Suprasorb X + PHMB: the clinical evidence

This new dressing combines the efficacy of Suprasorb X with the antibacterial properties of PHMB. The dressing is effective against a wide range of microorganisms, including meticillin-resistant Staphylococcus aureus, and has consistently been shown to provide pain relief. This article outlines the clinical evidence available on the dressing’s healing properties. Examples are also given of patient outcomes achieved following its use in day-to-day clinical practice.

Keywords: moisture balance; topical antimicrobial agent; infection; pain

As evidenced by the previous articles in this supplement, antiseptic agents have a wide therapeutic spectrum against a number of organisms found in wounds and are a relatively safe adjunct to the wound management armoury. However, if used purely as a cleansing agent at dressing change, their effect can only be temporary. To maximise the impact of polyhexamethylene biguanide (PHMB) in a critically colonised or infected wound, Activa Healthcare has incorporated it into its HydroBalance dressing, Suprasorb X. This article describes the clinical evidence on the effectiveness of Suprasorb X + PHMB in reducing pain and infection.

Suprasorb X

Suprasorb X comprises HydroBalance fibres, which are produced by the fermentation of Acetobacter xylinum. The result is a dressing with a high surface area of cellulose fibrils, which are woven into a mesh that regulates the absorption and donation of moisture at the wound-dressing interface. The dressing is therefore suitable for moderately exuding, low-exuding and dry wounds. Maintenance of a moist wound environment provides a cooling effect, which can relieve pain, facilitate autolytic debridement and increase granulation tissue formation and epithelialisation.

The clinical effectiveness of Suprasorb X has been demonstrated in the literature. In a randomised clinical study, Wild and Eberlein compared the autolytic debridement effects of Suprasorb X on chronic fibrinous lower-leg wounds with those of Aquacel, and found that the reduction of fibrin was faster in the Suprasorb X group. After four weeks, the proportion of fibrin in the wound had reduced to a mean of 16% compared with 35% in the comparator group.

Dini et al. demonstrated that, in 25 ambulatory patients, four weeks’ treatment with Suprasorb X resulted in a reduction in leg ulcer size and effective pain control. A case series of 25 patients showed that donor sites remained infection free, had good-quality granulation and epithelial tissue and no maceration following application of Suprasorb X. All patients reported that the dressing had a marked pain-reducing effect.

Suprasorb X + PHMB

Suprasorb X + PHMB combines the efficacy of Suprasorb X with the antimicrobial properties of an antiseptic. The ensuing advantages are that it:

- Reduces wound bioburden
- Reduces pain
- Promotes wound closure
- Hydrates the wound and absorbs exudate (HydroBalance).

It is indicated for wounds that are:

- Producing light to moderate exudate
- Dry
- Superficial or deep
- Critically colonised or infected
- At any stage of the healing process.

The PHMB is not bound to the HydroBalance fibres, and so exerts its antimicrobial effects both within the dressing and at the wound-dressing interface. Its mechanism of action is as follows: surplus exudate from the wound is...
absorbed by the dressing, and at the same time moisture is released to lightly exuding areas. The PHMB then kills the microorganisms within the wound exudate. The release of fluid allows antimicrobial activity on dry wounds. Its mechanism of action is illustrated in Fig 1.

The clinical evidence
Although few randomised controlled trials (RCTs) have been undertaken on Suprasorb X + PHMB, there is a plethora of case-study evidence on its overall efficacy. Case studies represent level III evidence, and as such are of value to the clinician. Indeed, they represent ‘real-life’ situations, reflecting the vicissitudes of patient presentations.

Infected wounds
A prospective, clinical study randomised patients with pressure ulcers contaminated with MRSA to either Suprasorb X + PHMB (n=15) or Prontosan-soaked gauze (n=15). Results showed that Suprasorb X + PHMB eradicated the MRSA in 13 patients after one week and in all patients after two weeks, whereas the control eradicated the pathogen in six patients in one week and 10 patients in two weeks. Suprasorb X + PHMB also promoted more granulation tissue formation after two weeks when compared with the control.

Mosti et al. evaluated the effect of Suprasorb X + PHMB on wound bed preparation in 18 patients with 30 painful, hard-to-heal wounds who were admitted for skin grafting. A subgroup of eight patients with critically colonised or locally infected wounds and an ulcer duration of between six months and four years received it as a primary dressing. Results showed effective debridement and infection control. Time to wound bed preparation was 6.2 (± 1.3) days. In the subgroup, bioburden reduced significantly from 572,500 colony forming units (CFUs) (± 401,986) to 74,500 (± 15,000) after three dressing changes.

Bacterial bioburden decreased from 765,000 (± 345,000) CFUs to 50,000 (± 15,000) after three dressing changes.

This antimicrobial effect has been observed in a variety of wound aetiologies. A multicentre evaluation of Suprasorb X + PHMB involving 50 patients with 79 wounds was undertaken in the USA. Wound aetiologies included venous and arterial leg ulcers, diabetic wounds, pyoderma gangrenosum and vasculitic ulcers; all wounds were deemed to be clinically infected or had a bioburden measured semi-quantitatively (1+ to 4+) or qualitatively (heavy, moderate, light, scant). All were treated for seven weeks, unless full healing occurred sooner.

Over 80% of the wounds either healed or achieved a clinical improvement. In a subset of eight patients (21 wounds) whose wounds had not previously responded to silver dressings, a decrease in wound size of 33% was reported after three weeks’ of treatment with Suprasorb X + PHMB. All wounds demonstrated continuous autolytic debridement and pain reduction.

Similarly, Davis used the dressing in four wounds that had not responded to silver dressings, two of which exhibited clinical signs of infection. Three wounds healed and pain levels reduced in all four.

Mulder et al. showed the dressing reduced bioburden and had a positive effect on healing in 26 wounds of various aetiologies in 12 patients, 11 of whom had previously been unresponsive to silver or iodine-impregnated dressings. Healing was reported in eight patients whose wounds were colonised with Pseudomonas aeruginosa and Staphylococcus aureus. The mean reduction in wound size was 2.2cm² (42%), over a mean of 25 days.

In a descriptive study, 40 patients whose wounds had been categorised as delayed healing for at least three weeks and were showing signs of critical colonisation or local infection were treated with Suprasorb X + PHMB. In 32 patients, treatment resulted in increased granulation tissue formation: 12% (± 18%) at baseline versus 79% (± 24%) at 27 days (± 25 days). The dressing was also associated with low pain levels, measured using a VAS.

Pain
In the study of 11 outpatients by Mosti et al. referred to above, patients reported a mean reduction in pain, using a visual analogue scale (VAS), from 7.3 (± 1.9) to 2.8 (± 0.8) within 3.4 weeks (± 0.8).
Surplus exudate is taken up from the wound into the dressing
Moisture is released from the dressing into the wound
Microorganisms are killed by the released PHMB

Fig 1. How Suprasorb X + PHMB works on the wound

Galitz et al.’s prospective comparative clinical study compared the effect of Suprasorb X + PHMB with that of a standard silver wound dressing on pain (both persistent and at dressing change) and microbial reduction in critically colonised or locally infected wounds.\(^1\) Thirty-seven patients were included for 28 days. All had chronic wounds, a VAS score of >4 and a bacterial load ≥++. Group 1 received Suprasorb X + PHMB and group 2 the silver dressing. A secondary dressing was used, depending on the exudate status.

Results to date demonstrated that both dressings reduced overall wound pain, although greater reductions were reported for group 1:
- After the first dressing change, a reduction in VAS scores was only recorded in group 1
- Significant reductions (p<0.05) in overall pain scores were recorded in group 1 after the first day
- After four weeks of treatment, the mean overall pain score in group 1 reduced to the lowest VAS category (none/minimal).

Results on the antimicrobial effect will be published at a later date.

Scleroderma ulcers are painful and hard to heal due to their distal location, atrophic peri-ulcer skin and requirement for immuno-suppressants. Cossu et al. used Suprasorb X + PHMB on the infected ulcers of eight patients attending an outpatient department.\(^1\) Standard scleroderma therapy was also given. In total, 27 ulcers were treated over a 20-week period. Dressings were applied twice weekly for three weeks and then once or twice weekly, depending on the wound state and the clinician’s judgement. Patients’ perception of pain was assessed using a VAS every four weeks; the physician graded ulcer severity on a scale ranging from 1 to 10.

At study end, there was a reduction in patients’ perceptions of pain and physician-reported ulcer severity, with mean scores falling from 8 at baseline to 2 at week 8 and 1 at week 20. All newly formed ulcers healed in 4–14 weeks; four of the 12 refractory ulcers healed completely in 15–19 weeks. The wound bed improved in the remaining ulcers, as determined using the TIME principles (debridement, control of infection, moisture balance and advancing wound edge).

In an observational study, Nielsen and Fremmelevholm assessed the use of Suprasorb X + PHMB on 16 patients with a plantar abscess, an infected wound or a partial or total forefoot amputation.\(^2\) Eighty per cent had diabetes. All patients underwent surgery, after which Suprasorb X + PHMB was applied for 24 hours. The dressing was changed one day after surgery. Thirteen patients reported they had no pain, two patients reported mild pain and one moderate pain at dressing removal.

**Effectiveness in clinical practice**

A four-week evaluation of this novel dressing involved 15 patients with a variety of wound types. Inclusion criteria were:
- Non-healing (non-progressing) wounds
- History of recurrent infections
- Wounds with devitalised tissue requiring debridement
- Painful wounds.

Exclusion criteria were:
- Patients with ischaemic wounds
- Wounds already progressing with other wound management dressings.

The results of the evaluation showed that Suprasorb X + PHMB can:
- Maintain a moist wound healing environment
- Aid autolytic debridement
- Promote formation of granulation tissue and wound contraction
- Reduce pain
- Reduce the incidence of infection and treat it.

In short, the dressing maintained a moist
wound environment and a healthy wound edge in wounds with low to moderate exudate levels. It also debrided devitalised tissue in sloughy wounds. In addition, it was associated with the development of healthy granulation tissue and a reduction in wound size in 12 wounds. None of the patients developed an infection, although a yellow film was observed on two patients, which requires further evaluation in respects of its cause and effect on the wound. Eight patients with painful wounds stated that their wounds were more comfortable during treatment with this dressing.

In highly exuding wounds, Suprasorb X + PHMB should be used with an appropriate secondary dressing, and the frequency of dressing change should be monitored to reduce the risk of maceration to the peri-wound skin. Most of the patients perceived that their wounds improved during the evaluation and the clinicians involved all agreed that they would consider using this dressing again.

**Key points**

1. Suprasorb X + PHMB has the twin advantages of promoting a moist wound healing environment while offering potent antimicrobial action.

2. It is indicated for critically colonised and locally infected wounds, and can be used on moderately exuding to dry wounds.

3. There is a wealth of case-study evidence showing that it prevents or eradicates wound infection and has marked pain-relieving properties.

4. The clinical effectiveness of this new dressing is also illustrated in a four-week evaluation involving 15 patients with a variety of wound types. None of the patients developed an infection, while eight patients with painful wounds stated that their wounds felt more comfortable during treatment.

**Case no. 1**

An 89-year-old patient had a grade III pressure ulcer of eight weeks’ duration on her foot (Fig 1). The granulation tissue appeared healthy but was not progressing. The patient was bed bound, nursed on an alternating mattress and her foot was fully offloaded. She had no concurrent illnesses but was taking supplementary nutrition. She was unable to state a pain score, but made clear verbal indications that dressing changes were painful.

A variety of dressings had been used previously, and a hydrogel had initially succeeded in debriding the wound. However, the wound had not progressed for four weeks, despite the use of Hydrofiber and cadexomer iodine dressings for two weeks respectively.

Suprasorb X + PHMB was considered because Moore suggested that PHMB reduces the wound bioburden. A foam was used as the secondary dressing. After 18 days, the wound bed had filled with granulation tissue and the wound reduced in width (Fig 2). Dressing change frequency reduced from three times a week to twice weekly. In addition, dressing changes appeared painless and stress free. The evaluation stopped at this point as this patient was admitted to hospital with an unrelated illness.
Case no. 2

This patient had a eight-month-old venous ulcer (Fig 1) that was producing copious amounts of exudate. It required daily dressing changes despite use of various wound dressings designed to absorb high levels of exudate.

We therefore decided to use Suprasorb X + PHMB. After eight days, the wound exudate was causing excoriation to the peri-wound skin and the wound had extended (Fig 2). This does not indicate a failure of the dressing to absorb exudate, but rather the need to consider the absorbency of the secondary dressing and the frequency of dressing change.

Case no. 3

This patient had a five-month-old, mixed aetiology ulcer (Fig 1) on the medial aspect of the left lower leg. The patient reported pain as 6 on a 1–10 scale and disturbed sleep, despite taking morphine-based analgesia. No vascular surgical intervention had been performed at the patient’s request. The ankle brachial pressure index (ABPI) was 0.78 with biphasic sounds. Reduced compression was attempted but not tolerated.

The wound was wet, causing extensive strikethrough onto the outer bandages, despite use of an alginate rope, an absorbent foam dressing, a wool layer and bandaging. The wound had also developed regular but intermittent wound infection, resulting in four episodes of cellulitis in two months.

Suprasorb X + PHMB was applied to reduce the recurrent infections and pain. The absorbent foam and outer padding continued to be applied. After six days, strikethrough had ceased. After 14 days the wound bed had debrided and there was evidence of healthy granulation tissue (Fig 2). Although the wound dimensions remained unchanged during the evaluation, the exudate levels reduced. We continued to change the secondary dressing daily, whereas the Suprasorb X + PHMB was changed every third day.

At the end of the four-week evaluation, the wound bed was filling with healthy granulation tissue. There was no recurrence of infection during the evaluation period, and the patient no longer experienced disturbed sleep at night.
Case no. 4

This patient had a static venous leg ulcer of three months’ duration (Fig 1) and was receiving four-layer compression bandaging plus an alginate primary dressing.

This patient had undergone laser vein surgery six months previously and the wound was progressing toward healing. Unfortunately, the ulcer recurred within three weeks, measuring 4 x 3 x 0.5cm and there were no signs of healing. As the wound bioburden appeared to be a contributing factor to non-healing, we dressed the wound with Suprasorb X + PHMB twice weekly. After four weeks, the wound had reduced in size to 3.5 x 2.5 x <0.5cm, devitalised tissue was debrided, healthy granulation tissue filled the wound bed and an epithelium had formed (Fig 2).

Case no. 5

This patient presented with a recalcitrant venous leg ulcer of 36 months’ duration. The wound bed was clean, with granulation tissue (Fig 1). A Hydrofiber dressing was being used under ‘lite-compression’ bandaging, but the wound was still not progressing towards healing.

Suprasorb X + PHMB was therefore applied. Within 10 days, a thin, continuous, shiny, slimy adherent yellow film had developed over the wound bed (Fig 2). We continued with the dressing for a further 14 days, and the yellow film resolved. After 24 days, healthy, patchy granulation tissue covered approximately 40% of the wound bed (Fig 3). The patient wore compression bandaging throughout the evaluation. Progression of the wound from days 1–24, in terms of dimension, tissue type or the health of wound bed, was negligible.
Case no. 6

The patient, who had an external fixator in place, presented with a surgical wound that had dehisced 18 months previously due to infection — this being a common feature of pin-site wounds (Fig 1). The wound had alternately deteriorated and progressed over this period.

Previous wound infections had been treated with antibacterial dressings, including silver, honey and iodine, and oral antibi-

The published literature and clinical case studies presented demonstrate that Suprasorb X + PHMB is an effective antimicrobial dressing, with proven action against a variety of bacteria, including MRSA. It also has pain-relieving properties and facilitates a moist wound environment, while pre-

Conclusion

The published literature and clinical case studies presented demonstrate that Suprasorb X + PHMB is an effective antimicrobial dressing, with proven action against a variety of bacteria, including MRSA. It also has pain-relieving properties and facilitates a moist wound environment, while pre-

References

7. Scottish Intercollegiate Network Guideline. Available at: http://www.sgn.ac.uk
11. Davis, C. Evaluation of pain control and healing rates using an advanced cellulose dressing with 0.3% PHMB. Poster presentation. SAWC Annual Congress, Tampa, 2006.