Clinical Studies with HMT Orthopaedic Shock Wave Treatment Device OssaTron

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Summary of Safety and Effectiveness results of the clinical study for chronic lateral epicondylitis with the OssaTron in the USA submitted to the FDA

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 lateral epicondylitis. Chronic lateral epicondylitis was defined as pain in the area of the insertion of the tendon that had persisted for six months or more.
The comparison of results between active treatment patients and placebo-treated patients was highly significant according to the statistical analysis. 90% of treated patients received a benefit from the treatment and 64 % had an excellent or good outcome. The complication rate was 4.7 % that were mild and transient in nature. The re-treatment rate is 12.9 %.

Material and Methods:
A total of 225 subjects were treated for chronic lateral epicondylitis. 183 subjects were randomized to either active ESWT or placebo treatment, and 42 subjects were not randomized to ESWT for investigator training purposes. A total of 165 randomized subjects followed to 8 weeks and showed a clinically, as well as a statistically significant difference in the treatment versus placebo groups ($p = 0.018$).
The study was conducted at seven institutions in the USA. Chronic lateral epicondylitis was defined as pain in the area of the insertion of the tendon that had persisted for six months or more. To be eligible for study participation, a subject had to have a pain score of 5.0 or greater on a 10 cm VAS based upon investigator assessment. Participants also recorded their self-assessment of the amount of pain experienced during activity. To be eligible for the study, subjects had to have a pain score of 5.0 or greater on a 10 cm VAS for this criterion. For this study subjects must have failed to respond to at least three attempts of conservative treatments.
Each subject was followed to 8 weeks post-treatment after which an initial success/fail status was assigned. Subjects assigned a success status at 8 weeks were required to return for follow-up at 12 weeks, 6 months and 12 months. Subjects assigned a fail status after 8 weeks had the opportunity to receive active ESWT or a repeat ESWT.
At the 8 weeks follow-up a success/fail status was assigned for each subject according to the following 3 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 during activity: Minimum 50% improvement over baseline and a VAS score of 4.0 or less
3 Use of pain medication: None or rare pain medications required for lateral epicondylitis.

A subject must have met all three success criteria for an overall status "Success" to be assigned at the 8 week visit.

Each study subject received a local or regional anesthetic prior to the study procedure. The affected arm 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 elbow to mimic the feel of the coupling membrane, and 1500 shocks were then delivered at 18 kV.

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Results:
Following a single OssaTron treatment, 52% of the active subjects met success criteria for the Investigator Assessment of pain, 59% of the active subjects met success criteria for self-assessment of pain during activity, and 85% of the active subjects met success criteria for use of pain medication.
The overall results of all subjects treated with ESWT represents the following table below. This includes: subjects randomized to active treatment, non-randomized subjects, and small subsets of active treatment subjects who failed to meet success criteria following a primary OssaTron ESWT treatment and elected to have a repeat treatment and, subsequently treated placebo subjects.

Number of patients treated in the study: 225

Grade	Success Rate in %	Combined Success Rate in %
Complaint free	45%	64%
Significantly better	19%	
Slightly better	26%	36%
Unchanged	10%	

The complication rate for this study was very low (4,7 %), and all complications were minor.
After 12 months the status "Success" maintained 87% of subjects out of the active ESWT group.

Conclusion:
The study findings have shown that ESWT with the OssaTron for chronic lateral epicondylitis is safe and effective. The comparison of results between active treatment patients and placebo-treated patients was highly significant according to the statistical analysis. 90% of treated patients received a benefit from the treatment and 64% had an excellent or good outcome. Therefore it was concluded that a single ESWT procedure with the OssaTron is an effective treatment for chronic lateral epicondylitis.

The use of the OssaTron® for the treatment of chronic lateral epicondylitis was approved by the Food and Drug Administration
March 14, 20