52. Safety and efficacy of ESWT in plantar heel pain – outcome of the STORZ FDA Study

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Methods: A prospective, multicenter, double-blind, randomized, placebo-controlled FDA trial was conducted among 250 subjects. Subjects were randomized to ESWT (0.25 mJ/mm^2) or placebo intervention. Both groups received three interventions of 2000 impulses, each session one week apart. The primary outcome was the percentage change of heel pain quantified by VAS composite score, as well as the change of Roles and Maudsley score at 12 weeks after the last intervention compared to baseline. Secondary endpoints were defined as single success rates (more than 60% reduction in single VAS), overall success rate, physician's judgment of effectiveness, patient's satisfaction with outcome, patient's willingness to recommend treatment, subject's analgesic medication consumption at 12 weeks and success rates at 12 months.

Results: 246 patients (98.4%) were available for intention-to-treat analysis at 12-week follow-up. ESWT resulted in a 69.2% reduction of heel pain regarding the primary endpoint VAS composite score compared to baseline, compared to 34.5% for placebo (p=0.0027, one-sided). ESWT was also significantly superior to placebo for the Roles and Maudsley score (p=0.0020, one-sided). The combined overall result of the eight secondary criteria also showed statistical significance (P = 0.0015 one-sided). Sensitivity analyses supported superiority of ESWT, and clinical success of the intervention persisted at 12 months. No clinically relevant device-related adverse events were recorded.

Conclusion: The results of the present study provide confirmatory proof of effectiveness of three interventions of ESWT without local anaesthesia in the treatment of refractory painful heel syndrome, with clinically relevant changes in pain scales.