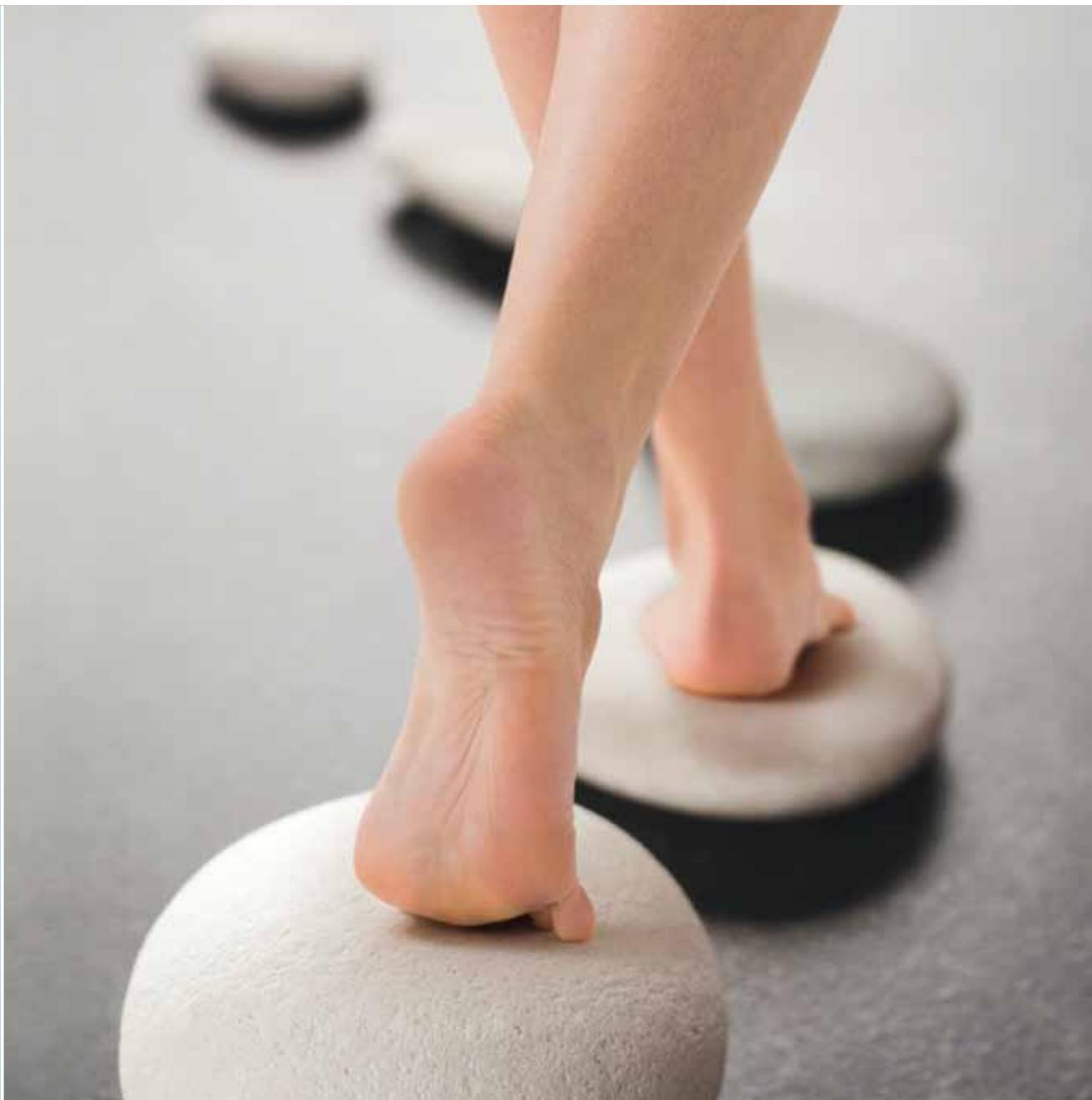


Prontosan[®]

Clinical and Scientific Evidence



B | BRAUN
SHARING EXPERTISE

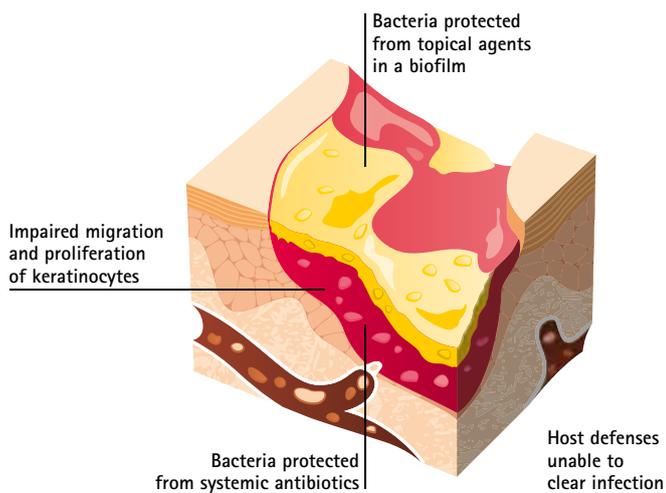
Prontosan®

Rationale for the use of Prontosan®

Millions of people around the world suffer from chronic wounds. Such patients have to come to terms with months of pain and reduced quality of life and the need for long-term care and treatment. Chronic wound patients and their caregivers would like nothing more than fast, lasting healing.

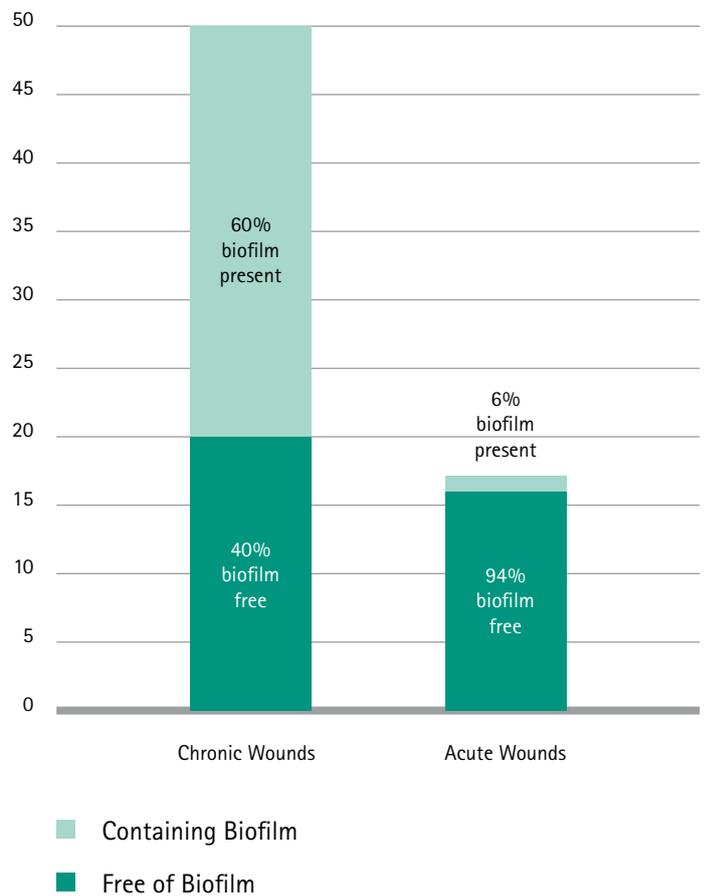
60% of chronic wounds have a biofilm present which is a major barrier to wound healing

The problems a biofilm creates:



Wound cleansing is a prerequisite for proper wound healing. Prontosan® physically removes debris, slough, bioburden and biofilm.

60% of chronic wounds and 6% of acute wounds are present with biofilm at a statistically significant difference ($p < 0.001$).



Biofilms in chronic wounds

James GA, Swogger E, Wolcott R, de Lancey Pulcini E, Secor P, Sestrich J, Costerton JW, Stewart PS.
Wound Repair Regen 2008;16(1):37-44.

Objective

This research examined chronic and acute wounds for biofilms and characterized microorganisms inhabiting these wounds.

Methods

Chronic wound specimens were obtained from 77 subjects and acute wound specimens were obtained from 16 subjects. Culture data were collected using standard clinical techniques. Light and scanning electron microscopy techniques were used to analyze 50 of the chronic wound specimens and the 16 acute wound specimens. Molecular analyses were performed on the remaining 27 chronic wound specimens using denaturing gradient gel electrophoresis and sequence analysis.

Results

Of the 50 chronic wound specimens evaluated by microscopy, 30 were characterized as containing biofilm (60%), whereas only one of the 16 acute wound specimens was characterized as containing biofilm (6%). This was a statistically significant difference ($p < 0.001$). Molecular analyses of chronic wound specimens revealed diverse polymicrobial communities and the presence of bacteria, including strictly anaerobic bacteria, not revealed by culture.

Conclusion

Bacterial biofilm prevalence in specimens from chronic wounds relative to acute wounds observed in this study provides evidence that biofilms may be abundant in chronic wounds.

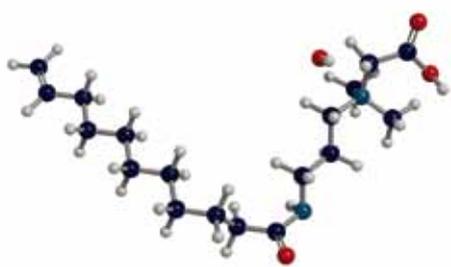
Prontosan®

Contents of Prontosan®

Prontosan® contains unique ingredients that have a double effect on the wound bed to create a wound environment optimal for healing.

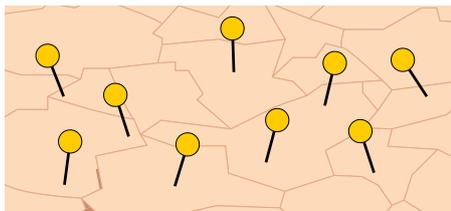
Betaine

Function in Prontosan®: Surfactant / Detergent

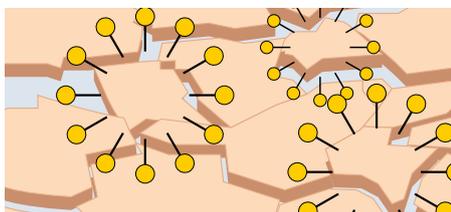


Betaine is a gentle effective surfactant which is able to penetrate, clean and remove the biofilm and wound debris. It is like a detergent that works by...

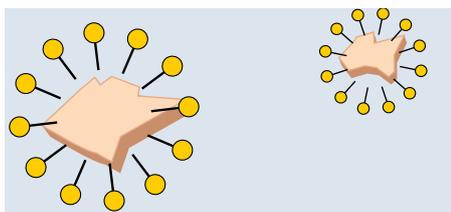
...reducing the surface tension of water



...supporting softening, loosening and detaching of dirt

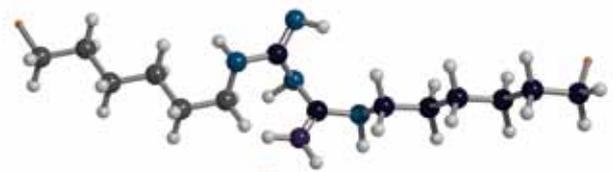


...and dispersing dirt (binds dirt in the solutions, preventing recontamination)



Polihexanide (PHMB)

Function in Prontosan®: Preservative



repeating structural unit

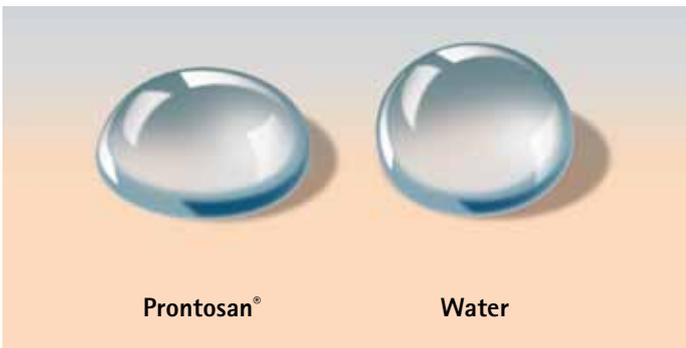
PHMB is a highly effective modern broad spectrum antimicrobial agent that reduces bioburden.

The mode of action can be described as a non-specific electrostatic interaction with the bacterial cell wall. The attachment of polihexanide to the bacterial cell wall results in a disorganisation of the biological structure of the bacteria.

Prontosan[®]

The powerful combination of Betaine and Polihexanide

How to determine cleansing power?

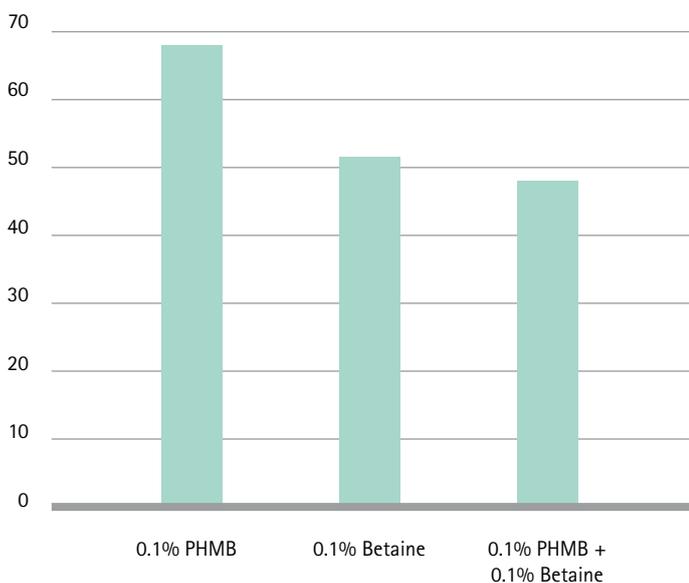


Surface tension is a parameter to measure cleansing efficacy.

The surface tension of Prontosan[®] solution is lower than the surface tension of water. This allows Prontosan[®] to remove biofilm better than water.

The combination of Polihexanide (PHMB) and Betaine synergistically improves the cleansing power of Prontosan[®]

Surface Tension (mN/m)



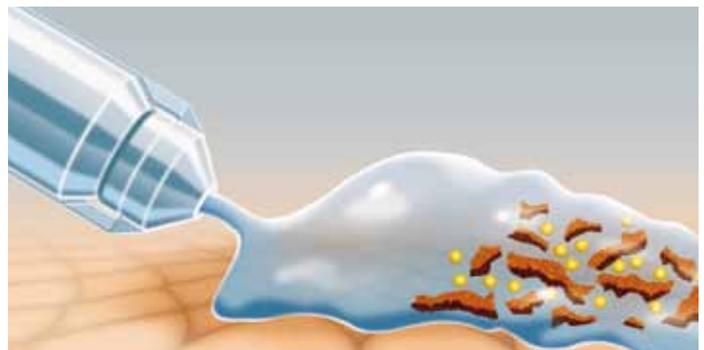
B. Braun internal tests (report available upon request)

The combination of 0.1% polihexanide and 0.1% betaine has a lower surface tension than the single substances. This results in a synergistic effect of the two substances in the mixture. Therefore, the physical cleansing power of Prontosan[®] (combination of 0.1% polihexanide plus 0.1% betaine) is superior to 0.1% betaine.

The optimal solution for removal of biofilm



The usually applied irrigation solutions (0.9% NaCl – water – Ringer solution) glide over the biofilm without removing it.



Prontosan[®] is able to remove the biofilm by destroying its structure by physical cleansing.

Prontosan®

Available evidence at a glance

Reference	Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
Clinical use of polihexanide on acute and chronic wounds for antisepsis and decontamination. Eberlein T, Assadian O. Skin Pharmacol Physiol 2010;23(Suppl 1):45-51.	Review	●	●	●	●			9
Addressing the challenge of wound cleansing in the modern era. Cutting KF. Br J Nurs 2010;19(11):24-29.	Review		●					10
The effectiveness of a 0.1% polihexanide gel. Valenzuela AR, Perucho NS. Rev ROL Enf 2008;31(4):247-252.	RCT	●			●	●		11
Evaluation of the efficacy and tolerability of a solution containing propyl betaine and polihexanide. Romanelli M, Dini V, Barbanera S, Bertone MS. Skin Pharmacol Physiol 2010;23(Suppl 1):41-44.	RCT			●	●	●		12
Experiences in using polihexanide containing wound products in the management of chronic wounds – results of a methodical and retrospective analysis of 953 cases. Moeller A, Nolte A, Kaehn K. Wundmanagement 2008; 3:112-117.	Cohort	●		●	●	●		13
Assessment of a wound cleansing solution in the treatment of problem wounds. Andriessen AE, Eberlein TE. Wounds 2008;20(6):171-175.	Cohort	●					●	14
Effect of different wound rinsing solutions on MRSA biofilm in a porcine model. Perez R, Davies SC, Kaehn K. WundM 2010;4(2):44-48.	Animal		●					15
Efficacy of various wound irrigation solutions against biofilms. Seipp HM, Hofmann S, Hack A, Skowronsky A, Hauri A. ZfW 2005;4(5):160-163.	In-vitro		●					16
Polihexanide and betaine containing wound care solution and gel reduce the growth of microorganisms by more than LOG 5 in-vitro. Stolarck R, Minnich K, Olinger S, et al. J Clin Pharmacol 2010;50(9):1071.	In-vitro			●				17
In-vitro test for comparing the efficacy of wound rinsing solutions. Kaehn K, Eberlein T. Br J Nurs 2009; 18(11):4-10.	In-vitro		●					18
Evaluation of toxic side effects of clinical used antiseptics in vitro. Hirsch T, Koerber A, Jacobsen F, et al. J Surg Res 2010;164(2):344-350.	In-vitro				●			19

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
Review	●	●	●	●			9

Clinical use of polihexanide on acute and chronic wounds for antisepsis and decontamination.

Eberlein T, Assadian O.
Skin Pharmacol Physiol 2010;23(Suppl 1):45-51.

Objective

This article gives a comprehensive review of the clinical use of polihexanide for the treatment of acute and chronic wounds. Current scientific literature is reviewed in order to give an overview of the properties of polihexanide-containing preparations relevant for the treatment of wounds, contraindications, available application forms and special aspects of practical use.

Abstract

Polihexanide is an antimicrobial compound suitable for clinical use in critically colonized or infected acute and chronic wounds. Its beneficial characteristic is attributable particularly to its broad antimicrobial spectrum, good cell and tissue tolerability, ability to bind to the organic matrix, low risk of contact sensitization and wound healing promoting effect. In addition, no development of microorganism resistance during polihexanide use has been detected to date, nor does this risk appear imminent. The aim of therapy using polihexanide is to reduce the pathogen burden in a critically colonized or infected acute or chronic wound. An increasing number of articles on the subject of wound antisepsis with polihexanide can be found in the medical literature. However, there is still little published information on the practical use of polihexanide-containing wound antiseptics. The use of polihexanide is not the only therapeutic option in management of wounds; therefore, priority is also given to prior surgical debridement and clarification of the cause of the underlying disease, including appropriate therapy.

Conclusion

- Polihexanide is an antimicrobial substance that is highly suitable for use in critically colonized or infected wounds.
- Polihexanide has a broad antimicrobial spectrum, good cell and tissue tolerability, the ability to bind to the organic matrix, a low risk of contact sensitization and a wound healing promoting effect.
- No development of microorganism resistance has been detected with polihexanide use to date, nor does this risk appear imminent.

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
Review	●						10

Addressing the challenge of wound cleansing in the modern era.

Cutting KF.

Br J Nurs 2010;19(11):24-29.

This article describes Prontosan®'s mode of action and reviews the current available efficacy data for Prontosan®.

Abstract

Over the past two decades a body of evidence has been generated to support the traditional use of water in cleansing wounds, with studies showing that the use of clean water doesn't increase the risk of infection or delay healing. However, recent advances in the understanding of wound management have encouraged reforms and led to the development of wound cleansing agents that have the potential to improve clinical outcomes. This article draws on in-vitro and in-vivo evidence including comparative studies of patients with acute and chronic wounds to consider the evidence supporting alternatives to water in wound cleansing.

Quote

"What differentiates Prontosan® from other polymeric biguanides is the inclusion of betaine in the formulation. The resulting low surface tension induced by the surfactant (e.g. betaine) supports physical removal of debris and bacteria."

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
RCT	●			●	●		11

The effectiveness of a 0.1% polihexanide gel.

Valenzuela AR, Perucho NS.
Rev ROL Enf 2008;31(4):247-252.

Objective

The objective of the study was to evaluate the effectiveness of Prontosan® Wound Gel and to assess if this gel met the recommendations for cleansing wounds provided by the National Group which Studies and Counsels Health Professionals regarding Bed Sores and Chronic Wounds (GNEAUPP) and by the Agency for Health Care Policy and Research (AHCPR).

Methods

A multicenter, randomized, open clinical trial was performed to compare the efficacy of Prontosan® Wound Gel with the recommendations of the GNEAUPP and the AHCPR for wound cleansing in the control of bacterial burden, wound healing, pain and wound odour. The wounds in the control group were cleansed with normal saline, and if debridement was required, autolytic debridement by means of hydrogel was carried out. The wounds in the experimental group were cleansed with normal saline and then a 0.1% polihexanide gel (Prontosan® Wound Gel) was applied.

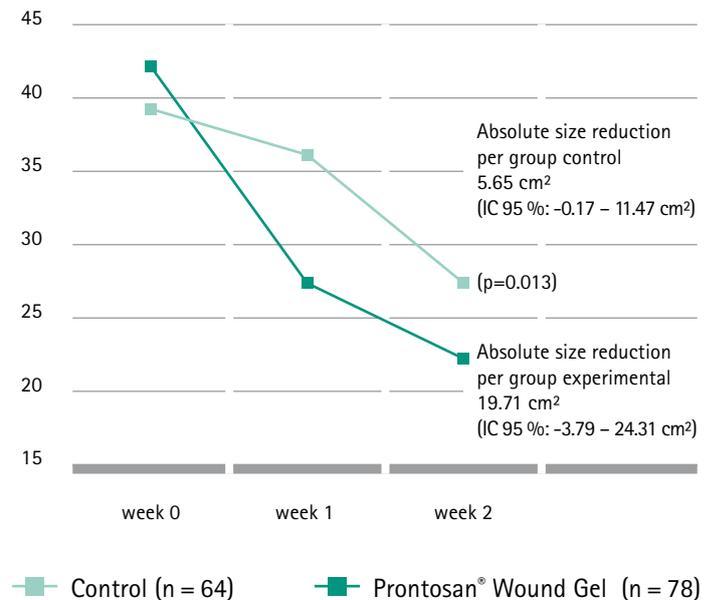
Results

The data obtained in the final evaluation of the lesions studied were as follows: a reversal in positive cultures ($p=0.004$); an improvement in the stagnation of the cicatrisation process ($p=0.000$); reduction in the size of the wound ($p=0.013$); an improvement in the percentage of granulation tissue ($p=0.001$); an improvement in the percentage of slough in the bed of the wound ($p=0.002$); an improvement in the presence of exudation ($p=0.008$); an improvement in the presence of purulent exudation ($p=0.005$); an improvement in the condition of skin nearby the wound ($p=0.021$); an improvement in pain control ($p=0.049$); an improvement in erythema in nearby skin ($p=0.004$); an improvement in edema in skin nearby the wound ($p=0.000$); an improvement in the heat in the skin nearby the wound ($p=0.004$); and an improvement in the odour ($p=0.029$).

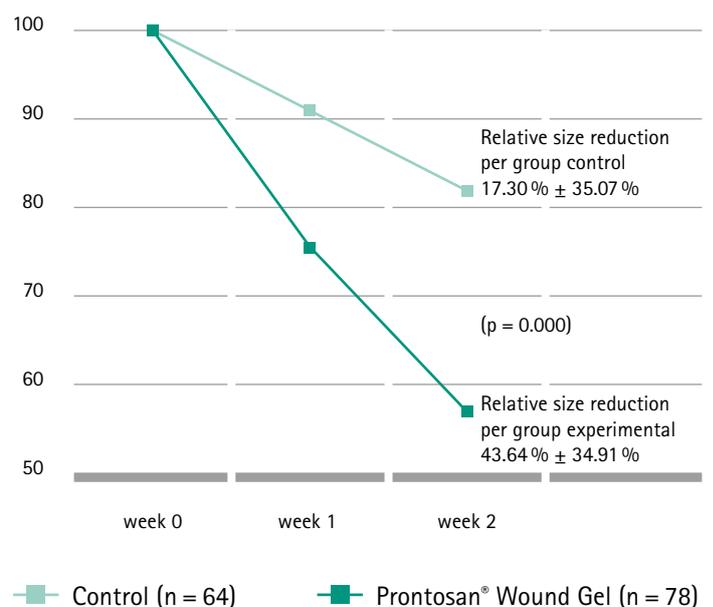
Conclusion

The results of this study show that Prontosan® Wound Gel is a highly effective wound cleansing agent that contributes successfully to wound bed preparation and increases patients' quality of life by alleviating pain and minimizing wound odour.

Absolute size reduction (cm²) per group



Relative size reduction (%) per group



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Cost-effective	Page
RCT	●	●	●	●		12

Evaluation of the efficacy and tolerability of a solution containing propyl betaine and polihexanide.

Romanelli M, Dini V, Barbanera S, Bertone MS.
Skin Pharmacol Physiol 2010;23(Suppl 1):41-44.

Objective

The objective of this randomized controlled trial was to investigate the effects of a wound cleansing solution containing polihexanide and betaine (Prontosan® Wound Irrigation Solution) in venous leg ulcers.

Methods

A portable device was used on the wound bed to assess surface pH, which has been shown to be one of the most useful non-invasive biophysical parameters in order to correlate the level of bacterial burden in different types of chronic wounds. In addition, patients were asked to self-assess subjectively the intensity of pain using a validated 10-mm visual analogue scale.

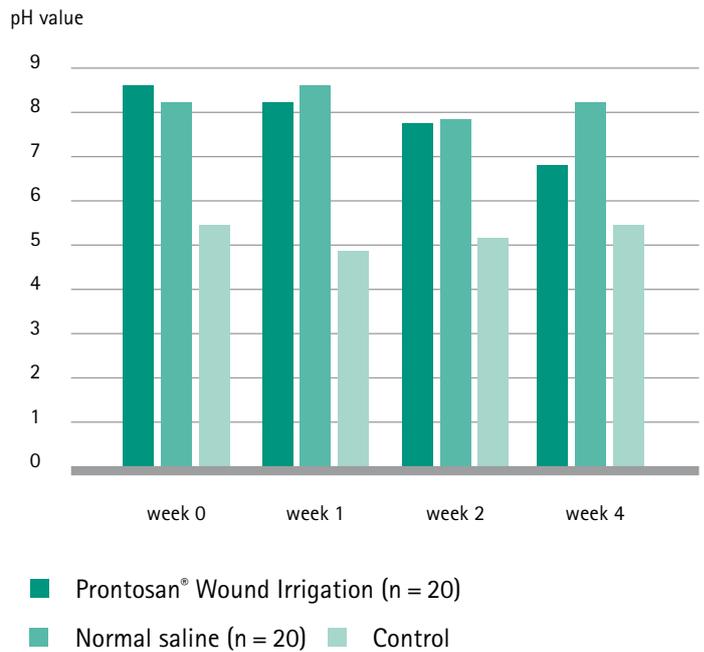
Results

Baseline pH on the wound surface (median range) was initially 8.9, and after 4 weeks of cleansing treatment and moist wound dressing was reduced and stable at 7.0 in the group treated with active cleanser. The pH value was significantly lower ($p < 0.05$) in this group compared to the control group at the end of the study. The treatment with the solution containing polihexanide and betaine (Prontosan® Wound Irrigation Solution) was well tolerated by the patients and was found useful in the absorption of wound odour. Pain was better controlled ($p < 0.05$) in the polihexanide and betaine group when compared to the control group.

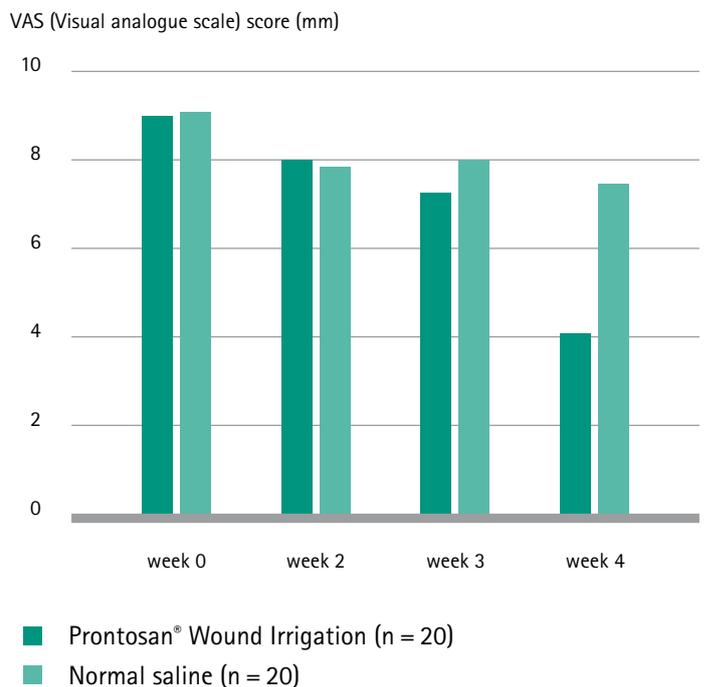
Conclusion

Treatment with Prontosan® Wound Irrigation Solution can lead to a decrease in pH, which is a surrogate marker for bacterial burden and is well tolerated for the treatment of chronic ulcers.

Results of pH measurement in the wounds during the study period of 4 weeks.



Pain evaluation during treatment of venous leg ulcers before and after 4 weeks of treatment with Prontosan® Wound Solution compared to standard therapy.



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Cost-effective	Page
Cohort	●		●	●		13

Experiences in using polihexanide containing wound products in the management of chronic wounds – results of a methodical and retrospective analysis of 953 cases.

Moeller A, Nolte A, Kaehn K.
Wundmanagement 2008;3:112-117.

Objective

The objective of this retrospective analysis was to assess the healing process of chronic and poorly healing wounds after the introduction of Prontosan® Wound Irrigation Solution and Prontosan® Gel to the standard of care at a municipal hospital in Germany.

Methods

The following interventions were added to standard wounds care: routine irrigation of the wound with Prontosan® Wound Irrigation Solution at every dressing changes and the additional application of Prontosan® Wound Gel to every wound if there was no or only moderate exudation. Two years after the implementation of Prontosan®, the charts of 953 patients were retrospectively analyzed.

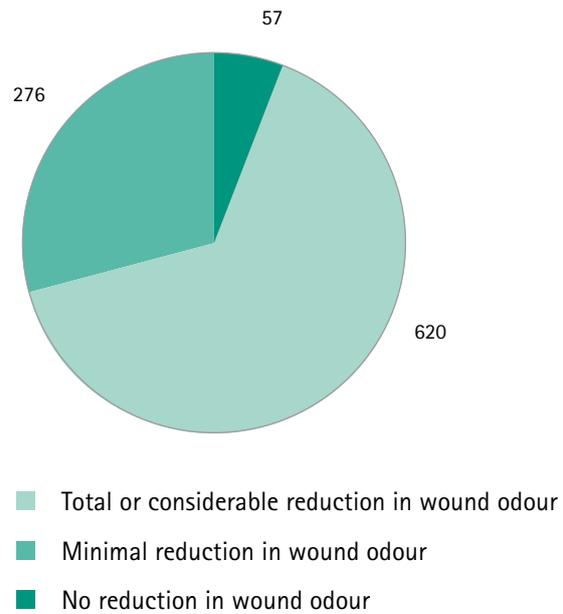
Results

In 80% of the wounds with improved findings, wound closure could be achieved with the combination therapy. Almost two thirds of the patients (620/953) found a great to complete reduction or improvement in odour. In 29 cases (3%) a first or renewed wound infection developed after the beginning of treatment. Only 1% of the treated patients reported a slight burning sensation, 99% had no pain or discomfort.

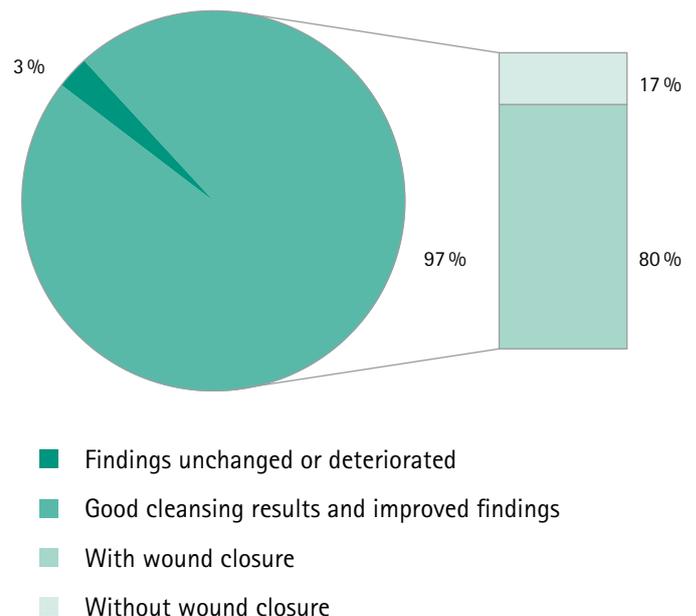
Conclusion

On the basis of the evaluated retrospective data it was decided to continue with the use of Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel for the treatment of chronic wounds at the Municipal Hospital Bielefeld Mitte in Germany.

Evaluation of wound odour reduction by patients.



Wound healing progress (n=953).



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Cost-effective	Page
Cohort	●				●	14

Assessment of a wound cleansing solution in the treatment of problem wounds.

Andriessen AE, Eberlein TE.
WOUNDS 2008;20(6):171-175.

Objective

This retrospective analysis of existing data was performed looking at the clinical efficacy and cost-effectiveness of using a wound cleanser (Prontosan® Wound Irrigation Solution) to treat problem wounds.

Methods

This retrospective analysis of existing data was performed looking at the clinical efficacy and cost-effectiveness of using a wound cleanser to treat problem wounds. Wound cleansing upon dressing changes using a polihexanide containing solution (Prontosan® Wound Irrigation Solution) in venous leg ulcers was compared to cleansing with either Ringer's solution or normal saline.

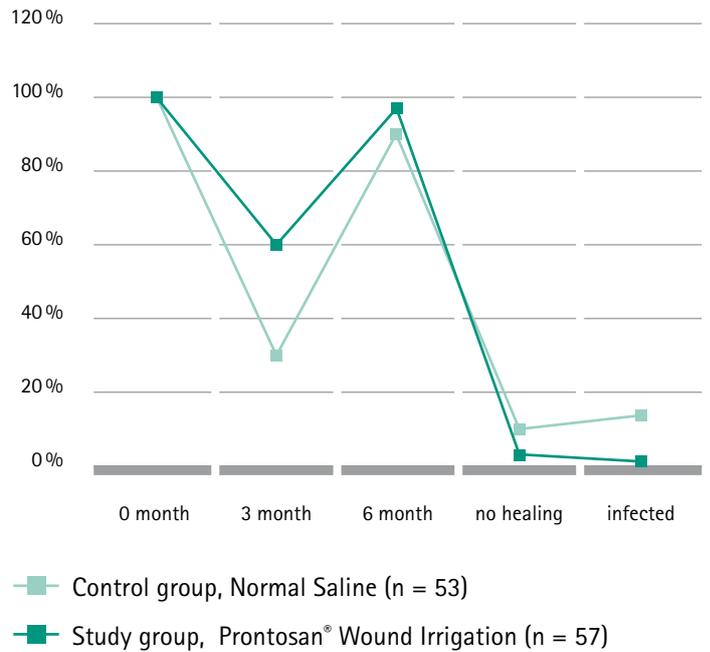
Results

The wounds of the patients treated with Prontosan® Wound Irrigation Solution healed faster and in more cases (97% versus 89%). The Kaplan-Meier mean estimate (and associated standard error [SE]) demonstrated a statistically significant difference between treatment groups ($p < 0.0001$) in time to healing. The Kaplan-Meier mean time to healing for the study group (SG) was 3.31 months ($SE = 0.17$) compared to 4.42 months ($SE = 0.19$) for the control group ([CG], normal saline/Ringer's solution).

Conclusion

Wound cleansing with Prontosan® Wound Irrigation Solution can lead to faster healing when compared to traditional wound cleansers such as normal saline and Ringer's solution and is therefore cost-effective.

% Healed Wounds, % Nonhealing Wounds, % Infected Wounds



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
Animal	●						15

Effect of different wound rinsing solutions on MRSA biofilm in a porcine model.

Perez R, Davies SC, Kaehn K.
WundM 2010;4(2):44-48.

Objective

The objective of this study was to assess the effectiveness of four wound cleansers on MRSA biofilm removal on dermal wounds in swine.

Methods

Partial thickness wounds on swine were spiked with MRSA and covered with polyurethane dressings for 24 hours to allow growth of biofilm. The wounds were then assigned to four groups. In three groups the wounds were cleansed twice a day by rinsing with i) Prontosan® Wound Irrigation Solution, ii) Ringer's solution, and iii) sterile saline. The wounds in the control group were not rinsed. Four wounds from each group were cultured at 48 and 72 hours respectively.

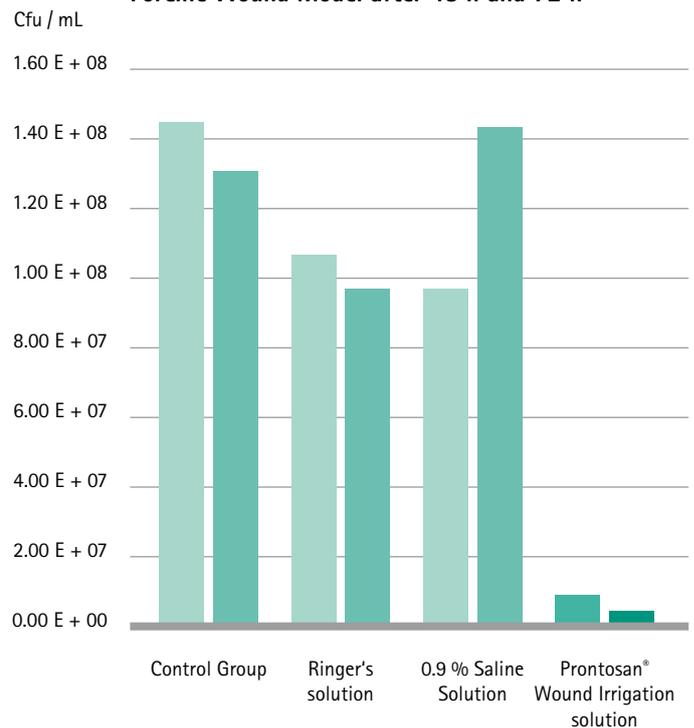
Results

Means of MRSA counts at 48 and 72 hours were significantly reduced ($p < 0.05$) in group i) compared to group ii) and iii).

Conclusion

Removal of MRSA biofilm was only demonstrated using Prontosan® Wound Irrigation Solution; both normal saline and Ringer's solution failed to reduce MRSA counts.

Determination of the Effects of Prontosan® Wound Irrigation solution on Methicillin Resistant Staphylococcus aureus Biofilms in a Partial Thickness Porcine Wound Model after 48 h and 72 h



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
In-vitro		●					16

Efficacy of various wound irrigation solutions against biofilms.

Seipp HM, Hofmann S, Hack A, Skowronsky A, Hauri A. ZfW 2005;4(5):160-163.

Objective

The objective of this study was to test the efficacy of three wound cleansing solution against biofilms.

Methods

The effectiveness of solutions applied for wound cleansing in clinical practice was evaluated by means of the Biofilmyl® method. This method permits the exact quantification of biofilms using endotoxins released from bacterial cell walls. First, biofilm test specimens were cultivated with *Pseudomonas aeruginosa* on silicone surfaces. Subsequently, in separate test series, the specimens were exposed to three different irrigants for 24 h each: a) normal saline solution, b) Ringer's solution, c) surfactant polihexanide solution (Prontosan® Wound Irrigation Solution).

Results

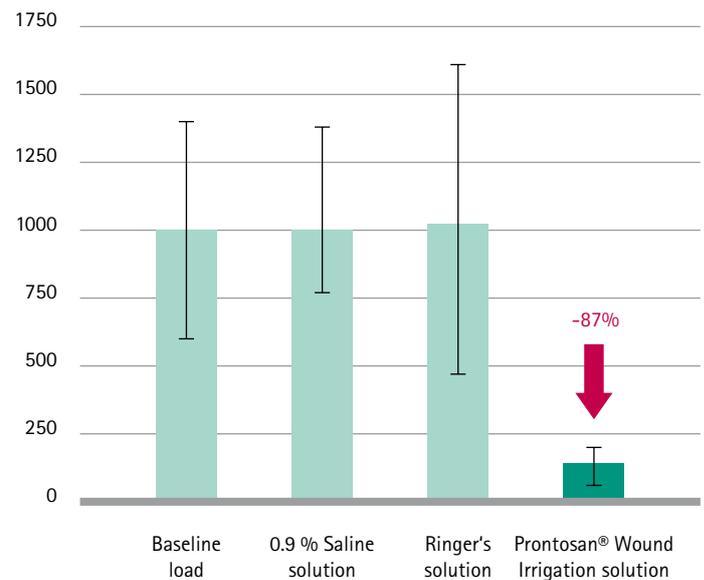
The results showed no decrease in the original biofilm load after exposure to normal saline solution as well as Ringer's solution, while the surfactant polihexanide solution (Prontosan® Wound Irrigation Solution) achieved a significant reduction ($p < 0.001$) of the biofilm by 87%.

Conclusion

Using the Biofilmyl® method, Prontosan® Wound Irrigation Solution shows a better reduction of biofilm when compared to normal saline and Ringer's solution.

Comparison of the efficacy of wound rinsing solutions on biofilm.

Biofilm equivalents (EU / ml)



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Cost-effective	Page
In-vitro			●			17

Polihexanide and betaine containing wound care solution and gel reduce the growth of microorganisms by more than LOG 5 in-vitro.

Stolarck R, Minnich K, Olinger S, et al.
J Clin Pharmacol 2010;50(9):1071.

Objective

To investigate the antimicrobial effects as a possible supportive mechanism of action of Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel.

Methods

In-vitro testing was performed according to USP 32-NF 27 2009, method 51 evaluating 13 microorganisms at 7, 14, and 28 days following exposure to 3 lots of the compounds/products.

Results

Growth reduction was nearly identical at each of the 3 evaluation days and above log 5 for all 3 lots of gel and solution in 12/13 organisms tested. Log 5.8 (average): *Staphylococcus epidermidis* (5.9, 5.8, 5.8); Log 5.7: *Pseudomonas aeruginosa* (5.7, 5.7, 5.6), *Serratia marcescens* (5.7, 5.7, 5.6), *Candida albicans* (5.7, 5.7, 5.7); Log 5.6: *Vancomycin resistant Enterococcus faecalis* (5.6, 5.6, 5.6), *Proteus mirabilis* (5.7, 5.6, 5.6); Log 5.5: *Staphylococcus aureus* (5.5, 5.5, 5.5), *Methicillin-resistant Staphylococcus aureus* (5.5, 5.5, 5.4), *Acinetbacter baumannii* (5.6, 5.5, 5.5); Log 5.4: *Escherichia coli* (5.5, 5.4, 5.4), *Enterobacter cloacae* (5.5, 5.4, 5.4); Log 5.3: *Enterococcus faecalis* (5.3, 5.3, 5.3). In *A. brasiliensis* the log reductions were for the gel 1.9 (1.9, 1.9, 1.8), 2.1 (2.1, 2.1, 2.1), and 2.5 (3.2, 2.2, 2.1) and for the solution 2.1 (2.2, 2.1, 2.0), 2.3 (2.3, 2.3, 2.2), and 2.8 (2.8, 2.8, 2.7) at 7, 14, and 28 days, respectively.

Conclusion

The log 5 reductions in antimicrobial activity in 12/13 microorganisms tested is suggested as a possible supportive mechanism of action of enhanced wound healing when using a combination of 0.1% polyhexanide and 0.1% of betaine either as a gel or an irrigation solution.

Log growth reduction at 7, 14 and 28 days for Prontosan® Wound Irrigation Solution and Prontosan® Wound Gel.

Microorganism	7 days	14 days	28 days
<i>Staphylococcus epidermidis</i>	5.9	5.8	5.8
<i>Pseudomonas aeruginosa</i>	5.7	5.7	5.6
<i>Serratia marcescens</i>	5.7	5.7	5.6
<i>Candida albicans</i>	5.7	5.7	5.7
Vancomycin resistant <i>Enterococcus faecalis</i>	5.6	5.6	5.6
<i>Proteus mirabilis</i>	5.7	5.6	5.6
<i>Staphylococcus aureus</i>	5.5	5.5	5.5
Methicillin resistant <i>Staphylococcus aureus</i>	5.5	5.5	5.4
<i>Acinetbacter baumannii</i>	5.6	5.5	5.5
<i>Escherichia coli</i>	5.5	5.4	5.4
<i>Enterobacter cloacae</i>	5.5	5.4	5.4
<i>Enterococcus faecalis</i>	5.3	5.3	5.3
<i>A. brasiliensis</i>	see abstract		

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
In-vitro		●					18

In-vitro test for comparing the efficacy of wound rinsing solutions.

Kaehn K, Eberlein T.
Br J Nurs 2009;18(11):4-10.

Objective

The aim of this study was to test the efficacy of four solutions to solubilise and remove wound coatings using a wound coating model.

Methods

An in-vitro model that mimics wound coatings (human plasma dried onto adhesive glass slides) was used to compare the efficacy of four sterile solutions used to cleanse wounds: saline and Ringer's (both salt solutions), a betaine surfactant-containing wound rinsing solution (Prontosan® Wound Irrigation Solution) and an antiseptic solution (Octenisept®).

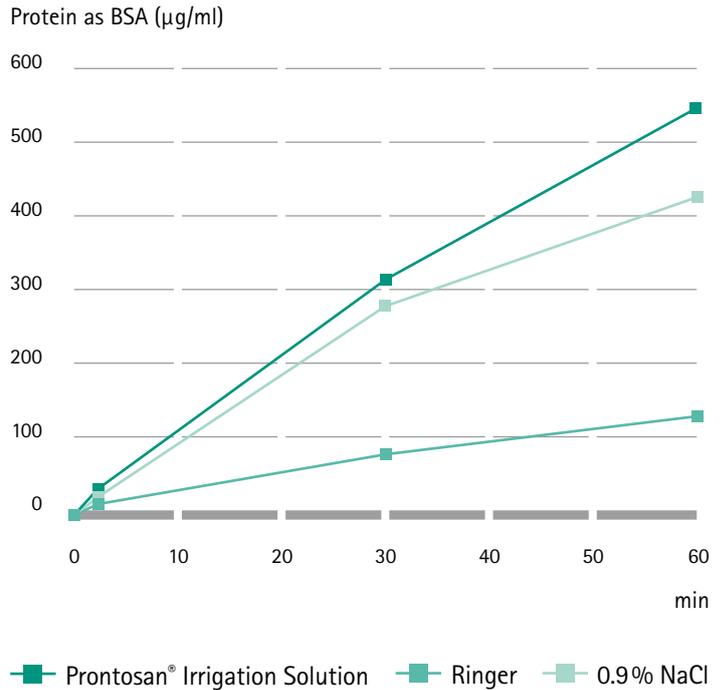
Results

Both salt solutions and the wound rinsing solution were found to remove protein from the test wound coatings, whereas the test coatings became fixed and insoluble when immersed in antiseptic solution (Octenisept®).

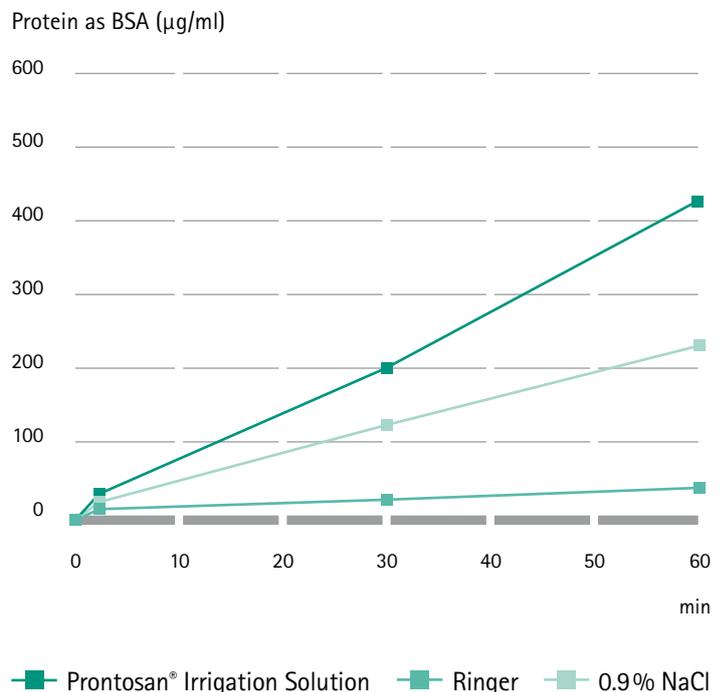
Conclusion

Saline solutions were less efficient than a betaine surfactant containing wound rinsing solution (Prontosan® Wound Irrigation Solution) in removing protein from adherent test wound coatings.

Protein concentrations in supernatants of the test series with plasma.



Protein concentrations in supernatants of the test series with fibrin slides.



Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
In-vitro			●				19

Evaluation of toxic side effects of clinical used antiseptics in vitro.

Hirsch T, Koerber A, Jacobsen F, et al.
 J Surg Res 2010;164(2):344-350.

Objective

The objective of this study was to evaluate cytotoxic effects of five clinically used products on human skin cells.

Methods

Five clinically used products (Prontosan®, Lavasept®, Braunol®, Octenisept®, and Betaisodona®) were tested. The minimal inhibitory concentration was determined against *Staphylococcus aureus*, *Enterococcus faecalis*, *Pseudomonas aeruginosa*, and *Escherichia coli*. The cytotoxic effects on primary keratinocytes, fibroblasts, and a HaCaT cell line were determined (MTT assay and BrdU-ELISA) at a wide range of concentrations.

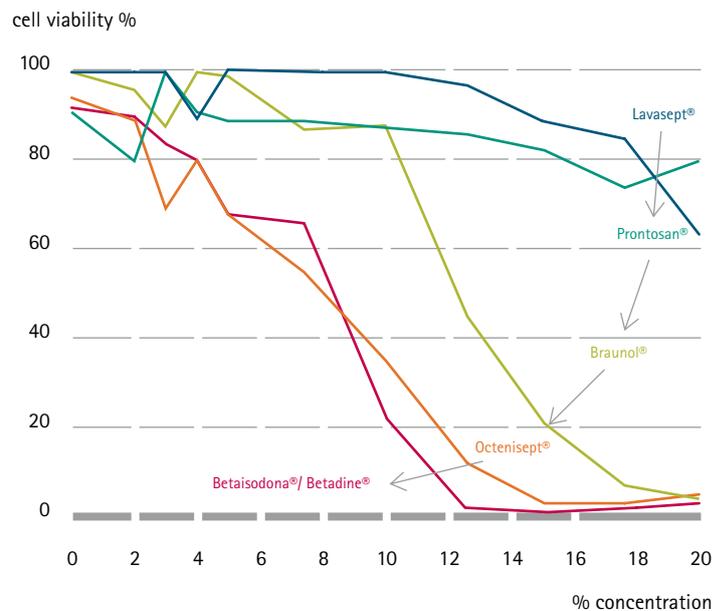
Results

The agents tested showed effective antibacterial properties (Octenisept®, Lavasept®, and Prontosan® showed higher efficacy than Braunol® and Betaisodona®) and different degrees of cytotoxicity. Lavasept® and Prontosan® demonstrated less toxicity on primary human fibroblasts and keratinocytes, whereas Octenisept®, Betaisodona® and Braunol® showed a significant ($p < 0.05$) decrease in cell viability to 0% on keratinocytes at concentrations of 4%, 7.5%, and 12.5%, and on fibroblasts at 7.5% and 10%, respectively.

Conclusion

Due to the cytotoxic effect of some antiseptics on human skin cells, it is advised that health care professionals balance the cytotoxicity of the medication, their antiseptic properties and the severity of colonization when selecting a wound care antiseptic. In this study, Lavasept® and Prontosan® showed best result regarding antibacterial efficacy and cell toxicity.

Cytotoxicity of products on skin cells.



Legend for Cytotoxicity graph:
 ■ Lavasept® ■ Prontosan® ■ Braunol®
 ■ Octenisept® ■ Betaisodona®/Betadine®