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Original Article

Analgesic effect and efficacy rate of radial extracorporeal shock wave therapy for plantar fasciitis: a retrospective study

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Abstract. [Purpose] This study aimed to measure the analgesic effects and efficacy of radial extracorporeal shock wave therapy, for which no consensus has been reached regarding optimal treatment parameters. [Participants and Methods] The study included 40 feet of 40 patients with plantar fasciitis. The visual analogue scale was used to determine the immediate and cumulative effects of radial extracorporeal shock wave therapy as well as the efficacy rate. Efficacy was calculated as a percentage visual analogue scale change of ≥20 mm and visual analogue scale improvement of ≥60%. [Results] Immediate and continued efficacy of radial extracorporeal shock wave therapy was observed and recorded. Efficacy rates based on a percentage visual analogue scale change of ≥20 mm and visual analogue scale improvement of ≥60% were both 57.5%. [Conclusion] Radial extracorporeal shock wave therapy has immediate and cumulative analgesic effects on plantar fasciitis. However, cumulative results of interventions with various treatment parameters are required to determine the optimal treatment parameter settings for diffuse pressure wave therapy for plantar fasciitis.

Key words: Radial extracorporeal shock wave therapy, Plantar fasciitis, Analgesic effect

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INTRODUCTION

The plantar fascia is a fibrous connective tissue that extends from the posterior tuberosity of the calcaneus to the basal phalanx of each toe and supports the arch of the foot[1)]. Excessive tensile stress on the plantar fascia membrane causes fibrosis, inflammatory changes, and degenerative changes that subsequently develop into plantar fasciitis[2)]. Plantar fasciitis is the most common cause of heel pain, with a lifetime incidence of approximately 10%[3)], and risk factors include limited dorsiflexion range of motion of the ankle joint, obesity, and prolonged standing[4)]. It has also been reported that plantar fasciitis is easily refractory and reduces quality of life due to persistent pain and limitation of activities[5, 6)]. Factors that contribute to intractability include the formation of poorly oriented collagen fibers, abnormal neovascularization, and hyperplasia of vascular fibroblasts[7)].

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In recent years, extracorporeal shock wave therapy (ESWT) has been used as one of the treatment methods for refractory plantar fasciitis. Two types of ESWT exist: focused extracorporeal shock wave therapy (fESWT) and radial extracorporeal shock wave therapy (rESWT). An fESWT delivers energy to the deep layers of the body, whereas rESWT propagates energy to the superficial layers, making it more effective in the treatment of musculoskeletal disorders[8]. fESWT can only be used by physicians, whereas rESWT can be used by physical therapists under the supervision of a physician; therefore, there are an increasing number of reports in the field of physical therapy regarding the effectiveness of rESWT interventions. There are many reports on the analgesic effects of rESWT, especially in plantar fasciitis cases.

Ibrahim et al.[9] presented the results of one intervention per week for a total of two interventions, in which they used an improvement of ≥60% on the visual analogue scale (VAS) score from base line as the index of efficacy and standardized irradiation intensity of 3.5 bar; they found that the efficacy rate was 92%. Malliaropoulos et al.[10] defined ≥60% improvement from the pre-intervention VAS values as effective and adjusted the irradiation intensity and number of interventions for each participant (mean irradiation intensity was 1.7 bar, mean number of interventions was 6.4 times); they found that with interventions conducted once a week, the efficacy rate was 19% after 4 weeks of intervention, 72% after 12 weeks, and 98% after 48 weeks. Differences in treatment parameters have been cited as a factor for variation in the results reported, and it has been pointed out that in order to set optimal treatment parameters for rESWT for plantar fasciitis, it is necessary to accumulate intervention results for each treatment parameter[10]. Therefore, the purpose of this study was to investigate the analgesic effect and efficacy rate of rESWT in patients with plantar fasciitis who were treated with our institution's treatment protocol, and to clarify its usefulness.

PARTICIPANTS AND METHODS

The study design was retrospective, and we retrieved the results of physical therapy evaluation from the medical records of patients with plantar fasciitis.

From February 2019 to August 2023, 101 patients (117 feet) with plantar fasciitis underwent rESWT at our hospital. For this study, 40 patients (11 men, 13 feet; 29 women, 35 feet; mean age=55.6 ± 12.5 years) who had undergone at least 3 interventions and whose immediate and cumulative effects could be followed, had no missing data, and did not meet the exclusion criteria were included. As for patients who had undergone both foot interventions, the data were extracted from the "first foot in which pain first appeared" for analysis (thus, from 40 patients and 48 feet to 40 patients and 40 feet). Excluded participants were those who had (1) difficulty understanding the purpose of the study due to significant cognitive impairment, (2) evidence of fracture, (3) infection, (4) swelling in the affected area, (5) diagnosis of a neurological disease, (6) history of shock wave therapy or surgery, or (7) Cases in which the cumulative effect of three or more interventions could not be observed.

MASTERPULS®MP100 (STORZ MEDICAL, Tägerwilen, Switzerland) was used for rESWT. Treatment conditions are shown in Table 1. The irradiation conditions were as follows: The intensity was the maximum intensity that the participant could tolerate (average=1.8 bar; range=1.3–3.7), and the frequency was 12 Hz. The intervention was performed according to the procedure described in the MASTERPULS®MP100 manual, using three dedicated attachments in sequence. The treatment sequence was as follows: First, 2,000 rounds of pressure wave irradiation (about 3 minutes) with the special attachment that performs pinpoint pressure wave irradiation, targeting "muscle tendons"; second, 2,000 rounds of irradiation (about 3 minutes) with the special attachment that simultaneously performs pressure wave irradiation and vibration stimulation, targeting "myofascia"; and third (last), consisted of relaxation with a special attachment that only performed vibration stimulation around the irradiated area (irradiation for about 1 minute), and finally, the treatment ended. The whole procedure was conducted for a total of 7 minutes.

The frequency of intervention was once a week for each participant, and for those with bilateral involvement, interventions were conducted on both sides on the same day. Termination of the intervention was determined based on patient requests and discussion and judgment by the attending primary physician and physical therapist. The average number of treatment sessions was 5.7, and the average duration of treatment was 40 days.

Table 1. rESWT conditions for plantar fasciitis

rESWT conditions	Setting
Intensity (bar)	1.8 ± 0.4
Frequency (Hz)	12
Number of impulses (shocks)	4,000
Treatment time (min)	7
Number of treatment sessions	5.7 ± 2.6
Treatment duration (days)	39.5 ± 18.2

Data are presented as mean ± SD.
rESWT: radial extracorporeal shock wave therapy; SD: standard deviation.

A VAS was used to evaluate pain before each rESWT intervention for each participant. The reason for the pre-intervention evaluation was that some of the plantar fasciitis cases were unable to reproduce their symptoms during the intervention (symptoms appeared after prolonged standing or walking), so the timing of VAS evaluation in all cases was standardized to pre-intervention. The VAS evaluates pain intensity by asking patients to plot a straight line from 0 mm for no pain to 100 mm for the strongest and most intolerable pain they have ever experienced, and record the distance (mm) from 0 mm as the pain intensity[11]. The immediate effect (comparison of VAS before the initial intervention and the second intervention), cumulative effect (comparison of VAS before the initial and final interventions), and efficacy rate of rESWT were determined. Efficacy rate was calculated using the amount of VAS change before the initial and final interventions and the improvement rate, with two indices: Minimal clinically important difference (MCID) (i.e. VAS change ≥20 mm)[12] and VAS improvement rate ≥60%. Although some studies have reported the effectiveness of rESWT using MCID as an indicator[13], to the best of our knowledge, no study has investigated efficacy rates using MCID as an indicator. We adopted this indicator because we hypothesized that it could be used as a determinant of the efficacy rate of rESWT. Since many studies have used a VAS improvement rate of ≥60% as an indicator of effectiveness[10, 14], we adopted it as one of the indicators in this study as well. The VAS improvement rate was calculated using the formula (VAS before initial intervention − VAS before final intervention) / VAS before initial intervention ×100.

Statistical analysis was used to examine the immediate and cumulative effects using a corresponding t-test, with a significance level of 5%. Additionally, comparisons were also made between immediate and cumulative effects. The efficacy rates were calculated using two measures: the percentage of subjects with a VAS change of ≥20 mm (i.e., MCID), and those with a VAS improvement of ≥60%. Statistical analysis was undertaken with R commander ver. 4.3.1.

Since this was a retrospective study using past medical records, information about the purpose and conduct of the study was disclosed through opt-out, and the opportunity to refuse was guaranteed whenever possible.

This study was conducted with the approval of the Josai International University Research Ethics Committee for Human Subjects (Approval No. 07F230041).

RESULTS

There was a significant improvement in VAS scores before the second intervention (44.7 ± 23.2 mm) compared to that before the initial intervention (55.2 ± 21.6 mm), indicating that rESWT had an immediate effect ($p<0.05$, effect size r=0.47) (Table 2). Additionally, there was a significant improvement in VAS scores before the final intervention (28.3 ± 22.1 mm) compared to that before the initial intervention (55.2 ± 21.6 mm), indicating that rESWT had a cumulative effect ($p<0.05$, effect size r=0.78) (Table 2). In a comparison of immediate and cumulative effects, the cumulative effect showed a significant improvement in VAS scores ($p<0.05$, effect size r=0.64) (Table 3).

The efficacy rates indexed using MCID and a VAS improvement of ≥60% were 57.5% (23/40 feet) and 57.5% (23/40 feet), respectively (Table 4).

Table 2. Immediate and cumulative analgesic effects of rESWT on plantar fasciitis (comparison using VAS values) (N=40)

	Before[a]	After[b]	Final[c]	Effect size
Immediate effect	55.2 ± 21.6	44.7 ± 23.2**	–	r=0.47
Cumulative effect		–	28.3 ± 22.1**	r=0.78

Unit: mm (mean ± SD).
**p<0.01; [a]: before initial intervention; [b]: before the second intervention; [c]: before final intervention.
rESWT: radial extracorporeal shock wave therapy; SD: standard deviation.
For immediate effects, we compared the value of the VAS score before the first intervention to that before the second intervention; for cumulative effects, we compared the value of the VAS score before the first intervention to that before the last intervention.

Table 3. Comparison of immediate and cumulative effects (N=40)

	Immediate effect	Cumulative effect	Effect size
VAS change	11.1 ± 20.0	25.6 ± 21.5**	r=0.64

Unit: mm (mean ± SD).
**p<0.01.
VAS: visual analogue scale; SD: standard deviation.
Difference in VAS values before the first and second intervention compared to the difference in VAS values before the first and last intervention.

Table 4. Efficacy rate of single rESWT intervention for plantar fasciitis estimated by two indices (N=40)

Index	Efficacy rate (%)
MCID[a]	57.5
VAS improvement rate[b]	57.5

[a]: MCID is the amount of VAS change ≥20 mm; [b]: VAS improvement rate ≥60%.
rESWT: radial extracorporeal shock wave therapy; MCID: minimal clinically important difference; VAS: visual analogue scale.

DISCUSSION

This study examined the immediate and cumulative analgesic effects and efficacy rates of rESWT for plantar fasciitis when the number of interventions was determined based on patient requests and the discussion and judgment by the attending primary physician and physical therapist, and irradiation intensity was set to the maximum range acceptable to the patient. The results showed that rESWT had both immediate and cumulative analgesic effects. The mechanisms by which rESWT produces analgesic effects reportedly includes the destruction of free nerve endings in the periphery[15, 16] and suppression of pain transmitters[17] for immediate effects, and the suppression of inflammatory cytokine synthesis[18] and promotion of angiogenesis and tissue repair[19] for cumulative effects. It has also been inferred that the regeneration of destroyed nerve endings can be delayed by multiple irradiations rather than a single irradiation[20], and this is another factor that contributes to the cumulative analgesic effect of rESWT. Our study results suggest that the combined effects of these analgesic mechanisms of rESWT resulted in both immediate and cumulative analgesic effects in our rESWT protocol.

Although the analgesic mechanism of rESWT is gradually becoming clear, the appropriate treatment parameters for each disease, including plantar fasciitis, are still unclear.

The results of the treatment protocol used in this study showed a 57.5% efficacy rate as measured using MCID and 57.5% efficacy rate as measured based on VAS improvement. The efficacy rate for short-term intervention reported by Ibrahim et al.[9] was 92%, a clear difference from the efficacy rate reported in this study. This difference in results may be explained by the difference in irradiation intensity. The irradiation intensity utilized in this study averaged 1.8 bar, whereas the intensity utilized by Ibrahim et al. averaged 3.5 bar. A study by Schimitz et al.[14] reported superior analgesia with 3.5 bar irradiation compared to 2.5 bar. These findings suggest that higher intensity of rESWT irradiation for plantar fasciitis may increase the analgesic effect. However, the stronger the irradiation intensity, the greater the burden on the patient. In a study by Malliaropoulos et al.[10], irradiation intensity and number of interventions were adjusted for each participant as in the present study, and the efficacy rate was low (19%) in the short term, but it increased as the number of interventions increased, from 72% after 12 weeks of intervention to 98% after 48 weeks. Although it has been pointed out that analgesic effects are more likely to be obtained when the number of interventions is increased[13], the results of previous studies suggest that high analgesic effects may be obtained with cumulative treatment even in the present study, which was a low-intensity intervention. On the other hand, some reports have indicated that irradiation intensity is not related to intervention results[21], suggesting that further study is needed regarding the setting of appropriate rESWT parameters.

The limitations of this study include the lack of standardization of patients' age, sex, and duration of disease, as well as absence of basic information such as body mass index, occupation, and sports history. It is possible that these personal factors influenced the results. In addition, the conditions of intervention in this study could not be standardized, and the intensity and number of interventions varied among patients. The varying conditions of intervention among patients may have influenced the results. Also, this study did not allow for comparisons with control groups, such as comparisons with the non-rESWT group or comparisons between a single intervention group and multiple intervention groups. In the future, we would like to examine factors that influence the analgesic effect of rESWT, with the objective of creating an optimal treatment protocol for rESWT for plantar fasciitis. Further, we intend to verify the effectiveness of rESWT by comparing it with the non-rESWT group and by setting conditions in which the number of interventions will be standardized.

Conference presentation

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Conflicts of interest

There is no conflict of interest.

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