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

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Introduction

The Tygerberg adult burns unit is a level three provincial service for severe burns. Burn patients of 12 years or older are admitted. Annually about 300 patients are treated, of which 110 would be intensive care admissions. The burn unit has bed capacity for 22 patients, of which 6 are intensive care and the rest ward beds. Adequate operating time is available to optimally manage about 50% of the patients weekly. During the colder periods from April to September management of patients is compromised due to the severe workload demands and lack of resources.

As an academic hospital, associated with Stellenbosch University, the burns unit has a responsibility to present medical students and registrars to a wide range of burn care products and wound care methods. With limited financial resources management of patients requires cost-effective therapies.

Cutimed Sorbact® was introduced into the Tygerberg burns unit for use on burn wounds in 2013. It is a relatively inexpensive dressing and was used in the unit at central line sites as part of the ICU central line associated bloodstream infection prevention protocols (CLABSI).

Due to a lack of experience using Cutimed Sorbact® on burn wounds and with no available specific burn wound clinical studies published in peer-reviewed burn journals it was decided to conduct a Random Prospective Pilot Product Clinical Study to compare Cutimed Sorbact® in a clinical environment with well-established antiseptic dressings for burns; Acticoat® and Silverlon®.

Sorbact® is marketed as a dressing containing antibacterial activity with a lipophilic (hydrophobic) active molecule DACC (dialkylcarbomyolchloride) that binds irreversibly to bacterial cell walls.[1-7] The bacteria are not disintegrated and their toxins are not released onto the wound bed.[3] Sorbact leaves non-hydrophobic micro-organisms in the wound to stimulate healing and it has a low likelihood of spreading bacteria during a dressing change [3]. It is non-allergenic, has an optimal microbiological binding capacity in a moist environment and there is no risk of developing antibiotic resistance [3]or allergies. The clinical indication in burn wounds was not well defined. A summary of articles reporting on burn cases treated with Sorbact is shown in figure 1.

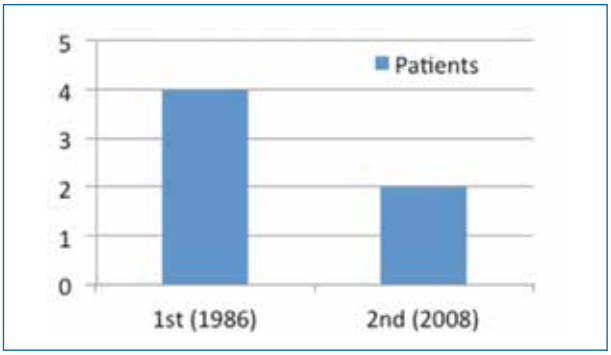

Figure 1: The estimated number of patients with infected burns treated with Sorbact in a literature review

Wadstrom et al. (1986) reported using Sorbact® on infected burn wounds but no clinical detail of the outcome was given except that the dressing was effective.[5] Kammerlander et al. (2008) in a multicentre observational study reported using the dressing on burns (2 % of 116 patients) but did not report on the specific outcome in burns.[7]

Acticoat® is a nano-crystalline impregnated sliver dressing and is considered a very effective antimicrobial dressing that releases ionised silver radicals that effectively kill more than 90 % of the surface bacteria within 30 minutes.[8] It then releases silver slowly for sustained bacterial killing for 3 days depending on the composition. Variations are on the market like Acticoat 7® that releases silver ions over a 7 day period. We chose the classical Acticoat that is active for 3 days.

Silverlon® is a particulate or metallic containing silver dressing and releases silver ions when moistened.[9]

Since many new products are presented to surgeons and clinicians each year it can become overwhelming selecting dressings.[4] It was decided in 2013 to do a random prospective product clinical study comparing Cutimed Sorbact® with control products Acticoat® and Silverlon®.

Material & Methods

The Study inclusions were with random patient selection with the presentation of partial or full-thickness burns. Patients were also

Figure 2: Dressing position

Figure 3: Dressing distant position

selected where all three dressings could be used simultaneously, at the same burn site and time, in a similar depth burn.

A Laser Doppler was not available to standardize depth assessment. Therefore the selection of the area was made by the senior author who has more than 10 years' experience as a specialist plastic and reconstructive surgeon.

The study excluded patients who were to go to theatre for an operation within less than three days.

A burn wound selected would be covered by the three dressings next to each other with the Sorbact® in the middle separating the two silver dressings (see Figure 2).

In some patients additional distant areas would be selected where the individual dressing would be applied alone for additional clinical data from Table 2 single areas: moistness, infection, epithelialisation, colour, granulation, slough. (See Figure 3).

A photograph using an 5 megapixel camera was taken before each dressing and after removal of the dressing by the first author in all cases except 2 where the co-authors took the photos.

Three pus swabs were taken using the Levine technique from the areas under the three dressings for microscopy, culture and sensitivity. This follows the process of cleaning or rinsing with saline and then pushing the pus swab gently into the central wound until deep exudate is absorbed then turning it 360 degrees

The Microbiology department at Tygerberg Hospital was not informed (blinded) of the study protocol to allow for an objective assessment of the swabs.

Wound assessment was performed by the first author in conjunction with the co-authors. The factors looked at on the wounds were wound bed appearance, slough, pus, biofilm, granulation, epithelium, smoothness and colour. The results of the microbiological blinded assessment will be assessed in relation to the clinical results recorded by photography.

Consent from the Tygerberg hospital medical superintendent was obtained prior to the study. The research was conducted in line with the Helsinki ethical guidelines. All patients consented to the use of their photos for record, research and medical education purposes.

The McNemar test was used for statistical analysis by Prof Martin Kidd from the Statistics department Stellenbosch University. Of the three dressings tested the McNemar test only compared two dressings at a time. Therefore for every parameter evaluated, the test was done for two different dressings only e.g. for slough, the test was done for Sorbact vs Acticoat; Sorbact vs Silverlon and finally Acticoat vs Silverlon. Therefore for the five clinical parameters evaluated for the three dressings, the McNemar test was to be done 3 x 5 times. All the clinical wound data had to be converted to numbers. And the clinical parameters evaluated were then given either the number 1 or 0. If the parameter assessed was present it was given a '1' and the number '0 if it was not present. For example if slough was present it was given a 1. If no slough was found it was given a 0. This is an obvious simplification of the results and doesn't account for a range of results across the spectrum of clinical changes for a given parameter assessed.

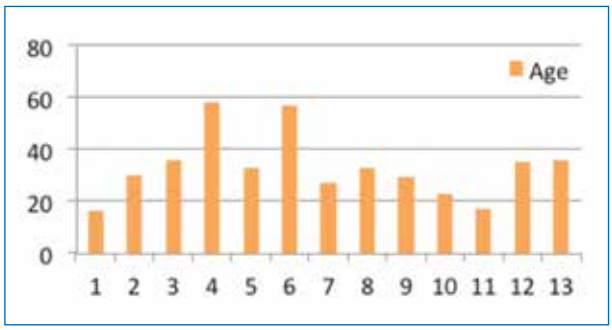

Figure 4: Average age distribution of the patients

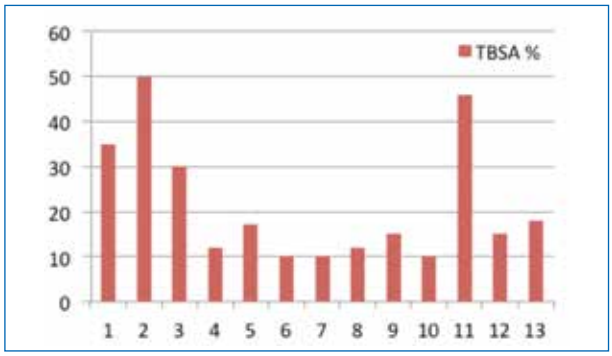

Figure 5: Average total body surface area (TBSA) distribution

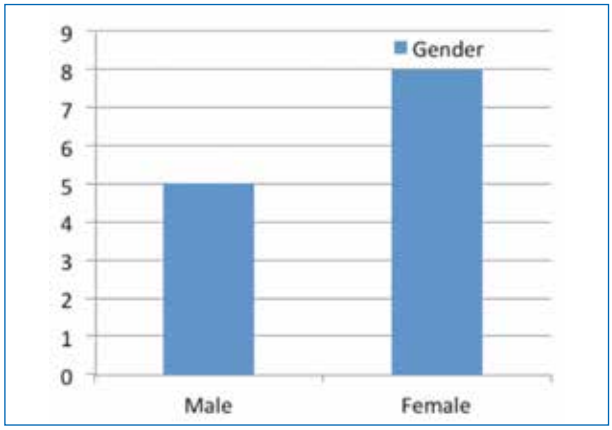

Figure 6: Gender of the patients

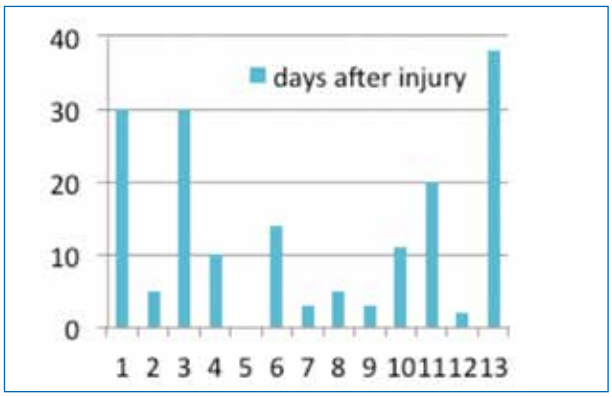

Figure 7: The days after the initial injury that the dressings were applied in each patient

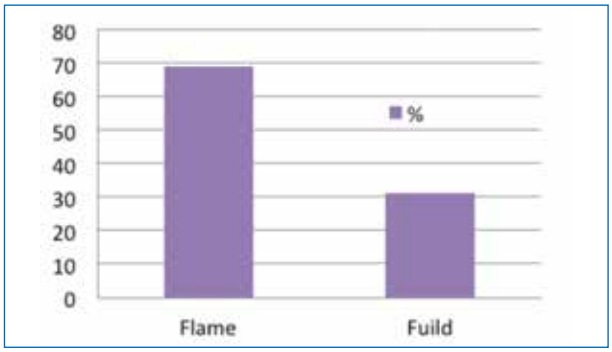

Figure 8: Mechanism of burns

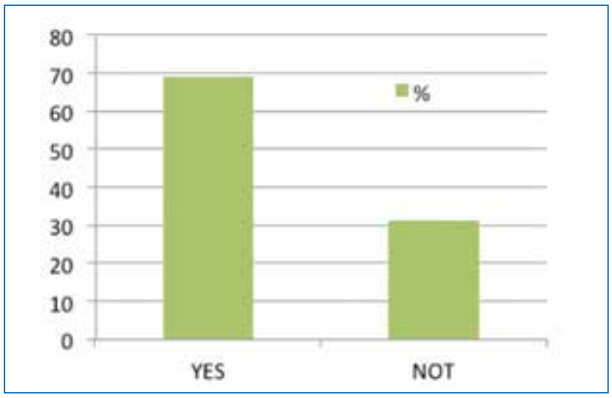

Figure 9: The percentage of microbiology results reported in the study

Results

Table 1: Demographic data of study

Age	Sex	TBSA %	Mechanism	Injury date	Dressing date	Days after injury	MCS report
16	F	35	Flame, house	2013/07/21	2013/08/16	30	Yes
30	M	50	Flame, shack	2013/08/23	2013/08/28	5	Not reported
36	F	30	Flame, stove	2013/07/30	2013/08/30	30	Yes
58	F	12	Hot H2O	2013/08/20	2013/08/30	10	Yes
33	M	17	Flame	2013/08/30			Yes
57	F	10	Flame, stove	2013/08/01	2013/08/15	14	Not reported
27	F	10	Flame	2013/09/04	2013/09/07	3	Yes
33	M	12	Flame, shack	2013/09/18	2013/09/23	5	Yes
29	F	15	Hot H_2O	2013/10/01	2013/10/04	3	Not reported
23	F	10	Hot H2O ?	2013/09/24	2013/10/04	11	Yes
17	F	46	Flame	2013/09/13	2013/10/03	20	Yes
35	M	15	Hot H2O	2013/10/02	2013/10/04	2	Yes
36	M	18	Flames	2013/08/31	2013/10/07	38	Not reported

13 patients were included in the pilot study. The original target was 20 patients for the first part. The total number of dressing areas that were tested was 57. This included 39 (3 wound areas x 13) control test areas and in the first six patients an additional 18 separate remote burn areas were chosen where the three different dressings were tested independently.

The average age of the patients was 33 years old and ranged from 16 to 58 years old as shown in Figure 4.

The average total body surface area (TBSA) percentage was 21,5. Four patients had TBSA larger or equal to 30% and the other nine was between 10 and 30 % TBSA as demonstrated below in Figure 5.

More females (eight) than males (five) were randomly included in the study as shown in Figure 6.

Table 2: Clinical data of the Sorbact® study

Central Area		Sorbact	Acticoat	Silverlon
patient	1	moist,bright red, clean, healthy pink areas	clear mucous, patchy bright red areas, thin yellow slime, focal pink & red healthy areas	shiny mucous, biofilm-like, light yellow. Pale pink, patchy shiny red areas
	2	Central area clean, light pink orange granulation, yellow slough on border	larger yellow slough 50%, light pink orange granulation towards middle wound	lots of yellow slough areas, small pink granulation islands
	3	granulating, some yellow small patches, clean	pink & red granulation, some yellow small patches, clean	mostly pink red granulation tissue, more yellow exudate, clean
	4	red light pink epithelium, clean	red light pink areas, clean	more white light pink epithelium, small red patches, clean
	5	less slough, thinner slough, pink epithelium on edges, no signs of overt infection	less slough, thick full thickness yellow slough, clean, pink epithelium on edges	thin slough,pink and white on edges, clean - no infection, no biofilm
	6	red, pink, smooth granulation, no slough, 2 minute yellow patches, shiny biofilm	red pink granulation, yellow thin exudate,deeper patches of yellow >4, allover, shiny	red, pink, more yellow patches, shiny biofilm
	7	light pink healed epithelium	some light grey Argyria in Acticoat area, healed	some light yellow grey dry scabs over healed epithelium
	8			
	9	light pink, thin white pseudoslough,dermal papillae, small area with thicker slough	thicker whitish pseudoslough, no dermal papillae, deeper burn, light yellow slough	light pink, very thin white pseudoslough,dermal papillae, clean wound
	10	healthy light pink dremal papillae, no bleeding/biofilm/wet, small patch thin yellow sl.	some bleeding areas, healing in area,larger area of slough dry & deep fix 10cm	bloody, wet, small areas light pink dermal papillae, thin y sl. Small area
	11	pink epithelization white dermis, small areas bright red	light pink epithelization, small red islands in between, no puss/biofilm/slough	pink epithelisation, dull red areas, hypergranulation, no puss/biof/sl
	12	mostly pink, few crusts of brown yellow, no biofilm	pink areas & mostly brownish gray yellow crusts, no biofilm	pink & yellow brown crusts, no biofilm
	13	Clean, red. No infection or biofilm.	Clean, red. No infection or biofilm.	Clean, red. No infection or biofilm.
Single Areas		Sorbact	Acticoat	Silverlon
Patient	1	moist,no exudate,no biofilm,nolight yellow,healthy pink islands in bright red wound bed	clean, no exudate,no biofilm,pink red patches with healthy pink areas	superficial areas clean & dry, deeper areas, mucuous-likelayer, light yellow
	2			
	3			
	4	healed partial thickness areas, pink purple epithelium	healing pink epithelium with dermal papillae visible	Not seen on photo
	5			
	6			
	7			
	8			
	9	Clean & dry, deeper areas with yellowslough, no signs of infection	Similar to Sorbact	Similar to Sorbact area
	10	FT wound, slough clean & dry,surrounding pink and white epithelium	pink areas between thick yellow slough areas, slough thicker than Sorbact area	good new epithelium with pigment return, small raw area 4x6 cm, red tissu
	11	Lighter pink than SII/Act,minute bleeding between pink epithelium	grayish staining of yellow slough, thin slough, no pus, red edges, small healing areas	light pink, grayish pseudoslough layer
	12	bright pink and red in most areas, small deeper area, yellow drier & crusty	pink red healed epithelium, no slough, clean	Light yellow deeper PTB, some grey yellow slough but appears 'clean'
	13			

Figure 10: Results of two of the patients after the removal of the dressings

The average days after injury when the dressings were applied were 14,25 days. The average number of days before the dressings was applied after the initial injury was about 18 days for the first five patients and 13 days for the last seven patients as seen in Figure 7.

Most of the injuries sustained were a result of flame burns (9/13) (69%). Scald burns accounted for the other cases (4/13) as seen in Figure 8.

Microscopy, culture and sensitivity was done in 9/13(69%) cases. In 4 patients pus swab results were not reported (4/9 = 31 %) as shown in Figure 9.

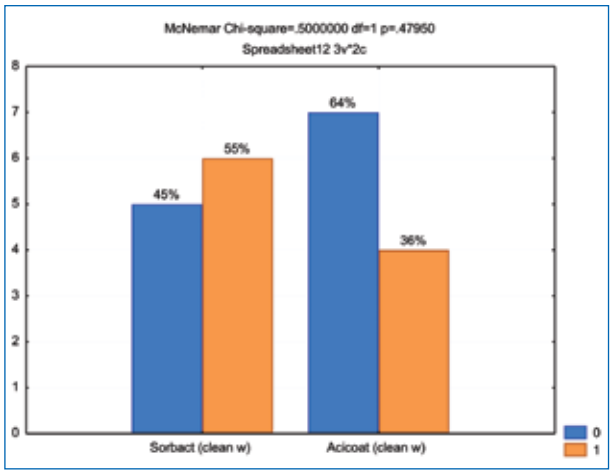

Figure 11: Sorbact (clean w) I Acticoat (clean w)

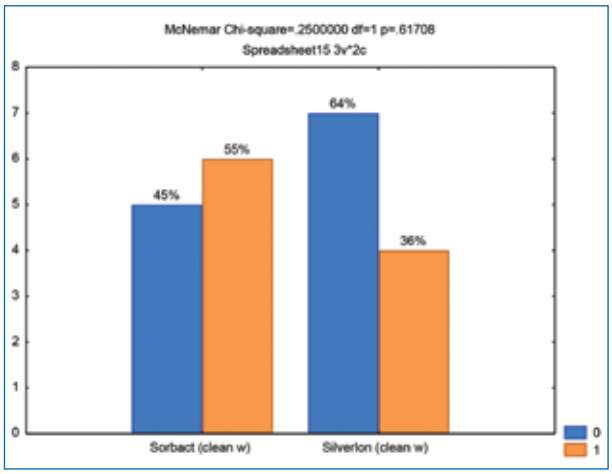

Figure 12: Sorbact (clean w) I Silverlon (clean w)

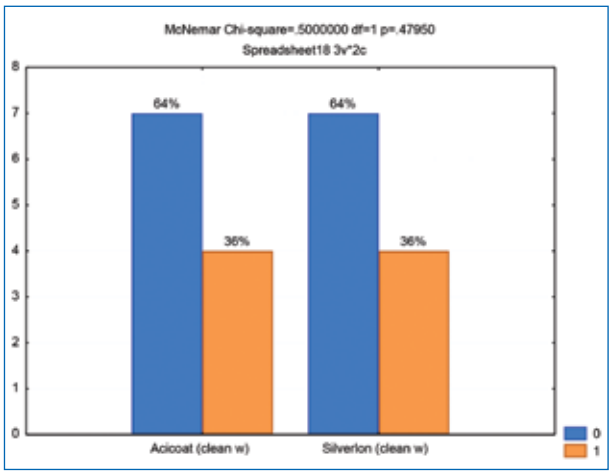

Figure 13: Acticoat (clean w) I Silverlon (clean w)

One patient's post-dressing photos were not found. The Sorbact® wound appeared clean in 7 of the 12 patients' wound data sets (includes the healed wound of patient 7 in Table 2). See Figure 10 for the results of two of the patients after the removal of the dressings.

With Acticoat® in comparison to Sorbact® the wounds appeared clean in 5 patients out of 12 (including healed area of patient 7).

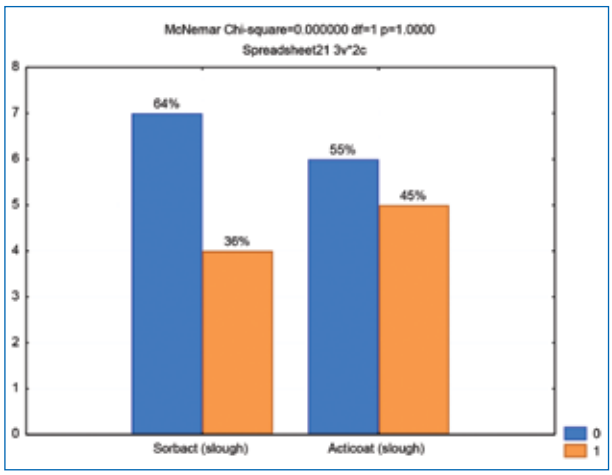

Figure 14: Sorbact (slough) I Acticoat (slough)

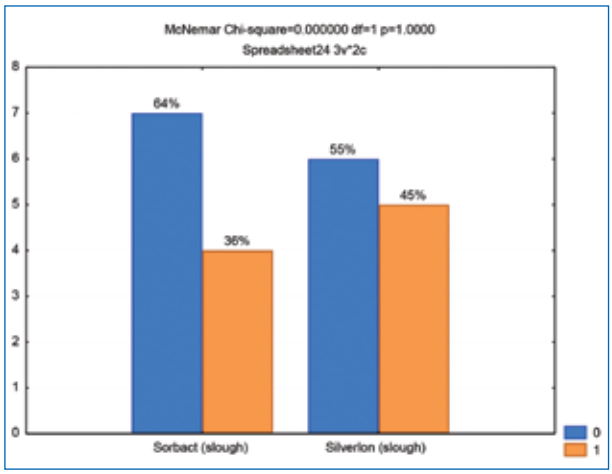

Figure 15: Sorbact (slough) I Silverlon (slough)

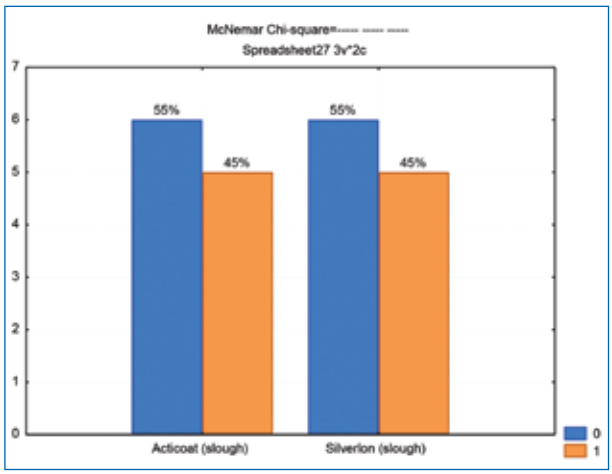

Figure 16: Acticoat (slough) I Silverlon (slough)

The Silverlon® wounds appeared clean in 5 patients although in 1 patient (patient 5) there was a thin slough area.

The clean appearance was comparable for all 3 dressings in the same patient only 3 times (Patient 3, 4 and 13). In 9/13 patients the clinical appearance of the wound differed between the three dressings however the result is not statistically significant with p-value not less than 0.05.

The McNemar graphs below show that there is significant comparison, where in Figure 11 & 12, Sorbact® shows marginal increase in clean appearance of the wound in comparison to the Silver dressings.

Slough was present under the Sorbact® dressing in 4 patients of which one wound had slough prior to the application in a full-thickness burn area (patient 5 in Table 2). Slough was found in 5 patients where Acticoat® was used and in 5 patients where

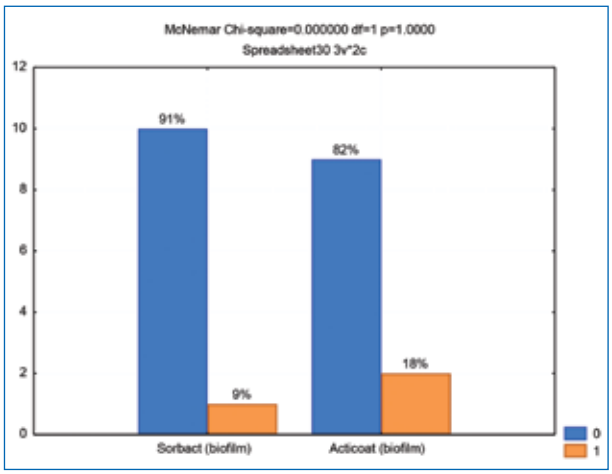

Figure 17: Sorbact (biofilm) I Acticoat (biofilm)

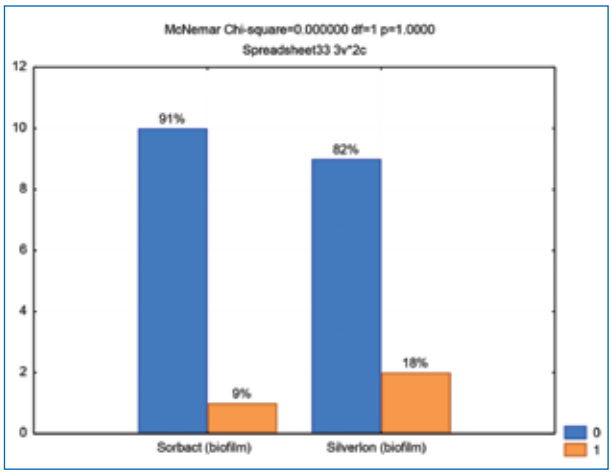

Figure 18: Sorbact (biofilm) I Silverlon (biofilm)

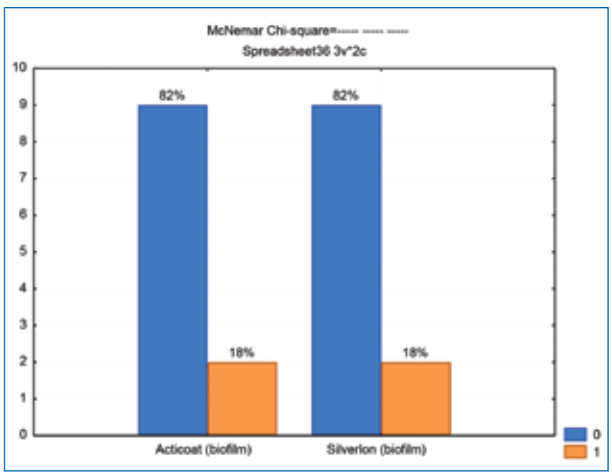

Figure 19: Acticoat (biofilm) I Silverlon (biofilm)

Table 3: Microbiology results of the Sorbact, Acticoat; Silverlon study

Patient	Sorbact	Acticoat	Silverlon	Wounds dressed after Injury (days)
1	Scanty N, GNB. Mixed growth	Scanty Ntf, GPC, GNB. Mixed growth	Scanty Ntf, GNB. Mixed growth	26
2	Not done			
3	Very Scanty Ntf. No B seen. MR Pseudomonas.	Very scanty Ntf. No B seen. Scanty Pseudomonas	No Ntf. No B observed. MR Pseudomonas cultured	30
4	No Ntf. No B seen. No growth	Scanty Ntf. No B seen. No growth	Scanty Ntf. Scanty GPC. IR Pseudo & Staff growth	19
5	No Ntf. No B seen. No growth	No Ntf. No B seen. No growth	No Ntf. No B seen. No growth	4
6	Not done			
7	No Ntf. No B seen. Scanty P.Mirabilis growth S	Not done	No Ntf. Scanty GNB. Moderate P.Mirabilis S	2
8	No Ntf. Scanty GPC. Skinflora cultured.	No Ntf. No B seen. Skinflora cultured.	No Ntf. No B seen. Skinflora cultured.	5
9	Not reported			
10	Moderate Ntf. No B seen. No growth	Scanty Ntf. No B seen. No growth.	Scanty Ntf. No B seen. No growth.	10
11	Moderate Ntf. Moderate GPC; Scanty GNB. PA; SF	Scanty Ntf. No B see. Scanty PA	Very scanty Ntf. Scanty GPC. MRSA	20
12	Scanty Ntf. No B seen. Only skinflora isolated.	Scanty Ntf. No B seen. No growth, aerobic org's.	Scanty Ntf. No B seen. No growth, Aerobic org's.	2
13	Only 1 swab reported			

Silverlon® was used. The McNemar graphs above show that there is significant comparison, where in Figure 14 & 15, Sorbact® shows marginal Slough reduction in comparison to the Silver dressings.

A shiny biofilm-like appearance was present once with Sorbact®, twice with Acticoat® and twice with Silverlon®. The McNemar graphs above show that there is significant comparison where in Figure 17 & 18 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.

Healing at the areas where the dressings were tested separately far from each other showed good healing under all the products (see single areas in Table 2). Single areas for controls were tested in 6 patients.

The statistical analysis of the data comparing two products at a time using the McNemar test showed no statistical difference of significance between any of the data sets as illustrated below.

Microscopy, culture and sensitivity (MCS) results were adequately reported in 9 out of 13 cases. In 3 patients the pus swabs were done but not reported and in one patient the only one pus swab was reported. In 7 patients out of 9 there were bacteria cultured (7/9) (78%). 2 patients had no growths (2/9) (22%).

Bacteria were observed on microscopy in 3 out of 9 cases (33.3%) with Sorbact®, in 1 out of 8 cases (12.5%) of Acticoat®, and in 4 out of nine cases of Silverlon®.

The McNemar graphs below show that there is significant comparison where in Figure 20 & 21 Sorbact® shows marginal reduction in Bacteria observed in comparison to the silver dressings, which showed the different level of bacteria observed in Figure 22 in comparison to themselves.

The function of neutrophils is to remove foreign material, bacteria and non-functional host cells and damaged matrix components that maybe present at the wound site.[17]

Neutrophils were present in 5 out of 9 cases (56%) with Sorbact®, in 6 out of 8 cases (75%) of Acticoat®, and in 5 out of 9 cases (56%) with Silverlon®.

The McNemar graphs below show that there is significant comparison where in Figure 23 Sorbact® shows lower presence of neutrophils in comparison to Acticoat®, Figure 24 Silverlon® shows the same profile of neutrophils in comparison to Sorbact®, Figure 25 Acticoat® shows a different profile of neutrophils in comparison to Silverlon®.

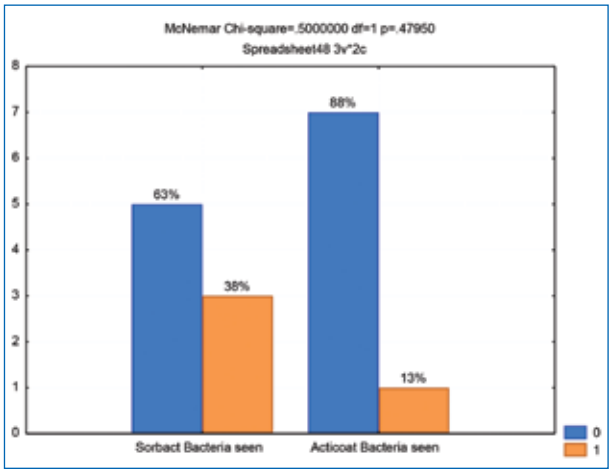

Figure 20: Sorbact Bacteria observedl Acticoat Bacteria observed

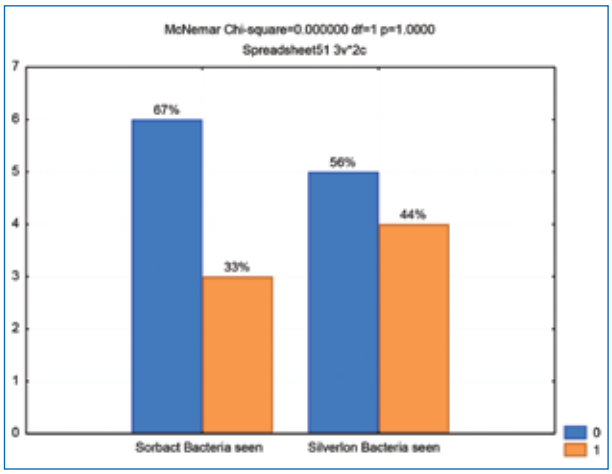

Figure 21: Sorbact Bacteria observed I Silverlon Bacteria observed

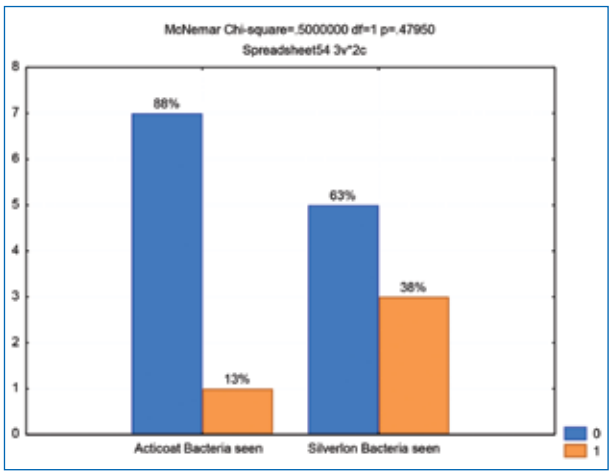

Figure 22: Acticoat Bacteria observed I Silverlon Bacteria observed

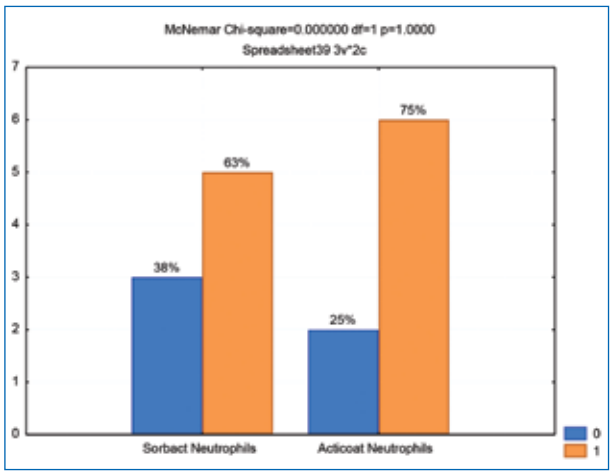

Figure 23: Sorbact Neutrophils I Acticoat Neutrophils

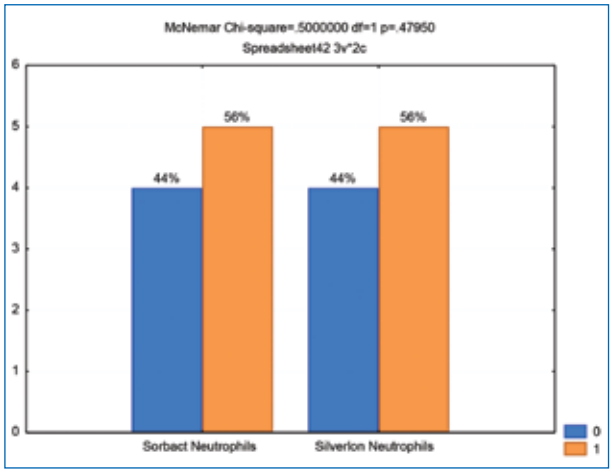

Figure 24: Sorbact Neutrophils I Silverlon Neutrophils

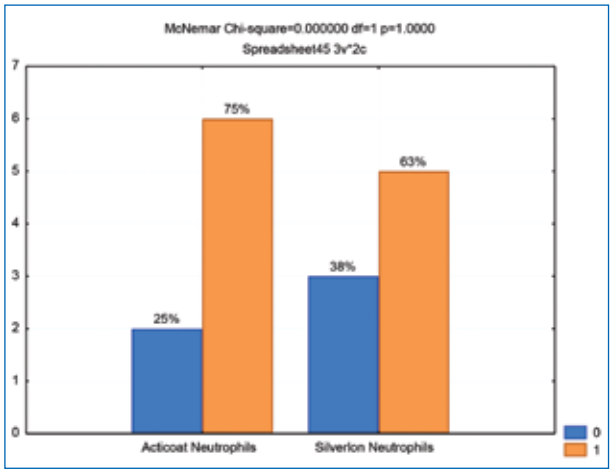

Figure 25: Acticoat Neutrophils I Silverlon Neutrophils

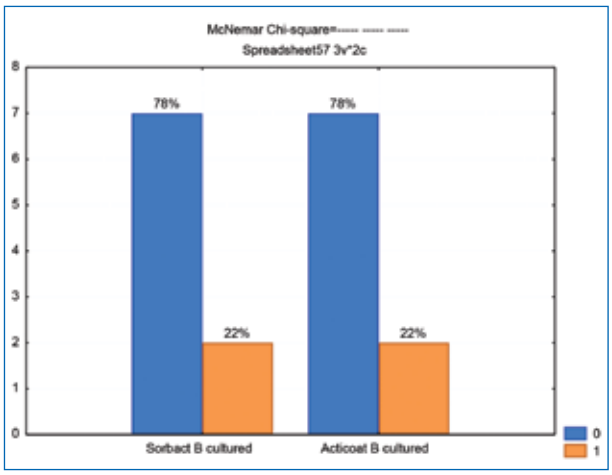

Figure 26: Sorbact B cultured I Acticoat B cultured

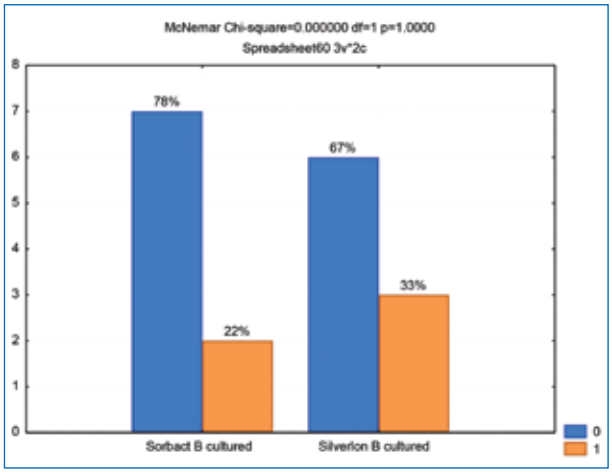

Figure 27: Sorbact B cultured I Silverlon B cultured

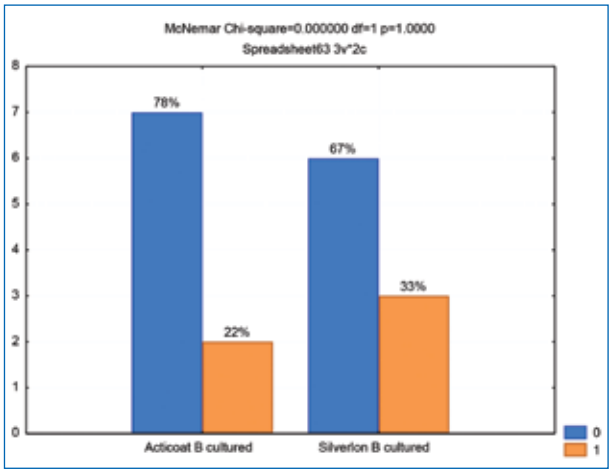

Figure 28: Acticoat B cultured I Silverlon B cultured

Swabs were taken from the wound and bacteria were cultured in 6 out of 9 cases (66%) with Sorbact® 2 of these cultures were of normal skin flora and one was reported as mixed growth. 3 out of 9 (33%) were therefore significant.

Bacteria were cultured in 5 out of 8 cases (62.5%) with Acticoat®. 1 of these cultures was of normal skin flora and 1 was reported as mixed growth. The one result not reported was where the Proteus Mirabilis was grown in both the other dressings. 2 out of 8 cases (25%) were therefore significant positive cultures and the omission of the report in the patient with Proteus Mirabilis (case 7 in Table 3) could have had a serious impact on the overall impression of the effectiveness of the dressing (3 out of 8 would be 37.5% incidence for Acticoat® compared to the 33% of Sorbact®).

Bacteria were cultured in 7 out of 9 cases (78%) with Silverlon®. 2 of these cultures were of normal skin flora and 1 was reported as mixed growth. 4 out of 9 cases (44%) were therefore significant.

Resistant bacteria were cultured in 1 case out of 9 (11%) with Sorbact® (multi-resistant (MR) pseudomonas Aeruginosa in case 3 in Table 3), and in three cases (3/9) (33%) with Silverlon®, and in 0 out of 8 cases (0%) of Acticoat®.

The McNemar graphs above show that there is significant comparison where in Figure 26 where Sorbact® and Acticoat®showed the equivalent bacteria culture, in Figure 27 where Sorbact® showed diffirence in bacteria culture to Silverlon. Figure 28 Acticoat® and Silverlon® showed the same bacteria culture profile as Figure 27 when in comparison to themselves.

The clinical significant bacteria that were cultured with Sorbact® were Pseudomonas Aeruginosa (in 2 patients), Proteus Mirabilis and Serratia Fouticola.

The clinical significant bacteria cultured from the Acticoat® area were Pseudomonas Aeruginosa in 2 patients (see Table 3).

The clinical significant bacteria cultured with Silverlon® were Pseudomonas Aeruginosa (in 2 patients), Staphylococcus Aureus (SA) and MRSA, and Proteus Mirabilis.

Discussion

The Microbiology department of the Tygerberg hospital was not informed of the study protocol in order to obtain blinded objective results from the pus swabs. An increased resistance was experienced from the Microbiology laboratory to do three specimens from the same patient which resulted in specimens not done as reported in Table 3. The Microbiology department was later informed about the study, after their repetitive enquiry and unwillingness to do 3 tests for the same patient simultaneously. The Pilot study was therefore terminated when the microbiology department only reported one of the 3 pus swabs.

The control areas can be challenged in terms of the results obtained in that the dressings were placed adjacent to each other and could have had an influence on one another. Therefore additional separate areas chosen from the first six patients for dressing application were included in addition to the control test areas .

Having the control and study dressings in the same depth burn wound of similar depth in the same area was considered to be the best choice for a comparative study of the dressings because the variables (example.g. local edema, inflammation and infection) that may affect testing on different sites is decreased.

The TBSA was not a factor considered in making the choice of dressings used because the wound size is not a reliable factor to differentiate antibacterial efficacy.

Initially the dressings were tested in patients who had wounds that were “older” (more than 18 days) , as reflected in the results, which showed the average days after initial injury that the dressings were applied was 18 days in the first five patients. Older as a safety measure assuming that in an older more established burn wounds with potentially deep sited infection or bacteria in the wound the Sorbact® dressing had any bad effects on the wound such as increased infection or delayed healing, the potential complications would not be as clinically significant as it would be in a fresher burn (less than 13 days) wound where there is less or no infection suspected.

As confidence in the Sorbact® dressings’ ability to compete with Acticoat® and Silverlon® grew, the dressings were applied on younger wounds (less than 13 days). This is reflected in that the average days after injury that the dressings were applied for the last six patients were seven days (excluding patient number 13 who was treated on day 38 after injury).

The earliest the dressings were applied was at day 2 in one patient and day 3 in two patients. From the successful use at this early stage it became apparent that Sorbact® was a good dressing for partial thickness burns where it can act as a temporary skin substitute with antibacterial properties.

Sorbact® can be classified as a skin substitute like Suprathel® which has antibacterial properties. Some of the differences of Sorbact®, in comparison to Suprathel®, would be that Sorbact® is relatively cheap and therefore highly cost-effective as a skin substitute. The other significant difference would be that Sorbact® is not sticky and is less effective than Suprathel® when this characteristic (cut and paste) is preferred for example when applying to rounded or folded surfaces where a dressing that sticks is practically easier to apply.

The subjective appearance of the Sorbact® wound areas were clean in 7/12 (58%) compared to 4/12 (33%) for Acticoat® and 5/12 (42%) for Silverlon®. The incidence of wound infection according to significant bacteria cultured from the wound with the dressings were 3/9 (33%) for Sorbact®, 2/8 (25%) for Acticoat® and 4/9 (44%) with Silverlon®. If the unreported result of the Acticoat in the patient who had Proteus Mirabilis (patient 7 in Table 3) was assumed to be positive for Acticoat as well the statistics for Acticoat and significant bacterial growth changes from 2/8 (25%) to 3/8 (37.5%). This would give the Sorbact® dressing the lowest incidence of significant bacterial growth at the wound site and this would be consistent with the clinical appearance that the Sorbact® wounds appeared cleaner than the controls tested.

The clinical appearance of the three dressings were relatively similar in 3 (patient 4, 12 and 13 in Table 2) out of 13 (31%) patients which can give the impression that in general there is a difference in the effectiveness of the dressings (different results in 9/13 (69%) patients). This clinical similarity did not correspond with similarity in microbiological profile. The patients with similar microbiology profiles were patients 5, 8 and 10 in Table 3.

A possible reason for the microbiology similarity may be related to the age of the burn wounds. Theoretically, in the fresher burn wounds the wound will be colonized over the next few days and not necessarily infected. One could expect to find similar results and

Table 4: Meta-analysis of Sorbact studies on wounds.

1985	Wadstrom et al	Staph. treated in pig		
1986	Wadstrom et al	Faster wound healing	12 patients	Non-healing wounds (Ulcer, Burn, Diabetic)
1987	Friman G.	New dressing Sorbact		
1990	Meberg & Schoyen	Umbilical cord infection	1400 patients	No increased infection
1990	Friman G	Chronic wounds	31 patients	69% infection gone, 31% same or worse
1990	Lunnegard et al	Chronic leg ulcers	3 patients	100% less infection
2004	Mussi et al	Pressure ulcers	19 patients (+ 14 controls)	Wound bed colour, edema, treatment days statistically better
2009	Gail Powell	Different chronic wounds	6 patients	100% reduced infection
2008	Kammerlander etal	Different ulcers, 2% burns	116 patients	81% success treated infection
2007	Hampton S	Different non-healing wounds		
2010	Skinner & Hampton	Diabetic Foot	4 patients	All better
2010	Derbyshire A	Leg ulcer follow-up	3 patients	100 % better
2011	Gentili et al	Chronic wounds	19 patients	10/15 less bacteria
2012	Nielsen; Andriessen	Diabetic; surgical wounds	60 patients	Adherence and Pain Sorbact
2012	Falk; Ivarsson	Fibroblast in vitro	1 model + control	50% >profliferation; 100% > healing < 72 h
2014	Jeffrey SL	NPWT wounds		Use as filler & liner

probably cleaner wounds compared to older burn wounds where one would expect to find bacterial infection.

The days after injury for dressings for the clinically similar observations of the wound (in patients 4, 12 and 13) were 19, 2 and 38 respectively. The days after injury for dressings for the microbiologically similar observations of the wound (in patients 5, 8 and 10) were 4, 5 and 10 respectively. The average days for the similar clinical wound appearance was about 27 days for the three patients and for the similar microbiology results the average days was about six days.

The similar microbiology result does seem to be related to some extent to the age of the burn wound. The clinical result similarity does not seem to be related to the age of the burn wound because these patients had varying wound age numbers with a very wide range of 2 – 38 days compared to the similar microbiology group's narrow range of 4 – 10 days.

The similarity group in the microbiology reports could possibly be from unenthusiastic reporting from the microbiology laboratory. As mentioned resistance was experienced for reporting all the specimens and a few specimens were subject to refrigeration and the reliability was acknowledged to be questionable by the microbiology department (this was the case with patient 10 and 11 in Table 3).

The close correlation in numbers of the presence of slough under the dressings (Sorbact® 4, Acticoat® 5 and Silverlon® 5) implies that the Sorbact® dressings were not compromising wound healing more than the silver dressings. From the observed analysis it cannot be said that Sorbact® is associated with statistically significantly less slough on the wounds.

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.

A meta-analysis of Sorbact/hydrophobic dressing clinical study results are presented in the table 4 below (This has been compiled from references 1-16).

For a more conclusive study the sample number of patient needs to be increased Only 13 patients were included in the study but the number of wounds analysed was 57 (3 wounds x 13 patients test control areas + 3 wounds x 6 patients individual control areas) which can be considered a significant number.

The McNemar statistical analysis limited the information analysed by simplification of the results to a number given to the presence (1) or absence (0) of a tested parameter. No variations or degrees of the parameters were taken into account. The full clinical picture as given in the broader description therefore cannot be appreciated fully by the statistical analysis.

It is difficult to estimate the reliability of the microbiology reporting considering the acknowledgement of refrigeration of some of the specimens.

Conclusion

The random prospective pilot study is valuable for highlighting the clinical result impression that the Cutimed Sorbact® is comparable to Acticoat® and Silverlon® on burn wounds. This study also is the first prospective study investigating Cutimed Sorbact® use in burn wounds only. The potential for using Cutimed Sorbact® on earlier or fresher burn wounds warrants its further study as a potential skin substitute.

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