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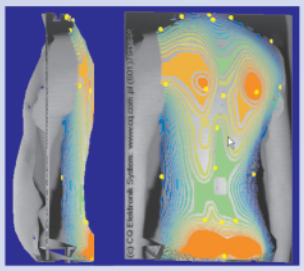

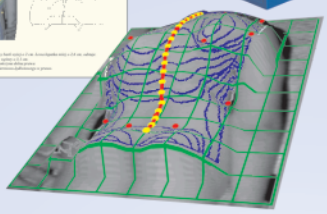

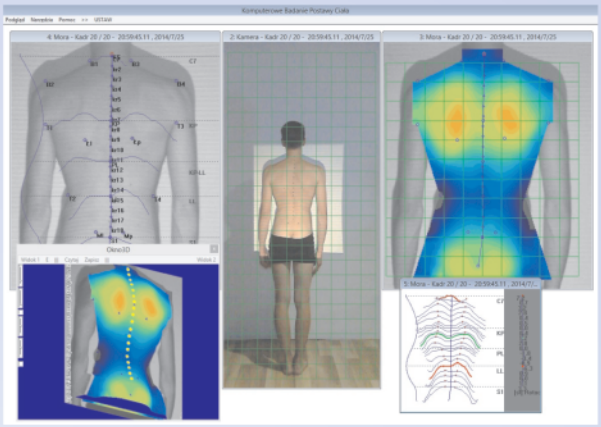

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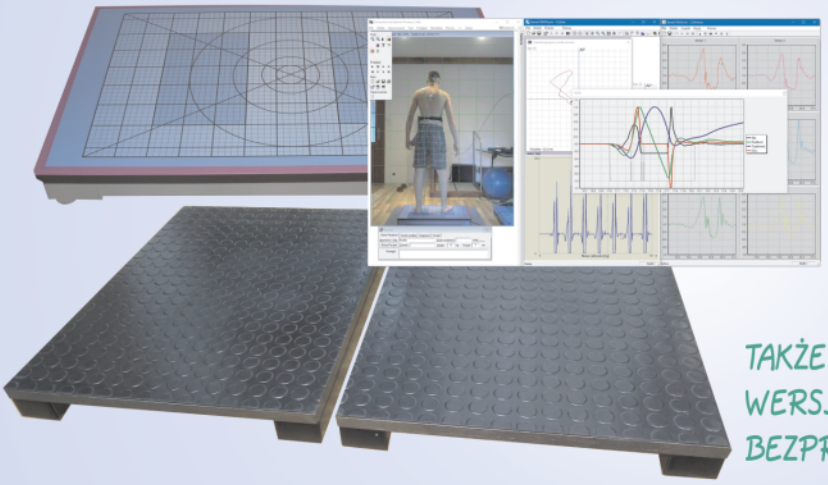

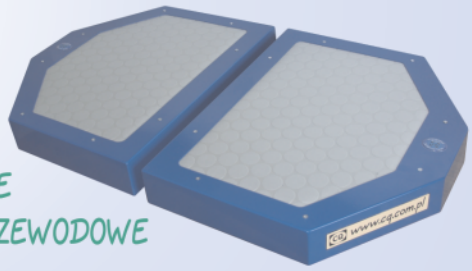

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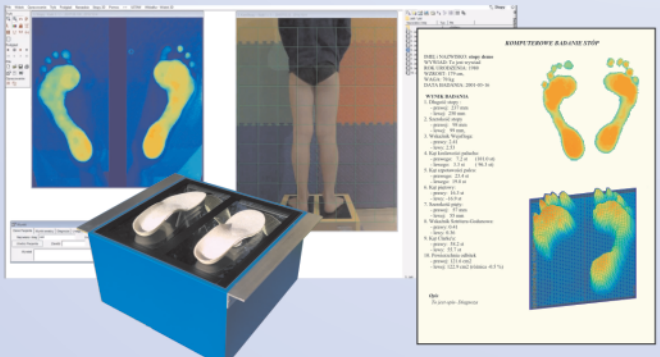

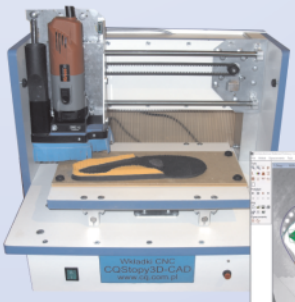

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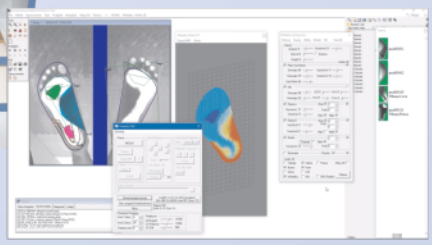

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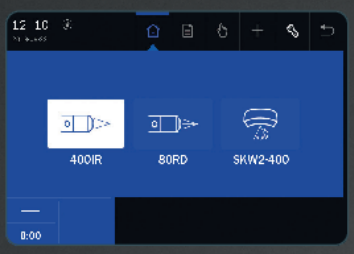

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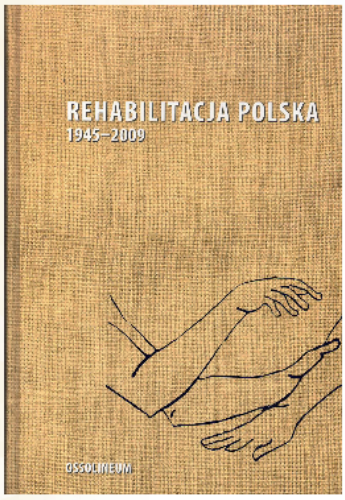

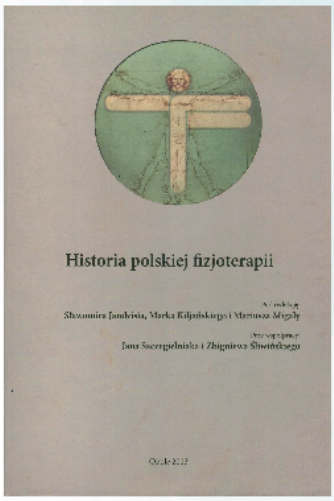

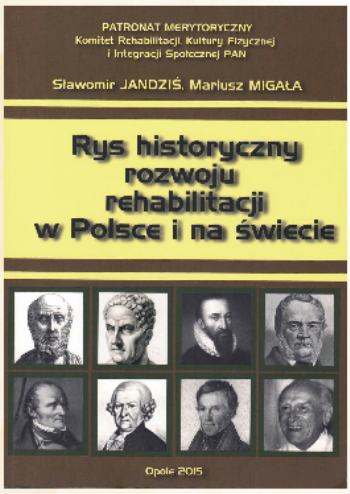

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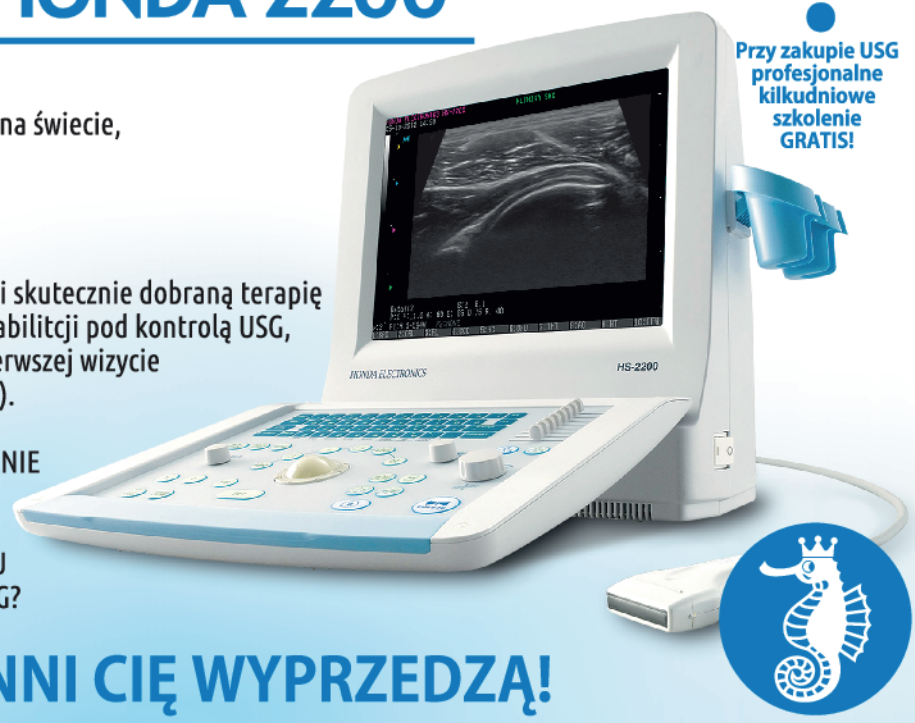

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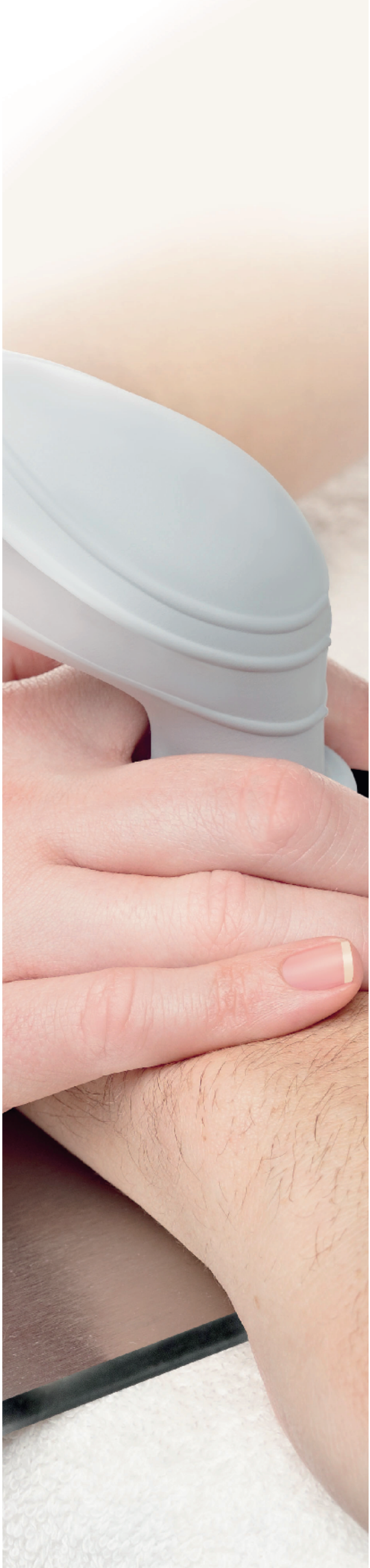

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Early Ultrasound Therapy versus Early Active Mobilization after Zone II Flexor Tendon Repair: A Pilot randomized controlled trial

Wczesna terapia ultradźwiękowa a wczesna aktywna mobilizacja po naprawie ścięgna zginacza strefy II: pilotażowe randomizowane badanie kontrolowane

Amr B. Salama[1,2(A,B,C,D,E,F)], Fatma Alzahraa H. Kamel[1,3(A,B,C,D,E,F)], Ahmed M. Zarraa[1(A,B,E)], Ashraf A. Khalil[4(A,B,C,D,E,F)], Ashwag Saleh Alsharidah[5(A,B,E)]

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Abstract

Purpose. This study aims to compare the effect of early ultrasound (US) therapy to early active mobilization (EAM) on the outcomes "Range of motion (ROM) and rate of tendon ruptures" of zone II flexor tendon repair. Subjects and Methods. 20 male patients (31 operated digits), who underwent zone II flexor tendon 4-strand repair, were divided randomly into 2 groups: Group (A); 10 patients (15 operated digits) who received early US therapy, and Group (B); 10 patients (16 operated digits) who received EAM. Patients received the treatment (3 sessions/week) from the 3rd day till the end of the 6th week postoperative. Active interphalangeal (IP) joints' ROM of each operated digit was measured using finger goniometer and Strickland's Original Scoring System was used to evaluate the ROM outcome at end of the 3rd and 6th postoperative weeks. Tendon ruptures were counted in each group if it occurred. Results. There was a significant improvement in the ROM outcome at end of the3rd and 6th week postoperative in group B compared to group A while no tendon ruptures occurred in either of the groups. Conclusion. The EAM seems to be superior over early US therapy in the improvement of the ROM outcome of zone II flexor tendon repair while both show no tendon ruptures.

Key words:

early ultrasound therapy, early active mobilization, flexor tendon repair

Streszczenie

Cel. Niniejsze badanie miało na celu porównanie wpływu wczesnej terapii ultradźwiękowej (US) z wczesną aktywną mobilizacją (EAM) na wyniki obejmujące „Zakres ruchu (ROM) i częstość zerwania ścięgien" w przypadku naprawy ścięgien zginaczy strefy II. Uczestnicy badania i metody. 20 pacjentów płci męskiej (31 zabiegów operacyjnych), którzy zostali poddani naprawie ścięgna zginacza strefy II przy użyciu szwów czteronitkowych, podzielonych losowo na 2 grupy: Grupa (A); 10 pacjentów (15 zabiegów operacyjnych), którzy zostali poddani wczesnej terapii ultradźwiękowej i grupa (B); 10 pacjentów (16 zabiegów operacyjnych), którzy zostali poddani EAM. Pacjenci zostali poddani leczeniu (3 sesje/tydzień) od 3. dnia do końca 6. tygodnia po operacji. Zakres ruchu aktywnych stawów międzypaliczkowych (IP) każdego operowanego palca mierzono za pomocą goniometru palcowego, a do oceny wyniku zakresu ruchu pod koniec 3. i 6. tygodnia po operacji zastosowano oryginalny system punktacji Stricklanda. W każdej grupie liczono zerwania ścięgien, jeśli wystąpiły. Wyniki. Nastąpiła znacząca poprawa zakresu ruchu pod koniec 3. i 6. tygodnia po operacji w grupie B w porównaniu z grupą A; w żadnej z grup nie wystąpiły zerwania ścięgien. Wnioski. Wydaje się, że EAM pomaga osiągać lepsze efekty w porównaniu do wczesnej terapii ultradźwiękowej w poprawie zakresu ruchu po naprawie ścięgna zginaczy strefy II, przy czym obie nie powodują zerwania ścięgien.

Słowa kluczowe:

wczesna terapia ultradźwiękowa, wczesna aktywna mobilizacja, naprawa ścięgien zginaczy

Introduction

Lacerations of the hand flexor tendons are common and cause direct loss of hand function [1]. Repair and rehabilitation of zone II flexor tendon lacerations, traditionally described as "no-man's land", is challenging for both hand surgeons and therapists [2].

Due to the narrow space in which the extrinsic flexor tendons is located and their limited vascularity in zone II, development of gliding-restricting adhesions is expected. Scar tissue during the healing process can limit tendon-excursion in the digital synovial sheath and restrict the involved fingers ROM [3]. One of the major complications after flexor tendon repair is development of peritendinous adhesions. Several surgical, pharmacological, and non-pharmacological options have been introduced to reduce postoperative tendon adhesions aiming to preserve the tendons gliding function without impairing the healing process [4].

The US therapy may be associated with an increase in tensile strength and mobility, improved collagen fibril alignment, and reduction in inflammatory infiltrate and scar tissue in the tendons [5]. These effects are considered the cornerstone for the use of US to facilitate tendon healing, repair, and prevention of undesirable adhesions [4].

Early mobilization is the most common method for rehabilitation after flexor tendon repair. Early passive mobilization (EPM) means passive flexion with either active or passive extension of the operated digits, while EAM means active flexion and extension of the digits [6]. Place and hold therapy is a type of EAM, where the finger is passively flexed and then actively field by the patient [7]. The EAM is distinguished by the use of low-tension active contractions in the repaired muscle-tendon unit is initiated within by the first 3 days but not later than the 5th day postoperatively [8].

Despite many publications on postoperative rehabilitation methods, restoration of function after zone II flexor tendon repair still represents a very challenging clinical problem and none of the methods proved to be superior consensually by authors [9]. Hence, this study has been developed to compare between the effect of early US therapy and EAM on the outcomes of zone II flexor tendon repair aiming to explore which method is superior since there is a lack of literature comparing these rehabilitation methods after flexor tendon repair.

Subjects and Methods

Study Design

The study was designed as a prospective, randomized, single-blind, controlled trial. The study was followed the Guidelines of Declaration of Helsinki on the conduct of human research.

Participants

A convenient sample of twenty male patients (31 operated digits) who underwent zone II flexor tendon primary direct 4-strand repair technique, aged from 20 to 35 years old,, selected from Cairo University hospitals, included in this study which was conducted from January 2017 to August 2017. Patients were excluded if they had associated vascular injuries requiring arterial repair, crush injuries and soft tissue loss, nerve injuries, tendon injuries of other zones, flexor pollicis longus repair, medical conditions inhibiting healing, preexisting problems such as arthritis limiting joint motion, isolated injuries to flexor digitorum superficialis (FDS) tendon or flexor digitorum profunds (FDP) tendon, tendon injuries in both hands, diminished cognitive capacity, or history of previously failed repair. The dominant hand in all patients in each group was the right one.

Randomization

Informed consent was obtained from each participant after explaining the nature, purpose, and benefits of the study, informing them of their right to refuse or withdraw at any time, and about the confidentiality of any obtained information. Anonymity was assured through coding of all data. The participants were randomly assigned into two by a blinded and an independent research assistant who opened sealed envelopes that contained a computer generated randomization card. No subjects dropped out of the study after randomization.

Interventions

A dorsal blocking cast was fabricated on each included patient after surgery to immobilize wrist joint in 20-30º extension, metacarpophalangeal (MCP) joints of 2nd to 5th digits in 40-50º flexion, and IP joints of 2nd to 5th digits in full but comfortable extension with free thumb [10]. The cast was fixed on the patient by a wrapped bandage.

The treatment was conducted for 6 weeks (3 sessions/week) started at the 3rd day and continued till the end of 6th week postoperative. Postsurgical medical care (medications including analgesics and antibiotics, and wound dressings) was provided for all included patients who were randomly assigned into 2 groups:

Group A included 10 patients (15 operated digits) who received early US therapy. At the 3rd day postoperative, with the cast in place, the bandage and the dressing on zone II were removed. The coupling gel medium was applied over the repaired area and a tap water-filled latex glove was placed over the gel. The gel was applied on the US treatment head (Ultrasound Unit PULSON 200 Gymna Uniphy N.V) then it was placed on the tap water-filled latex glove [11]. The US parameters were adjusted to: 1 MHz, 0.7 W/cm^2, 1:4 pulse ratio and the treatment duration was 5 min for each operated digit [12]. The US treatment head was moved over the tap water-filled latex glove continuously during therapy. After the end of the therapy duration, the dressing and the bandage were carefully reapplied. The use of tap water-filled latex glove was discontinued just after suture removal (by the end of 3rd postoperative week) and direct application of US with only gel was used. From the start of 4th week till the end of 6th week postoperative, the intensity of US was increased to 1 W/cm^2 [12].

Group B included 10 patients (16 operated digits) who received EAM. The EAM program was divided into 3 phases [8, 11, 13]:

- Phase 1.: From the 3rd day to the end of the 3rd week postoperative: With the cast in place, the bandage over the hand was removed and the following exercises were performed; Passive distal interphalangeal (DIP) joint flexion and extension "with proximal interphalangeal (PIP) joint and MCP joint flexed", passive PIP joint flexion and extension "with DIP joint and MCP joint flexed", passive composite flexion and active extension to the limit of the cast, and active place and hold exercises which consisted of; Active wrist extension till the limit of the cast with simultaneous passive tolerable unrestricted composite flexion of the digits, then the patient was asked to maintain the attained digits flexion actively for 5 seconds, then the patient relaxed allowing the wrist and MCP joints to passively flex, and the IP joints to actively extend. At end, the bandage was re-applied over the patient hand.
- Phase 2.: From 4th to 6th week: In addition to the previous exercises, the cast was removed for phase (2) exercises which were; Active IP joints flexion with MCP joints extension followed by full digital extension, and active tenodesis exercises which consisted of; Active wrist flexion with active digits extension, and active wrist extension with gentle active digits flexion in form of a straight fist, full fist, and hook fist alternatively. Then, the patient was re-immobilized in the cast.
- Phase 3.: During the 6th week: The cast was discontinued. In addition to the previous exercises, the following exercises were performed; Active flexor tendon-gliding exercises which consisted of moving the fingers through the following five positions respectively (straight hand, hook fist, full fist, table-top position, and straight fist), and flexor tendon-blocking exercises for PIP flexion and DIP flexion for each involved digit. Each previous exercise in each phase was performed 15 times/session and same per each 2 waking hours. In home, the patient was learned to perform the passive exercises and stabilization by his opposite hand. At the 4th and 6th postoperative weeks, the 2nd and 3rd phases of EAM program were added respectively to the US therapy for patients of group A.

Outcome Measures

At end of 3rd and 6th weeks postoperative, active ROM at PIP and DIP joints of each involved digit was measured using finger goniometer (Baseline 12-1011 Finger Goniometer, Metal, 180 Degree - 6" Deluxe) [14], [15]. The Strickland's Original Scoring System formula was used for calculating the attained percentage of the normal range of active finger PIP and DIP joints movement [16]:

$$\text{Strickland} = \frac{\text{active flexion PIP and DIP)} - \text{(extension deficit PIP and DIP)} \times 100\%}{175^{o}} = \%\ \text{normal PIP and DIP motion.}$$

The ROM outcome was classified as excellent if it is between 85-100%, good if it is between 70-84%, fair if it is between 50-69%, or poor if it is between 0-49%. The number of digits with poor score in each group was divided on the total number of all operated fingers in the same group and the result was multiplied by 100 to give a percentage of poor results in each group and the same was done for digits with excellent, good or fair scores in each group.

Statistical analysis

Age was compared between groups using unpaired t test. Chi squared test was conducted for comparison of distribution of the operated fingers between groups. Data of Strickland's Original Scoring System was expressed as a frequency distribution. As Strickland's Original Scoring System data was ranked data, the Mann–Whitney U test was carried out to identify the significance difference between the two groups. Wilcoxon signed ranks test was conducted for comparison between pre and post treatment in each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical measures were performed through the statistical package for social studies (SPSS) version 19 for windows.

Results

Twenty patients with zone II flexor tendon 4-strand repair participated in and completed this study. The mean ages of the patients were 37.6 ± 7.89 in group (A) and 35.1 ± 7.59 years in group (B), with no statistical difference between groups ($p > 0.05$). There was 1 patient had 4 operated digits, 2 patients had 2, and 7 patients had 1, while in group B there was 1 patient had 3 operated digits, 4 patients had 2, and 5 patients had 1. Also, in group A, 3 operated digits were little fingers, 3 were ring, 5 were middle, and 4 were index while in group b, 2 operated digits were little fingers, 3 were ring, 6 were middle, and 5 were index. There was no significant difference between the two groups in the number and distribution of operated fingers in patients ($p = 0.64$).

The frequency distribution of Strickland's Original Scoring System for both groups is presented at (table 1). In terms of a within-group comparison, the results clarify a significant improvement in the Strickland's Original Scoring System at end of 6th over end of 3rd week postoperative in group B ($p < 0.05$), while there was no significant difference in the Strickland's Original Scoring System between 3 and 6 weeks post operative in group A ($p > 0.05$). In terms of between groups comparison, there was a significant improvement of the distribution of Strickland's Original Scoring System in favor of group B over group A at end of both 3rd and 6th week postoperative ($p < 0.05$) (table 1).

Table 1. The frequency distribution and Mann-Whitney U -value of Strickland's Original Scoring System for between groups comparison and Wilcoxon Signed Ranks test for within groups comparison.

Time of evaluation	Strickland's Original Scoring System	Group A	Group B	Mann-Whitney U -value	p-value
Week 3	Poor	12 (80%)	4 (25%)	45	0.001**
	Fair	3 (20%)	6 (37.5%)		
	Good	0 (0%)	6 (37.5%)		
Week 6	Poor	6 (40%)	0 (0%)	24	0.0001**
	Fair	8 (53.3%)	6 (37.5%)		
	Good	1 (6.7%)	10 (62.5%)		
	Wilcoxon Signed Ranks Test				
Week 3 Vs Week 6	Z- value	1.89	2.82		
	p-value	0.06	0.005**		

Discussion

In the present study, early US therapy in group A showed improvement in the ROM outcome post flexor tendon repair. This could be proved by matching the current study group A results with what was found by Geetha et al. [12] when they compare early US therapy to postoperative immobilization and concluded superiority of early US.

Geetha et al. [12] reported that 75% of the operated digits had poor scores by the end of 12th week post flexor tendon repair during which the patients were kept in complete immobilization for 3 weeks postoperatively. By the end of the 8th postoperative week, the best outcome for operated digits which underwent early US therapy was that about 76% of them had good scores [12]. Group A results of the present study showed that 60% of the operated digits had fair and good scores and 40% of the operated digits had poor scores and that was only by the end of the 6th week postoperatively.

This could be interpreted by the effect of US on optimizing tendon healing and prevention of tendon adhesions, and therefore improving the ROM outcome of the operated digits in contrast to postoperative immobilization [4, 17, 18, 19].

In the current study, no tendon ruptures occurred in group A. This could be interpreted by the effect of US in improvement of the ultimate tensile strength of the repaired tendon [20, 21]. US might have these advantages due to its non-thermal effects, including stable cavitation, acoustic microstreaming, and micromassage. These have sufficient strength to alter cell membrane permeability and stimulate cellular activity which can facilitate tendon repair in an optimum way leading to more regular and denser tendons [5, 21].

The ROM results of EAM in group B in the present study could be matched with the ROM results found in the study done by Trumble et al. [7]. in which the mean active IP joints ROM was 122º ± 16º in patients who underwent EAM group by the end of the 6th postoperative week [7]. The ROM results of group B in the present study revealed that 62.5% of the fingers had good results (125-149˚) and only 37.5% of the fingers had fair results (90-124˚) by the end of 6th postoperative week. That seems to be similar in average to the ROM results of EAM in the study of Trumble et al. [8] and that ensures the effectiveness of EAM on enhancement of the ROM outcome post flexor tendon repair. This effect could be interpreted by the brief sufficient stress placed on the repaired tendon, developed only by EAM, which is very effective in creating tendon excursion.

In the current study, there were no tendon ruptures in group B. Some possible causes could explain this advantage. Some studies showed that EAM increases the tensile strength of the repaired tendon [17, 22]. Also, place and hold exercises with synergistic active wrist which exert about 9 N force on the tendon, located in the early safe zone (between 5 and 10N) for rehabilitation in a typical 4-strand repair [23]. Additionally, place and hold exercises were performed only in the available unrestricted tolerable passive composite ROM of the digits without a necessity for full arc forceful flexion and this decreased the work of flexion (WOF) [10]. Finally, in our study, clear instructions were provided for the patients about the proper way to move their hands during exercise. All of these factors might contribute to a decrease in the risk of gapping and possibility of tendon rupture postoperatively.

The superiority of group B results over group A results, regarding the ROM outcome, found in the present study might be due to 3 possible causes. Firstly, the complete immobilization of the digits in group A for 3 weeks could result in 47% loss of muscle strength which was concluded in the study of Hortobagyi et al. [24]. As the muscles bring about movement within the joints, then significant weakness in the muscles will directly decrease the active ROM of the joints they are acting on. On the contrary, active muscle contraction promotes recovery of muscle tone and strength [25], and enhances the joints active ROM outcome post flexor tendon repair and this is what occurred in group B.

Secondly, Kubato et al. [26] concluded that both motion and tension enhance the tendons response to injury in contrast to deprivation from them which supports the superiority of EAM protocols. Tertiary, the exercises in EAM group were repeated daily for 15 times /2 waking hours in addition to the sessions (3 times weekly) while early US therapy was introduced only during the sessions. The differences in the frequency of the intervention might add to the superiority of EAM.

The superiority of EAM over early US therapy in the ROM outcomes, found in the present study, was mismatched to the conclusions of Geetha et al. [12] and Tang, [27]. Tang, [27] noted that the best functional results of 75% excellent to good scores (at 12th week post flexor tendon repairs) were reported after EAM and Geetha et al. [12] found exactly the same results from early US direct application therapy after 2-strand flexor tendon repair.

The evenness of both EAM and early US therapy found by Tang, [27] and Geetha et al. [12] differs than the superiority of EAM found in the present study and it might be due to some possible causes. Firstly, Geetha et al. [12] used the direct US application from the beginning, which provides the advantage of 100% sound waves transmission (therefore better outcomes than indirect application, used in the first 3 weeks in group (A) in the current study, which provided only 66-79% transmission) [11], but with possible disadvantage of wound dehiscence [12].
Additionally, all patients included in the study of Geetha et al. [12] underwent 2-strand repair not 4-strand repair like in the present study and Kannas et al. [28] concluded that multistrand repairs showed increased bulk and stiffness compared with 2-strand repairs. Hence, US therapy used for 4-strand sutures repaired tendons could result in poorer ROM outcomes than when it was used for 2-strand sutures repaired ones and that might add to the inferiority of group A ROM results in the current study.
On the other hand, the superiority of EAM was agreed upon by other studies compared active exercise therapy with other available postoperative rehabilitation methods like studies done by Farzad et al. [29], Stasinopoulos and Stasinopoulos, [30], Wada et al. [22] and Pienimäki et al. [31].
Farzad et al. [29] concluded that EAM provides greater ROM than EPM after zone 2 flexor tendon 2-strand repairs. Also, Stasinopoulos and Stasinopoulos, [30] noted that an exercise program is better than US therapy in treatment of chronic patellar tendinopathy. Additionally, Wada et al. [22] found that peritendinous adhesions are apparently absent in early actively mobilized repaired tendons in contrast to markedly developed extrinsic adhesions in immobilized ones. Also, Pienimäki et al. [31] concluded that progressive exercise therapy is more beneficial than US therapy in treating chronic tennis elbow.
Limitations of the present study were the differences between surgeons who participated in this study in skills and experience, physical and psychological conditions of the patients during the period of treatment, individual differences in patients and their response to the treatment, possible human errors, patient's nutrition, and patient's compliance.

Conclusion

The EAM seems to be superior over early US therapy in improvement of the ROM outcome of zone II flexor tendon repair while both show no tendon ruptures.

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