EDITOR'S CHOICE

Passive Mobilization With Place and Hold Versus Active Motion Therapy After Flexor Tendon Repair: A Randomized Trial

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Purpose Mobilization after flexor tendon repair in fingers has been a subject of debate for several years. Many hand surgery clinics have turned to early active mobilization. However, there is no strong scientific evidence suggesting that early active mobilization produces a better range of motion (ROM) than the Kleinert regimen when place and hold is added. Therefore, the purpose of this prospective randomized trial was to investigate whether active mobilization is superior to passive mobilization with place and hold after flexor tendon repair in the fingers. Our hypothesis was that patients who follow the active mobilization protocol have a better ROM than those who follow the passive protocol with place and hold.

Methods Sixty-four patients with a flexor tendon injury in zone I or II were included. After surgery, randomization to undergo either active mobilization or passive mobilization with place and hold was performed. The patients were followed-up for 12 months using outcome measurements, including ROM, strength, rupture frequency, Disabilities of the Arm, Shoulder and Hand score, ABILHAND questionnaire, and performance on the Purdue Pegboard test.

Results We were unable to find any significant difference between the 2 groups for any of the outcome measurements, ROM, grip strength, key pinch, rupture frequency, Disabilities of the Arm, Shoulder and Hand score, ABILHAND questionnaire, and performance on the Purdue Pegboard test.

Conclusions The outcomes were equivalent for both the mobilization groups. (*J Hand Surg Am.* 2022; $\blacksquare(\blacksquare): \blacksquare - \blacksquare$. Copyright © 2021 by the American Society for Surgery of the Hand. All rights reserved.)

Type of study/level of evidence Therapeutic I.

Key words Early active mobilization, flexor tendon repair, passive mobilization, place and hold, zones I and II.

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0363-5023/22/ - -0001\$36.00/0 https://doi.org/10.1016/j.jhsa.2021.11.031 HE TREATMENT OF FLEXOR tendon injuries of the fingers has undergone major changes over the years and has been a subject of debate since the beginning of the 20th century. In the 1970s, primary repair became widespread and internationally accepted.¹⁻³ At that time, hand rehabilitation developed and many centers started early passive mobilization. For a long time, the Kleinert protocol was the gold standard for postoperative mobilization of flexor tendon injuries.² Since the publication by Silfverskiöld and May⁴ in the early 1990s, we have been using a program incorporating rubber bands on all 4 fingers and passive flexion of the fingers with active contraction in the end range, the so-called place and hold.⁵

In recent years, many centers have initiated active mobilization after surgery. Several active mobilization programs have been described in the literature, and these differ substantially.⁶⁻⁹ The scientific evidence for active mobilization, however, has not been convincing. There are few comparative studies and only 1 randomized, controlled trial of high methodological quality. $^{6-8,10}$ Trumble et al¹⁰ compared active place-and-hold therapy with true passive motion in a prospective, controlled trial and found a greater range of motion (ROM) in the active group, without an increase in tendon ruptures. However, the study was not powered to identify a difference in rupture rate. There are a few recent review articles on the subject.^{11,12} Starr et al¹¹ found a significantly better ROM but a higher risk of ruptures with early active motion than with passive motion. They also found a lower rupture rate in later years, regardless of the mobilization program, indicating an improvement in surgical techniques and rehabilitation protocols. Neiduski and Powell¹² reported moderate-to-strong evidence of better outcomes with mobilization programs with place and hold than with passive flexiononly protocols. However, they were unable to find any benefits with true active motion.

The aim of this study was to investigate whether true active mobilization after flexor tendon repair results in a superior ROM and strength compared with passive mobilization with place and hold. We are unaware of other clinical trials comparing active motion therapy with passive flexion and place and hold. The hypothesis was that active mobilization results in an improved ROM after flexor tendon repair.

METHODS

Enrollment

Sixty-four patients were included in the study between 2013 and 2017 (Fig. 1). The trial was approved by the local ethics committee in Gothenburg, Sweden (number 551-13). The patients received both verbal and written information about the trial. Written informed consent was obtained before enrollment in the study. Rehabilitation was initiated the day after surgery or on the first working day if the surgery was performed during the weekend. Randomization was performed using a computer program, and the 2 different mobilization protocols were placed accordingly in sealed envelopes in a consecutive order numbered from 1 to 64. The patients were randomized after surgery but before the initiation of rehabilitation.

Inclusion and exclusion criteria

The inclusion criteria were primary repair of a cut flexor digitorum profundus tendon in digits II–V, repair within 72 hours after an injury, an injury in zone I or II, age >16 years, and the ability to go through early mobilization. The exclusion criteria were a concomitant severe injury such as a fracture or joint injuries, soft tissue defects or crush injuries, bilateral flexor tendon injuries, previously impaired function in the finger, and uncertainty about compliance with the rehabilitation protocol, eg, substance abuse. Patients with a concomitant injury to the flexor digitorum superficialis or a digital nerve were included, and those with distal injuries in zone I were not included because of the need for reinsertion.

Surgical technique

All surgeries were performed by specialists in hand surgery or experienced residents in hand surgery. The surgeries were performed with the patients under regional or general anesthesia. The wound was elongated using Bruner incisions when necessary. All tendons were sutured in the same manner. The flexor digitorum profundus tendon was repaired using 2 modified Kessler sutures, ie, a 4-strand core suture with a 4-0 nonabsorbable braided polyester suture (Ti-cron, Medtronic) and a running epitendinous suture, according to Silfverskiöld and Andersson,¹³ with a 6-0 nonabsorbable monofil polypropylene suture (Prolene, Ethicon). Pulleys were repaired when possible without compromising the mobility of the repaired tendon. Any concomitant injury to the flexor digitorum superficialis tendon was repaired according to the surgeon's preference, usually using a mattress suture with an absorbable or nonabsorbable 4-0 suture. Any injured digital nerve was repaired using microsurgical instruments and an 8-0 or 9-0 nonabsorbable polyamide monofilament (S&T AG).

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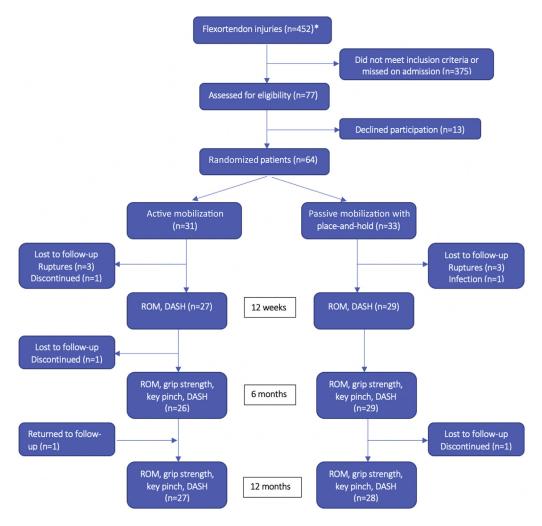


FIGURE 1: Consort flow chart. *This number has been taken from the operation planning program during the time period when the study was ongoing. The search criteria were the diagnosis of flexor tendon injury and the operation code for tendon suture combined. The number includes greater trauma, partial injuries, and other exclusion criteria.

Rehabilitaion

One to 3 days after the surgery, the patients met a hand therapist at the hand rehabilitation unit. There, the patients were randomized to undergo either passive mobilization with rubber bands and place and hold or pure active mobilization. The patients in both the groups were closely followed-up by the hand therapist according to a standardized protocol for 12 weeks. Additional follow-up appointments were made after 6 and 12 months. The patients in both the groups were allowed to perform all kinds of normal activities after 3 months and heavy manual work and gym training after 4 months.

Active mobilization: The active mobilization program used in this study is a modification based on 2 previously published programs.^{9,14} On the first day of mobilization, the patients' dressings were changed and a dorsal orthosis was made, ending at the level of

the proximal interphalangeal (PIP) joints, with the wrist in the neutral position and the metacarpophalangeal joints in $60^{\circ}-80^{\circ}$ of flexion. In addition, a removable volar plate, which kept the fingers extended, was used between the therapy sessions (Fig. 2). The patient was instructed to flex the fingers passively with the other hand, 1 at a time, and then keep the fingers in flexion and perform gentle squeezing-the so-called place and hold-for 3 seconds. The fingers were then actively extended as far as the orthosis allowed. This motion was performed for 5 repetitions, 10 times a day, with a 1.5-hour resting period between the sessions. In every second session, all the fingers were actively flexed 3 times. After a week, 10 repetitions, 10 times a day, were performed, with a resting period of 1.5 hours between the sessions. Four weeks after the surgery, the orthosis was removed and replaced by a wrist lacer (Wrist Lacer II, MedSpec) in the neutral

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FIGURE 2: The orthoses used for active mobilization with a dorsal orthosis ending at the level of the PIP joints and a removable volar plate.

position. Flexion and extension of the wrist for 10 repetitions, 4 times a day, and joint-by-joint mobilization of the injured finger for 3 repetitions, 10 times a day, were added to the previous protocol. Six weeks after the surgery, the exercise continued without protection until 12 weeks after the surgery.

Passive mobilization with place and hold: The patients had their dressings changed, and a new dorsal forearm plaster was made, ending at the level of the PIP joints, with the wrist in the neutral position and the metacarpophalangeal joints in $60^{\circ}-80^{\circ}$ of flexion, creating an extension block for the fingers. Rubber bands were attached to all the fingernails, and a small hook on which to hang the rubber bands was fastened to the plaster (Fig. 3), creating a resting position for the fingers between the training sessions. A night orthosis was also made to protect the fingers and maintain them in full extension. The patient was instructed to flex the fingers passively with the other hand, 1 at a time, and then keep the fingers in flexion and perform place and hold. The fingers were then actively extended as far as the plaster allowed. For 4 weeks, the patient performed this exercise for 10 repetitions, 10 times a day (7-8 repetitions on the first day), with a resting period of 1.5 hours between the sessions. After 4 weeks, the plaster was removed and replaced by a wrist lacer (Wrist Lacer II,

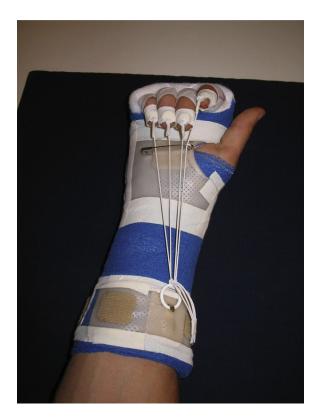


FIGURE 3: The passive mobilization equipment with rubber bands and a dorsal forearm plaster, ending at the level of the PIP joints, as an extension block for the wrist and meta-carpophalangeal joints.

MedSpec) in the neutral position, and the patient added 10 repetitions of true active flexion of the fingers to the previous program, performed 10 times a day. Six weeks after the surgery, the wrist lacer was removed and flexion and extension of the wrist initiated, which was continued until 12 weeks after the surgery.

Outcome measurements

The primary outcome measurement was active ROM in the PIP and distal interphalangeal joints. The secondary outcome measurements were grip strength, key pinch, Disabilities of Arm, Shoulder and Hand (DASH) score, ABILHAND questionnaire, and performance on the Purdue Pegboard test. DASH is an outcome questionnaire with 30 questions about functions and symptoms in the upper extremities, answered by the patient. Its scores range from 0 (no disability) to 100 (completely disabled).^{15,16} ABIL-HAND is an interview-based assessment tool that measures the patient's perceived difficulty with using their hands to perform manual activities in everyday life.^{17–19} The Purdue Pegboard test is used to measure unimanual and bimanual finger and hand dexterity. The results were also categorized according to Strickland and Glogovac,²⁰ based on the Strickland formula:

 $\frac{(Active PIP+DIP flexion) - (extension lag PIP+DIP)}{175^{\circ}} \times 100 = \frac{175^{\circ}}{\% of normal PIP and DIP motion}$

Follow-up

The patients were followed-up by 7 different hand therapists 1, 2, 4, 6, 8, 10, and 12 weeks after the surgery. At follow-up visits at 6 and 12 months, the measurements were made by a single hand therapist. The patients were examined according to a standard protocol using the abovementioned outcome measurements-except for grip strength and key pinch, which were only tested at the 6- and 12-month follow-up visits—at 8 and 12 weeks and 6 and 12 months. The examiner who performed the measurements at 6 and 12 months was blinded to the mobilization program that the patient was following. The ROM was measured using a goniometer and calculated as the total flexion in the PIP and distal interphalangeal joints minus an extension defect, if present. The grip strength was measured using a Jamar hydraulic hand dynamometer (Sammons Preston), whereas the lateral (key) pinch was measured using a hydraulic pinch gauge (Sammons Preston). The DASH questionnaire was filled out by each patient at baseline, representing the situation before the injury, and at 3, 6, and 12 months. Furthermore, the ABILHAND questionnaire was filled out by each patient at 3, 6, and 12 months. The patients were also asked about their compliance with the mobilization program during the entire rehabilitation period, ie, 12 weeks.

Statistical analysis

A sample size estimate based on the active ROM in the fingers was calculated based on a power of 80% to detect a difference of 20° between the 2 groups.¹⁰ This indicated a requirement for 32 patients in each group. Another sample size calculation was performed based on the hypothesis that the grip strength would be 35 ± 5 kg (mean \pm SD) in the active group and 30 ± 5 kg in the passive group, which resulted in 22 patients in each group, with 95% power.

Because the results were not normally distributed, as determined based on visual inspection of histograms and checking them using the Shapiro-Wilks test, median values were used instead of mean values and nonparametric analyses were performed. For the ROM, grip strength, and key pinch measurements, the Mann-Whitney U test was used, and the chi-square test was used for the Strickland categories.

RESULTS

Patient demographics

The patient demographics are described in Table 1. The total number of dropout patients was 9 (4 in the active group and 5 in the passive group) (Fig. 1). The dropouts consisted of 3 ruptures in each group, 1 infection in the passive group, and 1 patient in each group who failed to show up for their follow-up appointments. The ruptures were detected either at a scheduled follow-up visit or by the patient, who then contacted the clinic.

ROM

The combined ROM in the PIP and distal interphalangeal joints was similar in both the groups at all times during the follow-up period. There were no significant differences between the groups (Fig. 4). No significant difference was noted between the groups when the difference in the ROM of the injured finger was compared with that in the ROM of the corresponding uninjured finger on the contralateral hand.

When the results were categorized according to Strickland and Glogovac,²⁰ there was no significant difference between the active and passive groups (Table 2). However, 3 patients who fell in the "poor" category were found to belong to the active group. Furthermore, we found no significant difference in the ROM between the injuries in zones I and II.

Grip strength and key pinch

There were no significant differences in the grip strength and key pinch between the active and passive groups at any time point during the follow-up period (Figs. 5, 6). However, a power calculation was not performed for key pinch.

Rupture frequency

There were 3 ruptures each in the active and passive groups. Four of the 6 patients admitted that they had not followed the instructions and had done things that they were not supposed to, eg, removing the orthosis, grasping objects, and pulling up pants. The ruptures in the active group occurred up to 3 weeks after the surgery, and those in the passive group occurred 5-12 weeks after the surgery.

DASH, ABILHAND, and Purdue Pegboard

The results of the DASH scores, ABILHAND questionnaire, and Purdue Pegboard test were similar 6

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TABLE 1. Demographics			
Variable	Active Mobilization $n = 31$	Passive Mobilization With Place and Hold $n = 33$	
Age (y)			
Mean (range)	40 (17–74)	37 (18–62)	
Sex			
Female	11	8	
Male	20	25	
Occupation			
Employed	18	28	
Student	6	2	
Unemployed	1	1	
Retired	6	2	
Injury to dominant hand	13	14	
Injured finger			
Dig II	13	9	
Dig III	3	8	
Dig IV	1	4	
Dig V	14	12	
Concomitant injury			
FDS	17	13	
Digital nerve	10	16	
Zone			
Ι	7	10	
II	24	23	
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Dig, digit; FDS, flexor digitorum superficialis.

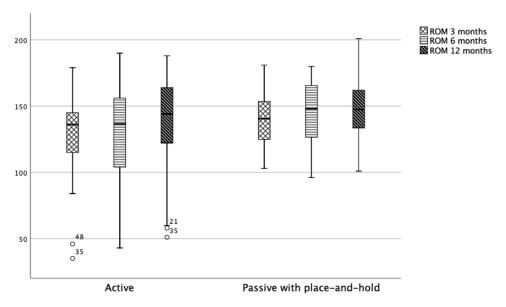
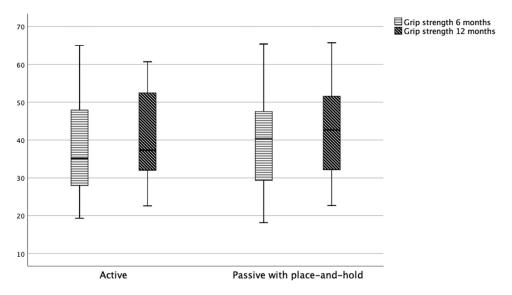


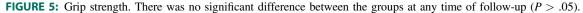
FIGURE 4: Range of motion the in PIP and distal interphalangeal joints minus an extension deficiency, if present. There was no significant difference between the groups at any time of follow-up (P > .05).

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TABLE 2. Strickland Categories*		
Strickland Category	Active Mobilization	Passive Mobilization With Place and Hold
3 mo		
Excellent	5 (4)	11 (7)
Good	13 (10)	13 (10)
Fair	6 (4)	5 (4)
Poor	3 (2)	0 (0)
6 mo		
Excellent	11 (8)	15 (10)
Good	6 (4)	9 (7)
Fair	6 (5)	5 (4)
Poor	3 (2)	0 (0)
12 mo		
Excellent	11 (8)	14 (8)
Good	10 (8)	10 (9)
Fair	3 (2)	4 (3)
Poor	3 (2)	0 (0)

*There was no significant difference between the groups. The chi-square test resulted in a P value of .32. The values within brackets are zone II injuries only.





between the 2 groups at 3, 6, and 12 months (Table 3).

DISCUSSION

The present trial did not reveal any significant differences in the ROM or grip strength between the active and passive mobilization groups at 3, 6, and 12 months of follow-up. The key pinch and rupture frequency were also similar between the groups during follow-up. Three patients fell in the "poor" Strickland category, all of whom were in the active group. We could not find any obvious reason for why these 3 had a substantially less ROM. In addition, the results of the DASH scores, ABILHAND questionnaire, and Purdue Pegboard test were similar between the groups at follow-up.

Trumble et al¹⁰ found a significantly better ROM with active mobilization than with passive mobilization. However, their passive group was purely

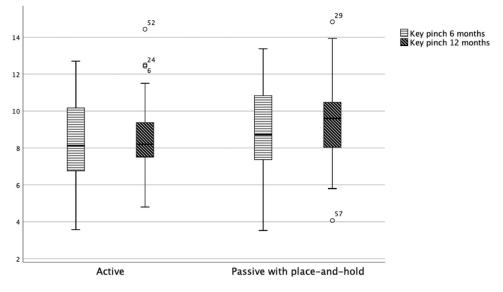


FIGURE 6: Key pinch strength. There was no significant difference between the groups at any time of follow-up (P > .05).

TABLE 3. DASH Score, ABILHAND Questionnaire, and Purdue Pegboard Test		
Follow-Up	Active Mobilization	Passive Mobilization With Place and Hold
DASH		
Baseline	0 (0)	0 (0.6)
3 mo	11 (13)	11 (17)
6 mo	8 (14)	7 (8)
12 mo	5 (11)	4 (11)
ABILHAND		
3 mo	44 (9)	41 (12)
6 mo	45 (6)	46 (3)
12 mo	46 (1)	46 (3)
Purdue Pegboard		
3 mo	15 (2)	14 (4)
6 mo	12 (2)	12 (3)
12 mo	13 (3)	12 (3)

passive, and their active group was similar to our passive group, with passive flexion of the fingers and place and hold in addition to flexion of the wrist. The terminology used for describing rehabilitation protocols has been confusing. An early active mobilization program might not include any active flexion of the fingers at all. This issue was stressed in the review article by Neiduski and Powell,¹² which suggested that the term "true active flexion" be used for mobilization programs in which the fingers are actively flexed through a flexion arc of motion during the first postoperative week. "Passive flexion" should be used for programs that include passive flexion, regardless of how the extension is performed. Finally, "place-and-hold" should be specified for protocols that include passive flexion of the fingers and isometric hold at the end range. According to Neiduski and Powell,¹² the active mobilization program used by Trumble et al¹⁰ falls under "early passive flexion with place-and-hold." For this reason, the current trial does not conflict with the findings of Trumble et al.¹⁰ Moreover, Neiduski and Powell¹² concluded that mobilization programs with place and hold are superior to true passive mobilization programs. However, they were unable to verify that true active mobilization programs were better than programs with place and hold. As far as we know, there are still no prospective, randomized trials comparing passive mobilization with place and hold and true active mobilization.

There has been some concern that early active mobilization can result in a higher rupture frequency. A systematic review by Starr et al¹¹ reported a higher rupture frequency in the active group than in the passive group. However, in the present trial, the number of ruptures was the same in both the groups. This rupture rate was higher than expected, and the reason might partly be attributed to close supervision of the patients in the trial, resulting in early recognition of the ruptures.

Rigo et al²¹ found a higher pinch strength at 6 months when active motion was added to a modified Kleinert regimen with rubber bands. In the present study, the patients in the passive group were slightly stronger both in terms of whole hand grip and key pinch, but the difference was not statistically significant.

The opinion that early active mobilization is better than passive mobilization with place and hold still has no support in the literature. An interesting future project would be to combine passive mobilization with rubber bands and place and hold with purely active elements. Rigo et al²¹ found no advantage of adding active flexion to the passive protocol after flexor tendon repair in zones I–III, whereas in zone II, there was a difference; however, the authors did not perform an analysis of those patients because it was not a part of the original study design and the sample size was too small.

We speculate that it might be beneficial for the fingers to hang in rubber bands, allowing minimal movement back and forth, between rehabilitation sessions of the passive protocol instead of resting the fingers against a fixed plate, as in the active protocol. The small movements might reduce the risk of adhesions. Even though there is a trend toward progressive active protocols, there is still a need for prospective intervention studies of high methodological quality to support the superiority of true active motion over passive mobilization with place and hold.

Even if a sample size calculation was performed, the total of 9 dropouts might have affected the strength of the study. Key pinch might not be the optimal outcome measure when flexor tendon injuries in the thumb are omitted, but we decided to use this measurement as a test of function and strength in the hand. Furthermore, the patients in the active group did not perform as many repetitions in each rehabilitation session as those in the passive group during the first week. However, after the first week, they performed the same number of repetitions and sessions as those in the passive group but added 3 repetitions of active flexion of the finger in each session. Additionally, they started flexion and extension of the wrist at 4 weeks instead of 6 weeks, as in the passive group. Patients in the active group were also allowed lighter activities 2 weeks earlier compared with those in the passive group. The small differences in repetitions and sessions between the programs were caused by the fact that we did not wish to change the passive program. Furthermore, we decided to follow the combination of previously published rehabilitation programs for active mobilization.

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