Prontosan® and Askina®

Clinical and Scientific Evidence

B BRAUN
SHARING EXPERTISE

Introduction

B. Braun Wound Care.
Right. From the start.

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.

Successful treatment depends on the hygienic state of the wound, wound bed preparation, choice of wound dressings, the therapist's experience and last but not least, the patient's condition.

Wound coatings, bacterial biofilms, pus, necrotic tissue, detrius and in particular, the bacterial biofilm, delay or inhibit wound healing. Removing this detritus, otherwise known as "detritolysis", accelerates wound healing.

B. Braun has developed a comprehensive range of wound care products which enables optimal wound management by supporting and accelerating endogenous healing.

B. Braun Wound Care products focus on every type of wound at each phase of wound healing. By providing innovative solutions such as Prontosan® Wound Irrigation Solution, bacterial biofilm can be efficiently removed thereby clearing the way for application of advanced wound dressings from the Askina® range, to assist in the complex task of tissue repair.

This guide includes the rationales for using Prontosan® and Askina® and gives an overview of the convincing clinical and scientific evidence available.

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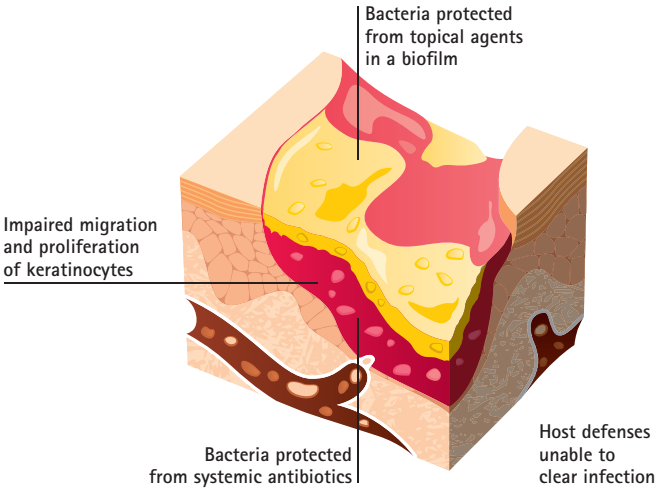
Prontosan®

Rationale for the use of Prontosan®

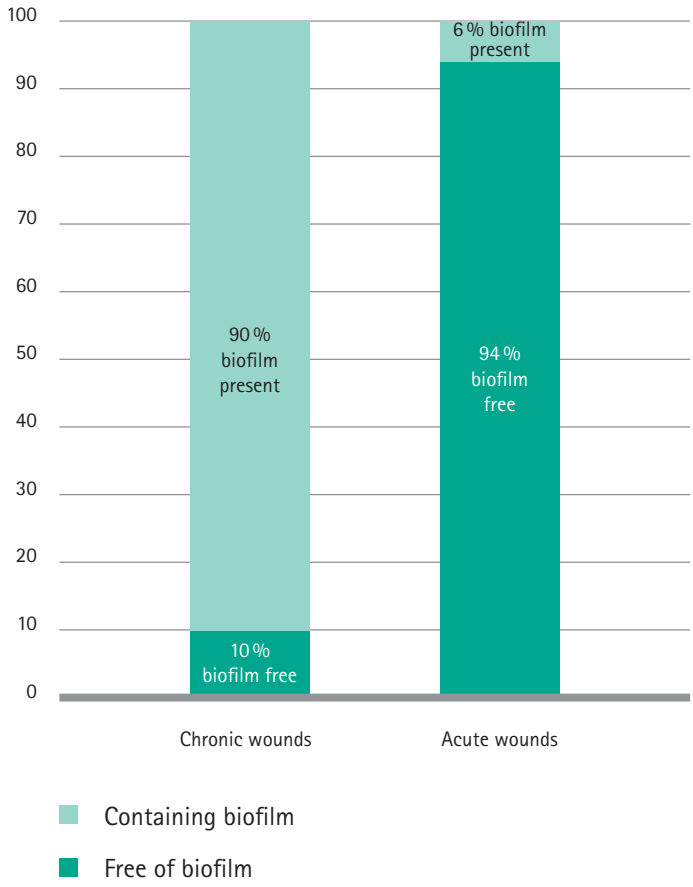
Millions of people around the world suffer from chronic wounds. Such patients have to come to terms with months of pain and reduced quality of life and the need for long-term care and treatment. Chronic wound patients and their caregivers would like nothing more than fast, lasting healing.

90 % 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.



Clinically addressing biofilm in chronic wounds

Attinger C. Wolcott R.
Advances in Wound Care 2012;1(3):127-132.

Background
A chronic wound is a wound that is arrested in the inflammatory phase of wound healing and cannot progress further. Over 90 % of chronic wounds contain bacteria and fungi living within a biofilm construct.

The Problem
Each aggregation of microbes creates a distinct biofilm with differing characteristics so that a clinical approach has to be tailored to the specifics of a given biofilm. Defining the characteristics of that biofilm and then designing a therapeutic option particular to that biofilm is currently being defined.

Basic/Clinical Science Advances
Biofilm becomes resistant to therapeutic maneuvers at 48 – 96 h after formation. By repeatedly attacking it on a regular schedule, one forces biofilm to reattach and reform during which time it is susceptible to antibiotics and host defenses. Identifying the multiple bacteria and fungi that make up a specific biofilm using polymerase chain reaction (PCR) allows directed therapeutic maneuvers such as application of specific topical antibiotics and biocides to increase the effectiveness of the debridement.

Clinical Care Relevance
Most chronic wounds contain biofilm that perpetuate the inflammatory phase of wound healing. Combining debridement with using PCR to identify the bacteria and fungi within the biofilm allows for more targeted therapeutic maneuvers to eliminate a given biofilm.

Conclusion
Therapeutic options in addition to debridement are currently being evaluated to address biofilm. Using PCR to direct adjunctive therapeutic maneuvers may increase the effectiveness of addressing biofilm in a chronic wound.

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.

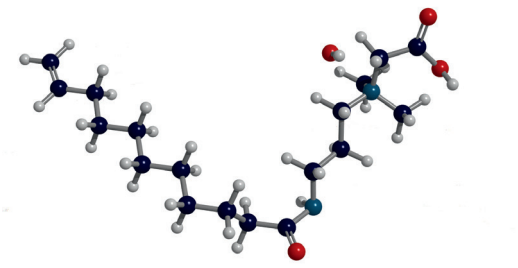
Conclusion
Bacterial biofilm prevalence in specimens from chronic wounds relative to acute wounds observed in this study provides evidence that biofilms may be abundant in chronic wounds.

Prontosan®

Contents of Prontosan®

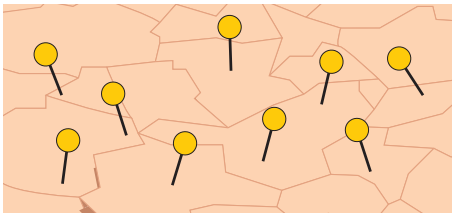
Prontosan® contains unique ingredients that have a double effect on the wound bed to create a wound environment optimal for healing.

Betaine
Function in Prontosan®: Surfactant / Detergent

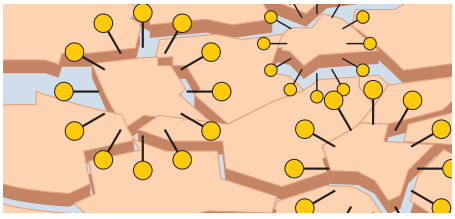


Betaine is a gentle effective surfactant which is able to penetrate, clean and remove the biofilm and wound debris. It is like a detergent that works by…

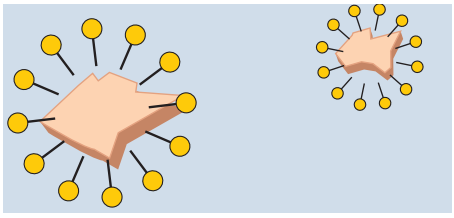
…reducing the surface tension of water



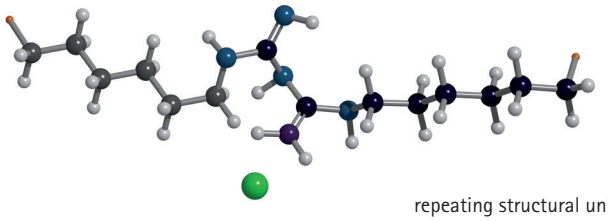
…supporting softening, loosening and detaching of dirt



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



Polihexanide (PHMB)
Function in Prontosan®: Preservative



repeating structural unit

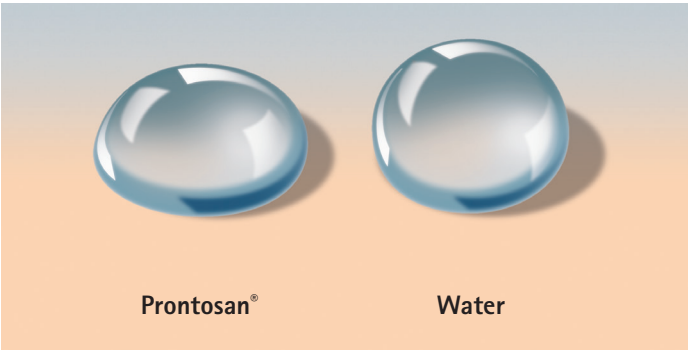
PHMB is a highly effective modern broad spectrum antimicrobial agent that reduces bioburden.

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

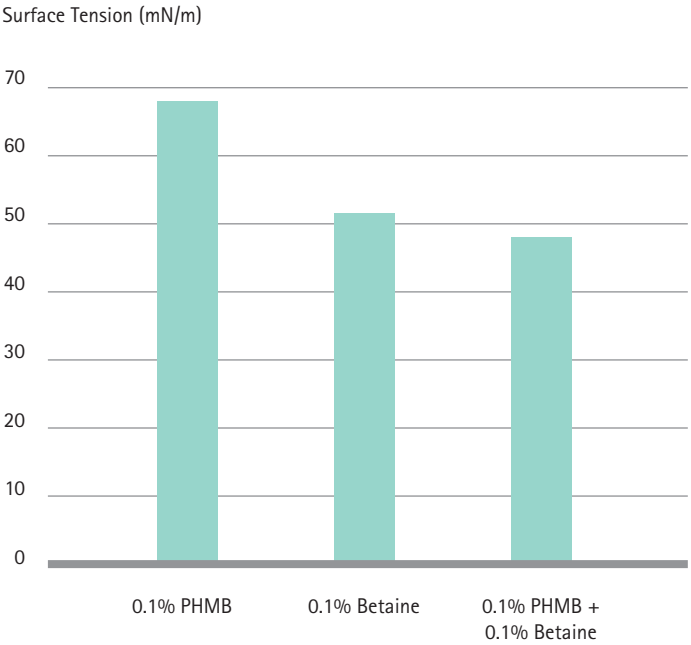
How to determine cleansing power?



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.

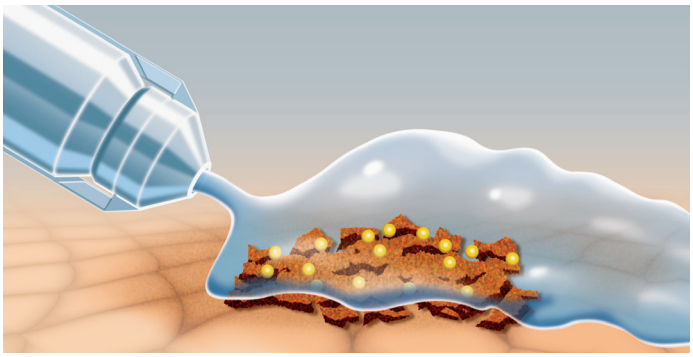
The combination of Polihexanide (PHMB) and Betaine synergistically improves the cleansing power of Prontosan®



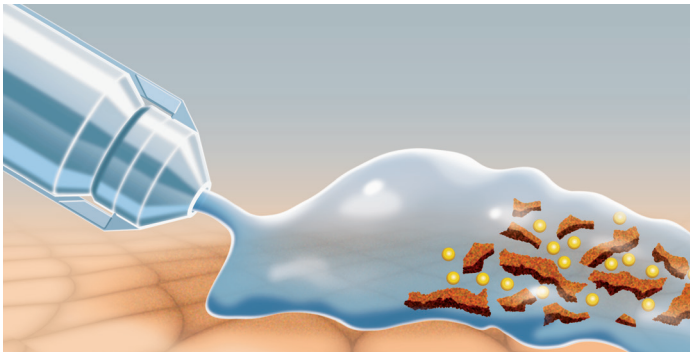
B. Braun internal tests (report available upon request)

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 it's 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	●	●	●	●			10
Addressing the challenge of wound cleansing in the modern era. Cutting KF. Br J Nurs 2010;19(11):24 – 29.	Review		●					11
The effectiveness of a 0.1 % polihexanide gel. Valenzuela AR, Perucho NS. Rev ROL Enf 2008;31(4):247 – 252.	RCT	●			●	●		12
Evaluation of the effcacy 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			●	●	●		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.	Cohort	●		●	●	●		14
Assessment of a wound cleansing solution in the treatment of problem wounds. Andriessen AE, Eberlein TE. Wounds 2008;20(6):171 – 175.	Cohort	●					●	15
Evaluation of the effectiveness of a polyhexanide and propyl betaine-based gel in the treatment of chronic wounds. Durante CM, Greco A, Sidoli O, et al. Minerva Chir. 2014 Oct;69(5):283-92.	Cohort	●	●			●	●	16
The Impact of Negative-Pressure Wound Therapy with Instillation Compared with Standard Negative-Pressure Wound Therapy: A Retrospective, Historical, Cohort, Controlled Study. Kim PJ, Attinger CE, Steinberg JS, et al. Plast. Reconstr. Surg. 133: 709, 2014.	Cohort	●					●	17
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		●					18
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			●				19
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		●					20
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				●			21
Intermittent exposure to wound irrigation solutions disrupts P. aeruginosa and S. aureus immature biofilms in-vitro. Lessing MC, McNulty AK. Wound Rep Reg 2012;20:A28.	In-vitro			●				22

Reference	Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
Effects of biguanides on the formation of streptococcal biofilms using a human embryo skin fibroblast cell culture model. Afinogenova AG, Grabovskaya KB, Kuleshevich EV, et al. Infections in Surgery 2011;1(9):5–13.	In-vitro		●	●	●			23
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		●					24
Cost-effectiveness of polyhexamethylen biguanide 0.1 % and betaine 0.1 % solution (Prontosan®) versus saline for cleansing of chronic wounds under the Brazilian Private Health System perspective. Mehl AA, Lopes Mensor L, Frassi Bastos D, et al. J Bras Econ Saúde 2013;5(3):135-146.	HTA						●	25

Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
Review	●	●	●	●			10

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.

Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
Review		●					11

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."

Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
RCT	●			●	●		12

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.

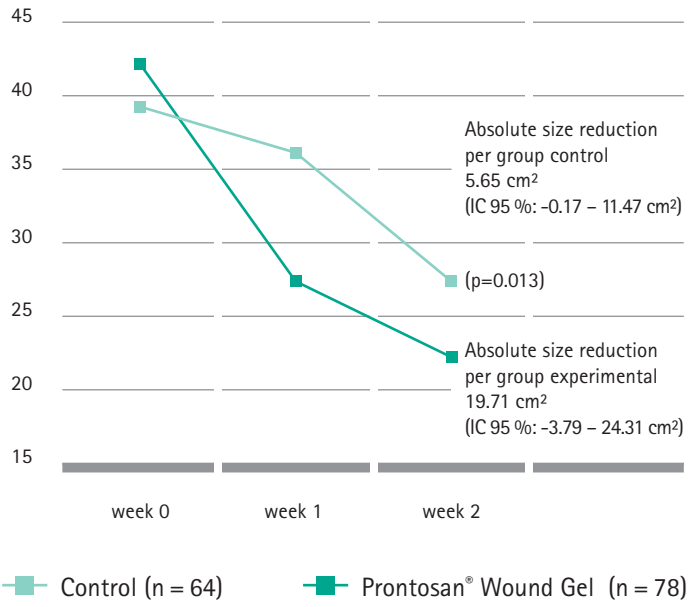
Results

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).

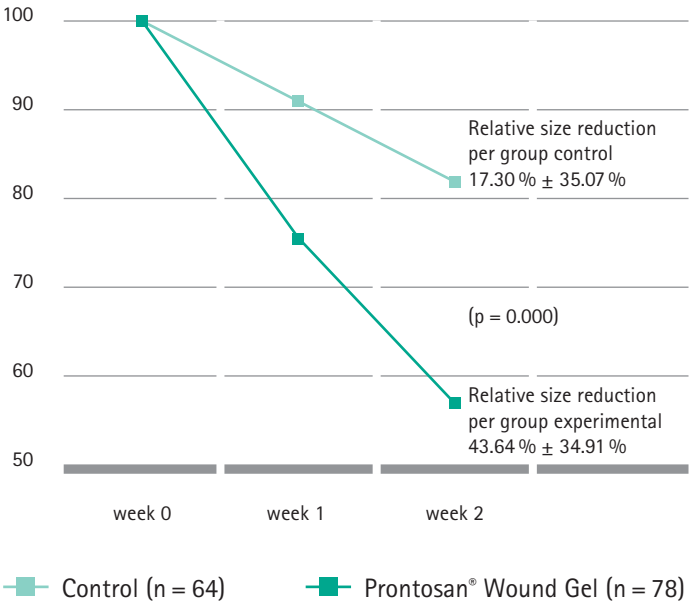
Conclusion

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



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
RCT	●		●	●	●		13

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.

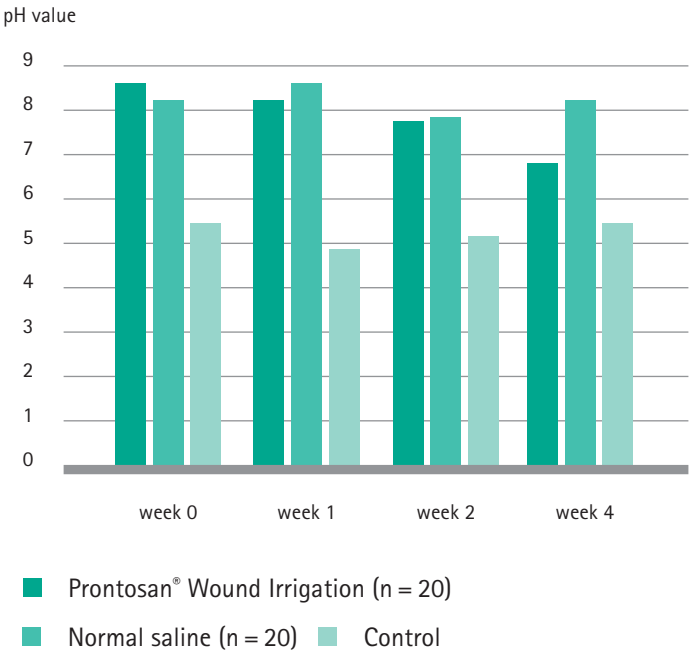
Objective
The objective of this randomized controlled trial was to investigate the effects of a wound cleansing solution containing polihexanide and betaine (Prontosan® Wound Irrigation Solution) in venous leg ulcers.

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.

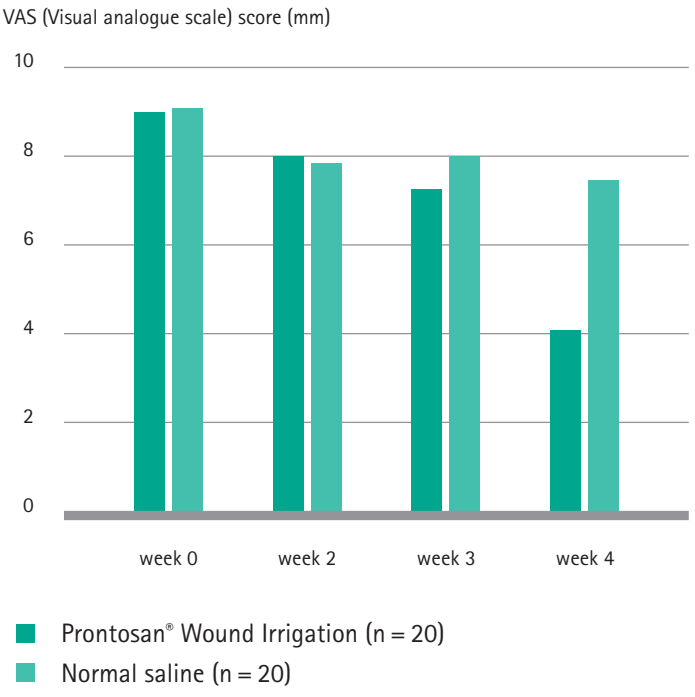
Results
Baseline pH on the wound surface (median range) was initially 8.9, and after 4 weeks of cleansing treatment and moist wound dressing was reduced and stable at 7.0 in the group treated with active cleanser. The pH value was significantly lower ($p < 0.05$) in this group compared to the control 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.



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
Cohort	●		●	●	●		14

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.

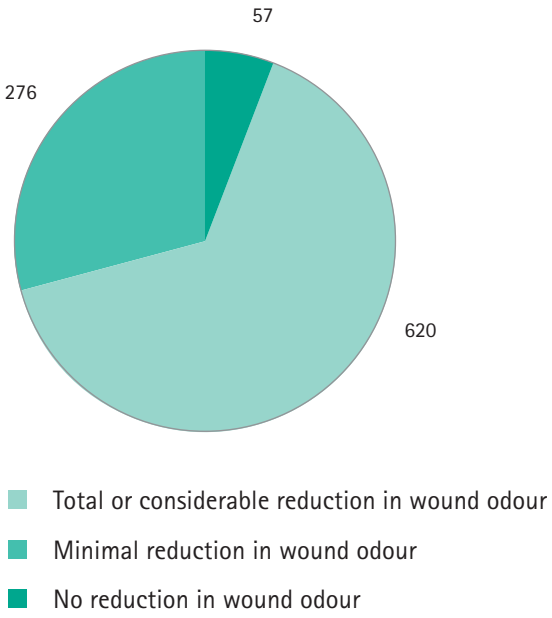
Results

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.

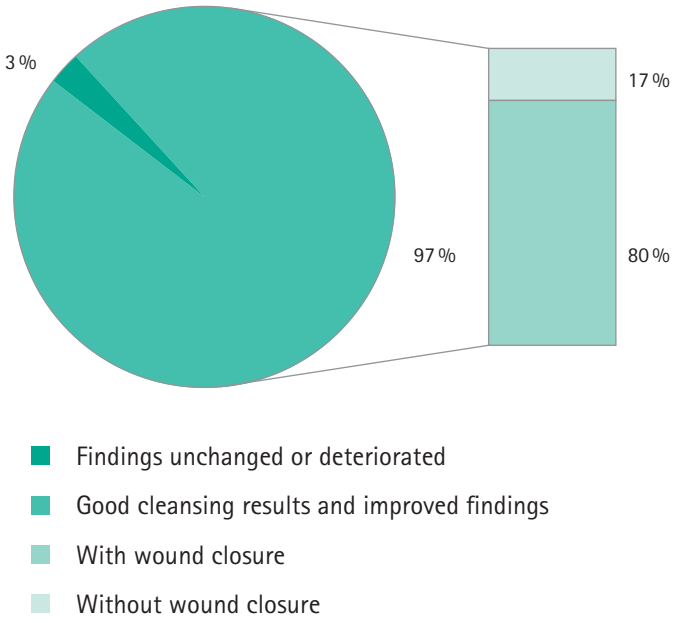
Conclusion

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).



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
Cohort	●					●	15

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.

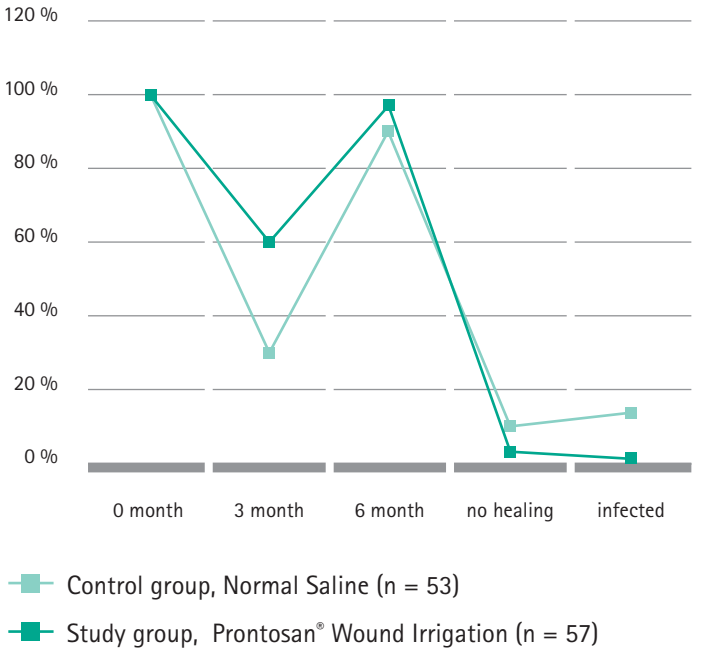
Results

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



Prontosan®

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

Evaluation of the effectiveness of a polyhexanide and propyl betaine-based gel in the treatment of chronic wounds.

Durante CM, Greco A, Sidoli O, et al.
Minerva Chir. 2014 Oct;69(5):283-92.

Objective

The objective of this multicenter observational clinical study was to evaluate the therapeutic effects of a polyhexanide and propyl betaine-based gel in the treatment of patients of every age, affected by chronic skin wounds.

Methods

124 patients (60 % females, from 4-day-old to 91-year-old, mean age 59 years) were treated with polyhexanide / propyl betaine (Prontosan® Wound Gel, B. Braun) applied directly on the surface of the wound and in the possible undermining, in combination with a secondary dressing. At the baseline visit and at subsequent checks were evaluated the wound diameter and characteristics (the wound bed and the surrounding skin and edges appearance, level and type of exudate) and local pain at dressing change.

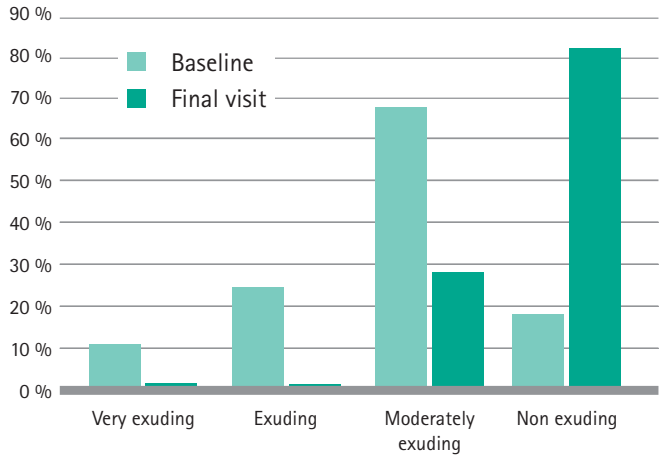
Results

The assessment and analysis between the initial visit and the final one showed the following results: The wound size and pain characteristics have decreased substantially and significantly ($P<0.001$) both in the size of the wounds (length: -17.5 ± 21.4 cm, width: -15.5 ± 21.1 cm; area: -8.3 ± 16.7 cm^2) and in the intensity of pain perceived by the patient (VAS: -4.67 ± 2.7; FLACC<1 ± 4); for patients less than 3 years old, the scale used was FLACC. Wound bed: it was found a significant increase in the percentage of improvement in patients: 90 % of them showed a reduction in the wound size, while 80 % of them showed a relative reduction in pain compared with that observed during the baseline visit, with the wound bed cleansed, granulating or reepithelializing. Just as significant was the decrease in percentage of subjects with wounds with fibrinous and partially necrotic bed, and / or with biofilm. Edges of the wound and periwound skin: the percentage of patients who have shown, during the treatment, an improvement in the clinical condition both of the wound edges and the surrounding skin has significantly increased, with a number of cases (75 %) who have reached complete skin integrity. In a smaller percentage, already at the initial visit, the wound edges (28 %) or the peristomal skin (18 %) have been found undamaged. Exudate: there was a reduction in the level of exudate, with 74 % of patients who showed no exudate at the final visit, compared with 15 % of patients with non-exudative wounds at baseline.

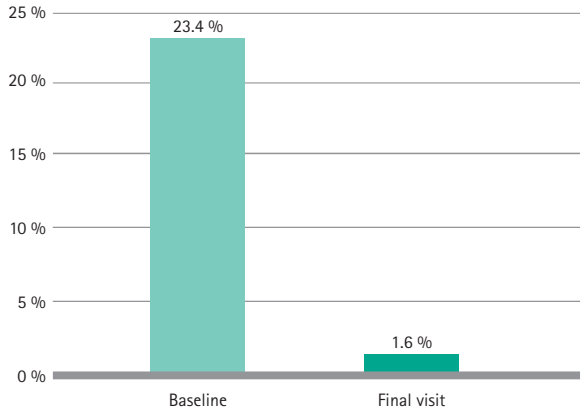
Conclusion

The treatment of chronic skin wounds through the use of a polyhexanide / propyl betaine-based gel (Prontosan® Wound Gel), in combination with a secondary dressing, showed significant improvements, such as a 30 % reduction of pain at dressing change, the reduction in the size and characteristics of the wounds and a reduction in the levels of exudate. All these factors have contributed to a reduction in the number of medications, thus reducing the overall cost of treatment.

Reduction in the level of exudate: 74 % of patients showed no exudate at the final visit, compared with 15 % of patients with non-exudative wounds at balseline



Patients with presence of biofilm



Prontosan®

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
Cohort	●					●	17

The Impact of Negative-Pressure Wound Therapy with Instillation Compared with Standard Negative-Pressure Wound Therapy: A Retrospective, Historical, Cohort, Controlled Study.

Kim PJ, Attinger CE, Steinberg JS, et al.

Plast. Reconstr. Surg. 133: 709, 2014.

Background

Negative-pressure wound therapy with instillation is a novel wound therapy that combines negative pressure with instillation of a topical solution.

Methods

This retrospective, historical, cohort-control study examined the impact of negative-pressure wound therapy with an instillation solution (Prontosan® Wound Irrigation Solution) and without instillation.

Results

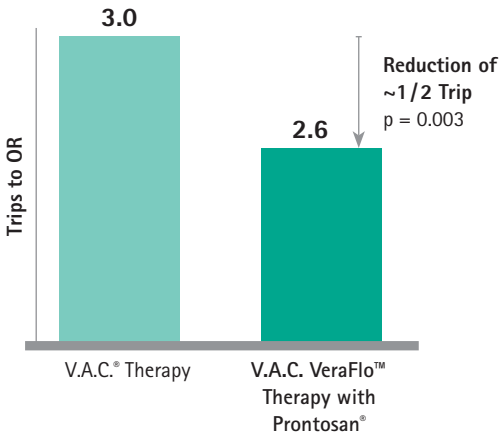
142 patients (negative-pressure wound therapy, n = 74; therapy with instillation, 6-minute dwell time, n = 34; and therapy with instillation, 20-minute dwell time, n = 34) were included in the analysis. Number of operative visits was significantly lower for the 6- and 20-minute dwell time groups (2.4 ± 0.9 and 2.6 ± 0.9, respectively) compared with the no-instillation group (3.0 ± 0.9) ($p \leq 0.05$). Hospital stay was significantly shorter for the 20-minute dwell time group (11.4 ± 5.1 days) compared with the no-instillation group (14.92 ± 9.23 days) ($p \leq 0.05$). Time to final surgical procedure was significantly shorter for the 6- and 20-minute dwell time groups (7.8 ± 5.2 and 7.5 ± 3.1 days, respectively) compared with the no-instillation group (9.23 ± 5.2 days) ($p \leq 0.05$). Percentage of wounds closed before discharge and culture improvement for Gram-positive bacteria was significantly higher for the 6-minute dwell time group (94 and 90 percent, respectively) compared with the no-instillation group (62 and 63 percent, respectively) ($p \leq 0.05$).

Conclusion

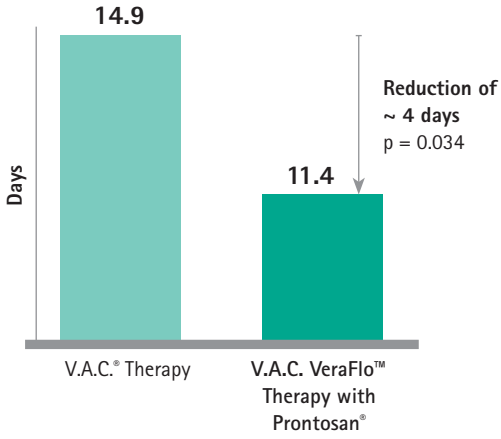
The authors' results suggest that negative-pressure wound therapy with instillation (6- or 20-minute dwell time) is more beneficial than standard negative-pressure wound therapy for the adjunctive treatment of acutely and chronically infected wounds that require hospital admission.

NPWT: n=74
NPWTi: n=34
20 min dwell time

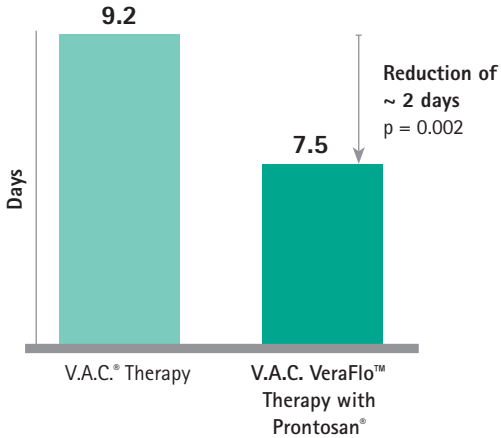
Reduced OR Visits



Reduced Length of Stay



Reduced Time to Final Surgical Procedure



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
Animal		●					18

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.

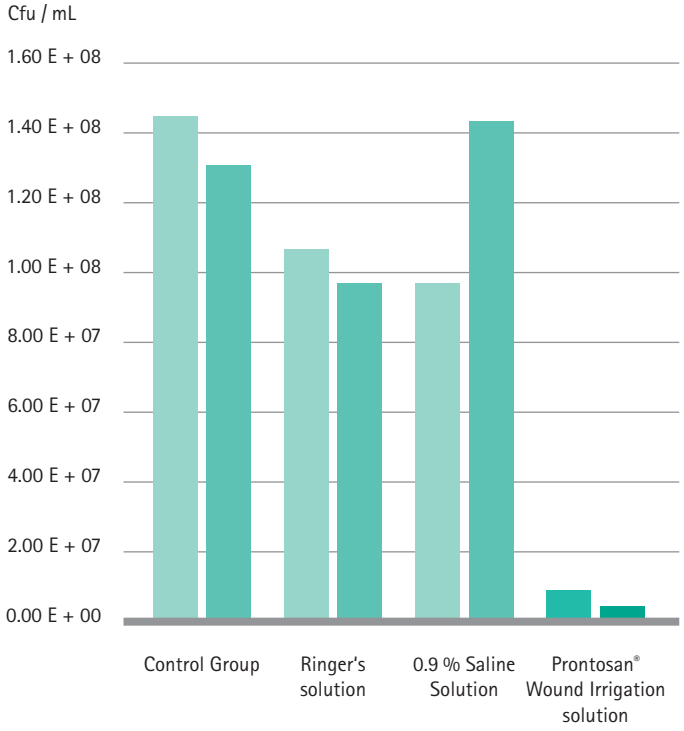
Objective
The objective of this study was to assess the effectiveness of four wound cleansers on MRSA biofilm removal on dermal wounds in swine.

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



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
In-vitro			●				19

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 albicanas (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 baumanii (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 % polihexanide 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
Staphylococcus epidermis	5.9	5.8	5.8
Pseudomonas aeruginosa	5.7	5.7	5.6
Serratia marcescens	5.7	5.7	5.6
Candida albicans	5.7	5.7	5.7
Vancomycin resistant Enterococcus faecalis	5.6	5.6	5.6
Proteus mirabilis	5.7	5.6	5.6
Staphylococcus aureus	5.5	5.5	5.5
Methicillin resistant Staphylococcus aureus	5.5	5.5	5.4
Acinetbacter baumanii	5.6	5.5	5.5
Escherichia coli	5.5	5.4	5.4
Enterobacter cloacae	5.5	5.4	5.4
Enterococcus faecalis	5.3	5.3	5.3
A. brasiliensis		see abstract	

Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
In-vitro		●					20

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

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

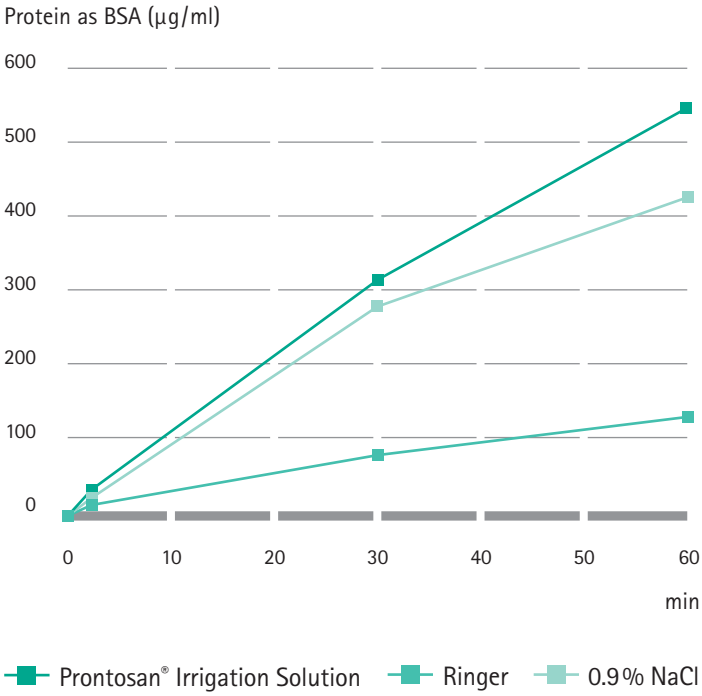
Objective
The aim of this study was to test the efficacy of four solutions to solubilise and remove wound coatings using a wound coating model.

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®).

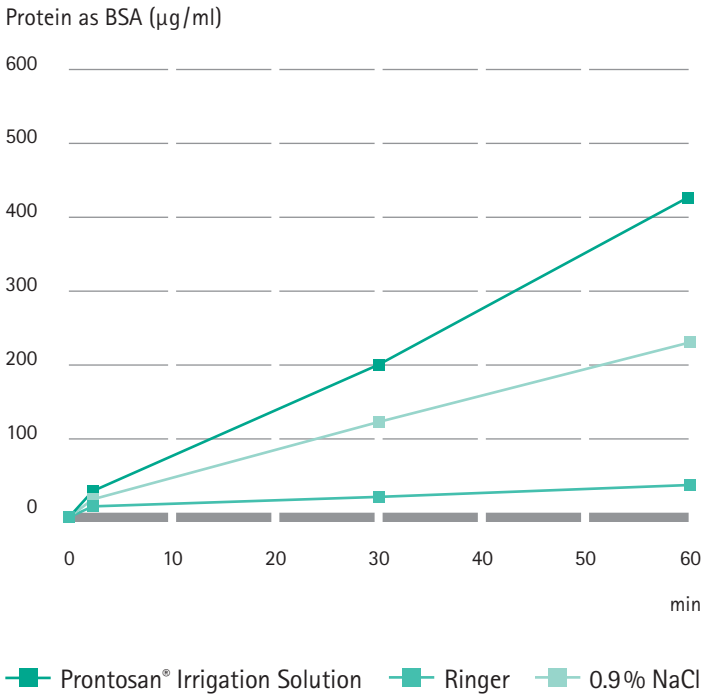
Results
Both salt solutions and the wound rinsing solution were found to remove protein from the test wound coatings, whereas the test coatings became fixed and insoluble when immersed in antiseptic solution (Octenisept®).

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.



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
In-vitro				●			21

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 (MTTassay and BrdU-ELISA) at a wide range of concentrations.

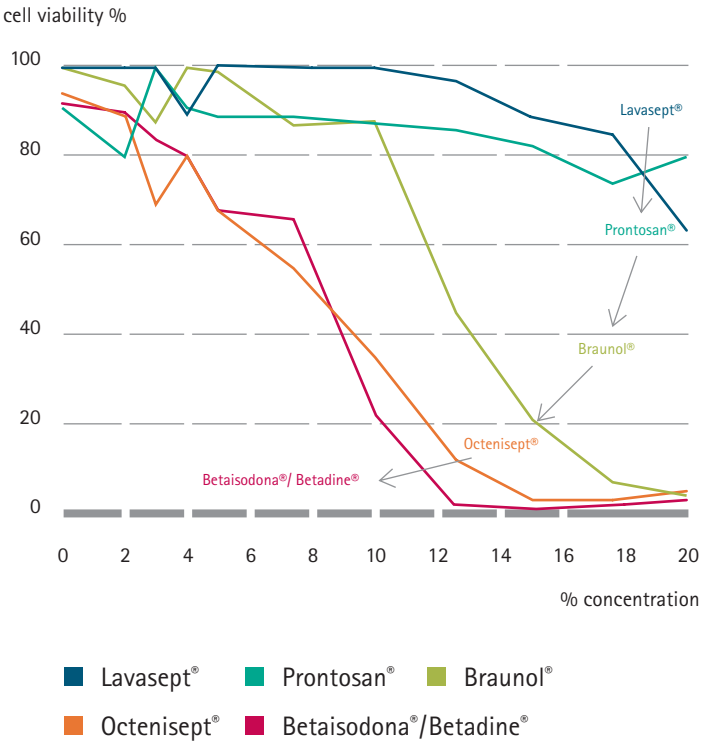
Results

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.



Prontosan®

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
in-vitro			●				22

Intermittent exposure to wound irrigation solutions disrupts *P. aeruginosa* and *S. aureus* immature biofilms in-vitro

Lessing MC, McNulty AK.
Wound Rep Reg 2012;20:A28.

Objective
The objective of this study was to evaluate the in-vitro susceptibility of immature *P. aeruginosa* and *S. aureus* biofilms to intermittent exposure of common wound irrigation solutions.

Methods
Immature *P. aeruginosa* (ATCC 27853) and *S. aureus* (ATCC 10832) biofilms were grown at 35 °C for 8 – 9 hours in the MBEC Assay system (Innovotech, Edmonton, Canada). The immature biofilms were then treated with one of five wound irrigants (5 % mafenide acetate; 0.004 % sodium hypochlorite with 0.003 % hypochlorous acid; 0.1 % polihexanide with 0.1 % undecylenamidopropyl betaine; 0.0125 % sodium hypochlorite; 0.9 % sodium chloride). Biofilms were removed from growth medium, immersed in fresh wound irrigant, and returned to growth medium according to one of two treatment profiles: 10-minute irrigant exposure every 2.5 hours or 5-minute irrigant exposure every 6 hours. Growth controls were immersed in fresh growth medium rather than wound irrigant. After 24 hours of treatment cycles, bacteria in growth controls and treated biofilms were quantified via colony counts. Three replicates were tested for each condition.

Results
Untreated biofilm growth controls exhibited approximately 7 log CFU/cm^2 for either *P. aeruginosa* or *S. aureus*. Both sodium hypochlorite solutions and the polihexanide with betaine solution reduced *P. aeruginosa* and *S. aureus* approximately 7 log CFU/cm^2 with both exposure profiles ($p < 0.05$). Neither mafenide acetate nor sodium chloride showed a reduction with either exposure profile.

Conclusion
These in-vitro data suggest that intermittent delivery of appropriate wound irrigation solutions (e.g. polyhexanide 0.1 % with 0.1 % undecylenamidopropyl betaine) may be helpful in reducing the bacteria that can cause biofilm.

Quote

"Chronic wounds are often colonized with biofilms that prevent healing. Negative pressure wound therapy with instillation can help remove infectious materials by providing delivery and removal of clinician-selected topical solutions (e.g. Prontosan® Wound Irrigation Solution) at specified time intervals."

Prontosan®

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
in-vitro		●	●	●			23

Effects of Prontosan® on the formation of streptococcal biofilms using a human embryo skin fibroblast cell culture model.

Afinogenova AG, Grabovskaya KB, Kuleshevich EV, Suvorov AN, Afinogenova GE. Infections in Surgery, 2011;1(9):5–13.

Objective

The objective of the study was to evaluate the impact of Prontosan® on the colonization of group B streptococci (GBS). GBS in the common cause of neonatal infections such as pneumonia, meningitis and sepsis and a frequent cause of diseases in pregnant women, immunodeficient patients, and elderly.

Methods

In this in-vitro study was used a human embryo skin fibroblast cell culture model. The test strains with a microbial load of 10^7 cfu/ml were incubated with fibroblasts for 30 min and 2 hrs with diluted Prontosan® (experiment) and without (control). All samples were evaluated under microscope to estimate fibroblast morphology and to calculate **microbial load, percentage of infected cells and index of adhesion.** Only sub-bactericidal doses of 0.5 µg/ml and 0.25 µg/ml of the polihexanide 0.1 % and betaine wound solution were used, as these concentrations are known not to exert cytotoxicity in human fibroblasts.

Results

While the fibroblast monolayer displayed a high microbial adhesion of Streptococci after 30 min of exposure, the monolayer was totally degraded by GBS after 2 hours.
In contrast to that, the presence of sub-bactericidal doses of the polihexanide/betaine solution resulted in a significant decrease of microbial adhesion (up to 95 %) 30 min and 2 hours upon treatment and subsequently promoted the preservation of the fibroblasts

Conclusion

The fibroblast cells were completely preserved in the presence of sub-bactericidal doses of polihexanide 0.1 % and betaine. These results show the effectiveness of Prontosan® for the prevention of biofilm formation and treatment of streptococcal infections.

Table 1. Microbial log reduction (no results for the control group after 2 hours of exposure, because of cell death at full extent)

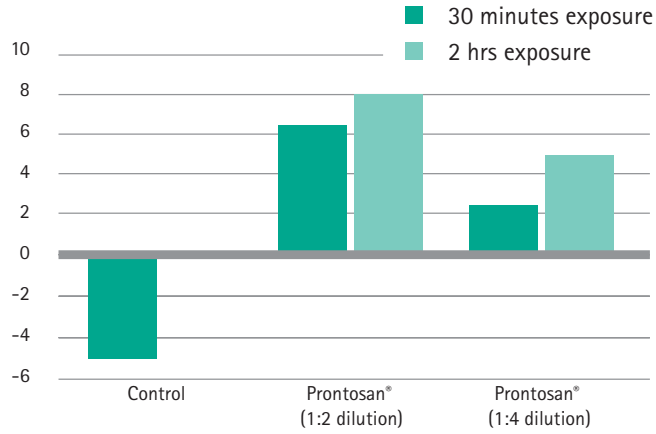


Table 2. Percentage of infected cells (no results for the control group after 2 hours of exposure, because of complete cell death)

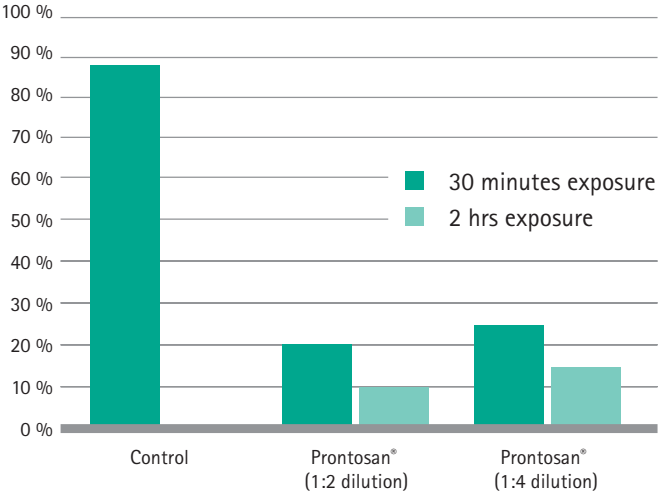
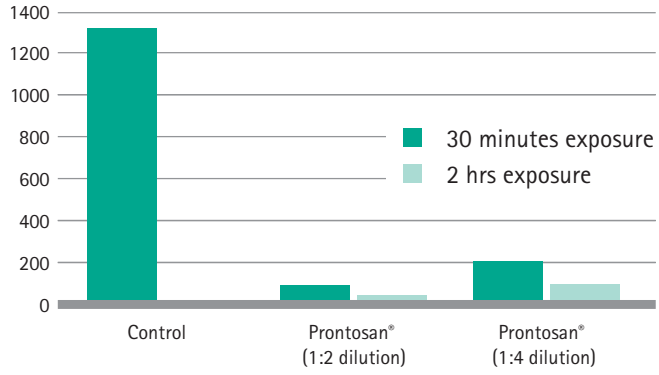


Table 3. Index of adhesion (the higher the index, the more pathogenic the bacteria are and the more skin cells are affected)



Prontosan®

Type	Improved wound healing	Prevention and removal of biofilm	Antimicrobial activity	Cytotoxicity and tolerability	Quality of life	Cost-effective	Page
In-vitro		●					24

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.

Prontosan®

Type	Improved Wound Healing	Prevention and Removal of Biofilm	Antimicrobial Activity	Cytotoxicity and Tolerability	Quality of Life	Cost-effective	Page
HTA						●	25

Cost-effectiveness of polyhexamethylen biguanide 0.1 % and betaine 0.1 % solution (Prontosan®) versus saline for cleansing of chronic wounds under the Brazilian Private Health System perspective

Mehl AA, Lopes Mensor L, Frassi Bastos D, et al.
J Bras Econ Saude 2013;5(3):135-146.

Introduction
The presence of biofilms in chronic wounds is an important cause of delays in healing process, what makes the cleansing of these wounds beds a critical point for such problem management. In the industrialized world, there is almost 1 – 1.5 % of reported incidence of chronic wounds, representing significant costs for healthcare systems. Solutions based in the association of polyhexamethylene biguanide (polihexanide, PHMB) and betaine, due to its surfactant and preservative function, can better promote wounds beds preparation than the traditional saline, avoiding complications such as secondary infections that can enlarge healing times and treatment costs for these wounds.

Objective
Evaluate cost-effectiveness of PHMB plus betaine solution (Prontosan®, B.Braun) for cleansing of chronic wounds from any etiology, compared to saline solution, under the scope of Brazilian private health system.

Methods
Systematic review of literature, cost-effectiveness and budget impact analysis of PHMB plus betaine solution versus saline under the perspective of Brazilian Supplementary Health System for cleansing of chronic wounds.

Results
In the basic scenario of the technology under assessment, incremental cost-effectiveness ratios have shown negative results, reflecting reduction of total treatment costs.

Conclusion
Incorporation of Prontosan® Solution by the Supplementary Health System in Brazil, in the economic point of view, has shown to be feasible, specially when the comparison is dislocated from acquisition prices to treatment costs. Under the perspective of incremental cost-effectiveness, the use of Prontosan® Solution would constitute an important improvement for management of chronic wounds, with no need of investment from payers.

Projected budget impact for the first year of inclusion

	Eligible population	Annual cost of Treatment	Budget impact	Budget impact USD
Prontosan® Wound Irrigation Solution	917'094	BRL 5'889.67	Mio. BRL 5'401.38	Mio. USD 1'906.95
Saline	917'094	BRL 5'972.35	Mio. BRL 5'477.21	Mio. USD 1'933.72
Incremental	4'389		Mio. BRL 75.83	Mio. USD 26.77

FX 25.02.2015: 1 BRL = 0.353 USD

Rationale for the use of Askina® dressings

Askina®

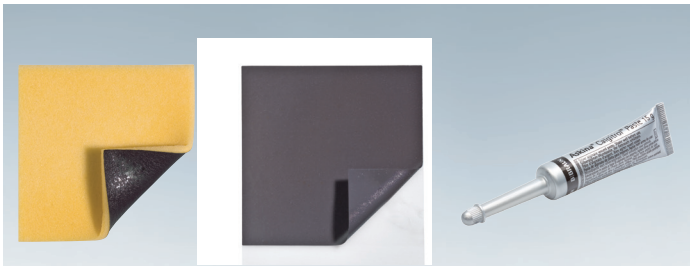
Healing a chronic wound requires care that is patient centered, cost effective and evidence based.

Through this understanding, B. Braun has developed a range of dressings designed to care for a wound and to support the natural healing process.

The products of Askina® range are based on various technologies aimed to achieve a specific treatment objective. As a result, the Askina® range offers a choice of dressings for each phase of the wound healing: from necrosis to epithelialization including the debridement and granulation phases.

Overview of the Askina® product range

Askina® Calgitrol® range



Askina® Calgitrol® Ag
Foam + silver alginate matrix

Askina® Calgitrol® THIN
Silver alginate matrix in thin form

Askina® Calgitrol Paste
Amorphous silver alginate matrix

Description

Askina® Calgitrol® Ag's patented matrix formulation combines calcium alginate and silver alginate with 10% of bonded water. In contact with exudate, the alginate matrix forms a soft gel allowing the liberation of silver ions.

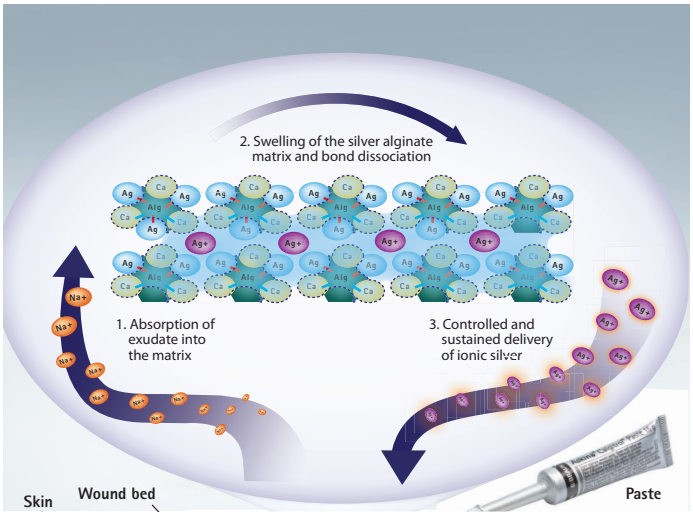
How it works (1)

Absorbtion of exudate leads to a swelling of the alginate and consequent dissociation of the silver and calcium alginate bonds. Since the silver-alginate bonds are weaker than the calcium-alginate bonds, they rupture first, leading to a preferential, controlled release of silver ions from the matrix. Such release provides for an extended, effective, and steady state delivery of ionic silver to the wound site. Sodium ions from the exudate replace the silver ions in the matrix, which maintains its molecular integrity over time, thus providing a reservoir and continuous source of ionic silver.

The flow of silver ions from the alginate matrix into the wound occurs by mass action law, with silver ions moving from high to low concentration areas. The extended release from the alginate matrix ensures that active ionic silver is delivered steadily over time, reaching immediate and effective antimicrobial concentrations in the wound.

This controlled bioavailability of silver ions ensures high antimicrobial wound activity without the risk of over-delivery of silver ions, the resultant wound discoloration, and potential for systemic absorption and toxicity.

How it works (1)



How it works (2)

Mechanism of action of silver ions:

Ionic silver is directed against multiple bacterial target sites, thus reducing the probability of generating resistance after repeated use.

1. The bacterial wall, with loss of bacterial integrity and pathogenicity
2. The bacterial protein structure, synthesis, and enzymatic activity, with impairment of the intracellular metabolic pathways and energy stores
3. The bacterial DNA, with inhibition of DNA replication and cell division

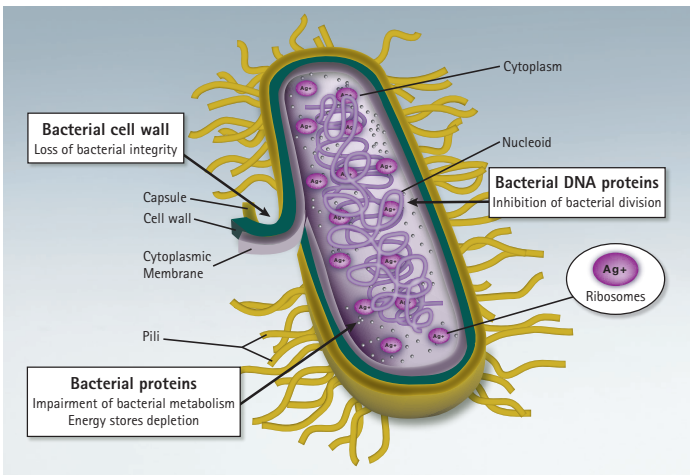


Figure adapted from Molecular Expression Web site. Michael Davidson and the Florida State University Research Foundation. http://micro.magnet.fsu.edu. Accessed January 2012.

[Feng QL et al 2000; Lansdown AB 2010]

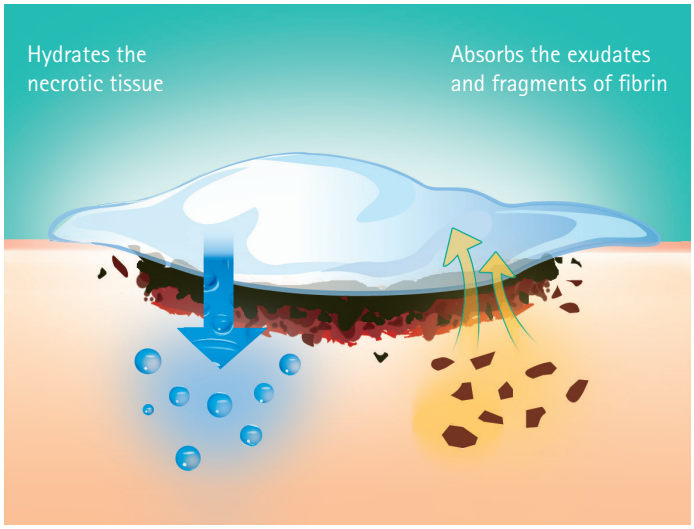
Overview of the Askina® product range

Askina® Gel

Description
Askina® Gel is a clear, viscous, sterile hydrogel

Composition:
- purified water (hydrating agent to provide moisture to the wound)
- glycerol (softening and absorbing agent)
- disodium EDTA (gelling agent)
- Carbopol 940 (acrylic polymer, thickener)
- Sorbital (modified starch polymer)

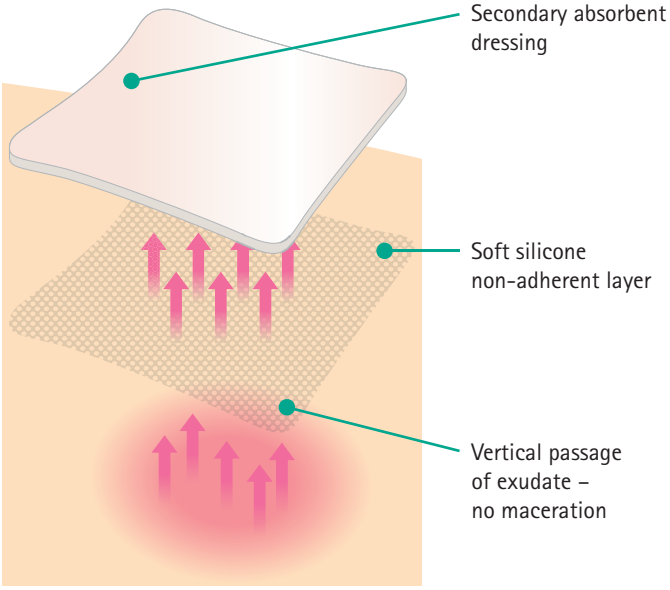
How it works
Askina® Gel, by providing a moist environment at the wound surface, assists in the debridement and removal of necrotic and other devitalised material. It rehydrates dry necrotic tissues by releasing moisture. It can also absorb wound slough and excess exudate.



Askina® SilNet

Description
Askina® SilNet is a thin, porous, soft silicone wound contact layer, consisting of a conformable non-woven material, coated on both sides with a soft silicone layer.

How it works
Askina® SilNet adheres gently to the wound and surrounding skin and facilitates atraumatic dressing removal. Its porous structure allows vertical passage of exudate into the secondary absorbing dressing.

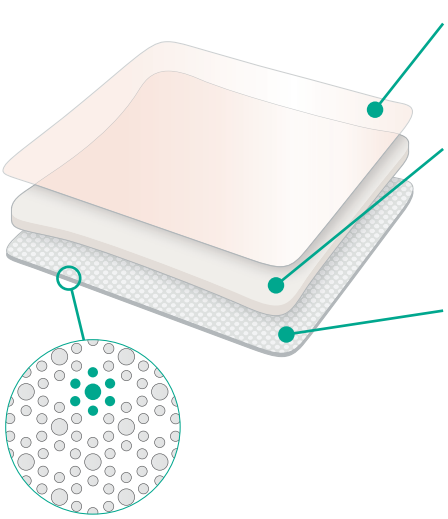


Askina® SilNet can be left in place for several days, as long as the exudate passes freely into the secondary dressing.

Askina® DresSil

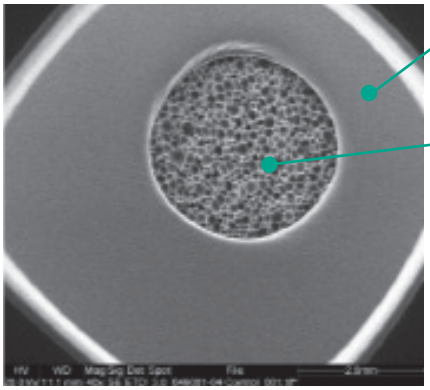
Description

Askina® DresSil is a self adherent foam dressing with soft silicone adhesive on one side and a vapour permeable waterproof film on the other. It combines the absorption capacity of the foam with the soft adhesion of the silicone contact layer.



How it works

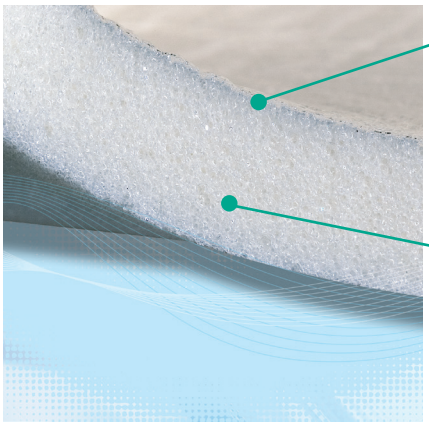
The silicone wound contact layer is perforated with repeated "flower pattern" holes to allow exudate to pass through to the foam layer, preventing exudate leaking onto the surrounding skin and maceration of the wound edges. The excess moisture is evaporated through the film backing material.



Askina® Foam

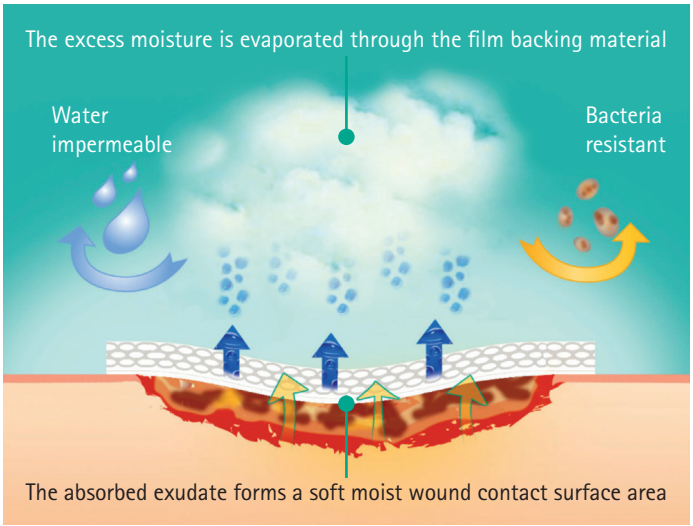
Description

Askina® Foam is a two layered non-adherent foam dressing consisting of:



How it works

Regeneration of absorption capacity



Askina®
Available evidence at a glance

Askina® Calgitrol® range

Reference	Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
Study of Silver Migration from Wound Dressing Materials using Porcine Serum Mr Christopher David; Jarvis, Sheffield, Analytical Services, Sheffield Assay Office, Sheffield, UK Report HOSP217 at B. Braun Hospicare, January 2007	In-vitro			●	33
Assessment of Bactericidal Potential of Askina® Calgitrol® Ag Dressings Dr Anthony Hayes and Mr Marc Isaacs, Confocal; Microscopy and Bioimaging Unit, Cardiff School of Biosciences, Cardiff, UK Report HOSP216 at B. Braun Hospicare, August 2006	In-vitro		●		34
Antimicrobial properties of ten silver-containing dressings Stephan Thomas, B.Pharm., Ph.D., F.R. Pharm. S. Pamela McCubbin B.Sc. Ph. D. Journal of wound care vol 12, No 8, September 2003	In-vitro		●		35–37
Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT C. Trial, MD; H. Darbas, MD J-P. Lavigne, MD; A. Sotto, MD; G. Simoneau, MD, L. Téot, MD; Y. Tillet, PharmD Journal of wound care vol 19, No 1, January 2010	RCT	●	●		38
Askina® Calgitrol® Ag: clinical use of an advanced ionic silver dressing E. Ricci, M. Pittarello, R. Cassino, M. Moffa, S. Ferrero, M, Gonella, E. Tonini Acta Vulnologica Volume 5, No. 3, Pages 105–111, September 2007	Cohort	●	●		39
Clinical effectiveness of silver alginate dressing in outpatient management of partial-thickness burns Supaporn Opasanon, Pornprom Muangman, Nantaporn Namviriyachote International Wound Journal Volume 7, Issue 6, pages 467–471, December 2010	Cohort	●	●		40
In Vitro Evaluation of the Antimicrobial Effectiveness and Moisture Binding Properties of Wound Dressings Pornanong Aramwit, Pornprom Muangman, Nantaporn Namviriyachote and Teerapol Srichana; International Journal of Molecular Sciences; Int. J. Mol. Sci. 2010, 11, 2864–2874	In-vitro		●		41–44
Log Reduction measure of efficacy of Askina® Calgitrol® Paste, Flamazine Cream and Flaminal® Hydro against cultures of P. aeruginosa, E. coli, S. aureus; report HOSP283A and HOSP303, 2011, IT Sligo	In-vitro		●		45
Measurement of serum silver from Askina® Calgitrol® Paste in a swine dermal wound model and evaluation of local tolerability NAMSA report HOSP 257, 2009	In-vivo animal study			●	46
Comparative Evaluation of Erythema and Edema Skin Reaction and Skin Discoloration Work carried out in conjunction with the University of Florida, USA, for the FDA submission file 510(k); Report HOSP240 at B. Braun Hospicare, 2005	In-vitro			●	47
Evaluation of Leachable Silver from a Wound Dressing Using the Swine Model Dr Joseph Carraway and Ms Wendy R. Sharp, NAMSA, Northwood, OH, USA. Report HOSP213 at B. Braun Hospicare, October 2006	In-vitro			●	48

Askina®
Available evidence at a glance

Askina® Gel

Reference	Type	Physical properties	Improved wound healing	Patient's comfort	Page
Passage of moisture in/out of gelatine Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 257PTDF REV001, July 2003	In-vitro	●			49
Tackiness of a hydrogel at 45°, 60° and 90°angles of inclination Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 257PTDF REV001, July 2003	In-vitro	●	●		50
Evaluation of Askina® Gel – product characteristics and the patient experience Isabella Beuken et al. European Conference on Advances in Wound Management; Harrogate, 9 – 11 November 2008	Cohort		●	●	51 – 52

Askina® SilNet

Reference	Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
Evidence of absence of stripping of epidermal cells SCANNING ELECTRON MICROSCOPE (SEM) ANALYSIS – carried out by Agenda 1 Analytical Services Limited, UK.; Report HOSP259 at B. Braun Hospicare, April 2009	In-vitro		●			53
Evidence for no impedance using Askina® SilNet when Askina® SilNet is placed against a foam dressing Laboratory Testing carried out at B. Braun Hospicare; Standard I.S. EN 13726-1:2002 Test Methods for primary wound dressings – Part 1: Aspects of Absorbency; Data referenced in BBH 264PTDF REV002, March 2011	In-vitro			●		54
Experiences of a combination of Askina® SilNet with Topical negative pressure Frans Meuleneire, EWMA Conference, Geneva, 2010	Cohort	●	●			55

Askina®
Available evidence at a glance

Askina® DresSil

Reference	Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
Evidence of absence of stripping of epidermal cells SCANNING ELECTRON MICROSCOPE (SEM) ANALYSIS – carried out by Agenda 1 Analytical Services Limited, UK; Report HOSP266 at B. Braun Hospicare, January 2010	In-vitro		●			56
Fluid handling capacity Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 301PTDF REV004, May 2011	In-vitro			●		57
Retention capacity Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 301PTDF REV004, May 2011	In-vitro			●		57
Wicking Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 301PTDF REV00, May 2011	In-vitro			●		58
Adhesiveness Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 301PTDF REV004, Mai 2011	In-vitro				●	59

Askina® Foam

Reference	Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
Fluid handling capacity Laboratory Testing carried out at B. Braun Hospicare; Standard I.S. EN 13726-1:2002 Test Methods for primary wound dressings – Part 1: Aspects of Absorbency Data referenced in BBH 283PTDF REV007, May 2011	In-vitro			●		60
Retention Capacity Laboratory Testing carried out at B. Braun Hospicare Data referenced in BBH 283PTDF REV007, May 2011	In-vitro			●		60

Askina® Transorbent®

Reference	Type	Improved wound healing	Patient's comfort	Page
Clinical evidence Comparison and evaluation of the performance characteristics, usability and effectiveness on wound healing of Askina® Transorbent® vs a hydrocolloid with foam backing Marie Brown-Etris, RN, CETN - President; Etris Associates, Inc. Philadeiphia, USA 5th European Conference on Advances in Wound Management Harrogate, 21 – 24 November 1995	RCT	●	●	61 – 63

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro			●	33

Study of silver migration from wound dressing materials using porcine serum

Mr Christopher David, Jarvis, Sheffield, Analytical Services, Sheffield Assay Office, Sheffield, UK

Report HOSP217 at B. Braun Hospicare, January 2007

Background and objective

The aim of this trial was to determine the quantity of silver ions released from the Askina® Calgitrol® Ag dressing during time by measuring the concentration obtained into porcine serum.

Method

Three batches of Askina® Calgitrol® Ag were analysed; tests were carried out in duplicate. A circular disk (3.9 cm diameter) was cut from each dressing and immersed in 20ml of porcine serum under fixed conditions. At fixed time intervals the porcine serum containing the dressing was filtered;

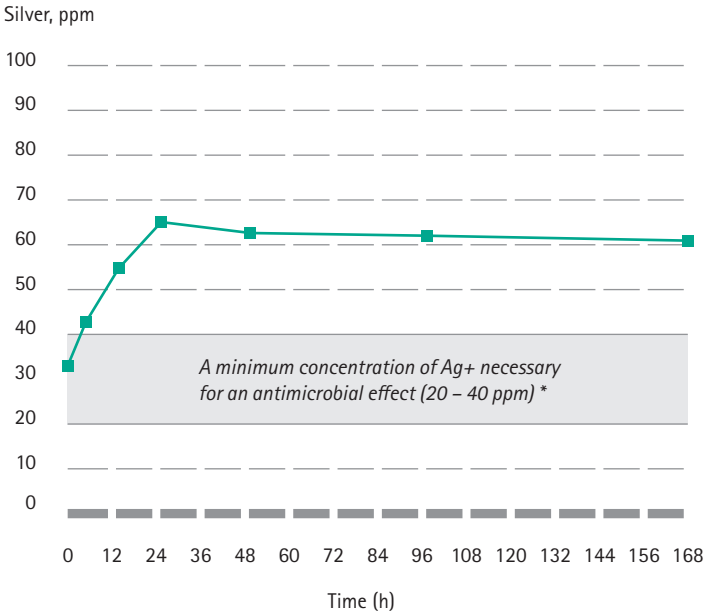
A The filtrate was analysed for silver content by ICP-OES (Inductively coupled plasma optical emission spectroscopy); this gives the percentage of silver released from Askina® Calgitrol® Ag.

B The residue of the dressing in the filter paper was completely broken down by mineral acids and analysed separately for silver content by ICP-OES; this gives the percentage of silver left in the dressing.

Results

Askina® Calgitrol® Ag releases a relatively low level of the total silver available in the dressing. Askina® Calgitrol® Ag releases silver gradually to a steady state value.

Silver ions released from Askina Calgitrol Ag (ppm)



Conclusion

Askina® Calgitrol® Ag wound dressings release silver ions through a controlled and sustained delivery. The resulting concentrations are maintained above the value of 30 – 40 ppm of silver ions, i. e. the concentration needed to obtain satisfactory antibacterial action. Askina® Calgitrol® Ag therefore ensures for sustained antimicrobial activity during a 7 day period.

* Edwards-Jones V. Antimicrobial and barrier effects of silver against methicillin-resistant Staphylococcus aureus. J Wound Care 2006; 15: 285 – 90.
Warriner R, Burrell R. Infection and the chronic wound. A focus on silver. Adv Skin Wound Care 2005; 18 Supp 1: 1 – 12.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		34

Assessment of bactericidal potential of Askina® Calgitrol® Ag dressings

Dr Anthony Hayes and Mr Marc Isaacs, Confocal Microscopy and Bioimaging Unit, Cardiff School of Biosciences, Cardiff, UK;
Report HOSP216 at B. Braun Hospicare, August 2006

Objective
To test the bactericidal potential of Askina® Calgitrol® Ag dressings on the following microorganisms: Staphylococcus aureus, Escherichia coli and Candida albicans

Method
To visualise bacteria and assess their growth characteristics, cell populations were stained using the LIVE/DEAD® Baclight™ bacterial viability kit (Molecular Probes; Invitrogen). The kit consisted of two fluorescent dyes, STYO 9 (green) and Propidium Iodine (red), pre-aliquoted in sealed plastic pipettes. The bacteria (Candida albicans ATCC2091; Escherichia coli ATCC 8739 and Staphylococcus aureus ATCC 6538P) were stained with the dye mixture and incubated on Askina® Calgitrol® Ag.

When the bacteria are alive or viable they fluorescence green; they change to red if the bacteria wall is damaged; hence dead or dying bacteria are stained red. At specific time intervals (0, 1, 2, 3, 4, 12 & 24 hours) the dressing was observed and scanned using a Leica TCS AOBS confocal laser scanning microscope.

Cell counts for live (green) and dead (red) micro-organisms were performed using Image J Software and were based on 10 images per time point. The values are expressed as percentage viability for each time point.

Results
After a 12 hour incubation period there were high levels of bacterial mortality, at 24 hours there was close to 100% cell death in all cultures.

Micro-organism viability (%) on Askina® Calgitrol® Ag dressings

	Ohrs	1 hr	2 hrs	3 hrs	4 hrs	12 hrs	24 hrs
C. Albicans	97.73	97.69	92.6	83.67	56.91	46.22	0
E. Coli	89.71	76.5	79.19	56.35	43.01	27.36	5.43
S. Aureus	100	100	99.27	99.1	95.17	76.7	0.55

Conclusion
Askina® Calgitrol® Ag wound dressings are able to immobilize bacteria within a 24 hour period.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		35 – 37

Antimicrobial properties of ten silver-containing dressings

Stephan Thomas, B.Pharm., Ph.D., F.R. Pharm. S. Pamela McCubbin B.Sc. Ph. D
Journal of Wound Care vol 12, No 8, September 2003

Background and objective

The aim of this in vitro study was to determine the ability to release silver in sufficiently high concentrations to exert a significant antimicrobial effect of 10 silver containing dressings.

Method

Test organisms

Three standard organisms were used: a Gram-positive bacteria S. aureus (ATCC 6538P), a Gram-negative organism, E. Coli (ATCC 8739), and a yeast, C. Albicans 'ATCC 2091). The test methods used during this study were designed to compare the performance of the dressings under different simulated conditions of use.
A non-woven swab was used as a negative control and Acticoat® as a positive control.

Method 1: Zone of Inhibition Test

Samples of each dressing were placed upon agar plates inoculated with 0.2 ml of a long-phase broth culture of each test organism. After incubation, the zone of inhibition was evaluated: a clear region around the perimeter of the test sample which was free of bacterial growth. The zone of inhibition method simulates the use of the dressings on lightly exuding wound and predicts the ability of dressings to kill or prevent bacterial growth in this situation.

Method 2: Challenge test

To portions of each dressing measuring 40 mm × 40 mm were added 0.2 ml of a long-phase culture of each test organism. After 2 h of incubation the dressing samples were transferred into Oxoid solution and vortexed to remove any viable organisms remaining in the dressing. Serial dilutions were performed and the number of viable organisms present determined using the standard surface counting technique.

The microbiological challenge test provides an indication of the ability of each dressing to kill or prevent the growth of predetermined numbers of bacteria applied directly to it in the form of suspension, to reflect the action of the dressing when applied to more heavily exuding wound.

Method 3: Microbial Transmission Test

In this test the strip of dressing forms the bridge between two separate agar blocks in a Petri dish: one sterile, the other inoculated with the test organism. The third test determines the ability of bacteria to survive on the dressing surface and migrate along it. The positive result suggests that it is possible that microorganisms could be transported laterally out of a contaminated wound onto the surrounding skin.

Method 4: Silver Content of the Dressing

The total extractable silver content of each dressing was determined following acid digestion of the sample using the inductivly coupled plasma optical emission spectroscopy (ICP – OES).

Results

Method 1: Summary of Zone of Inhibition Test Results

	S. Aureus (ATCC 6538P)	E. Coli (ATCC 8739)	C. Albicans (ATCC 2091)
Group A (Score 3) Products that show evidence of sustained activity over two or more days	Acticoat Aquacel Ag Calgitrol Ag Contreet H Silverlon	Acticoat Calgitrol Ag Contreet H Silverlon	
Group B (Score 2) Products that produce a well-defined zone of inhibition at on time interval	Arglaes Powder Silvasorb	Aquacel Ag Arglaes Powder	Acticoat Arglaes Powder Calgitrol Ag Contreet H Silvasorb Silverlon
Group C (Score 1) Products that produce no well-defined zone of inhibition in this test	Actisorb Avance Contreet Ag	Actisorb Avance Contreet Ag Silvasorb	Actisorb Aquacel Ag Avance Contreet Ag

Askina® Calgitrol® Ag has a sustained antimicrobial activity during two or more days.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		35 – 37

Method 2: Summary of microbial challenge test results

	S. Aureus (ATCC 6538P)	E. Coli (ATCC 8739)	C. Albicans (ATCC 2091)
Group A (Score 4) Products that demonstrate marked antibacterial activity after 2 hours incubation	Acticoat Calgitrol Ag	Acticoat Calgitrol Ag Contreet H Silverlon	Acticoat Calgitrol Ag Contreet H Silverlon
Group B (Score 3) Products that demonstrate marked antibacterial activity after 4 hours incubation	Silverlon	Contreet H Aquacel Ag Silvasorb	
Group C (Score 2) Products that demonstrate marked antibacterial activity after 24 hours incubation		Actisorb	
Group D (Score 1) Products that demonstrate limited evidence of anti-bacterial activity after 24 hours incubation	Aquacel Ag Contreet H Contreet Ag Silvasorb		Contreet Ag Aquacel Ag Silvasorb
Group E (Score 0) Products that demonstrate no convincing evidence of antibacterial activity after prolonged incubation	Actisorb Avance	Avance	Actisorb Avance

Rapid and wide range antibacterial activity: Calgitrol® and Acticoat® are the only dressings active within first 2 h after application, against all 3 tested microorganisms.

Method 3: Microbial Transmission Test

Product	S. Aureus (ATCC 6538P)	E. Coli (ATCC 8739)	C. Albicans (ATCC 2091)
	Transfer +/-	Transfer +/-	Transfer +/-
Acticoat	-	-	-
Actisorb	+	+	-
Actisorb *	-	-	-
Avance	+++	+++	+++
Aquacel Ag	-	-	-
Askina Calgitrol Ag	-	-	-
Contreet Ag	-	-	-
Contreet H	-	-	-
Silvasorb	-	-	-
Silverlon	-	-	-
Control	+++	+++	-

Each + indicates the results for a single test strip
* Only the inner core of the Actisorb was used in this test

Negative result for Askina® Calgitrol® Ag signifies the absence of risk of transmission of microorganisms through the dressing.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		35 – 37

Method 4: Silver content of the dressing and the total performance score

Product	Batch No	Ag content (mg/100 cm²)	Total performance score
Silverlon	102S02-01	546	19
Askina® Calgitrol® Ag	131-71	141	20
Acticoat	010814A-08 020214A	109 101	20
Contreet Ag	74853.01	47	9
Contreet H	31576B 267462 344046	31.2 32.4 31.4	13
Aquacel Ag	2H55863	8.3	10
Silvasorb	2082001	5.3	9
Actisorb Silver 220	0138-03 0135-04	2.9 2.4	2
Avance	1106947	1.6	0
Arglaes powder	527027	6.887 mg/g	0

The silver content of tested dressings indicates that major differences exist between these products, with values ranging from 1.6 to 546 mg/cm². Also included are the total scores achieved by each dressing in the various laboratory tests. Askina® Calgitrol® Ag has the second highest silver content and the best overall performance score (with Acticoat®).

Conclusion

Askina® Calgitrol® Ag, which contains a high concentration of silver, performed very well in all tests. The reason for this is likely to be that the silver, already available in the ionic form, is concentrated on the surface of the dressing in a hydrophilic coating which facilitates its rapid release.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
RCT	●	●		38

Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT

C. Trial, MD; H. Darbas, MD J-P. Lavigne, MD; A. Sotto, MD; G. Simoneau, MD, L. Téot, MD; Y. Tillet, PharmD

Journal of wound care vol 19, no 1, January 2010

Objective

To compare the efficacy and tolerability of a new ionic silver alginate matrix (Askina® Calgitrol® Ag) with that of a standard silver-free alginate dressing (Algosteril®).

Method

Patients with locally infected chronic wounds (pressure ulcers, venous or mixed aetiology leg ulcers, diabetic foot ulcers) or acute wounds were eligible for this prospective, open-label, controlled and randomised trial. Patients were randomised to receive one of the two dressings for a two-week period. Criteria of efficacy were based on the evolution, from day 1 to day 15, of local signs of infection using a clinical score ranging from 0 to 18, and the evolution of the bacteriological status for each wound. The latter was determined by (blind) bacteriological examinations of results obtained from two biopsies performed at days 1 and 15. A three-point scale (deterioration, unchanged, improvement) was also used. Acceptability, usefulness and tolerance were also assessed.

Results

Forty-two patients (20 women and 22 men, 68.9 ± 18.8 and 66.5 ± 15.7 years old respectively) were randomly assigned to receive either Askina® Calgitrol® Ag (n = 20) or Algosteril® (n = 22). Most had chronic wounds such as pressure ulcers (57%) or venous or mixed aetiology leg ulcers and diabetic foot ulcers (29%); few had acute wounds (14%). Clinical scores of infection were comparable in both groups at inclusion, 8.9 ± 2.4 and 8.6 ± 3.2 in the Askina® Calgitrol® Ag group and the Algosteril® group respectively (not significant), but decreased significantly in both groups at day 15, 3.8 ± 2.9 in the Askina® Calgitrol® Ag group ($p = 0.001$) and 3.8 ± 3.4 in the Algosteril® group ($p = 0.007$). There was no significant difference between the two groups at day 15. Although there was also no significant difference in bacteriological status between the treatment groups, a trend in favour of Askina® Calgitrol® Ag was found for the relative risk of improvement, especially in patients who were not treated with antibiotics either at the beginning of the study or during it. No differences between groups were observed regarding local tolerance, acceptability and usefulness of the dressings.

Conclusion

The regression of local signs of infection, local tolerance, acceptability and usefulness were similar for the two dressings. However, Askina® Calgitrol® Ag improved the bacteriological status of the wounds. Further trials are required to show that it has a positive impact on the healing process.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
Cohort	●	●		39

Askina® Calgitrol® Ag: clinical use of an advanced ionic silver dressing

E. Ricci, M. Pittarello, R. Cassino, M. Moffa, S. Ferrero, M, Gonella, E. Tonini
Acta Vulnologica Volume 5, No. 3, Pages 105–111, September 2007

Objective
This open ended, non-controlled, non-randomized study assessed the clinical efficacy of an absorbent, isolating composite ionic silver dressing. Thirty-seven patients with infected or critically colonised wounds, but without deep infection requiring general antibiotic treatment, were recruited for the study.

Method
The evaluation parameters were: pain; evolution of the bacterial population as measured by swab; change in wound surface area (Visitrak® system); evolution of the infection. The clinical picture of infection was defined by criteria according to Harding and to Sibbald.
Dressings were changed at saturation.
The observation period was two weeks.
The assessment parameters were:

1) Evolution of the infection (defined by clinical criteria according to Harding and Sibbald).
2) Evolution of the bacterial population as measured by swab.
3) Pain (as measured on a visual analog scale [VAS]).
4) Changes in the base of the wound (classified as necrotic, infected, clean).
5) Monitoring of exudate by clinical observation of the amount of exudate defined as high (presence of perilesional maceration), average (saturation of the dressing within 48 hours), low (saturation after 72 hours).
6) Clinical evaluation of the lesion by the caregiver (resolved, improved, unchanged, worse).
7) Tracking of wound surface area (Visitrak®, Smith & Nephew); a reduction in wound surface area is generally considered as the true indicator of the progress of healing, as demonstrated in a study by Falanga, since re-epithelialization is activated only after all the needs of the wound have been taken care of.
8) Dressing in terms of comfort, wear time, performance and residuals.

Results
Clinical signs of infection resolved in 34 of 37 cases (91.89 %) within the 2-week observation period.

Wound improvement with resolution of infection was observed within 14 days of treatment in 34/37 patients; pain when changing dressings was present, especially at the first dressing. The evolution of the bacterial populations was present from the first week. Performance in terms of patient/operator comfort was very high.

Conclusion
The study product showed excellent overall performance on all given criteria. These results suggest that Askina® Calgitrol® Ag is performant silver dressing in terms of clinical efficiency, but also in terms of patients' comfort.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
Cohort	●	●		40

Clinical effectiveness of silver alginate dressing in outpatient management of partial-thickness burns

Supaporn Opasanon, Pornprom Muangman, Nantaporn Namviriyachote

International Wound Journal Volume 7, Issue 6, pages 467 – 471, December 2010

A prospective descriptive study

Background and objective

The purpose of this study was to compare the efficacy of Askina® Calgitrol® Ag and 1 % silver sulfadiazine (1 % AgSD) in the outpatient management of partial-thickness burn wounds at Burn Unit, Siriraj Hospital. A prospective descriptive study was conducted between January 2008 and January 2009 in Burn Unit, Division of Trauma Surgery, Siriraj Hospital, Mahidol University, Thailand.

Method – study design

The 65 patients with partial-thickness burn wounds, less than 24 hours post-burn injury, had a total body surface area (TBSA %) less than 15 % were treated at Siriraj Outpatient Burn Clinic. All patients were divided into Askina® Calgitrol® Ag treated group (30 patients) and 1 % AgSD treated group (35 patients). The data were compared by the demographics including age, gender, % TBSA burn, pain score, number of wound dressing change, nursing time and time of wound healing. Patients included in both groups were comparable with no significant differences in demographic data of age, gender, location of burn and type of burn injury ($P > 0.05$ evaluated by paired Student's t-test) between both groups.

Results

The present results showed that average pain scores in the Askina® Calgitrol® Ag treated group were significantly lower than the 1 % AgSD treated group (2.23 ± 1.87 versus 6.08 ± 2.33, respectively) between both groups ($P < 0.02$). Patients treated with Askina® Calgitrol® Ag had significantly lower number of wound dressing change ($P < 0.02$) and nursing time ($P < 0.02$) compared with 1 % AgSD treated group. The Askina® Calgitrol® Ag group needed less frequent wound dressing. Healing time was 7 ± 3.51 days after the application of Askina® Calgitrol® Ag. This was significantly shorter than that of control wounds (14 ± 4.18 days).

Conclusion

The results suggest that Askina® Calgitrol® Ag significantly decreases the level of pain, the frequency of dressing changes and the healing time compared with 1 % AgSD treated group. The presented data suggest that Askina® Calgitrol® Ag is an effective dressing managing the partial-thickness burn wounds at the outpatient clinic.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		41 – 44

In vitro evaluation of the antimicrobial effectiveness and moisture binding properties of wound dressings

Pornanong Aramwit, Pornprom Muangman, Nantaporn Namviriyachote and Teerapol Srichana; International Journal of Molecular Sciences 2010, 11, 2864 – 2874

Background and objective

Abstract: A variety of silver-coated dressings and some impregnated with other chemicals are now available in the market; however, there have been few studies analyzing their comparative efficacies as antimicrobial agents. Besides antimicrobial properties, the ability to absorb moisture is also an important factor for healing. Bolton et al. suggested that the use of more moisture-retentive dressings generally supports faster healing compared with less moisture-retentive dressings. The objective of this study is to evaluate the antimicrobial effectiveness of five commercially available antimicrobial dressings in vitro. The moisture penetration of each dressing will also be investigated.

Method

Five commercially available silver-containing and chlorhexidine dressings, Urgotul® SSD, Bactigras®, Acticoat®, Askina® Calgitrol® Ag and Aquacel® Ag were tested to determine their comparative antimicrobial effectiveness in vitro against five common wound pathogens, namely methicillin-sensitive and -resistant Staphylococcus aureus, Bacillus subtilis, Escherichia coli and Pseudomonas aeruginosa. Mepitel®, a flexible polyamide net coated with soft silicone, was used as a control. The zones of inhibition and both the rapidity and the extent of killing of these pathogens were evaluated, as well as water vapour absorption capacity.

Corrected Zone of Inhibition Test

The antimicrobial effect of each dressing was tested using corrected zone of inhibition method. The bacterial isolates were grown in broth for 4 to 6 h, and the broth was used to inoculate Muller-Hinton agar plates to form a confluent lawn. The various wound dressings (about 1 cm^2) were applied to the center of each lawn, and all plates were incubated for 24 h at 37 °C. The inhibition zone surrounding the tested dressing was then determined.

Bactericidal Activities of Antimicrobial Dressings

In order to determine the onset and duration of antimicrobial activity of each dressing, bactericidal activities at different time points were determined by bacterial broth culture method which was adopted from Fraser et al. with some modifications.

Wound Dressing Water Vapor Absorption

Dressings (about 9 $inch^2$) were prepared in an aseptic manner and precisely weighed. Each dressing was placed in a desiccator pre-equilibrated with salts to make the relative humidity a desired value. Potassium sulfate or potassium acetate powder was placed in a desiccator to achieve a percentage relative humidity of about 90 % and 20 % at 30 °C, respectively, as reported by Greenspan. After 30 min, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 12, 24, 48 and 72 h, each dressing was taken from the desiccator using sterile forceps and again precisely weighed. The equilibrium moisture absorption was determined by the percentage weight change.

Results

Zone of inhibition test

Corrected zone of inhibitions (mm) generated by topical antimicrobial dressings.

Microorganism	Urgotul® SSD	Bactigras®	Acticoat®
S. Aureus	1.41 ± 0.86	1.13 ± 0.42	13.30 ± 0.78
MRSA	0.19 ± 0.11	0.36 ± 0.33	6.69 ± 0.14
B. Subtilis	2.39 ± 2.11	7.12 ± 1.24	10.98 ± 0.49
P. Aeruginosa	9.05 ± 3.34	0	17.62 ± 4.82
E. Coli	6.44 ± 1.22	0.78 ± 0.16	15.98 ± 0.84

Microorganism	Askina® Calgitrol® Ag	Aquacel® Ag	Mepitel®
S. Aureus	24.33 ± 3.12	12.97 ± 0.85	0.00
MRSA	8.11 ± 4.33	1.84 ± 0.95	0.00
B. Subtilis	5.62 ± 1.48	6.69 ± 1.39	0.00
P. Aeruginosa	21.08 ± 0.89	22.56 ± 1.77	0.00
E. Coli	12.42 ± 0.69	10.58 ± 0.47	0.00

Conclusion

Acticoat® and Askina® Calgitrol® Ag produced the largest zones of inhibition, which may be due to the high concentration of silver contained in these dressings (105 mg / 100 cm^2 and 141 mg / 100 cm^2, respectively) compared with 3.75 % of silver sulfadiazine in Urgotul® SSD and 0.5 % chlorhexidine in Bactigras®.

Askina® Calgitrol® Ag

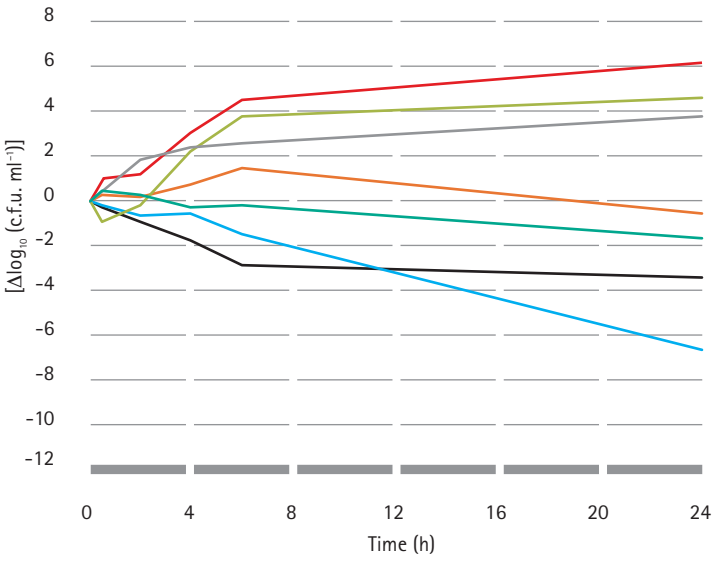
Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		41 – 44

Results

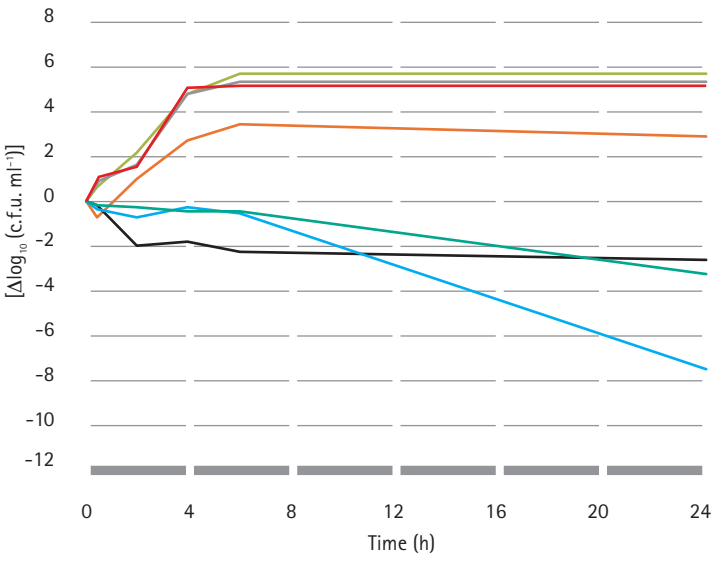
Bactericidal Activities of Antimicrobial Dressings

Bactericidal activity was indicated by a reduction in bacterial counts presented as log10 c.f.u. (colony forming units) ml-1over time. These curves also indicated the rate of bacterial killing and provided an additional index of efficacy against the described isolate. The normal growth rate of each organism was represented by the growth control and that of the Mepitel® dressing, which contained no antimicrobials.

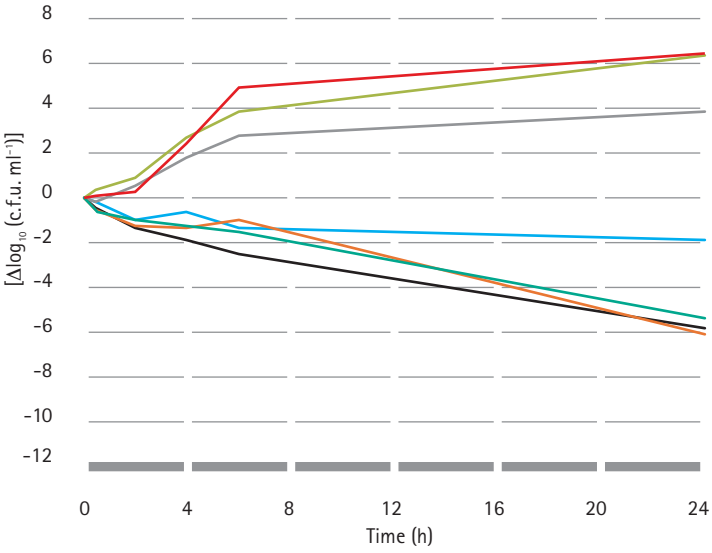
(a) Methicillin-sensitive Staphylococcus aureus (ATCC 6338P)



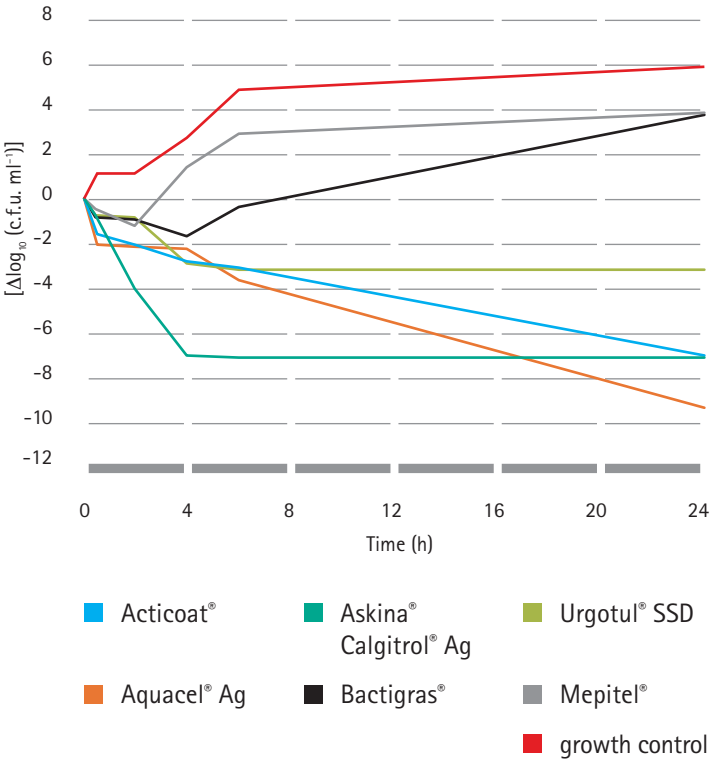
(b) Methicillin-resistance Staphylococcus aureus (ATCC 25923)



(c) Bacillus subtilis (ATCC 6633)



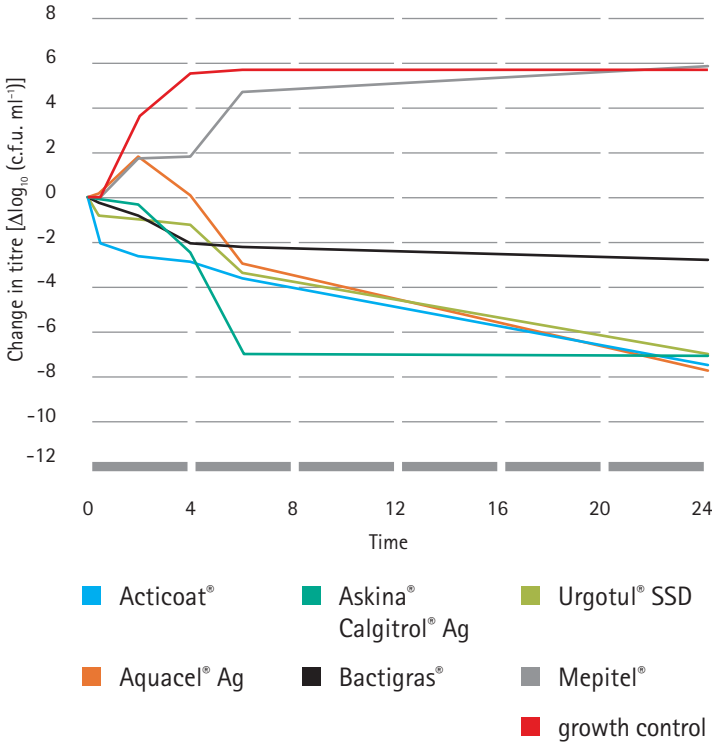
(d) Pseudomonas aeruginosa (ATCC 27853)



Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		41 – 44

(e) Escherichia coli (ATCC 25922)



Conclusion

Overall, Acticoat® seemed to be the most effective dressing against these five tested organisms, especially with Gram-positive bacteria, whereas Urgotul® SSD and Bactigras® seemed to have a lower antimicrobial effect compared with the other dressings. For the Gram-positive bacteria, S. aureus (Figure 1a,b) and B. subtilis (Figure 1c), the Acticoat® dressing exerted maximal bactericidal activity, achieving more than a 4 log reduction of bacterial growth after 24 h. The killing patterns of S. aureus and B. subtilis by silver dressings were similar to MRSA, except for Aquacel® Ag, which slightly reduced both S. aureus and B. subtilis counts but had no effect on MRSA.

With P. aeruginosa (Figure 1d), Acticoat®, Askina® Calgitrol® Ag and Aquacel® Ag exhibited a good bactericidal effect.

The maximal killing of P. aeruginosa was achieved at 4 h with Askina® Calgitrol® Ag and the reduction in bacterial counts was sustained. The killing pattern for E. coli (Figure 1e) by Askina® Calgitrol® Ag was similar to that for P. aeruginosa except for the maximal killing, which was found at 6 h.

All dressings exhibited bactericidal activity and achieved more than a 4 log reduction of E. coli (Figure 1e) except for Bactigras®, which had a less pronounced effect.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		41 – 44

Results

Wound dressing water vapor absorption

Figure 2 shows the percentage weight change of each dressing after being placed into the desiccators at a relative humidity of 96.1 % (Figure 2a) and 22.4 % (Figure 2b), respectively for 0.5 to 72 h. Acticoat, Bactigras, Mepitel, and Urgotul SSD absorbed or released very little moisture from the dressing at any humidity, whereas Askina Calgitrol Ag absorbed and released the most moisture in humid conditions. After being placed in high humidity, Askina Calgitrol Ag started to absorb moisture within 30 min and showed a significant weight change after 12 h. It also absorbed moisture close to 50 % of its initial weight after being placed in a high humidity environment for 72 h and still did not reach a saturated condition. Nevertheless, it started to release moisture after placing it in a low humidity environment for 3 h and released approximately 10 % of its weight after 72 h. In addition to Askina Calgitrol Ag, Aquacel Ag also showed a good absorption of moisture and had moisture release properties but to lower degree. Aquacel Ag absorbed moisture up to 30 % of its weight after 72 h in a high humidity environment after which it started to reach its saturated condition, whereas it showed approximately 4 % moisture release after placing it in a low humidity environment for 72 h.

Fig. 2a
Absorption capacity at 96,1% relative humidity

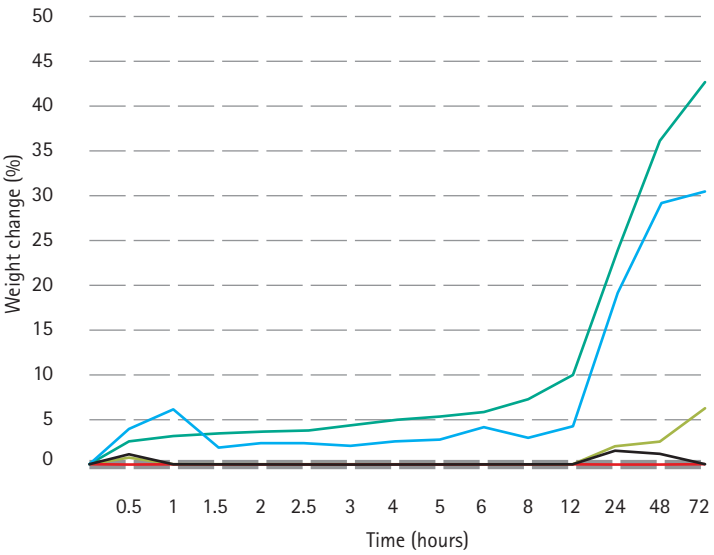
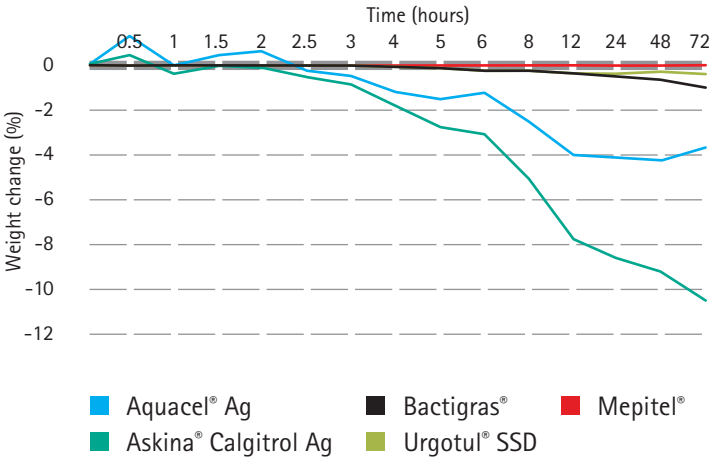


Fig. 2b
Moisture release at 22,4% relative humidity



Conclusion

Our results indicated that Askina Calgitrol Ag absorbed and released the most moisture of the dressings tested. This was most evident with the foam dressings since there are great variations in the location of the surface moisture. The greatest percentage weight change occurred with Askina Calgitrol Ag at high humidity. These data indicated that Askina Calgitrol Ag is a good alternative for treating wounds with high exudates and infection.

Askina® Calgitrol® Paste

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro		●		45

Log Reduction measure of efficacy of Askina® Calgitrol® Paste, Flamazine Cream and Flaminal® Hydro against cultures of P. aeruginosa, E. coli, S. aureus

Dr John Barrett and Dr Tom Patton, Institute of Technology, Sligo, Ireland; Report HOSP 283A, 2011
Dr John Barrett and Dr Tom Patton, Institute of Technology, Sligo, Ireland in conjuction with BCS Laboratories Inc; Report HOSP303, 2011

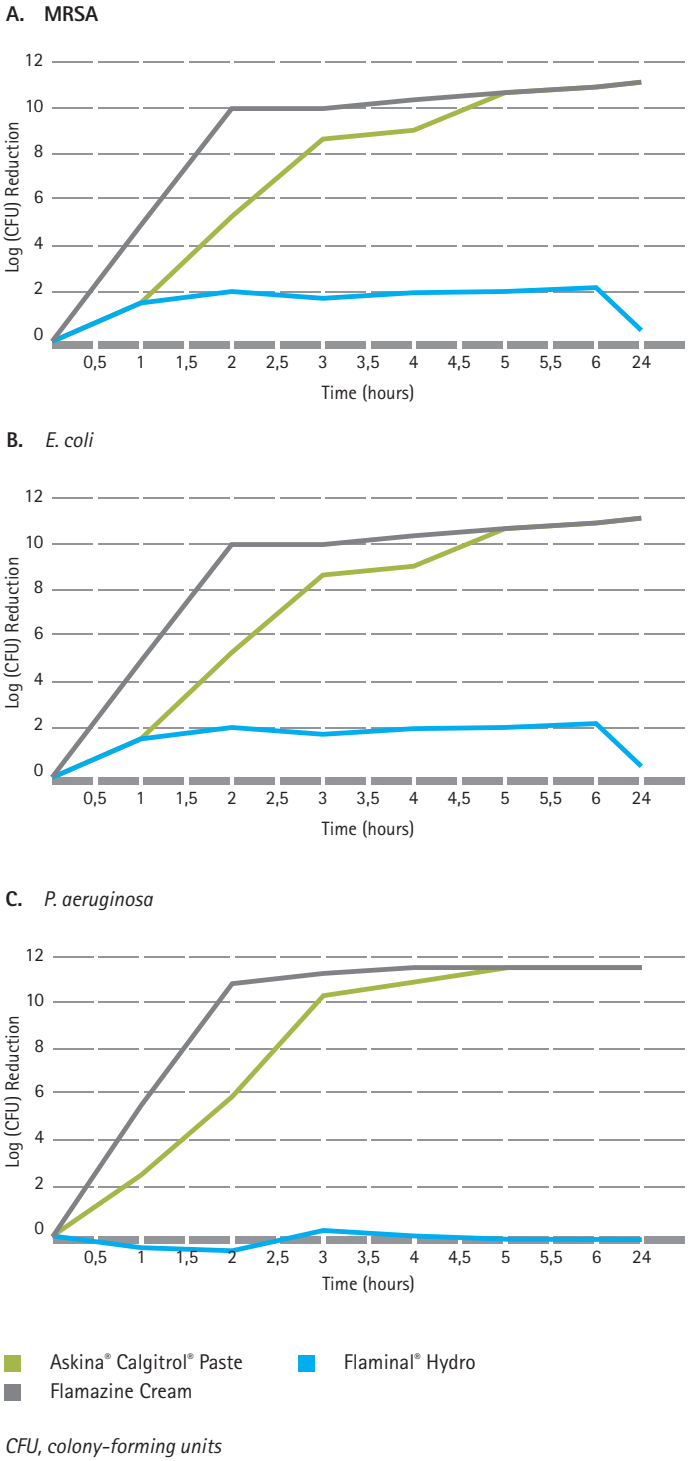
Objective
To evaluate antibacterial activity of Askina® Calgitrol® Paste compared to Flamazine cream and Flaminal® Hydro against cultures of P. aeruginosa (NCIMB 8626), E. coli (NCIMB 12416) and Methicillin resistant Staphylococus aureus (MRSA, ATCC BAA-44)

Method
Individual samples were tested by adding 5 g of test material to 45 ml of nutrient broth which had been seeded with 1ml of an overnight broth culture. A control sample (5 ml nutrient broth added instead of sample) was also prepared. At time 0 a dilution series was performed on the control sample and the colony forming units per ml (cfu/ml) were determined by pour plate. All samples were placed at a shaker table set to 200 rpm and were incubated at approximately 37 °C. Pour plates on all samples were again performed at times 1, 2, 3, 4, 5, 5 and 24h to determine the cfu/ml and thereby construct a Log Reduction (LR) measure of antimicrobial efficacy using the following formula for each point:
LR = Log10 (untreated carrier viable cell count) – Log10 (treated carrier viable cell count)

Conclusion
Askina® Calgitrol® Paste induced a 4-log reduction against MRSA in 2 hours, and a >7 to >9-log reduction against E. coli and P. aeruginosa over a period of 3 hours.
These results confirm Askina® Calgitrol® Paste's antibacterial efficacy, its rapid onset and significant reduction of bacterial load. The Askina® Calgitrol® Paste kill rates were similar to those for Flamazine, which is recognized as a standard of care for burns.

Results

Figure 3. Antimicrobial activity of Askina® Calgitrol® Paste – In vitro kill rates against (A) MRSA, (B) E. coli, and (C) P. aeruginosa



CFU, colony-forming units

Askina® Calgitrol® Paste

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro			●	46

Measurement of serum silver from Askina® Calgitrol® Paste in a swine dermal wound model and evaluation of local tolerability

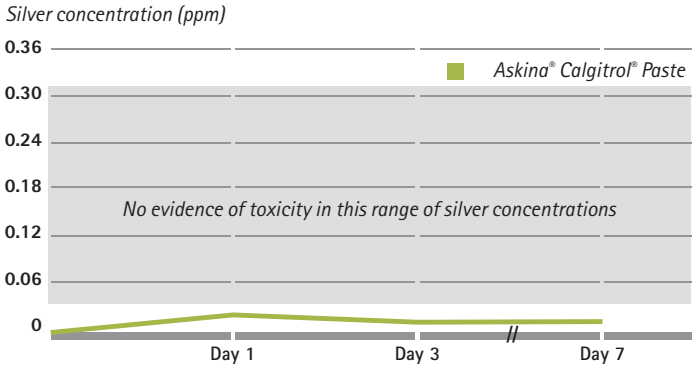
NAMSA report HOSP 257, 2009

Objective
Determination of the level of silver in blood serum and wound and skin discoloration after topical application of Askina® Calgitrol® Paste to full thickness dermal wounds in domestic swine.

Method
Two circular full thickness wounds (including epidermis and dermis) were made on each side of the back of one pig. Wounds (4 total) measured approximately 2.0 – 2.3 cm in diameter and approximately 5 – 7 mm deep. Once hemostasis was achieved, approximately 2.3 g of Askina® Calgitrol® Paste was placed into each wound. The wounds were covered with Askina Derm, PU film dressing.
The bandage was changed at the day 3. The residual Paste and slough were removed, and Askina® Calgitrol® Paste was reapplied, approximately 2.3 g in each wound.
Blood specimens were obtained at pretreatment (day 0), days 1, 3, and 7. The specimens were processed to serum, which was analyzed by inductively coupled plasma mass spectroscopy (ICP) for silver.
Wound sites and surrounding intact skin were evaluated for signs of discoloration.

Results
ICP Results
The serum silver levels increased from baseline upon application of Askina® Calgitrol® Paste.
The amount of silver detected in the serum after application of Askina® Calgitrol® Paste was in the range of 0.0084 – 0.0121 ppm.
The baseline blood levels of serum in humans who have been exposed to silver are typically less than 0.002 ppm.

Figure 4. Leachable silver detected in the blood stream



[NAMSA Report HOSP 257; Wan AT et al 1991]

Site evaluation
Minimal to moderate discoloration of the wound sites was observed at termination. There was no discoloration of the skin surrounding the wound.

Conclusion
Blood level of silver as high as 0.050 – 0.310 ppm have been detected, without evidence of toxicity, in burn patients being treated with silver containing agents. Based on this information, the blood serum levels of 0.01 ppm would not be anticipated to cause a toxic response.

Askina® Calgitrol® Paste was well-tolerated after topical application, systemic absorption of silver has been shown to be very low, and there was no skin discoloration.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro			●	47

Comparative evaluation of erythema and edema skin reaction and skin discoloration

Work carried out in conjunction with the University of Florida, USA, for the FDA submission file 510(k); Report HOSP240 at B. Braun Hospicare, 2005

Objective

To evaluate the irritation reactivity of several silver-containing dressings for: erythema, oedema, skin discoloration

Method

The skin on the inner forearm was swabbed in its entirety with 70 % isopropyl alcohol to remove traces of oils and cleanse the surface. Rectangles (approx. 6 ×12.5 mm) were cut from each dressing and affixed to a band-aid, which was then applied to the skin. Where the product was in the form of a foam gel, a one gram quantity of the gel was placed on the surface of the band-aid and then affixed to the skin in the appropriate place. The dressings were arranged to avoid the area of the bent elbow.

Results

None of the dressings caused Erythema. Two of the dressings (3 and 5) showed very slight to slight signs of Edema. All of the dressings showed signs of discoloration except Askina® Calgitrol® Ag and silver island dressing B.

Silver-containing dressings tested	Skin Discoloration	Erythema	Edema
Askina® Calgitrol® Ag – B. Braun Medical	0	0	0
Burn dressing A (nanocrystalline silver)	1	0	0
Burn dressing A (nanocrystalline silver)	3	0	1
Silver dressing B (nanocrystalline silver)	2	0	0
Silver dressing B (nanocrystalline silver)	3	0	2
Film silver dressing A	0	0	0
Film island dressing B	0	0	0

A 0 to 4 score was used to evaluate the skin reactions for erythema, edema and any discoloration.

Conclusion

Askina® Calgitrol® Ag wound dressings do not cause any discoloration or skin staining.

Askina® Calgitrol® Ag

Type	Improved wound healing	Antimicrobial activity	Tolerability and cytotoxicity	Page
In-vitro			●	48

Evaluation of leachable silver from a wound dressing using the swine model

Dr Joseph Carraway and Ms Wendy R. Sharp, NAMSA, Northwood, OH, USA.
Report HOSP213 at B. Braun Hospicare, October 2006

Objective
To evaluate the level of silver released from Askina® Calgitrol® Ag, following its application to full thickness wounds in a domestic swine.

Protocol – method
Two circular full thickness wounds (2.0 – 2.3 cm diameter; 5 – 7 mm deep) were surgically induced on the back of a single swine. Askina® Calgitrol® Ag dressings were placed on each wound with the dark side of the dressing against the wound, and held in place with a film dressing, Askina® Derm. At pretreatment (day 0), day 1, 3 and 7, a blood specimen was obtained and the specimen was processed to serum. The serum was analysed for silver by Inductively Coupled Plasma (ICP) Spectroscopy.

Results
Under the conditions of the study, the serum levels of silver were comparable at each interval (day1, day 3 and day 7). The highest level detected was 0.008 ppm, at day 7. When compared to the normal human blood levels of silver, this amount is considered insignificant.

Samples	Amount of silver in parts per million (µg/g)
Pretreat	ND
Day 1 (Orange Serum)	0.005
Day 1 (Yellow Serum)	0.005
Day 3	0.002
Day 7 (Dark Orange Serum)	0.008
Day 7 (Light Orange Serum)	0.007
Detection limit	0.001

ND = None Detected

Conclusion
Askina® Calgitrol® Ag wound dressings do not result in any significant elevation of silver ions into the blood serum.

Cytotoxicity study

ISO 10993 Method: Biological Evaluation of Medical Devices, Part 5: tests for Cytotoxicity; in vitro Method guidelines
Report HOSP201 at B. Braun Hospicare, December 2005

Objective
This in vitro biocompatibility study was conducted in order to determine the potential for cytotoxicity of Askina® Calgitrol® Ag.

Method
A single extract was prepared using single strength Minimum Essential Medium supplemented with 5 % serum and 2 % antibiotics (IX MEM). A 1:8 dilution of the test extract in IX MEM was placed onto three separate confluent monolayers of fibroblast cells propagated in 5 % CO_2. After incubation at 37° in the presence of 5 % CO_2 during 48 h, all monolayers (test, reagent control, negative control and positive control) were examined microscopically to determine any change in cell morphology.

Conclusion
Under the conditions of this study, the test extract (Askina® Calgitrol® Ag) showed no evidence of causing cell lysis or cytotoxicity.

Askina® Gel

Type	Physical properties	Improved wound healing	Patient's comfort	Page
In-vitro	●			49

Passage of moisture in/out of gelatine

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 257PTDF REV001, July 2003

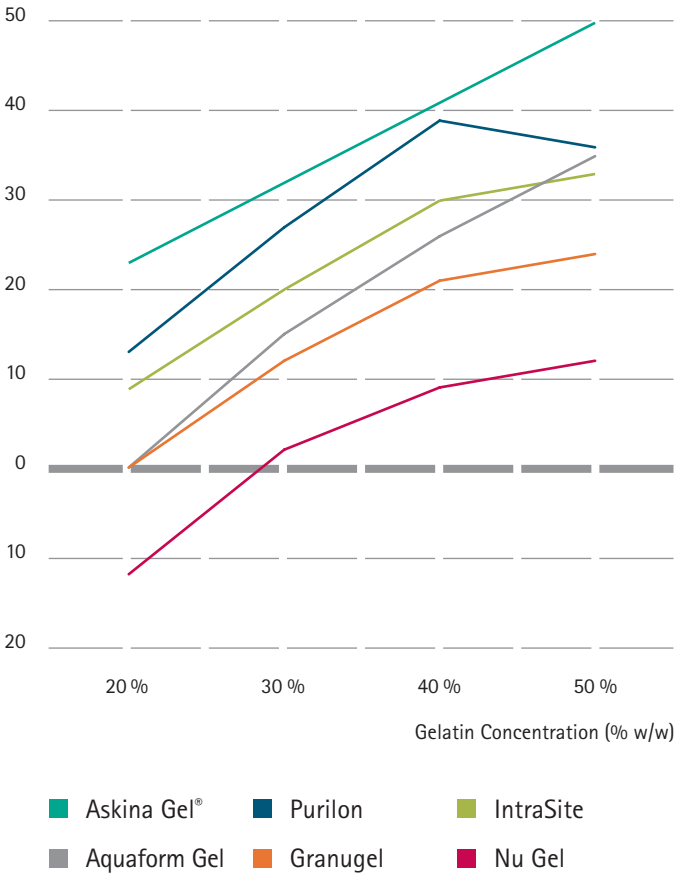
In-vitro test for comparing the capability of water donation of hydrogels

Background and objective
Hydrogels have a special ability to adapt to their environment and can either hydrate the wound or absorb exudate. In the case of necrotic wounds, hydrating helps to soften the necrotic tissue and to facilitate its removal which is less traumatic for the patient. The objective of this study was to determine the hydration capability of Askina® Gel, and to compare it to the other hydrogels present in the market.

Method
A given hydrogel was placed on a gelatine preparation and its loss of weight (hydration) or increase of weight (absorption) is determined after 48 hours. The gelatine preparation were solutions of gelatine (20 % – 50 %) with electrolytes, representing a good model of dry and necrotic wounds.

Results
Water donation was measured at different percentage of gelatine solution. The results are reported to the following graph:

Percentage change in sample weight (%)



Conclusion
Askina® Gel showed the best water donation capacity among tested samples.

Askina® Gel

Type	Physical properties	Improved wound healing	Patient's comfort	Page
In-vitro	●			50

Tackiness of a hydrogel at 45°, 60° and 90° angles of inclination

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 257PTDF REV001, July 2003

In-vitro test for comparing the stability of hydrogels

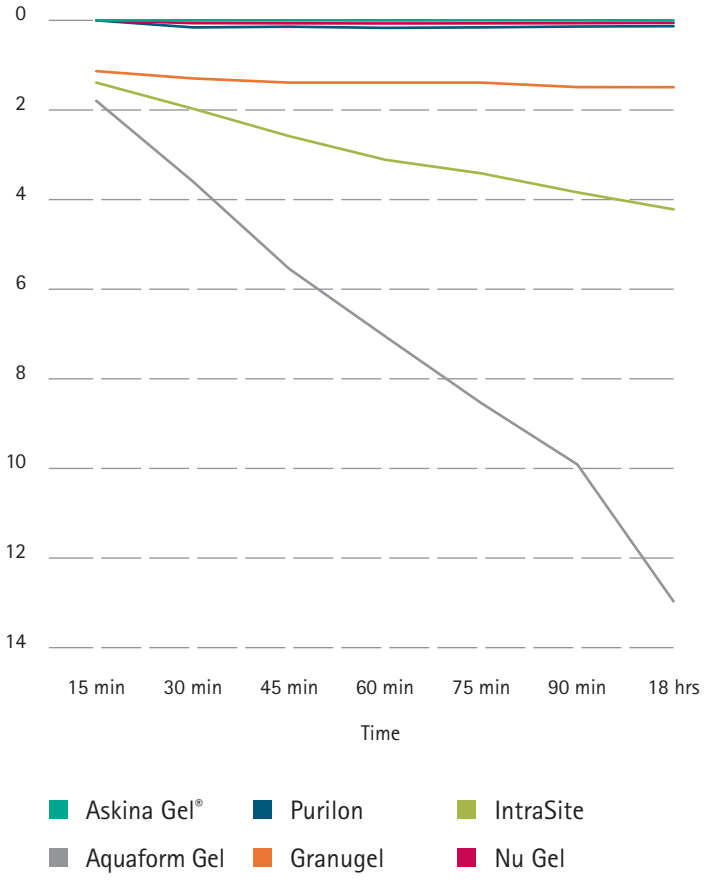
Background and objective
Tackiness may be defined as the more or less pronounced ability of a given hydrogel to adhere to the (wound) surface on which it has been placed, despite the tendency to flow away before the secondary dressing can be applied.

The objective of this study was to determine the tackiness of Askina® Gel, and to compare it with the tackiness of other hydrogels present in the market.

Method
To determine the tackiness of a hydrogels, 1g of hydrogel is placed on a series of glass plates inclined at 45, 60 and 90 degrees. The distance travelled by the gel after defined time periods is measured.

Results
Distance travelled by each hydrogel sample was measured and reported to the following graph:

Distance Travelled, cm



Conclusion
In the group of tested hydrogels, 3 hydrogels, including Askina® Gel, remained in place during 18 hours, which signifies excellent stability. In clinical condition, Askina® Gel can be applied in all positions, without risk of leakage.

Askina® Gel

Type	Physical properties	Improved wound healing	Patient's comfort	Page
Cohort		●	●	51 – 52

Evaluation of Askina® Gel – product characteristics and the patient experience

Isabella Beuken, Staff Nurse, Co-Authors: Emma McLeod, Staff Nurse, Ann McLinton, Practice Development Facilitator, Heather Hodgson, Tissue Viability Nurse Specialist Out Patient Department, Beatson West of Scotland Cancer Centre, Glasgow and , Gartnavel General Hospital, Glasgow

Results presented at the European Conference on Advances in Wound Management Harrogate, 9 –11 November 2008

Abstract

Background and objective

Radiotherapy is one of the major treatment modalities used in the management of cancer (SEHD, 2001). Almost all patients receiving radiotherapy are at risk of a degree of skin damage (NHSQIS, 2004) and the increasing use of chemoradiotherapy also affects the severity of skin reactions experienced (Wells et al, 2003). This therefore presents a significant challenge for the healthcare system to ensure optimum quality of care. When a moist desquamation skin reaction arises the integrity of the skin is compromised and the principles of moist wound healing apply (NHSQIS, 2004). A hydrogel is recommended as an option for the treatment of moist desquamation (NHSQIS, 2004) and have been explored for this use in other radiotherapy treatment centres (Macmillan et al, 2007).

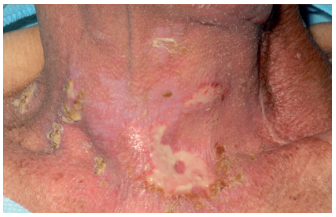
Method

Over a four week period, thirty six patients identified to have moist desquamation (RTOG 2b and RTOG 3), dry desquamation (RTOG 2a) where the skin was on the verge of breaking down, or a combination of both, were evaluated when using Askina® Gel as the skin care intervention.

The product was evaluated in the Out Patient Department of the cancer centre using a tool designed to assess the following product characteristics:

- use of the delivery system;
- product application;
- ability to spread the product over the wound;
- ability of the product to stay on the wound;
- ability to rehydrate the wound;
- removal of the product and removal of any residue left on the wound prior to further application.

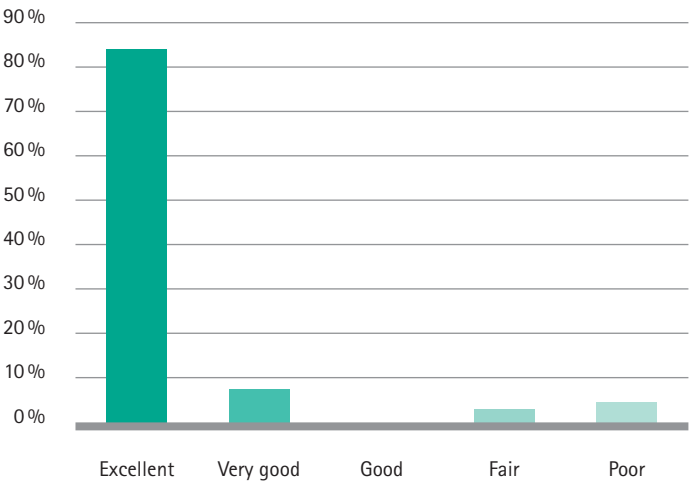
Score	Descreption
RTOG 0	No visible change to skin
RTOG 1	Faint or dull erythema
RTOG 2A	Tender or bright erythema
RTOG 2B	Patchy moist desquamation, moist oedema
RTOG 3	Confluent moist desquamation



Results

Askina® Gel was noted mainly as "Excellent" and "Very good" on all studied criteria.

Ease of using the Askina delivery system



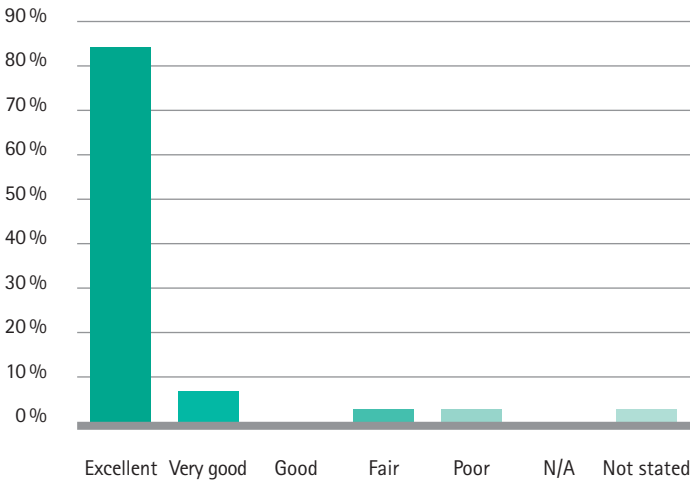
Conclusion

Results demonstrate Askina® Gel to having favourable product characteristics and to be suitable for use by patients who self care for their radiotherapy reaction. In regard to the study results Askina® Gel was accepted as a product of preference for the care of skin damage caused by radiation therapy in 2 major Scottish clinics.

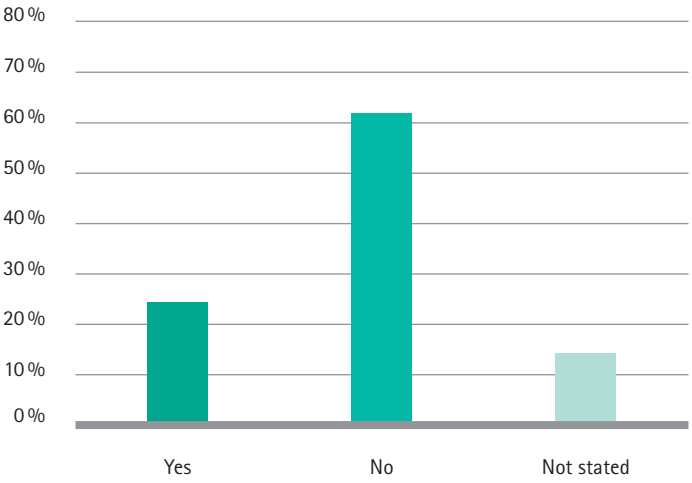
Askina® Gel

Type	Physical properties	Improved wound healing	Patient's comfort	Page
Cohort		●	●	51 – 52

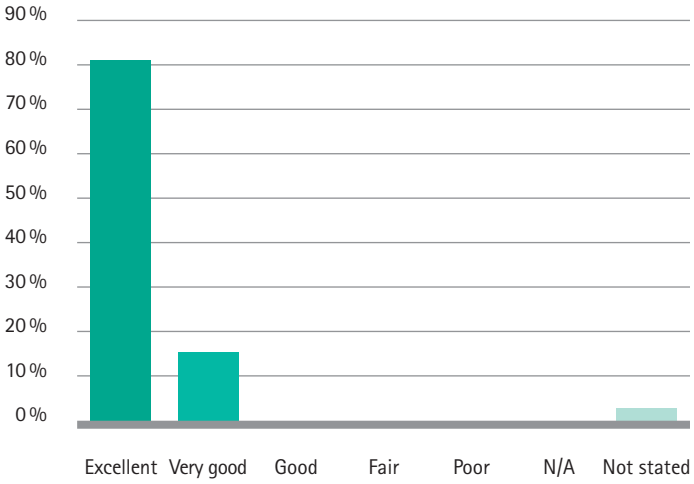
Ease of product application



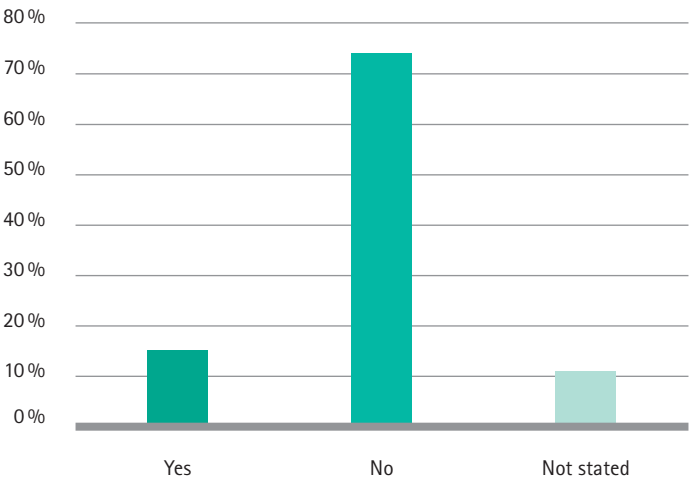
Did Askina Gel cause any pain?



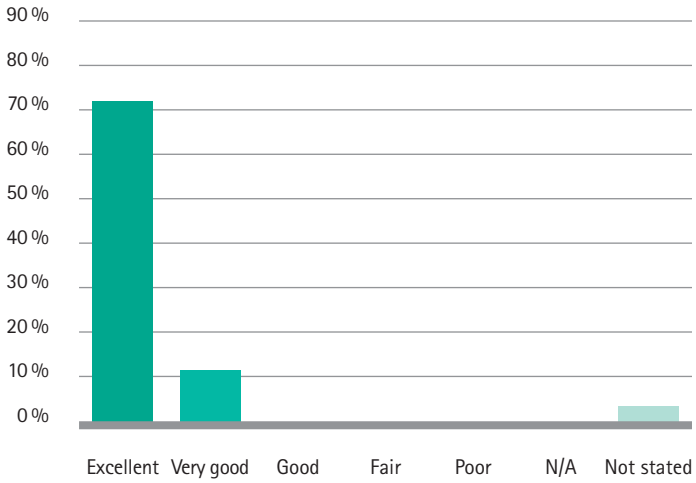
Ease of spread over the wound



Did Askina Gel cause any irritation?



Ability to stay on the wound on initial application



Askina® SilNet

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro		●			53

Evidence of absence of stripping of epidermal cells

SCANNING ELECTRON MICROSCOPE (SEM) ANALYSIS – carried out by Agenda 1 Analytical Services Limited, UK.
Report HOSP259 at B. Braun Hospicare, April 2009

Background and objective

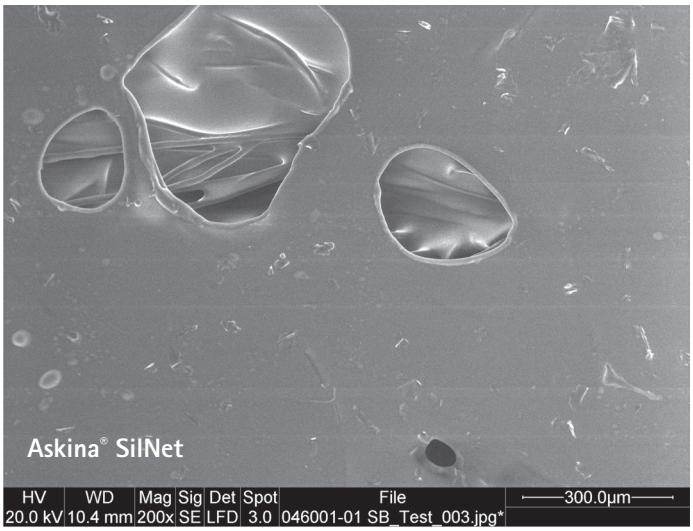
The aim of this study is to demonstrate that the silicone adhesive used in Askina® SilNet does not cause the stripping of epidermal cells. A silicone adhesive is extremely soft and will flow over the uneven skin surface to create a large effective contact area with the skin. As a result, less adhesion force per square millimetre is needed, compared with traditional dressings, to create the same level of fixation. This property helps to prevent damage to the skin barrier.

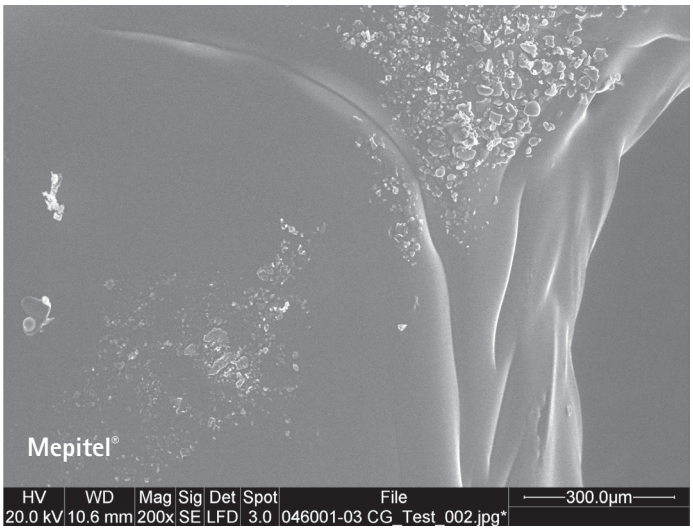
Method

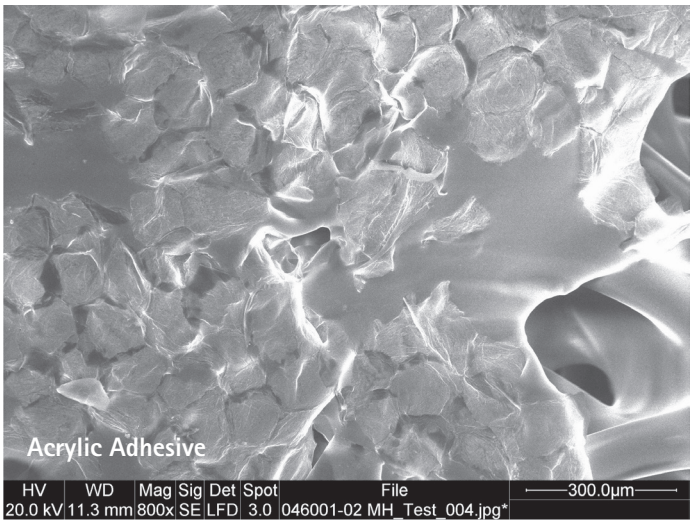
A small piece of Askina® SilNet was observed by the Scanning Electron Microscopy, the instrumentation used to observe minute surface details of small organisms/objects at high magnification by means of electron lenses. The system produces a magnified snap-shot image of the object (12.5 mm diameter circle surface). The samples of Askina® SilNet, Mepitel® (the market leading silicone contact layer) and Askina® Transorbent® (dressing with acrylic adhesive) were observed before applying the dressing on the skin, and after its removal from the skin.

Results

The snap shots of the surface of the 3 tested samples after removal from the skin:







There were no epidermal cells on the surface of Askina® SilNet and Mepitel®, while there were many epidermal cells present at the surface of Askina® Transorbent® (acrylic adhesive.)

Conclusion

Askina® SilNet is completely atraumatic, which does not cause any stripping of epidermal cells, even after repeated removal, comparable to the leading market product, Mepitel®. The use of this dressing is thus recommended for the protection of fragile skin.

Askina® SilNet

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro			●		54

Evidence for no impedance using Askina® SilNet when Askina® SilNet is placed against a foam dressing

Laboratory Testing carried out at B. Braun Hospicare; Standard I.S. EN 13726-1:2002 Test Methods for primary wound dressings – Part 1: Aspects of Absorbency; Data referenced in BBH 264PTDF REV002, March 2011

Objective:
To measure Fluid Handling Capacity (FHC) of Askina Foam dressing through the interface dressings.

Method:
The Absorbency, Vapour Loss and Fluid Handling Capacity of Askina® Foam dressing was evaluated with the following methode, first for the Foam dressing alone, than with an interface dressing positionned above. A 50 mm diameter (taken from the centre of the foam island) of the dressing, is placed in a Paddington Cup to which 20 ml of a solution [sodium ions and calcium ions] is added. The cups are weighed and placed in an incubator at 37±0.5 °C. At the end of the test the cups are removed from the incubator, allowed to equilibrate to room temperature and reweighed. From these weights the loss in weight due to the passage of moisture vapour through the dressing is determined. The base of each cup is then removed and any remaining fluid allowed to drain. The cup is then reweighed once again and the weight of fluid retained by the dressing is calculated by difference.

Results
Fluid handling capacity (FHC) of Askina® Foam through the interface dressing:

Conclusion
The difference between the fluid handling characteristics of "Foam" and "Foam + Askina® SilNet" are insignificant: Askina® SilNet does not impact the flow of liquid into Askina® Foam, and does not affect the vapour transmission.

Product	Company	Absorbency, g	Vapour Loss, g	Fluid Handling Capacity, g	Fluid Handling Capacity (10 ×10 dressing), g/100 cm²
Askina® Foam + Askina® SilNet	B. Braun	4.56	14.81	19.37	201.48
Askina® Foam + Mepitel	Mölnlycke	3.90	15.18	19.08	198.43
Askina® Foam + URGO/Restore Contact Layer Dressing	URGO/ Hollister	4.15	14.88	19.03	197.91
Askina® Foam (without any interface dressing)	B. Braun	4.50	14.90	19.40	201.76

*Fluid Handling Capacity can determine a dressing's ability to absorb exudate and transmit moisture. Fluid Handling Capacity = Absorbency + Vapour Loss

Askina® SilNet

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
Cohort	●	●			55

Experiences of a combination of Askina® SilNet with topical negative pressure

Frans Meuleneire, Woundcare Centre – AZ St Elisabeth, Zottegem – Belgium
Presented at EWMA Conference, Geneva, 2010

Background and objective

Topical Negative Pressure (TNP) is an innovative treatment for various types of complex or problematic wounds. Often we observe a firm adhesion of the foam dressing onto the wound surface. This is a major problem in fragile granulation tissue of wounds that are treated with TNP, especially during dressing changes. The use of an interface can avoid such problems.

Method

We assessed the wounds after use of the combination of Askina® Silnet with TNP treatment in 7 cases. Dressing changes were performed every 3 to 4 days. We evaluated the efficacy, trauma at dressing change, transfer of exudate through the silicone wound contact layer and pain at dressing removal. The results have been illustrated by photo documentation.

Results

In none of evaluated cases did we observe any negative consequence. At time of dressing change, the wound had a vital aspect. We did not observe any problem of adherence on the granulation tissue. Furthermore it was possible to change the dressings without use of painkillers.

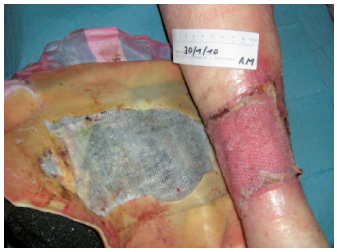
1. Lady with bilateral chronic venous leg ulcers. Exacerbating wounds. Planning: skin grafts. Pre-operative wound bed prepration with TPN (Topical Negative Pressure).

2. Start of TNP in combination with silicone interface. Need for protection against ingrowth of the granulation tissue into the sponge. Application of a Silicone dressing* as an interface between wound bed and the sponge

3. Both wounds have been treated with TNP. Negative pressure has been performed with –175 mm Hg (Interface dressings may influence the delivery of Topical Negative Pressure Therapy)

4. Twice a week, dressings have been changed. No trauma or pain has been observed at dressing removal.

5. Result after 7 days TNP with Silicone interface dressing. Five days later, on January 25th, a skin graft has been performed on both ulcers.



6. Five days post-operative, the dressing has been removed without adherence on the skin graft. The surrounding skin has been protected by a hydrocolloid.

7. After removal of the stitches and the surplus of skin graft at the edges, we can observe a 100% vital skin graft aspect. We still continue with the Silicone dressing* without TNP.

8. About 1 month after starting the combination of TNP with the new Silicone dressing*, the ulcers have been healed completely. Compression stockings have been applied to avoid odema.

Conclusion

This observational study demonstrates the advantage of using Askina® SilNet in combination with Topical Negative Pressure. This combination avoids ingrowth of the granulation tissue into the foam cells, which helps to create the most favourable means for the management of exudate and thereby assures the continuation of the healing process.

Askina® DresSil

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro		●			56

Evidence of absence of stripping of epidermal cells

SCANNING ELECTRON MICROSCOPE (SEM) ANALYSIS – carried out by Agenda 1 Analytical Services Limited, UK

Report HOSP266 at B. Braun Hospicare, January 2010

Background and objective

The aim of this study is to demonstrate that the silicone adhesive used in Askina® DresSil does not cause the stripping of epidermal cells. A silicone adhesive is extremely soft and will flow over the uneven skin surface to create a large effective contact area with the skin. As a result, less adhesion force per square millimetre is needed, compared with traditional dressings, to create the same level of fixation. This property helps to prevent damage to the skin barrier.

Method

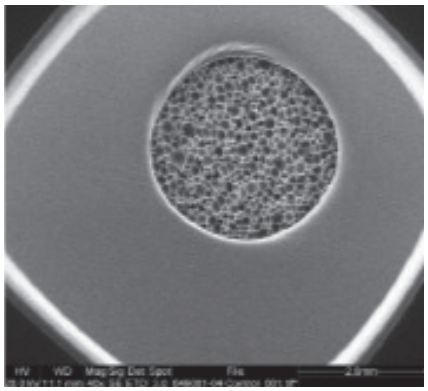
The small surface of Askina® DresSil was observed before applying the dressing on the skin, and after its removal by the Scanning Electron Microscopy, the instrumentation used to observe minute surface details of small organisms/objects at high magnification by means of electron lenses. The system produces a magnified snap-shot image of the object (12.5 mm diameter circle surface).

Conclusion

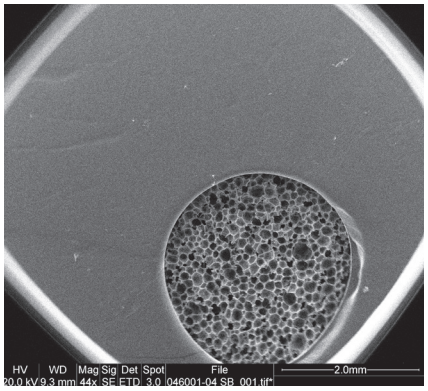
High level of silicone gives good security/flow, yet does not remove any skin cells on removal.

Results

Askina® DresSil BEFORE contact with skin cells



Askina® DresSil AFTER contact with skin cells



No stripping of skin cells

Askina® DresSil

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro			●		57

Fluid handling capacity

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 301PTDF REV004, Mai 2011

Background and objective

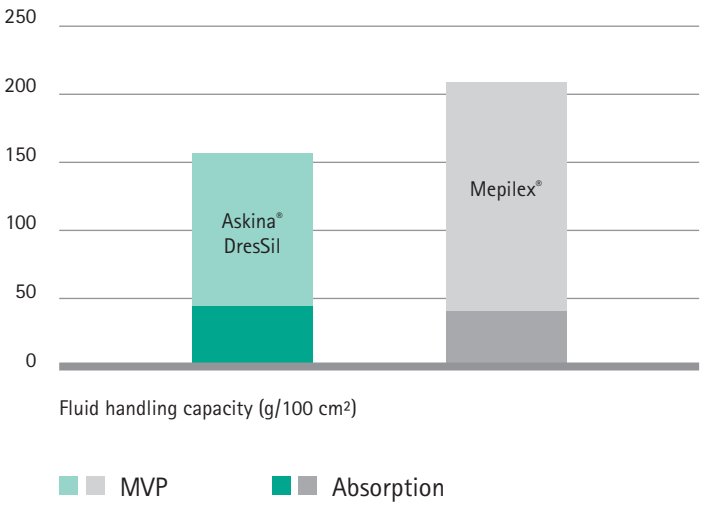
The good fluid handling characteristics of the dressing are important for patient comfort and safety (no maceration, no leaking), but also for healthcare professionals as they signify longer wear time and less frequent dressing changes.

The aim of this study was to assess the absorbency and vapour loss of Askina® DresSil in comparison with the market leading product, Mepilex®.

Method

The fluid handling charateristics were determined according to the Aspects of Absorbency is carried out as per Standard I.S. EN 13726-1:2002 "Test Methods for primary wound dressings – Part 1: Aspects of Absorbency" were measured according to the Standard I.S. EN 13726-1:2002 "Test Methods for primary wound dressings – Part 1: Aspects of Absorbency".

Results



Conclusion

The fluid handling characteristics of Askina® DresSil are in line with fluid handling characteristics of Mepilex®.

Retention capacity

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 301PTDF REV004, Mai 2011

Background and objective

The retention capability of the dressing is the ratio between capacity under pressure and free absorption capacity of the dressing. This property reflects the possibility to use the dressing under compression therapy.
The aim of this study was to compare the retention capability of Askina® DresSil and the one of the market leading products.

Method

The retention was determined according to the following method.

A 50 mm diameter is taken from the centre of the dressing and saturated with 0.9 % saline solution for 24 hrs. The sample is removed from the saline and reweighed. Then the sample is placed on a flat surface and a 1120 g weight (which is equal to a pressure of 35 mm Hg) is placed on the sample for three minutes. After three minutes, the weight is removed and the sample is reweighed. From these weights the % retention can be calculated.

Results

The results are expressed as a percentage of the liquid which is retained after the saturated dressing was placed under pressure. Askina® DresSil retains 70 % of the liquid under pressure.

Product	Company	Retention % / 24h
Askina® DresSil	B. Braun	70.04
Mepilex®	Mölnlycke	54.16
Allevyn® Gentle	S&N	54.26

Conclusion

The retention capacity of Askina® DresSil is higher than the retention capacity of the two leading competitor products. The product is suitable for use under compression therapy.

Askina® DresSil

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro			●		58

Wicking

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 301PTDF REV004, May 2011

Background and objective

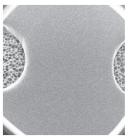
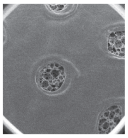
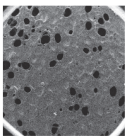
Askina® DresSil's silicone wound contact layer is perforated to allow exudate to pass through to the foam layer, preventing exudate leaking onto the surrounding skin and maceration of the wound edges.

The objective of this study was to determine the wicking properties of Askina® DresSil and to compare them with market leading competitor products.

Method

The same quantity (1 ml) of test liquid was placed on the surface of the dressing samples. The time needed for the liquid to be completely absorbed is measured.

Results

Product	Company	Type of perforation in the silicone layer	SEM image	Wicking time
Askina® DresSil	B. Braun	"Flower" pattern		38 sec
Mepilex®	Mölnlycke	Continous flood coating with micros-copic holes		3 min
Allevyn® Gentle	S&N	Uniform pattern of holes		> 60 min

The table resumes the wicking time of tested dressings with SEM images of the silicone layers. The wicking time of Askina® DresSil is the best among the tested dressings.

Conclusion

The distinctive design of Askina® DresSil's silicone contact – "flower pattern" holes in the coated adhesive enables very quick and vertical absorption of the exudate.

Askina® DresSil

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro				●	59

Adhesiveness

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 301PTDF REV004, May 2011

Background and objective

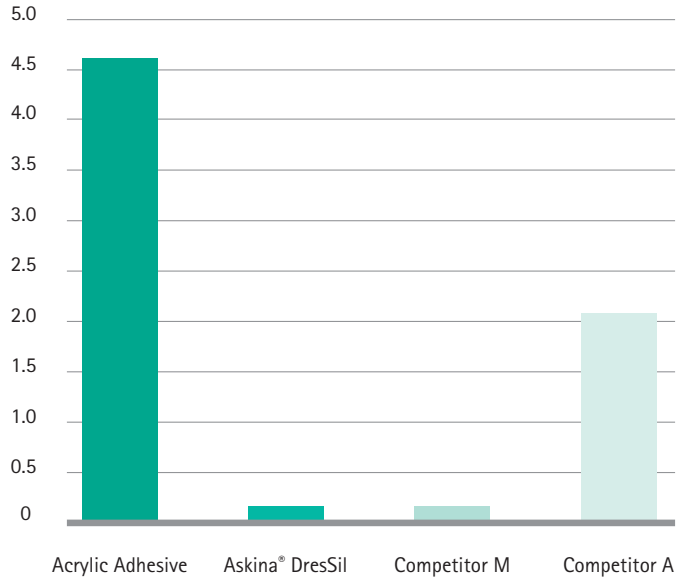
One of the major benefits of Askina® DresSil is its soft and safe adherence due to the silicone adhesive layer. The aim of this study was to compare the adherency of the Askina® DresSil with the adherency of the market leading product, and the one of a dressing with an acrylic adhesive.

Method

Adhesiveness is a modified version of the test Method 11.53. The dressing is peeled from a clear embossed polyethylene liner that has been stuck to the stainless steel plate with double sided tape. The strength needed to peel-off the dressing is measured.

Results

Adhesiveness, N/25mm



Conclusion

The adhesiveness of Askina® DresSil is similar to the adhesiveness of the market leading product. The silicone layer provides for the soft and safe adhesion and atraumatic dressing removal.

Askina® Foam

Type	Improved wound healing	Absence of pain	Fluid handling properties	Physical properties	Page
In-vitro			●		60

Fluid handling capacity

Laboratory Testing carried out at B. Braun Hospicare
Standard I.S. EN 13726-1:2002 "Test Methods for primary wound dressings – Part 1: Aspects of Absorbency"
Data referenced in BBH 283PTDF REV007, Mai 2011

Background and objective

The good fluid handling characteristics of the dressing are important for patient's comfort and safety (no maceration, no leaking), but also for the healthcare professionals as they signify longer wear time and less frequent dressing changes.

The aim of this study was to assess the absorbency and vapour loss of Askina® Foam and to compare them to those of four other non-adhesive foam dressings present in the market.

Method

The fluid handling charateristics were determined according to the "Test Methods for primary wound dressings – Part 1: Aspects of Absorbency", carried out as per Standard I.S. EN 13726-1:2002.

Results

Product	Absorbency, g/100cm²/24hrs	MVP (Moisture Vapour Permeation), g/100cm²/24hrs	Fluid Handling Capacity (10x10 dressing), g/100cm²
Askina® Foam (SE)	59	150	209
Allevyn Non-Adhesive (SE)	68	131	199
Biatain Non-Adhesive (SE)	84	121	205

Conclusion

Askina® Foam's fluid handling capacity is among the highest in the market which allows for longer wear time (3 – 7 days, depending on the amount of the exudate).

Retention capacity

Laboratory Testing carried out at B. Braun Hospicare
Data referenced in BBH 283PTDF REV007, Mai 2011

Background and objective

The retention capability of the dressing is the ratio between capacity under pressure and free absorption capacity of the dressing. This property reflects the possibility of use of the dressing under compression therapy.
The aim of this study was to compare the retention capability of Askina® Foam with the retention capacity of other non-adhesive foam dressings existing in the market.

Method

The retention was determined according to the following Method:

A 50mm diameter is taken from the centre of the dressing and saturated with 0.9 % saline solution for 24 hrs. The sample is removed from the saline and reweighed. Then the sample is placed on a flat surface and a 1120g weight (which is equal to a pressure of 35 mm Hg) is placed on the sample for three minutes. After three minutes, the weight is removed and the sample is reweighed. From these weights the % of retention was calculated.

Results

Product	% Retention, 24 hrs
Askina® Foam (SE)	74.34
Allevyn Non-Adhesive (SE)	48.70
Biatain Non-Adhesive (SE)	86.18

Conclusion

The retention capacity of Askina® Foam is between the highest in the market, which makes it ideal for the use under compression therapy.

Askina® Transorbent®

Type	Improved wound healing	Patient's comfort	Page
RCT	●	●	61 – 63

Product presentation

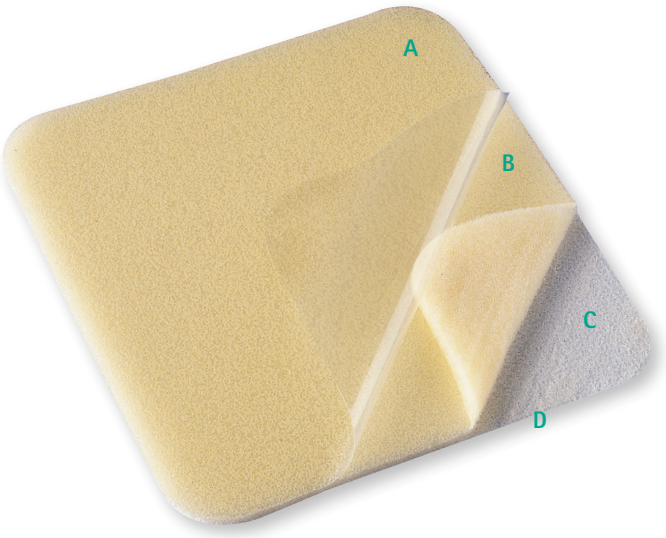
Description
The Transorbent® Technology features a patented design that provides a unique absorption process.

A Thin Polyurethane Layer
Impermeable to liquids and bacteria but vapour permeable.

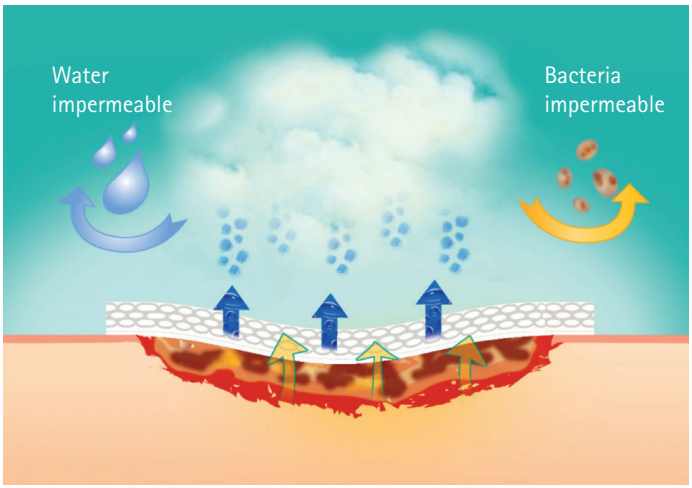
B Foam Layer
Provides a means for the escape of moisture vapour giving the dressing its comfortable smoothness and conformability.

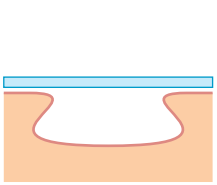
C Dry Hydrogel Layer
Absorbs wound exudate and preserves a moist healing environment. Excess exudate is evaporated through the foam and upper layers.

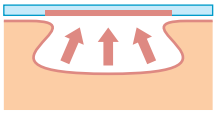
D Adhesive Layer
Sticks to the intact and dry surrounding skin but not to the wound surface.

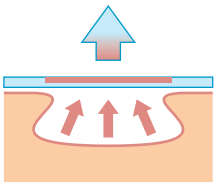


How it works




The dry hydrogel ...


... is able to transfer fluid away from the wound, capture it ...


... and eliminate the excess moisture.

Askina® Transorbent®

Type	Improved wound healing	Patient's comfort	Page
RCT	●	●	61 – 63

Clinical evidence

Comparison and evaluation of the performance characteristics, usability and effectiveness on wound healing, of Askina® Transorbent® vs a hydrocolloid with foam backing.
Marie Brown-Etris, RN, CETN - President / Etris Associates, Inc. Philadeiphia, USA
Results presented at the 5th European Conference on Advances in Wound Management / Harrogate, 21 – 24 November 1995
This data summarizes the resuits of a 7 site, 10 week investigation, involving 140 patients, of which 121 remained in the study throughout the 10 week period.

Background and objective

The objective of the study was to evaluate and compare two widely used dressings, Askina® Transorbent® with a leading hydrocolloid with foam backing, for the management of Stage II, Stage III and Stage LV pressure ulcers.

Method

This 10 week, multi-center study was stratified, open label and prospective. Wounds were randomized according to surface area and stage so that final comparison could be made among similar wounds.

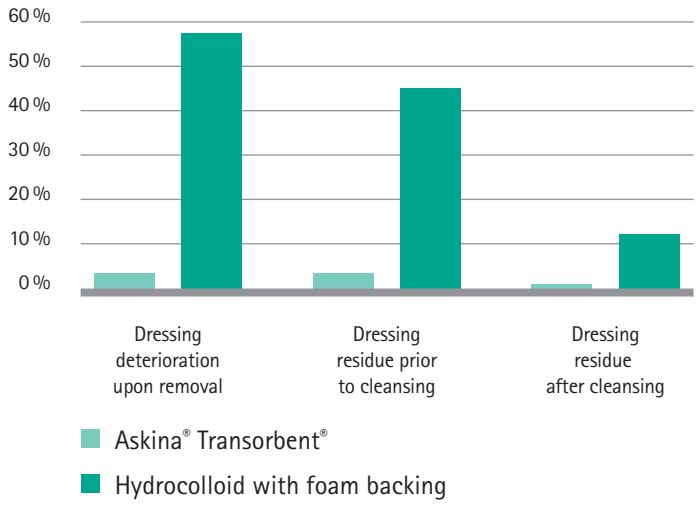
Once enrolled in the study, a baseline wound assessment and risk assessment using the Braden scale was performed on each participant and documented on the case report forms. The participant was visited weekly for evaluations.

The wound assessment included
- Metric measurement of wound dimensions.
- Tracing of wound on transparent film.
- Stage of wound.
- Wound location.
- Condition of margins and periwound area.
- Exudate level.
- Odour.

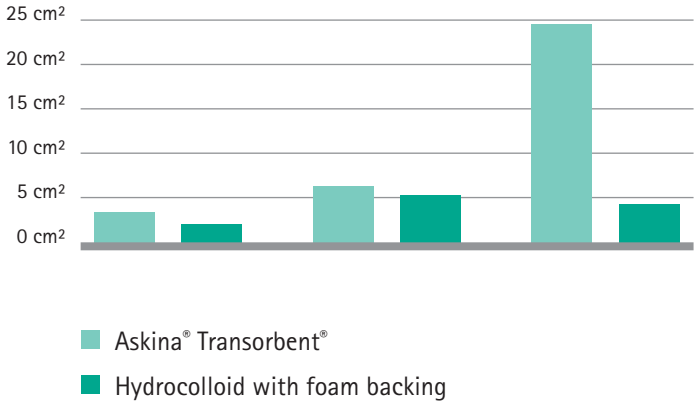
Additional data collected included
- Previous wound treatments.
- Form of pressure relief.
- Nutritional status
- Diagnostics and medical condition

Result

Dressing residue in periwound area



Surface area reduction over 10 Weeks



Askina® Transorbent®

Type	Improved wound wealing	Patient's comfort	Page
RCT	●	●	61 – 63

Conclusion
Askina® Transorbent® performed best overall.

This is evidenced by its ability to reduce wound surface area in healing wounds to a greater extent than the hydrocolloid when pressure ulcers were followed closely for up to 10 weeks.

The largest sampling (Stage III, 2 cm^2 – 30 cm^2) which produced data from 78 participants, demonstrated that there was a 21 % greater reduction in wound surface area in the Askina® Transorbent® group over the hydrocolloid group i.e., overall mean area reduction of 6.3 cm vs 5.2 cm. Stage 11 (2 cm – 30 cm) the overall mean reduction of 3.6 cm experienced by the subjects in the Askina® Transorbent® group was 57 % greater than the reduction of 2.3 cm observed with the subjects in the hydrocolloid group.

In addition, the results from the group treated with Askina® Transorbent® demonstrated statistically significant improvements over the group treated with the hydrocolloid dressing in the following areas:

- Dressing deterioration at the time of removal.
- Dressing residue prior to cleansing.
- Dressing residue after cleansing.

This confirms Askina® Transorbent® to be superior in its ability to maintain integrity and minimize the residue commonly associated with hydrocolloid deterioration.

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