

Wound bed preparation: case series using PHMB and betaine solution and gel - a UK perspective

Dr Leanne Atkin, Vascular Nurse Consultant/Lecturer, School of Human and Health Sciences, University of Huddersfield and Mid Yorkshire NHS Trust, Yorkshire, UK.

Dr John Stephenson, Senior Lecturer in Biomedical Statistics, School of Human and Health Sciences, University of Huddersfield, Huddersfield, UK

Dr Dawn M Cooper, Visiting Research Fellow, School of Biosciences and Chemistry, Sheffield Hallam University, Sheffield, UK.

Author to whom correspondence should be addressed:

Dawn Cooper, PhD BSc

Work address

Department of Biosciences and Chemistry

City Campus

Howard Street

Sheffield Hallam University

Sheffield,

United Kingdom

S1 1WB

Home address

35 June Avenue

Winlaton Mill

Blaydon

Tyne and wear

NE21 6SQ

E-mail: dawn.cooper@shu.ac.uk

Tel: 07808716100

CONTRIBUTIONS

Dr Cooper conducted data collection and analysis and prepared the manuscript with important intellectual input from Drs Atkin and Stephenson. All authors approved the final manuscript.

CONFLICTS OF INTEREST AND FUNDING

DMC is employed by B. Braun and LA and JS received consulting fees from B. Braun. There are no further conflicts of interest.

Abstract

The burden of wound care within the NHS is estimated at a cost of £5.3 billion per year and is set to rise annually by 30%. This case series describes the results of using PHMB and betaine wound irrigation solution and gels (Prontosan®) across the UK in chronic wounds up to 20 years old, with an observation period of greater than one month. Over half of the chronic wounds were healed and vast improvements to all other wounds were observed. Improvements to wound bed condition were reported as early as 2 days after commencing initial treatment, with decreases in: malodour, exudate, slough and pain reported across the case series. In addition to wound bed improvements, a reduction in dressing change frequency of 55% was observed in chronic wounds under the new treatment regime.

Key Words – Chronic wounds, PHMB, Prontosan, wound cleansing, wound bed preparation, biofilm.

Introduction

Resources associated with managing chronic non healing wounds is substantially greater than those associated with managing other wounds, with 20% more practice nurse visits and 104% more community nurse visits reported for patients with these wounds¹. The average annual cost of managing chronic wounds is reported at 135% compared with wounds that healed within 1 year¹, this is expected to rise by a third over the next decade².

Chronic wounds provide an ideal environment for the creation of biofilm³. Biofilm is associated with chronic inflammation⁴, increased slough, exudate⁵ and increased tolerance of microbes to antimicrobials and antibiotic therapy⁶. A recent meta-analysis, investigating prevalence of biofilms in chronic wounds, has reported a confirmed presence of biofilm in 78.2% of chronic wounds (95% CI 61.6% to 89.0%; p=0.002)⁷. As such all non-healing chronic wounds, that have failed to respond to standard care, are considered to have biofilms as an underlying cause of delayed healing^{8,9}. Recent wound biofilm consensus statements focus on cleansing as a strategy to address biofilms and recommends routine cleansing and disruption of biofilm at each dressing change⁹.

Prontosan®, wound irrigation solution and gels, contain polyhexanide (PHMB) and betaine surfactant, these ingredients work in combination to disrupt and remove biofilm as well as aiding the removal of debris and slough^{10,11}. Research studies have demonstrated significantly higher efficacy of PHMB and betaine irrigation solution and gels compared with normal saline for improving wound condition, reducing inflammatory signs and accelerating the healing of chronic wounds¹¹⁻¹³. Use of this cleansing system is therefore of interest to the wound care community. The aim of this work is to review and combine the results of multiple case studies in the UK into a case series to evaluate outcomes and

provide an overview of the effectiveness of PHMB and betaine wound irrigation solution and gels in chronic wounds.

Methods

Case studies from within the UK where PHMB and betaine wound irrigation solution and gels were used for wound bed preparation were collated. Inclusion criteria were use of PHMB and betaine wound irrigation solution alone (application of a 'soak' with PHMB and betaine solution, applied to the wound at dressing change) or PHMB and betaine irrigation solution used in addition to PHMB and betaine gel (wound soak with additional application of PHMB and betaine gel to wound to remain in situ between dressing changes) used on non-healing wounds or complex wounds. Soak times with cleansing solution varied according to wound condition, with the majority stating 5-10 minutes. Wounds were classified as non-healing if: they were determined as chronic or complex by the case study author, were of over 6 weeks in duration¹⁴ and/or were presenting with signs of complications (infection, suspected biofilm or necrosis identified)¹⁵. Exclusion criteria were: acute/ non-complex wounds, wound pathways, insufficient data, burns and primary focus of debridement pad use.

Case studies were assigned into treatment groups: solution group, PHMB and betaine irrigation solution alone; solution and gel group, PHMB and betaine irrigation solution in addition to PHMB and betaine gel. The proportion of wounds achieving partial healing in the two treatment groups, and as an entire cohort, were assessed. Impact on complete wound healing was analysed for wounds treated for >1 month. All other measurements were analysed by the whole cohort

Wound and patient characteristics were reported where available: number of patients and wounds, type of wound, previous treatment history, age of wound, wound details, malodour, exudate, slough and size; pain level, analgesia use; dressing change details, duration of new treatment and patient quality of life.

Results

35 case studies, complying with eligibility criteria, were available for analysis; 11 further case studies were excluded: 6 for use of a debridement pad as a primary treatment, 3 covering a biofilm pathway, 1 covering burn wounds and 1 due to scarcity of detail. The remaining 24 case studies comprised of 52 non-healing wounds across 50 patients, were included in the final analysis (Supplementary table 1). Solution and gel was used on 36 wounds; the remaining 16 wounds used solution alone. PHMB and betaine treatment was initiated for multiple reasons including: long duration of wound, > 1 month (n=20), > 3 months (n=15); failure to heal due to infection (n=14), post-surgery/trauma complications including dehisced wounds (n=7) and wound described as "complicated with healing by secondary

intention" (n=38). Multiple reasons were often cited. Duration of case studies ranged from 9 days to 10 months. Treatment was followed to complete wound healing for 12 (23%) wounds; for all other case studies (77%) the reason for ending observation was not documented.

Wound healing

Considering the chronic and complex nature of wounds in these case studies, a treatment duration of less than one month was determined to be unlikely to result in complete healing; case studies with treatment less than one month were excluded from analysis for complete healing. Case studies where treatment duration surpassed one month (23 wounds) were analysed. Of these 23 wounds, 12 (52%) resulted in complete wound healing, 10 wounds were treated with solution and gel and 2 were treated with solution alone. The majority (22%) of healed wounds were healed within 2 months. The completely healed wounds are summarised in Table 1.

Table 1

Treatment Duration	All Wounds > 1 month treatment (n=23)		Irrigation solution > 1 month treatment(n=4)		Irrigation solution and gel > 1 month treatment (n=19)	
	Healed	Cumulative Healed	Healed	Cumulative Healed	Healed	Cumulative Healed
2 months	6 (26.1%)	6 (26.1%)	0 (0.0%)	0 (0.0%)	6 (31.6%)	6 (31.6%)
3 months	3 (13.0%)	9 (39.1%)	1 (25.0%)	1 (25.0%)	2 (10.5%)	8 (42.1%)
6 months	2 (8.7%)	11 (47.8%)	1 (25.0%)	2 (50.0%)	1 (5.2%)	9 (47.4%)
10 months	1 (4.3%)	12 (52.2%)	0 (0.0%)	2 (50.0%)	1 (5.2%)	10 (52.6%)

Table 1: proportion of wounds with treatment duration of > 1 month, healed by treatment time for all wounds and treatment groups.

Of the remaining 11 wounds not reported as healed, healthcare professionals described 8 wounds as demonstrating improvements and wound size reduction; the remaining 3 wounds had no further details pertaining to healing progress.

Wound area

Wound area was reported for only 8 out of 52 wounds; all wounds measured demonstrated reduced size following treatment, with >90% reduction observed in 5 out of 8 wounds within 3-6 months and a mean wound size reduction of 75.6% observed (Table 2). Wound area reduction was calculated as wound area at the end of treatment, expressed as a percentage of initial wound area.

Table 2

Wound area before treatment	Age of wound	Type of wound	Treatment group	Wound area after treatment	Treatment duration	Wound areareduction
65 cm ²	7 months	Leg ulcer	Solution	0 cm ²	6 months	100%
35 cm ²	7 months	Leg ulcer	Solution	0 cm ²	3 months	100%
38 cm ²	6 months	Infected leg ulcer	Solution and gel	16 cm ²	3.5 months	58%
15 cm ²	>1 year	Leg ulcer	Solution	14 cm ²	1 month	7%
49 cm ²	5 month	Leg ulcer	Solution and gel	3 cm ²	5 months	94%
120cm ²	3 months	Buttock wound	Solution only	2 cm ²	11 weeks	98%
Full leg circumference x 8-17cm long	2 weeks	Leg cellulitis	Solution and gel	0 cm ²	3 months	100%
300 cm ²	Unknown	Grade 4 infected pressure ulcer	Solution and gel	157 cm ²	6 days	48%

Table 2 Wound area, treatment duration and type of wound for wounds with wound area measured (n=8).

Initial improvements

Description of initial signs of wound improvements were documented for 33 wounds (63%); for other wounds end point data only was available. The earliest initial improvements were observed within 2 days in the solution and gel group and reported within 4 weeks in the solution only group. Overall, for both treatment groups, initial wound improvements were observed within 1 week, for 19% of all wounds (10/52); by week 4, for 63% of wounds (33/52) had demonstrated some initial improvement in wound bed condition (Figure 1).

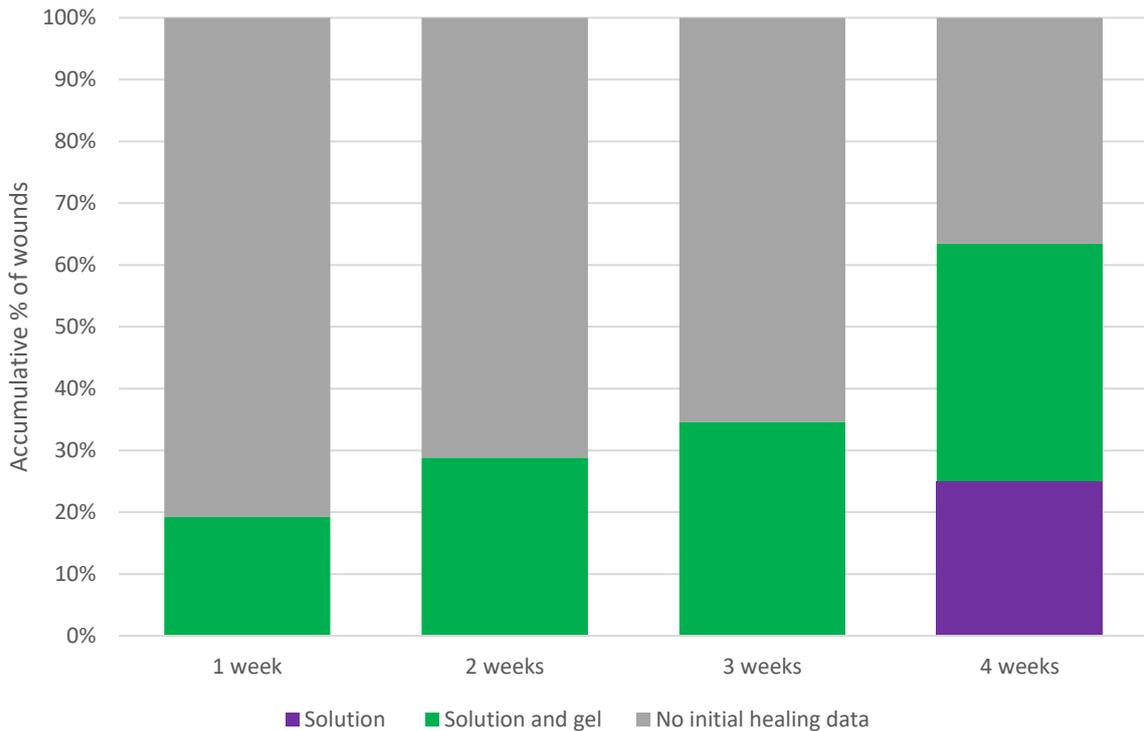


Figure 1, Accumulative percentage of wounds with initial healing (expressed by treatment group) and those with no initial healing data

Pain score

Pain was recorded either directly, via numeric pain score or binary pain status; or indirectly, by use of pain medication. Prior to commencing PHMB and betaine treatment, pain was reported for 21 wounds. Reduction in pain was reported for 18 of 21 painful wounds (86%); 2 wounds were reported being pain-free; 2 patients, previously unable to tolerate compression for leg ulcers, were able to initiate compression; 3 wounds (14%) were not followed up and 1 wound (5%) reported an increase in pain and stopped treatment.

Pain medication was taken by 8 patients including: paracetamol, co-codamol, Oramorph, co-dydramol, Nurofen, fentanyl lozenges, diclofenac and OxyNorm. 4 patients were followed up and all had reduced their pain medication, 2 of which had stopped taking any pain medication during the case study.

Malodour, excessive exudate and slough

Malodour was reported in 6 wounds initially; 5 were followed up, all reporting improvements; malodour was reduced in 2 wounds (33%) and resolved in 3 wounds (50%).

The presence of excessive exudate was described in 20 wounds (38%) at the start of the new treatment. In some cases additional details were recorded describing exudate: 1 wound was described as “purulent”, 1 as “green”, 1 as “medium”, 3 as “high” and 1 wound as “heavy”. Exudate was followed up for all 20 wounds, all reported reduced exudate; 10 out of 20 wounds (50%), exudate was fully resolved (Figure 2) by study end. Reduction in exudate was described by healthcare workers in 2 wounds as “immediate” and “rapid”; reductions were noted as early as after 2 days of treatments for 2 wounds, and after 1 week of treatment for 1 wound.

Slough was present initially for 16 wounds (31%), and described in 7 wounds as: “100% slough” (n=2), “thick” (n=2), “40% slough” (n=1), “large” (n=1) and “sticky” (n=1). Presence of slough alone was noted for 9 cases. Slough was removed from all (100%) initially sloughy wounds treated with PHMB and betaine (Figure 2).

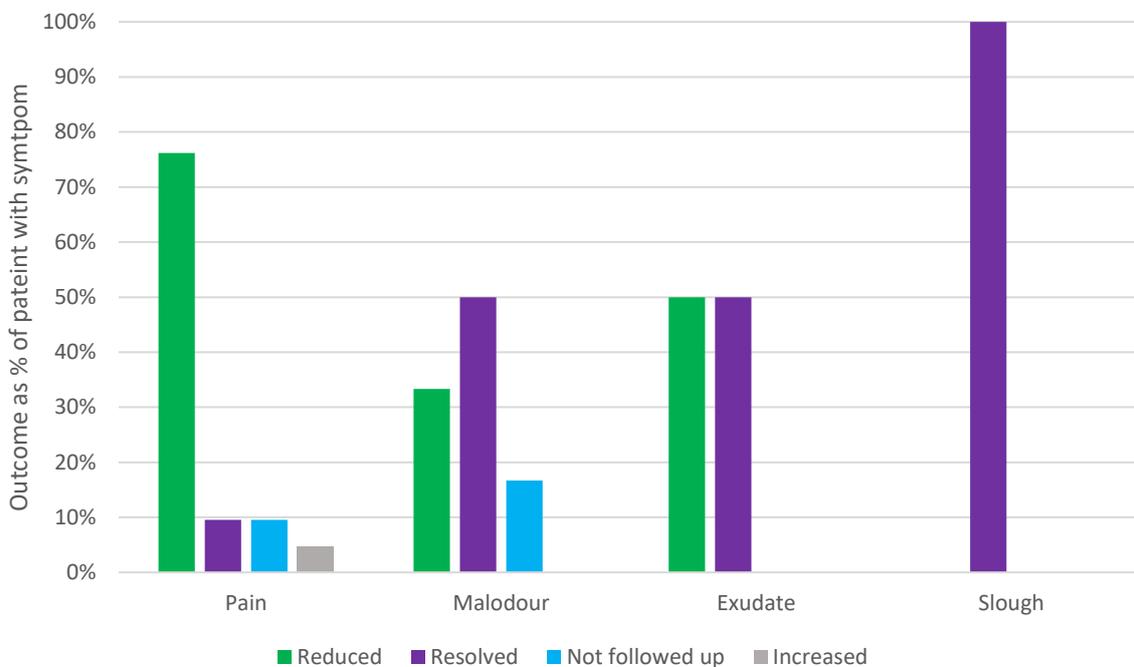


Figure 2 Outcomes of wound condition after treatment expresses as percentage of wounds displaying issue initially (overall results).

Dressing changes

Frequency of dressing changes was documented for 14 wounds (27%). Of these, 13 wounds were within the solution and gel group and 1 was within the solution-only group. Initially, 6 wounds were dressed daily; 3 were dressed on alternate days; 3 were dressed three times per week and 2 wounds were dressed twice per week. Before treatment with PHMB and betaine, dressings were changed on average 4.68 times per week (SD 2.14).

How often dressing were changed was followed up for 6 wounds, all were reduced (33-86%); with a mean reduction of 55% in dressing change frequency overall. Table 3 demonstrates that a reduction in dressing changes was observed as early as after 2 days of PHMB and betaine treatment. After treatment, dressing changes were reduced to 2.25 times per week (SD 0.88). This reduction was observed on average after 16.5 days (SD 8.8).

Table 3

Initial dressing change frequency	New dressing change frequency	Length of treatment before change	Calculated % reduction in dressing changes
3x/week	2x/week	2 weeks	33%
Daily	Weekly	4 weeks	86%
3x/week	2x/week	20 days	33%
Daily	3x/week	2 weeks	57%
Daily	Alternate days	Few weeks	50%
Daily	2x/week	2 days	71%

Table 3: Changes to dressing frequency over time after treatment with Prontosan® (both treatment groups) and calculated impact of reduced dressing change on dressing use and visits.

Patient quality of life

Comments relating to improved patient quality of life after PHMB and betaine treatment were recorded by 10 patients (20% of all patients). Improvements with mobility during the course of treatment was noted for 7 patients, with 1 patient starting swimming again and another was mobile enough to attend clinic for appointments rather than home visits. Psychological improvements were also noted for patients, with comments recorded including: “morale improved”, “able to attend first social occasion in 5 years”, “the ability to resume normal social activities”, “able to go on holiday aboard” and “able to engage in family life”.

Discussion

It is well acknowledged that the majority of chronic wounds contain a bacterial biofilm which is recognised as a leading factor in delayed healing¹⁶. Guidance states that for any chronic wound not reduced in size by more than 40% after 4 weeks, it is to be assumed that biofilm is the underlying cause, and to be treated accordingly by addressing biofilm through active cleansing and reducing biofilm reformation^{8,17-19}. Biofilms are highly resistant to standard cleansing with saline and tap water²⁰, whereas PHMB and betaine have been described in wound care guidelines as anti-biofilm

agents capable of reducing biofilm by combined actions of a surfactant and an antimicrobial^{20 17 8}. This case series sought to discuss the impact of treatment with **active cleansing with PHMB and betaine agents** on hard-to-heal complicated wounds.

Wound healing and wound area

Within the UK, 39% of all wounds are not healed within 1 year and these non-healed wounds cost substantially more than healed wounds¹. Here, in previously hard-to-heal or complicated wounds, wound improvement was observed in the majority of the wounds, with full healing observed in over half of wounds treated with **PHMB and betaine** for > 1 month. The case series data here is in alignment with previous large cohort analyses, demonstrating most complete wound healing occurring between 2-4 months after treatment with **PHMB and betaine**^{21,22}. Other large (953 patients) retrospective studies reported wound healing occurring in 80% of chronic wounds, after treatment with PHMB and betaine solution and gel²³. A limitation of the case series presented here is that we cannot assess what may have happened to the wounds had standard (saline) treatment continued; however, a RCT comparing PHMB and betaine gel with saline demonstrated a significant reduction in mean wound size ($p=0.013$) and percentage reduction in wound size ($p<0.001$) in the PHMB and betaine group after 2 weeks²⁴. With unhealed wounds costing 135% more than healed wounds¹, the progression of over half hard to heal wounds to fully healed may offer economic benefits in the reduction of the burden of wound care that warrant further investigation.

Initial improvements

A previous randomised control trial, comparing saline with PHMB and betaine treatment in 289 patients for 28 days, reported significantly quicker reduction in wound size and inflammatory signs in the **PHMB and betaine** group. In addition a case series evaluation of **PHMB and betaine** in the UK of chronic wounds demonstrated dramatic improvement in 70% of patients within 3 weeks²⁵. Our work found that initial improvements in wounds were observed as early as after 2 days of treatment with **PHMB and betaine** gel and solution and as early as 4 weeks when using solution alone. All initial improvements were seen within 4 weeks of starting **cleansing with PHMB and betaine** treatment. Considering the complexities of, and previous delayed healing in, the wounds in these case studies the rapid improvements observed support improvements reported in literature.

Pain score

Chronic wound patients often report pain; between 37.5%²⁶ and 63%²⁷ of patients with leg ulcer report pain. Similar results were observed in this case series, in which pain was reduced for the majority of patients, improving quality of life. The gold standard treatment for venous leg ulcers is compression

therapy²⁸. Patients, previously reported as being unable to tolerate compression, were able to commence compression treatment following cleansing with PHMB and betaine, which helped resolve their pain. Furthermore, an 80% reduction in patient pain has been reported, in chronic wounds, following PHMB and betaine treatment, compared with baseline saline treatment¹³. In addition, 77% of patients reported reduced pain within 31 days of PHMB and betaine treatment²⁹ and in other case series, all patients with chronic wounds reported pain reduction with PHMB and betaine treatment^{13,30}.

Reducing pain can have a direct impact on patients' quality of life. Chronic wounds can prevent patients from leaving home or walking due to pain, despite taking analgesia²⁵. The impact of the level of pain medication taken should also be considered. Indeed, in the current study all patients taking pain medication had their prescription reduced and half stopped taking any pain medication at all.

Malodour, excessive exudate, necrosis, slough and patient quality of life

Biofilm within a chronic wound can be responsible for and contribute to: increased slough⁵, higher amounts of exudate³¹, inflammation, due to prolonged host immune response³²⁻³⁴; signs of clinical infection⁸, increase bacterial load¹⁸, increased tolerance of microbes to antimicrobials and antibiotic therapy^{6,35}, which can all lead to delay of wound healing.

In the current study, exudate, malodour and slough were all improved with most fully resolved after treatment with PHMB and betaine, indicating underlying causes such as biofilm or infection were resolved. The wound bed improvements reported in this study are in alignment with findings of other studies^{12,13,23,25,29,36} as well as with randomised control trials²⁴. Additionally, the introduction of PHMB and betaine irrigation solution and gel as standard practice, for treatment of all wounds in one UK NHS trust, reduced healthcare-associated infections and surgical site infections by 92%³⁷ since the change in practice. Wound bed improvements, with PHMB and betaine, have been observed previously^{12,13} demonstrating reduced wound area, inflammatory signals¹² and more rapid wound healing, compared with standard treatment (saline).

Dressing changes

Greater demands are being made on community nursing because of an aging population, complex care provision and desire for care at home³⁸. Our work found dressing change frequency to be reduced on average by 55%. These results align with a recent large scale observational study, in which dressing change frequency was reduced within 60 days of treatment with PHMB and betaine gel¹³, as well as in other case series where daily dressing changes were reduced to alternate days after a few weeks²⁵. With district nurse visits and extra dressings accounting for over 69% of additional cost of unhealed

wounds³⁹, a reduction of 55% in dressing change frequency may reduce the need for such frequent district nurse visits and/ or outpatient appointments over the course of treatment of a wound. While data is unavailable for chronic wounds, reduction in district nurse visits of 25% for non-healed surgical wounds has been calculated to save £7258-£7432 per wound³⁹. Similar savings could be expected with reduced nurse visits for other non-healed wounds.

Limitations

Data collection in wound care is acknowledged to be difficult. Case studies can be inconsistent and lacking in details, is a known limitation. We found such inconsistencies in the case studies here and acknowledge that not all case studies could be included for all analyses. Case studies in wound care tend to have a bias to include the most difficult wounds, possibly due to historical practices of new innovations being tried on the most difficult wounds to 'see if it works'. Indeed here the authors observed large wounds with wound areas up to 300 cm² which had been unhealed for up to 20 years being selected as trial wounds. The duration of treatment in the case series here was not consistent and the reason for writing up the study at the time point allocated was not clear, with many wounds still undergoing treatment and in many cases wounds treated for less than for less than 1 month. The authors would recommend observation of broader use of PHMB and betaine wound irrigation solution and gel covering all chronic wounds, to fully understand the impact of changing wound cleansing practice from saline to use of an active wound cleansing agent as part of effective wound bed preparation.

Conclusion

Chronic wounds can take many months or years to heal, causing huge economic burden to the NHS and much patient discomfort. In this study, chronic wounds of up to 20 years pre-existing duration were observed during a period of treatment with PHMB and betaine irrigation solution and gels and demonstrated improvements in wound bed (exudate, malodour and slough) which may account for improved healing. Data indicates that PHMB and betaine would be beneficial to reduce wound healing and may have a potential positive economic impact in terms of a 55% reduction in dressing change frequency observed in this study; intervention studies looking at impact of all chronic wounds are advised to fully understand lifetime value and system benefits for the wider health economy.

Key points

- Chronic/complex non healing wounds respond well to the use of the anti-biofilm agent in wound cleansing, with observed improvements in wound bed condition.

- Improvements in wound size, pain, malodour, exudate, necrosis slough, patient quality of life and dressing changes were seen in a minimum of 2 days after treatment with PHMB and betaine
- Improvements in wound condition contributes to reduction in dressing change frequency.
- Use of a PHMB and betaine solution and gel may assist with the healing of chronic complex wounds.

References

1. Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. *Int Wound J* 2017; **14**(2): 322-30.
2. Casey G. Healing chronic wounds. *Kai Tiaki Nursing New Zealand* 2018; **24**(6): 18-22.
3. Zhao G, Usui ML, Lippman SI, et al. Biofilms and Inflammation in Chronic Wounds. *Advances in wound care* 2013; **2**(7): 389-99.
4. Yager DR, Nwomeh BC. The proteolytic environment of chronic wounds. *Wound Repair & Regeneration* 1999; **7**(6): 433-41.
5. Phillips PL WR, Feltcher J, Schultz GS. Biofilms made easy. *Wounds International* 2010; **1**(3): 1-6.
6. Wolcott RD, Rumbaugh KP, James G, et al. Biofilm maturity studies indicate sharp debridement opens a time- dependent therapeutic window. *J Wound Care* 2010; **19**(8): 320-8.
7. Malone M, Bjarnsholt T, McBain AJ, et al. The prevalence of biofilms in chronic wounds: a systematic review and meta-analysis of published data. *Journal of Wound Care* 2017; **26**(1): 20-5.
8. World Union of Wound Healing Societies(WUWHS), Florence Congress, Position Document. Management of Biofilm. Florence congress: Wounds International; 2016.
9. Bjarnsholt T, Eberlein T, Malone M, Schultz G. Management of Wound Biofilm Made easy. *Wounds International* 2017; **8**(2): 1-6.
10. Kaehn K, Eberlein T. In-vitro test for comparing the efficacy of wound rinsing solutions. *British journal of nursing* 2009; **18**(11): S4-S10.
11. Andriessen AE, Eberlein T. Assessment of a wound cleansing solution in the treatment of problem wounds. *Wounds: A Compendium of Clinical Research & Practice* 2008; **20**(6): 171-5.
12. Bellingeri A. Effect of a wound cleansing solution on wound bed preparation and inflammation in chronic wounds: a single-blind RCT. *Journal of Wound Care* 2016; **25**(3): 160-8.
13. Durante CM, Greco A, Sidoli O, Maino C, Gallarini A, Ciprandi G. Evaluation of the effectiveness of a polyhexanide and propyl betaine-based gel in the treatment of chronic wounds. *Minerva chirurgica* 2014; **69**(5): 283-92.
14. Understanding chronic wounds. *Journal of Community Nursing* 2015: 4-5.
15. Rutter L. Identifying and managing wound infection in the community. *British journal of community nursing* 2018; **23**: S6-S14.
16. Malone M, Bjarnsholt T, McBain AJ, et al. The prevalence of biofilms in chronic wounds: a systematic review and meta-analysis of published data. *J Wound Care* 2017; **26**(1): 20-5.
17. Leaper DJ, Schultz G, Carville K, Fletcher J, Swanson T, Drake R. Extending the TIME concept: what have we learned in the past 10 years?(*). *International Wound Journal* 2012; **9** Suppl 2: 1-19.
18. Schultz G, Bjarnsholt T, James GA, et al. Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. *Wound Repair And Regeneration: Official Publication Of The Wound Healing Society [And] The European Tissue Repair Society* 2017; **25**(5): 744-57.

19. International Wound Infection Institute(IWII). Wound infection in clinical practice. *Wounds International* 2016; 2016.
20. Wounds UK. Best Practice Statement: making day-to-day management of biofilm simple. London, *Wounds UK*, 2017. Available to down load from www.wounds-uk.com
21. Andriessen A, Esteves Cardozo M, Dias V. A randomized controlled multi-center study on wound cleansing and healing efficacy of a bio-cellulose dressing compared to a bio-cellulose dressing + phmb in patients with diabetic foot ulcers. *EWMA journal* 2011; **11**(2 Suppl): 137.
22. Kaehn K, Eberlein T. Polyhexanide (PHMB) and betaine in wound care management. *EWMA Journal* 2008; **8**(2): 13-7.
23. Möller AN, A. Kaehn, K. Experiences with the use of polyhexanide-containing wound products in themanagement of chronic wounds – results of a methodical and retrospective analysis of 953 patients. *Wund Management* 2008.
24. Valenzuela AR, Perucho NS. The effectiveness of a 0.1% polyhexanide gel. *Revista de enfermeria (Barcelona, Spain)* 2008; **31**(4): 7-12.
25. Horrocks A. Product focus. Prontosan wound irrigation and gel: management of chronic wounds. *British journal of nursing* 2006; **15**(22): 1222-8.
26. Hamer C, Cullum NA, Roe BH. Patients' perceptions of chronic leg ulcers. *Journal of Wound Care* 1994; **3**(2): 99-101.
27. Wissing U, Ek AC, Unosson M. Life situation and function in elderly people with and without leg ulcers. *Scandinavian journal of caring sciences* 2002; **16**(1): 59-65.
28. Andriessen A, Apelqvist J, Mosti G, Partsch H, Gonska C, Abel M. Compression therapy for venous leg ulcers: risk factors for adverse events and complications, contraindications - a review of present guidelines. *Journal of the European Academy of Dermatology & Venereology* 2017; **31**(9): 1562-8.
29. Naude L. The use of Prontosan® in combination with Askina® Calgitrol®: an independent case series. *Wounds International* 2018; **9**(1): 44-8.
30. Kilroy-Findley A. Development and implementation of a biofilm pathway for chronic wounds. *Wounds UK* 2018; **14**(2) 18-26.
31. Bradbury S, Fletcher J. Prontosan® made easy. *Wounds International* 2011; **2**(2): s25-s30.
32. Percival SL, Mayer D, Malone M, Swanson T, Gibson D, Schultz G. Surfactants and their role in wound cleansing and biofilm management. *Journal of Wound Care* 2017; **26**(11): 680-90.
33. Atkin L, Bučko Z, Montero EC, et al. Implementing TIMERS: the race against hard-to-heal wounds. *Journal of Wound Care* 2019; **28**: S1-S50.
34. Attinger CaW, R. Clinically addressing biofilm in chronic wounds. *Advances in wound care* 2011; **1**(3): 127-32.
35. Mahmoudi H, Pourhajibagher M, Chiniforush N, Soltanian AR, Alikhani MY, Bahador A. Biofilm formation and antibiotic resistance in meticillin-resistant and meticillin-sensitive Staphylococcus aureus isolated from burns. *Journal of Wound Care* 2019; **28**(2): 66-73.
36. Ricci E. Cleansing versus tailored deep debridement, a fresh approach to wound cleansing: an Italian experience. *J Wound Care* 2018; **27**(8): 512-8.
37. Collier M, Hofer P. Taking wound cleansing seriously to minimise risk. *Wounds UK* 2017; **13**(1): 58-64.
38. Bain H, Baguley F. The management of caseloads in district nursing services. *Primary Health Care* 2012; **22**(4): 31-8.
39. Guest JF, Fuller GW, Vowden P. Costs and outcomes in evaluating management of unhealed surgical wounds in the community in clinical practice in the UK: a cohort study. *BMJ Open* 2018; **8**(12): e022591-e.

Supplementary table

Wound	No wounds	Wound details	Previous treatment	Prontosan treatment	Wound outcome
Leg Ulcers	2	7 Month wounds, previous admission to hospital for IV antibiotics, 100% necrosis, 100% slough. 65cm ² and 35 cm ²	Auqafibre dressings, foam dressings, 2-3 times/week dressing changes	Wash only	With in 3 month, right leg was healed and left leg was improved. After 6 months all wounds were healed.
Foot Ulcers	1	5 Year foot ulcers with slough,	Dressing changes up to 4 times /week, Saline soaks and Hydrogel and silver dressings	Wash and gel	Improved wound healing. Dressing changes reduced to 2x per week. Improved mobility - able to attend clinic rather than home visit. Believed to be a cost saving due to reduction in dressing change (4 down to 2), reduced nursing visits and replacement of expensive dressings
Post surgery foot wound	1	9 week wound Toes of foot were amputated and following dry gangrene. Pt presented with severe infection spreading sepsis and rigors. Wound debridement of skin graft was performed.	Initial topical negative pressure therapy.	Wash and gel	1 week after start the wound was clean and the islets of graft had started to migrate across wound. Over next 6 months the wound remained clear from infection and the grafts continued to expand across the wound. No further episodes of infection were experienced to the point of full wound healing.
Calciphylaxis	1	Erythemic lesions and focal central necrosis to both legs which had worsened over 3.5 months presenting with malodour, purulent exudate and necrosis	Initially treated with inadine and surgical pads. . Admitted to hospital after approximately 3 months for IV antibiotics.	Wash and gel	2 weeks after initial treatment significant reduction in necrosis was observed with large areas of epithelialisation evident. Purulent exudate had gone and malodour diminished. Pain reduced so Pt was reduced to paracetamol. 6 weeks after the start of this treatment, superficial sloughy areas were all the remained, Pt now able to take daily showers and manage own wound care at home. Wounds healed.
Leg Ulcer	1	Recurrent exacerbating chronic infected venous leg ulcer for 6 months. Wound 38cm ² at start with 100% slough and covered on sticky structure laying proud of the wound with green malodourous exudate. High pain score of 8 unable to tolerate compression.	Multiple courses of broad spec antibiotics, topical antiseptic hydrofibre dressing, and support bandage toe to knee, daily dressing changes.	Wash and gel	3 days treatment = 25% granulation and raised shiny wound bed was no longer present and less peri-ulcer inflammation. 2 weeks after initiation of treatment the wound bed had reduced to 34 cm ² . and had 50% granulation, and a four layer bandage was commenced and tolerated. At this point frequency of wound dressing was reduced to 2 x per week. at week 14 the wound measured 16 cm ² with 98% granulation and dressing reduced to 1 x per week
Pressure Ulcer	2	2 x grade 4 pressure ulcers on right and left acetabulum both wounds 5 years old. Failed to heal or show signs of improvement.	Over the last 5 years have included, plastic surgery, vacuum assisted closure, silver dressings.	Wash and gel	Ulcer 1 required daily dressing changes for 4 weeks - then significant reduction in size and depth was noted (no details) and dressing changes reduced to alternate days. One occasion of

		Both wounds with: biofilm, necrotic tissue, constantly malodorous, bleeding and often became infected needing antibiotic therapy.	Washed with saline previously		colonisation was noted and treated with the addition of silver dressing for two weeks only. The wound was no longer malodorous, exudate considerably reduced, all bleeding stopped. Since using the prontosan system no antibiotics were needed by the Pt. Ulcer 2 excaudate reduction was immediate upon use of are treatment and dressing changes reduced to alternate days. Vast improvement to both wounds after 3 months.
Leg Ulcers	12	12 Leg ulcers, 8 venous, 3 mixed, 1 arterial (3 in more detail). 8 ulcers had suspected biofilm, 4 had no recent reduction in wound size. 1 = 4 month old, 1 = 3yr old. 8 with slough and 1 measured as 15 cm ²	All venous ulcer treated with 40mmHG compression therapy, mixed ulcers treated with 20mmHg compression therapy	Wash only	At first review 9/12 wounds reduced in size. 8/12 had visible reduction in slough. Case study for initial review only.
Leg Ulcer	1	Arterial leg ulcer, caused by trauma 5 months previous. Wound was malodorous with sanguineous exudate, local inflammation and erythema, 50% necrosis, thick slough and measured as 49cm ²	Previous treatment with antibiotics, several topical dressings including silicone and silver. Daily dressing changes to manage exudate and strike through.	Wash and gel	Within 2 weeks slough reduced to 20%, Malodour no longer present at 4 weeks. Wound size reduced to 3cm ² after 5 months and 90% granulation present.
Trauma	1	One week post injury wound edges were separated and sloughy base with medium exudate and surrounding erythema. Scab was sent away for microbiological testing =positive for Staph A	Steristrips and sterile dressing	Wash and gel	After 1 week, slough was still present and more pink granulation was visible, the wound was showing signs of improving. Wound completely healed in 2 months.
Buttock wound	1	6 week large wound (120 cm ²) wound presenting with discharge, 40% slough	Unhealthy tissue was excised in hospital. Pack wound daily with alginate dressing and maintenance of personal hygiene. Wound packing falling out within 12 hours.	Wash only	After 4 weeks reduced to 1-8 cm ² . Clean and showing signs of epithelialising around edges. After 11 weeks 2cm ² . As wound progressed dressing changes were reduced.
Post surgery foot wound	1	1st-3rd toes amputated, 5 month wound, too painful for debridement	No detail, use of total contact moulded inlay (TCI)	Wash and gel	After 3 weeks, wound appeared improved, minimal slough. Surrounding erythema had reduced. No pain in last two weeks. Treatment continued until 3 months, when wound nearly fully healed.
Leg Cellulitis	1	4 week cellulitis almost full circumferential cellulitic area -length of 8-17cm. Blistered areas, loose skin and patches of necrotic	Oral Flucloxacillin daily dressing changes of melolin and tubigrip. IV Flucloxacillin and benzyl penicillin in	Wash and gel	Within 2 weeks a significant reduction in cellulitis and dressing changed to aquacel. Alternate day dressing change. Wound completely healed in 12 weeks

		tissue and 3 exudous areas.	hospital. Saline washes		
Pressure Ulcer	1	Grade 4, 300 cm ² pressure ulcer with necrotic tissue covering 100% of wound. MRSA identified in wound. Wound submitted to sharp debridement	Not specified	Wash and gel	By day 20 wound had reduced to 165 cm ² , slough had reduced by 90%, dressing changes reduced to twice weekly. Day 26, wound slough was minimal.
Foot and leg ulcer	2	1 x Infected 10 month chronic foot ulcers with MRSA and Pseudomonas. High exudate. 1 x 3 month leg ulcer with exudate and expected biofilm.	The foot ulcer started on iv vancomycin and meropenam for 3 weeks no improvement. Leg ulcer treated with 3 courses of IV antibiotics and various antimicrobial dressings	Wash and gel	Foot ulcer: improvements noted in 1 week, pain significantly reduced by 2 weeks and dressing changes able to be performed without analgesia. Discharged home after 3 weeks. After 3 months steroids were stopped. Wound continue to heal well remaining infection and pain free. Leg ulcer: pain reduced within few days. 1 week - exudate reduced. Wound size and quality improved after 2 weeks. Pressure therapy recommenced after 2 weeks and dressing reduced to three times a week. 4 weeks = considerable improvements and pt. discharged home
Trauma	1	Head wound approx. 3 weeks not healing normally with slough and infection.	Cleansed and clips inserted, iv antibiotics. Emergency debridement of wound (surgery) performed multiple times. Swelling continued on ward requiring drainage and aspiration	Wash and gel	Reduction in necrotic tissue after few weeks and granulation was evident. Skin graft postponed as wound healing well. Discharged and dressing reduced to alternate days. Skin graft cancelled and dressing reduced to weekly. Full recovery and no graft needed