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The use of autologous platelet concentrate activated by autologous thrombin (APC+) is effective and safe in the treatment of chronic diabetic foot ulcers – a randomized controlled trial

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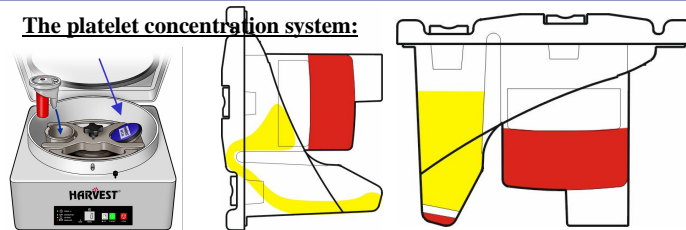
Introduction:

Diabetic foot wounds are difficult to heal and frequently lead to amputation despite optimal treatment. Natural healing is a complex procedure involving different growth factors, which may lack in chronic wounds. The effectiveness and safety of topical applied APC+ is investigated.

Methods:

A total of 59 patients suffering from chronic diabetic foot lesions with a duration > 6 weeks, Wagner stage 1-3, a size > 0,7 cm² and attending the Ambulatory Foot Clinic were screened, 42 patients finishing a 14 days run-in phase and meeting the study inclusion criteria were randomized into two groups (n=21). Patients with active infection, compromised circulation (ABI < 0,7) or venous stasis were excluded. One patient of the test group dropping out for non-medical reason (transport costs) was excluded from the final analysis. Both groups were treated according to the International Consensus of the Diabetic Foot and received weekly debridement, cleansing, coverage with a polyurethane foam, regular dressing changes and off-loading. Every two weeks the test group additionally received the topical application of APC+, which was produced from a small sample of patients whole blood and processed via the SmartPREPTM System (Harvest Technologies). Wound size and conditions were assessed weekly during the treatment period of 12 weeks and monthly during a 3 months follow-up. Primary endpoint was complete healing during the treatment period of 12 weeks. This study has been registered with clinical-trials.com (ISRCTN 28965380).

The platelet concentration system:

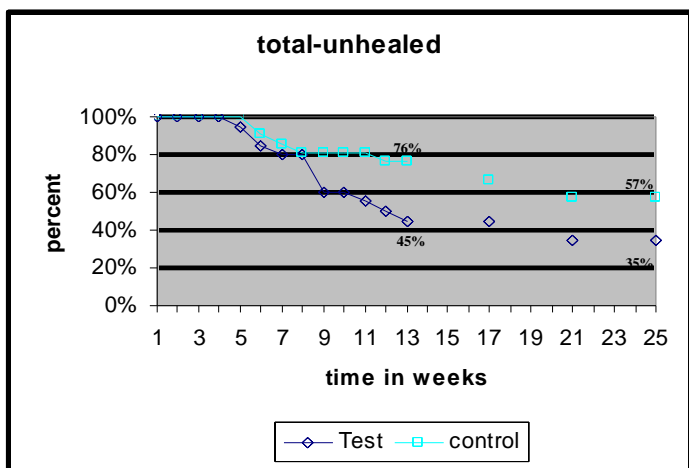


Treatment concept

1. Debridement
2. The use of platelet gel
3. Platelet gel on the wound
4. Wound dressing with polyurethan foam

Results:

Within the treatment period of 12 weeks more patients in the test group (11 out of 20, 55%) than in the control group (5 out of 21, 24%) achieved complete wound healing (p<0,05). The rate of healing based on the time to complete closure is potentially faster in the test group (9,2 vs. 12,2 weeks). The frequency and severity of adverse events was significantly higher in the control group (9 vs. 2, p=0,02), of which the most common was infection and any vascular complication



Example: 67 years old female diabetic patient
Chronic non-healing ulcer of the heel (test group).
Complete wound closure after 4 cycles of platelet gel application



Conclusion:

The use of growth factors released from activated platelet concentrates (APC+) could lead to a higher proportion of healed wounds, potentially faster healing rates and reduced treatment related complications.