

# Extracorporeal Shockwave Therapy for Chronic Skin Lesions – Preliminary Report

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In treating infected non-unions connected with chronic skin lesions with ESWT, we observed a significant impact on wound healing. In most of the patients, extremely rapid healing of the wounds was observed.

After successful animal trials, performed at the Department of Plastic and Reconstructive Surgery of the University of Innsbruck, we started our pilot trial. At the University of Kentucky, the new parabolic therapy head which delivers almost flat shockwaves was tested.

A standardized skin flap model was utilized in 16 adult rats to prove the effect of ESWT on the survival rate of the flap. An island flap (8x8 cm) was formed retaining its only attachment to the vascular pedicle at the groin on one side. The epigastric vessels were exposed with the right inferior epigastric vessel left intact and the left inferior epigastric vessel clamped with microclips then cut. The flap was immediately sutured back into its native position. Animals in the treatment group were exposed to 500 pulses at 0.15 mJ/mm<sup>2</sup> on the entire right half of the flap. The device used to apply the pulses was the DermaGold® which has a parabolic therapy head delivering defocused shockwaves (manufactured by MTS, Konstanz, Germany). At 7 days post-op all animals were euthanized and digital images of the flap area were taken. These images were analysed using the PictZar imaging software.

At the same time, there were 175 patients with 177 chronic skin lesions being treated in Vienna and 23 patients being treated in Berlin by means of ESWT with the DermaGold®. All therapies were performed without any kind of anesthesia as an outpatient treatment. We used the same form of dressing after ESWT that was applied before the treatment to be able to judge the effect of the treatment. Depending on the surface of the defect, different numbers of pulses were applied. The patients were treated in 1 up to 10 sessions depending to their tendency for regeneration and epithelialization.

Concerning the island flap:

For the control group (n=8) there was an average of 11.7 cm<sup>2</sup> area of necrosis to the skin flap. In the treatment group (n=8) necrosis of the same flaps were an average of 3.8 cm<sup>2</sup>. This represents an approximate reduction of 68%.

Concerning the clinical trial:

Of the 200 skin lesions in 198 patients, 149 (74.5%) showed complete healing, 10 (5%) had more than 50% of epithelialization and 15 (7.5%) had less than 50%. Twenty-six (13%) patients were lost to follow up. The treatment was tolerated by all patients without any kind of anesthesia. No adverse effects have been observed. In none of the cases was an increase of symptoms reported.

After these pilot studies evaluating the most efficient treatment parameters were completed, a prospective randomized IDE-trial to confirm our results in treating diabetic foot ulcers commenced in April.