Evidence Table

Clinical Area: Shockwave therapy for plantar fasciitis

Study Type: Randomized controlled trial.
Study Aim: To evaluate the efficacy of ESWT compared to placebo for patients with recalcitrant chronic plantar fasciitis.

Outcomes
- **Primary:** Change from baseline to 3 months in pain while walking for the first few minutes in the morning (assessed by a 10 point Visual Analogue Scale, VAS).
- **Secondary:** Other pain and function measures.

Design
- **Number of subjects:** N=114 (n=58 active treatment; n=56 placebo)
- **Description of study population:** Active treatment group: 18 male/ 50 female; Mean age=51 ± 11 years; mean no. months with heel pain=31 ± 33; placebo group: 23 male/ 33 female; Mean age=49 ± 10 years; mean no. months with heel pain=27 ± 24.
- **Inclusion criteria:** >18 years old; >6 months plantar fasciitis symptoms; >5 on a 10-point VAS scale for pain during the first few minutes of walking in the morning; history of 6 months of unsuccessful conservative therapy to include NSAIDS and a least two other therapies; baseline Roles and Maudsley Score$^1$ of 3 or 4.
- **Exclusion criteria:** Corticosteroid treatment within 1 month of treatment; other treatments within 2 weeks of study intervention; history of surgery for plantar fasciitis; other foot problems including peripheral neuropathy; contraindication to anesthesia or ESWT therapy.
- **Intervention:** Patients had a single treatment session with the Dornier Epos Ultra ESWT system. All patients were given a medial calcaneal nerve block (5mL of 1% xylocaine). In the active treatment, shock wave frequency began at 60 shocks/min (level 1) and was increased in increments of 30 shocks/min until 240 shocks/min were reached at level 7. Approximately 3500 shockwaves were administered at level 7, for an approximate total energy delivery of 1300 mJ/mm$^2$ (3800 total shocks). The placebo group received the identical treatment; however shockwaves were prevented from entering the patient’s foot by a foam cushion placed on the therapy head of the device. All patients were asked to eliminate athletic activities and pain medications for 6 weeks after the treatment session.
- **Source of outcome data:
- **Length of follow-up:** 3 months for blinded assessment. Follow-up for patients in the active treatment group was a total of 1 year.

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$^1$ 4-point patient self-assessment of pain and limitations of activity.
Validity
- **Blinding**? Double-blind.
- **Appropriate randomization procedures**? Yes.
- **Appropriate comparison intervention**? Yes.
- **Treatment/control groups comparable at baseline**? Yes.
- **Other than intervention, was care/follow-up similar in each group**? Yes.
- **Adequate compliance with intervention**? Yes.
- **Sufficient statistical power**? Yes.
- **Intention to treat analysis**? Yes.
- **Completeness of follow-up**: 92% were evaluated at the 3-month visit.
- **Industry funding**? Yes, study funded by Dornier MedTech America.
- **Conclusions regarding validity of methods**:
  - The study was funded by the device manufacturer which may have introduced bias.
  - The authors reported numerous secondary outcomes and subgroup analyses (not all of which were pre-specified). Multiple comparisons increases the likelihood of finding a significant difference by chance alone. The greatest weight was given to the primary outcome.

Results

**Primary outcome**: Change from baseline to 3 months, pain while walking for the first few minutes in the morning (10-point VAS scale).

<table>
<thead>
<tr>
<th></th>
<th>ESWT</th>
<th>Placebo</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (score, SD)</td>
<td>7.5 (1.5)</td>
<td>7.9 (1.5)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>3 months (score, SD)</td>
<td>3.9 (3.2)</td>
<td>5.3 (2.7)</td>
<td></td>
</tr>
</tbody>
</table>

**Selected secondary outcomes**

<table>
<thead>
<tr>
<th></th>
<th>ESWT</th>
<th>Placebo</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical success (No., %)(^1)</td>
<td>47%</td>
<td>23%</td>
<td>0.0099</td>
</tr>
<tr>
<td>Pain during normal daily activity(^2)</td>
<td>6.2 (2.0)</td>
<td>6.0 (2.0)</td>
<td>0.0524</td>
</tr>
<tr>
<td>Baseline (score, SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months (score, SD)</td>
<td>3.7 (3.1)</td>
<td>4.4 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Pain during sport activity(^2)</td>
<td>7.4 (2.4)</td>
<td>7.7 (2.1)</td>
<td>0.0904</td>
</tr>
<tr>
<td>Baseline (score, SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months (score, SD)</td>
<td>3.9 (3.5)</td>
<td>5.2 (2.9)</td>
<td></td>
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\(^1\)Clinical success=>60% improvement in primary outcome
\(^2\)Assessed using VAS
Adverse effects through 3 months

The only adverse effect (other than pain, in general) reported by more than 5% of either group was pain during treatment. This was reported by 79.3% in the ESWT group and 8.9% in the placebo group (0.0000).

Note: The difference in reported pain during treatment may indicate that blinding was not effective e.g. patients may have associated pain with active treatment.

Authors’ Conclusions
“Dornier Epos Ultra is a safe and effective treatment for recalcitrant plantar fasciitis.”

Reviewer’s Conclusions
One treatment session with the Dornier Epos Ultra ESWT device had a significantly greater impact on pain reduction than a placebo intervention for patients with chronic plantar fasciitis. The between-group difference in change in reported pain from baseline to 3 months was 1.0 point on a 10-point VAS. At 3 months, self-reported pain in the morning was a mean of 3.9 in the ESWT group and 5.3 in the placebo group, on a 10-point scale. The study was sponsored by the device manufacturer, no specific funding-related biases were identified.