Cutimed® Sorbact®

Safe and effective infection management

A Clinical Reference Guide

Cutimed®

Product: Cutimed Sorbact									
Author	Cooper and Jenkins	Powell	G. Mosti et al	Kleintjes, Schoeman, Collier	Groithier and Stephenson	Stanirowski et al	Bateman	Bullough et al	Haycocks and Chadwick
Title	Binding of two bacterial biofilms to dialkyl carbamoyl chloride (DACC)-coated dressings in vitro	Evaluating Cutimed Sorbact: using a case study approach	Comparative study of two antimicrobial dressings in infected leg ulcers: a pilot study	A random prospective pilot study of Sorbact versus Acticoat versus Silveron in a south African Adult burns unit	An Audit to determine the clinical effectiveness of a pathway for managing wound infection	Randomized Controlled Trial Evaluating Dialkyl carbamoyl Chloride Impregnated Dressings for the Prevention of Surgical Site Infections in Adult Women Undergoing Cesarean Section	Evidence is building to support using a DACC-coated antimicrobial wound contact layer with NPWT	The use of DACC-coated dressings for the treatment of infected, complex abdominal wounds	Use of DACC-coated dressings in diabetic foot ulcers:a case series
Year of publication	2016	2009	2015	2015	2015	2016	2015	2012	2011
Type of study	Vitro	Case study	Comparative study	Random prospective pilot study	Retrospective Audit	Randomised controlled Trial (RCT)	Case series	Case study	Case series
Level of evidence	3	3	2	3	3	1	3	3	3
Number of centres	1	1	1	1	1	1	1	1	1
Number of patients	0	6	40	13	151	543	10	4	19
Wound types									
Leg ulcers		✔	✔		✔		✔		
Pressure ulcers					✔		✔		
Skin grafts									
Dehisced surgical wounds					✔		✔	✔	
Diabetic foot ulcers									✔
Surgical wound		✔				✔	✔		
Fungating wounds		✔							
Burns				✔					
Other					✔		✔		
Effective at reducing bacterial bioburden									
Reduced bioburden levels	✔	✔	✔	✔	✔	✔	✔	✔	✔
Swab results			✔	✔			✔	✔	
Critical colonisation		✔	✔	✔	✔				
Prophylactic use					✔	✔		✔	✔
Local Infection		✔	✔				✔	✔	✔
Biofilms	✔			✔					
Effective against a wide range of bacteria and fungi									
Staphylococus Aureus			✔						
Pseudomonas	✔		✔	✔					
MRSA	✔		✔	✔					
Proteus mirabilis			✔	✔					
Enterococcus faecalis			✔					✔	
Escherichia coli			✔						
Klebisella			✔						
Enterobactercloacae									
Reduced signs and symptoms of infection									
Exudate levels		✔	✔		✔		✔	✔	✔
Odour		✔	✔		✔			✔	✔
Pain		✔	✔		✔			✔	✔
Wound healing progression		✔	✔	✔	✔	✔	✔	✔	✔
Removal of slough and devitilised tissue		✔		✔	✔			✔	
Quality and process outcomes									
Patient comfort		✔							✔
Easy application									
Cost savings		✔			✔	✔	✔	✔	
Saving nursing time		✔			✔	✔	✔		
Quality of life		✔			✔			✔	
Who would benefit from seeing this article?									
Wound Care	✔	✔	✔	✔	✔	✔	✔	✔	✔
Community Nurse	✔	✔	✔	✔	✔	✔	✔	✔	✔
Practice Nurses	✔	✔	✔	✔	✔	✔	✔	✔	✔
Podiatrists	✔	✔	✔	✔	✔	✔	✔		✔
Surgeons	✔	✔	✔	✔		✔	✔	✔	
Lymphodema Specialists			✔						
Procurement					✔	✔	✔		

Binding of two bacterial Biofilms to Dialkyl Carbamoyl Chloride (dacc) - coated dressings in vitro

Reference Cooper, R. Jenkins, L,. (2016). Journal of wound care. Vol 25. No 2.
Type of study Vitro Study

Objective In a lab environment (vitro) DACC coated dressings were tested against a non-coated dressing to establish its effectiveness of binding two bacterial Biofilms, Pseudomonas aeruginosa and MRSA.

Methods Samples of DACC – coated dressings and uncoated control dressings were placed in contact with plastic coverslips on which biofilms of either pseudomonas aeruginosa or methicillin – resistant staphylococcus (MRSA) had been cultivated for 24 hours.
Dressing samples were examined by scanning electron microscopy to detect the presence of biofilm.

Results The results demonstrated the following:

- Results suggested that the bacterial biofilm pseudomonas bounded to all the test products rapidly and extensively, however showing no marked difference between the coated and non-coated product.
- The bacterial Biofilm MRSA, was slower to uptake however after 3 hour contact there was a significant difference between the amount of biofilm on the DACC coated dressing compared to the non-coated.
- This would suggest that DACC was effective at binding both bacterial biofilms, whilst suggesting that the hydrophobic fatty acid derivative on the dressing enhanced biofilm binding in particular to the MRSA biofilm bacteria.

Conclusion This is the first demonstration that DACC-coated dressings bind MRSA and Pseudomonas aeruginosa biofilms in vitro.

Evidence of efficacy

Claims	Statement
Effective against a wide range of bacteria and fungi	“In 2006, the influence of cultural conditions on cell surface hydrophobicity of five planktonic bacteria (staphylococcus aureus, staphylococcus haemolyticus, Escherichia coli, Enterobacter cloacae, and pseudomonas aeruginosa) were investigated and the binding capacity to a dressing coated with a hydrophobic fatty acid derivative called DACC” “Maximum binding was observed at two hours and remained stable for 20 hours, showing that bacteria bound to the dressing did not multiply”
Biofilms	“Binding of MRSA biofilm to dressings was initially at a slower rate compared to pseudomonas aeruginosa. After a 3 hour contact period the coverage of uncoated dressing samples by MRSA biofilm was not as extensive as that of DACC – coated samples, suggesting that the presence of the hydrophobic fatty acid derivative on the dressing surface did enhance biofilm binding”

Evaluating Cutimed Sorbact: Using a case study approach – A six patient clinical evaluation

Reference Powell. G,. (2009). British Journal of Nursing. Vol 8. Supp 5.

Type of study Case study **No. of patients** 6

Objective To demonstrate good clinical outcomes using a bacterial binding dressing range on a variety of difficult wound types.

Methods Using a case study approach, 6 patients with a variety of wound types presenting clinically with increased bacterial bioburden were included in the evaluation.

Wound types

- Leg ulceration
- Breast wound
- Abdominal wound
- Pilonidal sinus

Results Six patients were evaluated using a range of the bacterial binding products and the following results were seen:

- A reduction in exudate levels and odour once commenced on the bacterial binding product range.
- Pain levels appeared to be managed and one patient was able to tolerate full compression, which prior to this treatment plan reduced compression could only be achieved.
- Reduced dressing changes were seen in three cases prior, the patients were receiving daily dressing changes which all changed to a minimum of twice weekly to weekly.
- Wounds that presented with slough and devitalised tissue appeared to improve and granulation tissue was visible once the treatment plan had been change.
- All the wounds showed signs of wound progression and a reduction in overall size, in some cases the wounds progressed onto healing.

Conclusion In all of the cases Cutimed Sorbact demonstrated that it can be an effective treatment for the management of different wound types where critical colonisation and signs of infection are observed.

Evidence of efficacy

Claims	Statement
Any dressing combination	“The primary dressing was changed to Cutimed Sorbact swabs with Sorbion S an absorbent secondary dressing, placed under compression” “It was decided to use Cutimed Sorbact pads under compression with a full compression hose kit”
Effective at reducing bacterial bioburden in critically colonised and infected wounds	“However, anaerobic organisms were resulting in odour and the priority was to remove or reduce this. Treatment with Cutimed Sorbact ribbon and Cutimed Sorbact pad was commenced, with dramatic improvements. Odour diminished by day three, exudate was reduced”
• Reduced exudate levels • Reduced odour • Removal of slough and devitalised tissue	“Within two weeks there was a marked reduction in the amount of exudate and improvement in the wound bed, and after four weeks a dramatic reduction to the wound size (from 17cm x 15cm to 11.5cm x 11cm)” “Treatment with Cutimed Sorbact ribbon and Cutimed Sorbact dressing pads was commenced, with dramatic improvements. Odour diminished by day three, exudate was reduced and the surrounding skin was much improved by week two. The results were marked and were not expected so quickly. De-sloughing was an added bonus in this case and the dressing worked well on high-to-medium exudate levels”
• Quality of life • Nursing time • Cost savings • Reduced pain	“The pain had also improved and at week eight dressing changes had reduced from daily to twice-weekly. Full compression had been initiated and was being well-tolerated” “The patient’s quality of life was improved by the reduction in exudate and the promotion of wound healing. Pain and odour were also reduced”

Comparative study of two antimicrobial dressings in infected leg ulcers: A pilot study

Reference Mosti. G, et al,. (2015). Journal of Wound Care. Vol 24. No 3.

Type of study Randomised comparative single centred study **No. of patients** 40

Objective To compare the efficacy of two different types of antimicrobial dressings, a bacterial binding (MB) dressing with a silver – containing hydrofiber (SCH) dressing, at controlling the bacterial loads of heavily colonised or locally infected chronic venous leg ulcers.

Methods

- Recruitment of patients presenting with hard to heal, critically colonised or locally infected leg ulcers, who could be treated with skin grafting.
- Patients were randomised to either the silver containing dressing or the bacterial binding dressing upon enrolment.
- The primary outcome of the evaluation was to measure reduction in bacterial load, the secondary outcomes were ease of application and also treatment related pain.
- To calculate the reduction in bacterial load, the wounds were swabbed at day 0 and again at day 4, the dressings on each wound was changed daily for both groups.

Wound types Leg ulceration

Results The results demonstrated the following:

- The bacterial binding dressing (MB) was found to be more effective at reducing bacterial load by an average reduction of 73.1% compared to 41.6% for the silver containing hydrofiber (SCH).
- The secondary outcome that measured pain, demonstrated a comparative reduction in both groups.

Conclusion The evaluation confirmed that both the bacterial binding (MB) and silver containing hydrofiber (SCH) dressings are effective at reducing bacterial load in wounds that are critically colonised or locally infected, without inducing adverse events, but with the bacterial binding (MB) dressing demonstrating a significantly more effective response.

Evidence of efficacy

Claims	Statement
Effective against a wide range of bacteria and fungi	“Staphylococcus aureus, methicillin – resistant Staphylococcus aureous (MRSA), Pseudomonona aeruginosa, Enterococcus faecalis, Escherichia coli, Klebisella, enterobactercloacae, and proteus mirabilis were most frequently found on the ulcer bed”
Effective at reducing bacterial bioburden in critically colonised and infected wounds	“After analysing the bacterial load within each group, the results showed a significant reduction of bacterial burden at D4 in both groups” “When comparing bacterial load between groups at D4, the reduction was significantly higher in the MB group (p<0.0001)”
No risk of allergic reactions	”Are both effective in reducing bacterial burden in critically colonised or locally infected chronic venous leg ulcers without inducing adverse events”

A random prospective pilot study of Sorbact versus Acticoat versus Silverlon for the treatment of burn wounds in a South African adult burns unit

Reference Kleintjes, W.G,. Schoeman, D,. Collier, L,. (2015). Wound Healing Southern Africa.

Type of study Random prospective pilot study **No. of patients** 13

Objective To compare three antimicrobial dressings in their effectiveness in managing bacterial bioburden in partial or full thickness burns.

Methods

- The study included a random selection of patients that presented with partial or full thickness burns where the surface area was large and even enough for all three dressings to be used on the same wound.
- Three swabs were taken from the areas underneath the dressings for microscopy, culture and sensitivity.

Wound types Partial or full thickness burns

Results The results demonstrated the following:

- DACC demonstrated a marginal difference in improved removal of slough.
- No compromise in wound healing compared to the silver products used.
- DACC appeared to clean the wounds better than the silver based products DACC 58% Acticoat 33% and Silveron 42%.
- DACC showed lower levels of neutrophils compared to the other products used.
- The incidence of wound infection according to significant bacteria:
- 33% DACC
- 25% Acticoat
- 44% Silveron

Conclusion The pilot study indicated that Cutimed Sorbact is comparable to Acticoat and Silveron when treating burn wounds.

Evidence of efficacy

Claims	Statement
• Reduced bioburden levels • Swab results	“Three pus swabs were taken using the Levine technique from the areas under the three dressings for microscopy, culture and sensitivity”
• Wound healing progression	“Healing at the areas where the dressings were tested separately far from each other showed good healing under all the products”
• Pseudomonas Aeruginosa • Proteus Mirabilis	“The clinical significant bacteria that were cultured with Sorbact were Pseudomonas Aeruginosa (in 2 patients), Proteus Mirabilis and Serratia Fouticola”
• Biofilms	“Sorbact shows marginal increase in biofilm reduction in comparison to the silver dressings, which showed the same biofilm reduction (Figure 19) in comparison to themselves” “The clinical appearance of a biofilm layer on the wound was less with Sorbact (1 case) than with Acticoat® (2 cases) and Silverlon® (2 cases) which is not statistically significant”
• Removal of slough and devitalised tissue	“The Sorbact wound appeared clean in 7 of the 12 patients’ wound data sets” “Sorbact shows marginal increase in clean appearance of the wound in comparison to the silver dressings”

An audit to determine the clinical effectiveness of a pathway for managing wound infection – A 151 patient clinical evaluation

Reference Groithier. G,. Stephenson. J,. (2015). Wounds UK. Vol 11. No 5.

Type of study Retrospective audit **No. of patients** 151

Objective

To establish the clinical effectiveness of a tool designed for the management and prevention of wound infection within a community setting.

Methods

- Data was collected on patients that presented with a wound at a tissue viability centre between January 2013 and March 2014, each patient being assigned to one of the following factors, Red for the management of wound infection, Amber for the management of critically colonised wounds, and Green for the management of a patient deemed as high risk of developing wound infection.
- Initial documentation was completed including wound type, location, and duration of wound, including all presenting signs and symptoms, with a follow up review of the patient after 4 weeks of treatment.

Wound types

- Leg ulceration
- Pressure ulceration
- Surgical wounds
- Wet leaky legs

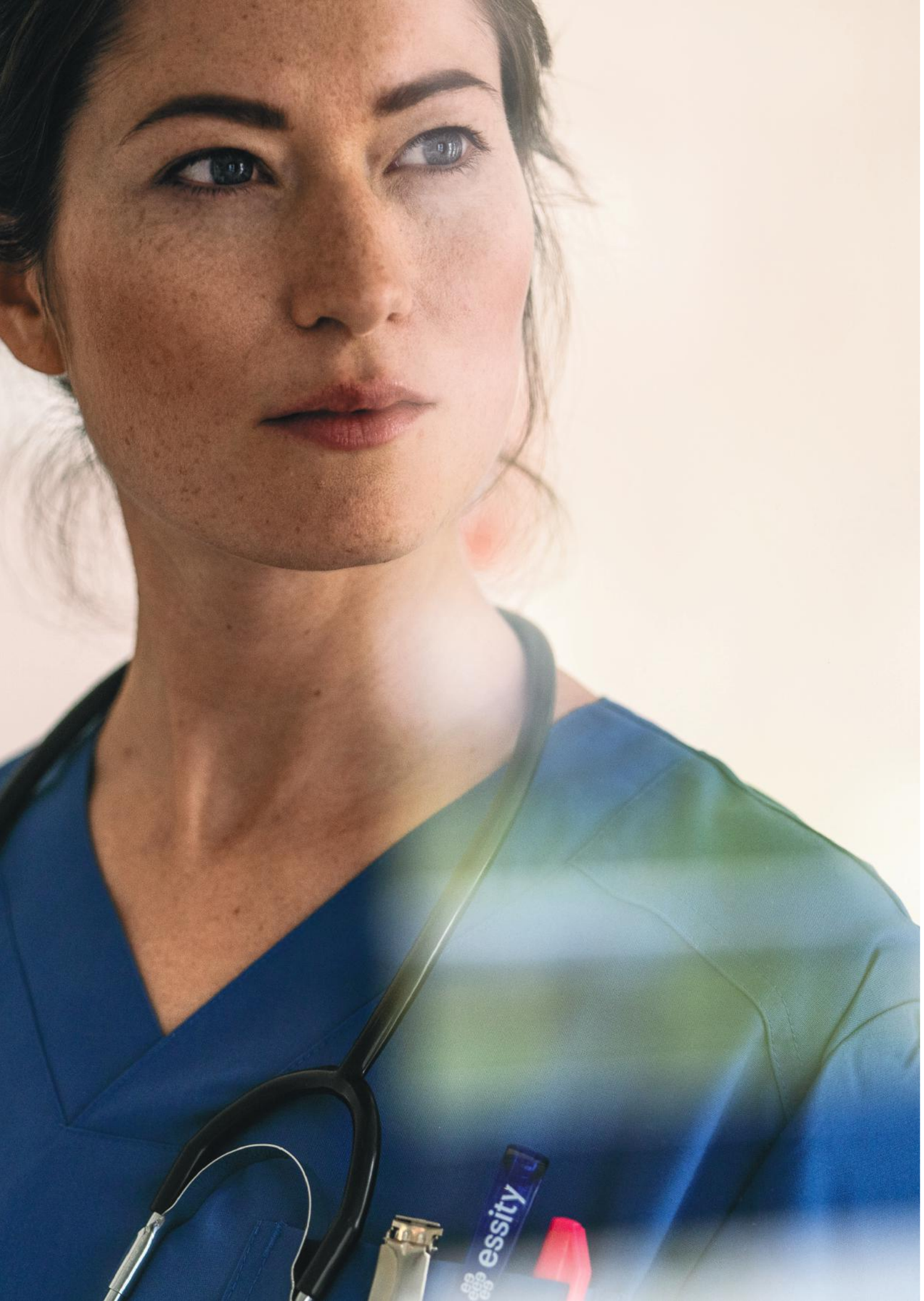
Results/ Conclusion

The results demonstrated the following:

- 92 wounds that were assigned to the green pathway at baseline 86.6% remained infection free and on the green pathway at the four week audit.
- 27 wounds were commenced onto the amber pathway, 75% were transferred to the green pathway indicating improvement in status.
- 28 wounds were assigned to the red pathway, 62.5% were transferred to the green pathway and 12.5% to the amber pathway demonstrating improvement.
- Majority of the wounds demonstrated an improvement in healing progression, with a reduction in signs and symptoms, only 7% demonstrated a decrease in wound healing.
- Two thirds of the patients exudate levels decreased.
- The cost analysis of introducing the pathway was as follows: Previous year 2011/12 cost to the organisation in excess of £130,000, reducing to £68,447 following the introduction of the pathway during 2013/14, indicating appropriate usage and practice in the management of wound infection was being achieved.
- The amber and green pathway demonstrated an additional spend of £88,517, however the total cost of dressings remained under budget by £38,657 for that particular year despite an increase in patient activity of 42%, indicating and supporting the reduction in symptoms and improvement in wound healing progression that was observed in the audit.

Evidence of efficacy

Claims	Statement
• Critical colonisation • Reduced bioburden levels	"Of the 27 wounds assigned to the amber pathway at baseline, 20 (69.0%) were still on a pathway at the 4-week audit. The majority (15; 75.0%) of these wounds had transferred to the green pathway at this point, indicating an improvement in status, with only four (20.0%) remaining on the amber pathway and one wound (5.0%) being transferred to the red pathway"
• Prophylactic use	"Of the 92 wounds assigned to the green pathway at baseline, 79 (85.6%) were still on a pathway at the 4-week audit. Of these 79 wounds, 70 (88.6%) remained on the green pathway, 5 (6.4%) had been transferred to the amber pathway and 4 (5.1%) had been transferred to the red pathway."
• Wound healing progression • Pain reduction • Odour reduction • Reduced levels of exudate	"The majority of wounds as assessed by the tissue viability staff showed improved healing progression over the 4-week period, with only 7% of all wounds reported to be indicating decreased wound healing. An improvement was represented by a decrease in symptoms. Symptoms included pain, malodour and exudate; a reduction was observed in more than half of all wounds" "The parameter in which the greatest proportions of wounds were seen to improve was exudate level (Gottrup et al, 2013): decreased levels were reported in about two thirds of all wounds, with a further quarter showing no change"
• Cost savings	"The annual spend for this local organisation in 2011/12 for products associated with treating wound infection before the introduction of the colour-coded pathway was reported in excess of £130,000 inclusive of silver, iodine and honey dressings. Following introduction of the pathway, this figure reduced to £68,447 during 2013/14 for products used to treat active wound infection (red pathway), suggestive that practice has improved for appropriate treatment of infected wounds" "Within the amber and green elements of the pathway, an additional spend of £88,517 was noted on products that could be safely used for prolonged periods of time (Haycocks et al, 2011). However, for 2013/14, the total cost of dressings remained at £38,657 under the allocated budget of £1.2 million, despite activity increasing by 42% within all services accessing dressing products paid for within this budget"
• Quality of life • Nursing time	"This has led to the patient now being able to participate in his own care, including one dressing change plus removal and re-application of compression hosiery, promoting independence and quality of life. Clinic appointments have reduced to weekly"



Randomized controlled trial evaluating Dialkyl Carbamoyl Chloride impregnated dressings for the prevention of surgical site infections in adult women undergoing caesarean section – A 543 patient clinical evaluation

Reference Stanirowski et al,. (2016) Surgical Infections. Vol 17. No 4.

Type of study Randomised controlled trial **No. of patients** 543

Objective The aim of the study was to evaluate the efficacy and cost-effectiveness of dialkyl carbamoyl chloride (DACC) impregnated dressings to prevent surgical site infection (SSI) in women subjected to a caesarian section surgical procedure.

Methods

- Randomised, controlled trial was conducted at the Mazovian Bro´dno Hospital, a tertiary care center performing approximately 1,300 deliveries per year, between June 2014 and April 2015.
- Patients were randomly allocated to receive either Sorbact surgical dressing (Sorbact) or standard surgical dressing (SSD) following skin closure.
- In order to analyze cost-effectiveness of the selected dressings in the group of patients who developed an SSI, the costs of ambulatory visits, additional hospitalisation, nursing care, and systemic antibiotic therapy were assessed.

Wound types Surgical wounds

Results The feedback included the following:

- 543 women undergoing elective or emergency caesarian section were enrolled. The SSI rates in the Sorbact group were significantly lower (1.8%) than in the SSD group (5.2%) ($p = 0.04$).
- The total cost of SSI prophylaxis and treatment was greater in the SSD group as compared with the Sorbact group (5,775 EUR vs. 1,065 EUR, respectively).
- Only in the Sorbact group did none of the patients required systemic antibiotic treatment or hospital readmission.

Conclusion The study confirmed the efficacy and cost-effectiveness of Sorbact dressings in SSI prevention among women undergoing Caesarian Section.

Evidence of efficacy

Claims	Statement
• Cost savings • Saving nursing time	"Total estimated cost of SSI prophylaxis and treatment was greater in the control group as compared with the study group, and amounted to 5,775 EUR vs. 1,065 EUR, respectively"
• Prophylactic treatment	"Our results confirmed effectiveness of the DACC dressings in SSI prevention after CS. Application of the hydrophobic dressing resulted in a decreased rate of SSI and its considerably milder course, with no need for systemic antibiotic therapy and hospital readmissions"

Evidence is building to support using a DACC-coated antimicrobial wound contact layer with NPWT

Reference Bateman, S D,. (2015). Wounds UK. Vol 11. No 1.

Type of study Case series **No. of patients** 10

Objective The aim of the evaluation was to explore the benefits of utilising DACC-coated antimicrobial dressings as a wound contact layer under Negative Pressure Wound Therapy (NPWT).

Methods
- Ten patients were referred to the wound care service, that had highly exuding wounds with confirmed wound swabs to conclude infection.
- All wounds were being treated with NPWT chosen by the trust.
- DACC was used to replace the current liner underneath the NPWT filler.

Wound types
- Surgical wounds
- Burns
- Ulceration
- Trauma

Results The results demonstrated the following:
- A negative microbiology was achieved in 60% of patients by end of week one and in all patients by week two.
- Chronic stasis of the wound was reversed and wound progression was seen in week one to week three, seeing a reduction in exudate levels by week two in all patients.
- There was a reduction in the treatment duration of NPWT once DACC was included as a liner.

Conclusion DACC coated dressings that are used as a wound contact layer have demonstrated to being an effective alternative when using NPWT, providing atraumatic wound bed protection, reduced exudate levels, and a reduction in the size of the wound bed.

Evidence of efficacy

Claims	Statement
• Swab results • Reduced bioburden levels • Local infection • Critical colonisation	"Ten patients were referred to the wound care service with exuding, infected wounds, confirmed with a wound bed swab taken one week prior to the introduction of Cutimed Sorbact" "Negative microbiology was achieved in 60% of patients at week 1 (n=6) and in all patients (n=10) at week 2. Mean time to negative microbiology was 10 days"
• Reduced exudate levels • Wound progression	"The results clearly demonstrate an overall success in exudate reduction by week two in all patients" "Stasis was reversed, with wound size reduced for all patients from week 1 to week 3"
• Cost savings • Saving nursing time	"There was a reduction in NPWT duration after the deployment of the DACC-coated wound contact layer Before the dressing was used as a liner, the total number of days all patients were under NHS care for these wounds was 476. When DACC was added to the NPWT regimen, this fell to 266 days, a 44% reduction"

The use of DACC-coated dressings for the treatment of infected, complex abdominal wounds – A four patient clinical evaluation

Reference Bullough et al,. (2012). Wounds UK. Vol 8. No 4.

Type of study Case study **No. of patients** 4

Objective The aim of the evaluation was to reduce the bacterial bioburden in four complex open abdominal wounds where standard treatment was not suitable.

Methods
- Patients presenting with complex open abdominal wounds were treated using Cutimed Sorbact Swabs as a wound contact layer and an appropriate absorbent secondary dressing, using swab results as an indicator of reduction in bacterial bioburden.
- Continued usage after infection was managed (prophylactic use) to keep the patient infection free during there stay in hospital.

Wound types
- Dehisced surgical wounds
- Open abdominal wounds

Results The results demonstrated the following:
- In all patients infection had resolved within 14 days.
- Patients continued with the product regime prophylactically and no re infection occurred during their hospital stay.
- Wound dimensions reduced on a weekly basis on an average size reduction of 6-10%.
- All the patients experienced a reduction in pain, exudate and odour whilst the treatment continued enabling some of them to be discharged into the community setting.

Conclusion Due to the complexity of the wounds presented, with many barriers to healing observed, Cutimed Sorbact was an effective antimicrobial supporting wound progression and ensuring the patient remained infection free.

Evidence of efficacy

Claims	Statement
• Swab results • Reduced bioburden levels • Local infection • Critical colonisation • Prophylactic use	"For all patients, infection had resolved within 14 days, but Cutimed Sorbact was continued prophylatically. No patients had a recurrence of infection during their hospital stay"
• Reduced exudate levels • Wound progression • Pain • Odour	"Wound size reduced dramatically by 6–10% on a weekly basis throughout treatment" "For all patients, there was a significant reduction in pain associated with dressing changes. Initially, nitrous oxide was administered during dressing changes due to the lengthy procedure. However, following a two-week period this was replaced by oral analgesia administered prior to treatment" "In each case, odour and exudate levels reduced significantly over the course of treatment with Cutimed Sorbact. This is due to the effective reduction"
• Reduction in slough and devitalised tissue	"The dressings effectively managed devitalised tissue, resulting in 100% granulation tissue within two weeks"

Use of DACC-coated dressings in diabetic foot ulcers: a case series – A 19 patient clinical evaluation

Reference Haycocks, S, Chadwick, P,. (2011). The Diabetic Foot Journal. Vol 14. No 3.

Type of study Case series **No. of patients** 19

Objective The aim of the evaluation was to test the DACC product in the ability to reduce the signs and symptoms and risk of infection in diabetic foot ulcers.

Methods

- The investigation was designed as a single centre, open, non-randomized case series, people attending the podiatry clinic with active diabetic foot ulceration were enrolled when they met the enrollment criteria and consent.

Wound types

- Diabetic Foot Ulceration

Results At the end of the evaluation:

- 29 wounds had one or more signs of infection
- Of the eight wounds that presented with maceration, 7 out of the 8 patients resolved by the end of the evaluation and the exudate levels reduced in all wounds.
- Six wounds presented with malodour at the start of the evaluation, with an improvement seen in all by the end of 28 days.
- All 29 wounds showed signs or wound progression with dimensions reducing over the evaluation period.

Conclusion The evaluation met with all the objectives set, demonstrating a positive healing environment for diabetic foot ulceration, with a seen improvement in wound dimensions in less than 4 weeks.

Evidence of efficacy

Claims	Statement
• Reduced bioburden levels • Local infection	"By study end, all 29 wounds had one or no signs of local infection (Table 1). Of the eight wounds with maceration at their margins at enrolment, seven resolved during the 28-day wear time" "All 19 wounds with associated erythema at enrolment experienced resolution of this sign by the end of the evaluation period"
• Odour reduction	"Six wounds on three participants were associated with malodour at enrolment. In all of these cases the malodour resolved during the course of the treatment period"
• Reduced exudate levels	"Exudate levels reduced during the investigation period in all 24 wounds with high volume exudate at enrolment"
• Pain reduction • Patient comfort	"Wound pain in this group – with its high incidence of peripheral neuropathy – was expectedly low; only six wounds on three participants were associated with any level of pain. During the evaluation period all three participants with wound pain at enrolment reported reductions in this measure by study end: one reported severe pain reducing to mild pain; the second moderate pain reducing to mild; and the third mild pain that was resolved by study end"
• Wound progression	"All 29 wounds reduced in size from enrolment to the end of the evaluation period (Table 2). Eight (27.6%) wounds healed completely, and a further 20 (69.0%) showed a reduction of >50% in size – with 34.5% (10/29) reduced by >75% of their size at enrolment"

Cutimed®,
an Essity brand

ESS0394
7/2021

PO Box 337,
Mount Waverley,
Victoria, Australia 3149
www.essity.com

Customer Service Australia
T 1300 276 633 F 1300 998 830
Customer Service New Zealand
T 0508 276 111 F 0508 998 830