

# Extracorporeal Shockwave Therapy for Non-Unions and Delayed Healing Fractures

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## Device and producing company:

OrthoGold 280 (USA) / Orthowave 280c (Outside USA), Tissue Regeneration Technologies (TRT), USA manufactured by MTS Europe GmbH, Germany

## Introduction:

The objective of every fracture treatment is to reunite the fracture fragments in an anatomical position and completely restore the function of the injured section of the skeleton as quickly as possible. Despite today's sophisticated technologies and good primary treatment, 1-3% of all bone fractures develop into pseudarthrosis. Surgical treatment with debridement of the pseudoarthrotic tissue, cleaning of the fragment edges, insertion of autologous spongiosa and stabilization with osteosynthesis material is considered the "gold standard" for the treatment of pseudarthrosis. However, these surgical procedures are extremely traumatic for the patient, costly, time-consuming, and are associated with a high rate of complications. Therefore after successful pilot studies, in December 1998 the Trauma Centre Meidling started to treat non-unions regularly with shockwave therapy. Different devices were used and success rates between 63% and 75% were generated. Since August 2005 we have used the Orthowave 280c, Tissue Regeneration Technologies (manufactured by MTS Europe GmbH, Konstanz, Germany).

## Methods:

From the start of the study, more than 50 patient-specific data items were stored in a database developed especially to permit the combination of a broad range of parameters. This database structure serves as the basis for quality assurance measures and enables the researchers to determine the optimal treatment parameters and other important criteria. This database containing documentation of the treatment of pseudarthrosis with ESWT is made available to all interested parties free of charge; it can be ordered from the authors. Treatment was basically envisaged as a single treatment. Depending on the region to be treated, shockwave therapy was administered under general, regional or local anaesthesia. Thus far, 527 patients have been treated. As of March 2008, results of 349 patients with complete follow up are available. The patients, referred from 45 different hospitals, consisted of 114 females (33%) and 235 males (67%). The mean age was 49.0 years with a range from 16-91years. The average delay between the injury or the last operation and the shockwave therapy was 11.7 months (in 241 / 69% patients more than 6 months, in 108 / 31% patients between 3 and 6 months / delayed healing). Eighteen of the non-unions were infected.

Depending on the localization, between 2,000 and 4,000 pulses were applied (1,000 pulses per treatment location). We used an energy flow density (EFD) of 0.35 mJ/mm<sup>2</sup> for all bone treatments. For evaluation, the bony consolidation of the fracture/non-union was observed on plain radiography or CT. Following shockwave therapy the pseudarthrosis is immobilized like a fresh fracture. This is usually carried out with a plaster cast or plastic splint; in 3 patients with especially mobile tibia non-unions, an external fixator was used. Fixation is not necessary when the pseudarthrosis has been treated with appropriate osteosynthesis material and this material exhibits no signs of loosening upon clinical or radiological examination. It can be assumed that the healing process is initially accompanied by neovascularization; for this reason, we try to prevent micro movements of the non-union during the first 3-4 weeks after treatment to preclude tearing of the new capillaries. It may be necessary, in some cases, for the patients to avoid full weight bearing on the affected extremity during this period. The patient's cooperation must be elicited by a detailed briefing since most patients are asymptomatic directly after the treatment, owing to the analgesic effects of the shockwaves, and want to put their full weight on the affected extremity again. A pseudarthrosis gap with a width greater than 5 mm shows a poor prognosis. In cases where bony remodelling of the non-

union could not be demonstrated after 3 to 6 months, patients were given the option of surgical repair. Numerous patients, especially those who had undergone multiple operations previously, refused this offer. This led to a relatively high number (15.9%) of repeated treatments. In exceptional cases (9), more than two treatments were carried out. The group of patients undergoing repeat ESWT included patients for whom a complicated pseudarthrosis operation was contraindicated for internal reasons or could have been carried out only at considerable risk to the patient.

**Results:** Osseous union was achieved in 282 (81%) of the pseudarthroses. No complications occurred other than the adverse reactions that have already been observed following shockwave therapy (i.e. local swelling, petechial bleeding and haematoma). Even though the mechanism of action of shockwave therapy has not yet been fully explored, we are convinced that ESWT is an effective, inexpensive and time-saving therapeutic modality with an almost zero rate of complications. Therefore in Austria, ESWT is considered as the therapy of first choice for non-unions and delayed unions that do not require surgical realignment.