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Original Article

Early ultrasound therapy for rehabilitation after zone II flexor tendon repair

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ABSTRACT

Background: In our Institute, most of the patients treated for hand injuries were industrial workers with poor compliance. For rehabilitation after zone II flexor tendon repair, we had tried various early mobilization protocols. As these protocols demanded a degree of commitment from the patients, our results were suboptimal. Hence, to improve the results, we implemented a new rehabilitation protocol by administering the pulsed ultrasound therapy during the early phase of tendon healing. **Materials and Methods:** This is a prospective study done over a period of five years from January 2008 to January 2013. A total of 100 patients and 139 digits with zone II flexor tendon injuries were studied. After randomization, we administered pulsed ultrasound therapy of different frequencies and intensities for a total of 72 patients and 99 digits and formulated three groups. The results of ultrasound treated cases were compared with each other and with the results of cases treated by immobilization protocol. The results were analyzed using 'Original Strickland' criteria. **Results:** 72% excellent-good results in ultrasound (Group 1) protocol, 75% excellent-good results in ultrasound (Group 2) protocol, and 77% excellent-good results in ultrasound (Group 3) protocol were achieved. There was no case of rupture in the first two groups. The rupture rate was 7% in ultrasound (Group 3) protocol. Only 25% excellent-good results were obtained in the immobilization protocol. **Conclusion:** After zone II flexor tendon repair, pulsed ultrasound therapy during the early rehabilitation phase is safe and effective. The results are comparable to early mobilization protocols.

KEY WORDS

Early ultrasound therapy; zone II flexor tendon repair; PIP Joint flexion contracture

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INTRODUCTION

Although injuries to the flexor tendons in the zone II region look trivial, sustained commitment of the patient, the surgeon and the therapist is necessary to get a reasonable functional outcome.

As our Institute is situated in an industrial corridor of the city, most of our patients are manual workers with poor compliance. Conforming to the established practice, we tried various early mobilization

protocols after zone II flexor tendon repair. As these protocols demanded a level of understanding and a degree of dedication from the patients, our results were suboptimal, with a high incidence of proximal interphalangeal joint (PIP) joint flexion contractures and tendon ruptures.

Hence, in our Institute "Immobilization" became the norm for patients who were not expected to be compliant. To improve the results in such patients, we thought of implementing a new rehabilitation protocol that could entirely be under the control of the therapist, without the active participation of the patient.

Ultrasound therapy is being used safely after tendon repair, during the remodeling phase (after three weeks) as an adjunct to mobilization to improve the tendon gliding. We thought of using this mode of treatment during the earlier phase of tendon healing.

The effects of ultrasound on tissues were demonstrated in many *in vitro* studies.[1-4] Such findings formed the basis, for the use of ultrasound to accelerate tendon healing and to prevent adhesions.[5] Though many clinical trials on animals are reported in the literature, there is no clinical study in the humans regarding the use of ultrasound during the early healing phase of the repaired tendons.

Encouraged by the *in vitro* and *in vivo* animal studies,[5-9] we conducted the trial by selecting the patients at random and administered pulsed ultrasound therapy of different frequencies and intensities. Thus, three ultrasound therapy groups were formulated.

The results of the ultrasound therapy in the three groups were analyzed and compared with each other and also with the immobilization group.

MATERIALS AND METHODS

This is a prospective study, done over a period of 5 years from January 2008 to January 2013, involving a total of 100 patients and 139 digits with zone II flexor tendon injuries. Permission to conduct the study was obtained from the institutional ethical committee. Patients were explained about the procedure and their written consents were obtained.

Patients with isolated injury to the FDS or FDP tendon, multiple level injuries of the flexor tendons, associated injury to the extensor apparatus and fractures were excluded.

All the cases were operated as emergency procedures by senior residents and hence, for tendon repair technically less demanding two-strand modified Kessler Mason suture was used. After surgery, patients were allocated to ultrasound therapy, as demonstrated in the CONSORT guideline flowchart [Figure 1]. The patients were asked to draw a card indiscriminately from an envelope containing a pack of cards labeled as ultrasound or immobilization in 2:1 ratio. This was to ensure more number of patients for our interventional ultrasound therapy. Thus, the treatment groups were randomized and the therapists had no control over the selection of the patients.

Immobilization protocol

After surgery, hands were immobilized for 3 weeks using dorsal slab with wrist kept in neutral position, MP joints in 70 degrees flexion and IP joints in extension. After 3 weeks, POP slab was removed and the patients were advised to attend therapy daily. From 3 to 6 weeks the therapy consisted of scar massage, active mobilization exercises, blocking exercises and place hold techniques. After 6 weeks, passive stretching and resisted exercises

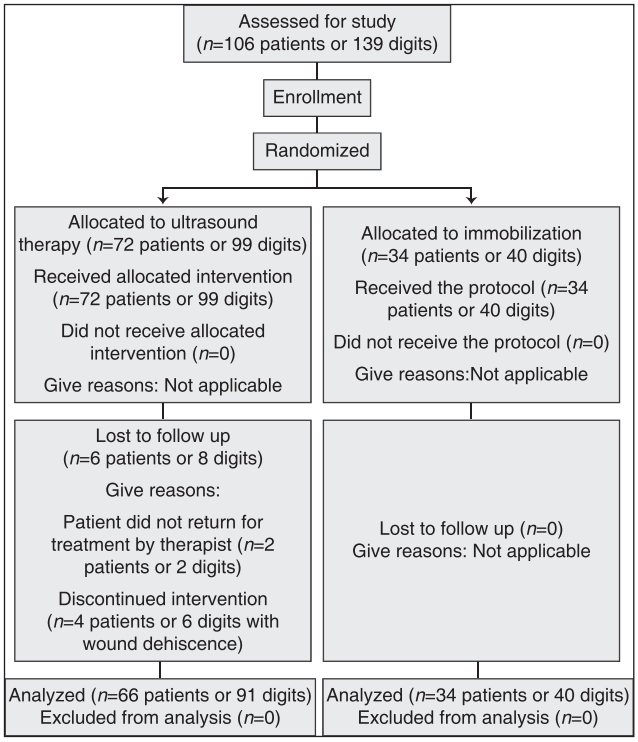

Figure 1: CONSORT flow chart

were added. After 8 weeks, the patients were allowed to lift weights and to join work.

By this protocol, we treated 34 patients with involvement of a total of 40 fingers. Out of this, 30 patients were males and 4 were females. Age group was between 22 and 50 years. The mean age was 35. Ten patients had associated digital nerve involvement.

Ultrasound protocol

After surgery hands were immobilized using dorsal slab with wrist in neutral, MP joints in 70 degrees flexion and IP joints in extension.

With the dorsal splint in place, the dressings on the volar aspect were removed. The coupling gel was applied to the zone II region. The ultrasonic treatment head was placed over the site of tendon repair and gently moved in order to iron out the irregularities in the near field and to avoid standing waves due to reflection.[10] Care was taken not to cause undue movements of the repaired finger. After ultrasound therapy, the dressings were carefully reapplied [Figure 2].

Group 1

To begin with, since January 2008, ultrasound of 1-MHz frequency at an intensity of 0.7 w/cm^2 was administered from the seventh postoperative day. The pulse ratio was kept at 2:8. The duration of therapy was 5 minutes. After 3 weeks, the intensity was increased to 1 w/cm^2. Twenty-six patients with involvement of a total of thirty eight digits were treated. Two patients were lost for follow up during the course of the therapy. Out of 24 patients, 23 were males and one was female. The age group was 10 to 45 years and the mean age was 25. Twelve patients had associated digital nerve involvement.

Figure 2: The ultrasonic head was applied gently and moved continuously over the region of tendon repair

Group 2

With the idea of further refining the technique, since August 2010, we started ultrasound therapy of 1-MHz frequency at an intensity of 0.3 w/cm^2 from the third postoperative day. We reduced the intensity due to fear of impaired skin healing as we had started the therapy earlier than the first group. After 3 weeks the intensity was increased to 1 w/cm^2. The pulse ratio was maintained at 2:8. The duration of the therapy was 5 minutes.

Nineteen patients with involvement of a total of 28 fingers were treated. One patient developed wound dehiscence and was dropped from the study. Out of 18 patients, 15 were males and 3 were females. The age group was 20 to 35 years. Six patients had digital nerve involvement.

Group 3

As there was significant reduction in the percentage of excellent results in Group 2, from October 2011, ultrasound therapy of 3 MHz frequency at an intensity of 0.5 w/cm^2 was administered from the fifth postoperative day. Due to cases of wound dehiscence, the intensity was increased only to 0.7 w/cm^2 after 3 weeks. This protocol was started for 27 patients with involvement of a total of 33 fingers. Three patients developed wound dehiscence within 2 days of starting ultrasound therapy and were dropped from the study. Out of 24 patients, 21 were males and 3 were females. Four patients had digital nerve involvement.

In all the ultrasound therapy groups, the splint was removed after 3 weeks and mobilization programe was commenced in addition to the ultrasound therapy. Passive stretching and resisted exercises were added after 6 weeks. Patients were allowed to lift weight after 8 weeks.

Results were assessed by an independent observer who was not involved in the study.

Our trial has been registered in CTRI and the registration identification number is CTRI/2013/04/003576.

Assessments

Active ranges of movements at PIP and DIP joints were measured after 3 weeks and at weekly intervals. Final assessment of the results was recorded at 12 weeks. Grip

strength was measured using a hand dynamometer at 12 weeks.

RESULTS

The results were analyzed using 'Original Strick land' criteria. The patients who were dropped from the study due to wound complications in the early phase were not included in the analysis of the results. Comparison of results between various protocols by the end of 3 months is given in Tables 1 and 2.

In ultrasound therapy Group 1 protocol, out of 36 digits, 16 digits achieved PIP + DIP joint flexion range between 150° and 175° and 10 digits between 125° and 150° in 8 weeks time. The range in the remaining digits was between 90° and 120°. Extensor lag was nil in 34 digits by the end of 6 weeks. By the end of 8 weeks, none of the digits had extensor lag. Grip strength of 95% compared to normal hand was achieved by 16 digits and 10 digits achieved grip strength of 80% compared to normal hand by the end of 12 weeks.

In ultrasound therapy Group 2 protocol, out of 27 digits, 13 digits achieved PIP + DIP joint flexion range between 150° and 175° by 8 weeks and 8 digits were in the range between 125° and 150° by 12 weeks. In remaining 6 digits the range was less than 90°. Extensor lag was nil in 18 digits and in 4 digits the extensor lag was between 10° and 40° by the end of 6 weeks. By 12 weeks, 3 digits presented with residual extensor lag between 10° and 30°. Grip strength was 90 % compared to normal hand for 21 digits in 12 weeks.

In ultrasound therapy Group 3 protocol, out of 30 digits, 23 digits achieved PIP + DIP joint flexion in the range of 125°-140° and 5 digits below 90° by the end of 8 weeks. In 2 digits tendons got ruptured after 3 weeks. Three digits presented with extensor lag and required passive stretching after 6 weeks. The degrees of extensor lag were between 10° and 25°. Extensor lag was nil in all digits except 1 by the end of 8 weeks, which was in the range of 15°-25°. Grip strength of 90% compared to normal hand was achieved by 23 digits in 12 weeks.

In Immobilization group, out of 40 digits, 10 digits achieved a PIP + DIP joint flexion in the range of 125°-150°. And in 30 digits it was below 90° by the end of 12 weeks. In 6 digits, extensor lag was nil by the end of 6 weeks. Remaining digits had extensor lag between 10° and 60°. Eighteen patients were left with residual PIP joint flexion contracture in the range of 25°-45° by the end of 12 weeks. Grip strength of 90% was achieved by 10 digits by the end of 12 weeks.

Statistical analysis

As there are more than three groups of data to be compared and the data sets represent a continuous distribution, the one way ANOVA test using the F distribution is chosen for the statistical analysis. The ANOVA test was performed using the statistical tools available in Origin 8.5.1 scientific data analysis software. This test compares the mean values of the distribution assuming equal variance for all the data [Table 3a,b]. The result of this analysis shows that there is statistically significant improvement of score (using $P < 0.05$ criteria) in ultrasound protocols compared to immobilization. However, when only the three ultrasound methods are compared, the P value is 0.066, which is

Table 1: Comparison of results between various protocols at 3 months (Original Strickland)

Protocols	US therapy group 1 (36 digits)		US therapy group 2 (27 digits)		US therapy group 3 (30 digits)		US therapy all groups (93 digits)		Immobilization (40 digits)	
Results	No. of digits	Percentage	No. of digits	Percentage	No. of digits	Percentage	No. of digits	Percentage	No of digits	Percentage
Excellent-Good	26	72	21	78	23	77	70	75	10	25
Fair	5	14	0	0	0	0	5	5	4	10
Poor	5	14	6	22	5	16	16	18	26	65
Ruptures	0	0	0	0	2	7	2	2	0	0

Table 2: Comparison of Excellent and Good results in various protocols (Original Strickland)

Protocols	Total no of digits	Excellent-Good		Excellent		Good	
		Number of digits	%	Number of digits	%	Number of digits	%
Ultrasound (Group 1)	36	26	72	16	43	10	29
Ultrasound (Group 2)	27	21	75	2	8	19	67
Ultrasound (Group 3)	30	23	77	—	—	23	77
Immobilization	40	10	25	2	5	8	20

slightly larger than the 0.05 criteria. Hence, there is a 6.6% probability that the difference in the mean value between the ultrasound Group 1 method and the other two methods may be due to chance factor. Since the *P* value is only slightly larger than the 0.05 level, further investigations with a larger data set and more variation in parameters such as ultrasound intensity, duration of exposure, etc. may reveal their beneficial effects on the improvement of outcome.

The Table 3a reveals that the best mean score of 78.4 ± 16.6 was achieved in ultrasound Group 1 protocol.

The mean scores of Group 2 and Group 3 protocols are 70.8 ± 14.38 and 70.8±13.39, respectively, which are more or less identical. A significant finding in the ultrasound (Group 1) treated patients was that, extensor lag was minimal in all cases, and only 2 patients required passive stretching after six weeks. The percentage of patients left with residual PIP joint flexion contracture in all the ultrasound groups, is much less compared to the immobilization group [Table 4].

The scars became soft and supple in the ultrasound-treated patients much earlier than patients treated with the immobilization protocol [Figure 3].

Wound dehiscence was observed in 3 patients in ultrasound (Group 3) protocol and for 1 patient in ultrasound (Group 2) protocol. Wound dehiscence was observed within 2-3 days of ultrasound therapy, and the therapy was discontinued immediately. The wounds were

Figure 3: The scars in the fingers and palm became soft and supple as early as 3 weeks.

Table 3a: One-way mean anova (F test)

Protocol	Sample Size	Mean	Standard Deviation	SE of Mean
Ultrasound therapy (Group 1)	36	78.47222	16.63299	2.77216
Ultrasound therapy (Group 2)	27	70.81481	14.38225	2.76786
Ultrasound therapy (Group 3)	28	70.85714	13.39351	2.53114
Immobilization	40	47	19.49622	3.08262

Table 3b: One-way mean anova (F test)

	DF	Sum of Squares	Mean Square	F Value	Prob >F
Model	3	21311.06712	7103.68904	25.97778	3.59712E-13
Error	127	34728.47487	273.45256		
Total	130	56039.54198			

Table 4: Incidence of PIP JOINT flexion contracture

Protocols	Total number of digits	Number of digits which required stretching after 6 weeks	Percentage (%)	Number of digits left with residual PIP joint flexion contractures	Percentage (%)
Ultrasound therapy (Group 1)	36	2 digits (15^0-20^0)	6	Nil	0
Ultrasound therapy (Group 2)	27	9 digits	33	3 digits	11
		3 digits (15-20^0)		1 digits (10-20^0)	
		3 digits (20-30^0)		2 digits (20-30^0)	
		3 digits (35-40^0)			
Ultrasound therapy (Group 3)	30	3 digits	10	1 digit (15-25^0)	3
		2 digits (10-20^0)			
		1 digit (15-25^0)			
Immobilization	40	34 digits	85	18 digits	45
		14 digits (10-20^0)		15 digits (25-35^0)	
		12 digits (35-40^0)		3 digits (above 45^0)	
		5 digits (45-50^0)			
		3 digits (above60^0)			

healed, with regular dressings. No further ultrasound therapy was given.

Tendon rupture was observed in 2 patients in ultrasound therapy (Group 3) protocol after 3 weeks. Both attained good results as early as, at the commencement of the mobilization. After this experience, in cases showing good results at 3 weeks itself, we did not increase the intensity further and adjusted the intensity according to the patient's response.

DISCUSSION

The therapeutic effects of ultrasound are many folds. Various studies have proved that ultrasound enhances healing.[11,12] Gan, Huys *et al*. studied the effects of ultrasound on repaired flexor tendons of the chicken limbs. They found that administration of ultrasound resulted in increased range of movement, advancement of scar maturation and reduction of the amount of inflammatory infiltrate. There was no adverse effect on tensile strength and that early administration was more beneficial than late.[13] Though high-intensity ultrasound has tissue destructive effects, low intensities may enhance the healing process of the surgically repaired tendons.[14] Its effects on decreasing peritendinous adhesions,[6] and enhancement of collagen fibrils maturation independent of the intensity applied[15] can explain the improved results obtained in this study.

The factors that determine the ultrasound energy delivered at the tissue level are the frequency, the pulse ratio, the intensity of the ultrasound and the duration of therapy. Appropriate titration of these factors as done in this study will ensure the safety of this modality of treatment. . The results of ultrasound therapy (Group 1) are better compared to other ultrasound therapy groups. Starting of the ultrasound therapy from the seventh day is safer, as the tensile strength of the wound increases from the seventh post operative day and the repaired skin wound will be strong enough to withstand the effects of ultrasound.[16] In our study, wound dehiscence was noticed in the other two groups, when ultrasound was started on the third or the fifth day.

It has been reported by Gelberman and his associates that peak fibronectin concentration and development of adhesions start by the seventh day.[17] Administration of ultrasound at this time would be ideal and safe to break down early adhesions before they get organized. Nil percentage of extensor lag in this group adds strength to this statement.

Relatively reduced percentage of excellent results was observed in the ultrasound therapy (Group 2) protocol. This can be explained by the fact that, lesser the frequency and intensity the lesser will be the absorption of ultrasound energy by the tissues. As the intensity was reduced to 0.3 w/cm^2, the effective energy delivered to the repaired flexor tendons might be less than optimal.

The results of 3-MHz ultrasound (Group 3) are worse compared to 1-MHz (Group 1 and Group 2) with nil percentage of excellent results and 7% of ruptures. When the frequency of ultrasound is high, there will be rapid absorption of ultrasound energy in the superficial tissues. Ultrasound energy absorption is highest for tissues with high collagen content. The absorption coefficient of tendon is 1.12 decibels/cm for 1 MHz and 3.36 decibels/cm for 3 MHz. The repaired flexor tendon, being superficial and highly collagenous, might have been unable to withstand high energy absorption and concentration during the early phase of healing. This could result in tendon ruptures and gap formation. Nil excellent results in the ultrasound therapy (Group 3) protocol might be due to gap formation.

Tim Watson (www.electrotherapy.org) suggested ideal frequencies and intensities of ultrasound for various anatomical regions and pathological conditions.[18] But the safe dose of ultrasound therapy for recent surgical wounds has not been specified in the literature. Merrick *et al*. (2003) demonstrated that ultrasound machines, delivering apparently the same treatment energy, give rise to different amounts of tissue heating and therefore the effects of ultrasound at the tissue level may not be accurately predictable.[19]

In this context, we like to stress that the optimal frequency and intensity of pulsed ultrasound can be determined only by clinical experience. But once the optimal parameters are defined, the intensity and duration can be well controlled by the therapist. As the patient's active participation is less, the desired effect on the tendon healing can be achieved with minimal chance of rupture.

Tang[20] after a 15 years review of reports of clinical outcomes associated with flexor tendon repair noted

that the best functional results of 75% excellent to good results were reported after early active mobilization. The rupture rate ranged from 4% to 10%. He concluded that adhesion formation and stiffness of fingers remain frustrating problems and suggested modern biologic approaches as one of the means of improving the outcome.

We suggest that early ultrasonic therapy can be one such approach as our results of 75% excellent to good results with rupture rate of 2% is comparable to mobilization protocols.

CONCLUSION

1. Pulsed ultrasound therapy in the early phase of tendon healing is safe. Our study shows, starting ultrasound therapy with 1-MHz frequency on the seventh post operative day with intensity of 0.7 w/cm^2 give high percentage of excellent-good results with no ruptures and PIP joint flexion contractures. If 3-MHz frequency is used, the initial intensity must be set at a lower level, and adjusted according to the patient's response after 3 weeks.
2. Pulsed ultrasound therapy can be used in patients who are not compliant for early mobilization protocols.
3. The results of early ultrasound therapy in zone II FTR are comparable with the results of established early mobilization protocols.[20]
4. As the ultrasound therapy is not interfering with mobilization protocols, it is possible to use it as an adjuvant to further improve the outcome.
5. The ideal frequency and intensity cannot be rigidly defined but can safely be arrived at by clinical experience.

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