CHAPTER **32**

ORTHOSPEC VERSUS PLACEBO FOR THE TREATMENT OF CHRONIC PROXIMAL PLANTAR FASCIITIS: Results of a Randomized, Placebo Controlled Double Blind Study

Jason T. Kline, DPM
D. Scot Malay DPM

PURPOSE

Plantar fasciitis is a common complaint faced by the podiatric physician.[1] Conservative therapies include padding, strapping, NSAIDs, night splints, and corticosteroid injections. Nonsurgical treatment of plantar fasciitis has been reported to have mixed results.[2,3]

For those patients not responding to conservative care, surgical options such as open plantar fasciectomy or endoscopic plantar fasciotomy have had varying rates of success and are less frequently performed because of post-surgical complications.[4,5]

Recently, extracorporeal shockwave therapy has been used as a successful adjunct in treating this condition. Advocates of shockwave therapy suggest that ESWT creates controlled local injury, resulting in neovascularization and infiltration of growth factors. Thus treatment stimulates healing by creating a wound environment.[6] Randomized controlled trials of both high and low energy shockwave delivery systems have had differing results.[7-9] Current high energy shockwave delivery systems require the patient to undergo regional nerve blocks with either intravenous sedation or general anesthesia. Some of these devices have recently reported that the patient receive one or more additional treatments to achieve the desired therapeutic effect.[8]

The Orthospec (Medispec) extracorporeal shockwave device is a new delivery system on the cusp of FDA approval. Shock waves are produced electro hydraulically and delivered to the treatment area by a rubber contact membrane. By enlarging the therapy zone, the energy of the shockwave is dispersed over a larger treatment area and results in less patient discomfort. Benefits include a one time treatment session of 25 minutes without the need for intravenous sedation or local anesthetic blockade.

A randomized, double blind, placebo-controlled investigation was performed to determine the efficacy of a one time treatment with Orthospec versus placebo in subjects with proximal plantar fasciitis. The study was multicenter in design, with investigators from Connecticut, Philadelphia, and Maryland. The primary outcome measured was change in the investigators assessment of heel pain between Orthospec active and placebo groups at 3 months. Secondary outcome measures included subject's self assessment of heel pain, self assessment of activity and function, and use of pain medications. Adverse events were also reported to assess the safety of the device at 6 and 12 months.

MATERIALS AND METHODS

After the initial screening process, one-hundred sixty-eight (168) subjects were randomized into active or placebo groups in a ratio of 2:1 (active: placebo). Subjects were over 18 years of age and had symptoms consistent with proximal plantar fasciitis for at least 6 months. Failure of at least two pharmacologic and two non-pharmacologic treatments were required prior to inclusion in the study. Consent forms were signed and demographic data collected for all subjects meeting the inclusion criteria.

Subjects were excluded from the investigation if they suffered from any recent systemic disease, malignancy, or infection. Anyone with a history of prior heel surgery, known plantar fascial tear, or bilateral cases was also excluded. Before the initial assessment by the blinded investigator, subjects may not have had steroid injections within six weeks, physical therapy within 2 weeks, or NSAIDs/narcotics within 48 hours.

The blinded investigator was responsible for performing the initial screening and history. He was

also responsible for performing all pre and post treatment assessments of heel pain. The assessments were accomplished with the PressureSpec device, a calibrated handheld instrument allowing quantification of heel pain when applied to the symptomatic area. Subjects were provided with a 10 point visual analog scale (VAS) to utilize for self-assessment of heel pain. Patient diaries were supplied for subjects to record use of pain medications. Assessment of activity and function was performed by the blinded investigator by interview at months 1, 2, and 3.

The unblinded investigator performed the actual active or placebo treatments. Subjects were positioned comfortably in an office chair with the affected heel placed adjacent to the contact membrane of the Orthospec device. Ultrasound gel was applied to the subjects' heel and contact membrane to allow for transmission of the shockwave. For those who were randomized to the placebo group, a special contact membrane with Styrofoam insulation was used to absorb the wave and block transmission. Subjects were provided with ear protection and all questions and concerns were answered before the session started.

Shockwave transmission started at a low energy level (Level 1) and progressed in a regulated fashion until the highest energy level (Level 7) was achieved. If subjects were unable to tolerate the higher energy levels, the unblinded investigator was notified and the energy level decreased. Treatment sessions lasted for 25 minutes, after which the investigator recorded the highest energy level achieved, adverse events, or device malfunctions. Subjects were also asked if they thought they received the active or the placebo treatment at the end of the session.

Subjects were followed up at months 1, 2, and 3 during which the blinded investigator evaluated the heel for any adverse events such as swelling, bruising, or paresthesias. Assessment of heel pain was performed with the PressureSpec device, and the Visual Analog Scale utilized for subjects' self assessment of heel pain. Questions regarding activity and function were asked in terms of number of blocks walked before experiencing heel pain. Finally, diaries were checked to assess the subject's use of pain medications.

Study participants were not allowed to use NSAIDs or narcotics before these monthly assessments within a time frame defined by washout periods (half-lives).

RESULTS

Demographic data was compared between active and placebo treatment groups and no significant differences were found regarding age, sex, involved heel, and number of conservative therapies. An average of 4.4 prior therapies was attempted by study participants. Conservative measures included physical therapy, NSAIDs, physiotherapy, night splints, and corticosteroid injections. Pre-existing medical conditions were also similar among active and placebo treatment groups.

A total of 196 patients were screened for the investigation, 172 of which were then randomized into either active or placebo treatment groups. Approximately 88.4% of patients completed the three month follow up, the others terminating early because they had either healed, worsened, or were lost to follow up. A total of 97.7% of randomized patients (168) were included in the analysis (last observation carried forward).

During the actual treatment, the two groups were similar in terms of number of shocks received, treatment duration, and treatment interruption. There were 5 cases of treatment interruption secondary to device malfunction and 1 case secondary to pain. A significant number of subjects in the placebo group were able to tolerate higher energy levels of shocks. This was expected since a Styrofoam block was used beneath the contact membrane. These subjects experienced little to no discomfort during the treatment session.

Table 1 represents the changes from baseline in the investigators assessment of heel pain at months 1, 2 and 3. This is the primary outcome measure of the study. Improvement in the active treatment group reaches statistical significance by months 2 and 3 when compared to placebo ($P < 0.05$). When looking at the relationship between investigator heel pain assessments with maximum energy level achieved, a greater therapeutic effect was seen in subjects who were able to tolerate higher energy levels of shockwaves. In those subjects who could not tolerate energy levels above 4.5, the therapeutic effects were less than those receiving placebo. This suggests that energy levels below 4.5 with the Orthospec device may be considered sub-therapeutic.

Table 2 shows the results of subjects' self-assessment of heel pain at months 1, 2 and 3. Statistical significance is reached by month 3 with greater improvement seen in the active treatment group.

Subjects were asked at baseline how far they could walk before experiencing plantar fascial pain and were followed up at months 1, 2, and 3. At baseline, the majority of patients in both treatment groups experienced pain before walking one block. When looking at Table 3, at month 3 both active and placebo treatment groups had none or only minimal limitations in activity and function. Therefore, we see an improvement in activity; however, this does not reach statistical significance when compared with the placebo group.

Table 4 illustrates a significant decrease in the use of pain medications in the active treatment group. One can see that significance is reached by month 2 and even becomes more significant at month 3.

Adverse events encountered during the investigation included bruising and mild local swelling. These events only manifested in the active treatment group and were transient and self-limited. Safety data for the 6 and 12 month follow up visits are still pending.

CONCLUSIONS

As far as the limitations of the study are concerned, there was no long term quality of life measurements included in the analysis. Comparison of the Orthospec to another treatment modality such as physical therapy or NSAIDs may have yielded more valuable information, however these patients had already failed a number of standard treatments.

In summary, the effectiveness of the Orthospec device was demonstrated in this study. Statistical significance was achieved in regards to change in investigators assessment of heel pain at three months (the primary endpoint). A significant decrease in subjects self assessment of heel pain was also demonstrated in the treatment group. Improvement was seen in the active treatment group in terms of increased activity and function, but did not reach statistical significance. There was a significant decrease in the use of analgesic medications in the active treatment group. There were 2 cases of bruising and 1 case of mild swelling,

Table 1

THE CHANGES FROM BASELINE IN THE INVESTIGATORS ASSESSMENT OF HEEL PAIN AT MONTHS 1, 2 AND 3

	Orthospec	Placebo	P-Value
Month 1			
N	111	54	
Mean[1]	-1.61	-1.27	0.34
Difference (95% CI)		-0.34 (-1.06, 0.37)	
Month 2			
N	111	54	
Mean[1]	-2.30	-1.31	0.026
Difference (95% CI)		-0.99 (-1.86, -0.12)	
Month 3 (1° Outcome)			
N	112	56	
Mean[1]	-2.51	-1.57	0.045
Difference (95% CI)		-0.94 (-1.87, -0.02)	

[1]Cochran M-H test, stratified by site & categorized -1, 0, 1.

Table 2

RESULTS OF SUBJECTS' SELF-ASSESSMENT OF HEEL PAIN AT MONTHS 1,2, AND 3

	Orthospec	Placebo	P-Value
Month 1			
N	110	54	
Mean[1]	-2.23	-2.12	0.79
Difference (95% CI)		-0.11 (-0.95, 0.72)	
Month 2			
N	111	54	
Mean[1]	-2.67	-1.94	0.102
Difference (95% CI)		-0.73 (-1.60, -0.15)	
Month 3 (1° Outcome)			
N	112	56	
Mean[1]	-3.39	-1.78	<0.001
Difference (95% CI)		-1.61 (-2.55, -0.67)	

[1]Cochran M-H test, stratified by site & categorized -1, 0, 1.

Table 3

DISTANCE THAT SUBJECTS COULD WALK BEFORE EXPERIENCING PLANTAR FASCIAL PAIN AT BASELINE AND MONTH 1.

	Orthospec	Placebo
Baseline, no.	111	56
No/Minor Limitation	12 (10.8)	9 (16.1)
6 - 10 Blocks	14 (12.6)	0 (0)
4 - 6 Blocks	6 (5.4)	6 (10.7)
1 - 3 Blocks	17 (15.3)	8 (14.3)
< 1 Block	62 (55.9)	33 (58.9)
Month 1, no.	110	54
No/Minor Limitation	33 (30.0)	14 (25.9)
6 - 10 Blocks	8 (7.3)	5 (9.3)
4 - 6 Blocks	15 (13.6)	6 (11.1)
1 - 3 Blocks	13 (11.8)	7 (13.0)
< 1 Block	41 (37.3)	22 (40.7)

Values are no.(%).

Table 4

USE OF PAIN MEDICATIONS

	Orthospec	Placebo	P-Value
Month 1			
Increase: n/N (%)	7/111 (6.3)	5/54 (9.3)	
No Change: n/N (%)	69/111 (62.2)	39/54 (72.2)	0.083
Decrease: n/N (%)	35/111 (31.5)	10/54 (18.5)	
Month 2			
Increase: n/N (%)	1/95 (1.1)	5/47 (10.6)	
No Change: n/N (%)	66/95 (69.5)	33/47 (70.2)	0.028
Decrease: n/N (%)	28/95 (29.5)	9/47 (19.2)	
Month 3			
Increase: n/N (%)	1/100 (1.0)	6/51 (11.8)	
No Change: n/N (%)	65/100 (65.0)	38/51 (74.5)	<0.001
Decrease: n/N (%)	34/100 (34.0)	7/51 (13.7)	

both of which were mild and transient. Pending FDA approval, Orthospec may be considered for alternative therapy in the treatment of recalcitrant proximal plantar fasciitis.

REFERENCES

1. McCarthy DJ, Gorecki GE. The anatomical basis of inferior calcaneal lesions. *J Am Podiatric Med Assoc* 1979;69:527.
2. Scherer PR. Heel pain syndrome: pathomechanics and non-surgical treatment. *J Am Podiatric Med Assoc* 1991;81:68-72.
3. Malay DS. Plantar fasciitis and heel spur syndrome: a retrospective analysis. In: Vickers NS, ed. Reconstructive Surgery of the Foot and Leg: Update 1996. Tucker (GA): Podiatry Institute; 1996:133-5.
4. Tomczak RL, Haverstock BD. A retrospective comparison of endoscopic plantar fasciotomy to open plantar fasciotomy with heel spur resection for chronic plantar fasciitis/heel spur syndrome. *J Foot Ankle Surg* 1995;34:400-7.
5. Kinley S, Frascone S, Calderone D, et al. Endoscopic plantar fasciotomy versus traditional open heel spur surgery: a prospective study. *J Foot Ankle Surg* 1993;32:595-603.
6. Perez M, et al. Extracorporeal shock wave therapy for plantar fasciitis. *Clinics Podiatr Med Surg* 2003;20:323-34.
7. Alvarez RG, et al. Symptom duration of plantar fasciitis and the effectiveness of orthotripsy. *Foot and Ankle Intl* 2003;24:916-21.
8. Haake M, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomized controlled multicentre trial. *BMJ* 2003;12:75.
9. Speed CA, et al. Extracorporeal shock wave therapy for plantar fasciitis: a double blind randomized controlled trial. *J Orthop Res.* 2003;21:937-40.