250 patients were randomly assigned to get ESWT or placebo. 12 month after intervention all primary criteria improved significantly after ESWT.

To determine the long time efficacy of extracorporeal shock wave therapy on chronic plantar heel pain a prospective randomized multi center trial was performed.

A total of 250 patients were enrolled and assigned to ESWT or identical placebo. 2000 treatment-impulses were applied at 0.25 mJ/mm2 without local anesthesia. 3 ESWT sessions were done with 2 weeks in between. The primary Criteria were: Heel pain when taking the first steps and during daily activities. Second criteria were local pain on pressure, Roles and Maudsley-Score and SF-36. The end point was 12 months after last ESWT. The study was performed in accordance to GCP guidelines.

12 month after ESWT success was observed in all criterias. The rate difference in all items after ESWT were statistically significant better in favor of the ESWT treatment. Regarding the change of pain score after ESWT the VAS composite score decrease from 8.3 at baseline down to 2.7 after ESWT, compared to 5.31 after identical placebo after 3 month. 12 month after ESWT the VAS score dropped down to 0.8. The percent change was 69% after ESWT and 34% after placebo. The same outcome was found in all secondary criteria as well. The a priori ordered hypotheses of the final statistical analysis plan was statistically significant (P < 0.025 one-sided) in all criteria. Only minor side effects as petechial bleeding, swelling and discomfort during treatment were detected.

The focused shock wave therapy is effective and save in treatment of chronic heel pain. Excellent outcome was found after 3 and 12 month. The effect size reached clinical relevance without relevant side effects.