



Introduction

Non healing wounds have a great economic impact because they need intensive wound care for very long periods, often disabling the patient and causing high health care costs. One of the key issues in tissue regeneration of chronically non healing wounds is controlled revascularisation. In textile implant materials tissue formation and vascularisation depend on the size and distribution of pores and fibers. An arrangement of pores of different orders

of magnitude will favour the tissue ingrowth and the formation of new blood vessels and capillaries. We developed a new textile wound dressing based on embroidery for the treatment of chronically non healing wounds. Embroidery technology allowed to achieve a 3-dimensionally structured textile architecture that combines pores for directed angiogenesis and elements for local mechanical stimulation of the wound ground (fig. 1).

Patients and Methods

We performed cytotoxicity assays using a 3T3 fibroblast cell line. In direct and indirect (using extracts) exposure methods, endpoints and time course of mitochondrial activity (MTT) and cell mass (DNA / direct counting) were measured. In both cases no significant toxic effects were detected. We chose pressure sores as a wound model for the evaluation of the theoretical effect of the mechanical induced angiogenesis since the treatment of these follows a strict regimen at the Swiss Paraplegic Centre Nottwil (Pressure relief, surgical debridement, standardised wound conditioning and treatment of concomitant diseases followed by plastic surgical wound closure in accordance with the clinical

guidelines). After signing an informed consent, we included all newly admitted patients with pressure sores of the pelvic region, deeper than grade 2 after Daniel. Since February 2000 we formed two randomised groups: "new textile treatment" (TP) and, as a control, the conventional treatment with saline soaked gauzes.

The initial wound volume after surgical debridement was set to 100 %. The end point was reached, when the wound volume decreased to 50 %, because every wound was closed by a flap procedure. The volume was taken as equivalent to the healing process and measured every 7 days.

Results

We admitted 39 patients since. 5 patients had to be excluded: 2 died, 1 with insufficient data, 1 with ulcer in irradiated area, 1 dismissed. The control group included 11 patients, the treatment group 18 patients. The distribution of age and concomitant diseases were comparable. The initial wound volume of the two groups were:

Initial Volume	WTD	TP
MEDIAN	20	41.5
MEAN	50.8	62.9
SD	70.9	87.9

The time to reach half of the initial volume was comparable:

T to 50%	WTD	TP
MEDIAN	14	14
MEAN	14.8	17.7
SD	5.5	7.9

Fig. 1: SEM image of the embroidered textile layer of the wound dressing. The porous structure is made from PET multifilament yarns, whereas the stiff elements for mechanical stimulation consist of PA monofilaments.

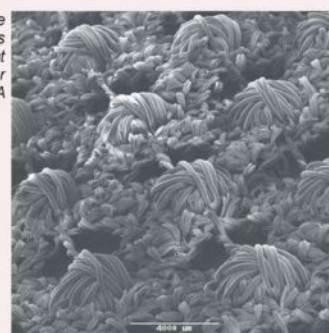


Fig. 2: Example of wound treatment with TP (TISSUPOR®): Female patient, age 69, wound volume after one week was 80ml. The dressing was changed twice a week. After 2 weeks the wound volume was 40 ml (left) The wound was surgically closed after 3.5 weeks of application, when the wound volume was 11ml (right).



Discussion and Conclusion

The application concept of TP (TISSUPOR®) is based on the working hypothesis that bleeding must be induced by changing the wound dressing to reactivate the wound healing by creating an acute inflammatory reaction and mechanical stimulation create directed angiogenesis resulted in less frequent dressing change (2 times per week instead of twice to three times a day). The time to reach 50 % of the initial wound volume is comparable in both groups. TP is therefore probably not superior to the conventional treatment concerning the rate of newly formed granulation tissue and wound-contracture. Due to the less frequent changes the patients comfort in sensate areas can be increased and costs could be reduced. In the same time the study shows, that the TP treatment will not produce negative effects on the speed of wound healing.

A European Wide multicenter study was initiated for the treatment of chronic wounds with a wide range of indications.

References

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