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Clinical Evidence Guide

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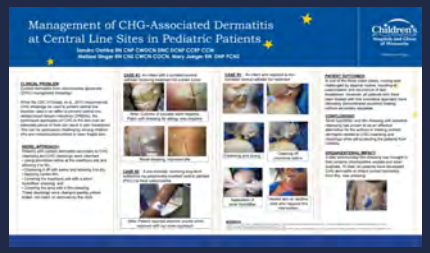
Clinical Evidence Pieces

Management of CHG-Associated Dermatitis at Central Line Sites in Pediatric Patients

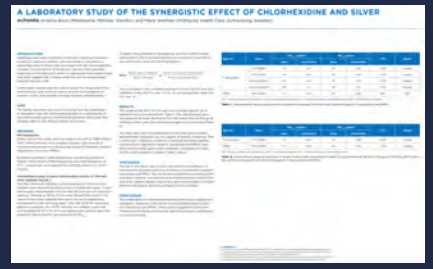


Laboratory study of the Antimicrobial Activity of a novel Antimicrobial Dressing with Soft Silicone Adhesive

An investigation into the ability of an Antimicrobial Dressing with Soft Silicone to Prevent Microbial Re-Growth

A Human Repeat Patch Test Study highlighting how Soft Silicone Adhesive Dressings can reduce pain.

A Laboratory Study of the synergistic effect of Chlorhexidine and Silver in a Cover Dressing



Clinical Performance of a New Clear Silicone Adhesive Dressing with Chlorhexidine and Ag for VADs

Management of CHG-Associated Dermatitis at Central Line Sites in Pediatric Patients

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CLINICAL PROBLEM:
Contact dermatitis from chlorhexidine gluconate (CHG) impregnated dressings.

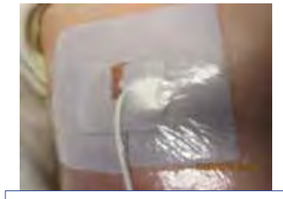
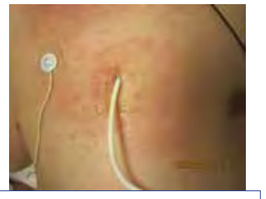
While the CDC (O'Grady, et al., 2011) recommends CHG dressings be used to protect central line insertion sites in an effort to prevent central line-related blood stream infections (CRBSIs), the continuous application of CHG to the skin over an extended period of time can result in skin breakdown. This can be particularly challenging among children who are immunocompromised or have fragile skin,

NOVEL APPROACH:
Patients with contact dermatitis secondary to CHG cleansing and CHG dressings were cleansed
- Using providone-iodine at the insertions site and allowing it to dry,
- Cleansing it off with saline and allowing it to dry,
- Applying barrier film,
- Covering the insertions site with a silver hydrofiber dressing, and
- Covering the area with a film dressing.

These dressings were changed weekly unless soiled, not intact, or removed by the child.

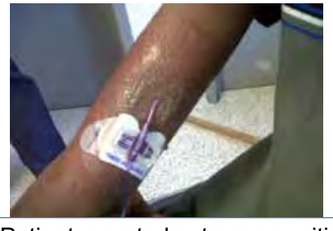
CASE #1: An infant with a tunneled central catheter receiving treatment for a brain tumor


Note: Cultures of exudate were negative. Patch with dressing for allergy was negative.

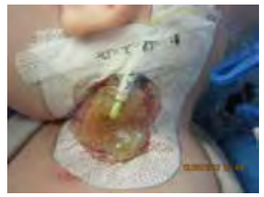
Novel dressing, improved site

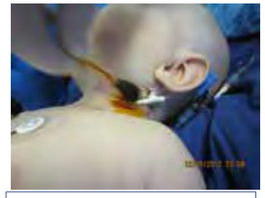
CASE #2: : A pre-schooler receiving long-term antibiotics via peripherally-inserted central catheter (PICC) to treat osteomyelitis



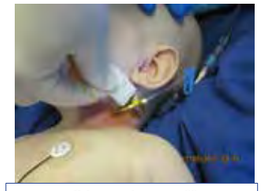
Note: Patient reported extreme pruritis which resolved with our novel approach.

CASE #3: : An infant who required a non-tunneled central catheter for treatment



Cleansing and drying



Cleaning off providone iodine

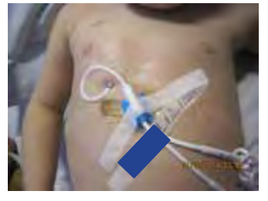
Application of silver hydrofiber

Healed skin on another child who required this intervention.

PATIENT OUTCOMES:
In one of the three noted cases, nursing was challenged by atypical routine, resulting in exacerbation and recurrence of skin breakdown. However, all patients who have been treated with this innovative approach have ultimately demonstrated excellent healing without secondary sequelae,

CONCLUSIONS:
Silver hydrofiber and film dressing with betadine cleansing has proven to be an effective alternative for the authors in treating contact dermatitis related to CHG cleansing and dressings while still protecting the patients from CRBSIs.

ORGANIZATIONAL IMPACT:
A new antimicrobial film dressing was brought in that contains chlorhexidine acetate and silver sulphate. To date, no patients have developed CHG dermatitis or irritant contact dermatitis from this new dressing.



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O'Grady, N. P., et al. (2011). Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Centers for Disease Control and Prevention. Retrieved from: http ://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf.
Weitz,N. A., et al. (2013). Chlorhexidine Gluconate Impregnated Central Acess Catheter Dressings as a Cause of Erosive Contact Dermatitis. *JAMA Dermatol. 2013;149(2):195-199.*

LABORATORY STUDY OF THE ANTIMICROBIAL ACTIVITY OF A NOVEL ANTIMICROBIAL DRESSING WITH SOFT SILICONE ADHESIVE

AUTHORS: Val DiTizio (Covalon Technologies Ltd., Ontario, Canada)

INTRODUCTION

Healthcare-associated infections in hospitals are a significant economic burden on healthcare systems. Although antiseptics are used to disinfect compromised skin, bacteria remain on the skin and bacterial re-growth occurs over time1. One of the solutions to help minimise infection is to incorporate antimicrobial agents within a dressing to be used as a protective cover on compromised skin and prevent bacterial contamination. A novel breathable and transparent polyurethane film dressing has been developed which has two antimicrobial agents (chlorhexidine and silver) incorporated into a soft silicone adhesive layer (Figure 1).

AIMS

This poster describes the results of a laboratory study that was undertaken to evaluate the in vitro antimicrobial efficacy of a novel film dressing with a soft silicone adhesive layer incorporating chlorhexidine and silver (SSF-CHX/Ag). The sustained antimicrobial performance of this dressing against eight clinically relevant microorganisms was assessed using an in vitro 7-day time-kill study.

METHODS

The antimicrobial efficacy of SSF-CHX/Ag was determined using a modified ISO 22196 assay2. Samples of each dressing were placed in Petri dishes and inoculated with the challenge organisms (8 individual 0.04 ml aliquots of 106CFU/ml). Moistened filter papers were placed adjacent to each sample to prevent inoculum evaporation and the inoculated test dressings were incubated at 30°C for 7 days. Organism survival was assessed after days 0.5, 1, 4 and 7 of incubation.

The "value of antimicrobial activity" (R-value) was calculated using the formula, R-value = (A0) – (AT), where A0 is the mean log10 of viable organisms recovered from test samples immediately after inoculation and AT is the mean log10 of viable organisms recovered after the contact time. This R-value represents a change in cell number, with a positive figure representing a reduction in the number of microorganisms. Antimicrobial activity was demonstrated by an R-value of ≥4.00, corresponding to a percentage reduction of ≥99.99 %.

All tests were performed in triplicate. The antimicrobial effect of SSF-CHX/Ag was compared with a film dressing with soft silicone adhesive layer containing no antimicrobial agents (control) (SSF). Three sizes of SSF-CHX/Ag were tested: 6 x 7 (Dressing A), 4 x 4 (Dressing B) and 10 x 12 cm (Dressing C).

Eight microorganisms were used in this test: Methicillin-resistant *Staphylococcus aureus* (MRSA, ATCC 33591), *Pseudomonas aeruginosa* (ATCC 9027), *Staphylococcus epidermidis* (ATCC 12228), *vancomycinresistant Enterococcus faecalis* (VRE, ATCC 51299), Klebsiella pneumoniae (ATCC 4352), *Enterobacter cloacae* (ATCC 13047), *Candida albicans* (ATCC 10231) and *Candida tropicalis* (ATCC 750)

RESULTS

Table 1 shows the average number of viable microorganisms immediately after inoculation of the dressing samples. The antimicrobial activity of the dressing samples is expressed by the R-value, the change in the number of viable microorganisms recovered at the start of the test (Table 1) and at various time points thereafter.

As set out in the Methods section, the higher the R-value the greater the antimicrobial activity. SSF-CHX/Ag showed an antimicrobial activity score of >4.00 against Gram-positive and Gram-negative bacteria as well as yeast over the course of the 7 day assay (Figure 2). This corresponds to a greater than 99.99 % reduction in microorganism numbers. The SSF control did not exhibit significant antimicrobial activity at any point over the course of the study, with some instances of positive microbial growth over the course of the 7 day assay (represented by negative values in Figure 2).

DISCUSSION

The results indicate that the antimicrobial dressing with soft silicone adhesive, in which the antimicrobial agents are incorporated into the adhesive layer, is associated with a sustained antimicrobial effect against a range of microorganisms for up to 7 days.

CONCLUSION

Based on the results of this *in vitro* evaluation, combining the chlorhexidine and silver with the soft silicone adhesive layer adds antimicrobial benefits to an adhesive layer already known for its atraumatic properties, providing antimicrobial efficacy over an extended time period against a range of clinically relevant microorganisms.

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2. ISO 22196:2007: Plastics – measurement of antibacterial activity on plastic surfaces.

Figure 1: IV Clear. The utilisation of a soft silicone adhesive layer facilitates atraumatic dressing changes and minimal pain on removal.

Microorganism	Number of viable microorganisms (Log_{10})			
	Dressing A	Dressing B	Dressing C	Control
Staphylococcus aureus	6.32	6.29	6.18	6.27
Staphylococcus epidermidis	5.86	5.78	5.83	5.60
Pseudomonas aeruginosa	6.33	6.36	6.30	6.35
Klebsiella pneumoniae	6.07	6.19	6.24	6.34
Enterobacter cloacae	6.29	6.27	6.32	6.25
Enterococcus faecalis	5.92	6.12	6.15	6.03
Candida albicans	5.66	6.04	5.83	5.87
Candida tropicalis	5.56	5.59	5.74	5.66

Table 1: Log_{10} values of the number of viable microorganisms (CFU/test sample) recovered from treated samples immediately after inoculation.

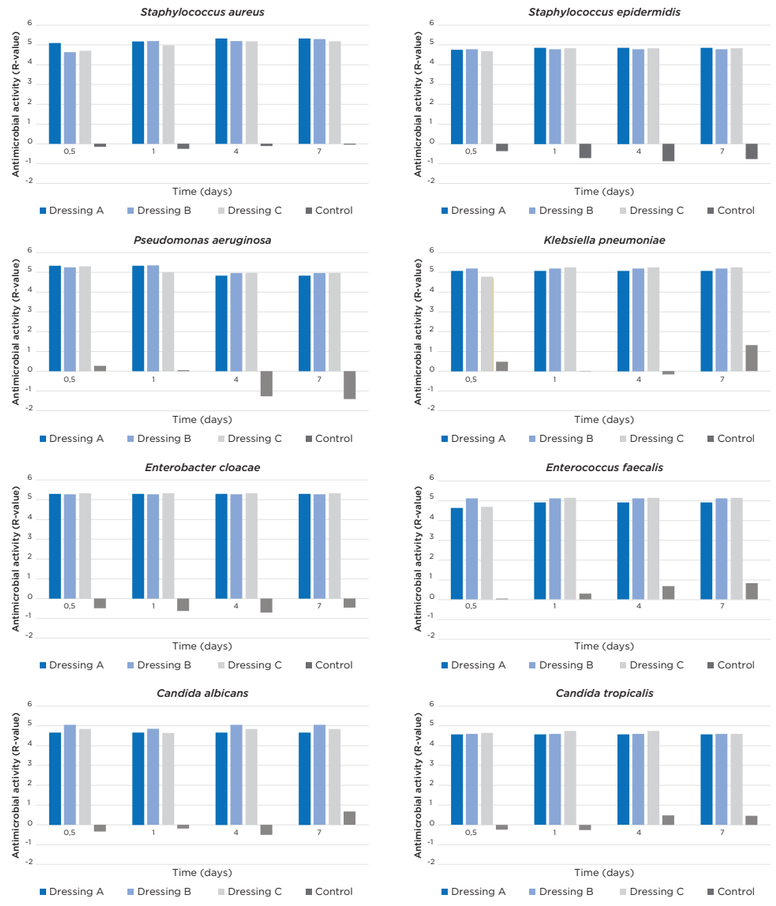

Figure 2: Average log reduction of microorganisms by SSF-CHX/Ag. Antimicrobial activity R-values represent a comparison between microbial numbers at the start of the test with numbers at various subsequent time points (Days 1, 4 and 7). The higher the R-value, the greater the antimicrobial activity and the greater reduction in microbial numbers over the course of the assay. An R-value (log reduction) of 4 represents a 99.99 % reduction in microbial numbers.

SSF-CHX/Ag exhibits significant antimicrobial activity at all time-points and across all microorganisms tested. The control dressing (SSF) shows no significant antimicrobial activity: in some instances, microbial growth is seen over the course of the study (represented as negative antimicrobial activity values). Three sizes of SSF-CHX/Ag were tested: 6 x 7 (Dressing A), 4 x 4 (Dressing B) and 10 x 12 cm (Dressing C).

AN INVESTIGATION INTO THE ABILITY OF AN ANTIMICROBIAL DRESSING WITH SOFT SILICONE TO PREVENT MICROBIAL RE-GROWTH

AUTHORS: Val DiTizio (Covalon Technologies Ltd., Ontario, Canada)

INTRODUCTION

The use of intravascular catheters is associated with a high risk of infection (superficial skin and bloodstream infection). They have a significant impact on patient health and are associated with increased healthcare costs (e.g. increasing the length of hospital stay)[1]. Skin antisepsis and the use of antimicrobial catheters and catheter site dressings are used to reduce the risk of catheter-related infections.[2,3] Recent developments in dressing technology have led to the incorporation of antimicrobial agents directly into the adhesive layer of film dressings.

AIMS

This poster reports on the results of an investigation that was undertaken to evaluate the antimicrobial activity of a film dressing with soft silicone adhesive layer incorporating a combination of antimicrobial agents (chlorhexidine and silver) against native skin microflora (Figure 1).

METHODS

This was a single-centre, blinded, within-subject randomized study, where each subject served as his or her own control by using five test sites per test area (Figure 2). A total of 37 human volunteers were enrolled and 34 completed the study. On study day 0, two skin sites located in the centre of the two test areas were sampled for baseline microflora counts (Figure 2, site "B"). Using a randomized schedule, one test area was prepped with 70% isopropyl alcohol for one minute, left to air dry and an immediate post-prep microflora sample was obtained.

Three test dressings were compared in this study: a film dressing with a soft silicone adhesive layer incorporating chlorhexidine and silver (SSF-CHX/Ag), a control film dressing with a soft silicone adhesive layer containing no antimicrobial agents (SSF), and a comparison film dressing with an acrylic adhesive border and a central pad containing chlorhexidine gel (AAF-CHX) (Table 1).

The dressings were applied to the prepped skin and left in place for 4 or 7 days. Quantitative skin cultures using the Williamson-Kligman scrub cup technique[4] were obtained from one side (by random assignment) after 4 days and the contralateral side after 7 days. Two locations under each dressing were sampled under the centre of each dressing and an area at least 1.0 cm distance from where the centre sample was taken. In the case of the AAF-CHX dressing, samples were taken from the centre of the dressing (area covered by the antimicrobial gel) and an area underneath the border clear/mesh tape area.

The study was approved by an external Institutional Review Board. Healthy adult volunteers without a primary skin disorder were screened before written consent was signed.

RESULTS

There was a significant reduction in the baseline skin microfloral population after skin prepping with 70% isopropyl alcohol ($p<0.05$) (Figure 3).

Microbial populations under center dressing site

Skin microflora regrowth measurement results showed that the microbial population under the center site of the SSF-CHX/Ag and AAF-CHX dressing was not significantly different from the 70% isopropyl alcohol post-prep population after 4 and 7 days of dressing wear ($p>0.05$) (Figure 4). However, the microbial population under the centre site of the control SSF dressing (no antimicrobial agents) was significantly greater than the alcohol post-prep population after 4 and 7 days. The microbial population under the centre site of the SSF-CHX/Ag and AAF-CHX dressings was significantly less than under the centre site of the SSF dressing ($p<0.05$). There was no significant difference under the centre site in microbial flora populations between SSF-CHX/Ag and AAF-CHX dressing after 4 and 7 days of dressing wear ($p>0.05$).

Microbial populations under off-centre dressing site

The microbial population under the off-centre site of the SSF-CHX/Ag dressing after 4 and 7 days was not significantly different from the alcohol post-prep population ($p>0.05$) (Figure 4). After 4 and 7 days, the microbial population under the off-centre site of the SSF-CHX/Ag dressing was significantly less than under the off-centre site of both the AAF-CHX and control SSF dressings ($p<0.05$). The microbial population under the offcentre site of both the AAF-CHX and control SSF dressings was significantly greater than the alcohol post-prep population. The microbial population under the off-centre site of the AAF-CHX dressing was significantly less than the control SSF dressing ($p<0.05$).

DISCUSSION

The SSF-CHX/Ag dressing maintained significant reductions in skin microflora for up to 7 days and this effect was equivalent to the AF-CHX dressing featuring the central antimicrobial gel pad. Unlike the AAF-CHX dressing, where the antimicrobial efficacy was restricted to beneath the central pad, the antimicrobial action of the SSF-CHX/Ag dressing extended to the edge of the film dressing for the duration of the study. The antimicrobial action across the entire skin-contacting surface of the SSF-CHX/Ag dressing helps minimise the opportunity for bacterial growth under the film dressing and reduces skin and/or wound infection risk.

CONCLUSION

The incorporation of chlorhexidine and silver into the soft silicone adhesive layer of the antimicrobial dressing effectively suppresses re-growth over the entire surface of the dressing for up to 7 days, minimising the risk of skin infection, particularly at catheter insertion sites.

REFERENCES

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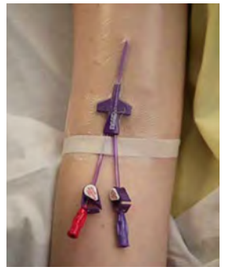

Figure 1: IV Clear in situ. The utilisation of a soft silicone adhesive layer facilitates atraumatic dressing changes and minimal pain on removal.

Dressing Abbreviation	Summary
SSF-CHX/Ag	Film dressing with soft silicone adhesive layer incorporating chlorhexidine and silver
AAF-CHX	Film dressing with acrylic adhesive border and central pad containing chlorhexidine gel
SSF	Film dressing with soft silicone adhesive layer containing no antimicrobial agents

Figure 1: Summary description of dressings used in this study.

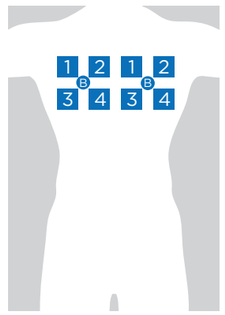

Figure 2: Site map for sampling of cutaneous microflora and positioning of the test dressings. The back is divided into two zones, each made up of four subsections, labelled 1–4. The location where baseline samples were taken is denoted B.

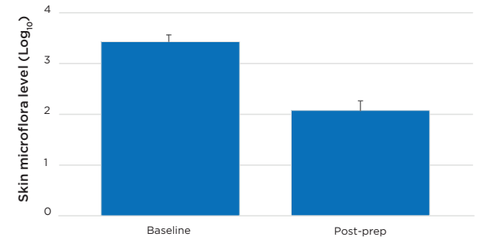

Figure 3: Reduction in skin microflora numbers from baseline levels after skin prepping with 70% isopropyl alcohol (mean 3 S.E.M.).

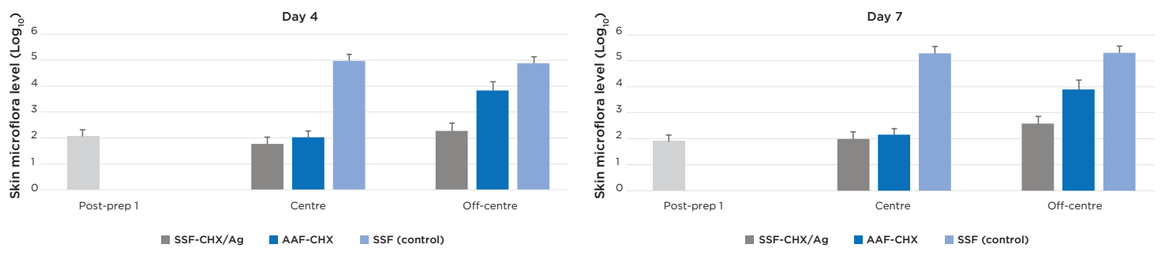

Figure 3: Human regrowth prevention study results (mean ± S.E.M.).

A HUMAN REPEAT PATCH TEST STUDY

AUTHORS: Val DiTizio (Covalon Technologies Ltd., Ontario, Canada)

INTRODUCTION

Catheter-related bloodstream infections (CRBSI) are the most frequent lifethreatening complication of vascular access. Although cutaneous antisepsis prior to catheter insertion helps minimise bacterial contamination of the insertion site, microorganisms can quickly grow back and pose a risk of causing infection. A novel breathable and transparent polyurethane film dressing has been developed for use at catheter insertion sites which has two antimicrobial agents (chlorhexidine and silver) incorporated into a soft silicone adhesive layer to aid minimising the risk of catheter site infection (Figure 1). The development of cutaneous irritation with prolonged use of dressings is not uncommon in wound care due to the potential release of chemicals as well as skin damage arising from skin stripping that accompanies application and re-application of adhesive products.

AIMS

This poster describes the results of a study that was undertaken to evaluate a film dressing with a soft silicone adhesive layer incorporating chlorhexidine and silver for the induction of contact sensitisation by repetitive applications to the skin of normal healthy volunteers in a repeated insult patch test (RIPT). In addition, the adhesive properties and pain upon removal at selected time points were evaluated and compared to a control and challenge dressing.

METHODS

Repeat patch tests are routinely used to determine the potential irritancy of products. The test evaluates the potential induction of contact sensitisation by repetitive applications of materials to the skin of healthy volunteers using a modified version of the Draize Test[1,2]. In addition to the film dressing with a soft silicone adhesive layer incorporating chlorhexidine and silver (SSF-CHX/Ag), a reference film dressing with a soft silicone adhesive layer containing no antimicrobial agents (SSF) was used as a control. For comparison studies, a film dressing with an acrylic adhesive border and central pad containing chlorhexidine gel (AAF-CHX) was included in the studies (Table 1). As the AAF-CHX dressing has two distinct areas (central antimicrobial pad (AAF-CHX-1) and adhesive border (AAF-CHX-2)) sensitisation and irritation were assessed in both areas.

This was a single-centre, blinded, within-subject randomised study. The test consisted of three phases, Induction, Rest and Challenge. A total of nine applications of test dressings were applied over a 3-week period to the back of 216 volunteers (63 male, 153 female). Test dressings were worn for 48 or 72 hours. Dressing adhesion and pain on removal was assessed on days 8 (Study Visit 4), 15 (Study Visit 7), 22 (Study Visit 10) and 38 (Study Visit 12) after first application. Following the Induction Phase, the volunteers had a 2-week exposure-free period (Rest Phase). During the Challenge Phase, a single 48-hour application of dressings was made to a naïve site for all volunteers. Skin evaluations were carried out post-removal of the test dressings. Assessment of skin irritation was based upon the Berger and Bowman scale[3] and scores represented the presence of clinically significant effects (at least 25% of the test site affected). Skin reactions were assessed at least 30 minutes post-removal of dressings and scoring was conducted using a 100W incandescent blue bulb lamp to illuminate the patch areas. Friedman Rank Sum test was used to analyse the irritation data and differences were considered significant at the 0.05 level. Additionally, volunteers assessed pain upon removal at Study Visits 4, 7, 10 and 12. Pain upon removal was rated on a scale from 0 (no pain) to 9 (worst possible pain). Adhesion was rated on a scale from 0 (≥90 % adhered), 1 (≥75 % to <90 % adhered), 2 (≥50 % to <75 % adhered), 3 (>0 % to <50 % adhered) to 4 (0 % adhered/ test dressing detached).

The study was approved by an external Institutional Review Board. Healthy adult volunteers not known to be allergic to chlorhexidine and/or silver and without a primary skin disorder were screened before written consent was signed.

RESULTS

Sensitisation

Interpretation of the data was based on the pattern of reactivity of the dressing during Induction Phase when compared to the severity and persistence of the reaction(s) observed at the Challenge Phase. Under the conditions of the study,there was no evidence of induced contact sensitisation for SSF-CHX/Ag, SSF and AAF-CHX (AAF-CHX-1 and AAF-CHX-2).

Irritation

Assessment of skin irritation was based upon the Berger and Bowman scale3. Analysis of irritation scores during Induction Phase showed that the SSF-CHX/Ag and SSF showed significantly less irritation ($p<0.05$) than the surrounding adhesive border of AAF-CHX (AAF-CHX-2) at each evaluation and overall (Figure 2). Additionally, sites covered with the SSF-CHX/Ag and SSF exhibited significantly less irritation ($p<0.05$) than the central pad area of AAF-CHX (AAF-CHX-1) at two time points (Study Visits 4 and 7) and overall.

Adhesion and pain on removal

Based upon adhesion scores obtained during Induction Phase, AAF-CHX showed a stronger adherence (3.79 3 0.04, mean 3 SEM) at Visits 4, 7 and 10 compared with the soft silicone adhesive dressings (SSF-CHX/Ag, 3.07 3 0.07 and control SSF, 2.7 3 0.08). The film dressings showing the greatest level of skin adhesion also showed the greater level of pain reported by patients. Based upon pain scores obtained during Induction Phase, SSF-CHX/Ag and SSF elicited very low pain scores in patients compared with AAF-CHX ($p<0.05$) and were, on average, 10x lower than the level of pain on removal experienced in patients wearing AAF-CHX (Figure 2). For example, patients with SSF-CHX/Ag nor SSF did not score greater than a 3 in the pain scale, whilst a proportion of patients with AAF-CHX experienced significant pain, scoring up to the maximum pain scores (Figure 3).

DISCUSSION

The level of adhesion is an important property of dressings placed on skin. There must be a balance between there being enough adhesion for the dressing to remain in place upon application and for the duration of the wear time but not enough to cause tissue trauma and pain on removal. Many traditional dressings incorporate acrylic as the adhesive but this adhesive can be aggressive leading to pain upon removal, tissue damage and irritation[4]. Soft silicone is an alternate adhesive technology offering a more appropriate level of adhesion, balancing the need for adhesion to tissue but being easily removed with minimal pain on removal. This study showed that the test subjects using film dressings with a soft silicone adhesive layer (SSF-CHX/Ag and SSF) experienced up to ten times lower pain levels than those with the film dressing with acrylic adhesives (AAF-CHX). Acrylic adhesive dressings have a tendency to leave residues on the skin and this, together with the likelihood that these aggressive dressings result in local tissue damage, is likely to lead to the elevated irritation scores seen in skin under the adhesive border of AAF-CHX.

CONCLUSION

The results of this study suggest that the film dressing with a soft silicone adhesive layer incorporating antimicrobial agents will be extremely well-tolerated by patients. These dressings balance the need for adhesion to the skin with being atraumatic and minimising irritation and pain on removal.

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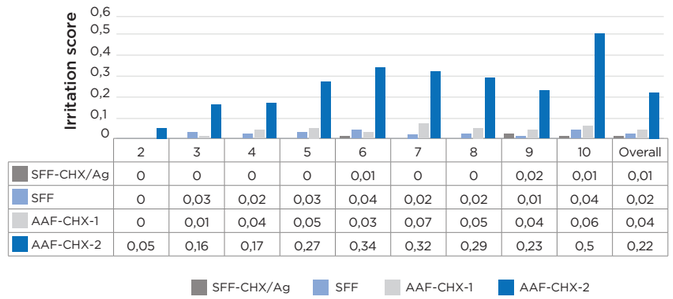
Figure 1: IV Clear. The utilisation of a soft silicone adhesive layer facilitates atraumatic dressing changes and minimal pain on removal.

Dressing Abbreviation	Summary
SSF-CHX/Ag	Film dressing with soft silicone adhesive layer incorporating chlorhexidine and silver
AAF-CHX	Film dressing with acrylic adhesive border (AAF-CHX-2) and central pad containing chlorhexidine gel (AAF-CHX-1)
SSF	Film dressing with soft silicone adhesive layer containing no antimicrobial agents

Table 1: Summary description of dressings used in this study.



	2	3	4	5	6	7	8	9	10	Overall
SFF-CHX/Ag	0	0	0	0	0,01	0	0	0,02	0,01	0,01
SFF	0	0,03	0,02	0,03	0,04	0,02	0,02	0,01	0,04	0,02
AAF-CHX-1	0	0,01	0,04	0,05	0,03	0,07	0,05	0,04	0,06	0,04
AAF-CHX-2	0,05	0,16	0,17	0,27	0,34	0,32	0,29	0,23	0,5	0,22

Figure 2: Mean irritation score3 results from each Study Visit and overall. There is a significant difference between SSF-CHX/Ag and SSF versus AAF-CHX-2 at each evaluation and overall. A significant difference is seen between SSF-CHX/Ag and SSF versus AAF-CHX-1 at Study Visit 4 and 7.

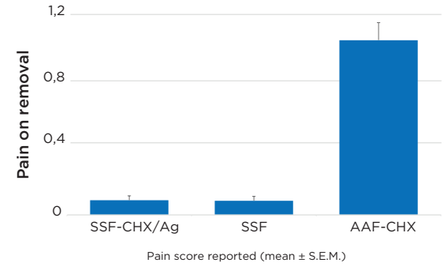


Figure 3: Comparison of pain experienced on dressing removal

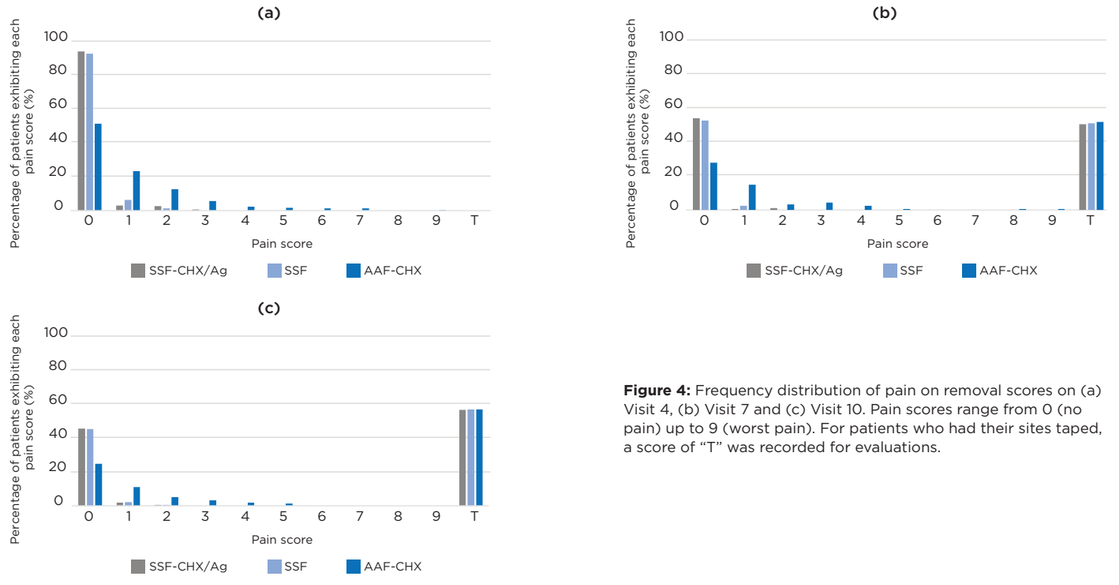


Figure 4: Frequency distribution of pain on removal scores on (a) Visit 4, (b) Visit 7 and (c) Visit 10. Pain scores range from 0 (no pain) up to 9 (worst pain). For patients who had their sites taped, a score of "T" was recorded for evaluations.

A LABORATORY STUDY OF THE SYNERGISTIC EFFECT OF CHLORHEXIDINE AND SILVER

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INTRODUCTION

Healthcare-associated infections (HAIs) are a significant economic burden on healthcare systems. Skin antisepsis is a key factor in preventing many of these HAIs associated with skin microorganisms. However, the persistence of bacteria on the skin after antiseptic treatment and the bacteria's ability to repopulate these treated areas over time[1] suggest that, in cases where the skin is compromised, infection remains a risk.

Combination therapy may be used to extend the range over which antimicrobials work and may help to prevent the emergence of resistant strains and provide a synergy between antimicrobials.[2,3]

AIMS

This poster describes the results of a study that was undertaken to evaluate in vitro the antimicrobial activity of a combination of two antimicrobial agents, chlorhexidine diacetate (CHA) and silver sulphate, against five different strains of bacteria.

METHODS

Microorganisms

Strains used in this study were two type strains (ATCC 15692 (PAO1), ATCC 15442) and two clinical isolates (isolate A & isolate B) of *Pseudomonas aeruginosa* and one type strain of Methicillin-resistant *Staphylococcus aureus* (MRSA).

Bacterial suspensions were prepared by inoculating colonies to Mueller-Hinton Broth (MHB) followed by overnight incubation at 37°C. Suspensions were adjusted to a working dilution of 1-2x10^6 CFU/ml.

Checkerboard assay to assess antimicrobial activity of CHA and silver sulphate (Ag_2SO_4)

The MICs (Minimum Inhibitory Concentrations) of CHA and silver sulphate were determined using a broth microdilution assay[4]. A two-dimensional checkerboard with two-fold dilutions of each substance were run. Volumes at 50 Ql of CHA were diluted from column 1 to column 8 and silver sulphate from row A to row H, respectively, were added in a 96-well assay plate. Then 100 Ql of the respective bacteria suspension (at 1-2x10^6 cells/ml) was added to each well and incubated at 35°C for 24 hours. Appropriate controls were also prepared. Optical density was measured at OD_{595}.

To assess the synergistic or antagonistic activity of antimicrobial combinations, the Fractional Inhibitory Concentration Index (FICI) was determined using the following formula:

$$FICI = \frac{MIC\ for\ CHA\ in\ combination}{MIC\ for\ CHA\ alone} + \frac{MIC\ for\ silver\ sulphate\ in\ combination}{MIC\ for\ silver\ sulphate\ alone}$$

The combination was considered synergistic when the FICI was ≤0.5, indifferent when the FICI was >0.5 to <4, and antagonistic when the FICI was >4.

RESULTS

The values of the MICs of CHA and silver sulphate against the 5 bacterial strains are presented in Table 1. The checkerboard assay was repeated at lower dilutions to find the lowest dilution that gives inhibitory effect when the antimicrobial agents are combined (Table 2).

The data show that the combination of CHA and silver sulphate demonstrated synergistic activity against all strains of bacteria. That is, there was a reduction observed in the CHA and silver sulphate concentrations required to inhibit *P. aeruginosa* and MRSA when these antimicrobial agents were combined, compared with their activity when assayed in isolation (Table 1 and 2).

DISCUSSION

The aim of this study was to assess the antimicrobial efficacy of chlorhexidine diacetate and silver sulphate in combination against *P. aeruginosa* and MRSA. The results demonstrate that combining CHA with silver sulphate improved the antimicrobial activity of both CHA and silver sulphate against type strains and clinical isolates with both antimicrobial agents showing synergism when combined.

CONCLUSION

The combination of chlorhexidine diacetate and silver sulphate has synergistic, enhanced antibacterial activity against several strains of *P. aeruginosa* and MRSA. These results suggest improved skin antisepsis when these antimicrobial agents are used in combination in a cover dressing.

Species	Strain	MIC_{CHA} (µg/ml)		MIC_{Ag} (µg/ml)		FICI	Result
		alone	combination	alone	combination		
P. aeruginosa	ATCC 15692	22	≤1.4	10	≤2.0	0.26	synergy
	ATCC 15442	44	≤1.4	10	≤2.0	0.23	synergy
	Clinical isolate A	44	≤1.4	10	≤2.0	0.23	synergy
	Clinical isolate B	44	1.4	10	2.0	0.23	synergy
MRSA	ATCC 12600	0.7	≤1.4	2.5	≤2.0	NPC	NPC

MIC = Minimum Inhibitory Concentration. CHA = Chlorhexidine diacetate. FICI = Fractional Inhibitory Concentration Index. NPC = Not Possible to Calculate.

Table 1: Checkerboard assay assessment of interaction between CHA and silver sulphate against *P. aeruginosa* and MRSA.

Species	Strain	MIC_{CHA} (µg/ml)		MIC_{Ag} (µg/ml)		FICI	Result
		alone	combination	alone	combination		
P. aeruginosa	ATCC 15692	22	≤0.14	10	0.39	0.045	synergy
MRSA	ATCC 12600	0.7	0.05	2.5	0.63	0.32	synergy

MIC = Minimum Inhibitory Concentration. CHA = Chlorhexidine diacetate. FICI = Fractional Inhibitory Concentration Index.

Table 2: Checkerboard assay assessment at lower dilutions than presented in table 1 to find the lowest dilution that gives inhibitory effect when the antimicrobial agents are combined against *P. aeruginosa* and MRSA.

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Clinical Performance of a New Clear Silicone Adhesive Dressing with Chlorhexidine and Silver for Central Vascular Access Devices (VADs): Wearability, Comfort and Incidence of Irritant Contact Dermatitis

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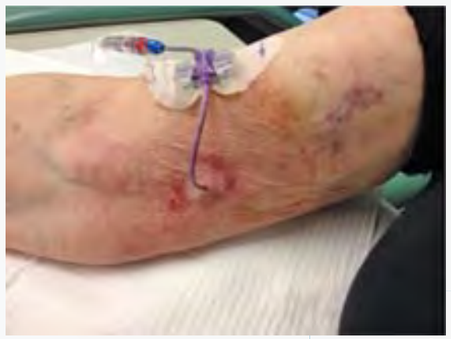
Background

- Vascular access devices (VADs) are essential to the treatment of oncology patients.
- Cutaneous changes in oncology patients lead to increased incidence of irritant contact dermatitis (ICD) at Peripherally Inserted Central Catheter (PICC) insertion sites.[1]
- ICD is precipitated and exacerbated by exposure to adhesives and antiseptics.
- Best practice guidelines for ICD recommend elimination of the cause. This can be done by avoiding or eliminating the most likely irritant, i.e. CHG and the occlusive transparent semipermeable dressing, followed by substitution of an alternate agent and/or dressing.[1]



Skin with Irritant Contact Dermatitis

Consequences of Irritant Contact Dermatis (ICD)

- ICD may contribute to unnecessary removal of the PICC due to suspicions of site dermatitis representing infection.
- ICD may lead to development of a localized infection at the PICC site in immunocompromised patients which may increase the risk for CLABSI. [2,3]

Study Aims

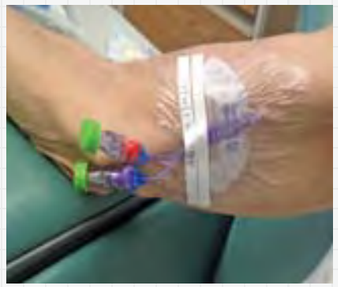
- A feasibility pilot to determine clinical performance and wearability of a novel Clear Silicone Adhesive Dressing with Chlorhexidine and silver on PICCs among oncology patients with cutaneous skin changes and previous episodes of ICD.

Project

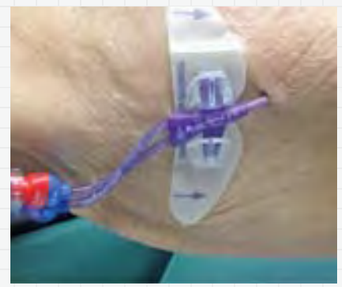
- 18 adult outpatients receiving standard PICC dressings were invited to be part of a 30-day trial using the new dressing from June 20 – July 20, 2013.
- Weekly dressing changes and data collection were done by the Ambulatory Infusion Center RNs.

Results...

- 72% (13/18) rated the dressing clinically superior with optimal performance during activities of daily living (ADLs).
- 28% (5/18) rated the dressing acceptable.
- 100% (18/18) rated the dressing as very comfortable (no pain) on removal.
- 100% of subjects showed absence of irritant contact dermatitis.



Dressing post 1-week of wear



Skin post removal of clear silicone adhesive dressing

Conclusion

The Clear Silicone Adhesive Dressing was found to have these unique and highly desirable characteristics:

- A clear polyurethane film coated with an antimicrobial silicone adhesive which allows for visualization of the catheter site.
- Protection from ICD with the non-sensitizing silicone layer.
- Combined silver and Chlorhexidine antimicrobial protection over the full surface area of the dressing for up to 7 days.

Implications

- Based on this evidence-based pilot, this new dressing has been adopted in our outpatient infusion center for high-risk patients.
- The dressing is comfortable and secures VADs to the skin while providing antimicrobial protection with little or no ICD.

Recommendations

- A rigorous randomized clinical trial (RCT) is needed to evaluate effectiveness of the impregnated anti-microbial agents in reducing CLABSI and ICD in acutely ill hospitalized patients.

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