

# Ultrasound Guidance Does Not Improve the Results of Shock Wave for Plantar Fasciitis or Calcific Achilles Tendinopathy: A Randomized Control Trial

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## Abstract

**Objective:** To establish whether the use of ultrasound to direct shock waves to the area of greater calcification in calcaneal enthesopathies was more effective than the common procedure of directing shock waves to the point where the patient has the most tenderness. **Design:** Two-armed nonblinded randomized control trial with allocation concealment. **Setting:** The Sports Clinic at Sydney University. **Patients:** Participants 18 years or older with symptomatic plantar fasciitis (PF) (with heel spur) or calcific Achilles tendinopathy (CAT). Seventy-four of 82 cases completed treatment protocol and 6-month follow-up. **Interventions:** Patients were randomized to receive either ultrasound-guided (UG) or patient-guided (PG) shock wave at weekly intervals over 3 to 5 weeks. **Main Outcome Measures:** Reduced pain on visual analog scale (VAS) and improved functional score on Maryland Foot Score (MFS) (for PF) or Victorian Institute of Sport Assessment-Achilles (VISA-A) (for CAT). Follow-up was at 6 weeks and 3 and 6 months. **Results:** Comparative 6-month improvements in MFS for the 47 PF cases were PG +20/100 and UG +14/100 ( $P = 0.20$ ). Comparative 6-month improvement in VISA-A score for the 27 CAT cases were PG +35/100 and UG +27/100 ( $P = 0.37$ ). Comparative (combined PF and CAT) 6-month improvement in VAS pain scores for all 38 PG cases were +38/100 with +37/100 for all 36 UG shock wave cases. **Conclusions:** Although both treatment groups had good clinical outcomes in this study, results for the 2 study groups were almost identical. **Clinical Relevance:** This study shows that there is no major advantage in the addition of ultrasound for guiding shock waves when treating calcaneal enthesopathies (PF and CAT).

**Key Words:** shock wave, plantar fasciitis, Achilles, calcaneal enthesopathy, tendinopathy, ultrasound guided

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## INTRODUCTION

Enthesopathy, “bone spurs,” and calcific tendinopathy are pathologies commonly associated with insertional heel pain. Although the etiologies of the 2 major calcaneal enthesopathies [plantar fasciitis (PF) and calcific Achilles tendinopathy (CAT)] are thought to be different, there are similarities in demographics, presentation, and chronicity. Calcification in tendinopathy refers to an abnormal deposition of calcium hydroxyapatite surrounded by inflammation in the tendon.<sup>1</sup> It can be associated with substantial pain and impaired function in the affected area, although bone spurs in the heel can also be present in asymptomatic cases. Plantar fascia heel spurs develop as a consequence of degenerative changes that occur in the plantar fascia enthesis and calcification in the fascia.<sup>2,3</sup>

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Calcaneal (plantar and Achilles) spurs are prevalent in older people and more common in women than men younger than 50 years.<sup>4</sup>

Extracorporeal shock wave therapy (ESWT) (used in medicine initially to treat kidney stones, with the assistance of imaging guidance) is now a well-established treatment modality in sports and musculoskeletal medicine. The most substantive evidence base exists for chronic PF, where a recent meta-analysis of 11 high-quality randomized controlled trials showed efficacy of shock wave in reducing pain versus placebo or physical therapy.<sup>5</sup> It is not established whether shock wave is successful because of dissolution of calcification, mechanotherapy to stimulate tendon healing, or neurophysiological pain reduction.<sup>1,6</sup> Although there are multiple types and brands of musculoskeletal shock wave, recent systematic review has found that clinical results do not seem to vary by shock wave type.<sup>7–9</sup> Systemic reviews conclude that shock wave in general is effective (for calcaneal enthesopathy), affordable, and has a very low rate of complications or side effects.<sup>6,10</sup> However, results and protocols of treatment have been variable.<sup>5,11</sup>

In current clinical foot and ankle practice, shock wave therapy is often aimed at the site of the patient’s pain. This is known as the patient-guided (PG) or biofeedback method. Studies have shown that pain in calcific tendinopathy does not necessarily correlate with area of calcification.<sup>12</sup> Studies of calcification in the shoulder in particular have shown that navigation-guided shock wave to the site of calcification

may be more effective in improving patient pain and function, as well as decreasing calcification seen on radiological images.<sup>10,13,14</sup> Navigation-guided shock wave traditionally uses low-dose radiation x-ray (fluoroscopy) and sometimes ultrasound to identify and focus treatment on the area of calcification.<sup>15</sup>

This study attempted to establish whether the use of ultrasound to direct shock waves to the calcaneal enthesis or area of greater calcification is more or less effective than the procedure of directing shock waves to the point where the patient has the most tenderness. We hypothesized that for moderate depth occurrences of calcification (ie, PF with heel spur) that perhaps ultrasound-guided (UG) shock wave may be more effective, whereas for the most superficial occurrences of calcification (ie, CAT), PG shock wave may be as effective.

## METHODS

### Subjects

Between March 2012 and June 2013, eligible patients were recruited. Emails and letters were sent to potential referrers (community-based medical doctors or allied health care practitioners) notifying them of the study and eligibility criteria. To be eligible, patients needed to have (1) pain and impaired function in tissue under study (Achilles tendon or plantar fascia); (2) proven calcification or spur which was visible on our study ultrasound machine; and (3) not had a cortisone injection to the area in the previous 3 months. The use of cortisone injection was excluded as the short-term effects of cortisone can be quite powerful and might mask treatment outcomes. Our study design was to evaluate the effect of ultrasound on symptomatic heel spur irrespective of the duration of symptoms. As this was a randomized study, patients could continue with other treatment interventions during the research. Patients were excluded if they were younger than 18 years, pregnant, or on anticoagulant therapy.

Eligible participants read and signed a consent form before being enrolled in the study. Duration of follow-up was a minimum of 6 months. Most patients completed their final follow-up assessment at the 6-month period. However, we allowed an extension for the 6-month follow-up assessment to be conducted until 12 months to reduce the dropout rate.

### Procedures

This was a 2-armed nonblinded randomized control trial with allocation concealment. All participants with CAT or PF received active shock wave therapy. Patients were randomly allocated to receive either PG shock wave (without ultrasound guidance) or UG shock wave. Stratified randomization was performed by one of the researchers not directly involved in patient treatment. A computer generated Excel program was used to produce a random number list for each site of pathology. This was accomplished by producing 2 random number lists in Excel, one for each site. Forty numbers (1-40) were generated in each list and randomized to either obtain treatment 1 (PG) or treatment 2 (UG). This group allocation (PG or UG) was written on a paper and then placed in identical opaque envelope apart from the number. With each new participant, the shock wave practitioner would open a sequentially numbered envelope to find out the treatment the participant would be receiving, at which point

blinding effectively ended. The shock wave treatment and consultations were free of charge to the patient and performed by a practitioner at weekly intervals. Patients were required to complete a minimum of 3 and a maximum of 5 treatments to have completed study requirements. This is in accordance with a recent systematic review showing optimum extracorporeal shock wave therapy (ESWT) treatment protocol which requires a minimum of 3 treatment sessions at 1-week intervals, with 2000 impulses per session.<sup>9</sup> There were 3 practitioners who delivered treatment over the duration of the study. All 3 were trained in the delivery of shock wave therapy and use of ultrasound.

Both the manufacturers of the shock wave and ultrasound units provided machines rent-free for the duration of the study. The ultrasound was a Sonosite M-Turbo (Sonosite, Inc., Bothell, Washington). The shock wave machine was a Chattanooga Intellect Radial Pressure Wave RPW (DJO Global LLC, Vista, California). Shock waves were delivered by a hand-held device placed on the patient's skin. Coupling gel was used between the patient skin and the hand-held device to allow transmission of the shock waves. The shock wave machine was set to deliver 2000 radial pressure waves at a rate of 15 waves per second. Shock wave energy was gradually increased from 1.4 to 1.8 bars using the machine's automated built-in feature. The lower energy settings used were as recommended by the manufacturer to ensure patient comfort. No local anesthetic was used, as participants in the PG group needed to be able to point to the site of their pain for the study purposes. After treatments, patients could take oral paracetamol (acetaminophen) or apply ice to the area if desired.

The initial study protocol planned inclusion of a third group with calcific supraspinatus tendinopathy. However, we abandoned this arm of the study after very poor recruitment for this condition (2 patients only) and have excluded these from the results.

### Outcome Measures

Primary outcome measures were reduced pain and improved function. Pain was measured on the 100-mm visual analog scale (VAS).<sup>16</sup> Pain and function with activities of daily living were recorded on validated patient-filled questionnaires: Victorian Institute of Sport Assessment-Achilles (VISA-A) for CAT<sup>17</sup> and the Maryland Foot Score (MFS) for PF.<sup>18,19</sup> Questionnaires and the VAS were filled in before each shock wave session and at each follow-up visit 6 weeks and 3 and 6 months after the final shock wave session. At the conclusion of the study at 6-month follow-up, all patients were asked to fill in a questionnaire designed by the researchers documenting their impression of the treatment effect.

### Statistical Analysis

Statistical analysis was performed using Microsoft Excel. Overall, the groups were treated as independent. We then conducted a parametric analysis using a 2-tailed Student *t* test to compare intergroup measurement averages/average differences at baseline and after treatment. As we were testing the mean difference between groups, we assumed normality.  $P < 0.05$  was considered to be of statistical significance.<sup>20</sup>

Cases were included in analyses if data were present and excluded where data were missing. Where participants presented with multiple pathologies, each site was randomized separately, and we treated them as independent in the final statistical analysis.

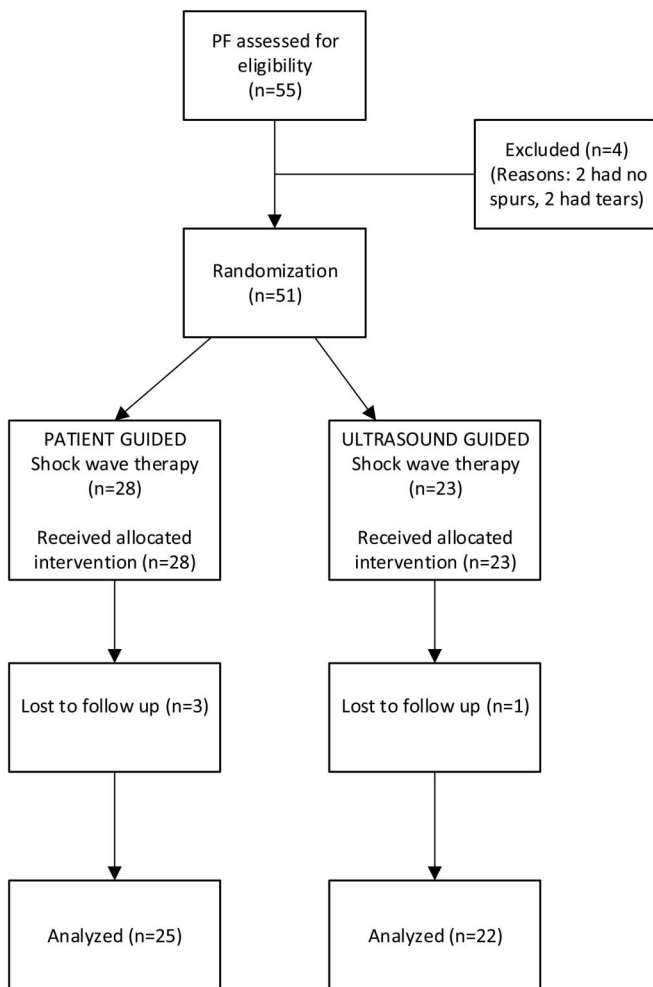
To improve clarity of results, VAS measurements were inverted (0 pain became 100 points; 100 pain became 0 points) for the presentation of results to correspond with functional outcome measures, so that a positive change on all measures indicated improvement.

**ETHICAL CONSIDERATIONS**

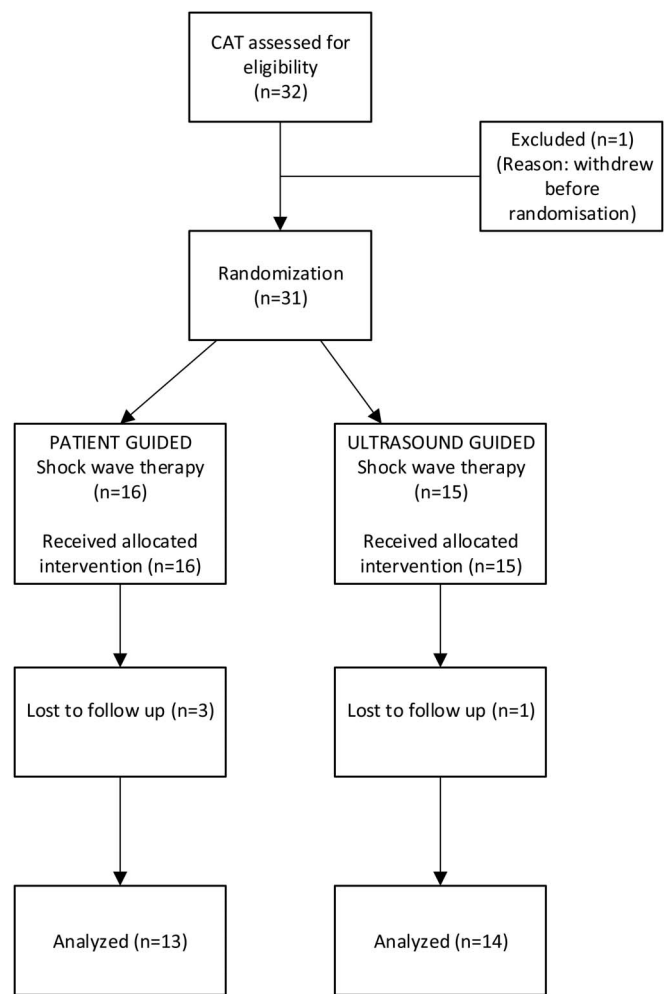
The University of Sydney Human Research Ethics Committee (HREC2012/2588) approved the study. The trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12612000260820).

**RESULTS**

Fifty-one subjects were randomized for the PF arm and 31 were randomized for the CAT arm. Flowcharts of all 87 cases (55 PF and 32 CAT) initially assessed for eligibility are shown (Figures 1 and 2).



**Figure 1.** CONSORT diagram showing the flow of PF (with heel spur) participants through each stage of the randomized trial.



**Figure 2.** CONSORT diagram showing the flow of Calcific Achilles Tendinopathy (CAT) participants through each stage of the randomized trial.

Each site-specific subgroup was randomized separately. Reasons for exclusion were as follows: 2 PF cases had no spur; 2 PF had tears; 1 CAT requested to switch treatment group. After exclusion, we had 82 cases from 65 patients (23 men and 42 women). Fourteen patients had bilateral pathology. One had 3 areas of pathology that involved both plantar fascia and an Achilles tendon. Randomization resulted in roughly equal numbers between the 2 treatment groups, with 44 PG and 38 UG cases.

Case distribution according to site (randomization) was 51 PF (28 PG and 23 UG) and 31 CAT (16 PG and 15 UG). Eight patients were lost to long-term (6-month) follow-up, leaving 74 (47 PF and 27 CAT) by the conclusion of the study. A posttreatment survey was also completed at the final 6-month follow-up by approximately three quarters of the cases.

Demographics for the full analysis set of participants are shown according to subgroup (Tables 1 and 2). The study population was on average middle aged, with equal distribution of sexes in the CAT group (Table 2). There were 3 times more females than males in the PF group (Table 1). Our study demographics are similar to previous studies.<sup>4</sup>

Completion of treatment protocol and long-term (6-month) follow-up was thus achieved in 74/82 cases. Analysis of this group is provided in Table 3. Comparative (PG vs UG) 6-month

**TABLE 1. Demographics of the PF With Heel Spur Group Analysis**

PF With Heel Spur Characteristics	Patient Guided	Ultrasound Guided
No. of cases, n	28	23
Age, yr	53 ± 14	51 ± 13
Male sex, n	5	5
Baseline VAS pain (0-100)	61 ± 21	63 ± 26
Baseline MFS (0-100)	66 ± 15	71 ± 15

improvement in VAS pain scores (combined PF and CAT) and functional scores (MFS and VISA-A) are depicted in Table 3 and Figure 3. We combined the pain scores for PF and CAT as the same scoring system (VAS) was used. This had the added advantage of improving the power for this analysis. A similar combination of the functional scores (MFS and VISA-A) could not be done, as these were 2 different measurement systems.

No significant difference in pain or functional outcomes was found between PG and UG shock wave for PF and CAT. These findings were consistent during treatment and in the duration of follow-up to 6 months. Overall, patients in both groups showed gradual improvement in symptom and function as compared with baseline.

The final data showing outcomes of treatment and follow-up of all study participants are depicted by line graph for both the plantar fascia and Achilles subgroups (Figures 3–5).

**Plantar Fasciitis With Heel Spur**

Functional MFS showed steady improvement with subsequent treatment and follow-up in both groups. The greatest improvement from baseline in both outcome scores occurred by 3 months of follow-up for both VAS (PG +43/100, UG +43/100, *P* = 0.47) and MFS (PG +21/100, UG +17/100, *P* = 0.21).

**Calcific Achilles Tendinopathy**

During shock wave treatments, when compared with baseline, VISA-A improvements did not vary between groups after the fourth treatment [PG +14/100, UG +15/100 (*P* = 0.43)] or at 6-month follow-up [PG +35/100, UG +27/100 (*P* = 0.37)].

**Shock Wave Posttreatment Questionnaire Analysis**

The posttreatment survey consisted of 7 questions asking patients to rate their impression of shock wave. Here, the PF with heel spur and CAT responses are combined into PG (n = 32) and UG (n = 30) groups and represented in chart form for

**TABLE 2. Demographics of the Calcific Achilles Tendinopathy (CAT) Group Analysis**

CAT Characteristics	Patient Guided	Ultrasound Guided
No. of cases, n	16	15
Age, yr	46 ± 13	50 ± 14
Male sex, n	5	8
Baseline VAS pain (0-100)	57 ± 23	51 ± 25
Baseline VISA-A score (0-100)	40 ± 17	41 ± 19

*VISA-A, Victorian Institute of Sport Assessment-Achilles.*

**TABLE 3. Comparative 6-month Improvements Between Patient-Guided and Ultrasound-Guided Groups**

Comparative 6-mo Improvement	No. of Cases, n	Patient Guided	Ultrasound Guided	<i>P</i>
Combined VAS (PF and CAT)	74	+38/100	+37/100	1.0
MFS	47	+20/100	+14/100	0.20
VISA-A	27	+35/100	+27/100	0.37

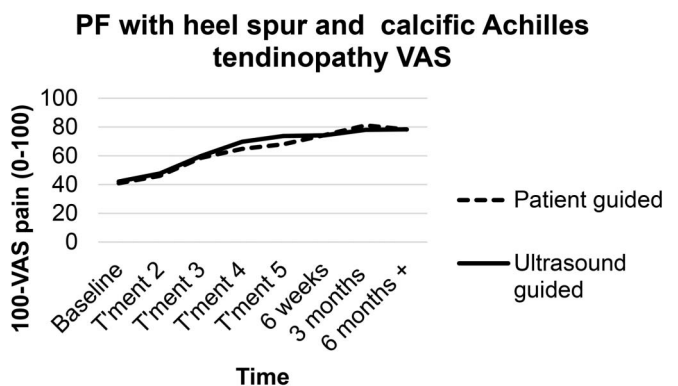
*CAT, calcific Achilles tendinopathy; PF, plantar fasciitis (with heel spur); VISA-A, Victorian Institute of Sport Assessment-Achilles.*

3 of the survey questions. There were no significant differences in patient impressions of the value of treatment between groups. Most participants felt their symptoms were “better,” with only 1 participant reporting a worsening of symptoms in response to question 1 (Figure 6). Overall, nearly half the participants reported they were undertaking more exercise after shock wave (Figure 7). Overall, although 13% of the subjects felt their symptoms were similar or worse, a greater number (23%) were doing less exercise after the study was completed (Figures 6 and 7). The reason for reduction in exercise despite improvement in symptoms can only be speculated as being due to life circumstances, which may not be related to the symptoms. The participants were everyday individuals rather than elite athletes with financial or competitive reasons to continue exercising. Over two-thirds of respondents felt that shock wave had “definitely” helped them, whereas only 1 felt it had made them worse (Figure 8). Less than a fifth of participants reported any pain or side effects of treatment. None of the side effects were serious—they included pain, minor skin damage (rash or bleeding), and tingling. No one required surgery or injectable medications. Ninety-seven percent of respondents felt that shock wave was helpful overall and reported they would have future treatments if needed.

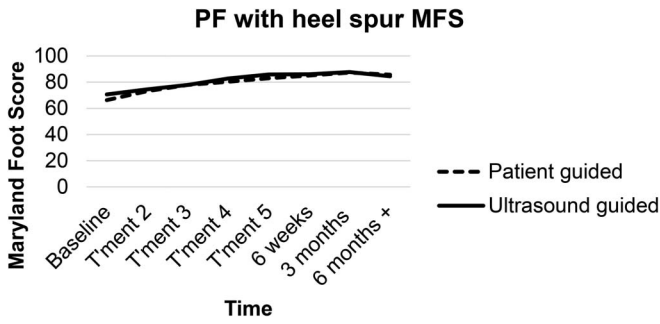
**DISCUSSION**

**Comparison of Groups**

Overall our study showed that there was no difference between UG and PG shock wave for either the superficial



**Figure 3.** Combined (PF with heel spur and calcific Achilles tendinopathy) VAS. Visual analog scale measurements were adjusted to mirror functional outcome measures. Thus, a positive change here and on all measures indicated improvement.



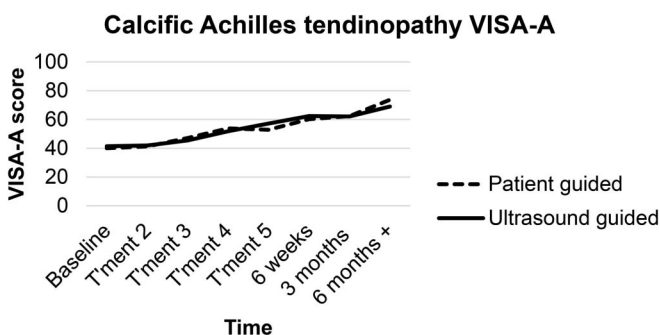
**Figure 4.** Maryland Foot Score (MFS) for plantar fasciitis (PF) with heel spur group. Functional outcome from baseline to final 6-month follow-up.

condition of CAT or the slightly deeper PF. Although UG techniques seem to be beneficial for calcific shoulder tendinopathies,<sup>14</sup> they do not seem to be required for foot and ankle pathology, which is more superficial.

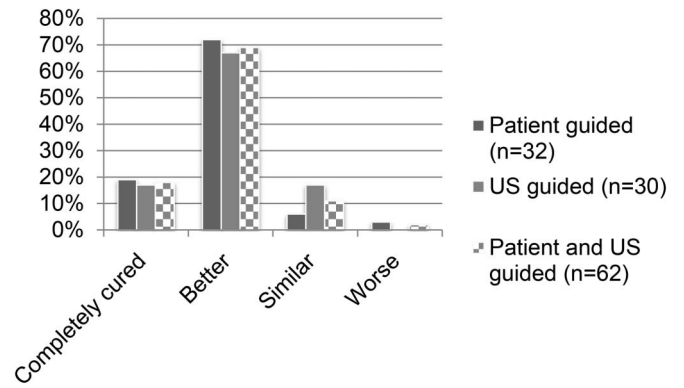
**Study Limitations**

There were some limitations of this study. From a comparison of treatments viewpoint, the major limitation was that the study was unblinded for both treating practitioners and patients. However, all patients and practitioners were aware that active treatment was being used, so there was no expectation that 1 arm would fail. The practitioners providing treatment in the study and referrers were shielded from the follow-up synthesis and statistical analysis for the period that patients were being recruited and treated. However, treating practitioners did discuss patient progress during follow-up treatments as part of routine clinical management (knowing which arm the patient was in), and therefore this shielding from results was not absolute.

Neither functional outcome measures were ideal for our study population that mainly comprised middle-aged, sedentary to moderately active individuals. The MFS was too focused on general disability when many of our patients with PF were not severely disabled. The lack of a validated disease-specific instrument for PF presents a similar problem encountered by other researchers.<sup>11</sup> By contrast, VISA-A is a validated tool for any clinically diagnosed Achilles tendinopathy regardless of site.<sup>17</sup> However, it assumed participation in high-level Achilles loading sports with most



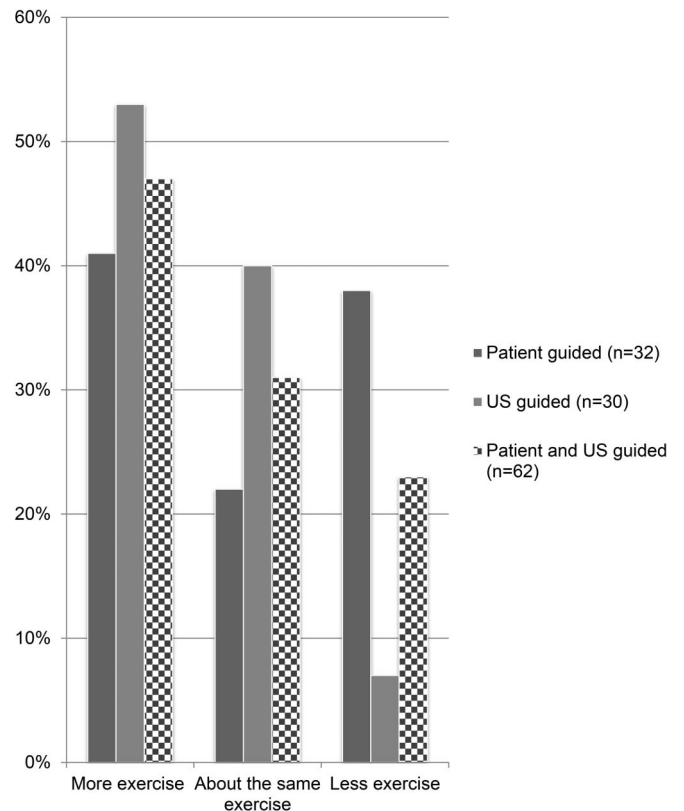
**Figure 5.** VISA-A (Victorian Institute of Sports Assessment-Achilles) for calcific Achilles tendinopathy.



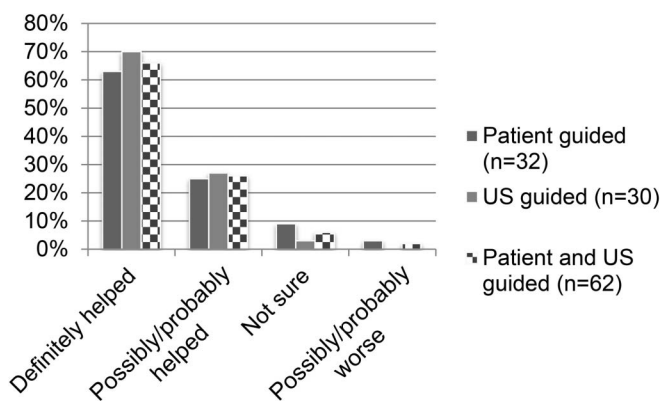
**Figure 6.** Question 1: how much better or worse are your symptoms compared with the time just before you had your first shock wave treatment?

questions focused on sport when many of these patients in fact did not play sport and were limited in activities of daily living (ie, everyday walking).

Approximately 90% (n = 74/82) of study participants completed all aspects of treatment and long-term follow-up. Patients had options of attending clinic or submitting email or postal correspondence to submit the final feedback. A user-friendly web-based tool such as “Survey Monkey” could be used for follow-up of similar future studies. Ease of completing results would be improved with



**Figure 7.** Question 3: how much exercise are you doing now compared with when you first started getting shock wave treatment?



**Figure 8.** Question 4: what is your impression of the value of the shock wave treatment in helping to relieve your symptoms?

web-based follow-up, although this may be counterbalanced by the greater ease of ignoring email reminders compared with phone calls and letters. We did improve follow-up by allowing an extension of up to 12 months to complete the 6-month follow-up, given we had some patients who were difficult to obtain responses from at exactly 6 months. The fact that a small number of patients completed their 6-month follow-up at closer to 12 months is a limitation, although we expect that there were unlikely to be treatment effects beyond the 6-month timeframe.

A further study limitation was the possibility of being underpowered to detect only a small difference between the treatment groups. We calculated a sample size of 37 per group (74 subjects total). Our power calculations after the final group numbers had been analyzed were a power of 0.90 in detecting a large difference between groups (at the 0.05 level of significance) and a power of 0.50 in detecting a moderate difference between the groups.<sup>21,22</sup> We therefore consider this study as being able to reliably rule out a large difference in treatment effect but not to have ruled out a small or moderate treatment effect. However, (to detect actual differences between the treatment groups) the power of the combined analysis was greater than the power when considering the individual pathologies only. Because PF and CAT are different pathologies, there is a limitation in combining them for analysis. However, we chose varieties that had in common the presence of a spur, and we also undertook analysis of the groups separately. Both PF and CAT tend to have the spur attached to the calcaneus (rather than within the soft tissue) and both tend to present in older patients with more chronic symptoms than PF or Achilles tendinopathy (AT) without calcific spurs.<sup>23</sup>

A small number of patients with bilateral pathology were included. Although each treatment site was randomized separately and treated as an independent case, it is possible that each case was not completely independent.

#### **Implications for Mechanism of Shock Wave Efficacy in the Heel**

Various studies of calcific supraspinatus tendinopathy showed superiority of imaging-guided ESWT directed at the calcific area, and they made a recommendation for navigation-guided

treatment with what they called as “appropriate shockwave generators.”<sup>6,14,24</sup> Although shock wave mechanism of action is still poorly understood, our study suggests that navigation of shock wave in the foot and ankle using ultrasound does not improve outcome. The implication is either that accuracy of shock wave without ultrasound is sufficient in the foot and ankle region, or, alternatively, that shock wave has an effect on surrounding (painful) soft tissue structures (possibly having impingement or high tissue pressure) rather than a direct effect on calcific spurs.

For calcific heel enthesopathies (PF and CAT), our study with moderate power found no difference between PG and UG results of shock wave therapy in terms of pain or function outcome at 3 or 6 months of follow-up.

#### **ACKNOWLEDGMENTS**

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