CHAPTER **19**

EXTRACORPOREAL SHOCK WAVE THERAPY UTILIZING THE ORTHOSPEC® DEVICE: Theory and Study Design

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Plantar fasciitis is a common problem facing the podiatric physician, with an estimated two million patients treated in the United States each year.[1] Conservative therapies such as stretching, icing, arch supports, night splints, nonsteroidal anti-inflammatory medications, corticosteroid injections, ultrasound and other physical therapy modalities have proven to be highly successful. Patients and physicians alike experience a high degree of frustration when these measures fail, and surgical intervention often becomes necessary. Surgical interventions include heel spur resection, plantar fasciotomy (open versus endoscopic), and external neurolysis, each with varying degrees of success. A number of patients have simply decided to "live with the pain," despite numerous attempts at treatment.

Extracorporeal Shock Wave Therapy (ESWT) has recently evolved as an alternative for those patients failing traditional treatment and not desiring surgical intervention. A shock wave is generated utilizing electomagnetic, piezoelectric, or electrohydraulic methods and applied to the area of maximal tenderness via a contact membrane. Light sedation and local anesthesia are required prior to the application of some forms of the shock waves (Ossatron®). The amount of energy and total number of shock waves administered has been varied in recent studies.

Several different mechanisms have been proposed regarding the action of shock waves, although currently no substantial evidence exists for their validity. One theory states that the waves initiate cell membrane damage, diminishing their ability to transmit pain signals. The neovascularization theory states that the shock waves destroy calcium and produce microfractures in bone, causing an influx of blood and inflammatory cells. A chronic pathologic condition is transformed into an acute one, creating an environment for bone and soft tissue healing. The Gate Control theory states that the shock waves flood the peripheral nervous system and block the original noxious stimuli at the spinal cord level.

Our institution is currently involved in a multicenter, double blind, placebo controlled study involving the Orthospec® device (Medispec). Orthospec® is similar to the Ossatron® device in that shock waves are created by the "spark gap" method (electrohydraulic) and applied to the heel via a contact membrane. The manufacturers of Orthospec® have designed a larger therapy zone that allows the energy of the shock wave to be distributed over greater surface area. As a result, patients experience less pain during treatment, and there is no need for sedation or regional anesthetic blockade.

LITERATURE REVIEW

The use of extracorporeal shock waves in medicine was first developed in the 1980s in Germany as a treatment for kidney and gallstones, known as lithotripsy. These shock waves possessed high-energy intensities and were focused over a very small surface area.

The patient underwent general anesthesia and imaging was required to focus the energy to the kidney stones. German orthopedists first began to explore the use of shock waves for orthopedic applications in the 1980s. The first preclinical trials investigating the effects of shock wave therapy on the musculoskeletal system appeared in 1989.

Yeaman et al studied the effects of shock waves on developing bone utilizing the proximal tibias of 18 rats. Each bone was exposed to shock waves from the Dornier XL-1 lithotripter that caused focal growth dysplasia in 44% of treated bones. However, there was no effect on overall bone growth unless a large lesion was produced.[2]

Haupt investigated the influence of shock waves on fracture healing in rats. 26 fractures were exposed to 500 shock waves at 14 or 18 kV, while 14 rats served as placebo. The results suggest that subjecting the fractures to shock waves has a positive effect on healing as evidenced by mechanical stability and radiographic signs of healing.[3]

In 1995 Delius studied the acute effects of shock waves on bone utilizing 19 rabbits as models. The shock waves were found to induce periosteal detachment, subperiosteal hemorrhages, and displaced bony trabeculae

in the medullary canal. The bone cortices remained completely intact, and radiographs revealed lucencies in the marrow, but without any gross fractures.[4]

Several studies were also performed investigating the effects of shock waves on soft tissues. Rompe and colleagues sought to determine the effect of ESWT on tendon. Using an intact achilles tendon and paratenon from a rabbit, shock waves were administered at varying degrees of energy. Gross and histological changes were detected at higher energy intensities (> 0.28 mJ per mm2) and the investigators recommended lower levels when treating tendon disorders.[5]

In 2000, Vaterlein used femoral condyles of 24 rabbits to investigate the effect of shock waves on joint cartilage. The left femoral condyle was exposed to waves at an energy level of 1.2 mJ, while the right condyle served as a control. They discovered no evidence of gross, histologic, or radiographic pathology at 3, 12, and 24 weeks.[6]

The first efficacy studies of ESWT appeared in the literature in 1991 and were largely based in Europe. Clinical trials were performed for conditions such as nonunions, plantar fasciitis, epicondylitis, and tendinosis calcarea. Krishek and colleagues studied the effect of low energy ESWT on 50 patients with refractory plantar fasciitis. Subjects were administered 3 treatments of 500 pulses each and followed prospectively. They concluded that the low energy shock waves were effective compared to placebo.[7]

A clinical trial based in Taiwan consisted of 80 patients with painful heel syndrome who received low energy shock wave therapy. After 6 months, 59.3% of patients had no further complaints, 27.7% reported feeling significantly better, while 13% felt slightly better. There were no cases of patients feeling worse after the course of treatment.[8]

Ogden et al investigated the effects of shock waves delivered by the Ossatron® to 302 randomized patients satisfying rigorous inclusion criteria. Subjects received 1500 shocks at 18 kV after receiving ankle block anesthesia, while a Styrofoam block was used for the placebo group. At 3 months follow up, 56% more of the active treatment patients had a successful result compared to the placebo group.[9]

A study by Weil included 36 patients with symptomatic heel pain present for greater than 6 months. ESWT was administered using 1500- 3000 pulses at 17-21 kV and average follow up was 8.4 months. They reported a satisfaction rate of approximately 80% and a 78.1% mean percentage of improvement.[10]

Recently there has been clinical evidence suggesting that ESWT is not effective for the treatment of chronic plantar fasciitis. A study recently published in the Journal of the American Medical Association the effectiveness of ultrasound guided ESWT for the treatment of plantar fasciitis. Each subject received 1000 mJ/mm2 over a three week time period and each were compared with a group of patients receiving placebo. The investigators concluded there was no benefit of shock wave therapy over the placebo group.[11]

Haake et al administered ESWT utilizing the Dornier Epos Ultra® on 272 patients with six months of failed conservative treatment for heel pain. 135 patients received the active treatment while 137 received a placebo. At 12 weeks, 34% of subjects reported a successful outcome in the treatment group, while 30% of patients in the placebo group also reported positive results. No statistical significance was found between the two groups.[12]

MATERIALS AND METHODS

The goal of the current study, sponsored by Medispec, is to demonstrate a statistically significant difference between Orthospec® and Orthospec® placebo treatments in regard to change from baseline of the Visual Analog Pain Score (VAS) at three months post treatment. Treatments are being conducted at three separate centers involving 183 patients. The subjects are randomized into two groups, active or placebo, in a ratio of 2:1. The subject and the primary investigator are blinded to the treatment being administered by the unblinded investigator. To be included in the study, subjects had to satisfy a strict set of inclusion and exclusion criteria (Tables 1 and 2).

The initial screening visit includes signing an informed consent as well as collection of demographic data. A thorough history is taken including any medical conditions, prior surgeries, social and family history, use of medications, and drug allergies. Baseline vital signs are obtained, as well as a thorough pedal vascular and neurologic examination. Once the specific location of tenderness is noted, a calibrated pressure device quantifies pain level. A set of standard radiographs is taken documenting any abnormalities.

The pretreatment evaluation is performed to quantify the patient's level of discomfort. The subject is asked how painful their heel feels upon first rising in the morning utilizing a visual analog scale. The number of blocks the patient can walk without pain quantifies activity and function. The type and amount of pain medications taken for plantar fasciitis is also documented during the pretreatment session. Patients are reminded to comply with the standard wash out periods of pain medications before initiating treatment. The investigator

Table 1

INCLUSION CRITERIA

Age > 18 years
Symptoms > 6 months Treatment > 4 months
Pain > 5 by visual analog scale and investigator assessment
2 failed pharmacologic treatments
2 failed nonpharmacologic treatments
Single site of tenderness over plantar calcaneal tuberosity

assessment of heel pain is recorded utilizing the calibrated pressure device.

Prior to the patient entering the treatment room, the unblinded investigator administering the active or placebo treatment prepares the Orthospec® device. A Styrofoam pad is used in the contact membrane for those receiving the placebo. The subject's heel is then positioned so firm contact is made between the focally tender area and the contact membrane. Ultrasound gel is applied to the heel and contact membrane to allow transmission of the shock wave. ESWT is then administered at a frequency of 150 shocks/minute for a total of 3800 shocks. The treatment session lasts for approximately 25 minutes and the level of energy is gradually increased according to patient tolerance. Any adverse events or device malfunctions are carefully recorded during each session.

During the follow up period, the subject records data in a diary supplied by Medispec. Patients write down their level of heel pain upon first rising in the morning, number of blocks walked without discomfort, and any use of pain medications. A follow up appointment with the primary investigator are scheduled each month for a total of three months. Investigator assessment of heel pain is performed during the post treatment evaluations.

DISCUSSION

The emergence of extracorporeal shock wave therapy for the treatment of chronic plantar fasciitis has been the focus of much research and controversy. Recent studies regarding its efficacy have demonstrated conflicting results. While much still remains to be learned in terms of mechanism of action, ESWT offers a noninvasive treatment alternative for patients not desiring the risk of surgical intervention. The focus of this study is to evaluate the efficacy of the Orthospec® in treating heel pain versus placebo.

Table 2

EXCLUSION CRITERIA

Recent significant disease
Prior surgery for plantar fasciitis
Neuropathy, malignancy, or infection
Plantar fascial tear
Bilateral cases
Pregnancy
Corticosteroid injection within 6 weeks
Physical therapy within 2 weeks
Narcotic use
NSAIDS within 48 hours
Anticoagulant medication

The Orthospec® investigational device has been used in Europe to treat a variety of orthopedic conditions including tendinosis calcarea of the shoulder, lateral epicondylitis, and Achilles tendonitis. The device is unique in that it does not require the use of anesthetics, sedation, or imaging. The treatments are performed on an outpatient basis as a single 25minute session. By enlarging the "therapy zone", the shock waves are distributed over a wider surface area, and allows for decreased pain during treatments.

The shock waves are created by the electrohydraulic or "spark gap" method where an electrode ignites a charge within a water contained semi-ellipsoid chamber. A portion of water is vaporized and reflected off the chamber through the contact membrane. The shock wave then passes through the conducting medium and to the intended treatment area. The amount of energy delivered may be adjusted from levels 1-7, depending on patient tolerance (.07mJ/mm2- .32 mJ/mm2). General contraindications to ESWT are the presence of malignancy, use of a pacemaker, and use over a healing fracture.

ESWT administration utilizing the Orthospec® is still pending FDA approval. The results of this multicenter, placebo-controlled study remain to be seen. Several questions remain regarding the use of ESWT in general: Which patients are best suited for the therapy? What are the potential harmful side effects of shock wave therapy? What are the long-term results of ESWT? The answers to these questions may strengthen the case for extracorporeal shock wave therapy in treating recalcitrant plantar fasciitis.

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