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ADDITIONAL EFFECT OF RADIAL SHOCKWAVE THERAPY TO SPLINTING IN THE SHORT-TERM TREATMENT OF TRIGGER FINGER: A RANDOMIZED CONTROLLED TRIAL STUDY

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ABSTRACT

Background and aim: Trigger finger is a condition that involves a sudden locking or release of a finger while bending or straightening. Various treatment options exist for this condition, including splinting and radial shock wave therapy (RSWT).

Methods: This study was conducted as a randomized controlled trial on 38 patients with trigger fingers assigned to two treatment groups. The first group received the combined treatment of RSWT and splinting, while the second group received splinting alone. The parameters assessed included pain intensity (VAS), functional disability (Quick DASH), frequency of triggering, and functional impact of triggering at baseline, 6 weeks (after treatment termination), and 3 months post-treatment.

Results: A repeated measures analysis of variance test showed that all measured scores improved significantly over time. However, the contrast of time and group in the variables of pain intensity (VAS), functional impact of triggering, frequency of triggering and hand disability index (Quick DASH) was not significant.

Conclusion: This study showed that both approaches are effective in reducing symptoms and improving function in patients with trigger finger. The interaction of time and group was not significant for variables, indicating that the addition of shockwave did not make a significant difference in any of the indices in short-term follow-up.

KEYWORDS

Trigger finger, combined treatment, splinting, radial shock wave therapy (RSWT), non-surgical treatment

INTRODUCTION

Trigger finger (TF), also known as digital stenosing tenosynovitis or stenosing flexor tenosynovitis, is a condition in which the flexor tendon "triggers" or "snaps" in reaction to finger movement[1,2]. A flexor tendon nodule or swelling may result from irritation and inflammation of

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the tendon and/or sheath, which would hinder the tendon's normal excursion beneath the pulleys.

High pressure at the proximal edge of the A1 pulley and the difference between the flexor tendon's diameter and its sheath at the metacarpal head are thought to be the causes of this condition[1-3]. The connection between this disorder and recurrent trauma is often emphasized in academic literature; however, the primary cause remains ambiguous[4].

The prevalence of TF is 2-3% within the general population and around 10% in patients with diabetes mellitus and rheumatoid arthritis[5,6]. The ring finger is the most commonly affected finger, accounting for 27% of cases[7]. Additionally, the dominant hand is more frequently affected than the nondominant hand[2,8]. TF exhibits an aged-related pattern, affecting children under six years and adults over 40, particularly women aged between 50 and 60 years. Moreover, individuals with rheumatoid arthritis and diabetes may suffer from TF in several fingers[5,9-12].

There is no universally recognized treatment for TF, and its handling differs among researchers and medical doctors[13]. Even though surgery and steroid injections are a widely accepted and effective treatments for individuals with severe symptoms or unsuccessful conservative management[14]. Although they are uncommon, side effects from steroid injections can include skin depigmentation, flexor tendon rupture, and fat necrosis[2]. Complications related to surgery, like hypoesthesia, infection, and tendon rupture, can occasionally arise, especially in patients with diabetes[15].

NSAIDs, cryotherapy, corticosteroid injections, extracorporeal shockwave therapy (ESWT), hand splints, and musculoskeletal ultrasound are the most important conservative treatments that may be employed[16-18]. None of the conservative treatments indicated above are superior to the others, though. The severity of triggering, prior treatments, the onset of triggering, the patient's level of activity, and the preferences of both the patient and the therapist all influence the treatment that is chosen for each patient[4,19].

Complications were not mentioned in articles that praised the benefits of splinting[20,21]. Certain studies especially evaluated splinting as a first treatment option especially for milder ones. Splinting arms to promote differential tendon gliding while modifying the biomechanics of the flexor tendons. On which joints to include in the splint and the extent of joint placement, however, authors disagree[1,2]. For a maximum of three to six weeks, the suggested splint maintains the metacarpophalangeal (MCP) joint at 0° of extension or 10° to 15° of flexion. After a year, the recurrence rate with this treatment was 12%[4,19,22].

Recently, ESWT has gained favor as a substitute for traditional conservative methods in the treatment of musculoskeletal disorders, including calcific shoulder tendonitis, long bone non-union, lateral epicondylitis, plantar fasciitis, patellar tendinopathy, femoral head avascular necrosis, and carpal tunnel syndrome[23-26]. It is thought that ESWT works by inducing biological activity in cells, which leads to a mechanosensitive feedback loop involving certain transduction pathways and gene expression between the stimulated cells and the acoustic impulse[27,28]. The effect of ESWT in the management of trigger fingers have also demonstrated promising results[29]. However, to the best of our knowledge, the additional effect of shock wave therapy to splinting as a first option in the treatment of trigger fingers has not been evaluated. Therefore, the purpose of this research was to evaluate the effects of radial shock wave therapy plus splinting versus splinting alone on patients with trigger fingers.

MATERIALS AND METHODS

Study design and settings

During 2023-2024, patients who were referred to Firoozgar Hospital's Physical Medicine and Rehabilitation Clinic were included in the study population, which was conducted as a randomized clinical trial (RCT) with a two-group design. The study was performed in accordance with the Declaration of Helsinki, and the study protocol was approved by the ethics committee of Iran University of Medical Sciences (Ethics approval code: IR.IUMS.FMD.REC.1401.383). A written informed consent was obtained from all patients before the study. The study was registered in the Iranian Registry of Clinical Trials under number IRCT20230405057829N1.

Participants

A total of 38 (17 females, 21 males) patients aged 29-78 years qualified for the study. One patient did not take part in follow-ups and withdrew from the study.

Inclusion criteria:

- Age over 18 years
- Diagnosis of trigger finger grade two or three according to Quinnell criteria[30]

Exclusion criteria:

- Patients who have undergone physiotherapy, corticosteroids, or surgery before the study
- Patients with local infection, malignancy, rheumatoid arthritis, pregnancy, or cardiac arrhythmia
- Patients with musculoskeletal problems or nerve damage in the upper limb

Intervention

38 Subjects were randomly assigned into two groups (19 in each group) using randomly generated treatment allocations. The first group received splint treatment, and the second group received splint treatment plus radial shockwave therapy. Before starting treatment, patients were evaluated for demographic and clinical information, including age, gender, occupation, type of affected finger and hand, duration of symptoms, and use of previous

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treatment methods. The first group received splinting to place the MCP joint in 15 degrees of flexion for 6 weeks, and the second group received the same splinting plus 6 sessions of radial shockwave therapy at one-week intervals (1500 impulses, 2 bar and 15 Hz) using a Storz Medical Master-plus MP100 device.

Randomization

The splinting-only group (n = 19) and the splinting plus radial shockwave therapy (RSWT) group (n = 19) were assigned at random in a 1:1 ratio to the research participants. To ensure that the allocation was random and that the group sizes were equal, permuted block randomization was used, with a block size of 4. To prevent selection bias, the randomization sequence was generated by an unbiased statistician on a computer and concealed in sequentially numbered, opaque, sealed envelopes (SNOSE). and symptom frequency), and a statistician used coded, de-identified datasets to do the data analysis.

Outcome measures

Pain intensity (VAS) was considered as a primary outcome and secondary outcomes included frequency of triggering, functional impact, and Quick DASH score. All patients were evaluated before treatment, after 6 weeks (after treatment termination), and 3 months after treatment.

VAS: A 100 mm VAS as a valid and reliable tool for pain measurement was used to measure the maximum pain intensity of patients in the last two days. Patients were asked to mark their pain from 0 (no pain) to 100 (the worst pain possible) on the VAS ruler[31].

Quick DASH (Disabilities of Arm, Shoulder, and Hand) is a valid and reliable assessment tool which uses 11 questions to measure physical function and symptoms of patients with musculoskeletal disorders of upper limbs. Total scores range from 0 (no disability) to 100 (most severe disability)[32]. We used a validated translated version of Quick DASH in this study[33].

Frequency of triggering: To assess frequency, the number of triggering events was recorded during 10 cycles of opening and closing the patients' fingers.

Functional impact of triggering: This variable assesses the degree to which the finger trigger interferes with normal daily function and the person's ability to carry out everyday tasks. The scale used for this assessment is 0–10.

Only the person who analyzed the data was blinded to the assignment.

Sample size

According to the study conducted by Chen et al.[34] and also using the sample size formula to compare the mean results of the two groups (the main outcome variable is VAS score with a maximum difference of 2.5 units) and considering a test power of 80% and a confidence level of 95%, the minimum sample required for each group was calculated as 17 people. Due to the possibility of patient dropout during the study, we consider the number to be 10% higher than the calculated sample size (19 people in each group).

Statistical analysis

After data collection, patient information was analyzed in two groups using SPSS version 22 statistical software. For quantitative data analysis, central indices including mean and standard deviation were used. While for qualitative data analysis, percentage frequency (%) was used. First, the normality of the distribution of variables was examined using the Kolmogorov-Smirnov test. The Kolmogorov-Smirnov test (KS) revealed a normal distribution of the

		Intervention group (n =19)	Control group (n=18)	p value
Age		53.58 (11.92)	50.39 (11.94)	0.456
Gender	Male Female	9 (56.3%) 10 (47.6%)	7 (43.8%) 11 (43.8 %)	0.603
Side	Right Left	9 (47.4%) 10 (55.6%)	10 (52.6%) 8 (44.4%)	0.618
Affected Finger	1 2 3 4 5	6 (46.2%) 1 (25.0%) 4 (50.0%) 4 (57.1%) 4 (80.0%)	7 (53.8%) 3 (75.0%) 4 (50.0%) 3 (42.9%) 1 (20.0%0	0.559
Trigger finger grade	2 3	13 (50.0%) 6 (54.5%)	13 (50.0%) 5 (45.5%)	0.969
VAS		4.00 (1.97)	3.61 (1.29)	0.472
QuickDASH		30.17 (15.12)	30.97 (10.89)	0.855
Functional impact of triggering		5.26 (1.75)	5.39 (1.03)	0.786
Frequency of triggering		6.32 (1.73)	5.50 (1.29)	0.112

Table 1. *Demographic characteristics in the two study groups.*

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data, so parametric tests were used. Accordingly, T-test and Chi-square tests were used to compare baseline values between the two groups. Mixed ANOVA and post-hoc tests were applied to assess the main as well as interaction effect of time and group. Greenhouse-Geisser estimates of sphericity were used to correct degrees of freedom when Mauchly's test was significant. The results of the analyses were interpreted and reported based on the significance level of $p<0.05$.

RESULTS

A total of 38 patients met eligibility criteria and were entered in the study across two groups. One patient in the control group didn't participate in follow-ups and dropped out of the study. Finally, a total of 37 patients who completed the study were analyzed.

Table 1 shows the demographic details and characteristics of the study population for the intervention (shockwave and splint) and control (splint) groups. The two groups do not differ significantly in terms of baseline and demographic characteristics *(Table 1)*.

The time-group interaction effect was not statistically significant in any of the outcome measures including VAS (df = 1.57, F = 1.99, p value = 0.155), Quick DASH (df = 1.30, F = 0.58, p value = 0.558), functional impact of triggering (df = 1.38, F = 0.29, p value = 0.665) and frequency of triggering (df = 1.69, F = 0.07, p value = 0.902) *(Table 2)*.

Otherwise, within-group comparisons indicate significant results *(Table 3)*. In both groups improvement of frequency of triggering, Quick DASH and functional impact of triggering was significant in all time periods (after 6 weeks, after 3 months and between 6 weeks and 3 months). For VAS, a significant improvement was observed only after 6 weeks and 3 months in both groups *(Table 3)*.

Generally, the shockwave protocol was well tolerated by patients, and no serious side effects were reported.

DISCUSSION

According to results of the present randomized clinical trial, both groups showed significant improvement in VAS, Quick DASH index, frequency of triggering, and functional impact of triggering. However, the interaction effect of time and group was not significantly different in any of the outcome measures.

The benefits of orthotic devices in the treatment of trigger fingers have been shown in previous studies. On which joints to include in the splint and the extent of joint placement, however, authors disagree[1,2]. For a maximum of three to six weeks, the suggested splint maintains the metacarpophalangeal (MCP) joint at 0° of extension or 10° to 15° of flexion[20]. Joint immobilization with a splint for 6-10 weeks could reduce pain and triggering symptoms[1,2].

On the other hand, ESWT has been used in the treatment of various musculoskeletal diseases with a success rate ranging from 65% to 91% and minimal side effects[29]. It has been suggested that ESWT through a stimulatory effect enhance cellular regeneration, neovascularization, collagen synthesis and release of growth hormone factor to promote the healings of tendons. An inhibitory effect on nociceptors and hyperstimulation mechanisms are also involved in pain modulation[29].

Recent studies have also demonstrated the potential effect of ESWT in the treatment of trigger fingers.

In the study by Vahdatpour et al. in 2020, 19 patients with trigger finger grade >1 were included in the study and treated with (radial + focused) ESWT in three sessions with one-week intervals. The results of this study showed that shock wave treatment led to improvements in the variables of VAS, severity, functional impact, and Quick DASH immediately after the completion of treatment, 6 weeks, and 18 weeks[35]. Similarly, Dogru et al, demonstrated the positive effect of ESWT in pain and function of 18 patients with grade two trigger finger in a before-after study. The type of shock wave in this study was Radial ESWT, which was applied during 10 sessions twice a week[36]. These two before-after studies demonstrated positive effect of ESWT in the treatment of trigger fingers; however, they didn't have any sham or control group. To our knowledge, only Chen et al.[34], examined the effect of ESWT compared to placebo. They studied the effect of 4 sessions wide-focused ESWT in the treatment of 60 patients with grade 2 trigger fingers. Patients were allocated in three groups: high-energy ESWT, low-energy ESWT, and sham and were evaluated at intervals of 1, 3, and 6 months later. In Chen's study, improvement was seen in all variables except functional impact after 6 months of intervention in all three groups. Although the magnitude of improvement in the high-energy ESWT group was significantly greater than

		Intervention mean (SD)	Control mean (SD)	Mean difference (CI 95%)	p value
VAS	6th weeks 3rd months	2.53 (1.38) 2.42 (1.77)	2.83 (1.20) 2.39 (1.03)	0.30 (-0.56,1.17) -0.03 (-1.00, 0.94)	0.478 0.947
QuickDASH	6th weeks 3rd months	24.76 (14.77) 22.70 (15.63)	26.93 (10.89) 24.28 (9.96)	2.17 (-6.53, 10.87) -1.58 (-7.21, 10.39)	0.616 0.716
Functional impact of triggering	6th weeks 3rd months	3.89 (1.85) 3.37 (2.08)	4.28 (1.36) 3.61 (1.33)	0.38 (-0.70, 1.47) 0.24 (-0.93,1.41)	0.481 0.678
Frequency of triggering	6th weeks 3rd months	5.11 (1.82) 4.05 (1.26)	4.22 (0.94) 3.33 (0.97)	-0.88 (-1.86, 0.09) -0.71(-1.47, 0.03)	0.075 0.062

Table 2. *Between-group comparisons of outcome measures during the study.*

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		Intervention group Mean difference (95%CI)	p value	Control group mean difference (95%CI)	p value
VAS	Baseline vs 6 weeks Baseline vs 3 months 1st vs 2nd follow-up	-1.47 (-2.00, -0.94) -1.57 (-2.33, -0.82) - 0.10 (-0.62, -0.41)	<0.001 <0.001 1.00	-0.77 (-1.32, -0.23) -1.22 (-1.99, -0.44) -0.44 (-0.79, -0.08)	0.001 0.003 0.129
Quick DASH	Baseline vs 6 weeks Baseline vs 3 months 1st vs 2nd follow-up	-5.40 (-7.67, -3.13) -7.47 (-10.30, -4.64) -2.06 (-3.38, -0.75)	<0.001 <0.001 0.001	-4.03 (-6.36, -1.69) -6.68 (-9.59, -3.77) -2.65 (-4.00, -1.30)	<0.001 <0.001 <0.001
Functional impact of triggering	Baseline vs 6 weeks Baseline vs 3 months 1st vs 2nd follow-up	-1.36 (-1.93, -0.79) -1.89 (-2.64, -1.14) -0.52 (-0.92, -0.12)	<0.001 <0.001 <0.001	-1.11 (-1.69, -.52) -1.77 (-2.54, -1.00) -.66 (-1.07, -.25)	<0.001 <0.001 0.001
Frequency of triggering	Baseline vs 6 weeks Baseline vs 3 months 1st vs 2nd follow-up	-1.21 (-1.83, -0.58) -2.26 (-3.15, -1.36) -1.05 (-1.77, -0.33)	<0.001 <0.001 0.002	-1.27 (-1.91, -.63) -2.16 (-3.08, -1.24) -.88 (-1.63, -.14)	<0.001 <0.001 0.014

Table 3. *Within-group comparisons of outcome measures during the study.*

the other two groups, there was no significant difference between the sham and low-energy ESWT groups. Their study demonstrated a dose-related effect of wide-focused ESWT as well as a significant placebo effect of ESWT in the treatment of trigger fingers[34].

In the 2016, Yildirim compared the effect of shock wave with corticosteroid injection in 40 patients with grade 2 trigger finger. In the shock wave group, patients underwent ESWT with 2.5 frequency, 15 bar, and 1000 shocks for three sessions at one-week intervals. In both groups, frequency, VAS, and Quick DASH variables were evaluated at 1, 3, and 6 months after treatment. In the results of this study, significant improvement occurred in pain and symptoms in both treatment groups with no significant difference between the two groups[27].

Two studies comparing the effect of shockwave with US demonstrated conflicting results.

In a study by Wah et al.[37] in 2020, 29 patients with grade 2 and 3 trigger finger were studied in two treatment groups. In one group, 19 patients were treated with US + paraffin bath and exercise, and in the other group, 10 patients were treated with ESWT + ice massage and exercise. The type of shockwave in this study was Radial ESWT, which was performed over 10 sessions, twice a week. Patients in both groups were evaluated for pain and quick DASH at intervals of 1, 2, 3, and 4 weeks after the initial treatment. The results of this study showed that the US group had greater improvement in pain and quick DASH than the shockwave group[37].

In contrast to the Wah study, the results of the Alfaifi study in 2025 showed that both US and shockwave treatment methods led to improved function, range of motion, and pain reduction, although the therapeutic effects of shockwave were longer than those of US. In this study, 24 patients with trigger finger from two groups completed their treatment stages. 13 patients were treated with ESWT and 11 patients were treated with US. The number of treatment sessions for all patients was 10 sessions over a period of 5 weeks, and the patients were evaluated for improvement in variables after 5 and 10 sessions[38].

Although previous studies concluded that shockwave therapy could lead to improvement in pain, frequency, and functional disability, evidence regarding its placebo effect and its superiority over other conservative treatment is lacking. To our knowledge, this is the first study to investigate the effect of adding shockwave therapy to orthosis as a first treatment option. The result of the present study indicated that adding shockwave therapy to splinting did not produce any difference in pain, symptoms and function of patients with trigger finger compared to splinting alone. However, the preliminary results of this study should be interpreted considering the limitations of this study. First, this study examined patients with grade 2 and 3 trigger fingers, while this method might have different results in milder or more severe grades. Moreover, different participants factors that may have influenced the results were not considered in this study. Additionally, a short-term follow-up may not provide adequate time to observe the effect of shock wave therapy which should be addressed in future studies. The combination therapy may be beneficial for some groups of patients. Different variables such as daily activities, symptom severity, and individual patient characteristics should be a consideration in future studies. For better evaluation of this modality, future high-quality studies should examine shockwave therapy compared with a sham control group and other conservative treatments. Comparison of radial versus focused ESWT and different treatment protocols could be another consideration in future studies.

CONCLUSION

According to results, both groups showed significant improvement in pain intensity, functional disability, frequency, and functional impact of triggering. However, the result of this study suggests that the addition of shockwave therapy to the splint did not cause any difference in the VAS, Quick DASH, functional impact, and frequency indices compared to splint treatment alone in short-term follow-up.

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