

ESWT in Chronic Decubitus Ulceration in Complex Neurological Disability

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Device and producing company:

Dermagold (USA), Tissue Regeneration Technologies (TRT) Orthowave 180C (Outside USA), MTS Europe GmbH

Introduction:

Skin ulceration in complex neurological disabilities is often chronic causing pain, risk of septicaemia and limitation of activities leading to a decreased quality of life. Chronic ulcers are also expensive in terms of nursing time and financial cost of treatment. We have previously described provisional findings of a study of ESWT on chronic ulceration. This paper presents the final findings of the study.

Methods:

A randomised double-blind cross-over study, with washout period, of ESWT and a placebo ESWT was used. All patients in a large long-stay hospital specialising in chronic neurological conditions were eligible for inclusion in the study. Patients were randomised into treatment with ESWT first or with the placebo ESWT head first. Treatment periods were weekly for four weeks. There was a two week washout period between the two forms of 'treatment'. After six weeks the treatment methods crossed over. The machine used was the Orthowave 180c with two heads – one active and one inactive. The machine fired for both the ESWT and the placebo treatments thus the noise was the same for both treatment groups. The area and depth of the ulceration was recorded by tracing the outline of the ulcer onto an acetate sheet and measuring the area using a computerised grid system (Visitrak™ [Smith & Nephew]). For each observation the average of three measurements were taken.

Results:

Fifteen ulcers (in 13 patients) were included in the study; eight were on the buttocks/sacrum/trochanter and seven were on the feet/ankles. Where there was some healing prior to the study (5) there was no evidence that the ESWT increased the rate of healing. Where there was small surface area ulceration but with a sinus present (3) there was no evidence of healing; but for those with static chronic ulcers all showed improved healing after the start of ESWT. Where the placebo head was used first there was no healing until after the ESWT treatment started. After the research period those with sinuses were treated using a different technique of ESWT and there was some evidence that healing began to occur though this needs further study under research conditions. Some patients showed a deterioration in the size of the ulceration on starting ESWT. These were patients with undermined ulcers with vulnerable ischemic skin. There was then improved healing – thus the ESWT assisted debridement of the ulcers.

Discussion:

It is uncertain why there was no effect of ESWT on those ulcers already showing healing, and this needs further study. The non-healing of the sinuses was probably due to the technique being used, and this needs further research. The main finding was that those ulcers that had not been healing prior to the study all improved, with some healing completely. Considering that some of these ulcers had been present for many months, or even years, this indicates that ESWT has a potential place in the treatment of chronic ulceration in people with complex neurological disabilities.

Conclusion:

We were unable to demonstrate any benefit of ESWT on ulcers that were already healing or where there was a sinus present. In the latter case this was probably due to the technique being used. ESWT had a significant effect on healing of those ulcers that had not been showing any healing prior to the study.