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ORIGINAL ARTICLE

Comparing the use of a novel antibiotic-free film-forming topical wound dressing versus a topical triple antibiotic in dermatologic surgical procedures including Mohs micrographic surgery

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Abstract

Background There is no universally accepted protocol of topical wound care after cutaneous surgical procedures. The current practice is to use petrolatum-based products, commonly containing topical antibiotics. The rise in antibiotic -resistant bacteria and increased risk of allergic and contact dermatitis due to the use of topical antibiotics is well established.

Objective To compare the prevalence of contact dermatitis, the infection rate and the subjective measures of healing of a novel, antibiotic-free, film-forming silicone-based wound dressing to a topical triple antibiotic petrolatum-based ointment in patients undergoing invasive dermatological interventions in two arms: (1) Mohs micrographic surgery (MMS) and (2) a combination of various routine dermatologic surgical procedures.

Design The 231 patients were enrolled in this open-label, randomized, single-blinded study. Patients applied the products immediately after surgery and daily afterwards. Clinicians evaluated the surgical site for infection or contact dermatitis at all follow-up visits. Acute wound healing progression was assessed using a rating scale against clinical experience and expected results from −4 (much worse) to +4 (much better).

Results Contact dermatitis was significantly decreased in the wound dressing group compared to the topical antibiotic group (0 vs 15.9%, $P < 0.001$). There was no difference between the study arms (Mohs vs. non-Mohs, $P = 0.242$). Infection rate was not significantly different between the groups ($P > 0.05$) and between the study arms ($P > 0.05$). Assessor-rated secondary outcomes like healing time, healing quality, erythema and new tissue quality were significantly better in the wound dressing group, while comfort and perceived overall satisfaction were better in the antibiotic group. Patient-rated outcomes did not show any difference between groups and between study arms.

Conclusion The wound dressing used in this study is a topical silicone gel preparation and presents a viable alternative to topical antibiotics for postoperative wound care without enhancing the risk of infection.

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Conflicts of interest

Dr. Anthony V. Benedetto reports non-financial support from Stratpharma, during the conduct of the study; personal fees from Stratpharma, outside the submitted work. Dr. Jonathan Staidle, Dr. Jason Schoenfeld, Dr. Ernest Benedetto and Dr. Paul Benedetto have nothing to disclose.

Funding

The research products used in this trial were provided by the manufacturer (Stratpharma, Switzerland). None of the investigators own any shares in the company or of the products in any form. Stratpharma had no involvement in the conduct of the trial. However, Stratpharma was given an opportunity to perform the statistical analyses of the data and review the paper prior to the submission of this manuscript. There are no restrictions imposed on the investigators to publish these results in peer-reviewed journals.

Background

The majority of cutaneous surgical procedures are performed in an outpatient setting, and surgical site infections (SSI) remain of utmost concern. Yet, there is still no preferred regimen universally accepted for postoperative wound care or an ideal topical agent, which can maintain a moist wound environment for optimal healing, while it prevents surgical site infections and excessive scarring.[1] Consequently, anyone who performs outpatient cutaneous surgery, specifically, dermatologists and dermatologic surgeons, currently utilizes different non-standardized postoperative wound care protocols of unclear level of evidence.[1] A large percentage of dermatologists still instruct their patients to use petrolatum-based topical antibiotics postoperatively as the conventional wound care modality to offset the risk of SSI, and to promote wound healing.[1] Dermatologists also have been identified as the top prescribers of topical antibiotics.[1-4] This routine practice of prescribing topical antibiotics for postoperative wound care, however, has failed to show any evidence-based benefit over the use of other non-antibiotic topical wound dressings.[4] While SSIs and associated potential bacteremia are still a major concern for even superficial cutaneous wounds, the rate of such complications has been shown to be quite low.[5-7] Significant negative effects of topical antibiotics on postoperative wounds include delayed wound healing, allergic contact dermatitis, inflammatory chondritis, anaphylaxis and Stevens–Johnson syndrome.[1,8-12] Additionally, an increasing prevalence of multidrug-resistant bacterial strains has also been described.[1,13-15] These clinically significant iatrogenic events continue to arise in the face of a paucity of any large-scale randomized control trials that better define the role of topical antibiotics in cutaneous surgery.[1]

Over-the-counter topical antibiotics are currently recommended by dermatologists 43% of the time and frequently used by patients on their postsurgical or traumatic skin wounds based on the misconception that topical petrolatum-based antibiotics promote better wound healing and help prevent skin infections.[1] This belief was recently substantiated by the results of prospective questionnaire distributed by the authors to patients visiting a private ambulatory surgery centre over a six-month period. The results revealed that over 74.7% of polled patients ($N = 962$) preferred using a petrolatum-based topical antibiotic product for incidental cuts, burns or abrasions (Table 1). Data have shown, however, that topical antibiotic products have no statistically significant advantage over white petrolatum in preventing SSIs.[16] Based on the lack of evidence-based data indicating superiority, the emerging clinical recommendation is to discontinue the use of topical petrolatum-based products with or without antibiotics and to limit the use of oral antibiotics.[17] It was also recommended that a different standard in postoperative wound care be considered, and a universally preferred ideal single topical agent which can promote acute wound healing be identified, especially as the demand for dermatologic procedures continues to grow.[1,18]

An antibiotic-free, film-forming silicone gel wound dressing (WD) approved for application onto de-epithelized skin and granulating open wounds was chosen for this study to compare its efficacy in preventing SSIs, while observing wound healing outcomes and side-effects. The WD product is semi-occlusive, gas-permeable and bacteriostatic, and limits transepidermal water loss, thereby providing an optimal moist environment to promote cutaneous wound healing.[19] Silicone has been considered a first-line non-invasive therapy for the treatment of hypertrophic and keloidal scars for many years; however, previously it would only be applied once the wound had healed.[20]

Several case studies have already revealed the utility of the WD when used for postprocedure healing and for additional challenging dermatologic cases such as non- or slowly healing scalp wounds, including erosive pustular dermatosis and in cases of chronic eczematous cheilitis.[21-23] Given the WD's ability to be applied onto open granulating wounds and de-epithelized skin, it is well suited to promote rapid re-epithelialization and scar prevention when it is used immediately after any surgical procedure or incidental trauma to the skin.

In this study, our primary objectives were to compare the prevalence of contact dermatitis, subjective measures of healing and the infection rate of postsurgical wounds treated with the novel WD to those treated with a triple antibiotic (TA) ointment containing bacitracin zinc, neomycin sulphate and polymyxin B sulphate in a cohort of patients divided into two treatment arms. Arm one underwent Mohs micrographic surgery for non-melanoma skin cancer (NMSC), and arm two underwent non-Mohs routine dermatologic surgical interventions. The secondary objectives were to compare patients' ratings of satisfaction, the comfort and ease of application of the two products when applying them immediately to the postsurgical wounds.

Table 1 Responses of a patient survey documenting their customary use of over-the-counter first-aid cream or ointment

Product	Number (%) $N = 962$
Triple antibiotic	442 (45.8)
Polysporin	247 (25.7)
Petrolatum-based ointments	76 (7.9)
Bacitracin	31 (3.2)
Other creams/butters	26 (9.1)
Petrolatum-based products with vitamins included	25 (2.6)
Cortisone/hydrocortisone	25 (2.6)
Products containing aloe vera	14 (1.5)
First-aid cream containing antiseptics	6 (0.6)
No response/no preference	37 (3.8)

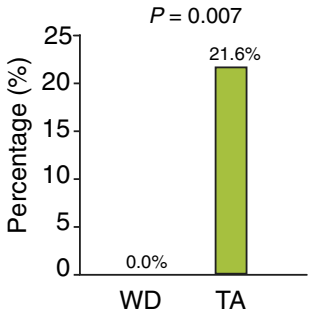

Figure 1 Contact dermatitis rate.

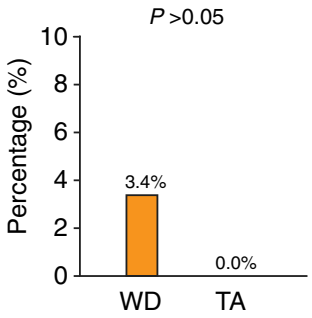

Figure 2 Infection rate.

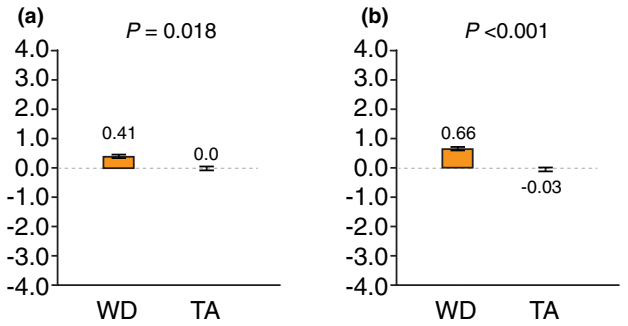

Figure 3 (a) Healing time. (b) Healing quality.

Materials and methods

A randomized, placebo-controlled single-blinded trial was conducted on a cohort of patients who underwent Mohs micrographic surgery for NMSC (arm 1) and a cohort who underwent non-Mohs routine cutaneous surgical procedures (arm 2). Patients in both arms were randomized to receive and utilize either the WD product (Stratamed®, Stratpharma AG, Basel, Switzerland) or the TA product (Neosporin®, Johnson & Johnson, New Brunswick, NJ, USA) as their exclusive postoperative wound care treatment. Due to the highly recognizable and different physical properties of both studied products, the design was chosen to be single-blinded to the clinical investigator. The wound healing was measured and assessed by the clinical investigators using standardized photographs. Randomization was carried out prior to trial initiation via WinEpi Software.[24] All patients 18 years and older who were undergoing any surgical intervention or Mohs micrographic surgery for NMSC were eligible to enter the study. Patients with a history of significant medical or surgical conditions, those unable to give informed consent or unable to administer the WD or TA as directed were excluded from the trial. Additionally, those with a history of known allergy to the contents of the TA, and when randomly allocated to the antibiotic arm, were excluded from participating in the study but were still included in the data analysis so as to calculate the prevalence of contact dermatitis. Investigator assessment of incidental allergic contact dermatitis was confirmed by patch testing to differentiate from normal wound healing inflammation. Incidental, possible infections were confirmed by microbiological culture. As the clinical investigator was single-blinded, the patient had to be unblinded first and subsequently a patch test was performed on the patient with the TA or WD, depending on the randomly assigned treatment.

Patient information obtained included height, weight, gender, history of any skin or chronic medical condition, history of tobacco smoking and Fitzpatrick skin type. The anatomical location and dimensions of each sutured surgical wound were recorded and photographed at the time of entry into the trial, after suture removal, and prior to discharge.

All patients had their randomly assigned topical wound dressing applied immediately postprocedure and were bandaged with the same type of non-adhesive physical dressing and tape and directed to keep this in place and dry for 48 h. Patients were instructed to apply their topical product at least twice a day beginning on day 3 and until suture removal. Patients receiving appropriate prophylactic oral antibiotics were dispensed immediately postoperatively who met the indications of the 2008 advisory statement recommendations for post-cutaneous-surgery prophylactic antibiotics.[17] These patients included those with high-risk cardiac conditions; patients with prosthetic joints at high risk for hematogenous total joint infection; immunocompromised patients with chronic systemic diseases, such as labile diabetes mellitus and severe arthropathies; and patients with surgical sites assumed preoperatively to be colonized or potentially at risk for infection. Also, patients who were treated by Mohs surgery for skin cancers or other types of interventional cutaneous surgery located adjacent to or involving mucosal surfaces such as the perioral and ano-genital areas; involving cartilaginous tissue of the ears and nose; and the lower extremities; as well as patients who received skin grafts anywhere on the body and sizeable skin flaps in the centre of the face; and for patients with extensive inflammatory skin disease according to established evidence-based criteria for patients at risk for postsurgical

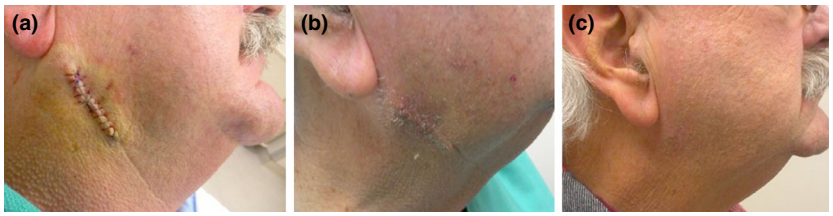

Figure 4 This 66-year-old patient treated with silicone WD gel is shown immediately following Mohs surgery and repair (a), one week postoperatively following suture removal (b), and seven months postoperatively at final assessment (c).

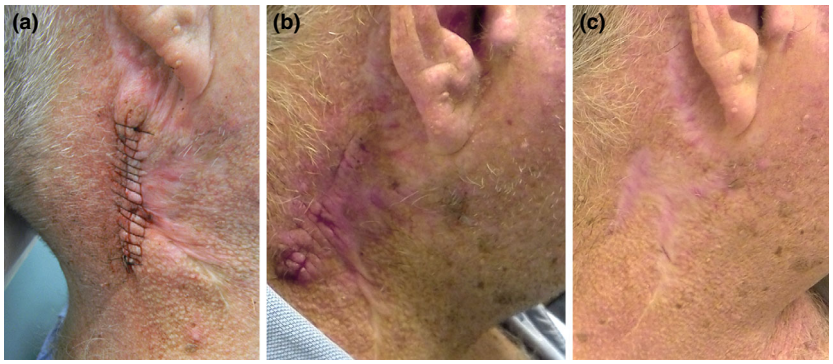

Figure 5 This 61-year-old patient treated with TA ointment is shown immediately following Mohs surgery and repair (a), one week postoperatively following suture removal (b), and seven months postoperatively at his final assessment (c).

wound infections, especially if they underwent prolonged and deep Mohs resections or those patients with a known history of developing MRSA postoperatively were also given appropriate prophylactic oral antibiotics immediately after surgery.[17] These patients were excluded from the data analysis to measure incidence of infection as oral antibiotic prophylaxis would bias the incidence of SSIs.

Study visits coincided with regularly scheduled follow-up visits at which time the surgical wounds were photographed and assessed for the presence of infection or contact dermatitis.

Investigators checked adherence to the study protocol and product usage according to the patient information sheet, questioning the patient at every visit.

One of the challenges of this study was to rate acute wound healing using validated scales. To the authors' knowledge, there are no effective scales validated for the measurement of acute wound healing. There are available scales for chronic wounds and scar outcomes, but these scales do not capture the essential assessment of the wound in the early days after a dermatologic surgical intervention. The study design had the dermatologic surgeon evaluating the patient for wound healing time, healing quality, erythema and new tissue quality, using a Likert rating scale against expected results from −4 (much worse) to +4 (much better) including the expected reference grade of zero (0) in a single-blinded setting. It was decided to evaluate different variables that the authors consider clinically important when evaluating an acute wound. The documented measurements of 'healing quality' and 'tissue quality' represent the ability of the healing area to resemble healthy nearby tissue during and after acute wound healing. Patient's rating of pruritus or pain on a 10-point scale and patient compliance were assessed and recorded at each follow-up visit. Patients also graded their respective product for ease of application, comfort after application and overall satisfaction of their particular product using a 5-point scale (1 = excellent; 2 = good; 3 = moderate; 4 = sufficient; 5 = unsatisfactory). For the final assessment, each patient was asked to document their assessment of the performance of their wound care product using the same 5-point scale as used for their previous postoperative assessments. This 5-point scale was used to rate the tolerability, efficacy, ease of use, overall satisfaction with the treatment and their subjective feeling about the physical sensation of the product on their skin. Contact dermatitis and infection rates were analysed via chi-squared test, and all other measures were analysed using the Mann–Whitney test with mean and standard deviation reported. Data analyses were 2-tailed, with a confidence interval of 0.95, power of 0.80 and statistical significance set at $P \leq 0.05$.

Results

The two arms of the study screened 231 patients for inclusion: 67 in the Mohs surgery arm (1) and 164 in the non-Mohs surgery arm (2). Seven patients were excluded due to known allergy

to one or more of the ingredients contained in the TA in both study arms (14 exclusions in total); however, they were included in the statistical analysis for prevalence of contact dermatitis. Of all the patients, 17 were prescribed an oral antibiotic immediately postoperatively (4 in the Mohs arm and 13 in the non-Mohs arm). To prevent bias, they were excluded from the outcome measurement analysis of SSIs. Of the 17 patients, 16 received oral cephalosporin; 7 out of 17 patients had been randomized in the investigational device group WD, and 10 in the control group TA. None of these 17 patients developed infection. One patient in the WD group was excluded due to non-compliance to the protocol and product application, resulting in 29 patients in the WD group and 30 patients in the TA group in the Mohs arm (1), while in the non-Mohs arm (2) there were 82 patients in the TA group and 75 patients in the WD group for final data analysis. Patient ages were similar, and a variety of anatomical surgical site locations were included in both groups and study arms (Table 2).

Table 2 Patient demographics

Arms	Arm 1: Mohs surgery		Arm 2: Non-Mohs surgery	
Characteristic	**WD (n = 29)**	**TA (n = 30)**	**WD (n = 75)**	**TA (n = 82)**
Mean age (years; ±SD)	70 (±13)	69 (±12)	60 (±19)	63 (±16)
Gender (mean)				
Female	9 (30%)	14 (47%)	28 (37%)	29 (35%)
Male	21 (70%)	16 (53%)	46 (62%)	52 (64%)
Not available			1 (1%)	1 (1%)
Surgical sites				
Abdomen	0	0	5	3
Axilla	0	0	0	2
Back	2	0	7	16
Buttock	1	0	1	1
Calf	1	0	7	0
Cheek	1	3	3	4
Chest	0	3	2	6
Chin	0	0	3	1
Ear	0	0	0	2
Elbow	1	1	0	0
Foot	0	0	3	5
Forearm	1	3	3	2
Forehead	3	2	2	3
Genitals	0	0	0	1
Hand	3	0	0	1
Jaw	0	0	0	4
Knee	1	0	1	1
Lip	1	0	1	2
Neck	1	5	3	3
Nose	5	1	3	2
Peri-Orbital area	0	2	4	1
Perineum	0	0	0	1
Scalp	0	2	8	7
Temple	2	2	2	2
Thigh	0	1	4	5
Upper arm/ shoulder	4	5	10	7
Wrist	2	0	0	
Not recorded	0	0	3	

WD, wound dressing; TA, topical antibiotic.

Contact dermatitis and infection rates

The rate of contact dermatitis was lower in the WD group compared to the TA group as confirmed by patch testing (0 vs 18.9%, respectively; n = 230; $P < 0.000$). There was no difference of contact dermatitis between arms ($P = 0.242$). The frequency of infection was not different between treatment groups, with 2 cases reported in the WD group (1.9%) and no cases reported in the TA group as confirmed by microbiological cultures (0; $P = 0.14$). There was no difference of infection rate between study arms ($P = 0.469$) (Figs 1,2).

Measures of healing and clinician's overall satisfaction

The clinician's rating of healing time was better in the WD group (0.35 ± 0.95) compared to the TA group (0.02 ± 0.09; $P = 0.014$). The quality of healing was also better in the WD group compared to the TA group (0.44 ± 0.10 vs 0.00 ± 0.10, respectively; $P < 0.001$). The quality of the newly formed tissue as rated by the assessor was better in the WD group compared to the TA group (0.35 ± 0.10 vs -0.03 ± 0.10, respectively; $P = 0.009$). The observed erythema was lower in the WD group compared to the TA group (0.17 ± 0.12 vs -0.19 ± 0.12, respectively; $P = 0.040$). The comfort of product usage was better in the TA group compared to the WD group (1.40 ± 0.08 vs -1.16 ± 0.08, respectively; $P = 0.027$). The overall satisfaction was also better in the TA group compared to the WD group (1.49 ± 0.09 vs 1.23 ± 0.09, respectively; $P = 0.049$). The ease of application did not differ between the WD and TA groups. Ease of application was rated (1.12 ± 0.05) in the WD group compared to (1.18 ± 0.05) in the TA group ($P = 0.382$). No difference was found between the Mohs and non-Mohs arm except for the outcome 'ease of application'. The treatment products were considered easier to apply when used on non-Mohs patients ($P = 0.026$), but no other effects between study arms could be identified. The results are summarized in Tables 3 and 4 (Fig. 3).

Patient's assessment of the treatment and products

Comfort, ease of product application, pain and pruritus were assessed at every visit by the patients. The results were not significantly different between groups. At the final visit, patient assessments of product tolerability, efficacy, ease of use, feel on skin and overall patient satisfaction with the products also did not significantly differ between groups. Patient ratings of product assessments are listed in Table 5.

Table 3 Mean values and std. error for assessor-rated outcomes per treatment group

	Control/ Stratamed	Arm	Mean	Std. Deviation	*N*
Ease_of_Application	Control	Mohs	1.07	0.254	30
		Non-Mohs	1.29	0.568	72
		Total	1.23	0.506	102
	Stratamed	Mohs	1.07	0.371	29
		Non-Mohs	1.16	0.441	73
		Total	1.14	0.423	102
	Total	Mohs	1.07	0.314	59
		Non-Mohs	1.23	0.510	145
		Total	1.18	0.467	204
Comfort	Control	Mohs	1.27	0.828	30
		Non-Mohs	1.54	0.934	72
		Total	1.46	0.908	102
	Stratamed	Mohs	1.14	0.516	29
		Non-Mohs	1.18	0.420	73
		Total	1.17	0.447	102
	Total	Mohs	1.20	0.689	59
		Non-Mohs	1.36	0.742	145
		Total	1.31	0.729	204
Overall_Satisfaction	Control	Mohs	1.40	0.932	30
		Non-Mohs	1.57	1.019	72
		Total	1.52	0.992	102
	Stratamed	Mohs	1.14	0.441	29
		Non-Mohs	1.32	0.724	73
		Total	1.26	0.659	102
	Total	Mohs	1.27	0.739	59
		Non-Mohs	1.44	0.889	145
		Total	1.39	0.850	204
Healing_Time	Control	Mohs	−0.03	0.320	30
		Non-Mohs	0.07	0.635	72
		Total	0.04	0.561	102
	Stratamed	Mohs	0.41	1.181	29
		Non-Mohs	0.29	1.047	73
		Total	0.32	1.082	102
	Total	Mohs	0.19	0.880	59
		Non-Mohs	0.18	0.871	145
		Total	0.018	0.872	204
Healing_quality	Control	Mohs	−0.07	0.365	30
		Non-Mohs	0.07	0.757	72
		Total	0.03	0.667	102
	Stratamed	Mohs	0.66	1.233	29
		Non-Mohs	0.23	0.993	73
		Total	0.35	1.078	102
	Total	Mohs	0.29	0.966	59
		Non-Mohs	0.15	0.885	145
		Total	0.19	0.908	204
Erythema	Control	Mohs	−0.30	0.952	30
		Non-Mohs	−0.07	1.025	72
		Total	−0.14	1.005	102
	Stratamed	Mohs	0.34	1.675	29
		Non-Mohs	0.00	1.000	73
		Total	0.10	1.231	102
	Total	Mohs	0.02	1.383	59
		Non-Mohs	−0.03	1.010	145
		Total	−0.02	1.127	204
New_tissue_Quality	Control	Mohs	−0.03	0.556	30
		Non-Mohs	0.03	0.691	72
		Total	0.01	0.652	102
	Stratamed	Mohs	0.45	1.213	29
		Non-Mohs	0.26	0.986	73
		Total	0.31	1.053	102
	Total	Mohs	0.20	0.961	59
		Non-Mohs	0.14	0.858	145
		Total	0.16	0.887	204

Discussion

The results of this randomized, open-label study demonstrated that as a primary dressing, the WD was significantly better than TA for the prevention of contact dermatitis, without a significant difference in infection rate. The WD also provided statistically significant improvements in assessor-rated wound healing properties compared to the TA control.

The prevalence of contact dermatitis in the current study was 18.9% in the TA group with no cases in the WD group. Previous reports have demonstrated contact dermatitis rates of ~13% with topical antibiotics.[1,25-27] The decision to use the petrolatum-based topical triple antibiotic ointment as the control was reached only after confirming the results of a survey from 962 prospective patients who answered a questionnaire asking them what their favourite over-the-counter first-aid cream or ointment was they typically use to help heal a scratch, cut or burn. Over 74% of those patients that responded admitted that they preferred using an antibiotic ointment, and in particular, 45% preferred Neosporin® (Table 1). In addition, a recent report by Nguyen *et al.* identified in their study approximately 43% of dermatologists recommend the use of a topical antibiotic in the postoperative instructions to their patients, validating the selection of TA as the control in our study.[1]

In contrast, silicone is naturally inert and hydrophobic, resulting in high biocompatibility and non-absorption into the skin.[28] However, until recently, silicone was only indicated once the wound had re-epithelized. This studied WD product is the first topical silicone wound dressing approved for open wounds or de-epithelized skin, thus providing an ideal wound dressing option without the risks associated with topical antibiotics.

Table 4 Tests between treatment groups and treatment arms

Source	Dependent variable	Type III sum of squares	df	Mean square	*F*	Sig.	Partial eta squared	Noncent. parameter	Observed power[a]
Control vs. Stratamed	Ease_of_Application	0.164	1	0.164	0.768	0.382	0.004	0.768	0.141
	Comfort	2.541	1	2.541	4.988	0.027	0.024	4.988	0.604
	Overall_Satisfaction	2.796	1	2.796	3.936	0.049	0.019	3.936	0.506
	Healing_Time	4.640	1	4.640	6.203	0.014	0.030	6.203	0.698
	Healing_quality	8.215	1	8.215	10.391	0.001	0.049	10.391	0.894
	Erythema	5.348	1	5.348	4.253	0.040	0.021	4.253	0.537
	New_tissue_Quality	5.345	1	5.345	6.936	0.009	0.034	6.936	0.746
Arm	Ease_of_Application	1.076	1	1.076	5.049	0.026	0.025	5.049	0.609
	Comfort	1.041	1	1.041	2.044	0.154	0.010	2.044	0.296
	Overall_Satisfaction	1.259	1	1.259	1.773	0.185	0.009	1.773	0.263
	Healing_Time	0.006	1	0.006	0.008	0.930	0.000	0.008	0.051
	Healing_quality	0.858	1	0.858	1.086	0.299	0.005	1.086	0.179
	Erythema	0.137	1	0.137	0.109	0.742	0.001	0.109	0.062
	New_tissue_Quality	0.169	1	0.169	0.219	0.640	0.001	0.219	0.075

[a]Computed using alpha error = 0.05.

Table 5 Patient assessments of products

Measure	WD	TA	*P*-value
Treatment comfort	1.27 (±0.83)	1.14 (±0.52)	0.44
Ease of application	1.07 (±0.37)	1.07 (±0.25)	0.61
Pain	0.31 (±0.66)	0.17 (±0.65)	0.15
Pruritus	0.48 (±0.99)	0.63 (±1.40)	0.83
Product tolerability	1.10 (±0.41)	1.18 (±0.39)	0.24
Efficacy	1.34 (±0.55)	1.34 (±0.63)	0.86
Ease of use	1.14 (±0.58)	1.07 (±0.26)	1.00
Feel on skin	1.28 (±0.53)	1.29 (±0.46)	0.77
Overall satisfaction	1.34 (±0.81)	1.18 (±0.39)	0.70

TA, topical antibiotic; WD, wound dressing.

The infection rates were not significantly different between the two groups; 2 cases of infection occurred in the WD group. The physical properties of silicone materials are antimicrobial in nature (see Kottman[29] for review); thus, it was expected that the WD would exhibit comparable infection rates as TA.

The clinicians' subjective ratings showed statistically significant improvements in the WD group over the TA group when comparing healing time, erythema and new tissue quality (Figs 4,5). The utility of the WD product is in its application to compromised or sutured skin immediately postoperatively or post-trauma, which allows for earlier reduction in the inflammatory response and possible reduction in excessive scar formation. Prolonged inflammation during wound healing may contribute to abnormal scar formation.[20-23] The liquid consistency of the WD allows the product to form a full-contact film over the wound bed, which is particularly convenient for contoured or mobile areas. Given the known anti-inflammatory and antimicrobial characteristics of WD, as well as its gas permeability and ability to reduce transepidermal water loss, the earlier the contact of the WD with the wound bed, the more likely it can provide a more suitable hydrating and protective environment to enhance and accelerate re-epithelialization of a healing wound.

Measures related to the feel and application of the products were rated similarly between the WD and the TA. In hindsight, these results should not be surprising given that both products are topical formulations with similar consistencies. A benefit of the WD product is that when used sparingly as directed by the package insert, the studied WD dries to form a thin, invisible, non-sticky, protective film that can be covered with secondary dressings, sunblock or even cosmetics.

This study had some limitations. Patients were seen at variable time sequences with respect to their follow-up suture removal and wound check appointments, so that there may have been a potential for recall bias for patients when answering the wound care product surveys. It is reasonable to conclude that healing wounds of different sizes, from various anatomic sites in a variety of different patients, may have also contributed to the results observed in this study when comparing the WD treatment to the petrolatum-based TA product. Because the surgery locations and assessment times were not standardized and to limit this bias, we used a scale with the physician's expectation as baseline so the location and healing times would be standardized in every further assessment. In addition, as this trial was not designed as a repeated measurements study, the standardization of follow-up assessment times was not essential. Moreover, the standardization of anatomical wound locations would have reduced the recruitment capacity for this trial and was therefore sacrificed in order to achieve a relevant sample size.

Conclusion

Although this study recruited 231 patients, it is the first comparative study demonstrating the utility of a topical silicone wound dressing in a gel format indicated for application immediately

after surgery to sutured skin, open wounds, granulation tissue or compromised skin. In the current study, Mohs and non-Mohs surgical wounds treated with the film-forming WD demonstrated statistically significant improvements in wound healing parameters compared to those treated with the triple antibiotic ointment. Additionally, a higher prevalence of contact dermatitis was observed in the antibiotic group without a significant difference in the occurrence of infection between the study groups.

Our current postsurgical wound care regimen includes recommending petrolatum as the preferred postprocedure topical wound care product. However, it was known to the study team that a large majority of patients were still using over-the-counter TA wound care products even when instructed not to do so. That was the reason why we performed a survey on 962 patients attending our clinic, revealing that a majority of patients still relied on TA as an after procedure wound care product. As documented in a recent study by Nguyen, *et al*., we, as clinicians, are partly responsible for this patient preference.[1] Even though most dermatologists are making informed and standard recommendations to their patients, the reality is that a substantial amount of dermatologists (~43%) and the majority of our patients (~75%) invariably select from habit and instinctively use over-the-counter petrolatum-based topical antibiotic products commonly and in particular (~45%) TA.[1] This was the reason we chose TA as our control and not petrolatum.

The authors believe that the antibiotic-free silicone gel WD is a viable alternative to topical antibiotics or any other petrolatum-based product, with or without antibiotics, for postoperative wound care without enhancing the risk of infection or jeopardizing normal wound healing. Silicone gels utilized as a postsurgical primary wound dressings may reduce not only the cosmetic and psychological burden of scar formation, but also the problem of postsurgical infections, chemical irritation or contact dermatitis and antimicrobial resistance. The Centers for Disease Control has estimated that each year at least 2 million people in the United States become infected with bacteria resistant to antibiotics, and over 23 000 die as a direct result of these infections.[30] Using a silicone gel as a postoperative wound dressing may help to alleviate the mounting concerns over the increasing incidence of antimicrobial resistance.

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References

1 Nguyen JK, Huang A, Siegel DM, Jagdeo J. Variability in wound care recommendations following dermatologic procedures. *Dermatol Surg* 2020; **46**: 186–191.
2 Del Rosso JQ, Leyden JJ. Status report on antibiotic resistance: Implications for the dermatologist. *Dermatol Clin* 2007; **25**: 127–132.
3 Lapolla WJ, Levender MM, Davis SA, Yentzer BA *et al*. Topical antibiotic trends from 1993 to 2007: use of topical antibiotics for non-evidence-based indications. *Dermatol Surg* 2011; **37**: 1427–1433.
4 Del Rosso JQ, Kim GK. Topical antibiotics: therapeutic value or ecologic mischief? *Dermatol Ther* 2009; **22**: 398–406.
5 Maragh SL, Brown MD. Prospective evaluation of surgical site infection rate among patients with Mohs micrographic surgery without the use of prophylactic antibiotics. *J Am Acad Dermatol* 2008; **59**: 275–278.
6 Halpern AC, Leyden JJ, Dzubow LM, McGinley KJ. The incidence of bacteremia in skin surgery of the head and neck. *J Am Acad Dermatol* 1988; **19**: 112–116.
7 Futoryan T, Grande D. Postoperative wound infection rates in dermatologic surgery. *Dermatol Surg* 1995; **21**: 509–514.
8 Kluytmans J, van Belkum A, Verbrugh H. Nasal carriage of Staphylococcus aureus: epidemiology, underlying mechanisms, and associated risks. *Clin Microbiol Rev* 1997; **10**: 505–520.
9 Campbell RM, Perlis CS, Fisher E, Gloster HM, Jr. Gentamicin ointment versus petrolatum for management of auricular wounds. *Dermatol Surg* 2005; **31**: 664–669.
10 Cronin H, Mowad C. Anaphylactic reaction to bacitracin ointment. *Cutis* 2009; **83**: 127–129.
11 Greenberg K, Espinosa J, Scali V. Anaphylaxis to topical bacitracin ointment. *Am J Emerg Med* 2007; **25**: 95–96.
12 Sheth VM, Weitzul S. Postoperative topical antimicrobial use. *Dermatitis* 2008; **19**: 181–189.
13 Alanis AJ. Resistance to antibiotics: are we in the post-antibiotic era? *Arch Med Res* 2005; **36**: 697–705.
14 Brian MJ. Mupirocin-resistant MRSA transmission associated with community hospitals and nursing homes. *J Hosp Infect* 2010; **75**: 141–142.
15 Mulvey MR, MacDougall L, Cholin B, Horsman G *et al*. Community-associated methicillin-resistant *Staphylococcus aureus*, Canada. *Emerg Infect Dis* 2005; **11**: 844–850.
16 Smack DP, Harrington AC, Dunn C, Howard RS *et al*. Infection and allergy incidence in ambulatory surgery patients using white petrolatum vs bacitracin ointment. A randomized controlled trial. *JAMA* 1996; **276**: 972–977.
17 Wright TI, Baddour LM, Berbari EF, Roenigk RK *et al*. Antibiotic prophylaxis in dermatologic surgery: advisory statement 2008. *J Am Acad Dermatol* 2008; **59**: 464–473.
18 Del Rosso JQ. Wound care in the dermatology office: Where are we in 2011? *J Am Acad Dermatol* 2011; **64**(Suppl 3): S1–S7.
19 Sandhofer M, Schauer P. The safety, efficacy, and tolerability of a novel silicone gel dressing following dermatological surgery. *Skinmed* 2012; **10** (Suppl 1): S1–S7.
20 Mustoe TA, Cooter RD, Gold MH, Hobbs FD. International clinical recommendations on scar management. *Plast Reconstr Surg* 2002; **110**: 560–571.
21 Monk E, Benedetto E, Benedetto A. Successful treatment of nonhealing scalp wounds using a silicone gel. *Dermatol Surg* 2014; **40**: 76–79.
22 Uva L, Aphale A, Kehdy J, Benedetto A. Erosive pustular dermatosis successfully treated with a novel silicone gel. *Int J Dermatol* 2016; **55**: 89–91.
23 Marini L, Odendaal D, Smirnyi S. Importance of scar prevention and treatment—An approach from wound care principles. *Dermatol Surg* 2017; **43**: S85–S90.
24 de Blas I, Ruiz-Zarzuela I, Vallejo A. WinEpi: Working In Epidemiology. An Online Epidemiological Tool. http://www.winepi.net 2006.
25 Zug Gehrig KA, Warshaw EM. Allergic contact dermatitis to topical antibiotics: epidemiology, responsible allergens, and management. *J Am Acad Dermatol* 2008; **58**: 1–21.
26 Zug KA, Pham AK, Belsito DV *et al*. Patch Testing in Children From 2005 to 2012: results from the North American contact dermatitis group. *Dermatitis* 2014; **25**: 345–355.

27 DeKoven JG, Warshaw EM, Belsito DV, Sasseville D *et al*. North American contact dermatitis group patch test results 2013–2014. *Dermatitis* 2017; **28**: 33–46.
28 Colas A, Curtis J. Silicone biomaterials: History and chemistry. In: Ratner BD, AS Hoffman, FJ Schoen JE Lemons, eds. Biomaterials science. An introduction to materials in medicine, 2nd edn, Elsevier, Amsterdam, 2004: 80–86.
29 Kottmann A, Mejia E, Hemery T, Klein J *et al*. Recent developments in the preparation of silicones with antimicrobial properties. *Chem Asian J* 2017; **12**: 1168–1179.
30 Centers for Disease Control. https://www.cdc.gov/drugresistance/index.html. Accessed 4 May, 2018.