Comparative Effectiveness of Focused Shock Wave Therapy of Different Intensity Levels and Radial Shock Wave Therapy for Treating Plantar Fasciitis: A Systematic Review and Network Meta-Analysis

Ke-Yin Chang, MD, Ssu-Yuan Chen, MD, PhD, Wen-Shiang Chen, MD, PhD, Yu-Kang Tu, PhD, Kuo-Liong Chien, MD, PhD

ABSTRACT. Chang KV, Chen SY, Chen WS, Tu YK, Chien KL. Comparative effectiveness of focused shock wave therapy of different intensity levels and radial shock wave therapy for treating plantar fasciitis: a systematic review and network meta-analysis. Arch Phys Med Rehabil 2012;93:1259-68.

Objectives: To compare the effectiveness of focused shock wave (FSW) therapy of different intensity levels and a new alternative, radial shock wave (RSW) therapy, for managing plantar fasciitis.

Data Sources: Electronic databases including MEDLINE and PsycMed were searched from January 1996 to June 2011.

Study Selection: Randomized controlled trials comparing shock wave and placebo therapy were included. Two reviewers independently scrutinized eligible articles, and disagreement was resolved by discussion. Literature searching identified 93 nonduplicate citations, of which 12 trials comprising 1431 participants were included.

Data Extraction: Information, such as patient characteristics, shock wave intensity, and outcome measures, was extracted by 1 reviewer and checked by another. Both reviewers assessed the trials’ quality by using the Jadad scale.

Data Synthesis: FSW therapy of different intensity ranges was treated as 3 subgroups, whereas studies using RSW therapy were regarded as a separate group. The success rates of treatment and pain reduction magnitudes were used as the outcomes. The traditional meta-analysis showed that medium and high-intensity FSW therapy had reliably higher success rates and pain reduction than the placebo, while the effectiveness of low-intensity FSW therapy and RSW therapy appeared less convincing because of very large confidence intervals. After employing network meta-analysis, the probability of being the best therapy was the highest in RSW therapy, followed by low-, medium-, or high-intensity FSW therapy. The meta-regression indicated that the success rate of FSW therapy was not related to its intensity, whereas elevated energy efflux densities tended to relieve pain more.

Conclusions: Setting the highest and mostly tolerable energy output within medium intensity ranges is the ideal option when applying FSW therapy on plantar fasciitis. RSW therapy is considered an appropriate alternative because of its lower price and probably better effectiveness.

Key Words: Fasciitis, plantar; Meta-analysis [publication type]; Rehabilitation.

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PLANTAR FASCIITIS, a common foot disorder, is manifested as pain originating from the insertion of plantar fascia near the medial tubercle of the calcaneus, and is the worst at the first step in the morning. Women, obese people, and athletes participating in frequent running activities have a higher risk of developing plantar fasciitis. The pathophysiology of plantar fasciitis remains unclear and is probably related to overuse or poor foot biomechanics, such as pes planus or intrinsic muscle weakness. Several methods are known to relieve plantar heel pain, including special footwear, night splinting, stretching exercises, and local corticosteroid injections. Approximately 10% of the patients have an unsatisfactory response to conservative therapy and are traditionally referred for surgical release for plantar fascia. However, risks of overrelease and injury to adjacent nerves leave surgical intervention as a last resort. Therefore, extracorporeal shock wave therapy, which was originally applied on breaking renal calculi, has been introduced in treating recalcitrant plantar fasciitis since the mid-1990s.

Shock wave modalities can generate rapidly rising acoustic waves with high-peak pressure amplitudes, and the majority of energy flux is concentrated on a small focus. Its biological mechanisms for treating plantar fasciitis comprise destroying sensory unmyelinated nerve fibers and eliciting neovascularization in degenerative tissues. Its effectiveness is influenced by the applicator position, use of local anesthetics, and most importantly, its corresponding intensity levels, defined as energy flow through an area with perpendicular orientation to the

List of Abbreviations

<table>
<thead>
<tr>
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<tr>
<td>CrI</td>
<td>credibility interval</td>
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<tr>
<td>FSW</td>
<td>focused shock wave</td>
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<tr>
<td>OR</td>
<td>odds ratio</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>RSW</td>
<td>radial shock wave</td>
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<tr>
<td>VAS</td>
<td>visual analog scale</td>
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</table>

Arch Phys Med Rehabil Vol 93, July 2012
wave propagation. Some authors favor adjusting the shock wave intensity to the maximum level of tolerance with the hopes of further pain relief. However, with the increase of energy flux density, the magnitude of pain may be elevated for a short period of time owing to local swelling and tenderness derived from shock wave application. Additionally, higher intensity treatment usually requires local analgesia, which is known to reduce its effectiveness. Therefore, the most effective intensity range is of clinical importance, but current literature reviews fail to provide quantitative analysis concerning this issue.

Radial shock wave (RSW) therapy, compared with conventional focused shock wave (FSW) therapy, does not have a focus at the site of the effect. The waves disperse eccentrically from the applicator tip without concentrating the shock wave field in the tissue. Its application on calcific rotator cuff tendinopathy has shown significant pain alleviation and improvement of shoulder function. Regarding the advantage of wider effective regions without the requirement of precisely locating the painful points, several studies have been conducted to test its utility in treating plantar fasciitis. However, whether RSW therapy is superior to FSW therapy in relieving plantar heel pain remains uncertain, and this issue may be explored by network meta-analysis, a method used to determine the comparative effectiveness of treatments that have not been compared directly in a randomized trial. It is an extension of traditional meta-analysis but allows comparisons for more than 2 alternative therapies by integrating direct and indirect evidence. This methodology contributes tremendously to cost-effective studies and offers useful information to medical decision makers. Hence, the purpose of this study was to undertake a network meta-analysis to determine the effectiveness of FSW therapy of different intensity levels and to compare with a new alternative, RSW therapy for managing plantar heel pain.

METHODS

Study Selection
We conducted a systemic literature search without language restriction for all relevant articles through 2 online databases, MEDLINE and PubMed, from January 1996 to June 2011. MEDLINE is available in approximately every medical library and can cover nearly all published citations regarding our study topic. PubMed is a free database mainly derived from MEDLINE but also comprises other life science journals and online books. We employed PubMed to confirm that all relevant trials were retrieved. Furthermore, using PubMed is also beneficial for readers who cannot access MEDLINE. The search strategy combined the Medical Subject Headings and keywords shock wave with terms related to plantar fasciitis (plantar fascia, plantar fasciitis, and heel pain). Cochrane Collaboration Central Register of Controlled Clinical Trials, Cochrane Systematic Reviews, ClinicalTrials.gov, and bibliographies of included trials and related meta-analyses were manually searched for additional references.

The inclusion criteria for the trials included: (1) randomized controlled trials, (2) comparison between shock wave and placebo therapy, (3) adult participants without restriction to specific populations, (4) patients complaining of heel pain near the proximal plantar fascia on the medial calcaneal tuberosity, and (5) symptoms that lasted for more than 3 months. For the purpose of our meta-analysis, studies that lacked reporting of success treatment rates were not enrolled.

Trials were excluded if they (1) were deficient of a fixed range of treatment intensity in the intervention group, (2) compared different methods of shock wave application within the same range of energy output, or (3) consisted of patients suffering from fracture or surgery on the involved heels. Because many conservative treatments, such as physical therapy, steroid injection, or splint wearing, might provide certain degrees of pain relief in patients with plantar fasciitis, only studies using sham therapy as controls were included in our meta-analysis.

The treatment intensity of FSW therapy was divided into 3 levels including: (1) low intensity (energy flux density \( \leq 0.8 \text{mJ/mm}^2 \)), (2) medium intensity (energy flux density \( 0.8-2.8 \text{mJ/mm}^2 \)), and (3) high intensity (energy flux density \( \geq 2.8 \text{mJ/mm}^2 \)), whereas studies employing RSW therapy were regarded as another group for meta-analysis. The success rates of intervention and the mean difference in visual analog scales (VASs) between baseline and after therapy were regarded as the primary and second outcomes. When variances for net changes of VASs were not reported directly, we estimated them from variances at baseline and at the end of follow-up. Because the follow-up duration varied between each study, we chose the outcome reported at 6 months or at the follow-up closest to 6 months for analysis.

Data Extraction and Quality Assessment
Two authors (K.Y.C. and S.Y.C.) independently evaluated all potential articles on eligibility for inclusion and extracted data, such as patient characteristics, information of shock wave therapy, and details of outcome measures. The Jadad scale was used for validity assessment, comprising randomization, double-blinding, and patient withdrawals. The aggregate scores range between 0 and 5 points. Trials with scores less than 3 were considered to have lower methodologic quality and were not selected for further meta-analysis. If disagreement existed between 2 reviewers, it was resolved by discussion and consensus.

Data Synthesis and Analysis
Pair-wise comparisons of low-intensity FSW therapy versus placebo, medium-intensity FSW therapy versus placebo, high-intensity FSW therapy versus placebo, and RSW therapy versus placebo were analyzed by traditional meta-analysis using Stata 10.0. The random effect model was used to calculate the pooled odds ratios (ORs) or the mean difference in VASs on the existence of heterogeneity, whereas the fixed-effect model was applied if the heterogeneity was not present. The OR indicates the odds of success in treatment rates in the targeted group divided by that in the control or other intervention groups. A value of greater than 1 represents favorable outcomes in the targeted group. The heterogeneity was determined by I-squared and Cochran’s Q test. The relationship between the intensity levels of FSW therapy and the success rates after treatment or reduction in pain scales was further explored by meta-regression. The network meta-analysis was conducted by using a Bayesian Markov chain Monte Carlo method and fitted in WinBUGS 1.4.3. Three different sets of starting values with 50,000 burn-ins and a further 50,000 iterations for each chain were employed to obtain the posterior distributions of model parameters. Convergence of iterations was evaluated using the Gelman-Rubin-Brooks statistic. The mixed-treatment comparisons were applied to investigate the ORs for success treatment and the reduction of VAS by means of a random effect model. The analysis provided evidence of treatment effectiveness from direct and indirect comparisons among FSW therapy of different intensity ranges, RSW therapy, and placebo therapy.
SHOCK WAVE THERAPY FOR PLANTAR FASCIITIS, Chang

Results

Study Characteristics

Of the 93 nonduplicate citations identified from the literature research, 25 randomized controlled trials (RCTs) were screened for eligibility. Assessment of the full text articles revealed that 4 compared shock wave therapy with treatments rather than sham designs.22-25 Three investigated different methods of shock wave application within the same energy range,7,8,26-28 and 1 did not report the success rate of treatments.14 In addition, 2 articles had less than 3 points in the Jadad scale, owing to a lack of double-blind designs (fig 1).29,30 Therefore, after excluding the above mentioned trials, a total of 12 RCTs (1431 participants; age range, 25–87y; body mass index range, 20–39kg/m²; pain duration range, 6–312mo, trial duration range, 3–60wk; and baseline VAS range, 3.0–8.9) met our inclusion criteria and were enrolled into meta-analysis. Of the included studies, 2 compared low-intensity FSW therapy with a placebo,21,32 5 compared medium-intensity FSW therapy with a placebo,17,33-36 2 compared high-intensity FSW therapy with a placebo,37,38 1 compared high-intensity FSW therapy with medium-intensity FSW therapy,39 and 2 compared RSW therapy with a placebo.12,33 In traditional pair-wise meta-analysis, medium- and high-intensity FSW therapy were associated with a significant pooled reduction in VAS compared with the placebo (OR = 1.56, 95% CrI, 1.07–1.91, respectively). Significant heterogeneity was observed in the groups comparing low-intensity FSW therapy or RSW therapy with the placebo. Low-intensity FSW therapy and RSW therapy had higher pooled ORs (OR = 2.36, 95% CrI, .50–11.14 and OR = 2.72, 95% CrI, .74–10.07, respectively) than medium- and high-intensity FSW therapy, but their 95% CrI both cover the value of 1 by employing a random effect model (appendix 1, fig 3).

For network meta-analysis with Bayesian mixed-treatment comparisons, the ORs and corresponding 95% CIs were higher than the data performed by traditional pair-wise meta-analysis. RSW therapy had the highest effectiveness versus the placebo (OR = 38.26, 95% CrI, 2.13–202.4), followed by low-, high-, and medium-intensity FSW therapy (OR = 6.15, 95% CrI, 4.7–27.87; OR = 2.87, 95% CrI, .36–10.07; OR = 2.51, 95% CrI, .59–7.15, respectively) (table 3). Nevertheless, only the 95% CrI of the ORs regarding RSW therapy versus the placebo did not cross the value of 1. The probabilities of being ranked as the best treatment for RSW therapy, and low-, medium-, and high-intensity FSW therapy were 82.7%, 12.3%, 1.7%, and 3.1%, respectively.

Reduction in Pain Scales

Only 9 studies provided adequate information to estimate the reduction in the VAS and its standard error. Of the included trials, 2 compared low-intensity FSW therapy with a placebo,13,32 2 compared medium-intensity FSW therapy with a placebo,13,36 2 compared high-intensity FSW therapy with a placebo,7,38 1 compared high-intensity FSW therapy with medium-intensity FSW therapy,39 and 2 compared RSW therapy with a placebo.12,13 In traditional pair-wise meta-analysis, medium- and high-intensity FSW therapy were associated with a significant pooled reduction in VAS compared with the placebo (−1.21, 95% CrI, −1.76 to −0.67 and −3.3, 95% CrI, −3.58 to −0.8, respectively) by using a fixed effect model. There was significant heterogeneity across studies comparing RSW therapy or low-intensity FSW therapy versus a placebo (P = .000 and I² = 98.7%, P = .000, respectively). By employing a random effect model, RSW therapy and low-intensity FSW therapy tended to surpass the placebo in pain reduction (−10.32, 95% CrI, −30.17 to 9.83 and −1.59, 95% CrI, −4.33 to 1.15, respectively), but a huge 95% CrI that crossed the value of 0 was observed in both groups (see appendix 1, fig 4).

For network meta-analysis, RSW therapy had the most significant pooled reduction in the VAS, followed by low-, medium-, high-intensity FSW therapy and placebo treatment (−6.08, 95% CrI, −8.29 to −3.41; −2.37, 95% CrI, −5.44 to 0.81; −2.18, 95% CrI, −6.15 to 1.86; −1.14, 95% CrI, −5.44 to 3.24; and −0.6, 95% CrI, −3.57 to 3.30, respectively) (see appendix 1). However, only the 95% CrI of RSW therapy in pain reduction did not cover the value of zero. The probabilities of being the best therapy to relieve pain were 91.0%, 2.8%, 4.2%, and 1.8% regarding RSW therapy, and low-, medium-, and high-intensity FSW therapy, respectively.

Relationship Between the Intensity Levels of FSW Therapy and Clinical Success Rates or Magnitudes of Pain Reduction

All the 9 studies comparing FSW therapy with a placebo were included for meta-regression to explore the relationship...
Table 1: Summary of Follow-Up Duration, Methods for Placebo Treatment, Study Numbers, Success Rates, and Definition of Successful Treatment for the Included Trials

<table>
<thead>
<tr>
<th>Source (author)</th>
<th>Total Follow-Up Duration (mo)</th>
<th>Time Point Reporting Success Rates (mo)</th>
<th>Methods for Placebo Treatment</th>
<th>Group</th>
<th>Number (person or heels*)</th>
<th>Success Rates</th>
<th>Definition of Successful Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-intensity FSW therapy vs placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rompe et al</td>
<td>60</td>
<td>6</td>
<td>Minimal pulses (30 pulses per treatment)</td>
<td>FSW</td>
<td>49</td>
<td>28/49</td>
<td>Better than the good level in the Roles and Maudsley scores</td>
</tr>
<tr>
<td>Haake et al</td>
<td>12</td>
<td>3</td>
<td>Polyethylene foil</td>
<td>FSW</td>
<td>127</td>
<td>43/127</td>
<td>The Roles and Maudsley scores of 1 or 2</td>
</tr>
<tr>
<td>Medium-intensity FSW therapy vs placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speed et al</td>
<td>6</td>
<td>3</td>
<td>Minimal energy pulses (.04mJ/mm²)</td>
<td>FSW</td>
<td>46</td>
<td>19/46</td>
<td>50% improvement of morning pain from baseline</td>
</tr>
<tr>
<td>Rompe et al</td>
<td>12</td>
<td>6</td>
<td>Sound reflecting pad</td>
<td>Placebo</td>
<td>42</td>
<td>15/42</td>
<td>50% reduction in morning pain</td>
</tr>
<tr>
<td>Ogden et al</td>
<td>12</td>
<td>3</td>
<td>Styrofoam block</td>
<td>Placebo</td>
<td>144</td>
<td>67/144</td>
<td>&gt;50% improvement in morning pain; no pain during walking; no medication for heel pain</td>
</tr>
<tr>
<td>Gollwitzer et al</td>
<td>3</td>
<td>3</td>
<td>Polyethylene foil</td>
<td>FSW</td>
<td>20</td>
<td>11/20</td>
<td>&gt;60% decrease of VAS</td>
</tr>
<tr>
<td>Marks et al</td>
<td>6</td>
<td>6</td>
<td>Zero energy pulse</td>
<td>Placebo</td>
<td>16</td>
<td>9/16</td>
<td>&gt;50% decrease of VAS</td>
</tr>
<tr>
<td>High-intensity FSW therapy vs placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Theodore et al</td>
<td>12</td>
<td>3</td>
<td>Air cushion</td>
<td>FSW</td>
<td>76</td>
<td>41/76</td>
<td>&gt;60% improvement in pain</td>
</tr>
<tr>
<td>Kudo et al</td>
<td>3</td>
<td>3</td>
<td>Foam cushion</td>
<td>Placebo</td>
<td>53</td>
<td>25/53</td>
<td>&gt;60% improvement in pain during initial walking</td>
</tr>
<tr>
<td>High-intensity FSW therapy vs medium-intensity FSW therapy</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Liang et al</td>
<td>6</td>
<td>6</td>
<td>NA</td>
<td>FSW (high intensity)</td>
<td>43*</td>
<td>25/43</td>
<td>Cured or great improvement on the 6-point Likert scale</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FSW (medium intensity)</td>
<td>34*</td>
<td>21/34</td>
<td>VAS score less than 1 cm</td>
</tr>
<tr>
<td>RSW therapy vs placebo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gerdesmeyer et al</td>
<td>12</td>
<td>3</td>
<td>Placebo hand piece</td>
<td>RSW</td>
<td>125</td>
<td>77/125</td>
<td>&gt;60% improvement in pain for at least 2 of the 3 pain measurements</td>
</tr>
<tr>
<td>Ibrahim et al</td>
<td>6</td>
<td>6</td>
<td>Heel clasp</td>
<td>Placebo</td>
<td>118</td>
<td>49/118</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RSW</td>
<td>25</td>
<td>25/25</td>
<td>&gt;60% improvement in pain from baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td>25</td>
<td>4/25</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: NA, not applicable.
*Indicates the numbers of heels.
Table 2: Summary of Shock Wave Intensity, Treatment Doses, Characteristics of Pain for Outcome Analysis, Use of Local Anesthesia, VAS at Baseline, After Intervention, and the Corresponding Difference for Each Trial

<table>
<thead>
<tr>
<th>Source</th>
<th>SW Intensity (mJ/mm²)</th>
<th>Treatment Dose</th>
<th>Group</th>
<th>Characteristics of Pain for Analysis</th>
<th>VAS at Baseline (cm)</th>
<th>VAS After Intervention</th>
<th>Difference in VAS</th>
<th>Use of Local Anesthesia</th>
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</thead>
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<td>Low-intensity FSW</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rompe et al³¹</td>
<td>0.08</td>
<td>Total 3000 pulses</td>
<td>FSW</td>
<td>Night pain</td>
<td>3.1 (0.8)</td>
<td>0.6 (1)</td>
<td>−2.5 (0.9)</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>3.0 (1.0)</td>
<td>3.2 (0.9)</td>
<td>0.2 (0.9)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.08</td>
<td>4000 pulses × 3 sections</td>
<td>FSW</td>
<td>Morning pain when taking first steps</td>
<td>7.8 (2.4)</td>
<td>4.0 (3.2)</td>
<td>−3.8 (2.8)</td>
<td>+</td>
</tr>
<tr>
<td>Haake et al³²</td>
<td>0.08</td>
<td></td>
<td>Placebo</td>
<td></td>
<td>7.7 (2.3)</td>
<td>4.5 (3.4)</td>
<td>−3.2 (3.0)</td>
<td></td>
</tr>
<tr>
<td>Medium-intensity FSW</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speed et al³³</td>
<td>0.12</td>
<td>1500 pulses × 3 sections</td>
<td>FSW</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.16</td>
<td>2100 pulses × 3 sections</td>
<td>FSW</td>
<td>Morning pain when taking first steps</td>
<td>6.0 (1.3)</td>
<td>2.1 (2.0)</td>
<td>−3.9 (1.7)</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>7.0 (1.3)</td>
<td>4.7 (1.9)</td>
<td>−2.3 (1.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.22</td>
<td>1500 pulses (total 324.25J)</td>
<td>FSW</td>
<td>Morning pain when taking first steps</td>
<td>8.08</td>
<td>3.43</td>
<td>−4.65</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>8.14</td>
<td>4.28</td>
<td>−3.86</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.25</td>
<td>Total 1.5mJ/mm²</td>
<td>FSW</td>
<td>Morning pain when taking first steps</td>
<td>7.5 (1.5)</td>
<td>NA</td>
<td>NA</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>7.1 (1.7)</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.16</td>
<td>Total 4500 pulses</td>
<td>FSW</td>
<td>Pain before each treatment</td>
<td>5.22 (1.29)</td>
<td>NA</td>
<td>−2.825 (2.606)</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>4.57 (3.28)</td>
<td>NA</td>
<td>−0.178 (4.442)</td>
<td></td>
</tr>
<tr>
<td>High-intensity FSW</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Theodore et al³⁷</td>
<td>0.36</td>
<td>Total 1300mJ/mm²</td>
<td>FSW</td>
<td>Morning pain when taking first steps</td>
<td>7.7 (1.4)</td>
<td>3.4 (2.7)</td>
<td>−4.3 (2.3)</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>7.7 (1.5)</td>
<td>4.1 (3.1)</td>
<td>−3.6 (2.6)</td>
<td></td>
</tr>
<tr>
<td>Kudo et al³⁸</td>
<td>0.64</td>
<td>Total 3800 pulses (2330mJ/mm²)</td>
<td>FSW</td>
<td>Pain during initial walking</td>
<td>7.5 (1.5)</td>
<td>3.9 (3.2)</td>
<td>−3.6 (2.7)</td>
<td>+</td>
</tr>
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<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>7.9 (1.5)</td>
<td>5.3 (2.7)</td>
<td>−2.6 (2.3)</td>
<td></td>
</tr>
<tr>
<td>High-intensity FSW</td>
<td></td>
<td></td>
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<tr>
<td>vs medium-intensity FSW</td>
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<tr>
<td>Liang et al³⁹</td>
<td>0.56</td>
<td>2000 pulses × 3 sections</td>
<td>FSW (high intensity)</td>
<td>Averaged pain severity in the past</td>
<td>5.0 (2.2)</td>
<td>2.7 (2.5)</td>
<td>−2.3 (2.4)</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>0.12</td>
<td></td>
<td>FSW (medium intensity)</td>
<td>1wk</td>
<td>5.7 (2.6)</td>
<td>3.0 (2.5)</td>
<td>−2.7 (2.5)</td>
<td>−</td>
</tr>
<tr>
<td>RSW therapy versus</td>
<td></td>
<td></td>
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<tr>
<td>placebo</td>
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<td></td>
</tr>
<tr>
<td>Gerdesmeyer et al¹²</td>
<td>0.16</td>
<td>2000 pulses × 3 sections</td>
<td>RSW</td>
<td>Morning pain when taking first steps</td>
<td>7.5 (1.49)</td>
<td>NA</td>
<td>−4.2 (2.9)</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>7.5 (1.57)</td>
<td>NA</td>
<td>−3.3 (3.1)</td>
<td></td>
</tr>
<tr>
<td>Ibrahim et al¹³</td>
<td>0.17</td>
<td>2000 pulses × 2 sections</td>
<td>RSW</td>
<td>Current level of heel pain</td>
<td>8.5 (0.3)</td>
<td>0.5 (0.1)</td>
<td>−8.0 (0.2)</td>
<td>−</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Placebo</td>
<td></td>
<td>8.9 (0.2)</td>
<td>7.4 (0.5)</td>
<td>−1.5 (0.4)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: NA, not applicable; SW, shock wave; −, no anesthesia; +, anesthesia.
between the intensity levels of FSW therapy and clinical success rates. The intensity of FSW range between .08 and .64mJ/mm², and the corresponding regression coefficient was .06 (95% CrI, −1.96 to 2.10, \(P = .94\)), meaning that every 0.1mJ/mm² increase in therapeutic intensity accounted only for a .006 increase in log OR of success rates. Regarding the relationship between the intensity level and the reduction in pain scales, only 6 studies offering the changes in VAS were enrolled. The regression coefficient was −2.73 (95% CrI, −15.42 to 9.95, \(P = .582\)), indicating that every 0.1mJ/mm² increase in therapeutic intensity might be associated with a .273 decrease in VAS (fig 5).

**DISCUSSION**

In the present study, traditional pair-wise meta-analysis showed that medium- and high-intensity FSW therapy had reliably higher success rates of treatments and magnitudes of pain reduction against plantar fasciitis than sham therapy. Low-intensity FSW therapy and RSW therapy might be more effective than the placebo groups, but the limited numbers of studies included and the heterogeneity across trials resulted in a wider range regarding both outcome parameters. After applying the network meta-analytic methods, we were able to rank each kind of therapeutic approach. The probability of having the best treatment success or greatest pain relief was the highest in RSW therapy, followed by low-, medium-, or higher-intensity FSW therapy. The meta-regression for FSW therapy of different energy levels indicated that the success rate of treatment was not related to its intensity, while elevated energy efflux density might have a slight tendency to reduce pain scores more.

Previous reviews that investigated the usefulness of FSW therapy led to inconclusive results. In 2002, Ogden et al enrolled 8 clinical trials that consisted of 840 patients in total, and each fulfilled the self-designed quality criteria with follow-up duration of more than 1 year. They employed a vote counting method for a quantitative data synthesis and claimed...
that the success rate ranged from 34% to 88%. Nevertheless, the quality assessment of the included studies appeared inadequate, most of which were not randomized controlled and double-blinded. In 2005, Thomson et al. conducted a systematic review involving 1290 patients from 11 RCTs, 6 of which provided sufficient data for meta-analysis. The pooled analysis of data comprising 897 participants revealed a weight mean difference of .42 cm in the VAS compared with the placebo at around 12 weeks after initiation of FSW therapy. Because .42 cm reduction in pain scales was not considered clinically significant, the authors did not advocate the use of FSW therapy in clinical practice. However, the unfavorable outcome might be derived from lack of adequate grouping. Therefore, in 2007, Rompe et al. performed another systematic review comprising 17 trials with more than 2100 subjects registered, and summarized the results according to FSW therapy of different intensity levels. They did not proceed with a pooled meta-analysis in terms of heterogeneity existing across studies. Although their reviews pointed out that FSW therapy with various outflow density possibly resulted in dissimilar pain reduction, whether FSW therapy with higher intensity had better effectiveness remained undetermined.

Medium-intensity FSW therapy contributed to the majority of studies used for meta-analysis in the present review. The traditional pair-wise comparisons for their success rates of treatment indicated minimal heterogeneity of results between...
For treating plantar fasciitis, FSW therapy should not be inferior to the placebo, but physicians may hesitate to use it as the first priority against plantar fasciitis because of the large uncertainty.

The results of meta-regression demonstrated that the energy efflux densities of FSW therapy might be related to the magnitude of pain reduction but less relevant to clinical success rates. Previous literature indicated higher energy treatment destroyed more unmyelinated sensory nerve fibers and might contribute to long-term analgesia. Chow and Cheing found that directing FSW therapy with a maximum tolerable energy density is better than with a fixed energy density in terms of pain relief. Nevertheless, Liang et al suggested that high- and medium-intensity treatments exhibited nearly the same improvement in pain. According to our meta-regression, every 0.1mJ/mm² increase in therapeutic intensity was associated with a .273 decrease in the VAS. We favor the tendency that elevated energy density of FSW therapy can relieve pain more, although the phenomenon may be clinically insignificant because of slight difference in pain scales. As a result, we suggest treating plantar fasciitis with medium-intensity FSW therapy, because it has the highest energy output without the requirement of local anesthesia.

RSW therapy, a relatively new modality to FSW therapy, demonstrated a tendency to be the best therapeutic option in both traditional and network meta-analysis. Its potential advantage over FSW therapy comprises a broader treatment area, has less requirement of precise focusing, and is free of adjunct local anesthesia. Lohrer et al compared RSW therapy with medium-intensity FSW therapy by using functional measures, indicating that both shock wave modes had nearly equal efficacy for plantar fasciitis. Rompe et al found that the plantar fascia specific stretching method was superior to RSW therapy, but they recruited patients with acute plantar fasciopathy rather than recalcitrant plantar fasciitis. Therefore, different selection criteria of participants might contribute to the unsatisfying outcome of RSW therapy in this study. According to our quantitative analysis, the major concern of employing RSW therapy as the first priority is the uncertainty derived from a wide 95% CrI of pooled ORs and VAS difference. Given that the Ibrahim study had far better success rates of treatment than the Gerdesmeyer et al study, we conclude that the phenomenon came from heterogeneity between the 2 trials manifested in the high discrepancy in participant numbers and clinical outcomes. However, even treating the Ibrahim study as an outlier, the Gerdesmeyer study still demonstrated favorable outcomes of intervention compared with the control group. Concerning the economical superiority of RSW therapy to FSW therapy, it is worth conducting another RCT to further prove its effectiveness against plantar fasciitis.

Our meta-analysis offered 2 clinical implications. First, because the potential dose-responsive relationship exists between the magnitude of pain reduction and intensity levels of FSW therapy, the treatment modality should provide sufficient energy efflux densities. Because high-intensity FSW therapy requires adjuvant local anesthesia, which may be detrimental to final outcomes, we suggest that investigators who wish to apply FSW therapy on plantar fasciitis should choose medium-intensity FSW therapy with the highest level of energy output. For example, .25mJ/mm² is considered appropriate, and most patients can tolerate it without prior anesthesia. Second, for the physicians who attempt to purchase a shock wave machine for treating plantar fasciitis, RSW therapy is a good alternative choice because of its lower price and possible equal or better effectiveness than traditional FSW therapy.

Fig 5. The relationships between energy efflux densities of FSW therapy and (A) natural logarithm of ORs of clinical success rates and (B) reduction in VASs after intervention.
Study Limitations

In the present meta-analysis, 3 limitations need to be listed. In terms of using success rates of treatment as the primary outcome measure, we acknowledged that employing some functional assessment scales was more clinically useful than reporting success rates of pain reduction. However, only a few studies adopted changes in daily function for outcome measurement. In order to perform a quantitative analysis from the diverse data, the practical way was using self-defined clinical success rates. Regarding the criteria of clinical success rates of treatment, it is not identical among all the studies enrolled. Most investigators used pain relief as more than 50% or 60% compared with baseline, while some defined success as significant improvement in foot functional scores. The difference of definition probably increased the heterogeneity, and thus we chose reduction in VAS as another measurement to prove our definition probably increased the heterogeneity, and thus we chose reduction in VAS as another measurement to prove our observations in pooled ORs. There was no contradiction between these 2 outcome parameters. Another limitation is the discrepancy of the values obtained between traditional and network meta-analysis. Because significant heterogeneity exists within certain subgroups, the uncertainty will be magnified while integrating them for mixed-treatment comparisons, which is evident by enlarged 95% CrIs. Fortunately, the corresponding outcome of each subgroup seems to follow the same orders in both kinds of meta-analysis, which makes our results more convincing.

CONCLUSIONS

The present meta-analysis provides quantitative evidence to support the use of shock wave therapy for plantar fasciitis. The success rates of treatment were not related to energy levels, while the magnitudes of pain reduction might disclose a slight dose-response relationship. Therefore, for investigators who already own an FSW modality, setting the highest and mostly tolerable energy efflux densities without anesthesia in the range of medium intensity is the preferable option. However, for those who attempt to choose between FSW therapy and RSW therapy for treating plantar fasciitis, we recommend RSW therapy because of its lower price and likely better effectiveness in clinical practice.

Appendix 1: Traditional Pair-Wise Comparisons of Treatment Effect Expressed as ORs and Mean Differences in VASs With a 95% CI for RSW Therapy and FSW Therapy of Various Intensity Levels Against Placebo Treatment

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Mean Difference in VAS (95% CI)</th>
<th>I-Squared of OR/ I-Squared of VAS (%)</th>
<th>P of OR/ P of VAS</th>
<th>Model Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-intensity FSW therapy</td>
<td>2.36 (0.50–11.14) – 1.59 (–4.33 to 1.15)</td>
<td>91/98.7</td>
<td>0.001/0.000</td>
<td>Random effect model</td>
</tr>
<tr>
<td>Medium-intensity FSW therapy</td>
<td>1.56 (1.23–1.96) – 1.21 (–1.76 to 0.67)</td>
<td>0/39.5</td>
<td>0.743/0.199</td>
<td>Fixed effect model</td>
</tr>
<tr>
<td>High-intensity FSW therapy</td>
<td>1.43 (1.03–1.91) – 0.33 (–0.58 to 0.08)</td>
<td>58/8.0</td>
<td>0.119/0.66</td>
<td>Fixed effect model</td>
</tr>
<tr>
<td>RSW therapy</td>
<td>2.72 (0.74–10.07) – 10.32 (–30.17 to 9.53)</td>
<td>89.5/98.9</td>
<td>0.000/0.000</td>
<td>Random effect model</td>
</tr>
</tbody>
</table>

Mixed Treatment Comparisons of Treatment Effect Expressed as Difference in VASs With 95% CIs Between RSW Therapy and FSW Therapy of Various Intensity Ranges

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Treatment Effects (95% CI)</th>
<th>Treatment Effects Compared With Placebo (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>0.062 (–0.3734 to 0.5019)</td>
<td>0</td>
</tr>
<tr>
<td>Low-intensity FSW therapy</td>
<td>–2.376 (–5.443 to 0.8112)</td>
<td>–2.439 (–5.476 to 0.720)</td>
</tr>
<tr>
<td>Medium-intensity FSW therapy</td>
<td>–2.181 (–6.15 to 1.864)</td>
<td>–2.243 (–6.199 to 1.777)</td>
</tr>
<tr>
<td>High intensity FSW</td>
<td>–1.141 (–5.44 to 3.248)</td>
<td>–1.204 (–5.48 to 3.169)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.

References


Supplier
a. StataCorp, 4905 Lakeway Dr, College Station, TX 77845.