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Treatment of Painful Heel Syndrome With Shock Waves

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In a prospective clinical study, the effectiveness of shock waves on painful heel syndrome in 80 patients (20 men and 60 women) with an average age of 48 years was investigated. Six patients had bilateral treatments. Each treatment consisted of 1000 impulses of shock waves at 14 kV. A 100-point scoring system (70 points for pain and 30 points for function) was used for evaluation. The intensity of pain was measured with a visual analog scale from 0 to 10. The overall results were no complaints in 20.6%, significantly better in 52.9%, slightly better in 17.6%, and unchanged in 8.8% of 64 patients (68 heels) with 12 weeks followup; no complaints in 59.3%, significantly better in 27.7%, slightly better in 13% of 52 patients (54 heels) with 6 months followup. None of patients' symptoms became worse. Seventeen patients (18 heels) who did not respond favorably to the first treatment had significantly better results after a second treatment. There were no device-related problems, and no systemic or local complications. Shock wave treatment is a new modality of therapy that is safe and effective in the treatment of patients with painful heel syndrome.

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There is no consensus as to the exact cause of painful heel syndrome or the role of heel spur in the causation of heel pain. Because the most common site of heel pain is the insertion of the dense plantar aponeurosis on the medial tubercle of the calcaneal tuberosity, the term plantar fasciitis often is used.[9] The clinical diagnosis of painful heel syndrome is relatively straightforward and is confirmed with radiography. However, the treatment can be difficult and frustrating. There is little argument that conservative treatment is the initial treatment of choice.

Conservative treatment with shoe inserts, orthotics, night splints, nonsteroidal antiinflammatory drugs, local steroid injection, physical therapy, or an exercise program has provided some success.[1,5,10] In patients in whom conservative treatment fails, surgical intervention with either an open or an endoscopic release of the plantar fascia is recommended.[1,3,10]

Recently, shock wave therapy has been introduced for the alleviation of painful heel syndrome and other orthopaedic conditions such as tennis elbow, calcifying tendinopathy of the shoulder, and nonunion of fractures of the long bones.[4,7,11] The purpose of the current clinical study was to investigate prospectively the effect of shock waves on painful heel syndrome.

MATERIALS AND METHODS

From August 1998 to May 1999, 80 patients (86 heels) were enrolled in a prospective clinical study to evaluate the effect of shock waves on painful heel syndrome. Six patients had bilateral involvement. The inclusion criteria included patients with refractory painful heel syndrome with an inadequate response to conservative treatment provided for at least 6 months who otherwise might consider surgery as an alternative. The conservative treatments included a combination of nonsteroidal antiinflammatory drugs, shoe inserts, prescribed orthotics, night splints, corticosteroid injections, physical therapy, heel exercise program, and herbal medicines. The exclusion criteria included patients with symptoms and conservative treatments for less than 6 months, systemic or local infection, diabetes mellitus, obstructive peripheral vascular disease, metabolic disease such as gout, pregnancy, and patients younger than 18 years.

Shock wave treatment was provided with an OssaTron (High Medical Technology, Kreuzlingen, Switzerland). All patients signed an informed consent form. The details of the procedure and potential risks were discussed fully before treatment. Patients discontinued all other treatments for at least 2 weeks before shock wave treatment. The outpatient procedure was done with the patient in a supine or prone position using local anesthesia (2% xylocaine).

The location of the treatment area was adjusted with a control guide. Surgical lubrication gel was applied to the contact area before treatment. Each patient was given 1000 impulses of shock waves at 14 kV (0.18 mJ/mm^2 energy flux density) generator voltage to the affected heel. Seventeen patients (18 heels) also received a second treatment. The vital signs and patient's heel pain were monitored throughout the course of treatment. Immediately after treatment, the affected heel was checked for discoloration, swelling, ecchymosis, or hematoma. The patients were discharged with an ice pack and nonnarcotic analgesics. Nonsteroidal antiinflammatory drugs were not prescribed.

Followup examinations were scheduled for 6, 12, and 24 weeks after treatment. The intensity of pain was measured with a visual analog scale from 0 to 10, with 10 being the absence of pain and 0 indicating severe pain. The visual analog scale scores were reversed for keeping a scoring system consistent with the other scoring parameters. This change did not alter or affect the statistical significance of the study. A 100-point scoring system that included 70 points for the pain score and 30 points for the functional score was used for clinical evaluation. The scoring system is shown in Table 1.

TABLE 1. A 100-Point Scoring System Used in Clinical Evaluation

I. Pain Scores (70 Points)

1. Pain on maximal distance for level walking (0–45 points)

Distance	Points
0 meter	0
<100 meters	15
<1000 meters	30
>1000 meters	45

2. Pain when the patient begins to walk (0–5 points),

Yes	0
No	5

3. Pressure pain (0–20 points),
   (0 point for severe pain; 20 points for no pain)

II. Functional Scores (30 Points)

1. Pain at work (0–10 points)
   (0 for severe restriction; 10 points for no restriction)
2. Pain during activities of daily living including sports (0–10 points)
   (0 for severe restriction; 10 points for no restriction)
3. Pain at night (0–10 points)
   (0 for severe restriction; 10 points for no restriction)

Eighty patients (60 women and 20 men) with an average age of 48 years (range, 19–75 years) were included in the current study. The right heel was affected in 38 patients and the left heel was affected in 42 patients. Six patients had bilateral involvement. The average duration of the condition was 12 months (range, 6–36 months). Seventeen patients (18 heels) also received a second treatment.

RESULTS

Six patients (six heels) were excluded because of inadequate followup. The remaining 74 patients (80 heels) were included in the analysis 6 weeks after treatment. The results were analyzed statistically by a paired t test with statistical significance at $p < 0.05$. The average visual analog scales on the intensity of pain was 2.9 ± 1.2 before treatment and 5.7 ± 2.0 after treatment ($p < 0.001$). The average total pain scores were 29.3 ± 14.6 before treatment and 49.2 ± 13.9 after treatment ($p < 0.001$). The differences of pain scores before and after treatment for level walking, pain when the patient begins to walk, and pressure pain were statistically significant ($p < 0.001$). The average functional scores were 15.2 ± 4.6 before treatment and 21.6 ± 6.0 after treatment ($p < 0.001$). The differences of various functional scores including pain at work, pain during activities of daily living including sports, and pain at night between the patient's status before treatment and after treatment were statistically significant ($p < 0.001$). The overall results by 6 weeks were no complaints in six patients (six heels) (7.5%), significantly better in 23 patients (25 heels) (31.3%), slightly better in 35 patients (38 heels) (47.5%), and unchanged in 10 patients (11 heels) (13.8%). Forty-three of 80 heels (53.7%) had at least 50% improvement and no patients complained of more severe pain.

Sixty-four patients (68 heels) completed followup evaluations at 12 weeks. The results were analyzed statistically by a paired t test with statistical significance at $p < 0.05$. The average visual analogue scales on the intensity of pain were 2.9 ± 1.3 before treatment and 7.3 ± 2.0 after treatment ($p < 0.001$). The average total pain scores were 29.3 ± 14.9 before treatment and 59.9 ± 11.8 after treatment ($p < 0.001$). Improvements in the maximum distance for level walking, pain when the patient begins to walk, and pressure pain before and after treatments were statistically significant ($p < 0.001$). The average functional scores were 15.9 ± 4.4 before treatment and 25.7 ± 6.0 after treatment ($p < 0.001$). The differences of various functional scores including pain at work, pain during activities of daily living including sports, and pain at night between before treatment and after treatment were statistically significant ($p < 0.001$). The overall results were no complaints in 14 patients (14 heels) (20.6%), significantly better in 34 patients (36 heels) (52.9%), slightly better in 10 patients (12 heels) (17.6%), and unchanged in six patients (six heels) (8.8%). Fifty-three of 68 heels (78%) had at least 50% improvement and none of the patients' symptoms became worse.

Fifty-two patients (54 heels) had been followed up for 6 to 9 months. The results were compared statistically with a paired t test with statistical significance at $p < 0.05$. The average visual analog scales on the intensity of pain were 2.7 ± 1.2 before treatment and 8.7 ± 1.9 after treatment ($p < 0.001$). The average total pain scores were 28.1 ± 15.2 before treatment and 65.3 ± 9.9 after treatment ($p < 0.001$). Improvements in maximum distance for level walking, pain when the patient begins to walk, and pressure pain before and after treatment were statistically significant ($p < 0.001$). The average functional scores were 16.1 ± 4.5 before treatment and 28.2 ± 3.2 after treatment ($p < 0.001$). The differences of various functional scores including pain at work, pain during activities of daily living including sports, and pain at night between before treatment and after treatment was statistically significant ($p < 0.001$). The overall result were no complaints in 32 patients (32 heels) (59.3%), significantly better in 14 patients (15 heels) (27.7%), and slightly better in six patients (seven heels) (13%). Forty-nine of 54 heels (90.7%) had at least 50% improvement and none of the patients' symptoms became worse.

The overall results at 6 weeks, 3 months, and 6 months are summarized in Table 2.

The results of 64 patients (68 heels) at 12 weeks were compared statistically with their results at 6 weeks. The visual analog pain scales were 6.0 ± 1.8 at 6 weeks, and 7.2 ± 1.9 at 12 weeks ($p < 0.001$). The average total pain scores were 51.3 ± 12.6 at 6 weeks, and 59.7 ± 11.9 at 12 weeks ($p < 0.001$). The improvement in maximum distance for level walking pain when the patient begins to walk, and pressure pain by 12 weeks as compared with 6 weeks was statistically significant ($p < 0.001$). The average functional scores were 22.9 ± 5.0 at 6 weeks, and 25.6 ± 4.4 at 12 weeks ($p < 0.001$). The differences in the scores for pain at work, pain during activities of daily living including sports, and pain at night were statistically significant for improvement at 12 weeks ($p < 0.001$). The comparison in the results between 6 and 12 weeks are summarized in Table 3. At least 50% improvement was seen in 41 of 68 heels (60.3%) by 6 weeks, and 53 of 68 heels (78%) by 12 weeks. It seemed that the effect of shock waves on painful heel syndrome continued to improve from 6 to 12 weeks.

The results of 52 patients (54 heels) at 6 months were compared statistically with their results at 3 months. The visual analog pain scales were 7.3 ± 1.9 at 3 months, and 8.7 ± 1.9 at 6 months ($p < 0.001$). The average total pain scores were 60.3 ± 11.8 at 3 months, and 65.2 ± 9.9 at 6 months ($p < 0.001$). The improvement in the maximal distance for level walking, pain when the patient begins to walk, and pressure pain by 6 months as compared with 3 months was statistically significant ($p < 0.001$). The average functional scores were 26.0 ± 4.0 at 3 months, and 28.1 ± 3.3 at 6 months ($p < 0.001$). The improvements in the scores of pain at work, pain during activities of daily living including sports, and pain at night were statistically significant ($p < 0.001$). The comparison in the results between 3 and 6 months are summarized in Table 3. At least 50% improvement was observed in 43 of 68 heels (79.6%) by 3 months and in 49 of 54 heels (90.7%) at 6 months. It seemed that the effect of shock waves on painful heel syndrome continued to improve from 3 to 6 months and is time-dependent.

Seventeen patients (18 heels) had a second treatment 30 to 50 days after the first treatment. The improvement between the first and the second treatments were compared statistically with a Wilcoxon signed ranks test with statistical significance at $p < 0.05$. The average visual analog pain scales were 2.4 ± 1.3 after the first treatment, and 3.8 ± 1.4 after the second treatment ($p = 0.006$). The average total pain scores were 24.8 ± 15.0 after the first treatment, and 39.3 ± 15.0 after the second treatment ($p = 0.003$). The improvements in the maximum distance for level walking, pain when the patient begins to walk, and pressure pain after the second treatment as compared with the first treatment were statistically significant ($p < 0.05$). The average functional scores were 14.2 ± 4.4 after the first treatment, and 17.3 ± 4.1 after the second treatment ($p = 0.014$). The improvement in the scores for pain

TABLE 2. Overall Results at 6 Weeks, 12 Weeks, and 6 Months After Shock Wave Treatment for Painful Heel Syndrome

Parameters	Followup 6 Weeks	Followup 12 Weeks	Followup 6 Months
Number of patients/heels	74/80	64/68	52/54
Complaint free	6 (7.5%)	14 (20.6%)	32 (59.3%)
Significantly better	25 (31.3%)	36 (52.9%)	15 (27.7%)
Slightly better	38 (47.5%)	12 (17.6%)	7 (13.0%)
Unchanged	11 (13.8%)	6 (8.8%)	—

TABLE 3. A Comparison of Results in 68 Cases at 6 and 12 Weeks, 54 Cases at 3 and 6 Months After Shock Wave Treatment for Painful Heel Syndrome

Parameters	Followup 6 Weeks	Followup 12 Weeks	Followup 3 Months	Followup 6 Months
Number of patients/heels	64/68	64/68	52/54	52/54
Pain scores	51.3 ± 12.6	59.7 ± 11.9	60.3 ± 11.8	65.2 ± 9.9
Functional scores	22.9 ± 5.0	25.6 ± 4.4	26.0 ± 4.0	28.1 ± 3.3
Visual analog scale	6.0 ± 1.8	7.2 ± 1.9	7.3 ± 1.9	8.7 ± 1.9
Complaint free	6 (8.8%)	13 (19.1%)	11 (20.3%)	31 (57.4%)
Significantly better	24 (35.3%)	37 (54.4%)	29 (53.7%)	15 (27.8%)
Slightly better	32 (47.1%)	12 (17.7%)	9 (16.7%)	8 (14.8%)
Unchanged	6 (8.8%)	6 (8.8%)	5 (9.3%)	

at work and pain during activities of daily living including sports and pain at night was statistically significant after the second treatment as compared with the first treatment ($p < 0.05$). It seemed that a second treatment for painful heel syndrome was beneficial regardless of the results of the initial treatment.

No systemic or local complications such as hematoma or ecchymosis occurred for which the patients required special attention or treatment. There were no device-related problems. Approximately 75% of the patients required only mild pain medication such as acetaminophen, and no patients received narcotic analgesics.

DISCUSSION

The exact cause of painful heel syndrome is unknown, although degenerative processes with an inflammatory reaction may play an important role. The calcaneal spur may be an incidental finding on radiographs, and its relationship to heel pain is unclear.[9,10] The goals of any treatment are to alleviate pain and restore function. The results from conservative treatment vary and there is no agreement on the best method of treatment.[9] Likewise, the results of surgery with either an open or an endoscopic plantar fascia release also are inconsistent, although satisfactory results are reported in as many as 80% of patients in several series.[1,3,10] In patients in whom conservative treatment has failed, surgery has been the only alternative, but its success rate barely exceeds that of shock wave therapy, and surgery still can be performed if shock wave therapy fails.[4]

The mechanism of shock wave therapy is not yet known. However, the value of shock waves has been proven in the treatment of pseudarthrosis with a 75% success rate, and there is a positive effect in tennis elbow, calcifying tendinitis of the shoulder, and painful heel syndrome.[2,4,6–8,11] Rompe et al [6] showed dose-dependent changes in the tendon and paratenon after shock waves in an experimental rabbit Achilles tendon model. Rompe et al[7] compared the results of 15 patients with painful heels treated with 1000 impulses of extracorporeal shock waves therapy of 0.06 mJ/mm^2 given three times at weekly intervals with the results of equal number of patients treated with placebo and concluded that there was significant alleviation of pain and improvement of function in patients who were treated with shock waves.

The early clinical results of the current study were very encouraging with 38.8% of patients having complete or nearly complete resolution and 47.5% of patients having partial improvement by 6 weeks; 73.5% of patients had complete or nearly complete resolution and 17.6% had partial improvement by 12 weeks. In addition, at 6 months, 87% of patients had complete or nearly complete resolution, 13% had partial improvement and none of the patients' symptoms became worse. When the results at 12 weeks were compared with the results at 6 weeks, the improvements in pain relief and functional restoration were statisti-

cally significant. The improvements in pain relief and function restoration also were statistically significant when the results at 6 months were compared with those at 3 months.

The authors observed that after shock wave treatment for painful heel syndrome, the symptoms may continue to improve from 6 weeks to 6 months and the effects of shock wave seem to be time-dependent. Seventeen patients (18 heels) in whom initial shock wave treatment failed, responded favorably to a second treatment. It seemed that repeated shock wave treatment can be beneficial for patients with painful heel syndromes and has a positive cumulative effect.

Treatment of painful heel syndrome with shock waves has produced a high rate of success in pain relief and functional restoration with negligible complications. Shock wave therapy is a new therapeutic modality that is safe and effective in the treatment of patients with painful heel syndrome.

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