Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain

Intonia HW Chow Physiotherapy Department, Queen Elizabeth Hospital and Gladys LY Cheing Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Kowloon, Hong Kong

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Objective: To compare the effectiveness of different energy densities of extracorporeal shock wave therapy (ESWT) for managing chronic heel pain.

Design: A randomized clinical trial.

Setting: Hospital-based practice.

Subjects: Fifty-seven patients with chronic heel pain were recruited; eight patients withdrew from the study.

Interventions: Subjects were randomized into three groups receiving: (1) a ‘fixed’ energy density, (2) ‘maximum tolerable’ energy density, or (3) control treatment once a week for three weeks.

Outcome measures: Pain on palpation, pain on tension, maximum tolerable walking/standing duration and Foot Function Index were assessed before treatment in each treatment session and at the three-week follow-up.

Results: By week 3, the ‘maximum tolerable’ energy density group experienced a 66% cumulative reduction in pain from tension, a 65% reduction on palpation and a 112% cumulative increase in maximum tolerable walking/standing duration. The ‘fixed’ energy density group experienced a 45% cumulative reduction in pain from tension, a 32% reduction in pain on palpation, and a 45% increase in walking/standing tolerance. The ‘maximum tolerable’ energy density group also showed a significantly greater reduction in Foot Function Index scores than the other two groups. Therapeutic effects were maintained at least up to the three-week follow-up period. The control group had no significant changes in any outcome measures across time periods.

Conclusion: The delivery of ESWT with a maximum tolerable energy density is a more effective treatment protocol than a fixed energy density in terms of relieving pain and restoring the functional activity of people suffering from chronic heel pain. The analgesic effects were maintained at least up to the three-week follow-up.

Introduction

A painful heel is a common orthopaedic syndrome, and about 10% of the general population may experience heel pain during their life.¹ It is more
prevalent among middle-aged or elderly people. In the past two decades, extracorporeal shock wave therapy (ESWT) has been used to manage soft tissue pain in the vicinity of bone structures. Various studies have shown that ESWT has a high success rate in pain relief and functional restoration for managing heel pain with negligible complications. Among all the treatment parameters, energy density is the most important parameter for determining the treatment effectiveness of ESWT. High-energy shock waves are expected to exert a direct mechanically disintegrating effect on hard surfaces while low-energy shock waves are regarded as a form of hyperstimulation analgesia.

Various studies have used different energy densities in managing heel pain. They have all demonstrated positive clinical outcomes. However, the classification of the energy level of ESWT is arbitrary and inconsistent among different authors. There is no concrete research evidence to support the appropriate selection of treatment parameters for managing chronic heel pain. Some studies used fixed energy density while some used a range of variable energy densities. The mode by which energy density was adjusted was not mentioned in these studies, whether it was adjusted in each treatment or during the treatment is unknown. With reference to the classifications made in previous studies, the present study defined low energy density as less than 0.1 mJ/mm², and medium energy density as higher than 0.1 mJ/mm² but lower than 0.2 mJ/mm². Any ESWT delivered at higher than 0.2 mJ/mm² is regarded as high energy density.

The aim of the present study was to examine whether a ‘fixed’ or a ‘maximum tolerable’ energy density would produce a greater reduction in pain when managing chronic heel pain.

Methods

Subjects
The criteria for inclusion were those above 18 years of age who had a diagnosis of unilateral heel pain for at least three months. They needed to be able to complete the visual analogue scale (VAS) independently. Those suffering from knee/ankle problems, arthritis or neurological abnormalities, or who had prior experience in receiving ESWT were excluded. Ethical approval was obtained from a local ethical committee. All subjects gave their informed consent before receiving treatment.

Fifty-seven subjects were recruited from a local physiotherapy outpatient clinic. They were blind to the group allocation and randomly allocated into three groups using the Bebbington’s method: the ‘fixed’ energy density group (n = 19), the ‘maximum tolerable’ energy density group (n = 19), and the control group (n = 19). Eight subjects dropped out from the study. Hence, 49 subjects (15 male, 34 female), with an average age of 50.94 (10.61) years, completed the study. A flow diagram of the study is shown in Figure 1.

Treatment procedures
A radial ESWT unit (EMS Medical, The Swiss DolorClast, Switzerland) was used. It pneumatically generated extracorporeal shock wave impulses with different working pressures. The working pressure was converted into energy density based on the conversion graph presented in the operation manual of the ESWT unit.

Subjects wore an ankle stabilization splint and were placed in a prone lying position. Shock waves were applied directly to the marked tender spot. Ultrasound gel was used as a coupling agent and the applicator of the ESWT unit was held perpendicular to the treatment surface throughout the treatment (Figure 2). For the ‘fixed’ energy density group, the starting energy density was 0.05 mJ/mm². The energy density was stepped up gradually until it reached the highest possible tolerable pain level reported by the subject. The corresponding energy density was recorded in the first session and was used in the subsequent sessions. For the ‘maximum tolerable’ energy density group, the starting energy density was 0.05 mJ/mm². The energy density was stepped up gradually until it reached the highest possible tolerable pain level reported by the subject. The corresponding energy density was recorded in the first session and was used in the subsequent sessions. For the ‘maximum tolerable’ energy density group, the starting energy density was 0.05 mJ/mm² and it was increased by a ‘staircase’ method. The investigator adjusted the energy density to the subject’s maximal tolerable level after every 200 impulse application. The energy density delivered in every 200 impulses was recorded. In both the ‘fixed’ and ‘maximum tolerable’ energy density groups, 1000 shock wave impulses administrated at 3 Hz were given. Previous studies have shown that the selected number of impulses and frequency of ESWT are effective at treating chronic heel pain.
Patients with diagnosis of chronic heel pain
\((n=57)\)

Randomization

‘Fixed’ Energy Density Group
Week 1
\((n=19)\)

‘Maximum Tolerable’ Energy Density Group
Week 1
\((n=19)\)

Control Group
Week 1
\((n=19)\)

Week 2
\((n=19)\)

Withdrawn \((n=1)\)

Week 2
\((n=19)\)

Week 2
\((n=18)\)

Withdrawn \((n=3)\)

Week 3
\((n=19)\)

Withdrawn \((n=1)\)

Week 3
\((n=15)\)

Withdrawn \((n=1)\)

Follow-up
\((n=17)\)

Follow-up
\((n=18)\)

Follow-up
\((n=14)\)

Completed trial
\((n=17)\)

Completed trial
\((n=18)\)

Completed trial
\((n=14)\)

Figure 1 A flow diagram of the study.

the control group received ESWT delivered at a frequency of 3 Hz with a total of 30 impulses, and the energy density was fixed at the lowest level \((0.03 \text{ mJ/mm}^2)\).\(^6,7\) These parameters remained unchanged in the subsequent sessions. All subjects received three weekly treatments. Then, three weeks later, they attended an assessment session (hereafter referred as ‘a three-week follow-up’).

Outcome measures

Outcome measures, including heel pain on palpation and tension, maximum tolerable walking/standing duration and scores on the Foot Function Index (FFI), were recorded before each ESWT treatment. Pain was registered using the VAS, which consisted of a 10-cm line with ‘no pain’ to the left and ‘pain as bad as it could be’ to the right. The subjects rated their perception of pain by making a mark on the VAS line. The distance from the left to the mark was measured and the accuracy was corrected to one decimal place.

To evaluate pain on tension, the subjects lay prone with one knee flexed, and passive ankle dorsiflexion with simultaneous big toe extension was performed. This ensured that the tension over the plantar aspect of the sole was up to its full passive end range. The subjects were asked to rate their present stretching pain using the VAS. To evaluate pain on palpation, an ankle stabilization splint was put on when subjects lay in a prone position with their ankle hanging over the edge of the bed. The splint was used to secure and standardize the ankle joint in the same plantigrade position in each treatment session. The most tender spot on the heel was identified by the investigator by manual palpation. The location of the tender spot and the contour of the foot were
precisely recorded with permanent marker on a plastic scale, which was used in subsequent sessions to relocate the treatment area. Afterwards, the subjects had to rate their pain using the VAS when experiencing a standardized pressure of 80 N/cm² at a speed of 10 N/s applied perpendicularly to the tender spot with the use of a pressure algometer.

To evaluate functional tasks, the subjects reported their maximum tolerable walking/standing duration in terms of time (in hours). The subjects were also asked to complete the Foot Function Index (FFI), a self-administered questionnaire consisting of 23 items divided into three unique subscales. The FFI was specifically designed to measure the impact of foot pathology on function in terms of pain, disability, and limitation of activities.17,18

Statistical analysis
A repeated measures analysis of variance (ANOVA) was performed. The level of significance was set at 0.05. The baseline patients’ profile was compared using two-sample t-tests. The data of the outcome measures were presented as the mean ± standard deviation and normalized values. Normalized values were calculated in terms of a percentage of the baseline data (obtained in week 1 before receiving ESWT treatment). By comparing the normalized data, we can easily observe the percentage change in outcome measures across treatment sessions. For multiple comparisons, the Bonferroni correction was used to adjust the level of significance (adjusted P-value = 0.05/number of tests performed).

Results
There was no significant difference in the demographic characteristics and baseline assessments of subjects among the three treatment groups (Table 1). The average total energy applied in each session was higher in the ‘maximum tolerable’ energy density group than in the other two groups (Table 2).

Pain on palpation
The VAS scores were significantly decreased by 37% (3.72) (P < 0.001) and 83% (1.03) (P < 0.001) after six weeks (included three weeks of treatment and three-week follow-up) within the ‘fixed’ energy density and the ‘maximum tolerable’ energy density group (Table 3). In contrast, the VAS scores for the control group did not change significantly (P > 0.067). The ‘maximum tolerable’ energy density group showed a faster reduction in VAS scores than did the ‘fixed’ energy density group. A post-hoc analysis indicated that a significant difference was obtained mainly from the comparisons made between week 1 and week 3, and week 2 and week 3 in both treatment groups.

Despite this, the between-group difference reached a significant level by week 2 (P < 0.001), week 3 (P < 0.001), and the follow-up session (P < 0.001) (Table 3). These P-values were still significant even after being adjusted by the Bonferroni correction (0.05/4 = 0.0125). Post-hoc tests indicated that there were significant differences between the control group and the two active ESWT groups at week 2, week 3, and at the follow-up session.

Pain on tension
The VAS scores were significantly decreased by 54% (2.32) (P < 0.001) and 81% (0.86) (P < 0.001) after six weeks within the ‘fixed’ energy density and the ‘maximum tolerable’ energy density group (Table 3). In contrast, the VAS scores for the control group remained more
or less the same across all sessions ($P = 0.064$). There was only a 3% cumulative reduction by the follow-up session (Table 3). A post-hoc analysis indicated that a significant difference was obtained mainly from comparisons made between week 1 and week 3, and week 2 and week 3. No significant difference was found between week 3 and the follow-up session in both treatment groups.

Despite this, the between-group difference in VAS scores reached a significant level by week 2 ($P = 0.001$), week 3 ($P < 0.001$), and the follow-up session ($P < 0.001$). These $P$-values were still significant even after being adjusted by the Bonferroni correction. Post-hoc tests indicated that there were significant differences between the control group and the two active ESWT groups at week 3 and the follow-up session. The 'maximum tolerable' ESWT had a more significant decrease in VAS scores than the 'fixed' ESWT (Table 3).

### Foot Function Index – pain subscale ($FFI_{pain}$)

The Foot Function Index – pain subscale ($FFI_{pain}$) scores were significantly reduced by 27% (3.94) ($P < 0.001$) and 71% (1.95) ($P < 0.001$) after six weeks within the 'fixed' energy density and the 'maximum tolerable' energy density groups (Table 4). The control group had no significant change in $FFI_{pain}$ scores over time ($P = 0.542$). A post-hoc analysis indicated that a significant difference was obtained mainly from comparisons made between week 1 and week 3, and week 2 and week 3 in both treatment groups.

For the between-group comparison, the difference in $FFI_{pain}$ scores reached a significant level by week 3 ($P < 0.001$) and the follow-up session ($P < 0.001$). These $P$-values were still significant even after being adjusted by the Bonferroni correction (0.05/3 = 0.0167). Post-hoc tests indicated that there were significant differences between the control group and the two active ESWT groups at week 3 and the follow-up session.

### Table 1 Baseline demographic profile of subjects with chronic heel pain

<table>
<thead>
<tr>
<th></th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>5</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>12</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Age (years)</td>
<td>51.94 ± 11.68</td>
<td>50.22 ± 10.74</td>
<td>50.64 ± 9.75</td>
<td>0.797</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>24.47 ± 3.62</td>
<td>23.96 ± 4.05</td>
<td>24.31 ± 2.98</td>
<td>0.463</td>
</tr>
<tr>
<td>History of heel pain (months)</td>
<td>10.38 ± 3.58</td>
<td>10.00 ± 3.33</td>
<td>10.12 ± 2.81</td>
<td>0.815</td>
</tr>
<tr>
<td>Pain on tension</td>
<td>5.01 ± 1.11</td>
<td>4.63 ± 0.80</td>
<td>4.24 ± 0.74</td>
<td>0.076</td>
</tr>
<tr>
<td>Pain on palpation</td>
<td>5.92 ± 0.95</td>
<td>6.11 ± 1.23</td>
<td>5.70 ± 1.16</td>
<td>0.629</td>
</tr>
<tr>
<td>Maximum tolerable walking/standing duration (hours)</td>
<td>0.88 ± 0.27</td>
<td>0.85 ± 0.27</td>
<td>0.94 ± 0.30</td>
<td>0.542</td>
</tr>
<tr>
<td>Foot Function Index</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain subscale</td>
<td>5.41 ± 1.33</td>
<td>6.63 ± 1.44</td>
<td>6.96 ± 1.17</td>
<td>0.105</td>
</tr>
<tr>
<td>Disability subscale</td>
<td>4.51 ± 1.71</td>
<td>5.82 ± 1.35</td>
<td>5.58 ± 0.83</td>
<td>0.218</td>
</tr>
<tr>
<td>Activity limitation subscale</td>
<td>2.01 ± 0.76</td>
<td>2.47 ± 0.53</td>
<td>2.33 ± 0.58</td>
<td>0.107</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± standard deviation.

### Table 2 The average total energies applied in each treatment group over time

<table>
<thead>
<tr>
<th></th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>19.2 ± 2.9</td>
<td>21.4 ± 2.6</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>19.2 ± 2.9</td>
<td>26.8 ± 3.6</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Week 3</td>
<td>19.2 ± 2.9</td>
<td>30.1 ± 3.6</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>Total energy (J)</td>
<td>57.7 ± 8.7</td>
<td>69.6 ± 8.8</td>
<td>0.6</td>
<td></td>
</tr>
</tbody>
</table>

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The decrease in the FFI pain scores for the ‘maximum tolerable’ energy density group was more profound than for the ‘fixed’ energy density group (Table 4).

### Table 3  The mean scores of visual analogue scale of pain intensity on palpation and on tension recorded over time

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>$P$-value (between-group)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain on palpation</td>
<td>5.92 ± 0.95</td>
<td>6.11 ± 1.23</td>
<td>5.70 ± 1.16</td>
<td>0.592</td>
</tr>
<tr>
<td>Pain on tension</td>
<td>5.01 ± 1.11</td>
<td>4.63 ± 0.80</td>
<td>4.24 ± 0.74</td>
<td>0.076</td>
</tr>
<tr>
<td><strong>Week 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain on palpation</td>
<td>4.79 ± 0.83</td>
<td>3.61 ± 0.90</td>
<td>5.62 ± 1.15</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pain on tension</td>
<td>3.85 ± 1.29</td>
<td>2.83 ± 0.91</td>
<td>4.12 ± 0.66</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain on palpation</td>
<td>4.01 ± 0.77</td>
<td>2.14 ± 0.61</td>
<td>5.58 ± 1.10</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pain on tension</td>
<td>2.76 ± 1.49</td>
<td>1.57 ± 0.82</td>
<td>4.01 ± 0.58</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain on palpation</td>
<td>3.72 ± 0.69</td>
<td>1.03 ± 0.54</td>
<td>5.71 ± 1.07</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pain on tension</td>
<td>2.32 ± 1.26</td>
<td>0.86 ± 0.66</td>
<td>4.11 ± 0.70</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*$P$-value (within-group) Pain on palpation $< 0.001$ Pain on tension $< 0.001$ 0.067 0.064

Raw data are expressed as mean ± standard deviation. Normalized data are presented within brackets.

The decrease in the FFI$_{pain}$ scores for the ‘maximum tolerable’ energy density group was more profound than for the ‘fixed’ energy density group (Table 4).

### Foot Function Index – disability subscale (FFI$_{disability}$)

The FFI$_{disability}$ scores were significantly decreased by 24% (3.45) ($P < 0.001$) and 68% (1.87)

### Table 4  The mean Foot Function Index scores for the pain subscale recorded over time

<table>
<thead>
<tr>
<th></th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>$P$-value (between-group)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
<td>5.41 ± 1.33</td>
<td>6.63 ± 1.44</td>
<td>6.96 ± 1.17</td>
<td>0.105</td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
<td>4.64 ± 0.89</td>
<td>3.48 ± 1.03</td>
<td>6.95 ± 1.15</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td>3.94 ± 0.95</td>
<td>1.95 ± 0.89</td>
<td>6.94 ± 1.17</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*$P$-value (within-group) Pain on palpation $< 0.001$ Pain on tension $< 0.001$ 0.542

Raw data are expressed as mean ± standard deviation. Normalized data are presented within brackets.
Different energy densities of ESWT

Table 5 The mean Foot Function Index scores for the disability subscale recorded over time

<table>
<thead>
<tr>
<th></th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>(P)-value (between-group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>4.51±1.71</td>
<td>5.82±1.35</td>
<td>5.58±0.83</td>
<td>0.218</td>
</tr>
<tr>
<td></td>
<td>(100.00±0.00)</td>
<td>(100.00±0.00)</td>
<td>(100.00±0.00)</td>
<td></td>
</tr>
<tr>
<td>Week 3</td>
<td>4.07±1.48</td>
<td>3.16±1.32</td>
<td>5.53±0.82</td>
<td>0.011</td>
</tr>
<tr>
<td></td>
<td>(90.24±32.81)</td>
<td>(54.30±22.68)</td>
<td>(99.10±14.69)</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>3.45±1.31</td>
<td>1.87±0.82</td>
<td>5.51±0.76</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>(76.50±29.05)</td>
<td>(32.13±14.09)</td>
<td>(98.75±13.62)</td>
<td></td>
</tr>
<tr>
<td>(P)-value (within-group)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.110</td>
<td></td>
</tr>
</tbody>
</table>

Raw data are expressed as mean ± standard deviation. Normalized data are presented within brackets.

\(P < 0.001\) after six weeks within the ‘fixed’ energy density and the ‘maximum tolerable’ energy density group (Table 5). In contrast, the control group only showed a negligible change in FFI\(_{\text{disability}}\) scores over time \((P = 0.110)\). A post-hoc analysis indicated that a significant difference was obtained mainly from comparisons made between week 1 and week 3, and week 2 and week 3 in both treatment groups.

The between-group difference in FFI\(_{\text{disability}}\) scores reached a significant level by week 3 \((P = 0.011)\) and the follow-up session \((P < 0.001)\). These \(P\)-values were still significant even after being adjusted by the Bonferroni correction. Post-hoc tests indicated that there were significant differences between the control group and the two active ESWT groups at week 3 and the follow-up session, but that the ‘maximum tolerable’ ESWT had a more significant decrease in FFI\(_{\text{disability}}\) scores than did the ‘fixed’ ESWT group.

Table 6 The mean Foot Function Index scores for the activity limitation subscale recorded over time

<table>
<thead>
<tr>
<th></th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>(P)-value (between-group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>2.01±0.76</td>
<td>2.47±0.53</td>
<td>2.33±0.58</td>
<td>0.107</td>
</tr>
<tr>
<td></td>
<td>(100.00±0.00)</td>
<td>(100.00±0.00)</td>
<td>(100.00±0.00)</td>
<td></td>
</tr>
<tr>
<td>Week 3</td>
<td>1.68±0.66</td>
<td>1.04±0.30</td>
<td>2.28±0.55</td>
<td>0.016</td>
</tr>
<tr>
<td></td>
<td>(83.58±32.83)</td>
<td>(42.11±12.15)</td>
<td>(97.85±23.60)</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>1.50±0.59</td>
<td>0.66±0.33</td>
<td>2.31±0.54</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>(P)-value (within-group)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.434</td>
<td></td>
</tr>
</tbody>
</table>

Raw data are expressed as mean ± standard deviation. Normalized data are presented within brackets.

Foot Function Index – activity limitation subscale (FFI\(_{\text{activity limitation}}\))

The FFI\(_{\text{activity limitation}}\) scores were significantly reduced by 25\% (1.50) \((P < 0.001)\) and 73\% (0.66) \((P < 0.001)\) after six weeks within the ‘fixed’ energy density and the ‘maximum tolerable’ energy density groups (Table 6). A post-hoc analysis indicated that the significant difference was obtained mainly from comparisons made between week 1 and week 3, and week 2 and week 3 in both treatment groups. In the control group, there was no significant change in FFI\(_{\text{activity limitation}}\) scores over time \((P = 0.434)\).

For the between-group comparison, the difference in FFI\(_{\text{activity limitation}}\) scores reached a significant level by week 3 \((P = 0.016)\) and the follow-up session \((P < 0.001)\). These \(P\)-values were still significant even after being adjusted by the Bonferroni correction. Post-hoc tests indicated that there were significant differences between the

\[\text{Different energy densities of ESWT} \quad 137\]

\[\text{Different energy densities of ESWT} \quad 137\]
control group and the two active ESWT groups at week 3 and the follow-up session, but that the ‘maximum tolerable’ ESWT had a more significant decrease in FFI activity limitation scores than did the ‘fixed’ ESWT (Table 6).

Maximum tolerable walking/standing duration

The maximum tolerable walking/standing duration was significantly increased by 59% (1.40) ($P < 0.001$) and 180% (2.32) ($P < 0.001$) after six weeks within the ‘fixed’ energy density and the ‘maximum tolerable’ energy density groups (Table 7). A post-hoc analysis indicated that a significant difference was obtained mainly from the comparison made between week 1 and week 3, and week 2 and week 3 in both treatment groups. However, the control group showed no significant change in walking/standing tolerance ($P = 0.307$).

Despite this, the between-group difference in the maximum tolerable walking/standing duration reached a significant level by week 2 ($P = 0.022$), week 3 ($P < 0.001$) and the follow-up session ($P < 0.001$). These $P$-values were still significant even after being adjusted by the Bonferroni correction (0.05/4 = 0.0125). Post-hoc tests indicated that there were significant differences between the control group and the two active ESWT groups at week 3 and the follow-up session, but that the ‘maximum tolerable’ ESWT had a more significant increase in maximum tolerable walking/standing duration than did the ‘fixed’ ESWT.

### Table 7 The mean maximum tolerable walking/standing duration (in hours) recorded over time

<table>
<thead>
<tr>
<th></th>
<th>‘Fixed’ energy density group</th>
<th>‘Maximum tolerable’ energy density group</th>
<th>Control group</th>
<th>$P$-value (between-group)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>0.88±0.27(0.00±0.00)</td>
<td>0.83±0.27(0.00±0.00)</td>
<td>0.94±0.30(0.00±0.00)</td>
<td>0.542</td>
</tr>
<tr>
<td>Week 2</td>
<td>1.05±0.35(119.32±39.77)</td>
<td>1.29±0.37(155.42±44.58)</td>
<td>0.99±0.25(105.32±26.60)</td>
<td>0.022</td>
</tr>
<tr>
<td>Week 3</td>
<td>1.28±0.33(145.45±37.50)</td>
<td>1.76±0.31(212.05±37.35)</td>
<td>0.98±0.20(104.26±21.28)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Follow-up</td>
<td>1.40±0.40(159.01±45.43)</td>
<td>2.32±0.39(279.52±47.00)</td>
<td>1.00±0.22(106.38±23.40)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>$P$-value (within-group)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
<td>0.307</td>
<td></td>
</tr>
</tbody>
</table>

Raw data are expressed as mean ± standard deviation. Normalized data are presented within brackets.

### Discussion

Our findings indicated that the two active ESWT groups, with energy densities ranging from 0.09 to 0.14 mJ/mm², were effective in relieving pain and restoring function in people with chronic heel pain. These positive improvements lasted at least up to the three-week follow-up. These results are consistent with those reported by Rompe et al.⁷ and Hammer et al.³ Our study further demonstrated that the ESWT application with maximum tolerable energy density produced a significantly greater pain reduction and functional improvement than the fixed energy density did. Most outcome measures showed significant differences between week 1 and week 3 indicating that at least two sessions of ESWT are required to produce significant clinical results. The negative findings by Haake et al.¹⁹ may be due to variations in the treatment parameters and to inconsistent treatment procedures.

In fact, energy density determines clinical outcomes. Haupt and Chvapil²⁰ argued that shock waves at low energy density produce stimulatory effects on cell cultures and enhance the healing of wounds, while shock waves of high energy density may inhibit cell growth and interfere with the repair potential of the cell due to cell destruction and necrosis. Therefore, the most effective treatment outcome can only be achieved by using optimal treatment parameters. Obviously, this optimal level of energy density should be high enough to allow successful and effective treatment,
while at the same time, low enough to keep side effects and pain to a minimum. This is the concept of a ‘window effect’ of treatment effectiveness. Further investigations are necessary in order to determine the ‘window effect’ of treatment effectiveness for different musculoskeletal conditions.

The analgesic mechanisms of ESWT

The mechanisms of the production of analgesia and the specific biological effects of ESWT are still controversial. The high stress force generated by ESWT may result in internal microdisruption of fascial tissue. It then facilitates the process of neovascularization (promotes tissue healing and stimulates new tissue growth). This phenomenon is supported by the larger number of capillaries or dilated microvessels observed in wounds that had been exposed to ESWT compared to those that had not been exposed. Therefore, ESWT can improve the circulation at the heel, facilitate the removal of pain-producing metabolites, and result in pain relief and improvement in daily functioning.

Shock waves are also regarded as a mechanical-physical stimulus and produce extracellular cavitations when passing through human tissues. Steinbach et al. and Johannes et al. reported that the application of ESWT (energy density > 0.12 mJ/mm²) can induce the ionization of molecules and lead to an increase in membrane permeability, mitochondrial alterations, cytotoxicity, metabolic actions on tissues, and the liberation of proteins and mediators acting locally on pain and nerve endings. Cavitation may result in damage to local nerve endings and cell membranes, and hence affects the transmission of pain signals. This explains why patients experience an increase in tolerance for pain after receiving ESWT. Our findings suggest that the relatively higher energy density used in the ‘maximum tolerable’ energy density group initiated the above biological effects within the treated tissue, and consequently produced more significant clinical improvement.

Another explanation for the analgesic effect of ESWT is the gate control theory. Krischek et al. believed that ESWT activated the small-diameter fibres and the serotonergic system, which ultimately modulated the transmission through the dorsal horns. Haake et al. conducted an animal study to support the activation of an endogenous opioid system to be the antinociception effect of ESWT. Their findings showed that only ESWT with an energy density greater than 0.11 mJ/mm² was sufficient to modulate the endogenous opioid system in rats. This explained why the ‘fixed’ energy density group and the control group were not likely to activate the system, while the ‘maximum tolerable’ energy density group did. In this group, the energy density became greater over time (0.10 mJ/mm² in week 1; 0.12 mJ/mm² in week 2 and 0.14 mJ/mm² in week 3). It seems that the pain threshold of the subjects increased across sessions and that the continuous release of endogenous opioids in the spinal cord can inhibit subsequent painful inputs by blocking the release of the pain neurotransmitter in the afferent nerve fibres. Hence, the subjects experienced a reduction in their sensation of pain and could tolerate a higher energy density level.

It is postulated that diffuse noxious inhibitory control is the pivotal pain-relieving mechanism explaining the treatment effect of ESWT that resulted in the present study. Diffuse noxious inhibitory control was first reported in animal studies; it describes the inhibition of activity in convergent or wide dynamic range-type nociceptive spinal neurons that is triggered by a second, spatially remote, noxious stimulus. Inhibition of the spinothalamic tract cells would presumably decrease perceptions of pain by diminishing ascending noxious evoked impulses to the brain. Diffuse noxious inhibitory control is mediated largely by supraspinal structures. Its underlying pain-relieving principle is counter-irritation. That is, ‘one pain masks another’. This explains why the ‘maximum tolerable’ energy density could
effectively reduce the subjects’ perception of heel pain. In fact, previous human studies have already documented that there is a decrease in perception of the pain caused by a noxious stimulus when a second noxious stimulus is applied elsewhere on the body.\textsuperscript{36,37} Diffuse noxious inhibitory control can inhibit the perceived intensity of pain in humans.

**Limitations of the present study**

The recommendation on energy density and the mode of ESWT delivery derived from the present findings applies only to ESWT devices using a pneumatic generating system. Since the physical properties of the generated shock waves and the spatial distribution of the energy density or the focus pressure heavily depend on the sound source and the focusing device used, the results of the present study cannot be generalized to ESWT generated by other mechanisms. The subject size was small and the follow-up period was short in the present study, hence the long-term effects of ESWT on chronic heel pain should be evaluated in subsequent studies.

**References**


