Med. Sci. Res., 1995; **23**, 671–673

Combination of occlusive dressings and electrical stimulation in pressure ulcer treatment

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Keywords: Pressure ulcers, chronic wounds, electrical stimulation, occlusive dressings.

Introduction: Knowledge of the greater efficiency of wound healing in a moist environment dates back to the early 1960s, when Winter [1] first demonstrated significantly faster wound epithelisation in occluded experimental wounds in pigs as compared to air-exposed controls. In 1963, the beneficial effect of occlusion was also established in human wounds [2]. This discovery gained considerable attention, yet not until two decades later, when the development of new technologies facilitated the production of a new generation of wound dressings, was it employed in routine wound treatment. As they are based on the control of the wound microenvironment, mainly tissue hydration, these dressings are known as occlusive. Occlusive dressings experienced a great upswing in a very short period, despite the limited knowledge of the full biological effects of wound occlusion.

Winning recognition for non-conventional wound treatments, one of them being electrical stimulation, is much more difficult than for this new concept in conventional wound care. Various applications of electricity have been studied for their capacity to enhance wound healing [3].

In the present preliminary study, we combined conventional wound care with occlusive dressings with electrotherapy, which proved successful for pressure ulcer management in an earlier extensive clinical trial [4]. This combined treatment is in line with an almost ten year old vision by Turner [5]. He foresaw the evolution of chronic wound dressings in three stages: traditional "passive" wound dressings have been overtaken by "interactive" occlusive dressings, which are able to control the wound microenvironment but do not release any active substances into the wound. In the future he foresaw the development of "active" dressings, which would actively affect the healing process. The combined treatment employed in our preliminary research can be observed as an active – electronic – dressing, in which the concept of wound environment control is supplemented by electrical stimulation, which actively influences healing.

Looking for the optimum therapy for chronic wounds, the main purpose of the present study was thus to assess the efficacy of the combination of occlusive wound dressings and electrical stimulation in the treatment of pressure ulcers and to compare it with that of occlusive dressings alone and of electrical stimulation alone.

Patients and methods: Twelve male patients (29–42 years) with spinal cord injuries, who had developed pressure ulcers, participated in the study. They were selected consecutively as they were hospitalised at our Rehabilitation Institute. They were informed of the purpose of the research and they expressed their willingness to participate by signing an Informed Consent Form.

In all patients the same wound treatment was introduced – cleaning with a physiological solution and covering with semiocclusive foam gel dressings (Tielle, Johnson & Johnson Medical, Gargrave, UK). The dressings were changed as necessary or at the latest after one week.

With respect to the additional therapy with electrical stimulation, the patients were randomly assigned either to the electrically stimulated (ES) group or to the control group which received sham treatment (CO). Accordingly, all patients had a pair of self-adhesive stimulation electrodes (Encore Tm Plus, Axelgaard Manufacturing, Ltd., Fallbrook, USA) placed on the healthy skin at the dressing edge for two hours daily and connected to the stimulators (Figure 1). Half of the devices actually delivered electrical stimulation (ES group), while the other half were inactive (CO group).

The electrical stimulation program consisted of 4-second trains of biphasic, charge-balanced asymmetrical current stimuli, which alternated with pauses of the same duration (4 seconds). The stimulation intensity was set in the active

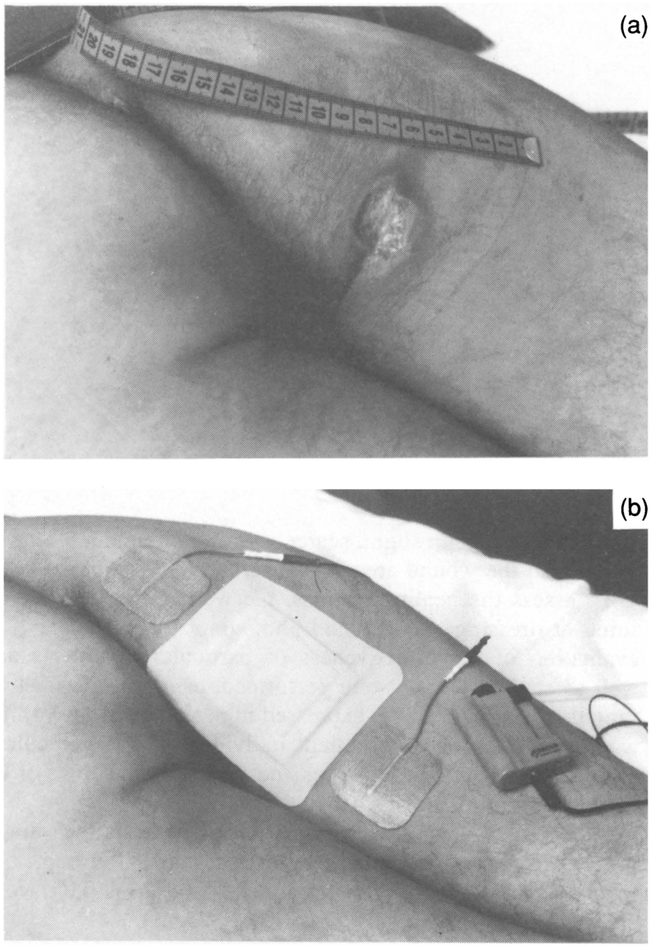

Figure 1: (a) The pressure ulcer, and (b) electrodes and dressing placement, the electrical stimulator.

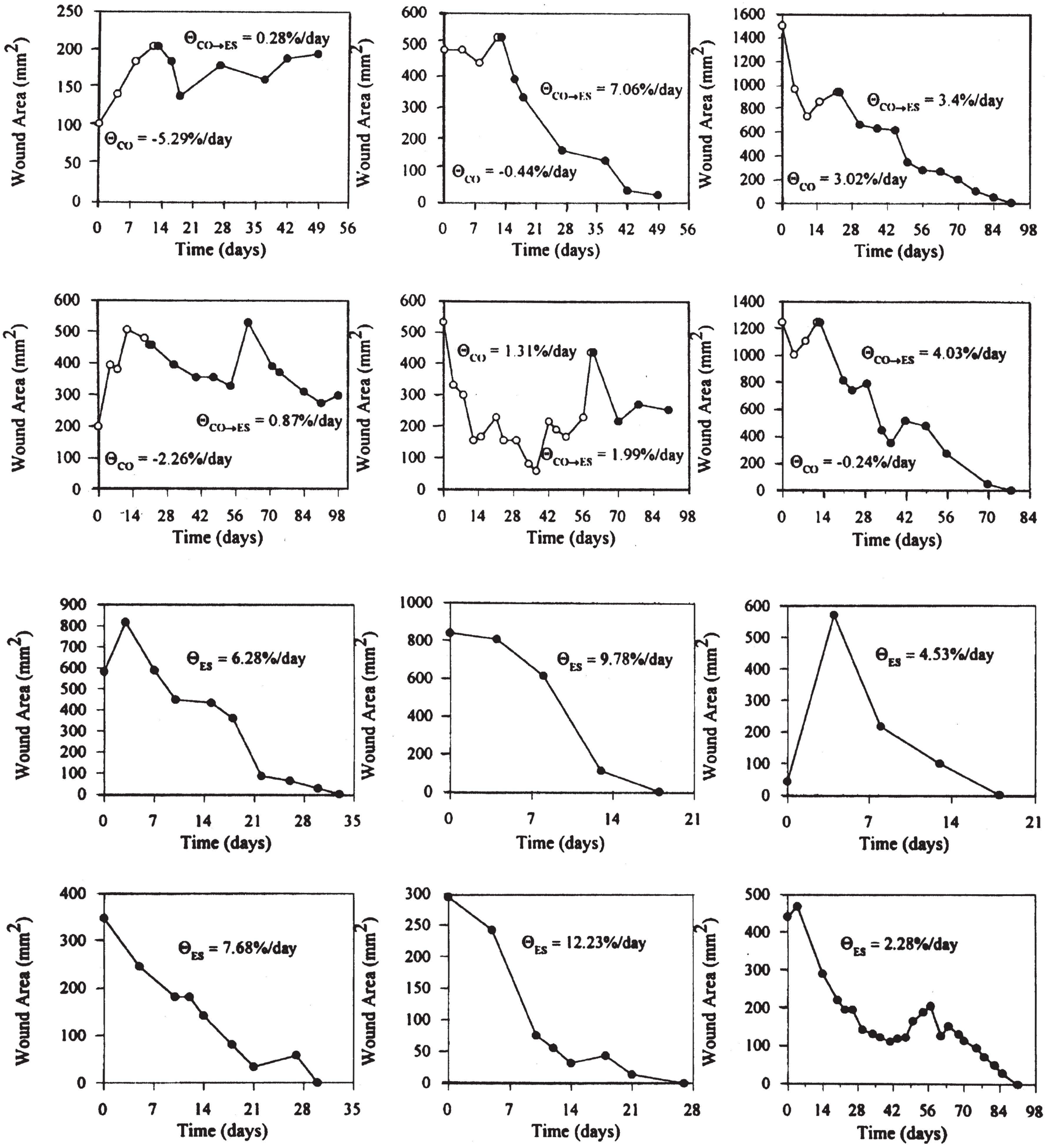

Figure 2: Wound area time plots: (a) for the wounds which were initially treated solely conventionally (CO group, empty circles), and later crossed-over to electrical stimulation treatment (CO → ES, filled circles, and (b) for the wounds receiving combined treatment with occlusive dressings and electrical stimulation (ES group).

stimulators so that a slight, scarcely visible contraction of the muscles in the wound area was achieved.

To assess the healing process, the wound area was measured at dressing changes and photographs were taken. An evaluation of the effectiveness of particular treatments as well as statistical tests were performed, using the parameter "relative healing rate" θ, expressed in per cent per day [4]. θ was calculated for each patient individually. For particular groups or patients, mean values and standard deviations of θ were determined.

Student's t-test was used to test the hypothesis regarding the equality of mean relative healing rates of groups of wounds receiving different treatments and $p < 0.05$ was considered significant.

Results: Treatment of pressure ulcers with occlusive dressings alone in 6 patients constituting the CO group did not prove successful. Moreover, treatment had to be stopped after an unpleasant odour, unhealthy exudate, non-healing, and in some cases also pain were observed. The increase in the wound area was reflected in the negative average value of the relative healing rate θ_{CO} ($\theta_{CO} = -0.66 \pm 1.16\%$ per day). For obvious ethical reasons the occlusive dressing treatment was substituted by a combination of conventional treatment with standard gauze dressing and electrical stimulation, which had been found to be beneficial in our previous study [4].

Following the introduction of electrical stimulation, all six cases improved and they healed with an average relative healing rate of $\theta_{CO \to ES} = 2.93 \pm 1.01\%$ per day. Statistically, the value of $\theta_{CO \to ES}$ differed significantly from the average relative healing rate during the wound occlusion θ_{CO} ($p < 0.05$).

The combined treatment of 6 wound cases from the ES group with occlusive dressings and electrical stimulation, on the other hand, led to very fast and successful healing. The relative healing rate θ_{ES} was 7.13 ± 1.46% per day.

Figure 2a shows the wound area time plots with respective relative healing rates for individual wounds from the CO or cross-over group CO → ES. Figure 2b shows those for wounds from the ES group.

The hypothesis that the average relative healing rates of the ulcers from the CO group (θ_{CO}) and those which were additionally given electrical stimulation (θ_{ES}) were the same could be rejected. The ulcers which received electrical stimulation healed significantly faster ($p < 0.05$).

Discussion: The results presented here demonstrate that the combination of occlusive dressings and electrical stimulation is a promising therapeutic method for chronic wounds, notwithstanding the fact that the occlusive dressings *per se* did not prove to be a sound choice for pressure ulcer treatment. The effectiveness of the combined treatment is interesting for the extensive problem of chronic wounds. Despite various underlying aetiologies, they are all characterised by a common feature – failure of blood supply and subsequent tissue ischaemia, which is the immediate cause of their formation and problematic healing.

The beneficial effects of occlusive dressings have been unequivocally demonstrated in acute wounds, where the optimisation of the microenvironment over the wound area leads to faster resurfacing of the lesion [6]. More equivocal, however, are the effects of occlusion in chronic wounds. Healing in general is an extremely energy-demanding process, which cannot run smoothly if the blood supply to the injured area is disturbed. Lundeberg *et al.* [7] have shown that pulsed electrical stimulation can increase local blood flow significantly in the stimulated area. It seems that improved blood perfusion is the basic mechanism responsible for the stimulatory effect of the electrical current on regeneration. Pulsed currents thus interfere with the principal factor responsible for the appearance and persistence of chronic wounds. By means of electrical stimulation, the injured tissue is brought to a condition favourable for the beneficial effects of occlusion. Both concepts seem to supplement each other reasonably in solving the problem of healing chronic wounds.

Also interesting is a comparison of these results with our previous, more extensive clinical trial in which we used standard gauze dressings and the same type of electrical stimulation [4]. The average healing rate of 43 wounds treated solely in the conventional manner – with gauze dressings – was 3.18% per day. 63 additionally stimulated wounds healed at an average relative healing rate of 4.44% per day. The difference between the mean healing rates of these two groups of wounds was statistically significant ($p < 0.01$).

The difference in sample size between the past study, dealing with 106 cases, and the present, with only 12, precludes collective statistical analysis. However, comparison of the rate of healing between both stimulated groups of wounds – covered with gauze ($\theta = 4.44\%$ per day) and occluded ($\theta = 7.13\%$ per day) – reveals significantly faster healing of the latter. This implies a synergistic action of occlusive dressings and electrical stimulation.

Finally, we should stress why the type of electrical stimulation is particularly suitable for combination with occlusive dressings. At first, the charge-balanced impulses with a zero direct current component do not induce electrochemical reactions at the electrodes and dressings, which could alter the structure of the dressing or else lead to the undesired electrochemical transport of substances into the wound. Another very convenient characteristic is the placement of the electrodes. Our method assumes positioning of both electrodes on the intact skin at the wound edge. This precludes any interference with the dressing properties, such as permeability and absorbing capability.

These results deserve the attention of clinicians dealing with chronic wounds and call for confirmation in a more extensive clinical trial, probably with some other occlusive dressings.

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This study was supported by the Ministry of Science and Technology of the Republic of Slovenia. Johnson & Johnson S.E. Inc., Ljubljana, Slovenia, provided the wound dressings.

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Paper received: 8th June 1995; amended 1st August 1995.