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Evaluation of Low-Energy Extracorporeal Shock-Wave Application for Treatment of Chronic Plantar Fasciitis

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Background: Although the application of low-energy extracorporeal shock waves to treat musculoskeletal disorders is controversial, there has been some limited, short-term evidence of its effectiveness for the treatment of chronic plantar fasciitis.

Methods: From 1993 to 1995, a prospective, two-tailed, randomized, controlled, observer-blinded pilot trial was performed to assess whether three applications of 1000 impulses of low-energy shock waves (Group I) led to a superior clinical outcome when compared with three applications of ten impulses of low-energy shock waves (Group II) in patients with intractable plantar heel pain. The sample size was 112. The main outcome measure was patient satisfaction according to a four-step score (excellent, good, acceptable, and poor) at six months. Secondary outcome measures were patient satisfaction according to the four-step score at five years and the severity of pain on manual pressure, at night, and at rest as well as the ability to walk without pain at six months and five years.

Results: At six months, the rate of good and excellent outcomes according to the four-step score was significantly (47%) better ($p < 0.0001$) in Group I than in Group II. As assessed on a visual analog scale, the score for pain caused by manual pressure at six months had decreased to 19 points, from 77 points before treatment, in Group I, whereas in Group II the ratings before treatment and at six months were 79 and 77 points ($p < 0.0001$ for the difference between groups). In Group I, twenty-five of forty-nine patients were able to walk completely without pain at six months compared with zero of forty-eight patients in Group II ($p < 0.0001$). By five years, the difference in the rates of good and excellent outcomes according to the four-step score was only 11% in favor of Group I ($p = 0.071$) because of a high rate of good and excellent results from subsequent surgery in Group II; the score for pain caused by manual pressure had decreased to 9 points in Group I and to 29 points in Group II ($p = 0.0006$ for the difference between groups). At five years, five (13%) of thirty-eight patients in Group I had undergone an operation of the heel compared with twenty-three (58%) of forty patients in Group II ($p < 0.0001$).

Conclusions: Three treatments with 1000 impulses of low-energy shock waves appear to be an effective therapy for plantar fasciitis and may help the patient to avoid surgery for recalcitrant heel pain. In contrast, three applications of ten impulses did not improve symptoms substantially.

A painful heel, often combined with an inferior calcaneal spur, is a common orthopaedic syndrome[1-5]. The cause of this clinical entity remains enigmatic. The use of conservative methods, with a stretching protocol regarded as the mainstay of nonoperative treatment, alleviates the condition in most patients[6-9] . When conservative treatment has failed, surgical release of the plantar fascia has been undertaken with variable results[10-12].

To our knowledge, the first paper reporting favorable results after application of shock waves for the treatment of painful heel syndrome was published in 1996[13]. Since then, there have been only a few reports of the short-term results of the application of low-energy extracorporeal shock waves as a new nonsurgical treatment of chronic plantar fasciitis[14-17]. The exact mechanism of action of this modality is unclear[18].

The current study was designed to compare the six-month and five-year results of three applications of 1000 impulses with those of three applications of ten impulses of low-energy extracorporeal shock waves to the painful heel.

Materials and Methods

Study Design

A prospective, two-tailed, randomized, controlled, observer-blinded pilot trial was performed to compare the outcomes of three applications of 1000 impulses of low-energy shock waves with those of three applications of ten impulses of

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low-energy shock waves in patients with intractable heel pain. One hundred and nineteen patients (fifty-one female and sixty-eight male; mean age, forty-six years) who had had pain for a mean of nine months (range, six to twenty months) were eligible for the study. All 119 patients had been previously treated unsuccessfully. Eighty patients had been given medication, mostly nonsteroidal anti-inflammatory drugs; 110 had worn shock-absorbing shoe inserts; forty-two had performed some kind of stretching exercises on a regular basis; nineteen had used night splints; and eighty-one had been treated with a cast for at least two weeks. An average of 1.9 corticosteroid injections (range, one to five injections) had been given to the 119 patients, and an average of three different physical therapy regimens (range, one to five different regimens), such as icing, ultrasound, magnetic field therapy, iontophoresis or phonophoresis, contrast baths, and radiation therapy, had been tried. One hundred and twelve patients agreed to the randomization procedure, and they formed the study sample.

Inclusion Criteria

The criterion for entry into the study was heel pain localized to the site of the insertion of the plantar fascia and intrinsic muscles on the medial calcaneal tuberosity on the anteriormedial aspect of the heel for more than six months. The severity of the pain was recorded, and a low pain score was not an exclusion criterion. The location of the pain was tested by exerting pressure on the heel under sonographic control. Conservative therapy had to have failed for at least six months before referral to our hospital. In order to allow positioning of the shock-wave focus, a plantar heel spur had to be seen radiographically in the area of the medial calcaneal tuberosity. The size of the spur did not play a role as an inclusion criterion.

Exclusion Criteria

The exclusion criteria, elicited from the patient's medical record, included dysfunction of the knee or ankle, local arthritis, generalized polyarthritis, rheumatoid arthritis, ankylosing spondylitis, Reiter syndrome, neurologic abnormalities, nerve entrapment syndrome, a previous operation on the heel, an age under eighteen years, pregnancy, an infection, or a tumor. Thirteen patients were excluded from the study on the basis of these criteria.

Except for previously worn shoe inserts, no additional treatment—for example, nonsteroidal anti-inflammatory drugs—was allowed during the first three months after application of the extracorporeal shock waves. Three patients in Group I and seven in Group II took such drugs; this was regarded as indicating failure of the extracorporeal shock-wave application, and the patients were withdrawn from the study. They were instructed to use the foot but to avoid painful stress.

Randomization

After six weeks with no treatment of any kind and after they gave informed consent, the patients were evaluated again to make sure that no exclusion criteria applied. Then they were randomized into the two treatment groups with use of identical sealed envelopes. The first application of shock waves was carried out immediately after the identification of the treatment group.

The randomization began in 1993 and, as had been planned previously, was stopped (in 1995) after fifty patients in one of the two groups had not used additional treatment or drugs for three months after shock-wave application (Fig. 1).

Group I

Group I received a total of 3000 impulses of an energy flux density of 0.08 mJ/mm^2. The group consisted of twenty-one women and twenty-nine men, with a mean age of forty-four years (range, twenty-six to sixty-one years). The mean duration of pain was eight months (range, six to nineteen months).

Group II

Group II received a total of thirty impulses of an energy flux density of 0.08 mJ/mm^2. There were twenty women and thirty men, and their mean age was forty-nine years (range, thirty-one to sixty-three years). The mean duration of pain was ten months (range, six to twenty months).

Method of Treatment

Extracorporeal shock waves were applied by an experimental device (Siemens Osteostar; Siemens AG, Erlangen, Germany) characterized by the integration of an electromagnetic shock-wave generator in a mobile fluoroscopy unit. By means of an acoustic lens, the focus of the shock-wave source is just at the center of the c-arm. The typical cigar-shaped focal extent of the device, defined as the –6 dB focal contour in the x, y, and z directions around the focus location, covers an area of 50 mm in the axis of the shock wave, with a diameter of 7.0 mm perpendicular to the shock-wave axis. These technical parameters are very comparable with those of modern shock-wave units for treatment of musculoskeletal disorders.

Once the tip of the plantar heel spur was situated in the center of the c-arm, the shock-wave unit was docked to the foot by means of a water-filled cylinder. Common ultrasound gel (University Hospital, Mainz, Germany) was used as a contact medium between the cylinder and the skin. Three times, at weekly intervals, 1000 or ten impulses of an energy flux density of 0.08 mJ/mm^2 were administered to the heel; this dose was selected on the basis of experience in an earlier study[19]. Shock waves are considered low-energy when the energy flux density ranges from 0.05 to 0.10 mJ/mm^2, making the use of local anesthetics unnecessary, although the treatment is unpleasant.

Method of Evaluation

All patients were assessed before and after treatment. At a mean of twenty-four weeks (range, twenty-two to twenty-six weeks) after the last application of the extracorporeal shock waves, follow-up was performed by a blinded observer, an orthopaedic surgeon who had not been involved in the selection of the patients or in the shock-wave treatment and who did not ask the patients about the number of impulses applied.

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Another blinded observer, also an orthopaedic surgeon, performed another follow-up examination at a mean of five years (range, fifty-four to sixty-six months). The protocols of treatment and evaluation were closely monitored to guarantee that the treating physician did not evaluate his or her patients at the time of follow-up.

Primary Outcome Measure

The primary outcome measure was defined prospectively as the pain rating at six months after shock-wave application compared with the pretreatment condition. The rating, according to modified criteria of the Roles and Maudsley score[20], was defined as excellent (no pain, patient satisfied with the treatment outcome, and unlimited walking without pain), good (symptoms substantially decreased, patient satisfied with the treatment outcome, and ability to walk without pain for more than one hour), acceptable (symptoms somewhat decreased, pain at a more tolerable level than before treatment, and patient slightly satisfied with the treatment outcome), or poor (symptoms identical or worse and patient not satisfied with the treatment outcome). Treatment was considered successful when the patient had an excellent or good score.

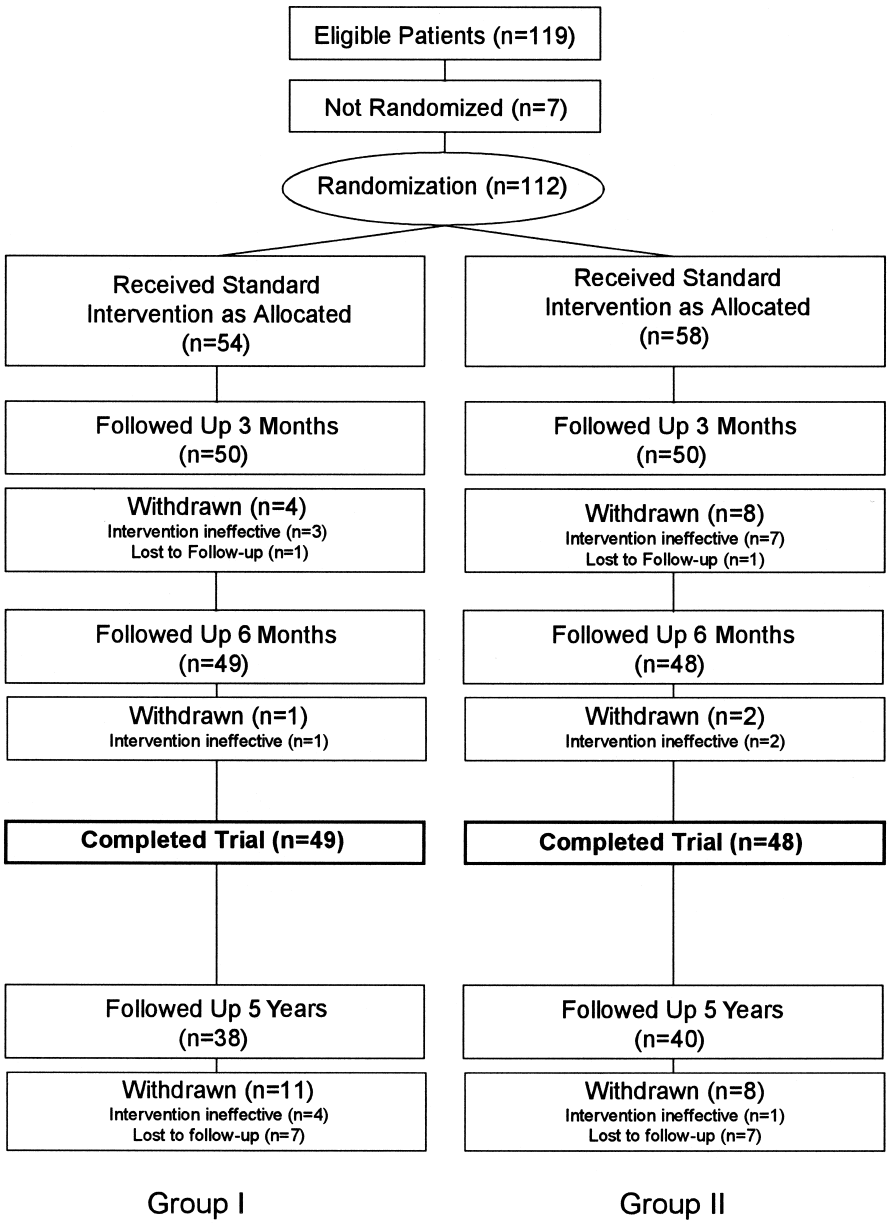

Fig. 1

Profile of the randomized, controlled trial.

Secondary Outcome Measures

The Roles and Maudsley score[20] at five years was defined prospectively as a secondary outcome measure. Other prospectively defined secondary outcome measures were the extent of pain at night, at rest, and on manual pressure as specified on a visual analog scale ranging from 0 (no pain) to 100 (worst imaginable pain) at six months and at five years. To assess pain on manual pressure, the physician used his or her thumb to gradually increase pressure on the patient's contralateral unaffected heel until pain began; then a comparable amount of pressure was applied to the affected heel, and the patient rated the pain that it caused. The exact amount of pressure was not measured.

Walking ability without a need for rest to relieve pain in the heel was rated as 0 (less than five minutes), 1 (less than fifteen minutes), 2 (less than thirty minutes), 3 (less than forty-five minutes), 4 (less than sixty minutes), or 5 (unlimited).

All patients had a radiograph made of the heel before the treatment and at the six-month follow-up evaluation.

Statistical Analysis

The aim of this study was to assess whether there was a dose-dependent effect of low-energy extracorporeal shock-wave therapy in the treatment of recalcitrant heel pain. Our hypothesis was that three applications of 1000 impulses is superior to three applications of ten impulses with regard to the results at six months.

The methods for statistical analysis had been determined by the local Institute for Medical Statistics and Documentation before the study was started. Accordingly, the statistical analysis was performed at that institute when the study was completed.

The Wilcoxon rank-sum test was applied for the comparison of the two

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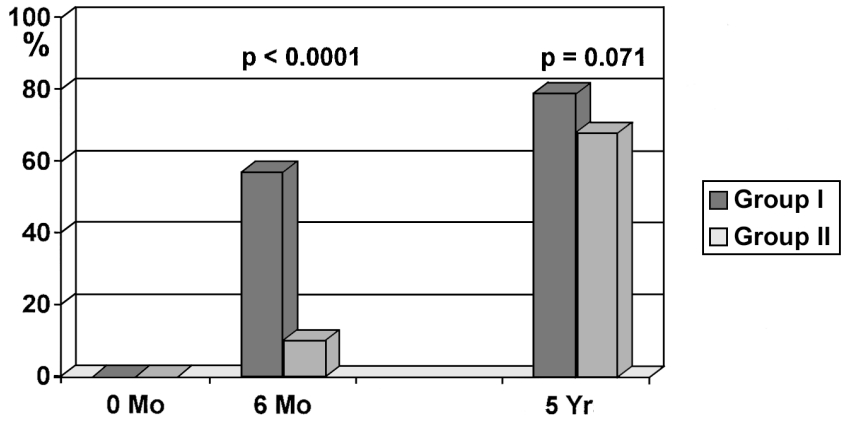

Fig. 2
Percentage of patients with a good or excellent outcome according to the modified four-step Roles and Maudsley scale[20].

groups for such pseudo-continuous, non-normally distributed variables as pain at night, pain at rest, and pain on manual pressure[21]. The Roles and Maudsley score[20] and walking ability, categorical variables, were compared between groups with the Fisher exact test and its extension to 2 × n contingency tables. The level of significance was set at 95%. Differences with p values of <5% were considered significant. Multiple adjustment was not performed for secondary outcome parameters that were measured in an explorative way. The primary outcome measure, the Roles and Maudsley score at six months, was tested in a confirmatory way[22].

As this was a pilot study, no sample size or power calculation could be performed before it was started. The six-month results of this comparative study were analyzed on the basis of the total number of patients whom we originally intended to treat—that is, fifty patients in each group.

Results

Follow-up

As had been previously planned, the randomization process was stopped after fifty patients in either group had not used additional treatment or drugs for three months after the shock-wave application. To reach this goal, 112 patients were randomized to the two treatment groups: fifty-four were assigned to Group I and fifty-eight, to Group II. At three months, three patients in Group I and seven patients in Group II had to be excluded from the study because, as mentioned, they had had additional conservative therapy during that time. One patient in each group could not be contacted, leaving fifty patients in both groups as the basis for the current study.

At six months, forty-nine of the fifty patients in Group I could be evaluated. One patient refused to participate in the study any longer because the shock-wave therapy had not improved his condition. In Group II, forty-eight of the fifty patients could be examined at six months. Two patients stopped participating because the shock-wave application had not improved their condition. At five years, thirty-eight of the fifty patients in Group I could be examined. Four patients stopped participating because the shock-wave application had not improved their condition, and seven patients could not be contacted. At five years, forty of the fifty patients in Group II could be evaluated. One patient stopped participating because the shock-wave therapy had not improved his condition, and seven patients could not be contacted (Fig. 1).

Primary Outcome Measure

Modified Roles and Maudsley Score[20] at Six Months

At six months, six (12%) of the forty-nine patients in Group I had an excellent result, twenty-two (45%) had a good result, twenty (41%) had an acceptable result, and one (2%) had a poor result. In Group II, none of the forty-eight patients had an excellent result, five (10%) had a good result, twenty (42%) had an acceptable result, and twenty-three (48%) had a poor result. The rate of good and excellent outcomes (i.e., success-

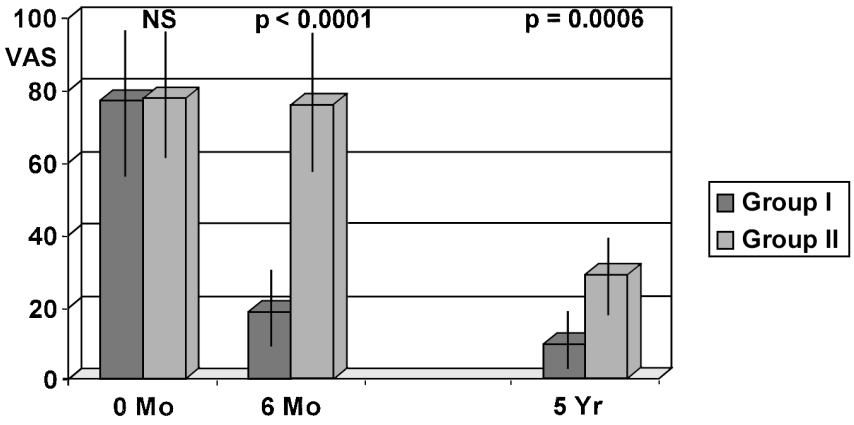

Fig. 3
Scores on a visual analog scale (VAS) for pain on manual pressure before and after low-energy extracorporeal shock-wave therapy for chronic heel pain. NS = not significant.

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TABLE I Scores* for Subjective Variables in Patients Receiving Three Thousand Shock-Wave Impulses (Group I) and Those Receiving Thirty Shock-Wave Impulses (Group II)

	0 mo			6 mo			5 yr		
	Group I (N = 50)	Group II (N = 50)	P Value	Group I (N = 49)	Group II (N = 48)	P Value	Group I (N = 38)	Group II (N = 40)	P Value
Night pain	31 ± 8	30 ± 10	0.8681	6 ± 10	32 ± 9	<0.0001	4 ± 8	11 ± 15	0.0015
Resting pain	27 ± 14	26 ± 14	0.0890	7 ± 10	25 ± 13	<0.0001	4 ± 9	11 ± 12	0.0033

*The scores were determined on a visual analog scale of 0 (no pain) to 100 (worst imaginable pain).

ful results) was 47% higher (95% confidence interval, 37% to 57%) in Group I than in Group II, and the difference between the groups was significant ($p < 0.0001$).

A post hoc power analysis of the primary outcome measure—with use of the relative success rates in Group I (0.57 ± 0.50) and Group II (0.10 ± 0.31), the given sample sizes in Group I (forty-nine) and Group II (forty-eight), and the significance level of the test to reject the null hypothesis ($\alpha = 0.05$)—showed a statistical power of 0.9.

Secondary Outcome Measures

Modified Roles and Maudsley Score[20] at Five Years

At five years, twelve (32%) of the thirty-eight patients in Group I had an excellent result, eighteen (47%) had a good result, seven (18%) had an acceptable result, and one (3%) had a poor result. In Group II, fifteen (38%) of the forty patients had an excellent result, twelve (30%) had a good result, nine (23%) had an acceptable result, and four (10%) had a poor result. With the numbers available, this difference of 11% (95% confidence interval, 4% to 18%) in the success rate between the two groups was no longer significant ($p = 0.071$) (Fig. 2). It should be noted that many of the good and excellent results in Group II followed surgery performed subsequent to the shock-wave therapy, as discussed below.

Pain on Manual Pressure

During the five years that these patients were followed after treatment, the mean score for pain on manual pressure gradually decreased from 77 ± 13 points (before treatment) to 19 ± 12 points (at six months) and 9 ± 11 points (at five years) in Group I. In Group II, the mean scores were 79 ± 11 points before treatment, 77 ± 10 points at six months, and 29 ± 25 points at five years. There was a significant difference between Group I and Group II at both six months ($p < 0.0001$) and five years ($p = 0.0006$) (Fig. 3).

Night Pain and Resting Pain

Night pain in Group I was significantly less than that in Group II at six months ($p < 0.0001$) and five years ($p = 0.0015$). In addition, resting pain in Group I was significantly less than that in Group II at six months ($p < 0.0001$) and five years ($p = 0.0033$) (Table I).

Walking

The ability to walk without pain was also significantly better in Group I than it was in Group II at six months ($p < 0.0001$) and five years ($p = 0.0023$) (Fig. 4). In Group I, twenty-five of forty-nine patients were able to walk completely without pain at six months compared with zero of forty-eight patients in Group II ($p < 0.0001$).

Radiographic Evaluation

Radiographs made at six months after treatment did not show any structural changes of the hindfoot.

Complications

The low-energy extracorporeal shock-wave therapy was felt to be unpleasant by all patients, although it was not thought to

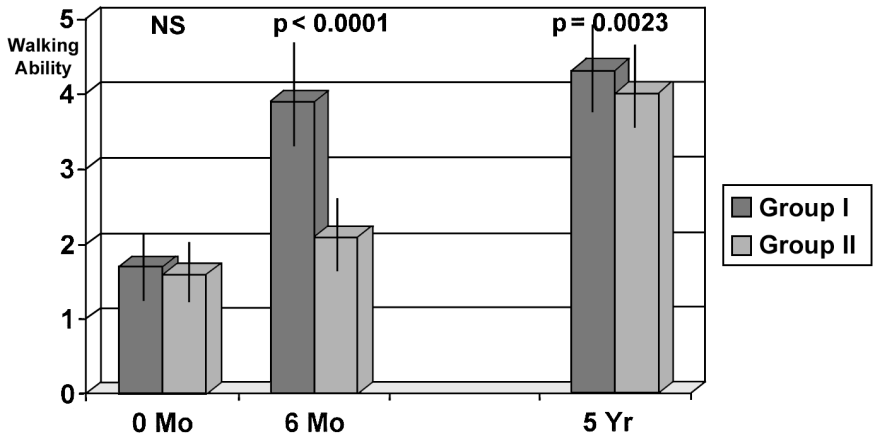

Fig. 4

Grades for walking ability (see text) before and after low-energy extracorporeal shock-wave therapy for chronic heel pain. NS = not significant.

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be as unpleasant as the local infiltration that all patients had experienced during the various and unsuccessful treatment regimens prior to the current study. No patient stopped the shock-wave procedure because of pain. No side effects were seen at the follow-up examinations at six months and five years. There were no hematomas, infections, or abnormal neurologic findings.

Additional Treatment

Between three and six months: Between three months and six months, nine of the forty-nine patients in Group I took oral nonsteroidal anti-inflammatory drugs and had local infiltration with corticosteroids and anesthetics and one patient had the calcaneal spur removed surgically. In Group II, only four of the forty-eight patients did not need any additional treatment. Patients took nonsteroidal anti-inflammatory medication and/or had local injections, and one had surgical release of the plantar fascia.

At five years: At an average of five years (range, fifty-four to sixty-six months), none of the thirty-eight Group-I patients were receiving conservative therapy on a regular basis and five (13%) had undergone surgery. One of these five patients had an excellent result; two, a good result; and two, an acceptable result. In Group II, nine (23%) of the forty patients were receiving regular conservative treatment at five years and twenty-three (58%) had been operated on. Nine of the twenty-three patients had an excellent result after the operation, ten had a good result, two had an acceptable result, and two had a poor result. There were significantly more operative procedures in Group II than in Group I ($p < 0.0001$). As a consequence of the high (83%) rate of excellent and good results after surgery in Group II, the results in Group I and Group II were no longer significantly different five years after shock-wave application.

Discussion

In a review of the literature since 1966, Atkins et al.[1] and Crawford et al.[2] found only eleven randomized, controlled trials assessing the treatment of plantar fasciitis. There was limited evidence of the effectiveness of topical corticosteroids administered by iontophoresis, dorsiflexion night splints, and low-energy extracorporeal shock-wave therapy.

A satisfying clinical outcome after application of low-energy extracorporeal shock waves was first reported in patients with chronic tendinosis of the elbow[22]. We showed comparable short-time results for patients with plantar fasciitis and a heel spur[13]. Similarly positive outcomes have been confirmed in clinical studies from various university hospitals[15-17]. Maier et al.[16] reported good or excellent results, according to the modified Roles and Maudsley score, in thirty-six of forty-eight heels at twenty-nine months. The clinical outcome was not influenced by the duration of the follow-up period. No negative side effects were reported. Wang et al.[23] reported that thirty-three of forty-one patients were either free of symptoms or substantially better at twelve weeks after shock-wave therapy. Ogden et al.[24] performed a randomized, placebo-controlled study with 119 patients in the treatment group and 116 patients in the placebo group. Twelve weeks after a single application of 1500 high-energy shock waves at 18 kV with the patient under regional anesthesia, the result was successful in 47% of the patients. The success rate after the sham treatment was only 30%. This study led the United States Food and Drug Administration to approve shock-wave therapy for painful heels. Buch et al.[25] reported the results of another randomized, placebo-controlled study, involving 150 patients, for the United States Food and Drug Administration. Therapy with 3800 high-energy impulses was applied once with the patient under regional anesthesia. At three months, 70% of the patients in the treatment group and 40% of those in the placebo group fulfilled the success criterion, which was a change in the visual analog score for pain while walking for the first few minutes in the morning. Chen et al.[26] studied eighty patients treated with 1000 shock-wave impulses at 14 kV. Of fifty-four patients who were evaluated at six months, 59% had no symptoms and 27% had substantial improvement.

In the current study, six months after low-energy shock-wave treatment, the results of three applications of 1000 impulses were significantly better than those of three applications of ten impulses (57% good or excellent outcomes compared with 10% good or excellent outcomes).

At five years, Group II had a substantial improvement in all parameters compared with those at the six-month follow-up evaluation, and the overall outcome, based on the four-step score, was no longer significantly better in Group I.

It should be noted that separating the clinical results into only four broad categories, with use of an unvalidated modified Roles and Maudsley scale[20] originally designed for the upper extremity, may not provide a sufficiently sensitive test. However, Group-I patients also fared better with regard to pain on manual pressure, at night, and at rest and with regard to walking. Five years after the shock-wave therapy, 13% of the patients in Group I and 58% of the patients in Group II had been operated on. Of the twenty-three patients who were operated on in Group II, 83% had a good or excellent outcome. If even more patients in this group had undergone surgery, the ratings concerning pain and walking may have reached levels comparable with those in Group I.

None of the outcome variables in our study is free from the possibility of observer bias, although this risk was kept low by making sure that an independent observer evaluated the patients before and after treatment. Pain, however, may be influenced by many factors and is difficult to measure. While we attribute the substantial improvement in Group II at five years to the surgical procedures that the patients had undergone during the follow-up period, the excellent long-term results in Group I have to be regarded with caution. It is known that the vast majority of patients with heel pain have improvement within a few months after the onset of symptoms. Clinical evidence of the efficacy of any treatment during this time is difficult to obtain[5]. The self-limiting character of the disease therefore has to be considered as does the fact that spontaneous improvement is difficult to distinguish from a long-lasting

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effect of low-energy extracorporeal shock-wave application.

No side effects were recorded following the application of the low-energy extracorporeal shock waves in our patients. This clinical experience is supported by previous histological and magnetic resonance imaging-based studies[16,27]. In contrast, high-energy shock waves, which are also used for the treatment of heel pain[17,24-26], may produce side effects such as periosteal detachment and small fractures of the inner surface of the cortex[28].

In conclusion, the current pilot study revealed dose-related effects of low-energy extracorporeal shock-wave therapy in patients with chronic plantar fasciitis. The therapy with three applications of 1000 impulses appeared to be a useful, noninvasive treatment method with negligible side effects that reduced the necessity for a surgical procedure. Nevertheless, low-energy shock-wave application cannot be recommended as a first-line procedure for chronic heel pain. Although the United States Food and Drug Administration recently approved a shock-wave device for therapy for heel pain[29], additional controlled studies are still needed to verify the results of this study and to define the precise role of this new modality in the treatment of chronic plantar fasciitis. ■

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