FDA Clinical Investigation for Extracorporeal Shock Wave Therapy for chronic heel pain syndrome

Summary of Safety and Effectiveness results of the clinical Study for plantar fasciitis with the OssaTron in the USA

Summary:

A multicenter, randomized, placebo-controlled, double blind clinical study was performed in 7 Institutions in the USA to determine safety and effectiveness of extracorporeal shock wave therapy (ESWT) with the OssaTron of chronic heel pain syndrome (plantar fasciitis). Chronic heel pain syndrome was defined as pain in the area of the insertion of the plantar fascia on the medical calcaneal tuberosity that had persisted for six months or more. The success rate following a single treatment with the OssaTron is 76%. The success rate for patients undergoing repeat treatment, following a failed primary treatment, is 81% based on investigator's assessment. The complication rate is 4.7% and the re-treatment rate 10.7%.

Introduction

The objective of this multicenter, randomized, placebo-controlled and double blind clinical study was to determine safety and effectiveness of extracorporeal shock wave therapy (ESWT) for chronic heel pain syndrome (plantar fasciitis) with the OssaTron. The study was also designed to demonstrate the durability of the treatment results to a minimum of six months post treatment and to provide safety and effectiveness data concerning repeat extracorporeal shock wave treatment in patients who have failed to respond to the initial treatment.

Material and Methods:

A total of 235 subjects were randomized to either active ESWT or placebo treatment. 41 subjects were not randomized to ESWT for investigator training purposes. 276 subjects completed the study.

The study was conducted at seven institutions in the USA. Chronic heel pain syndrome was defined in this study as symptoms of moderate to severe pain in the affected heel at the origin of the plantar fascia on the medial calcaneal tuberosity that had persisted for at least six months prior to study enrollment. To be eligible for study participation, a subject had to had a pain score of 5.0 or greater on a 10 cm VAS based upon investigator assessment. At each evaluation the investigator blinded to randomization assignment assessed the subjects heel pain by applying pressure on the affected heel at the origin of the plantar fascia on the medial calcaneal tuberosity. The investigator used a pressure sensor to record the amount of pressure applied to elicit the baseline response, and thereafter to apply the same amount of pressure at each follow-up assessment to assure consistency in evaluation. Participants also recorded their self-assessment of the amount of pain experienced during the first 5 min. of walking. To be eligible for the study subjects had to have for this criterion a pain score of 5.0 of greater on a 10 cm VAS. For this study subjects must have failed to respond to at least three attempts of conservative treatments.

Styrofoam block was placed against the coupling membrane of the shock head to absorb the shock waves completely. A fluid-filled IV bag was then placed between the Styrofoam block and the subject's elbow to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV.

Subjects were followed pre-treatment, 4 weeks, 8 weeks and 12 weeks post treatment. An initial success/fail status was assigned based on findings at 12 weeks post treatment evaluation. Subjects assigned a success status at 12 weeks were required to return for follow-up at 6 and 12 months. Subjects assigned a fail status after 12 weeks had the opportunity to receive active ESWT or a repeat ESWT. A total of 37 subjects out of the placebo group received an active ESWT (change group) after 12 weeks follow-up and an assessment as fail status. 21 subjects out of the active group received a repeat ESWT.

FDA Clinical Investigation for Extracorporeal Shock Wave Therapy for chronic heel pain syndrome

At the 12 weeks follow-up a success/fail status was assigned for each subject according to the following 4 criteria:

1. Investigator assessment of pain: Minimum 50% improvement over baseline and a VAS score of 4.0 or less.
2. Subject's self assessment of pain: Minimum 50% improvement over baseline and a VAS score of 4.0 or less.
3. Subject's self assessment of activity: Improvement of 1 point on a 5 point scale or maintenance of a baseline score of 0 or 1.
4. Use of pain medication: No pain medications required for heel pain.

A subject must have met all for success criteria for an overall status "Success" to be assigned at the 12 week visit.

Each study subject received a local anaesthetic or an ankle block prior to the study procedure. The affected leg was then draped from the view of the study subject. Each study subject assigned to active treatment then underwent an ESWT with a total of 1500 shocks at 18 kV. For subjects assigned to placebo treatment, a Styrofoam block was placed against the coupling membrane of the shock head to absorb the shock waves completely. A fluid-filled IV bag was then placed between the Styrofoam block and the subject's heel to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV.

Results:

	All 4 Success criteria met after 12 weeks
Active ESWT group, Single ESWT	56/119, (47.05%)
Placebo group	35/116, (30.17%)
Non-randomized group, Single	24/41, (58.54%)
Change group, Single ESWT	20/37, (54.1%)
Repeat ESWT	11/21, (52.38%)

Following a single OssaTron treatment, 47.05% of the subjects randomized to active treatment met all 4-success criteria, compared to only 30.17% in the placebo group. The success rate in active ESWT group at 12 weeks was 56% higher than the success rate in the placebo group.
The majority of the treatment effect was observed in the blinded investigator assessment of heel pain. The average percent improvement in VAS score from baseline to 12 week follow up was 60% and the improvement for the subject self assessment of pain during the first few minutes of walking was 61%.

	Met investigator assessment of pain	Met subject self assessmentof pain
Active ESWT group,Single ESWT	74/119, (62.18%)	71/119, (56.66%)
Repeat ESWT	17/21, (80.95%)	12/21, (57.14%)

FDA Clinical Investigation for Extracorporeal Shock Wave Therapy for chronic heel pain syndrome

The overall results of all subjects which received a single ESWT (active, non-randomized, change) with the OssaTron represents the following table:

Grade	Success criteria	Success rate in %	Combined Successrate in %
Complaint free	4/4	51%	76%
Significantly better	2/4, 3/4	25%	
Slightly better	1/4	10%	24%
Unchanged	0/4	14%	

The complication rate for this study was very low, and all complications were relatively minor. Only 13 complications or adverse events occurred related to the 273 active procedures (4.7%). The most commonly reported complications were post-treatment pain and mild transient neurological symptoms (numbness, tingling) in the treated foot. No unanticipated or serious adverse events occurred in any patients. A total of 218 active ESWT with the OssaTron have been performed for the 197 subjects of the active, non-randomized, change and repeat treatment group, so that the re-treatment rate is only 10.7%.

Conclusion:

The study findings have shown that ESWT with the OssaTron if chronic heel pain syndrome (plantar fasciitis) is safe and effective. The success rate following a single treatment with the OssaTron is 76%. The success rate for patients undergoing repeat treatment, following a failed primary treatment, is 81% based on investigator's assessment. The complication rate is 4.7% and the re-treatment rate 10.7%. The low re-treatment rate suggests that some of the subjects who were assigned a final status "failed" because they have not met all 4 success criteria, may have been sufficiently satisfied with the outcome of their treatments.