reconstructive surgery. Recent studies of Rath demonstrated the safety of early active mobilization of claw deformity correction[3] and opposition transfers[4] in small cohort studies that were compared to a historical cohort of patients that had received immobilization. These studies indicated that early active mobilization might lead to similar outcomes with reduced rehabilitation time compared to immobilization. However, these cohorts were not controlled in a randomized clinical design and information on secondary outcome measures such as pain, swelling, grip, pinch and hand function was limited. To establish the effectiveness of the concept of early active mobilization protocol more rigorously, we designed a randomized clinical trial to compare early active mobilization with immobilization of tendon transfers for claw deformity correction in the hand of patients with Hansen's disease.

Material and Methods

Patients

Patients with claw deformity referred to a large regional Leprosy reconstructive surgery hospital were asked to participate in a single centre trial from May 2005 to June 2006. During this period, 69 patients had surgery for claw deformity correction by the first author, of whom 50 met the criteria for inclusion in the randomized clinical trial (RCT). Therapists in the outpatient department selected the participants for the trial. Data of all 50 patients obtained during postoperative therapy were analyzed for early results. Forty-six patients were available for followup beyond 1 year for late analysis (Figure 1).

Patients were included when they had: (A) Ulnar nerve paralysis of more than one year and completion of multi-drug therapy for treatment of Hansen's disease. Hands with combined ulnar and low median nerve paralysis were also included, provided the ulnar nerve paralysis had been present for at least one year. (B) A mobile claw hand without contractures at the time of surgery[5] (C) A latent claw deformity where digits can voluntarily achieve the intrinsic plus position {metacarpophalangeal (MCP) joint flexion with proximal interphalangeal (PIP) joint in full extension} but claw with an extension force applied by the therapist over the MCP joint. Latent claw digits underwent tendon transfer simultaneously to avoid the possibility of future clawing.[6] (D) Good pre-operative isolation of the flexor digitorum sublimus (FDS) of the middle finger indicated by voluntary contraction of the donor FDS

Patients were excluded when they had: (A) complicated claw hands[7] defined as the inability to extend PIP with MCP joint blocked in flexion (negative Bouvier test[5]) or MCP contracture in extension, and (B) an FDS middle finger unsuitable as donor due to weakness of the flexor digitorum profundus.

Approval was obtained from the institutional review board and informed consent signed by all patients.

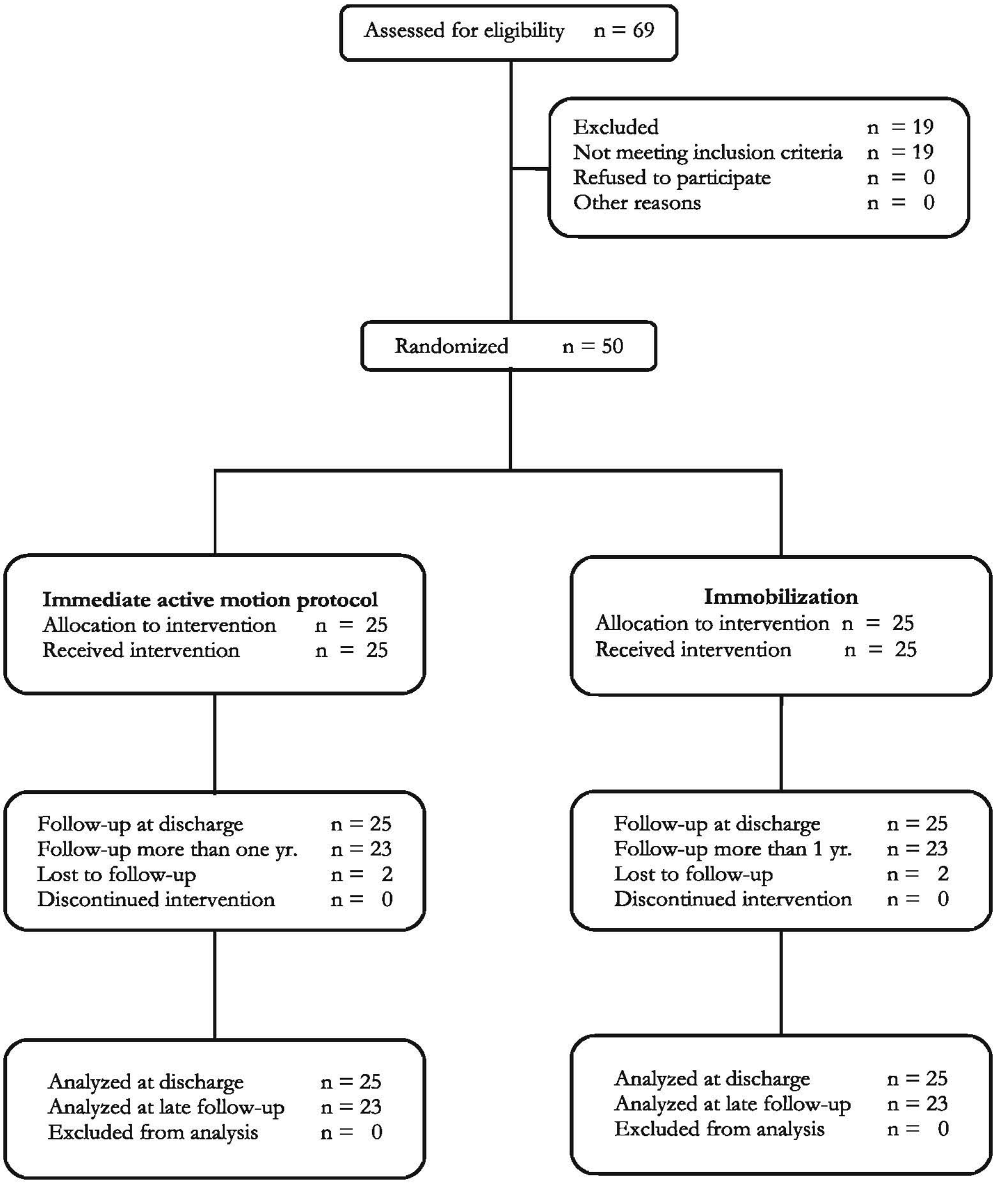

Fig 1: Flow chart of patients in the randomized clinical trial

Group allocation

The patients were divided equally into a group receiving an immediate active motion protocol (IAMP) or receiving an immobilization protocol for 3 weeks following surgery (Immobilization group). Randomization into 2 groups was performed using an unmarked sealed opaque envelope that was mixed thoroughly in a box. A person not involved in the trial did the group assignment by opening an envelope picked at random from a box after completion of surgery and wound closure. A therapist not involved in the care of the patient and blinded to group assignment performed the last followup assessment at home or at a regional followup clinic.

The groups were similar for age, gender, site, type and duration of paralysis (Table 1). Seven hands in the IAMP group and 5 hands in the Immobilization group had combined ulnar and median nerve paralysis. Four digits in the IAMP group and three in the Immobilization group had latent clawing. All 50 hands had 4 digit claw corrections.

Table 1: Descriptive data for the Immediate Active Mobilization group and Immobilization group at Baseline

Intervention Group	IAMP	Immobilization	p value
Age	30.8±10.4	28.28±10.2	0.54
Male	20	19	
Female	5	6	
Duration of Paralysis	4.3 ± 3.6	2.84 ±1.8	0.79
Type of paralysis			
Ulnar	18	20	
Median & Ulnar	7	5	
Site	Rt=15	Rt=12	
	Lt=10	Lt=13	

Note: Values are meaning of ± SD of n. values indicates the significance level of the t-test comparing both groups

IAMP: Immediate active mobilization protocol

Surgical techniques

The surgical procedure was similar to that described by Rath[3]. The FDS of the middle finger was sectioned between the C1 and A2 pulley using an oblique volar incision in the finger, retrieved though a small incision distal to the carpal tunnel and split lengthwise into 4 equal parts. The tendon slips were routed along the lumbrical canal to each finger and inserted to the A1 and proximal A2 pulleys. With wrist in neutral position the tendon slips were tensioned to produce MCP joint flexion of 50^0 to 70^0 with more flexion in the ulnar digits. The tendon slip was folded back, attached to itself with a Pulvertaft's weave and sutured using a 3-0 non-absorbable suture as described by Rath[3] (Fig. 2). The hands for the IAMP group were supported for pain relief with a Plaster of Paris dorsal splint extending to the PIP joint with the wrist in neutral position and MCP joint in 70^0 flexion. A circular Plaster of Paris (POP) cast was applied in the same position in the Immobilization group for 3 weeks.

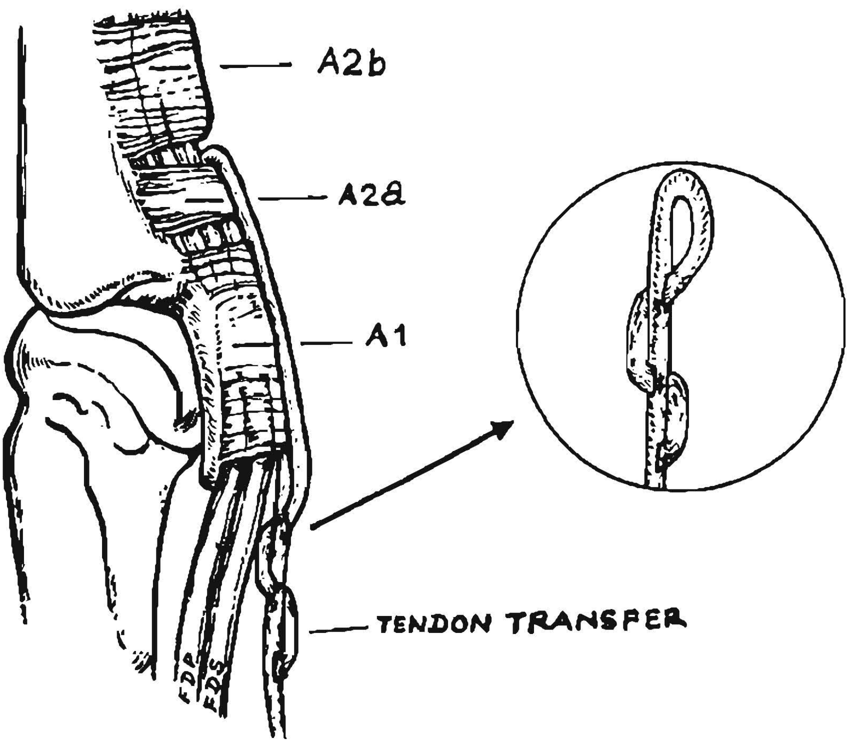

Figure 2 : Diagram to illustrate the insertion of Flexor Digitorum Sublimis slip to A1 and A2a flexor pulley and the Pulvertaft's weave for tendon attachment.

FDP : Flexor Digitorum Profundus FDS : Flexor Digitorum Sublimis

Therapy protocols Appendix 1

The postoperative rehabilitation was institution-based (inpatient) and under supervision of a therapist trained specifically for care of paralyzed hands and feet. The post-operative protocols were similar in both groups except that the transfer was actively mobilized on the 2nd post operative day in IAMP group and at the beginning of 4th postoperative week in Immobilization group. As a result, the treatment protocol in 1st, 2nd, 3rd and 4th post operative weeks in IAMP group corresponded to the 4th, 5th, 6th and 7th post-operative weeks in Immobilization group. In addition, in the Immobilization group, digital casts in full extension were applied during first 2 weeks as the standard post Immobilization therapy protocol to assist concentrate transfer action on the MCP joint.

In the first 2 weeks of therapy, patients were trained to perform active flexion of the MCP while attempting to keep the PIP in full extension and to perform fist closure by active PIP flexion. For opening the fist, the PIP's are actively extended at first by keeping the MCP flexed and then MCP extension for achieving an open hand position. The therapist blocked the MCP at 30° with a dorsal splint to avoid overstretching of the transfer. From the position of maximum MCP extension in open hand position, the flexion sequence was repeated to fist closure.

During the first 2 weeks in the Immobilization group, we used PIP digital casts in full extension to concentrate transfer action during MCP flexion and relaxation of transfer during MCP extension. The cast was removed each day during therapy and the sequence to achieve open hand position and fist closure is followed similar to that in the IAMP group. Digital casts were discontinued by the end of second week as the transfer action (of MCP flexion) is usually integrated with that of extensor digitorum communis action producing PIP extension. Ability to maintain actively the MCP in flexion and the PIP between the range of 0-30^0 indicates good integration of the transferred tendon with the action of extensor digitorum communis. When necessary, digital casts were continued longer until this integration was established.

We started transfer strengthening exercises and light functional activities following good integration of the transfer. At the end of the 3rd week of therapy, patients in both groups received occupational therapy for daily living activities restricted to a weight limit of 0.5 kg. Hands in both groups were supported after therapy with a dorsal blocking splint keeping MCP in 70^0 flexion in the 1st week and 50^0 in the 2nd week. Thereafter, the dorsal blocking splint was reduced to 30^0 and used only at night for 3 months. Patients were usually discharged from rehabilitation at the end of 4th weeks of therapy. All patients were discharged with good integration of transfer and deformity correction. For patients with only ulnar nerve paralysis, a pre-requisite for discharge was the ability to perform activities of daily living (ADL) like dressing, grooming and eating. Activities of daily living assessments in hands with combined ulnar- median nerve paralysis were not done following claw correction as these hands required an opposition transfer to achieve ADL. Hands with swelling and poor integration of transfer continued with therapy till good deformity correction and ADL was achieved. The discharge was decided independently by the treating therapist and the physician conducting the trial remained blinded to the timing of discharge.

We advised patients to return for clinical followup monthly for 3 consecutive months after discharge, then at a 3-month interval for 1 year and subsequently once a year. Patients with good transfer integration and strength were allowed to return to sedentary occupation at 8 weeks and unrestricted activities at 12 weeks following discharge from rehabilitation.

Outcome assessment

The primary goal of the immediate mobilization was to obtain earlier discharge from rehabilitation with successful claw deformity correction and without an increase of tendon transfer insertion pullout. Therefore, primary outcome measures were deformity correction, active range of motion (AROM) of digits, tendon transfer pullout incidence and time until discharge. As secondary outcome measures, we measured swelling, hand strength, pain and dexterity.

To assess hand function, we asked patients to move the hand actively to an open hand position (MCP and IPs joints fully extended), intrinsic plus position (MCP flexed and IPs extended) and fist position. The MCP and PIP angles in open hand and intrinsic plus position indicate the level of deformity correction.[3] The intrinsic plus position, in addition, provides an objective assessment of transfer integration following claw digits correction [3]. Active range of motion of each digit was calculated by subtracting angles at open hand position from fist closure angles. All angles in the individual patients were recorded in steps of 5^0.

Tendon transfer insertion pullout was objectively assessed by inspection of the MCP angles recorded daily for the first 2 weeks of therapy and then at the end of each week. As described earlier[3], rapid extension of MCP in open hand position with loss of MCP flexion in intrinsic plus position and decrease in AROM of MCP indicates transfer insertion pullout.

Swelling was determined measuring the volume of the operated hand using a water displacement method.[8] The percentage increase of postoperative over preoperative volume was compared for both groups at discharge from rehabilitation.

Grip strength was measured using a Jamar dynamometer and key pinch strength was measured using a pinch dynamometer (North Coast Medical Inc. Morgan Hill, CA, USA). To compare groups, the percentage change over the pre-operative strength was determined.

Pain was measured using a visual analogue scale (VAS) with scores from zero (no pain) to 10 (most severe pain). Assessments were done at the end of each week of therapy. Post-operative time in weeks when a zero-score was achieved was compared for both groups.

Hand dexterity was measured using the timed pick-up test The percentage change in time (sec) compared to the pre-operative score was determined for comparison of the groups.

Deformity correction, AROM, timed pick-up test, pinch and grip strengths were assessed during followup. Return to work was assessed at 3 month followup after discharge from rehabilitation. Outcome assessments of both groups were compared at (1) discharge from rehabilitation (discharge analysis) and (2) last followup more than one year after the operation (followup analysis).

Statistical Analysis

Parametric data analysis with independent sample t- test for equality of means was used to determine the mean, standard deviation, standard error of mean, 95% confidence interval. A p-value < 0.05 was taken as significant. All data were analyzed with statistical software SPSS 12.0.1 (SPSS Inc. 233 S Wacker Dr, Chicago, IL 60606).

Results

Data were collected between June 2005 and December 2007. Data were available for all 50 patients at discharge from rehabilitation. The last followup data beyond one year were available from 46 patients (Figure 1). The average followup at last clinical review was 17.9 months ± 4.7 (SD) for the IAMP group and 16.7 months ± 3.7 for the Immobilization group.

There was no difference between the groups in the MCP angles at discharge and at follow up in both the intrinsic plus position (P=0.146)[appendix 2] and the open hand position (P=0.143).[appendix 3] In the open hand position at discharge there was significantly less extension lag in the donor digit PIP angles (p=0.021)[appendix 4] in the IAMP group compared to the Immobilization group. In the intrinsic plus position at discharge , the PIP of index and the donor digit had significantly less extension lag in the IAMP group (p=0.018 and p=0.003 respectively)[appendix 5] compared to the Immobilization group. However, both groups were similar at follow up (p=0.784).[appendix 5] The total active digit flexion did not differ between both groups at discharge (p= 0.105)[appendix 6] and followup (p=0.479).[appendix 6]

There was no incidence of transfer insertion pullout in any of the patients in both groups. Patients were discharged from rehabilitation significantly earlier (p<0.001) in the IAMP group [36 ± 7.17 (SD) days; range 30-64] compared to the Immobilization group [54 ± 3.7 (SD) days; range 40-58]. Morbidity was significantly reduced by a mean of 22 days by immediate postoperative active mobilization of tendon transfer (p<0.001).

In the IAMP group complete relief of pain was achieved significantly earlier at, on average, 2.9 weeks compared to 5.6 weeks in the Immobilization group (p<0.001).[appendix 7] Pain persisted until 4 weeks after surgery in one IAMP group patient compared to 19 patients in the Immobilization group. There was no difference between the groups in postoperative swelling of the hand at discharge from rehabilitation (p=0.07).[appendix 7] There was no swelling of the hand at final assessment. Similarly, there was no difference in the timed pick-up test between the groups at the discharge from rehabilitation (p=0.8) [appendix 7] and final assessment (p=0.5).[appendix 7] There was no difference in the pinch or grip strength in both groups at discharge and followup.[appendix 8]

Discussion

The purpose of this study was to compare a postoperative tendon transfer management protocol of immediate active motion with immobilization. Using a randomized controlled trial design in which patients were operated by a single surgeon enabled bias-free comparison of tendon transfers for claw deformity correction. We found that immediate postoperative active motion for tendon transfer for claw corrections is safe and without an increased risk of insertion pullout. In addition, there is quicker resolution of pain, earlier restoration of hand function and significant reduction of morbidity compared to immobilization. Donor digits in the IAMP group had less extension lag at discharge but at followup the results were similar to the immobilization group. Similarly, improvements in intrinsic plus positions with IAMP observed at discharge did not persist at followup. Patients were discharged from rehabilitation 22 days earlier with full independent ADL with IAMP.

The concept of immediate active motion of tendon transfer follows the principle of early active motion protocols for tendon repairs[1], which has significantly improved the results of flexor and extensor tendon injuries. Our previous studies demonstrated the feasibility and safety of immediate active mobilization of opposition tendon transfers[4] and claw deformity correction by pulley insertion.[3] The major limitations of these studies were that we compared the prospective trial with a retrospective cohort that lacked reliable historical information on pain, swelling, hand function and strength. The present study demonstrates that pain was relieved significantly earlier with immediate active motion and this might explain the quicker restoration of hand function.

Our previous reports[3,4] demonstrated earlier restoration of hand function and morbidity reduction with IAMP but long term outcomes of tendon transfer was similar compared to immobilization. This RCT reaffirms the results of the previous studies[3,4] and suggests that early motion protocol affects the initial phase of rehabilitation and the long-term results are as good as immobilization.

The earlier use of the hand in daily life may significantly affect the cost of tendon transfer surgery. This is line with other reports in the literature. For example, Rath[3] demonstrated earlier restoration of hand function by an average of 21 days following claw correction with immediate active mobilization and predicted the economic impact with the change in post-operative protocol. Germann et al[9] concluded in patients receiving extensor indicis proprius transfer for thumb extension that hand function recovered quicker after early dynamic motion than after immobilization, shortening total rehabilitation time and making dynamic motion treatment highly cost-effective. Megerle et al[10] concluded that early active motion has comparable outcome to dynamic motion after transfer of the extensor indicis tendon without resulting in more complications.

There are number of limitations of the present study. A first limitation is that there is no objective data on return to productive activities. All patients in both groups with isolated ulnar nerve paralysis returned to their previous activities by 3 months after discharge from rehabilitation. As patients in the IAMP group were discharged on an average 22 days earlier, it is therefore presumed that return to work is quicker in the IAMP group, although this was not objectively quantified in the present study. It should be noted that hands with median nerve paralysis needed a further opposition transfer and this prolonged rehabilitation time. A second limitation is that the outcomes of pick-up test and pinch power in the 12 ulnar and median nerve paralyzed hands were excluded from the analysis. The third limitation is that we did not assess cost savings associated with the earlier discharge in the IAMP group. A fourth limitation is that there are not data on patient satisfaction outcomes.

There are surgical technique aspects that should be considered before further application of IAMP to other tendon transfers. The prerequisite of a strong insertion may limit the choice of donors and sites of insertion. For example, Stiles-Bunnel's transfer for claw correction may not be suitable for early motion as the lateral bands are too thin for a Pulvertaft weave. Similarly, donors requiring lengthening by fascial grafts are unsuitable for Pulvertaft weave and this will limit the choice of donors.

This study was performed on claw hands with complete sensory loss in Hansen's disease. In these hands, there is a possible danger of patients creating to much force on the transfer due to lack of pain sensation. In other patient groups, such as after traumatic nerve injury, this danger may be less apparent, as there is usually some sensation restored at the time of tendon transfer. Additionally, the professions of the patients in this study are probably such that they are doing work that is more demanding, putting the sutured tendons at a higher risk. Taken together, this suggests that the application of IAMP following claw correction in other patient groups with intrinsic paralysis may also be safe, although this should be further investigated in clinical trials.

We did not compare therapy time per session between both groups. However, we did record time per therapy session for the last 22 patients in the trial. In the first 2 weeks of therapy, the mean time per session for early mobilization group (n=10) was 24.5 min ± 4.9 (SD) compared to 42.5 min ± 5.8 for the immobilization group (n=12). In the 3rd and 4th week of therapy, time per session was similar to both groups.

The present study demonstrates that an early motion protocol results in quicker restoration of function. This may be due to the combination of instantaneous transfer integration and earlier pain relief. The reduced morbidity and speedy recovery of disability allows the individual to return to work and social activities. Future trials should investigate the economic and social impact of this new postoperative protocol and should indicate whether the same technique can be applied to other patient groups.

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Appendix 1

Therapy Protocol

The goal of therapy for dynamic claw deformity correction is to achieve MCP stability and integration of the transfer with the extrinsic muscles. Integration of transfer is possible only with a stable MCP i.e. a successful transfer contraction. An integrated transfer produces PIP extension, which is an essential step for successful deformity correction.

The aim of therapy is to initiate

Pre-operatively

1. Isolation exercise for the donor tendon: Contraction on command of the donor flexor digitorum Sublimis while keeping the PIP joint other digits in extension. This exercise initiates relaxation of the FDS of the adjoining digits, to facilitate PIP extension following tendon transfer.

Postoperatively

2. Prevent rupture, edema, adhesions and contractures
3. Contraction of the donor tendon to produce MCP flexion, followed by
4. Ability to achieve complete PIP extension in any MCP positions (neutral to any flexed position) indicates integration of the transfer activity
5. Restore the normal sequence of digital motion i.e. MCP flexion followed by PIP flexion for fist closure and PIP extension followed by MCP extension for fist opening.

THERAPY PROTOCOL

	Immediate Active Mobilization Group	Immobilization group
First and second week post-op.	Dorsal blocking splint is removed at 48 hours and the patient is encouraged to perform active flexion of the MCP while attempting to keep the PIP in full extension and then fist closure by active PIP flexion. For opening the fist, the PIP are actively extended keeping the MCP flexed and then MCP extension for achieving an open hand position. A 30^0 dorsal MCP block splint is used by the therapist to avoid overstretching of the transfer. From the position of maximum MCP extension in open hand position, the flexion sequence is repeated. The hand is supported after therapy with a 70^0 dorsal blocking splint in the 1^{st} week and 50^0 Dorsal blocking splints in the 2^{nd} week.	Plaster of Paris cast
Third and Fourth week	Transfer strengthening exercises and light functional activities. At the beginning of 3^{rd} week the patients are sent to occupation therapy for daily living activities restricted to a weight limit of <500 Gms. or 1 pound. The dorsal blocking splint is reduced to 30^0 and used at night only for 3 months to protect from inadvertent stretching of the transfer during sleep. Patients are discharged from rehabilitation after achieving independent ability to perform daily living activities like, dressing, grooming and eating. Discharge	Plaster of Paris cast A digital cast with PIPJ in full extension is applied to assist transfer integration exercises. The hand is supported after therapy with a 70^0 dorsal blocking splint.
Fifth and Sixth Week		Transfer strengthening exercises and light functional activities. At the end of 6^{th} week the patients are sent to occupation therapy for daily living activities restricted to a weight limit of <500 Gms. or 1 pound. The dorsal blocking splint is reduced to 30^0 and used at night only for 3 months to protect from inadvertent stretching of the transfer during sleep. Patients are discharged from rehabilitation after achieving independent ability to perform daily living activities like, dressing, grooming and eating.
Seventh and Eighth week		Discharge

Appendix 2 : Analysis of metacarpophalangeal joint flexion angles in the intrinsic plus position

Finger	Intervention group	Discharge Mean (deg)	Discharge S.D. (deg)	Discharge p-value	followup Mean (deg)	followup S.D. (deg)	followup p-value
Index	IAMP Immob.	71.20 70.20	5.64 7.43	0.595	75.22 73.26	8.46 5.56	0.359
Middle	IAMP Immob.	71.40 69.00	6.04 7.77	0.229	75.65 73.48	8.43 5.73	0.312
Ring	IAMP Immob.	69.80 68.20	5.86 5.57	0.327	75.22 71.74	8.59 6.33	0.125
Little	IAMP Immob.	67.40 67.00	6.79 6.45	0.832	74.57 73.70	8.27 7.26	0.703
Total Digits	IAMP n=100 Immob. n= 100	69.95 68.60	6.22 6.87	0.146	75.16 n=92 73.04 n=92	8.27 6.20	0.051

IAMP : Immediate active motion protocol
Immob. : Immobilization
SD : Standard deviation
Deg : degrees

Appendix 3 : Analysis of metacarpophalangeal joint angles in the open hand position

Finger	Intervention group	Discharge Mean (deg)	Discharge S.D. (deg)	Discharge p-value	Follow-up Mean (deg)	Follow-up S.D. (deg)	Follow-up p-value
Index	IAMP Immob.	32.00 33.80	9.57 9.39	0.505	7.83 10.65	15.73 11.00	0.484
Middle	IAMP Immob.	34.80 36.20	8.48 9.39	0.582	9.57 13.48	15.88 9.10	0.311
Ring	IAMP Immob.	34.20 36.40	9.43 7.97	0.378	10.87 13.26	19.11 14.51	0.635
Little	IAMP Immob.	31.20 33.80	12.44 9.92	0.418	13.91 15.87	21.48 18.87	0.744
Total Digits	IAMP n=100 Immob. n=100	33.05 35.05	10.05 9.14	0.143	10.54 n=92 13.32 n=92	18.04 13.77	0.243

IAMP : Immediate active motion protocol
Immob. : Immobilization
SD : Standard deviation
Deg : degrees

Appendix 4 : Analysis of proximal interphalangeal joint angles in the open hand position

Finger	Intervention Group	Discharge Mean (deg)	Discharge S.D. (deg)	Discharge p-value	Follow-up Mean (deg)	Follow-up S.D. (deg)	Follow-up p-value
Index	IAMP Immob.	0.60 1.60	8.46 6.73	0.646	7.17 9.57	13.13 12.61	0.532
Middle	IAMP Immob.	0.00 6.40	9.13 9.84	0.021	13.70 19.57	24.04 24.63	0.418
Ring	IAMP Immob.	1.00 4.20	10.00 9.43	0.065	8.48 8.70	23.28 19.14	0.973
Little	IAMP Immob.	5.40 7.40	8.41 9.48	0.434	11.09 9.35	18.40 13.84	0.719
Total Digits	IAMP n=100 Immob. n=100	1.25 4.90	9.22 9.10	0.005	10.10 n=92 11.79 n=92	20.01 18.45	0.553

IAMP : Immediate active motion protocol
SD : Standard deviation
Immob. : Immobilization
Deg : degrees

Appendix 5 : Analysis of proximal interphalangeal joint angles in the intrinsic plus position

Finger	Intervention Group	Discharge Mean (deg)	Discharge S.D. (deg)	Discharge p-value	Follow-up Mean (deg)	Follow-up S.D. (deg)	Follow-up p-value
Index	IAMP Immob.	8.40 15.60	10.18 10.64	0.018	17.61 20.87	15.66 20.82	0.551
Middle	IAMP Immob.	7.40 16.20	9.48 10.03	0.003	18.70 22.17	20.90 26.88	0.627
Ring	IAMP Immob.	11.20 17.20	10.83 10.52	0.053	15.65 15.87	19.96 22.29	0.972
Little	IAMP Immob.	12.00 16.00	11.37 11.37	0.219	12.61 8.91	16.71 14.92	0.433
Total Digits	IAMP n=100 Immob. n=100	9.75 16.25	10.50 10.50	0.000	16.14 n=92 16.96 n=92	18.28 21.93	0.784

IAMP : Immediate active motion protocol
SD : Standard deviation
Immob. : Immobilization
Deg : degrees

Appendix 6 : Total active motion of digit flexion								
		Discharge			Follow-up			
Finger	Intervention Group	Mean (deg)	S.D. (deg)	p-value	Mean (deg)	S.D. (deg)	p-value
Index	IAMP Immob.	196.80 193.40	23.18 27.38	0.638	228.91 225.22	25.72 22.44	0.606
Middle	IAMP Immob.	201.20 191.20	27.62 28.59	0.215	223.70 216.09	31.92 38.61	0.470
Ring	IAMP Immob.	195.00 188.00	28.43 23.85	0.350	219.13 217.17	33.91 34.64	0.845
Little	IAMP Immob.	187.40 183.20	29.16 25.08	0.588	209.78 210.00	31.13 27.96	0.980
Total Digits	IAMP n=100 Immob. n=100	195.10 188.95	27.25 26.17	0.105	220.38 n=92 217.12 n=92	30.86 31.48	0.479

IAMP : Immediate active motion protocol
SD : Standard deviation
Immob. : Immobilization
Deg : degrees

Appendix 7 : Outcomes of Immediate Active Motion Protocol and Immobilization Group For Pain, Swelling and Timed Pick Up Test				
Intervention group		IAMP	Immobilization	P value
Zero Pain level (VAS score) achieved in weeks		2.9±0.9	5.6±1.2	<0.001
Swelling expressed as percentage increase of pre-op volume		15.8±12.2	14.2±14.4	0.07
Timed pick up test expressed as percentage of pre-op pick up time in ulnar nerve paralyzed hands	Discharge	96.2±30.5	100.31±41	0.8
	followup	87.9±41	101.5±85.7	0.5

Note: Values are mean of ± SD of n. and p values indicates the significance level of the t-test comparing both groups
IAMP: Immediate active motion protocol Immob.: Immobilization

Appendix 8 : Grip and Pinch data

	Interve-ntion group	Pre – Operative			Discharge				Follow-Up			
		Mean	SD	Range	Mean	SD	Range	% of pre-op strength	Mean	SD	Range	% of pre-op strength
Grip In Kg	IAMP	18.46	±6.24	11.5 - 29	5.75	±3.23	1 - 12	31.15	18.61	±6.46	10 - 33	100.81
	Immob-Ilization	16.22	±7.78	1 - 38	6.70	±4.31	2 - 11.5	41.31	16.70	±5.28	8 - 26	102.96
Pinch In Kg	IAMP	3.54	±1.28	1 - 6.5	2.65	±1.58	0.5 - 8.5	74.86	3.34	±1.21	1.5 - 5.5	94.35
	Immob-ilization	3.50	±1.99	1 - 9.2	2.22	±1.00	0 - 3.5	63.43	2.95	±1.13	1.0 - 5.5	84.29

CHAPTER 6

Early Active Motion versus Immobilization after Tendon Transfer for Foot Drop Deformity: A Randomized Clinical Trial

Santosh Rath, Ton A. R. Schreuders, Henk J. Stam, Steven E. R. Hovius, Ruud W. Selles. Early Active Motion versus Immobilization after Tendon Transfer for Foot Drop Deformity : A Randomized Clinical Trial

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Abstract

Background : Immobilization after tendon transfers has been the conventional postoperative management.

Purposes : To determine whether early active mobilization following a tendon transfer for foot drop correction is safe, with no increase in tendon insertion pullout and compared to immobilization reduces rehabilitation time and results in similar functional outcomes (active ankle dorsiflexion, plantarflexion, range of motion and walking ability).

Methods : We randomized 24 patients with surgically–corrected foot drop deformities to postoperative treatment with early mobilization (Mobilized) with active motion at five days (n = 13) or four weeks of immobilization (Immobilized) with active motion at 29 days (n = 11). In both groups, the tibialis posterior tendon was transferred to extensor hallucis longus and extensors digitorum communis for foot drop correction. The primary outcome measures were tendon insertion pullout, active ankle dorsiflexion and plantarflexion, active total range of motion, and rehabilitation time. Rehabilitation time was defined as the time from surgery until discharge from rehabilitation with independent walking. The minimum time for followup was 16 months (mean 19 months, range 16-38 months) in both groups.

Results : There was no incidence of tendon pullout in both groups. Rehabilitation time in the Mobilized group was reduced by an average of 15 days. The various functional outcomes of foot drop deformity correction was similar in both groups.

Conclusions : In Hansen's disease early active mobilization protocol for foot drop correction has no added risk of tendon pullout and provides similar functional outcomes compared to immobilization. Early mobilization had the advantage of earlier restoration of independent walking.

Introduction

While an ankle foot orthosis (AFO) may be the preferred option to treat foot-drop deformity in patients with a peripheral nerve injuries or an intervertebral disc prolapse since this intervention is non-invasive and cheap, it has limited use for foot-drop in Hansen's disease as the majority of patients in endemic countries are manual or agriculture workers habituated to bare-feet walking. In addition, for those using footwear, social and religious practices requires them to remove these for entering places of worship and homes. Therefore, anterior transfer of the tibialis posterior tendon is often used for foot-drop correction as this allows walking without an orthosis and removes part of the social stigma associated with deformities in Hansen's disease but is often rejected by the patients due to the long rehabilitation time.

Immobilization is the conventional postoperative management after tendon transfers to the feet. The period of immobilization for foot drop correction with a tibialis posterior tendon transfer is 4 weeks[10,11,13–15,17,18] and is followed by a rehabilitation period of another 4-6 weeks. [11,14]

Recent studies have demonstrated no added risk of tendon insertion pullout with immediate postoperative active mobilization after tendon transfers to the hand for opposition[6] and claw deformity correction[7,9] in patients with Hansen's disease. In these studies, early mobilization of tendon transfers of the hand reportedly restored hand function earlier and reduced morbidity while producing similar functional outcomes at followup. An earlier small prospective cohort study on early active mobilization after tibialis posterior transfer for foot drop correction demonstrated no incidence of tendon insertion pullout, reduced rehabilitation time, a low complication rate, and earlier independent walking compared to a historical cohort of patients that had received immobilization.[8] These cohorts were, however, not controlled in a randomized clinical design and outcome assessment was limited by the inadequate data of the historical cohort.

We therefore asked whether early active mobilization after tibialis posterior transfer for foot drop compared with immobilization would (1) have a similar low rate of tendon insertion pullout, (2) reduce rehabilitation time, and (3) result in similar functional outcomes in terms of active ankle dorsiflexion (ADF), plantar flexion (APF), active total ankle ROM, strength of dorsiflexion, walking performance, Stanmore score,[19] and resolution of functional problems.

Patients and Materials

From July 2005 until June 2006 we performed a tendon transfer for foot drop correction in 39 patients with Hansen's disease with irreversible common peroneal nerve paralysis of more than one year duration. The diagnosis and treatment of the disease was performed at the field level by trained medical staff of the National Leprosy Eradication Programme. The neurologic deficit was documented by the physiotherapist using the manual muscle strength test (MMST) grading.[2] All patients had completed multidrug therapy for Hansen's disease and the muscle strength of the ankle dorsiflexors was MMST Grade-0. We excluded 9 patients with clawed toes having additional surgery, active neuropathic plantar ulcers, absorption of toes, and Charcot's arthropathy of foot and ankles (Fig. 1). Six patients expressed their inability for repeated followup and were therefore excluded (Fig.1). These exclusions left 24 patients for the RCT; these were randomized postoperatively into one of two groups: those receiving early mobilization (mobilized group) or those receiving 4 weeks of immobilization (immobilized group). Randomization was performed using unmarked sealed opaque envelopes that were mixed in a box. A person not involved in the trial assigned the patients to the groups by opening an envelope picked at random from the box after completion of surgery and wound closure to avoid any influence of group allocation on surgery procedures. Thirteen patients were allocated to the Mobilized group and 11 to the

Immobilized group. The groups were similar in age, gender, side of involvement, and duration of paralysis (Table 1). For a power analysis, we used data on rehabilitation time from a previous prospective cohort study [8] on patients using early active mobilization (rehabilitation time, 44 ± 8 days) and a historical cohort of patients immobilized (rehabilitation time, 57 ± 8 days). We calculated that with a 10 day difference in rehabilitation time between both groups and a group size of 10 patients we would have a power of 97%.

Table 1 : Comparison of baseline data of patients in the two groups

Variables	Mobilization Group	Immobilization Group	P value
Age (years)*	29 ± 12	32 ± 10	0.524
Gender (male: female)	12:1	10:1	
Duration of paralysis (months)*	41 ± 3	40 ± 3	0.959
Duration of follow-up (months)*	19 ± 6 (range 16-38)	19 ± 5 (range 16-38)	0.960

*Values are expressed as mean ± SD.

The tibialis anterior, extensor hallucis longus, extensor digitorum longus and extensor digitorum brevis were grade 0 in all 24 patients (Table 2). Five patients in each group had incomplete common peroneal paralysis with Grade III or more in peroneus longus and peroneus brevis muscle. The tibialis posterior, the flexor hallucis longus and flexor digitorum longus had an grade V in all patients. Data of all 24 patients obtained during postoperative therapy were analyzed for early results. Twenty-three patients were available beyond 1 year for followup analysis (Figure 1). The minimum time of followup at the final assessment was 16 months (mean 19 months; range, 16 to 38 months) for both groups (Table 1). One patient had no followup after discharge from rehabilitation therapy and could not be traced owing to geographical relocation. Approval was obtained from the institutional review board and informed consent signed by all patients.

Table 2 : Pre-operative Manual Muscle Strength Test of 24 Patients With Foot Drop Deformity											
Hosp no.	Group	TA	EHL	EDL	EDB	PL	PB	TP	GS	FHL	FDL
2103	"m"	0	0	0	0	0	0	5	5	5	5
2107	"m"	0	0	0	0	0	0	5	5	5	5
2109	"m"	0	0	0	0	3	3	5	5	5	5
2133	"m"	0	0	0	0	0	0	5	5	5	5
2145	"m"	0	0	0	0	0	0	5	5	5	5
2150	"m"	0	0	0	0	1	1	5	5	5	5
2349	"m"	0	0	0	0	0	0	5	5	5	5
2148	"m"	0	0	0	0	5	5	5	5	5	5
2291	"m"	0	0	0	0	5	5	5	5	5	5
2240	"m"	0	0	0	0	5	5	5	5	5	5
2340	"m"	0	0	0	0	5	5	5	5	5	5
2091	"m"	0	0	0	0	0	0	5	5	5	5
2104	"m"	0	0	0	0	1	1	5	5	5	5
2121	"i"	0	0	0	0	0	0	5	5	5	5
2141	"i"	0	0	0	0	0	0	5	5	5	5
2144	"i"	0	0	0	0	0	0	5	5	5	5
2250	"i"	0	0	0	0	0	0	5	5	5	5
2290	"i"	0	0	0	0	0	0	5	5	5	5
2293	"i"	0	0	0	0	0	0	5	5	5	5
2131	"i"	0	0	0	0	5	5	5	5	5	5
2162	"i"	0	0	0	0	5	5	5	5	5	5
2227	"i"	0	0	0	0	5	5	5	5	5	5
2289	"i"	0	0	0	0	5	5	5	5	5	5
2336	"i"	0	0	0	0	5	5	5	5	5	5

TA : Tibialis Anterior

EHL : Extensor Hallucis Longus

EDL : Extensor digitorum Longus

EDB : Extensor digitorum brevis

PL : Peroneus longus

PB : Peroneus brevis

TP : Tibialis posterior

GS : Gastro soleus

FHL : Flexor Hallucis Longus

FDL : Flexor digitorum Longus

"m" : Early mobilization group

"i" : Immobilization group

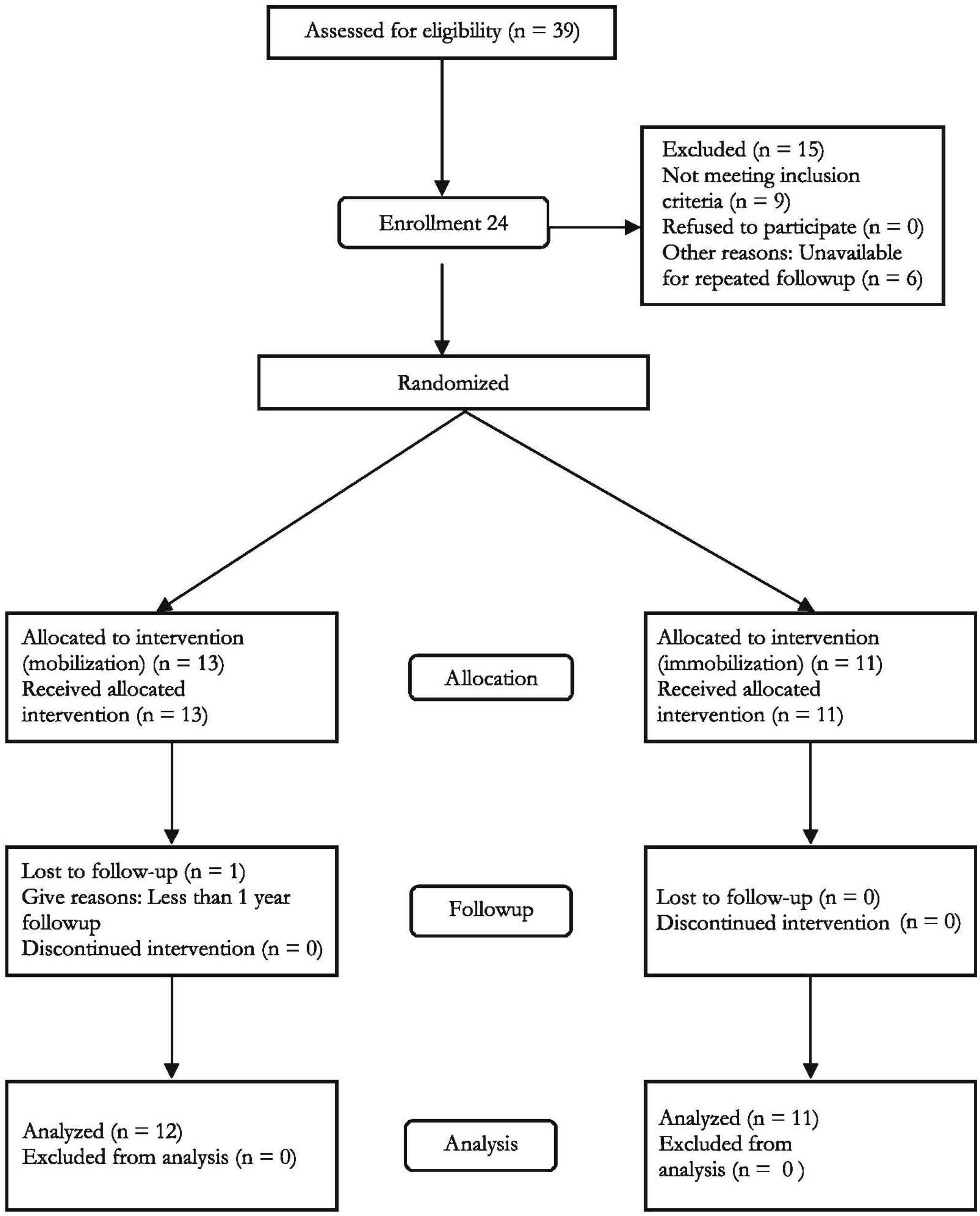

Fig. 1 : A CONSORT flow diagram illustrates the design of our RCT comparing early mobilization versus immobilization after tendon transfer for foot drop.

In all patients, a tibialis posterior tendon transfer for foot drop correction was performed by the circumtibial route.[14] Patients were operated on under sedation using wide local infiltration of 1% lidocaine with 1:10000 adrenaline and without the use of a tourniquet. The surgical technique is similar to that described by Srinivasan et al.[14] The tibialis posterior tendon was detached from its insertion to the navicular bone, retrieved in the lower leg, and split to the musculotendinous junction into two slips. Each slip was then transferred to the foot separately along the circumtibial route passing anterior to the ankle and superficial to the extensor retinaculum. One slip was inserted into the tendons of the extensor digitorum longus with maximum tension and the second slip was inserted into the extensor hallucis longus tendon in neutral tension. The transfer was inserted using a Pulvertaft's weave[5] and the points of entry and exit were sutured using 2-0 Ethibond® (Ethicon, Inc, Somerville, NJ). Percutaneous lengthening of the Achilles tendon was always performed before the tendon transfer because passive ankle dorsiflexion was less then 20° in all patients.

During the suturing of the transferred tendon slips, the limb was put in a prefabricated splint that maintained the knee in 60° flexion and the ankle in 20° dorsiflexion to ensure standardization of tendon transfer tension. After completion of surgery the ankles were immobilized in 20° dorsiflexion in both groups with a below-knee posterior splint in the Mobilized group and a below-knee cast with a walking heel in the Immobilized group. In the Mobilized group the below-knee posterior splint was removed on postoperative day 5 for therapy. In the Immobilized group the cast was removed on the 29th postoperative day for therapy with the foot supported by a splint between therapy sessions.

Patients in both groups were allowed non-weight bearing crutch walking from postoperative day 2. The Immobilized group patients were allowed partial weight bearing when pain subsided. Due to logistic reasons, all patients were housed in an unsupervised residential accommodation at the institution during the rehabilitation period. Rehabilitation was supervised by a therapist not involved in the selection of patients for the trial. Blinding of the therapist to group allocation was not possible as the Immobilized group required removal of the cast on the first day of therapy. A therapist (NP), not involved in the care of the patient and therefore blinded to group assignment, discharged the patient and performed the final followup assessments beyond 1 year.

The rehabilitation protocol was similar in both groups except that active mobilization started on postoperative day 5 in the Mobilized group and at the beginning of postoperative week 5 in the Immobilized group. As a result, the therapy protocol in postoperative week 2 to 5 in the Mobilized group corresponded to postoperative weeks 5 to 8 in the Immobilized group. The therapy program consisted of once a day 10 repetitions of active dorsiflexion exercises in the first week of therapy (postoperative week 2 in the Mobilized group, postoperative week 5 in the Immobilized group), 25 repetitions of active dorsiflexion and plantar flexion exercises in the second week of therapy (postoperative week 3 in the Mobilized group, postoperative week 6 in the Immobilized group), partial weight bearing using parallel bars in the third week of therapy (postoperative week 4 in the Mobilized group, postoperative week 7 in the Immobilized group), and full weight bearing and gait training in the fourth week of therapy (postoperative week 5 in the Mobilized group, postoperative week 8 in the Immobilized group). The limb was supported after therapy in a posterior splint in 20° dorsiflexion for 3 weeks and thereafter only at night for 3 months. Patients in both groups were discharged from rehabilitation when they had obtained MMST grade IV of the transferred muscle and independent walking without any aids. Unrestricted activities of daily living were allowed 3 months after discharge from rehabilitation.

The main risk of early mobilization is tendon transfer rupture or insertion pullout. Therefore, we evaluated the presence of transfer pullout by monitoring active dorsiflexion, position of the foot at rest, and active ankle ROM of the foot on a daily basis for the first 2 weeks of therapy and then at the end of each week. A sudden or progressive reduction of dorsiflexion and ROM would indicate rupture or impending insertion pullout. The measurements were performed using a hand-held goniometer with the patient in a sitting position with the knee in 90° flexion.

Clinical review was recommended once a month for 3 months, then every 3 months for 1 year, and then once a year. At each visit the functional outcome measurements were (1) ADF angle, (2) APF angle, and (3) active ankle ROM between plantarflexion and dorsiflexion. Rehabilitation time was defined as the time from surgery until discharge from rehabilitation with independent walking. Additionally, at the last followup, the strength of active dorsiflexion was measured with MMST (0-5) score[2] and the 6-minute walking test[3] was performed to determine functional walking performance. The surgical outcomes were graded using the Stanmore System,[19] which is a 100 point scale with seven scoring categories.

A patient-specific index of what the patient's rate as the most important problem attributable to impairment from foot drop was determined based on the study methodology of McCormick et al for ulnar nerve paralysis.[4] These problems were difficulty in walking (76%), running (61%), climbing stairs (61%), scraping the toes during swing phase of gait (61%), and riding a bicycle (30%). All patients were conscious of their awkward gait and cosmesis. Impact of the index intervention on these functional problems was scored by the patient as complete or partial resolution or no change at last followup.

Data obtained at discharge and the last followup was compared for both groups using the nonparametric Mann-Whitney U test. We determined differences in tendon insertion pullout, rehabilitation time and functional outcomes (active ankle dorsiflexion, plantar flexion, ROM, strength of dorsiflexion, walking ability, Stanmore score and resolution of functional problems) between the Mobilized and the Immobilized groups. All data were analyzed with SPSS® 16.0.1 statistical software (SPSS Inc, Chicago, IL).

Results

We observed no insertion pullout of the transferred tendon in any of the patients in either group. Rehabilitation time was 43 ± 5 days for the Mobilized group and 59 ± 2 days for the Immobilized group. As a result, patients in the Mobilized group were discharged from rehabilitation, on average, 15 days earlier compared to the Immobilized group ($p < 0.001$). We found no differences between the groups in ADF, APF, and total ankle ROM angles at discharge and at last followup (Table 3). The strength of dorsiflexion was similar in both groups at last followup. Dorsiflexion was MMST Grade V in 10 patients and Grade IV and Grade III in one patient each in the mobilized group. In the immobilized group there were 10 patients with MMST Grade V and one with Grade IV. The 6-minute walking distance was similar in both groups at last followup. At last followup 12 patients in the Mobilized group had Stanmore scores between 96 to 98 (average score, 97) and one patient had a score of 69 (Table 4). All 12 patients in the Immobilized group had scores ranging from 93 to 98 (average score, 97) (Table 4).The common functional problems of walking, climbing stairs, scraping the toes during the swing phase of gait, and riding a bicycle were resolved by tibialis posterior tendon transfer in both groups. All patients in both groups had improved gait and cosmesis.

Table 3. Comparison of Outcomes of The Mobilization and Immobilization Group At Discharge and Last Follow-up Assessment

	Group	Mean	P value (Mann Whitney U test)
ADF D	"m" (n = 13)	18.5	0.69
	"i" (n =11)	18.9	
ADF L	"m" (n = 12)	17.7	0.26
	"i" (n = 11)	20.8	
APF D	"m" (n = 13)	−7	0.95
	"i" (n = 11)	−7	
APF L	"m" (n = 12)	5.1	0.45
	"i" (n = 11)	2.1	
TAM D	"m" (n = 13)	12.0	0.91
	"i" (n = 11)	12.0	
TAM L	"m" (n = 12)	22.8	0.52
	"i" (n = 11)	22.9	
MMST grading	"m" (n = 12)		0.56
	"i" (n = 11)		
Six minute walking	"m" (n = 11)		0.28
	"i" (n = 10)		

"m" : mobilization group; "i" : immobilization group;
ADF D : active dorsiflexion angle at discharge;
ADF L : active dorsiflexion at last followup;
APF D : active plantarflexion at discharge [Negative sign (-) when active ankle plantar flexion does not reach neutral or Zero position and the angles are recorded in the dorsiflexion range];
APF L : active plantarflexion at last followup;
TAM D : total Active motion at discharge;
TAM L : total active motion at last followup; MMST : Manual Muscle Strength Test

Table 4: Results of Tibialis Posterior Tendon Transfer Using the Stanmore System [19]																								
		Mobilization Patients												**Immobilization Patients**										
Parameter	**Points**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**
Pain (15points)		15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15
No pain at any time or not worse	15																							
Mild pain or slightly worse	10																							
Moderate pain or moderately worse	5																							
Severe pain or marked worse	0																							
Need for orthosis (15 points)		15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15
No	15																							
Occasional (once a week)	10																							
Frequently (twice a week)	5																							
Regularly (greater than twice a week)	0																							
Normal shoes (5 points)		3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Yes	5																							
Yes, but prefers certain types	3																							
No	0																							
Functional outcome (10 points)		10	10	10	10	10	3	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Normal daily activity and normal recreation	10																							
Normal daily activity and limited recreation	6																							
Limited daily activity and recreation	3																							
Severe limitation on daily activity and recreation	0																							

MRC : Medical Research Council

Discussion

In this study we evaluated whether early active mobilization of tendon transfer for foot drop would not increase tendon insertion pullout, would reduces rehabilitation time and would have similar functional outcomes (active ankle dorsiflexion, plantar flexion, ROM, walking ability, Stanmore score, and resolution of functional problems) compared with immobilization.

There are a number of limitations to our study. First, the number of patients enrolled in the trial was relatively small. A power analysis indicated that a group of 10 patients would be sufficient to determine whether there was a reduced rehabilitation time. We did not anticipate important differences in functional outcome between both groups and although we found none, the group size would not be sufficient to detect small differences in functional outcome. Second, we did not asses direct or indirect cost reductions associated with earlier discharge of patients in the Mobilized group. Our patients remained in the institution during their rehabilitation and this increased the cost of treatment compared with those receiving rehabilitation therapy on an outpatient basis. This added cost can be avoided as postoperative therapy can be initiated on an outpatient basis if facilities are available locally. Third, we did not measure whether patients returned to productive employment quicker with early mobilization. All patients in both groups reportedly returned to their previous activities 3 months after discharge from rehabilitation. As patients in the Mobilized group were discharged on an average 15 days earlier, we presumed return to work would be quicker in the Mobilized group, although we did not objectively quantify this in the study. Fourth, we used no validated system of scoring change in functional problems and subjective satisfaction after tendon transfer. Improvement in running was not assesses properly as patients were advised to avoid running for fear of stretching the transfer.

In this study, there was no incidence of tendon insertion pullout during the early active mobilization of the foot drop tendon transfer. This finding is similar to a previous report on early active mobilization in the same patient group[8] and also in line with our studies on early active mobilization of tendon transfer to the hand.[6,7,9] In addition, this is in line with the study of Silfverskiold and May[12] on early active mobilization after tendon transfers to the hand using mesh-reinforced suture techniques that also reported no insertion pullout. Similarly Germann et al.[1] in their study on dynamic splint-assisted mobilization of extensor indicis proprius transfer for thumb extension had no incidence of transfer insertion pullout. Taken together, these studies indicate that the risk of tendon insertion pullout is negligible with early mobilization of these tendon transfers.

In this randomized controlled trial, patients in the early mobilization group had a 15-day shorter rehabilitation time compared to the immobilization group. This finding is similar to our study comparing a prospective cohort with historical data in which we found a 13-day reduction in rehabilitation time.[8] The reduction in rehabilitation time after early mobilization for foot-drop correction in this study is less than the 22 days reduction achieved for early mobilization for claw deformity correction of the hand.[9] However, patients who had tendon transfers for the hands were mobilized on the 2nd postoperative day[7, 9] while in this study patients were not mobilized before the 5th postoperative day. Additional studies are needed to investigate if mobilization for foot tendon transfers can be started earlier than the 5th postoperative day to further reduce rehabilitation time.

The functional outcome of early mobilization of foot drop tendon transfers was similar to the immobilization group in this study. Thus, although we had expected a small functional benefit with early mobilization of foot drop because of less disuse atrophy, this was not shown in the present study. The finding of similar functional outcome is in line with the findings of previous report on foot drop[8] and early mobilization of tendon transfers to the hand.[1, 6, 7, 9, 12] These studies demonstrate that the benefits of early tendon transfer mobilization are limited to reduce rehabilitation time but have no further advantage over immobilization in terms of functional recovery. It is possible that the group size was too small to show subtle differences and this warrants further studies with larger number of patients. The Stanmore score of patients in this study [Table 4] is comparable to foot drop correction by combined anterior transfer of tibialis posterior and flexor hallucis longus[15] and by insertion of tibialis tendon proximal to the ankle joint.[16]

The quicker discharge from rehabilitation may affect the cost of tendon transfer surgery for foot-drop correction. For example, Germann et al.[1] reported that hand function recovers quicker in patients receiving extensor indicis proprius transfer for thumb extension after early dynamic motion than after immobilization, making early dynamic motion treatment for tendon transfer highly cost-effective. The total costs for tendon transfer surgery include the institutional charges for the operation (infrastructure, consumables), personnel costs for surgeons, therapists, and other staff, and work-loss compensation.[1] Future trials should determine a possible cost reduction with early mobilization of tendon transfer compared to the present practice of immobilization.

For future studies, several aspects of the surgical technique could be considered before further application of early mobilization to other foot tendon transfers. The prerequisite of a strong insertion may limit the choice of the tendon donor and the site of insertion. The transfer insertion site for tendon-to-tendon attachment should be of sizable dimension for a Pulvertaft weave.[5] Further investigation are required to determine if tendon transfer insertion to bone can be a solution in situations where the Pulvertaft weave is not possible due to tendon size mismatch. In addition, the technical feasibility of early mobilization after tibialis posterior tendon transfer to bone insertion to restore ankle dorsiflexion needs to be investigated. Tendon-to-bone insertion was not attempted in this trial owing to the concern for neuropathic tarsal disintegration in Hansen's disease.[14, 18]

In summary, this study demonstrates that early active mobilization of tendon transfer to the foot is feasible with no added risk of insertion pullout. The earlier restoration of independent walking with early mobilization compared to immobilization is a significant advantage with the potential of important reduction of the total costs and the loss of work for the patients. The large effects in reduction of rehabilitation time after early mobilization in this study as well as in a number of previous studies[1,6,7,9,12] on tendon transfers of the hand warrant further clinical trials to expand the application of early mobilization to other tendon transfers of the foot.

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CHAPTER 7
General Discussion

Introduction

Immobilization for periods extending from 3-6 weeks has been the traditional postoperative protocol for tendon transfers. The main purpose of this thesis was to investigate the feasibility, safety and application of early postoperative active mobilization for tendon transfers in loss of nerve function due to m. leprae. The outcomes were compared with outcomes in patients who were treated with postoperative immobilization. The concept of early postoperative active mobilization for tendon transfers was applied to three common tendon transfers to the hand and foot. The process involved increasing the strength of the tendon transfer insertion site by modifications of standard surgical techniques to withstand the stress of early mobilization. The therapy protocol of early active mobilization was developed along with an objective method of monitoring insertion integrity during therapy. There was no incidence of tendon insertion pullout in these trials. The results in these trials were compared to historical results of a similar group of patients with immobilization after tendon transfer. The long term results of early active mobilization and immobilization were similar in all these trials. Earlier discharge from treatment was an added advantage with early active mobilization of tendon transfers.

The concept of early active mobilization was then rigorously tested in randomized clinical trials (RCT). The RCT comparing early mobilization with immobilization on 50 claw hand deformity patients provided information on the early postoperative phase of rehabilitation in addition to confirmation of the results of the previous trials. There was no incidence of insertion pullout in these studies. Significantly earlier relief of pain, swelling and instantaneous integration of transfer were the benefits of early mobilization compared to immobilization. Postoperative morbidity was reduced by nearly 40% with early mobilization and patients returned home earlier with independent function after deformity correction with tendon transfers. An overwhelming majority of immobilized patients in the RCT would opt for early active mobilization if offered the choice. These trials demonstrated that early active mobilization of tendon transfers is safe and can reduce morbidity when selection criteria's are met and precautions exercised to avoid a transfer insertion pullout.

Patient selection

Patient selection is quintessential to the success of early mobilization protocols of tendon repair.[1] The patient has to understand the rationale of the protocol, co-operate with the therapists in moving the part in spite of some degree of discomfort and follow the precautions to avoid a pullout or rupture of the repair. Children, incoherent patients and those with communication difficulties are unsuitable for the early mobilization programme.

Similarly, the success of the active mobilization protocol for tendon transfer depends on patient selection. The patient has to be compliant to all instruction, reliable for taking precautions, and understand the therapy process of donor tendon isolation and integration. Donor tendon isolation involves learning to contract one tendon that is to be transferred, while relaxing the other surrounding muscle. For example, to achieve flexor digitorum sublimis (FDS) donor isolation, the patient has to learn to flex the PIP joint only while keeping the DIP immobile. This is only possible by relaxing the FDP muscle during contraction of the FDS of the digit. Since the FDP has a mass action on four digits, all DIP joints are kept extended during this isolation exercise.

Schiber[2] demonstrated that individuated finger movements are produced not by independent sets of muscles acting on each digit, but by the activity of several muscles in cooperation, many of which act on more than one digit. Donor tendon isolation is the learned activity of a selected tendon to achieve individuated finger joint movement. The example of FDS isolation is a process of achieving individuated PIP joint flexion movement with contraction of FDS and simultaneous relaxation of extensor digitorum communis and FDP.

Donor tendon isolation is utilized postoperatively to activate tendon transfer contraction which results in the desired new motion. The visual and propioceptive feed back facilitates integration of this new movement with those of other existing muscles acting on the joint. The preoperative donor tendon isolation probably leads to formation of new neuronal channels in the motor and pre-motor cortex and these are utilized immediately after surgery by early active mobilization.[3] Cooperation and ability to isolate the donor tendon contraction preoperatively is essential for early mobilization protocol.

Enhancing strength of tendon transfer insertion

For the opposition transfer (chapter 2) the FDS tendon was inserted to the capsule of the MCP joint and the distal end was secured additionally on the ulnar aspect of neck of 1st metacarpal. For the "lasso" procedure and tibialis posterior transfer the transfer slip was anchored by Pulvertaft weave, which is the strongest tendon to tendon suturing technique.

Protocol to monitor integrity of tendon transfer insertion during early post operative active mobilization

An objective system of daily documentation can track the integrity of the tendon insertion. Any lengthening of the transfer is detected by loss of the resting position and reduction of the range of active motion produced by the transfer. Using this objective system any loss of tension could be detected early and when necessary remedial action could take place to avoid further deterioration and restore proper tension.

Prospective trials

The prospective trials (chapter 2, 3, 4) established the protocol of early post operative active mobilization applied to tendon transfers for the three most common Leprosy deformities and demonstrated their safety.

Randomized controlled trials

The major limitation of the above three trials was that the outcomes were compared with retrospective historical cohorts. To test the hypothesis stringently, randomized clinical trials (RCT) of early postoperative active mobilization vs. postoperative immobilization were conducted for claw (chapter 5) and foot drop (chapter 6) deformity.

The aim of the RCT was

1) To establish the effectiveness of the concept of early active mobilization protocol and
2) Compare results of early postoperative active mobilization with immobilization

RCT results

RCT on claw hand deformity (chapter 5)

Immediate postoperative active motion for tendon transfers for claw digit correction is safe and without an increased risk of insertion pullout . The RCT on claw demonstrated quicker resolution of pain, earlier restoration of hand function, and significant reduction of morbidity compared with those of immobilization. Patients with early mobilization were discharged from rehabilitation 22 days earlier with full independent ADL. Donor digits in the early mobilization group had less extension lag at discharge, but at followup the results were similar to the immobilization group. Similarly, improvements in deformity correction with early mobilization observed at discharge did not persist at followup.

RCT on foot drop correction (chapter 6)

The RCT on foot drop demonstrated a quicker restoration of independent walking and significant reduction of morbidity with early mobilization and patients were discharged from rehabilitation 15 days earlier with full independent walking. The advantages of early mobilization over immobilization did not persist at followup. The above findings indicate that early motion protocol affects the initial phase of rehabilitation, and the long-term results are as good as those of immobilization. Patient's satisfaction with early mobilization is high and given a choice, majority of patients that were immobilized in the trial will prefer the early mobilization protocol.

Comparison of results with published reports

There are no published RCT in the literature investigating early mobilization following opposition transfer, claw deformity and foot drop correction for comparison. There is a RCT comparing dynamic splint assisted early mobilization with immobilization of extensor indicis proprius transfer to restore thumb extension.[3]

Germann et al[3] compared early dynamic motion versus postoperative mobilization in patients with of extensor indicis proprius transfer to restore thumb extension in a prospective randomized study and demonstrated shorter rehabilitation time with early mobilization. The dynamic outrigger splint assisted motion protocol saved an average of 10 days in duration and time off work which was over 25% of the overall treatment period. The average number of hand therapy sessions was also considerably reduced. The present RCT (chapter 5, 6) demonstrates a saving of nearly 40% of overall treatment period and earlier functional recovery.

The two methods of early mobilization i.e. dynamic mobilization using an outrigger splint and active mobilization was compared in a RCT following of extensor indicis proprius transfer for thumb extension.[4] Both treatment protocols demonstrate comparable clinical results and early active motion did not result in a higher rate of complications but fails to speed up rehabilitation compared to dynamic mobilization. Early active mobilization protocol is cheaper as this does not require the splint costing over $100.[3]

The earlier use of the hand in daily life with early mobilization may considerably affect the cost of tendon transfer surgery. This is consistent with reports that dynamic early motion leads to recovery of hand function earlier, reduces total rehabilitation time thus making early motion protocol highly cost-effective compared to immobilization. The study[3] demonstrated that the dynamic protocol led to a considerable reduction of overall treatment cost by $580 per patient.

The present studies (chapter 5, 6) did not assess the exact economic benefit of early active mobilization over immobilization due to methodological difficulties. Primarily, majority of the participants in the trial were subsistence farmers and had no fixed income. Many were below the national poverty line earning less than 1 US dollar a day. Each day of lost income i.e. opportunity cost, was a significant financial set back for the individual. There is no compensation for loss of work for the individual in India, so calculating the cost to the nation for the individual's loss of work was not feasible.

Limitation of the RCT

One of the major limitations of the trial was that the exact time patients returned to full economic activities was not objectively researched. Many of these patients, specially the manual workers and farmers had suboptimal earnings before surgery as their work was affected by the paralysis. Given the limitation for assessing the individuals' earnings pre disease, pre surgery and post surgery; making an economic analysis of the impact of earlier restoration of function was not feasible. Subjective enquiry suggests that every participant in the trial returned to their previous activities by 3 months after discharge from rehabilitation. It is therefore presumed that those with early mobilization returned to work quicker and thereby limited their loss of earning during the period of deformity correction.

Limitations of the technique

The prerequisite of a strong insertion limits the choice of donors and sites of insertion. The insertion site must allow for a strong attachment to be suitable for early postoperative active mobilization. For example, Stiles-Bunnell's transfer for claw correction may not be suitable for early motion, as the lateral bands are too thin for a Pulvertaft weave. Similarly the extensor indicis proprius transfer for opposition is unsuitable for early postoperative active mobilization as the tendon is not long enough for a secure second attachment to the ulnar side of the thumb. This limits the choice to donors with adequate length like FDS. Paucity of thick tendon grafts for lengthening excludes short tendons from being used as donors for early mobilization protocol.

Training therapists in the technique of early postoperative active mobilization requires time and resources and this fact has to be taken into account while assessing the economic benefits of early mobilization. However after the learning curve, the average therapist's time required for each patient is nearly 40% less compared to that required for immobilized patients in the first two weeks of therapy (chapter 5). This significant reduction in therapist's time with early mobilization makes the protocol cost effective.

Application of early active mobilization to tendon transfers for other clinical situations apart from Leprosy is necessary for wider usage of this protocol. Since the success of tendon transfer with immobilization is high, treating therapists need to be convinced about the benefits of lowered morbidity with early active mobilization to adopt the new therapy regimen. Training the therapists in this early mobilization technique should be easy as the treatment protocol is similar to that of immobilization of tendon transfer except for the timing of initiating the therapy. Further studies are necessary to validate the efficacy of early mobilization following other tendon transfers and application to different group of paralytic conditions.

Future areas of research

It is now necessary to develop surgical techniques to enable the use of short muscle tendons units elongated with grafts as donors for early active mobilization protocol. Further investigations are necessary to determine the strength of insertion that is safe for early mobilization at various locations. These will provide an objective guide for sensible donor selection for tendon transfer to correct various paralytic deformities.

Trials should now be conducted on traumatic and other paralytic conditions like poliomyelitis; Charcot Marie Tooth etc. to asses the efficacy of the protocol in patients with intact sensation as it is possible that pain might limit early active mobilization in these patient groups. From our experience this may not be an issue as the majority of hands with claw deformity had an intact median nerve and there was no difference in the pain VAS scores in patients with isolated ulnar paralysis vs. hands with combined median & ulnar paralysis.

Tendon transfers in anesthetic limbs: The trial was conducted on Leprosy deformities and all these limbs had an associated sensory loss. Loss of sensation was considered to be unsuitable for tendon transfers.[5] However, Brand[6] considered loss of sensation as the single most important indication for paralytic deformity correction since restoring normal movement patterns prevents pressure ulceration. This has been our observation too. The frequency of plantar ulceration is drastically reduced following foot drop correction. In the paralyzed hand, callosity reflecting abnormal pressure points disappears following successful tendon transfers. Comparative study of tendon transfer in sensate vs. insensate hands could provide insight into pressure ulcer prevention by deformity correction.

Rehabilitation of tendon transfer is often difficult in hands with near total anesthesia as encountered with combined complete median & ulnar nerve paralysis and triple nerve paralysis. Integration of transfer following postoperative immobilization in these hands can be delayed thereby increasing postoperative morbidity. Investigation is required to determine if this problem can be overcome with early postoperative active mobilization since integration of tendon transfer is instantaneous with this protocol.

The safety of early postoperative active mobilization for tendon transfer in spastic disorders like cerebral palsy, spinal cord injuries and cerebral vascular accidents needs to be investigated. Prolonged immobilization is the usual practice following tendon transfer in spastic limbs due to fear of insertion pullout and the feasibility of early mobilization in this group of patient's needs trial. We speculate that the immobilizing cast offers resistance to the constant pull on the insertion site by the spastic muscle and may be a contributing cause for higher incidence of dehiscence. Early mobilization will allow the joints to move thereby lessen the chance for tendon transfer pullout or rupture by the spastic muscle. In addition as the strength of the insertion site increases quicker with stressing, there will be overall benefits of early mobilization over immobilization in spastic conditions. A RCT investigating early mobilization with immobilization will provide insight to the proper post operative protocol for tendon transfers in spastics.

Future RCT's should include more objective outcomes like movement patterns in a movement laboratory and functional tests for dexterity and energy utilization. These will allow further comparison of early mobilization versus immobilization.

Neurophysiology of early active mobilization

Further research is necessary to investigate the neurophysiologic changes with immobilization after tendon transfer surgery. Studies have demonstrated reversible cortical changes with immobilization of hands in volunteers.[7] De Jong et al[8] attribute the clumsiness of hands during rehabilitation of flexor tendon repair to changes in the pattern of cerebral activations with immobilization. They reported that hand function was restored to normal after 6–8 weeks with re-organization of cerebral activation. Similarly using fMRI, cortical changes were noticed early following amputation of the hand and these returned to normal within 6 weeks of re-plantation.[9]

Reversible cerebral changes in response to long-term immobilization of the upper limbs were demonstrated in a study on immobilized wrist fractures.[10] Zanette et al[10] demonstrated that the immobilized muscle like the abductor pollicis brevis undergo reversible changes. They hypothesized that reduced upper limb sensory feedback after immobilization leads to simultaneous stimulation of larger territories of the cerebral cortex during an attempt of a particular movement and to a temporary alteration of the relationship of intracortical stimulation and inhibition required during a purposeful movement.

It can be extrapolated from the above studies that the relationship of the donor muscle intracortical stimulation and inhibition is temporarily deranged due to reduced sensory input from the transferred muscle-tendon unit during the period of immobilization. Our observation that the delay in isolation of the transferred tendon with immobilization can be explained by the cerebral changes in the representation of the donor tendon as suggested by Zanette et al.[10] Further studies using these techniques[10] can track cerebral changes and compare groups of tendon transfers mobilized early with groups after immobilization.

Bezuhely et al[11] hypothesized that early mobilization of tendon transfer allows the brain's ability to immediately use the activation of preexisting synergistic cortical finger movement programs. Our observations showed that foot drop patients operated under a local infiltration anesthetic could contract their tibialis posterior transfer intraoperative to achieve active dorsiflexion (chapter 5). It was also noticed that patients with the "lasso" procedure for claw correction had instantaneous integration of transfer on their first day of postoperative therapy at 48 hours (chapter 3). Future RCT should include fMRI studies to track cortical changes of tendon transfers immobilized and those with early mobilization. This will also provide information about the process of tendon transfer integration into movement patterns at its new site of insertion.

Supervised therapy

An early mobilization protocol requires strict therapist supervision to prevent attenuation and/ or rupture. Since integration of tendon transfer is instantaneous with early mobilization; therapist's assistance for re-education of the transfer may not be required as long precautions to avoid over stretching is adhered to. Future research should investigate in a RCT the need for supervised postoperative therapy with early mobilization. If patients can themselves reeducate their tendon transfer with instruction manuals, with video or under on-line instruction, the implication will be enormous for deformity correction programmes in developing countries as lack of trained therapists is a major hurdle for corrective surgery.

Cost savings

The cost savings with early mobilization could not be assessed in these studies due to lack of data on personal earnings as majority were sustenance farmers. There is no loss of work compensation in India, a valuable tool in assessing costs of morbidity. Earnings in dollar terms are low in India and therefore cost savings by early mobilization in dollars may not provide an appropriate comparison to that in developed countries. The economic impact of lower morbidity and reduced therapist's time with early mobilization following tendon transfer in developed countries needs to be assessed. Loss of work compensation data will provide a realistic assessment of cost saving with early mobilization. The cost savings in dollars can be significant in developed countries compared to India due to social security payments and higher wages. This may influence policy makers to encourage the use of early mobilization protocols routinely in the future.

Optimal time to begin postoperative therapy

Early mobilization began on the 2nd postoperative day for hand tendon transfers and on the 5th postoperative day for the foot transfers. These were arbitrarily decided at the beginning of the trial and further investigation is necessary to determine the optimal time for early mobilization. The question remains if early mobilization can be started earlier to further reduce morbidity from foot drop correction.

There is no consensus on the optimal day to begin therapy following flexor tendon repair. Halikis et al[12] compared work of flexion following tendon repair with immobilization, immediate mobilization, and mobilization delayed to three or five days. They found that a three-day delay decreased the peak work of flexion at one week, but a delay of five days did not have the same effect. More recently Zhao et al.[13] evaluating tendon glide and suture strength, reached somewhat different conclusions. They found day 7 to have the least favorable ratio of repair strength to force needed to overcome gliding resistance, and day 5 to have the most favorable ratio. A consensus on the ideal time to begin flexor tendon active mobilization will also help decide on the optimal time to start tendon transfer mobilization.

Patient's perspective

Finally studies are necessary to investigate in detail the patients' perspective and willingness to comply with early mobilization compared to immobilization. As shown in the trial, patients desire early mobilization and this coupled with cost savings is likely to make early mobilization of all tendon transfers a reality.

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Summary

Paralytic deformities of the limbs caused by peripheral nerves injuries, Leprosy, poliomyelitis, spinal cord injuries and degenerative conditions can be rectified using tendon transfers. Postoperative immobilization of tendon transfers for a period of 3-6 weeks has been the traditional regimen to allow healing of the attachment site. Re-education therapy takes a further 3-6 weeks. As a result, morbidity from surgery for paralytic deformity correction extends to a period of 6-12 weeks and this prolonged period of absence from work leads to considerable loss of income and inconvenience.

The main objective of the work presented in this thesis was to investigate if early active mobilization protocols for tendon transfer rehabilitation can be developed and applied to correction of various common paralytic deformities to the hand and foot in patients with Leprosy to reduce post operative morbidity following tendon transfer. We tested the hypothesis "that immediate active motion protocol for tendon transfers in Leprosy deformities would achieve outcomes similar to those of the standard practice of immobilization while reducing morbidity".

Chapter1 presents a general introduction to issues related to Leprosy, the stigma of deformities, the challenge for surgical correction of deformities and the cost of surgery for the patient due to loss of work during the long period of morbidity.

Chapter 2 describes a pilot study in 5 hands with isolated median nerve involvement with irreversible paralysis of the Abductor Pollicis Brevis muscle. The flexor digitorum superficialis tendon of the ring finger was used as donor to restore opposition and the transfer was actively mobilized 48 hours after surgery. Results were compared with historical records of 7 hands with identical paralyses and opposition tendon transfers which were immobilized after surgery in a cast for 3 weeks. We found no incidences of tendon pullout during immediate active mobilization. There were no differences in outcome between the two groups at late followup evaluations, with all opposition transfers achieving good results. The added advantage was that the immediate active mobilization reduced rehabilitation time by an average of 19 days and all 5 patients resumed their activities earlier than those immobilized. The pilot study suggested that immediate active mobilization after flexor digitorum superficialis tendon transfers to restore opposition in Leprosy patients is safe, with similar outcomes when compared to the immobilization group, but with reduced rehabilitation time. Based on this success of the pilot study, this same principle was applied to tendon transfers for correction of claw hand and foot drop deformities.

The application of immediate active mobilization for claw deformity correction is presented in Chapter 3, describing a prospective trial on 32 hands with claw deformity who received the "lasso" procedure" with the flexor digitorum superficialis tendon of the middle finger for four digit correction. The transfers were actively mobilized 48 hours after surgery. Results were compared with a historical cohort of 32 hands of similar paralysis with "lasso" procedure and postoperative immobilization. There was no incidence of transfer insertion pullout, establishing that immediate mobilization is safe. As in the pilot study, there was no clinically relevant difference in results of claw correction of both groups. However, morbidity was reduced by 21 days and return to daily living activities was earlier with immediate mobilization. This study demonstrated the feasibility of early mobilization for tendon transfers using relatively thin tendon slips (1/4 of the circumference) of the flexor digitorum superficialis tendon.

A prospective trial on early mobilization after tibialis posterior transfer for 21 foot drop correction is presented in chapter 4. Rupture or attrition of the tendon transfer attachment during early mobilization is the main concern of this protocol. The size of the transferred tendon, the site and technique of attachment determines the strength of insertion. The forces that act on the attachment are influenced by the strength of muscle contraction, the weight of the part moved, resistance to the motion and tendon drag due to surrounding edema and adhesion. For foot drop correction, the pull at the attachment site of the transferred tendon is presumed to be considerable due to the high stress during the gait cycle. Although early mobilization of tendon transfer was demonstrated to be safe in the hand, the safety for foot drop correction was a concern. In this prospective trial, active mobilization started on the 5th postoperative day and results were compared with a historical cohort of patients that were immobilized for 4 weeks. We found that early mobilization of tendon transfer to the foot in patients with Leprosy was safe and has similar outcomes with a reduced time to independent walking than immobilization. Morbidity reduction was 13 days for foot drop correction and this was considerably less compared to morbidity reduction with early mobilization for hand transfers.

The three above prospective studies determined the feasibility of using early active mobilization after these tendon transfers. The major limitation of these studies was comparison of results with historical cohort. This warranted further testing of the hypothesis in a randomized clinical trial (RCT) to compare the effectiveness of early postoperative active mobilization with that of conventional immobilization.

In Chapter 5, we describe the results of an RCT on claw deformity correction, comparing immediate active mobilization with immobilization in 50 hands. The study reaffirmed that immediate active motion protocol is safe and has similar outcomes compared with those of immobilization, with the added advantage of earlier pain relief and quicker restoration of hand function. Patients were discharged 22 days earlier with immediate active mobilization. Immediate motion after tendon transfer significantly reduced morbidity and reduced the rehabilitation time of Leprosy patients with a claw hand, which may save expenses by reducing time off work.

Chapter 6 described an RCT comparing early mobilization with immobilization after foot drop correction in Leprosy patients. The RCT confirmed the previous findings from the prospective cohort study that early mobilization is safe and has similar outcomes compared to immobilization. Restoration of independent walking was15 days earlier in the mobilization group, providing an important advantage to these patients since this may allow quicker return to work.

In the concluding chapter of this book, the findings of the RCT and limitations of the study is discussed and areas of research to further explore the concept of early active mobilization are introduced. Wider application of an early mobilization protocol for other tendon transfers is necessary to establish the validity of advantages of this protocol over immobilization. The economic benefits of early mobilization can make this the standard tendon transfer rehabilitation protocol of the future.

Samenvatting

Peestransposities, dat wil zeggen met veranderen van de aanhechting van de pees, hebben als doel de functie van de hand of voet te verbeteren en worden gedaan bij verlammingen van spieren zoals bij perifere zenuwaandoeningen (zoals de ziekte van Hansen), bij poliomyelitis of bij een dwarslaesie. Na een peestranspositie operatie is het gebruikelijk om een periode van drie tot zes weken te immobilisatie om de gehechte pezen te beschermen. De verdere revalidatie duurt vervolgens meestal ook nog 3 tot 6 weken. Hierdoor is de morbiditeit na een peestranspositie 6-12 weken. Gedurende deze periode kan de patiënt meestal niet werken wat, naast alle ongemak, leidt tot een aanzienlijk verlies van inkomsten en hoge kosten voor het individu en de maatschappij.

Het belangrijkste doel van de studies in dit proefschrift was om te onderzoeken of vroeg-actieve nabehandeling (?uitleggen?) na een peestranspositie veilig en succesvol gedaan zou kunnen worden bij operaties van een aantal deformiteiten in de hand en voet bij patiënten met de ziekte van Hansen (lepra). We hebben de hypothese getoetst dat vroeg-actieve nabehandeling bij peestransposities in lepra patiënten leidt tot even goede functionele uitkomsten als het standaardprotocol met immobilisatie maar met een verminderde morbiditeit.

Hoofdstuk 1 geeft een algemene inleiding over een aantal relevante aspecten van lepra; over de stigmatisering van patiënten met lepra, over de uitdaging van chirurgische reconstructies van deformiteiten welke worden veroorzaakt door lepra en over de kosten als gevolg van de operaties voor de patiënt door het verlies van inkomsten van de patiënt tijdens de lange revalidatieperiode.

Hoofdstuk 2 beschrijft een onderzoek in vijf handen van patiënten met een geïsoleerde uitval van de medianus zenuw en een volledige verlamming van de duimspieren (onder andere de Abductor Pollicis Brevis). De flexor digitorum superficialis pees van de ringvinger werd als donor gebruikt voor het herstellen van de duimoppositie. Bij deze patiënten werd 48 uur na de operatie al gestart met de vroeg-actieve nabehandeling. Resultaten werden vergeleken met de historische gegevens van 7 patiënten met een identieke verlamming waarbij na dezelfde ingreep 3 weken werd geïmmobiliseerd met gips. Er werden geen rupturen gezien met de vroeg-actieve nabehandeling en functionele resultaten waren gelijk in beide groepen. Een voordeel van de vroeg-actieve nabehandeling was dat de revalidatie gemiddeld 19 dagen korter was, waardoor de 5 patiënten sneller weer aan het werk waren dan de patiënten die geïmmobiliseerd werden. De positieve ervaring met deze 5 patiënten gaf aanleiding om deze methode ook toe te passen bij andere operaties.

De toepassing van de vroeg-actieve nabehandeling is in hoofdstuk 3 beschreven in een prospectief onderzoek van 32 handen na een "lasso procedure" met de flexor digitorum superficialis pees van de middelvinger voor correctie van een klauwstand van alle vier de vingers. Er werd 48 uur na de operatie gestart met de vroeg-actieve nabehandeling. De resultaten werden vergeleken met een historisch cohort van 32 handen met een soortgelijke verlamming en die na dezelfde "lasso procedure" een immobilisatie periode ondergingen. In geen van beide groepen werden rupturen of uitrekking van de getransponeerde pezen gevonden en de vroeg-actieve nabehandeling bleek daarmee net zo veilig te zijn. Vergelijkbaar met de pilot studie van hoofdstuk 2 werd tussen de groepen geen klinisch relevante verschillen gevonden in de functionele resultaten na een klauwhand correctie. Echter, de morbiditeit werd verminderd met 21 dagen en de terugkeer naar de activiteiten in het dagelijks leven was eerder in de vroeg-actieve nabehandeling groep. Deze studie toonde de haalbaarheid aan van de vroeg-actieve nabehandeling na peestransposities, zelfs met gebruik van een relatief dunne pees die per vinger maar 1/4 van de omtrek van de flexor digitorum superficialis pees van de middelvinger heeft.

Een prospectief onderzoek naar vroeg-actieve nabehandeling na een peestranspositie van de tibialis anterior pees voor een klapvoet correctie bij 21 patiënten wordt gepresenteerd in hoofdstuk 4. Het risico van een peesruptuur of het uitrekken van de getransponeerde pees is bij een vroeg-actieve nabehandeling groot aangezien bij klapvoet correcties de kracht op de getransponeerde pees veel groter is dan bij de eerder beschrijven correcties in de hand. In dit prospectieve onderzoek werd gestart met de vroeg-actieve nabehandeling op de 5e postoperatieve dag en werden de resultaten vergeleken met een historische cohort van patiënten die 4 weken werden geïmmobiliseerd. We vonden dat vroeg-actieve nabehandeling na peestransposities in de voet bij lepra patiënten veilig is en vergelijkbare functionele resultaten gaf als de immobilisatie groep maar met een 13-dagen kortere hersteltijd.

De drie hierboven beschreven prospectieve studies toonden de haalbaarheid van het gebruik van vroeg-actieve nabehandeling na peestransposities bij patiënten met lepra aan maar de belangrijkste beperking van deze studies is de vergelijking van de resultaten met historische cohorten. Dit rechtvaardigde het verder testen in gerandomiseerd klinisch trials (RCT) van de effectiviteit van vroeg-actieve nabehandeling in vergelijking met de conventionele nabehandeling met een periode van immobilisatie.

In hoofdstuk 5 beschrijven we de resultaten van een RCT voor klauwhand correcties waarbij in totaal 50 handen van patiënten met vroeg-actieve nabehandeling werden vergeleken met patiënten die geïmmobiliseerd werden na de operatie. Deze studie bevestigde opnieuw dat vroeg-actieve nabehandeling veilig is en vergelijkbare resultaten oplevert als immobiliseren, met als belangrijk voordeel een snellere pijnverlichting en sneller herstel van de handfunctie. Patiënten werden 22 dagen eerder ontslagen uit de behandeling in de vroeg-actieve nabehandeling groep. Vroeg-actieve nabehandeling na peestransposities vermindert derhalve de morbiditeit en de revalidatieperiode aanzienlijk na een klauwhandcorrectie bij patiënten met lepra, waardoor waarschijnlijk ook kosten worden bespaard door de kortere absentietijd van werk.

Hoofdstuk 6 beschrijft een RCT waarin vroeg-actieve nabehandeling vergeleken werd met immobilisatie na klapvoet correcties in lepra patiënten. De RCT bevestigd de eerdere bevindingen van de cohort studies dat vroeg-actieve nabehandeling veilig is en vergelijkbare functionele resultaten oplevert net als na immobilisatie. De periode tot zelfstandig lopen zonder hulpmiddelen was 15 dagen korter in de vroeg-actieve nabehandeling groep, wat een belangrijk voordeel is voor deze patiënten omdat zij sneller weer terug kunnen keren naar hun werkzaamheden.

In het laatste hoofdstuk van dit boek worden de bevindingen van de verschillende hoofdstukken en de beperkingen van deze studies besproken en beschrijven we de implicaties van het implementeren van het concept van vroeg-actieve nabehandeling. Het toepassen van vroeg-actieve nabehandeling bij andere peestransposities moeten verder worden onderzocht om ook voor deze transposities de voordelen van dit protocol te bepalen. De economische voordelen van vroeg-actieve nabehandeling kan deze nabehandeling mogelijk tot de standaard postoperatieve nabehandeling maken in de toekomst.

Dankwoord

The Leprosy Reconstructive Surgery Hospital at 'HOINA', Muniguda began in the summer of 1994. Muniguda is in the southern part of Orissa, an eastern state of India and is in one of the poorest districts of the state. Muniguda is an overnight train journey from the state capital, Bhubaneswar. My stay in the hospital campus during the monthly visits enabled me to understand many of the social and personal difficulties of people with Leprosy deformities.

My daughters Ritu and Nita were babies when I began my trips to Muniguda and each day I longed to return home to them. The relief of boarding the train back to Bhubaneswar was immeasurable. Staying away from home was the most difficult aspect of my work in HOINA and I'm indebted to my wife Alison for supporting my visits to Muniguda for 12 years. She realized the importance of the work to me personally and the need for Leprosy deformity correction in Orissa. My love to Ritu and Nita for supporting me to continue this work. Their visits to HOINA and interactions with the disabled children and Leprosy patients in HOINA over the years has taught them important values and as a family made us understand the needs of people around us.

Due to the remote location of the surgical unit and also the unavailability of physiotherapy facilities in the state, patients requiring Leprosy deformities correction stayed in HOINA for prolonged periods of time, extending from 4-6 months for each operation. Many had multiple procedures and stayed over a year. Children with multiple Leprosy deformities like Minati (in the back cover) grew up to be young adults in the hospital. For older patients, most of whom were subsistence farmers, loss of earning was the most important deterrent for their willingness to undergo deformity correction in spite of these services being provided free of cost. For those who were undergoing deformity correction, it was a difficult personal decision to be away from home, similar to my predicament. Each month during my visits I would be faced with the same question as to their discharge and return home. The period from operation to discharge was still 8-12 weeks and the challenge to reduce this is the basis of this research.

To the late Frederick Finseth I owe much for those long discussions and encouragement to begin the research on early mobilization of tendon transfers. To Addie his wife for her support and visits to Orissa with Fred. To late my father Gopal Rath who encouraged me to study medicine and confront challenges. To my mother Taramani for supporting me in my endeavor to continue surgical training and research for umpteen years. The ideology and determination they had instilled enabled me to undertake the prolonged period of Leprosy surgery and research. My appreciation to my brothers Prashant, Sushant and his wife Tiki, my sisters Santi, Basanti and Sukanti for support. To my in-laws Judy and Victor for their love and affection and understanding the need for my living and professional work in India.

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Finally it is to all my patients that I dedicate this research. I could initiate and bring this work to a conclusion because of their trust. I thank them for participating in this research with the hope that they will return home to their loved ones earlier.

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Curriculum Vitae

Santosh Rath was born on the 15th of October, 1957, in Orissa, India. In 1975 he started his study of Medicine at the SCB Medical College, Cuttack, Orissa, India and obtained his title as Medical Doctor at the Utkal University, Orissa in 1981. He began his Orthopaedics Residency programme in All India Institute of Medical Sciences , New Delhi , India in 1982 and was awarded Orthopaedics Master of Surgery Degree in 1985 (Head : Prof. P. K. Dave) and continued as a Senior Registrar in the same department till 1987.

He received the Talent Search Scheme (TSS) award from the Indian Council of Medical Research (ICMR) to peruse training in Hand Surgery in India. During the period 1986-87 he trained with Indian pioneers of Hand Surgery (Dr. BB Joshi, Mumbai, Prof. R.Venkataswamy, Chennai and Dr H.Srinivasan, JALMA, Agra). In 1988 he joined as a Hand Surgery Fellow at the Sydney Hospital, Sydney (Head: Bruce Connolly). During the years 1989-90 he was a Research Fellow at the Clinical Research Centre, Middlesex, UK (Head: Prof. Collin Green) conducting research on peripheral nerve regeneration.

In 1991 he returned back to India and set up practice in Bhubaneswar, the capital of the eastern state of Orissa. As a visiting Surgeon at the National Institute of Rehabilitation and Training, Olatpur, he began work on tendon transfer for paralytic deformities due to Leprosy. Between the years 1994-2006 he perused reconstructive surgery of Leprosy patients at the exclusive reconstructive surgery centre at HOINA in Muniguda, Orissa funded by LEPRA a UK based NGO. The challenge to provide reconstructive surgery to the large numbers of Leprosy deformities initiated this research on early postoperative active mobilization of tendon transfers in an effort to reduce rehabilitation time, loss of work and contain costs.

He is presently an Associate Professor of Orthopaedics at the Hi-Tech Medical College and Hospital, Bhubaneswar, India.