Prospective, Randomized, Controlled, Multi-Center Clinical Study of a Bioacellular Wound Dressing for the Treatment of Venous Ulcer Patients

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Introduction:
Chronic venous insufficiency (CVI), is the most common cause of lower leg ulceration affecting nearly 7 million people (2.3%) in the United States (1-3). The dressing evaluated in this study is a biosynthetic cellulose® (BWD) dressing, which has the ability to both donate and absorb moisture (4,5). BWD has been shown in clinical studies to reduce pain, to support wound dressing and to stimulate wound healing (4.6,7). The present study (Fig 1) reports on the results of a randomized, controlled, multi-center clinical study comparing the effectiveness of BWD (Fig 2 and Fig 3) with **compression therapy to standard care (**non-adherent contact layer) with **compression therapy, in the treatment of hard to heal venous ulcers in an outpatient setting.

Materials and methods:
Fifty patients were included in the study of which N=46 were included in the ITT group. Standard care (n=23) was used as a control (n=23)

Significant improvement in autolytic debridement (was used as a GC, Damien CJ. Phillips TJ, Dover JS. Continuing medical education: Leg ulcers. Analyzed ITT (n=18)

100% of the subjects treated with BWD reported no pain compared to 63% in the standard care group, p=0.005

Results:
Treatment with BWD plus compression was significantly more effective than standard care in fibrinolysis (removal of yellow tissue 83% vs. 26%; p=0.0001) (Fig 4) and reduction of wound pain (i.e. week-7, 100% of the subjects treated with BWD reported no pain compared to 63% in the standard care group, p=0.005) (Fig 5). Time to 75% granulation was 25 days for the BWD-treated group vs. 36 days for the control-treated group. Time to 50% re-epithelialization was 38 days for the BWD-treated group vs. 50 days for the control-treated group (Fig 6).

Discussion:
It is probable that superior and faster wound bed evolution is the result of the wound environment created by BWD. Because this dressing can both donate and absorb moisture, it behaves differently on wounded as compared to intact skin (4-6). The perimeter of BWD (in contact with intact skin) desiccates forming a thin cellulose-like sheet that adheres to the stratum corneum without re-injury, while the center of the dressing (in contact with the wound) remains moist but insulated from the exterior environment (Fig 2 and Fig 3).

Conclusion:
- BWD was safe and effective for fibrinolysis and pain relief
- Significant improvement in autolytic debridement (p=0.0001) leading to a cleaner wound bed in a shorter time period
- Significantly less wound pain than the group treated with standard care (p<0.05)
- Significant investigator preference and improved general wound appearance

References:

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**Suprasorb® K, Lohmann & Rauscher GmbH, Rendsdorf, Germany. **Viscopaste® **Profobe® Smith & Nephew Inc., Coban® LF, 3M Inc, **Adaptic®, Systagenix, **Allevyn® Smith & Nephew Inc.