Treatment of Painful Heels Using Extracorporeal Shock Wave

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Background and purpose: Shock wave therapy has been shown to improve many tendinopathies at the tendon–bone junction. The purpose of this study was to investigate the safety and effectiveness of extracorporeal shock wave therapy for the treatment of painful heels.

Methods: Sixty-six patients, including 45 women and 21 men with an average age of 47.70 years (range, 19–75 years), were included in the study. Each patient received 1,000 impulses of shock waves at a 14-kV generator voltage at the affected site under local anesthesia. Twelve patients received a second treatment, and two patients received a third treatment.

Results: Of 58 patients with 6 weeks' follow-up, five (9%) were complaint-free, 21 (37%) were significantly better, 27 (47%) were slightly better, and five (9%) were unchanged. Of 41 patients with 12 weeks' follow-up, 11 (27%) were complaint-free, 22 (54%) were significantly better, seven (17%) were slightly better, and one (2%) was unchanged. The results at 12 weeks were much better than those at 6 weeks. The effect of shock waves on painful heels continued between 6 and 12 weeks. Twelve patients who did not respond favorably to the first treatment showed significantly better results after a second treatment. Two patients who had a third treatment also achieved satisfactory results. There were no device-related problems or systemic or local complications.

Conclusions: Extracorporeal shock wave therapy is a new modality that is safe and effective in the treatment of painful heel spurs.

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Key words:
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There is no consensus as to the exact cause of painful heel and the role of heel spurs in causing the pain. The most common site of heel pain is at the insertion of the most dense plantar aponeurosis on the medial tubercle of the calcaneal tuberosity [1]. The clinical diagnosis of painful heel spur is relatively straightforward, especially with radiographic evidence of a calcaneal spur; however, treatment can be difficult and frustrating. Conservative management is the treatment of choice, but where this fails, surgical intervention using either open or endoscopic release of the plantar fascia is recommended [2–4]. Many conservative modalities have had some success, including shoe inserts, orthotics, night splints, non-steroidal anti-inflammatory drugs (NSAIDs), local steroid injection, physical therapy, and exercise programs [2, 4, 5]. Recently, extracorporeal shock wave therapy has shown success in the alleviation of painful heels and other orthopedic conditions such as tennis elbow, calcifying tendinopathy of the shoulder, and nonunion fractures of the long bones [6–8].

The purpose of this prospective clinical study was to investigate the effect of extracorporeal shock wave therapy in painful heels.

Patients and Methods

Patients were recruited between August 1998 and March 1999. Eligible patients had refractory painful heel spurs that failed to respond to conservative treatment for at least 6 months, and were considering surgery as an alternative option. Conservative treatments included either a single modality or a combination of modalities, including NSAIDs, shoe inserts, orthotics, night splints, corticosteroid injection, physical therapy, heel exercise programs, and herbal medicine. Patients were excluded if they had had symptoms for less than 6 months, if they had systemic or local infection, diabetes

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mellitus, obstructive peripheral vascular disease, or metabolic disease such as gout, or if they were pregnant or less than 18 years old.

All patients gave written informed consent after the details of the procedure and the potential risks in connection with it were fully discussed. Patients discontinued all current treatments for 2 weeks.

The procedure was performed in an outpatient setting, with the patient in the supine position under local anesthesia (2% xylocaine). Extracorporeal shock waves were generated using the HeathTronic OssaTon Orthopedic Lithoptripter (High Medical Technology, Kruezlinger GW, Switzerland). The location and depth of the treatment area were adjusted by the control guide, and surgical lubrication gel was applied to the contact area before treatment. Each patient was given 1,000 impulses of shock waves at 14 kV (generator voltage) to the affected heel. Vital signs and complaints about the heel were monitored throughout the course of treatment. Immediately after treatment, the affected heel was checked for discoloration, swelling, ecchymosis, hematoma, etc., and patients were discharged with an ice pack and non-narcotic analgesics. No NSAIDs were prescribed.

Follow-up examinations were scheduled at 6, 12, and 24 weeks after the procedure. The intensity of pain was measured using the visual analog scale [9] from 0 to 10, with 10 indicating no pain and 0 indicating severe pain. A 100-point scoring system — 70 points for pain and 30 points for function — was used for clinical evaluation (Table 1). Data are presented as the mean ± standard deviation. Results were analyzed by paired *t*-test, and statistical significance was set at a value of less than 0.05. Results at the 24-week follow-up and for patients who underwent a second procedure were analyzed by the Wilcoxon signed rank test.

Table 1. The 100-point clinical scoring system

Category	Points
Pain score (70 points)	
Level walking (0–45 points)	
Distance	
0 m	0
< 100 m	15
< 1,000 m	30
> 1,000 m	45
Run-up pain (0–5 points)	
Yes	0
No	5
Pressure pain (0–20 points)	
No pain	20
Severe pain	0
Functional score (30 points)	
Work (0–10 points)	
No restriction	10
Severe restriction	0
Free time/sports (0–10 points)	
No restriction	10
Severe restriction	0
Sleep (0–10 points)	
No restriction	10
Severe restriction	0

Results

From August 1998 to March 1999, 66 patients (45 women and 21 men) with an average age of 47.7 years (range, 19–75 years) were enrolled in this study. Thirty-four had an affected right heel and 32 an affected left heel. The average duration of disease was 11.97 (6–36). Twelve patients underwent a second treatment and two patients underwent a third treatment.

There were no cases of systemic or local complications such as hematoma or ecchymosis that required special attention, nor were there any device-related problems. Approximately three-quarters of the patients required no pain medication, and none required narcotic analgesics.

Fifty-eight patients completed the 6-week follow-up evaluation. The average intensity of pain using the visual analog scale was 2.38 ± 0.97 before treatment, and 5.76 ± 2.03 after treatment ($p < 0.001$). The average total pain score was 23.83 ± 14.03 before treatment, and 48.97 ± 14.64 after treatment ($p < 0.001$). The pre- and post-treatment differences in pain score on level walking, run-up pain, and pressure pain were also statistically significant ($p < 0.001$). The average functional score was 14.81 ± 4.30 before treatment, and 22.86 ± 5.06 after treatment ($p < 0.001$). The difference between pre-treatment and post-treatment functional scores, including pain at work, pain during free time including sports, and pain during sleep, were statistically significant ($p < 0.001$). The overall results are summarized in Table 2. Thirty-five of 58 heels (61%) showed at least a 50% improvement, and none showed worse pain.

Forty-one patients completed the 12-week follow-up evaluation. The average intensity of pain using the visual analog scale was 2.49 ± 0.90 before treatment, and 7.63 ± 1.98 after treatment ($p < 0.001$). The average total pain score was 25.93 ± 15.16 before treatment, and 61.20 ± 12.12 after treatment ($p < 0.001$). The improvements in distance of level walking, run-up pain, and pressure pain before and after treatment were statistically significant ($p < 0.001$). The average functional score was 14.98 ± 3.80 before treatment, and 26.68 ± 3.77 after treatment ($p < 0.001$). The improvements in pain scores at work, during free time including sports, and during sleep were statistically significant ($p < 0.001$). The overall results are summarized in Table 2. Thirty-six of 41 heels (87.8%) showed at least a 50% improvement, and none showed worse symptoms.

For these 41 patients, results at 6 and 12 weeks were compared (Table 3). There was a significant difference in both visual analog pain scores ($p < 0.001$) and average total pain scores ($p < 0.001$). The improvements in level walking distance, run-up pain, and pressure pain between 6 and 12 weeks were statistically significant ($p < 0.001$). The average functional score was 23.98 ± 4.77 at 6 weeks, and 26.68 ± 3.77 at 12 weeks ($p < 0.001$). The improvements in pain at

Table 2. Status of heel pain at 6 and 12 weeks after extracorporeal shock wave treatment

Pain level	6 weeks, No. (%) (n = 58)	12 weeks, No. (%) (n = 41)
Complaint-free	5 (9)	11 (27)
Significantly better	21 (36)	22 (54)
Slightly better	27 (47)	7 (17)
Unchanged	5 (9)	1 (2)

work, during free time including sports, and during sleep were significantly better at 12 weeks than at 6 weeks ($p < 0.001$). At least a 50% improvement was noted in 30 heels (74%) by 6 weeks, and 36 heels (87.8%) by 12 weeks. It appeared that the effect of shock wave on painful heels continued between 6 and 12 weeks.

Seven patients completed the 24-week follow-up evaluation. The average visual analog pain scores, total pain scores, and functional scores were significantly better after treatment than before ($p < 0.05$). Although the numbers were too small for definite conclusion, overall, two patients were complaint-free (29%), four were significantly better (57%), and one was slightly better (14%). Six of seven cases (86%) showed at least a 50% improvement, and none showed worse symptoms.

Twelve patients underwent a second treatment 30 to 50 days after the first treatment. The average visual analog pain score was 2.17 ± 1.27 after the first treatment, and 3.58 ± 1.44 after the second treatment ($p = 0.016$). The average total pain score was 22.17 ± 15.84 after the first treatment, and 39.42 ± 14.61 after the second treatment ($p = 0.005$). The improvements in level walking distance, run-up pain, and pressure pain after the second treatment were statistically significantly better than those after the first treatment ($p = 0.014$, 0.020, and 0.028, respectively). The average functional score was 15.58 ± 5.71 after the first treatment, and 19.92 ± 3.78 after the second treatment ($p = 0.033$). The improvement in pain at work was significant ($p = 0.048$), but the changes in pain during free time including sports and pain during sleep were not statistically significant ($p = 0.064$ and 0.261, respectively). Two patients who underwent three treatments showed improvements in pain relief and function after the third treatment.

Table 3. Comparison of results for 41 patients at 6 and 12 weeks after extracorporeal shock wave treatment for painful heel spurs

Variable	6 weeks	12 weeks	*p* value
Pain score	51.78 ± 14.14	61.20 ± 12.12	< 0.001
Functional score	23.98 ± 4.77	26.68 ± 3.77	< 0.001
VAS	6.34 ± 2.07	7.63 ± 1.98	< 0.001
Complaint-free	6 (15)	11 (27)	
Significantly better	17 (41)	22 (54)	
Slightly better	15 (37)	7 (17)	
Unchanged	3 (7)	1 (2)	

VAS = visual analog pain score [9]. Data are mean ± standard deviation of the number of heels (%).

Discussion

The exact cause of painful heels is unknown, although a degenerative process with inflammatory reaction may play an important role. The calcaneal spur may be an incidental radiographic finding, and its relationship to heel pain is unclear [1, 4]. The goals of treatment are to alleviate pain and restore function. The results from conservative treatment vary and there is no uniform opinion on the best method of treatment of painful heels [1]. Likewise, the results of surgery by either open or endoscopic plantar fascia release are inconsistent, although 80% satisfactory results are reported in most series [2–4]. In patients in whom conservative treatment has failed, surgery used to be the only choice, but its success rate barely exceeds that of shock wave therapy; surgery remains an option if shock wave therapy fails [6].

The mechanism of shock wave therapy is not yet known. However, the effect of extracorporeal shock waves has been proven in the treatment of pseudoarthrosis with a 75% success rate, and a positive effect has been reported in tennis elbow, calcifying tendinitis of the shoulder, and heel spurs [10, 11]. Rompe et al demonstrated a dose-dependent change in the tendon and paratendon after extracorporeal shock wave in a rabbit model [11]. They also compared 1,000 impulses of extracorporeal shock wave therapy of 0.06 mJ/mm^2 three times at weekly intervals with placebo, and concluded that there was significant alleviation of pain and improvement in function in shock wave-treated patients [7].

The early clinical results of our study were very encouraging, with 45% of heels achieving complete or nearly complete improvement, and 47% achieving partial improvement by 6 weeks; 80% achieved complete or nearly complete improvement and 17% achieved partial improvement by 12 weeks. Only one patient (2%) did not respond, and none became worse. When the results at 12 weeks were compared with those at 6 weeks, the improvement in pain relief and functional restoration were statistically significant. Thus, the effect of shock wave treatment on painful heels continued between 6 and 12 weeks. The effect of shock wave treatment between 12 and 24 weeks is unknown because the number of patients who completed the 24-week follow-up was too small for statistical significance. Twelve patients who did not have good results from the first treatment responded favorably to the second treatment. Two patients who had three treatments also showed significant improvements after the third treatment. It appears that repeated application of shock wave in the treatment of painful heels can be beneficial.

In conclusion, treatment of painful heels with extracorporeal shock wave produced a high rate of success in pain relief and functional restoration, and negligible complications. Extracorporeal shock wave is a safe and effective new therapeutic modality for the treatment of painful heels.

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