Clinical evaluation of a PHMB-impregnated biocellulose dressing on paediatric lacerations

• **Objective:** To evaluate the clinical benefits, primarily tolerability and reduction in pain levels, associated with the use of a PHMB-impregnated biosynthetic cellulose dressing (Suprasorb X + PHMB) on paediatric heel lacerations.

• **Method:** These lacerations were caused when children, who were being transported on their parents' bicycles, got their heels trapped in the wheel spokes. Where these injuries just comprised skin contusion and laceration, treatment had previously comprised cleansing followed by application of conventional dressings and moist wound healing dressings. However, the high incidence of infection necessitated regular dressing changes, which caused parents and children stress and anxiety. This clinical evaluation assessed the benefits of a new treatment protocol, where the PHMB-impregnated biocellulose dressing was applied and left *in situ* until epithelialisation occurred. A cork splint was used for 3 days to prevent *pes equinus* and to let the ankle joint rest. Change in wound size (cm^2), incidence of local infection, wound bed characteristics and pain levels (measured on a 0–10 paediatric pain scale) were assessed at 3-day intervals during the 14-day treatment period. Satisfaction with the dressing was also evaluated.

• **Results:** Twenty children (mean age 5.6 years (±1.33) were recruited into the study and included in the analysis. The mean baseline wound area was 8.60cm^2 (±6.57). The mean time to complete wound closure was 12.95 days (±7.69) with a mean total of 4.70 visits (±1.56). The mean VAS pain score was 9.55 (±0.69), compared with 0.15 (± 0.37) on day 14 ($p<0.003$). At the second visit (after 3 days) 17 of the 20 children were reported to be free of pain. No cases of local infection were noted.

• **Conclusion:** The dressing was found to be child and parent friendly. The evaluation also showed that it was well tolerated and achieved good healing outcome. It has now been incorporated into the clinic's treatment protocol for these wounds.

• **Conflict of interest:** None. The authors have no relevant financial interest in this article. All authors were involved in the critical revision of the manuscript for important intellectual content.

bicycle spoke heel injuries; polyhexamethylene biguanide; biocellulose wound dressing

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In the Netherlands, parents use their bicycles as a mode of transport for young children. Although people are advised to use child bike seats, injuries occur because children's feet get entangled in the bicycle spokes. Each year, 4 400 cases (an average of 12 per day) are severe enough to be referred to accident and emergency with painful heel flap injuries, which often become infected.[1] Thirty percent of these injuries are complicated by bone fractures.[1] Front wheel injuries mainly cause inversion, with laceration over the dorsum and medial aspect of the foot and medial malleolus.[2] Rear wheel injuries mostly cause eversion, with skin damage to the lateral and posterior aspect of foot and ankle, with the lateral malleolus at risk.

These injuries are graded into three classes, I–III, depending on their severity and extent.[2]

• Type I: skin contusion and laceration
• Type II: skin and soft tissue defects, with exposure of the Achilles tendon
• Type III: wide skin and soft tissue defects, with damage or rupture of the Achilles tendon.

Management of spoke injuries is based on this classification system.[2] Type I injury is usually managed with debridement, wound cleansing and dressings.[1,2] In type II injuries, after wound bed preparation, flap surgery is conducted to close the defect. Posterior heel injuries are often type II, and are typically covered with various flaps depending on the size of the defect, its location, the associated injuries, the extent of the trauma and the complexity of the defect.[2] In type III injuries, the typical approach is primary repair of the Achilles tendon, followed by flap surgery.[2]

At the Wound Healing Centre at BovenIJ Hospital in Amsterdam, we used conventional dressings and moist wound healing dressings, such as alginates, Hydrofiber and foams, in the treatment of type I injuries.[2] Although most of these injuries healed, there was a high incidence of local infection, result-

ing in dressings being changed every alternate day at the centre. This caused the children and their parents much stress and anxiety.[2] (Practitioners at the clinic were reluctant to use the two antimicrobial dressings available to them, cadexomer iodine and silver alginate dressings, on young children with this wound type.)

In order to reduce the dressing change frequency, a new dressing regimen was introduced that replaced the use of alginates, Hydrofiber and foam with a biosynthetic cellulose dressing impregnated with polyhexamethylene biguanide (PHMB), Suprasorb X + PHMB (Lohmann & Rauscher). The biosynthetic cellulose component is designed to absorb and donate fluid, depending on the condition of the wound bed, and so does not dry out.[3-5] The PHMB component has a broad-spectrum antimicrobial effect.[5,6-9] Moreover, the dressing forms an almost transparent blister-like roof over the wound, and so does not need to be removed for wound inspection.[4] The dressing has been shown to reduce pain in venous leg ulcers and burns. It can be left in place for up to one week,[3,5] which means that in acute wounds it can be kept *in situ* until there is a reasonable amount of epithelial tissue, reducing the anxiety and costs associated with frequent dressing changes.[5] These features seemed relevant for the treatment of these painful heel injuries in young children, which often become infected.[2]

This case series assessed the clinical benefits of using Suprasorb X + PHMB in young children with type 1 spoke wheel heel injuries.

Materials

Suprasorb X dressing is produced from bacterial cellulose, which is derived from the Gram-negative bacterium, *Acetobacter xylinum*, and processed into a biocompatible matrix material (Fig 1).[3-5] PHMB products contain a surface-active substance (surfactant, a wetting agent that lowers the surface tension of a liquid), which can penetrate difficult wound coatings such as slough or biofilms, to stimulate healing.[5-7]

Method

A clinical pathway was developed and implemented, with a view to improving the treatment outcomes for young children with spoke wheel heel

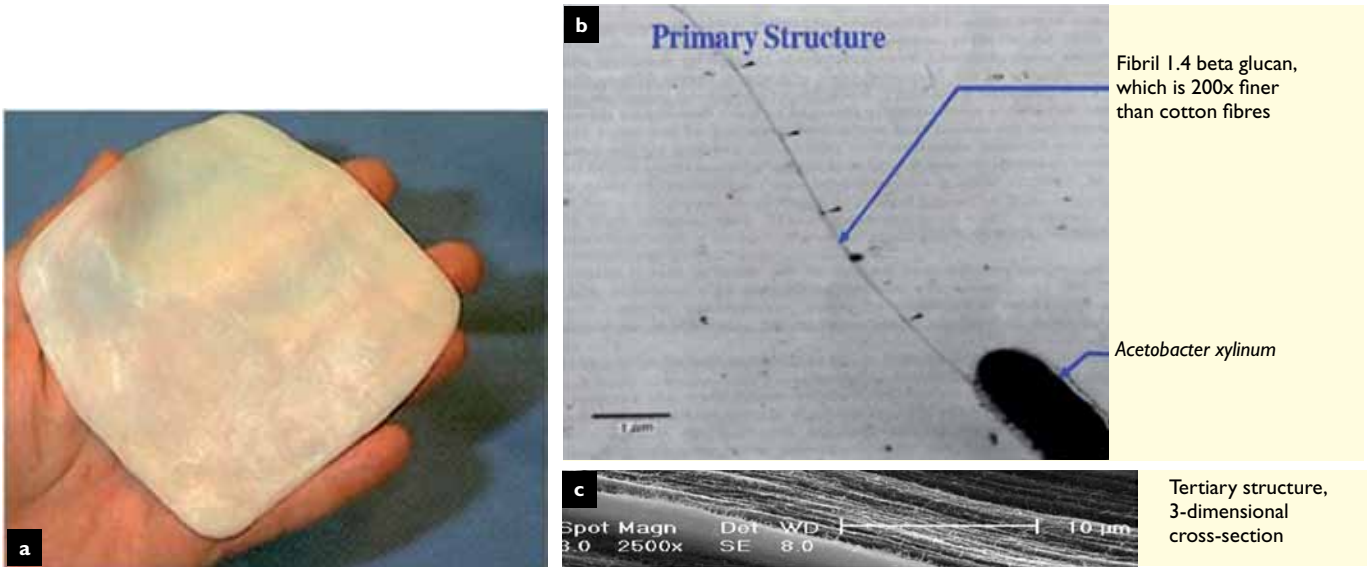

Fig 1. The Suprasorb X + PHMB dressing (a); the dressing comprises fibres produced by the Gram-negative bacterium, *Acetobacter xylinum* (b) and is processed into a biocompatible matrix material (c)

injuries. As stated above, the committee that developed the pathway selected Suprasorb X + PHMB (the biocellulose wound dressing) for use on type I injuries, mainly because of its antimicrobial properties, transparency and the low frequency of dressing changes required.

Children who presented at the clinic's emergency department between June and September 2010 with type 1 injuries were eligible for inclusion into the clinical evaluation. There were no exclusion criteria.

The hospital's ethics committee institutional review board (IRB) approved the evaluation; all parents (or legal guardian) gave written informed obtained.

Wounds were then usually debrided, cleansed with a 1.5% chlorhexidine and 15% cetrimide solution and, after a short interval, were covered with a moist wound healing dressing for approximately 20 minutes in accordance with the principles of the wet-to-dry phase (where it is proposed that a wound should be cleansed with a cleansing solution, which subsequently evaporates, resulting in the release of wound debris, exudate and pathogens into a temporary dressing).[6] After this, a new primary dressing — the biocelluose wound dressing — was applied, covered with a pad and fixed with a retention bandage. The children were treated at the clinic on an outpatient basis. The dressing was kept *in situ* until it fell off of its own accord when extensive epithelialisation had taken place. The dressing was only changed if there were clinical signs of local infection or for reasons such as increased pain or purulent exudate. When the outer areas of the wound had epithelialised, the dressing was cut to fit the smaller wound size. A cork splint was used to prevent *pes equinus*

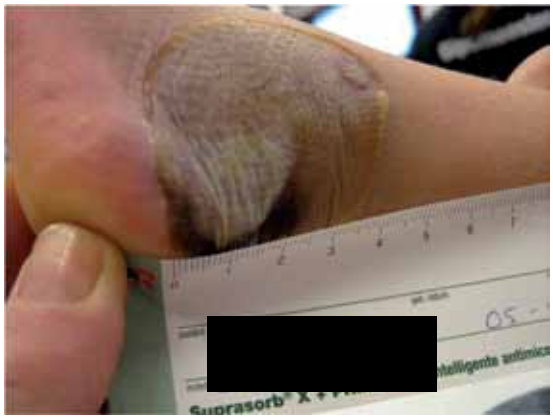

Fig 2. A typical case of a type I injury: presentation at day 0, showing the dressing *in situ*. The wound is visible with the dressing in place

and to rest the ankle joint. This was removed after 3 days, increasing the children's mobility.

The wound and surrounding skin were assessed by a physician assistant (J.G.A.), who had developed the evaluation protocol, at baseline and at 3-day intervals for 14 days, which is a liberal estimate of the time it takes for a type I injury to close.[2] The following parameters were assessed:

- Clinical signs of spreading local infection, based on the criteria outlined in the European Wound Management Association position document[10]
- Wound area: assessed using high-resolution digital images and grid tracing
- Wound bed status: the percentage of fibrin tissue, granulation tissue and epithelial tissue in the wound was visually and subjectively assessed using high-resolution digital images

- Pain: assessed using a validated 10-point faces visual analogue scale (VAS), specially designed for children.[11]

Assessments were performed at the clinic by a single trained physician. As the dressing is almost transparent, it was not necessary to remove it for assessment (Fig 2).

In addition to the above, satisfaction with the dressing was assessed at 3-day intervals, based on ease of dressing use (both at application and during wear); pain; durability of the dressing (whether it stayed in place until the wound had largely epithelialised), and the extent of any leakage. These were assessed using a three-point scale.

Statistical analysis

Statistical evaluation was performed using Statistical Package for the Social Sciences (SPSS 16.0). Where appropriate, tests were carried out at the 5% significance level with paired sample tests. The confidence interval was 95%. After the data had been collected, each item was analysed separately and item responses were summed to create a score for a group of items. Responses to a single item were treated as ordinal data.

Results

Twenty young children (mean age 5.6 years, median 6.00, range 2.1–8 [±1.33]) were recruited into the evaluation. All 20 were included in the analysis (11 male and nine female). No patients dropped out or were withdrawn from the study.

The mean baseline wound size was 8.60cm^2 (±6.57). Three children had multiple wounds: two children had two wounds each, and one child had three small wounds, which were very close together. Baseline patient characteristics at day 0 are given in Table 1.

All of the wounds healed within the 14-day treatment period. The mean time to complete wound closure was 12.95 days (±7.69), with a mean of 4.70 visits (±1.56). The mean baseline VAS pain score was 9.55 (± 0.69), which fell to 0.15 (± 0.37) on day 14 ($p<0.003$). At the second assessment (after 3 days), 17 of the children (85%) were reported to be pain free ($p<0.003$). The parents observed no anxiety or stress in their children during hospital visits as they were assured that the dressing would stay in place. No adverse events were reported.

Finally, we compared the costs for the previous dressing regimen with those for the current one (Table 2). Costs savings were calculated at €126.46 for the 14-day treatment period.

Discussion

Every attempt should be made to avoid wound-related trauma and pain in young children.[12,13] Part of the pain experience in children is based on anxi-

Table 1. Baseline wound characteristics (n=22 wounds)

Wound location:	
• Lateral malleolus	n=12
• Heel	n=5
• Both ankle and lateral malleolus	n=5
Mean wound size on day 0 (cm^2) (SD)	8.60 (±6.57)
Mean pain score on day 0 (VAS) (SD)	9.55 (± 0.69)
Tissue type:	
• Red	n=18 (82.0%)
• Yellow	n=2 (9.0%)
• Black	n=2 (9.0%

Table 2. Cost per dressing change and total treatment costs: moist wound healing dressing versus the biocellulose wound dressing

	Units/dressing change	Moist wound healing dressing (€)	Biocellulose wound dressing (€)
Gloves:			
• non-sterile	1	0.18	0.18
• sterile	1	1.10	1.10
Kidney dish	1	0.13	0.13
Sterile drap or field	1	0.27	0.27
Sterile gauze 10x10cm	3x2	0.81	0.81
Hand disinfectant	5ml	0.15	0.15
Wound cleansing solution	50ml	0.69	0.69
Moist wound healing dressing	1	8.26	
Biocellulose wound dressing	1		9.12
Staff costs	1	9.63	9.63
Total for each dressing change	1	21.22	22.08
Total for 14 days treatment	7	148.54	22.08
Savings during the 14-day evaluation period			**126.46**

The following sources were used to calculate the costs of dressing changes for traditional dressings, moist wound healing dressings and the biocellulose dressings: the list price in The Netherlands; the average price that can be claimed for a dressing change was based on the Dutch tariff

ety and fear of pain, such as that experienced at dressing removal.[12,13] Our results show that it was safe to leave the biocellulose dressing in place until the wound had epithelialised. That it was possible to leave the dressing in place for 14 days gave the children an important psychological advantage and also reassured their parents. The clinic visits did not cause the usual stress, as the parents were able to assure their children that the doctor would not touch the dressing. It should also be noted that the hospital environment is child friendly, with plenty of activities for children in the waiting room.

Cleansing, debridement and disinfection help to reduce bacterial load, and gently remove debris and exudate in order to prepare the wound bed for closure. When the problems caused by bacteria remain localised to a wound (critical colonisation), treatment with topical antiseptics may be indicated and is usually sufficient.[2,5-9]

When providing a topical approach to treatment, it is important to differentiate between inflammation, increased bacterial burden, and superficial and deep infection.[6-9,14] Microbiological management is aimed at achieving an optimal bacterial load in the wound, with an awareness of the signs both of infection and critical colonisation.[6-8] PHMB has a broad spectrum of activity against Gram-positive and Gram-negative bacteria, fungi and biofilms[5,8] and, due to its low toxicity, can be applied over a long period of time.[7] It has good tissue compatibility as it is active against the acid lipids found within the bacterial cell membranes, and has only a minor effect on the neutral lipids of human cell membranes. This helps to prevent damage to the surrounding healthy tissue.[7] The efficacy of PHMB has demonstrated in the management of non-healing chronic and/or refractory wounds, such as second degree burns, as well as for lavages.[5,7,9] PHMB has been shown to reduce inflammation, which may in turn reduce pain.

No infections were noted during the evaluation period, which also contributed to the short treatment times. This also helped limit any trauma to these young children, and is another indication that the dressing is safe. Finally, the dressing is appropriate to use on type I injuries, as they have low to moderate exudate levels. The dressing is not advised for the use on heavily exuding wounds.

Evaluation limitations

Because clinical evaluations using case series are descriptions of practice and do not have comparison or control groups, it is not possible to draw any conclusions on cause-and-effect relationships from the present evaluation. A randomised controlled trial with a larger sample would be needed to show significant differences in the clinical efficacy of the biocellulose dressing. However, financial and practical constraints mean that it is unlikely that such a trial will be conducted.

Conclusion

The biocellulose dressing was associated with good healing times and no infections were reported. Furthermore, the children reported that the dressing was largely pain free and they did not show anxiety at the clinic visits. The dressing was found to be safe and child and parent friendly. The clinical pathway has now been implemented in the hospital.

One final point: please ensure that appropriate spoke-guards — and not dress guards — are installed when ferrying children about on bicycles. ■

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