

# POLYHEXANIDE VERSUS SILVER WOUND DRESSINGS – FIRST INTERIM RESULTS OF A CONTROLLED, RANDOMIZED, PROSPECTIVE, MULTICENTRIC STUDY

Galitz C<sup>1</sup>, Hämmerle G<sup>2</sup>, Signer M<sup>3</sup>, Gruber-Mösenbacher U<sup>1</sup>; Traber J<sup>3</sup>; Eberlein Th<sup>4</sup>, Abel M<sup>5</sup>, Strohal R<sup>1</sup>

(1) Federal University Teaching Hospital of Feldkirch, Austria

(2) Federal Hospital of Bregenz, Austria

(3) Venenambulanz Kreuzlingen, Switzerland

(4) WundKompetenzZentrum Linz, Austria

(5) Medical & Regulatory Affairs, Lohmann & Rauscher GmbH, Rengsdorf, Germany

## Introduction:

The present study compares the potency of pain and microbial reduction of a PHMB-containing HydroBalanced biocellulose based wound dressing X+PHMB\* versus best local silver standard of care in patients of high wound pain and critically colonized or locally infected wounds.

## Materials and methods:

We performed a controlled, randomized, prospective, multicentric comparative study for a period of 28 days. Patients presenting with acute and chronic wounds of different origin were eligible:

- with an initial pain level of  $\geq 4$  or greater, as defined by the visual analogue scale (VAS, 0-10), and
- a wound associated semi-quantitative bacterial load of  $\geq ++$  or higher.
- signs of systemic infection and systemic antibiotic therapy were exclusion criteria.
- the wound size was maximal 200 cm<sup>2</sup>.

## Group 1\*:

- PHMB-containing HydroBalanced biocellulose based wound dressing X+PHMB\*
- secondary dressing depending on the exudation status (atraumatic dressing\*, non adhesive PU-foam\* or high absorbing dressing\*)

## Group 2\*\*:

- best local silver standard of care according to the current wound standards in the different centers

## Results:

We report the initial interim results of 37 patients with statistical validation. With regard to sex, age, body weight and heights as well as wound size and wound age both treatment arms showed no difference.

Both, X+PHMB\* as well as the silver dressings were able to reduce the overall wound pain (fig 1). In the evaluation of the parameter pain during night and day as well as before and after dressing change significant differences could be demonstrated between the two groups between start and end of the treatment.

- After the first dressing change the pain in the group 1, X+PHMB\*, was lower than in the group 2, best local silver standard (fig 2).
- The treatment with X+PHMB\* already resulted in a significant reduction of the overall pain after the first day (fig 1 and 3).
- At the end of 4 weeks treatment X+PHMB\* reduced the overall pain to the lowest category of the VAS (no / minimal pain) (VAS = 1.78) (fig 1 and 3).
- X+PHMB\* was significantly more effective and faster in reducing the parameter pain compared to best local silver standard (fig 1 and 3).

First trends in the other parameters (eg antimicrobial effect in comparison to silver) were elevated, which should be confirmed after the completion of the study.

## Conclusion:

The data of the interim analysis (shown with significant less pain for the HydroBalanced biocellulose based wound dressing X+PHMB\*) suggest a more patient-friendly structure – beside the antimicrobial effects and the promotion of wound healing by polyhexanide. Together with the high user satisfaction and the proven more easy way of using X+PHMB\*, our study proves that both, patients and health care workers, benefit from its use – the chance to save analgetic measures and dressings.

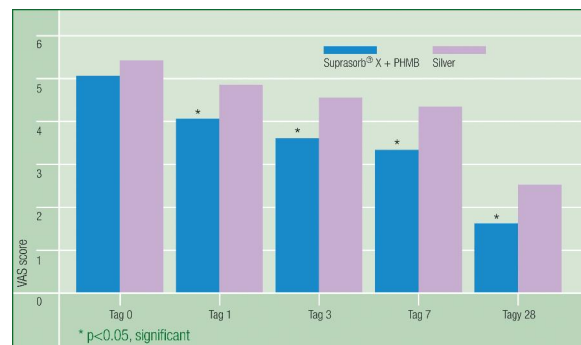


Fig 1: Very fast reduction of overall pain with X+PHMB\* already in the first week. Furthermore the result is confirmed after 28 days treatment ( $p < 0,05$ ).

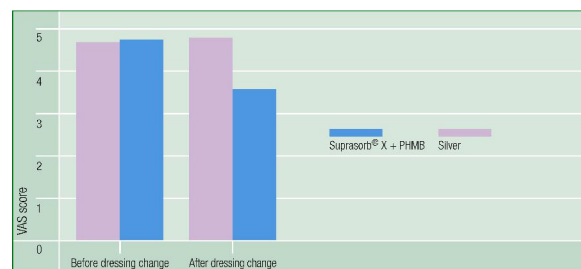


Fig 2: Pain at start visit 0 before and after dressing change

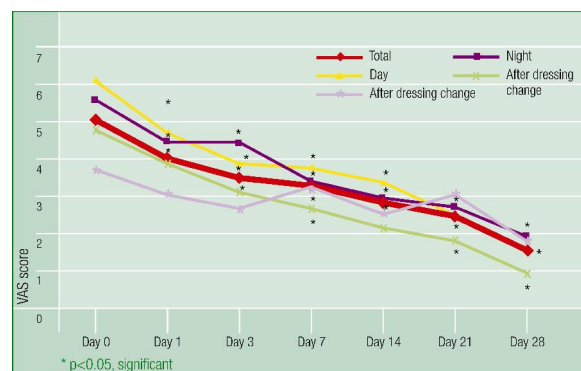


Fig 3: Reduction of pain by X+PHMB\* over 28 days

\* Group 1:  
X+PHMB: Suprasorb® X+PHMB; atraumatic dressing: Solvaline®; non adhesive PU-foam: Suprasorb® P; high absorbing dressing: Vliwazell®; Lohmann & Rauscher

\*\* Group 2 (best local silver standard of care):  
Acticoat® and Acticoat® Absorbent / Smith & Nephew; Aquacel® Ag / Convatec; Biatain® Ag / Coloplast; Silvercel® / Synergis (J&J); Urgotul® Ag / Urgo