

# Effectiveness of Extracorporeal Shockwave Treatment in 353 Patients with Chronic Plantar Fasciitis

Donald M. Norris, MD\*  
Kimberly M. Eickmeier, DPM†  
Bruce R. Werber, DPM‡

A 16-question post-treatment survey was sent to 874 patients after extracorporeal shockwave treatment for chronic plantar fasciitis. Of the 377 surveys returned, 353 were used for analysis. These patients were treated by 169 physicians in 19 states using either electrohydraulic or electromagnetic extracorporeal shockwave equipment. Seventy-six percent of the patients underwent treatment after having had continued pain for a year or longer. Seventy percent of patients who rated their pre-treatment pain level as severe (score  $\geq 8$  on a scale from 1 to 10) experienced sharp declines in pain, with a sharp decline considered to be a difference in pain level before and after treatment of 3 or more. In addition, 66% of patients who rated their pretreatment immobility as severe (score  $\geq 8$  on a scale from 1 to 10) experienced sharp declines in immobility. Of the patients who underwent extracorporeal shockwave treatment, 69% indicated that they would recommend this procedure to someone in a similar situation. If extracorporeal shockwave treatment were not available, 62% of patients indicated that they would have undergone open or invasive surgery, and 41% indicated that they would have continued with additional physician office visits. (J Am Podiatr Med Assoc 95(6): 517-524, 2005)

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As the population continues to age, the number of individuals who cannot perform certain physical functions will increase dramatically. In 1995, approximately 33% of women and 29% of men were unable to perform at least one of nine basic physical activities, such as walking 0.25 mile, climbing stairs, stooping, reaching up, standing, and being on their feet for 2 hours.<sup>1</sup> Approximately 2 million Americans per year develop plantar fasciitis.<sup>2</sup> This condition is defined as traction degeneration of the plantar fascial band at its proximal attachment on the medial tubercle of the

\*United Shockwave Therapies, Des Plaines, IL.

†Department of Podiatric Surgery and Medicine, Christie Clinic PC, Champaign, IL.

‡Instep Foot & Ankle Specialists, Warwick, RI.

Corresponding author: Kimberly M. Eickmeier, DPM, Department of Podiatric Surgery and Medicine, Christie Clinic PC, 1801 W Windsor Rd, Champaign, IL 61821.

calcaneus. Inflammation, fibrosis, and decreased vascularization of the fascia occur, causing symptoms of sharp heel pain on standing and walking after prolonged rest (poststatic dyskinesia). People particularly at risk include athletes and runners, overweight individuals, and those who are required to stand on hard surfaces for prolonged periods.

Plantar fasciitis is extremely painful and has led many individuals to seek surgery to alleviate pain and restore full mobility. Such approaches may not be particularly desirable in light of risks associated with invasive procedures. In recent years, a new non-invasive technology has appeared on the market to treat this ailment. Based on the principles of extracorporeal shockwave lithotripsy used to treat kidney stones, extracorporeal shockwave treatment seeks to eliminate the pain associated with chronic plantar

fasciitis and return individuals to pain-free mobility in an effective and noninvasive manner.

A shockwave is an acoustic or sonic wave measured in millipascals or bars of pressure (1 MPa = 10 bars). Currently, three methods are used to create and focus a shockwave to treat human tissue: electrohydraulic, electromagnetic, and piezoelectric. Electrohydraulic or “spark gap” devices for extracorporeal shockwave treatment use an electrode, similar to the spark plug in an automobile, submerged in distilled water to create a plasma bubble that compresses the surrounding fluid. An acoustic shockwave travels outward in a spherical manner and is focused onto the targeted tissue using a brass ellipse. Electromagnetic devices use a pulsiform electric current passed through a metal coil. A conductive membrane is applied to a coil with a magnetic field of opposite polarization. The two magnetic fields push the membrane away from the coil, which compresses the water nearby and creates a plane pulse. A rubber acoustic lens focuses the shockwave on the targeted tissue.

The purpose of this study was to begin to identify the impact of this therapy on patients who have undergone extracorporeal shockwave treatment. In an effort to evaluate this new technology, we designed a study to determine whether the patient’s pain from chronic plantar fasciitis was reduced and whether the patient’s mobility and function improved after treatment. We also assessed whether the improvement was short-term or long-lasting. We identified the various treatment modalities the patient used before and after the treatment and determined whether the patient would have considered surgery if extracorporeal shockwave treatment were not available. This information will provide insight into the effects of the therapy on various quality-of-life dimensions that are particularly important to individuals who are trying to live independently with full functionality. Such information will also enable a more “patient-centered” view of the effectiveness of this emerging treatment on key outcome variables related to pain and mobility.

## Methods

We surveyed patients and asked a series of questions related to their pretreatment and post-treatment experiences with chronic plantar fasciitis and strategies for dealing with it. In April 2003, a survey was mailed to 874 patients, the total pool of patients who had received extracorporeal shockwave treatment between August 1, 2002, and December 31, 2002. Of the 377 surveys returned, 353 were entered into a database

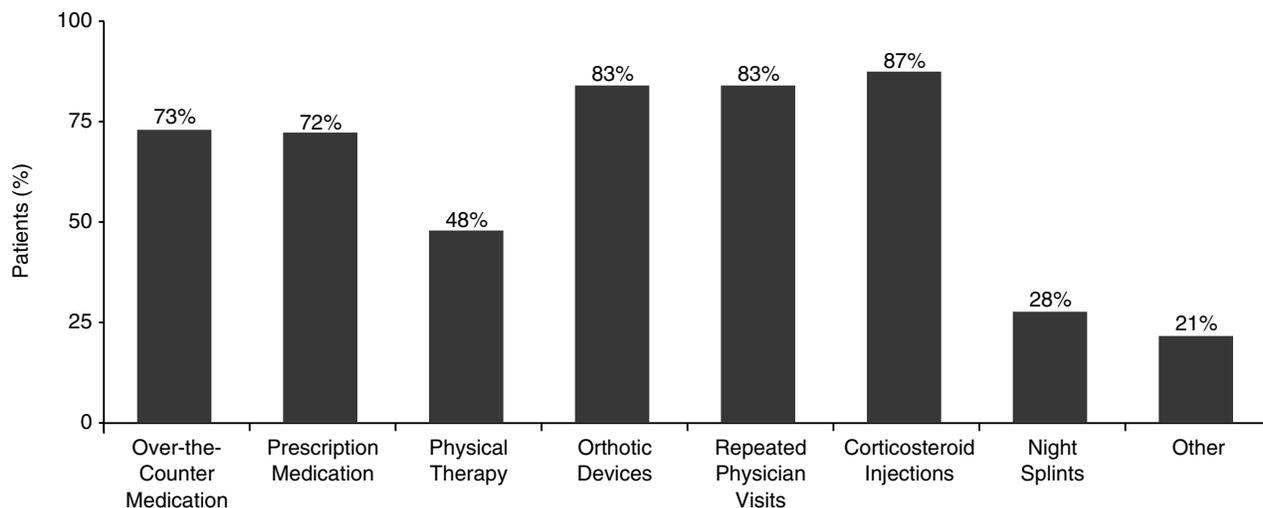
for analysis. The returned surveys reflect treatments by 169 different physicians in 19 states. Twenty-four surveys were discarded because the data were unreadable. The survey consisted of 16 questions relating to an individual’s experiences before and after therapy. The survey was designed to isolate the impact of the treatment on pain and mobility.

The single-treatment, high-energy protocols recommended by the manufacturers of the electrohydraulic (OssaTron; SanuWave Inc, Marietta, Georgia) and electromagnetic (Epos; Dornier MedTech America Inc, Kennesaw, Georgia) shockwave devices were used during this study. Using these suggested protocols, 1,300 mJ/mm<sup>2</sup> was ultimately delivered to the painful and pathologic area of the proximal attachment of the plantar fascia.

As the study is not based on a double-blind experimental design, we used statistical methods to determine whether differences in key outcome variables were due to chance or to the shockwave therapy itself. We used one-tailed tests of significance to measure differences in means. This is a more conservative test than a two-tailed test because it not only measures the difference in means but also restricts the directionality of that difference. Thus with respect to pretreatment and post-treatment pain levels, we tested whether there has been a reduction in pain and an increase in mobility, and not just whether there is a difference in scores.

## Results

In this survey, physicians used electrohydraulic devices (35% of the cases) and electromagnetic devices (65% of the cases) to treat chronic plantar fasciitis. There was no statistically significant difference in outcome or relief of pain noted between the two types of devices. Most patients (76%) sought extracorporeal shockwave treatment only after having experienced pain for 1 year or longer; 95% had pain for more than 6 months. Many patients enrolled in this study had sought multiple methods of conservative therapy to relieve the pain that they experienced from plantar fasciitis (Fig. 1). Eighty-seven percent of patients relied on corticosteroid injections to control the pain, 73% on over-the-counter medications, and 72% on prescription medications. Eighty-three percent of the patients required orthotic devices. Much of this therapy necessitated repeated physician visits. Of the approximately 21% of patients who indicated that they undertook other actions to relieve the pain; 5% mentioned stretching exercises; 5% used shoe inserts; and the others used casting, surgery, ice, and combinations of these approaches. Three



**Figure 1.** Percentages of patients using various conservative treatments before undergoing extracorporeal shockwave treatment.

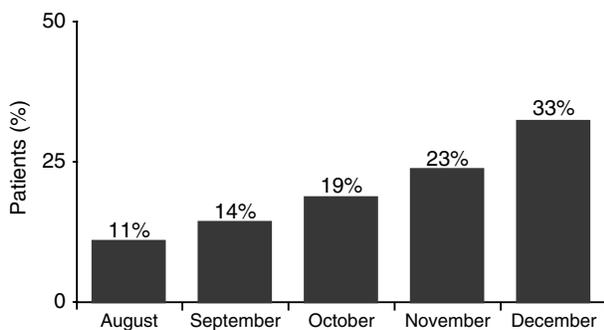
percent of respondents indicated that they had plantar heel surgery before shockwave treatment.

Respondents were then asked which, if any, of these treatments or previous treatments proved to be effective. Sixty-two percent of patients indicated that either one or a combination of these treatments was somewhat effective in controlling pain. These methods did not seem to offer a long-term solution to the problem because all of these individuals went on to receive extracorporeal shockwave treatment. Repeated corticosteroid injections were the most effective therapy in controlling pain. The use of orthotic devices was cited by 10% of patients as the next most effective therapy.

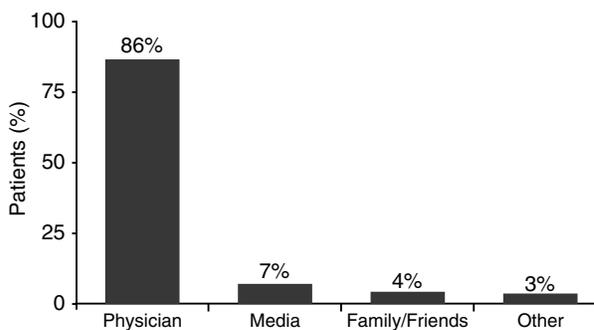
All of the patients in this study received treatment no less than 3 months before they were surveyed (Fig. 2). In subsequent analyses, we tested the hypothesis that outcomes vary by treatment date. When

asked how they learned about extracorporeal shockwave treatment, most patients indicated that they were educated about this treatment option by their physician (Fig. 3).

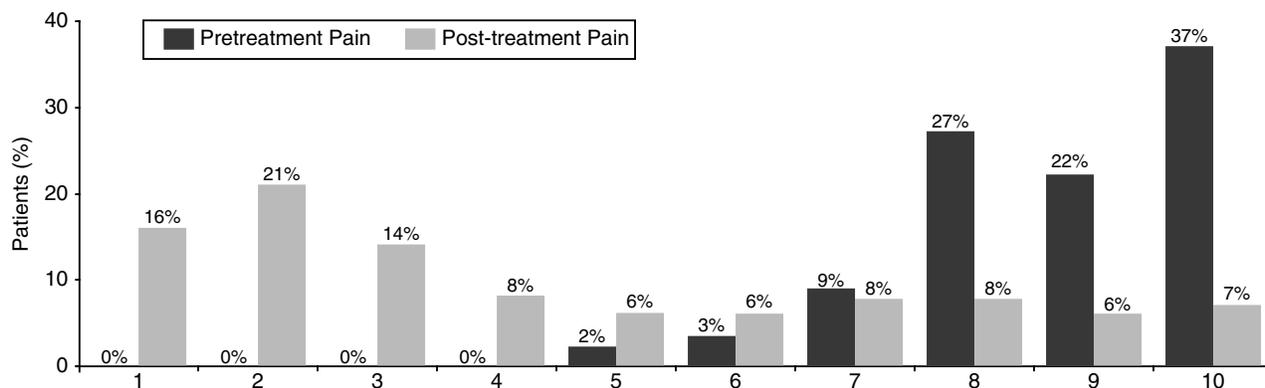
Each patient was asked to rate on a scale from 1 to 10, with 1 being no pain and 10 being very severe pain, the level of pain that they experienced before and after shockwave therapy (Fig. 4). A much higher percentage of individuals reported experiencing more severe pretreatment pain than post-treatment pain. In fact, 86% of respondents rated their level of pain as 8 or higher before therapy, compared with 21% after treatment. Furthermore, we found that 70% of patients who rated their pretreatment pain level as severe ( $\geq 8$ ) experienced sharp declines in their level of pain after treatment, with a sharp decline defined as a difference in pain level before and after treatment of 3 or more. The difference in the pretreat-



**Figure 2.** Percentage of patients undergoing extracorporeal shockwave treatment by month.



**Figure 3.** Sources of initial education about extracorporeal shockwave treatment.



**Figure 4.** Pain levels before and after extracorporeal shockwave treatment as measured by the visual analog scale.

ment and post-treatment pain scores is significant at the 1% level. We tested whether the reported differences were statistically significant using the Wilcoxon signed rank test, which evaluates the difference between two treatments using data from repeated experiments performed on the same population. The test does not make any assumptions about the underlying distribution of the test variable. Therefore, it is a particularly robust test of statistical significance. The null hypothesis is that there is no difference between pretreatment and post-treatment status. The results allow us to reject the null hypothesis and conclude that there is a significant sharp decline in the pain level after treatment.

We also tested whether the pretreatment and post-treatment pain scores were statistically significantly different from one another. The mean pretreatment pain score was 8.76, with an SD of 1.28. The 95% confidence interval (CI) for the pretreatment mean is 8.63 to 8.90. The post-treatment pain score was 4.68, with an SD of 2.95. The 95% CI for the post-treatment mean is 2.95 to 4.37. Across the sample of respondents, there was a 43% decline in the post-treatment pain score. The difference in the pretreatment and post-treatment scores is significant at the 1% level by the Wilcoxon signed rank test. We reject the null hypothesis that there is no decline from the pretreatment to the post-treatment pain scores; thus there is a very low likelihood that these declines in mean pain scores were due to chance.

We examined whether responses differ depending on when the treatment was actually completed. Table 1 displays the mean pain scores by the month in which extracorporeal shockwave treatment was received. For all groups, the decline from reported pretreatment to post-treatment pain scores was statistically significant. Also, although it seems that the decline is less dramatic when the interval between

treatment and the survey date is shorter, these differences are not statistically significant. Thus the decline in pain scores after treatment is constant throughout the 5-month period. The difference in pain levels before and after treatment declines from October (4.59) to November (3.64), and the decline is statistically significant. The difference in pain level is also statistically significant between October (4.59) and December (3.68), with the difference being lower in December. The differences in November and December are not statistically significant.

Each patient was asked to rate on a scale from 1 to 10, with 1 being total mobility and 10 being complete immobility, the level of mobility they experienced before and after extracorporeal shockwave treatment (Fig. 5). A much higher percentage of individuals reported experiencing pretreatment mobility-related problems than post-treatment problems. In fact, 45% of respondents rated their level of immobility as severe (score  $\geq 8$ ) before shockwave treatment, compared with 13% after treatment. In addition, 66% of patients who rated their pretreatment immobility as severe experienced a sharp decline in their level of immobility after treatment, with a sharp decline defined as a difference in mobility level before and after treatment of 3 or more. Using the Wilcoxon signed rank test, we found that there is a statistically significant difference in the mobility level before and after the treatment at the 1% level. This parallels our findings with respect to pain.

When testing pretreatment and post-treatment average mobility scores, we found that the mean pretreatment mobility score was 6.67, with an SD of 2.24. The 95% CI for the pretreatment mean is 6.44 to 6.91. The mean post-treatment mobility score was 3.74, with an SD of 2.68. The 95% CI for the postoperative mean is 3.46 to 4.02. Across all respondents, there was a 44% increase in mobility after treatment.

**Table 1. Pretreatment and Post-treatment Pain Scores by Month of Extracorporeal Shockwave Treatment in 353 Patients**

	Month Treatment Was Received				
	August	September	October	November	December
Pretreatment pain score (mean)	8.78 <sup>a</sup>	8.80 <sup>a</sup>	8.62 <sup>a</sup>	8.57 <sup>a</sup>	8.97 <sup>a</sup>
Post-treatment pain score (mean)	4.22	4.10	4.03	4.93	5.29
Decline in pain score (%)	-52	-53	-53	-42	-41

<sup>a</sup>Differences between pretreatment and post-treatment are significant at the 1% level.

The improvements in the post-treatment scores are significant at the 1% level by the Wilcoxon signed rank test. The null hypothesis that there are no improvements from the pretreatment to the post-treatment mobility scores is rejected.

We also examined whether responses differ depending on when the treatment was actually completed. Table 2 displays the mean mobility scores by the month in which shockwave therapy was received. For all groups, the decline in reported mobility scores after treatment was statistically significant.

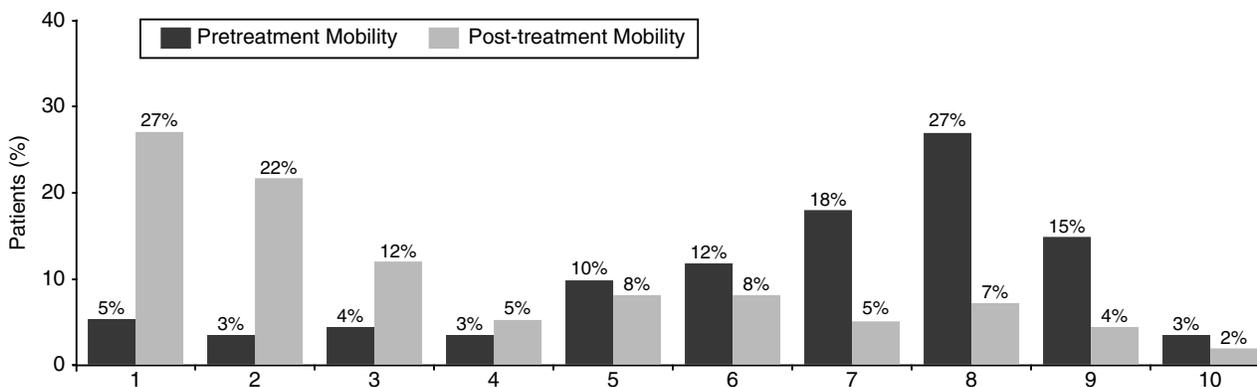
Patients were asked to identify the immediate and continued effects of extracorporeal shockwave treatment from their perspective. These patients indicated that for four of five dimensions of service use or treatment impacts, the effects of the treatment remained constant over time or actually improved. For example, whereas an equal proportion of individuals experienced reduced pain and relied on fewer medications immediately after treatment and on an ongoing basis, higher percentages reported increased mobility and fewer physician visits over time (Table 3).

Sixty-nine percent of the patients indicated that they did not experience any unusual foot problems after treatment. Most individuals continued their use of orthotic devices after treatment. This is to be ex-

pected, because the treatment is not anticipated to eliminate the need for orthotic devices. Patients were also asked whether they were prohibited or limited from performing certain activities before receiving shockwave treatment that they could now perform after having received the treatment. Most individuals indicated that they could now more fully engage in exercise (67%) and certain activities of daily living (52%) because of the treatment. Approximately 40% of patients indicated that they were now able to engage in social activities that they could not engage in before treatment.

Patients were also asked what actions they would have taken to deal with their plantar fasciitis in the absence of extracorporeal shockwave treatment. Note that before receiving the treatment, many of these individuals were already relying on a variety of techniques to deal with the symptoms associated with the problem, such as corticosteroid injections, frequent physician visits, medications, and orthotic devices. A small percentage, 2.56%, had undergone invasive surgery before treatment.

When asked how these patients would have dealt with the continued pain from plantar fasciitis if extracorporeal shockwave treatment had not been available to them, 62% said that they would have

**Figure 5.** Mobility scores before and after extracorporeal shockwave treatment.

**Table 2. Pretreatment and Post-treatment Mobility Scores by Month of Extracorporeal Shockwave Treatment in 353 Patients**

	Month Treatment Was Received				
	August	September	October	November	December
Pretreatment mobility score (mean)	6.76 <sup>a</sup>	6.39 <sup>a</sup>	6.91 <sup>a</sup>	6.17 <sup>a</sup>	6.98 <sup>a</sup>
Post-treatment mobility score (mean)	3.35	3.36	3.36	3.61	4.34
Decline in mobility score (%)	-50	-47	-51	-41	-38

Note: A lower number indicates improvement.

<sup>a</sup>Differences between pretreatment and post-treatment are significant at the 1% level.

**Table 3. Immediate and Continued Effects of Extracorporeal Shockwave Treatment**

	Patients (%)	
	Immediate Effect	Continued Effect
Reduced pain	64	64
Increased mobility	47	55
Decreased office visits	49	57
Decreased medication use	42	42
Decreased consultations	49	29

sought invasive surgery, 22% would have undergone physical therapy, 31% would have used their orthotic devices, 32% would have continued with the use of medication, and 41% would have continued to see their physician. Most patients (69%) would recommend the treatment, regardless of when they received it (83% in August, 84% in September, 83% in October, 67% in November, and 71% in December). Patients who were least likely to recommend the treatment were also those who showed the least dramatic improvements in mobility and in pain reduction.

## Discussion

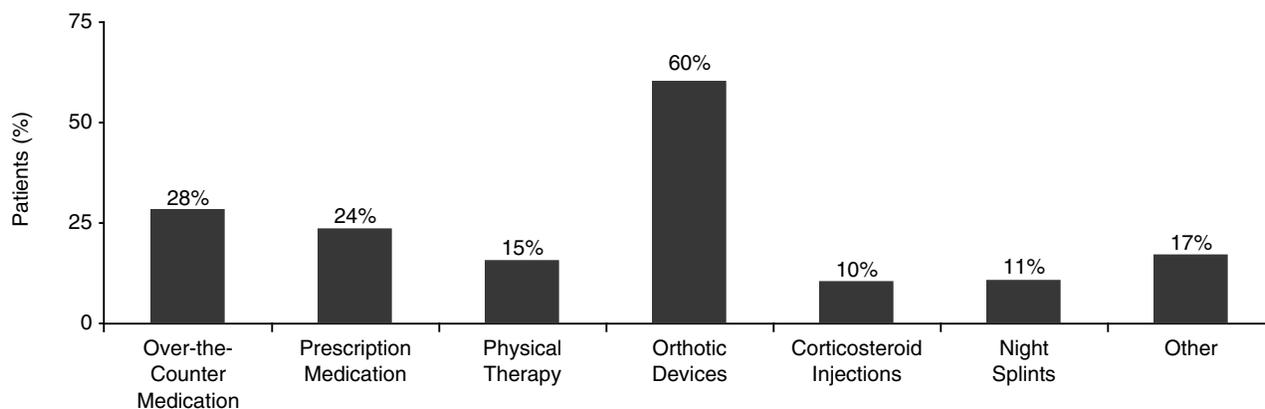
The most common foot ailment encountered in physician offices is chronic plantar fasciitis.<sup>3</sup> Plantar fasciitis accounts for 15% of all adult foot complaints.<sup>4</sup> More than 90% of patients treated for plantar fasciitis respond to conservative methods.<sup>5</sup> For the patient not sufficiently helped by conservative treatment, many surgical methods for treating “heel pain syndrome” have been suggested, including heel spur resection, open plantar fasciotomy, percutaneous plantar fasciotomy, and endoscopic plantar fasciotomy. Studies have confirmed that transecting the plantar fascia alters the integrity of the foot such that the stability of the foot decreases, the arch lowers,<sup>6</sup> and digital instability or claw toe deformity occurs. This re-

sults in transfer of pressure to the metatarsal heads, creating significant pathology in this area.<sup>7</sup> Chronic plantar fasciitis is characterized by continued pain for at least 6 months after three failed conservative treatments. What is particularly significant is that before extracorporeal shockwave treatment, most patients (87%) dealt with plantar fasciitis with corticosteroid injections (Fig. 1), whereas after shockwave treatment, only 10% continued with this approach (Fig. 6).

In a multi-surgeon prospective analysis of 652 patients who underwent endoscopic plantar fasciotomy, 62 complications were reported in 53 patients.<sup>8</sup> These complications included lateral column pain and midtarsal pain. Thirty-seven percent of the complications were from failure of the procedure to alleviate the patient’s pain. Some invasive surgical procedures require the patient to be nonweightbearing for 2 to 3 weeks, with suture removal at about the same time.

In our study, 76% of the patients had chronic plantar fasciitis for 1 year or longer, and 95% had it for at least 6 months. Most individuals relied on corticosteroid injections and medications to control the pain associated with plantar fasciitis. The patients surveyed indicated that repeated corticosteroid injections were the most effective treatment for the relief of pain. In most cases the response was only temporary.

Seventy percent of the patients who rated their pretreatment pain level as severe (score  $\geq 8$ ) experienced a sharp decline in their level of pain after treatment. There was a 43% decline in pain in all respondents across the sample. Sixty-six percent of the patients who rated their pretreatment mobility difficulty as severe (score  $\geq 8$ ) experienced significant improvement in mobility. There was an increase in mobility after treatment of 44% across the sample of all respondents. Sixty percent of the patients in this survey continued with the use of their orthotic devices. It is recommended that all patients treated for chronic plantar fasciitis continue using orthotic devices.



**Figure 6.** Percentages of patients using various treatments after extracorporeal shockwave treatment. Note that “other” includes exercise, shoe inserts, heat packs, surgery, and ice.

The faulty biomechanical structure of the foot that led to plantar fasciitis is not changed by extracorporeal shockwave treatment, and it may even worsen with invasive procedures.

Our findings indicate that after extracorporeal shockwave treatment, most patients require less medication and substantially fewer physician visits, which indicates a probable overall reduction in cost to the patient and the health-care system. More important, these patients indicated that after treatment, they participated more fully in physical exercise (67%), improved their activities of daily living (52%), and increased their participation in social activities (40%), indicating a better quality of life. Perhaps the best measure of treatment effectiveness is the extent to which those who received extracorporeal shockwave treatment would recommend it to others in a similar situation. Sixty-nine percent of the respondents would recommend the treatment to others, 22% would not, and 9% did not know.

Our study had several weaknesses related to experimental design for the investigation of a treatment modality. First, we did not compare the effects noted in the group of patients undergoing extracorporeal shockwave therapy with a placebo or standard therapy group. Second, because we did not conduct a controlled intervention trial, there was no randomization or multivariate matching on multiple covariates, so we were not able to equally distribute chance confounders. Third, we did not control for any known or potential confounders in our design or analysis, and we depended on statistical analyses to compare noted differences in the paired data for the participants before and after the therapy. Fourth, we did not use a health-measurement tool previously shown to yield valid data related to quality of life or econo-

metric improvement related to the cost of therapy. Last, because our patients were asked to relate their degree of pretreatment pain during the post-treatment period, our results are subject to recall bias. Our goal was to make clinical observations related to pain relief and activity experienced by patients undergoing extracorporeal shockwave treatment for chronic plantar heel pain, and our approach was a retrospective cohort study. Without an econometric analysis, any suggestion that extracorporeal shockwave treatment will reduce cost is merely speculation. Despite these limitations, we believe that our findings support the hypothesis that extracorporeal shockwave treatment reduces pain and improves function in patients with chronic plantar heel pain.

## Conclusion

The results of this survey demonstrate that extracorporeal shockwave treatment reduces the pain associated with chronic plantar fasciitis and increases mobility. The effects are rapid and seem to be sustained, as evidenced by the high degree of immediate pain relief reported and the continued relief of pain reported months after treatment. The decreased costs related to the reduced need for medications, office visits, and time away from work and the decreased disability contribute to the positive outcomes associated with extracorporeal shockwave treatment. The known risks and complications, as well as costs, associated with surgical plantar fascia release provide another incentive to accept extracorporeal shockwave treatment as an alternative treatment for intractable plantar fasciitis. Extracorporeal shockwave treatment is not only an effective treatment modality but may reduce the cost of treatment. It seems that physicians

now have a safe and effective technology for treating plantar fasciitis, a chronic and debilitating disease.

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