

STUDY USING A 21-DAY WOUND CARE SYSTEM

by Eric Lewis M.D.

Eric A. Lewis , A Medical Corporation.

Abstract

MOHS and shave excisions can result in saucer-shaped wounds that can be slow to heal in the elderly. These patients have difficulty in cleaning and changing wound dressings. Here we review our experience with traditional wound bandages changed every one to two days as compared to a new 21-day, stay-in-place dressing system (Miracle Dressing Wound Care System™ or “MDS”).

Methods

This is a retrospective review of healing times in our patients following MOHS or shave excisions using two different types of wound care. All patients received an excision procedure, wounds were cleaned with water, and a small amount of antibiotic ointment was applied. For the control group (n= 24), a BAND-AID® brand bandage was placed on the wound and patients were instructed to remove the bandage, clean the wound, and reapply a new bandage every one to two days, being careful to keep it dry during the entire healing process. In the test group (n=70), a 21-day high-moisture permeable, breathable, micro and macro-channeled rayon dressing containing marine extract crystals (including extracts from sea cucumber and abalone) was applied and patients were instructed not to change the dressing and to clean with water-soaked gauze daily while applying a small amount of antibiotic ointment every other day. Quantified endpoints were healing time (in days) and % healing at 21 days. The two groups were compared by 1-tailed Student's t- test assuming equal variances.

Results

Time to healing (or wound closure) was significantly shorter in the 21-day dressing test group ($p<0.001$) than the control group, with a mean of 27.8 days compared to 40.65 days in controls. Healing expressed as mm^2 per day was significantly greater ($p=0.013$) in the 21-day dressing group than controls with a mean of $12.75 \text{ mm}^2/\text{day}$ compared to $8.89 \text{ mm}^2/\text{day}$. The percentage of the wound that was healed by 21 days was significantly greater ($p<0.001$) in the test group than in controls, with a mean of 82.9% compared to 50.6% in controls. For each of the parameters examined, healing was remarkably accelerated in the 21-day dressing group. Furthermore, patients in the 21-day dressing group reported a higher satisfaction with post-surgical care at home compared to controls.

Conclusion

Our results showed superior healing using the 21-day breathable, stay-in-place dressing with marine extracts. It also showed reduced signs of surrounding skin disruption and pain as compared to traditional bandages. These results may be due to wound stripping that occurs with bandage changes in the control group, as well as the air breathability and liquid permeability of 21-day dressing. Moreover, the marine extracts may have been responsible for the decreased skin xerosis and micro-fissures in surrounding areas which can cause inflammation, bacterial colonization and slow wound healing. We have also used 21-day dressing for skin tears, second and early third-degree burns, ecchymoses, pressure injuries and their prevention with remarkable success. Gratis provision of MDS by MBET Health is gratefully acknowledged.

INTRODUCTION

MOHS and shave excisions can result in saucer-shaped wounds that can be slow to heal in the elderly. These patients have difficulty in cleaning and changing wound dressings. Improving the speed and quality of healing wounds is the primary function of any wound dressing. Other important functions include reducing pain and suffering, decreasing anxiety of both the patient and the caregiver while maintaining or improving the quality of peripheral skin. Here we report our experience with a new product purported to meet each of these objectives and to advance the field of wound care.

METHODS AND MATERIALS

All procedures and follow-up were conducted in my practice in Beverly Hills, CA – the Eric A. Lewis, A Medical Corp. Patients received a shave excision procedure with electrodesiccation and aluminum chloride for treatment of non-melanoma skin cancer. Wounds were cleaned with water, and a small amount of antibiotic ointment was applied. For the control group (n= 24), a BAND-AID® brand bandage was placed on the wound and patients were instructed to remove the bandage, clean the wound with water, and reapply a new bandage every one to two days, being careful to keep it dry during the entire healing process to prevent maceration. In the test group (n=70), a 21-day high-moisture permeable, breathable, micro and macro-channeled rayon dressing containing marine extract crystals (including extracts from sea cucumber and abalone) was applied and patients were instructed not to change the dressing and to clean with water-soaked gauze daily while applying a small amount of antibiotic ointment every other day. Quantified endpoints were healing time (in days) and % healing at 21 days. The two groups were compared by 1-tailed Student's t- test assuming equal variances.

Although completion of total wound healing takes 6 to 12 months, we use the completion of epithelialization as our end point to healing.

Miracle Dressing Wound Care System™ (“MDS”) is a new (R&D started in 2014; launched in June 2020) product developed and sold by MBET Health in Tarzana, CA.

The dressing component of MDS is a non-woven, regenerated cellulose fiber bandage containing a pressure sensitive adhesive. It has high moisture vapor permeability and 1 mm channels spaced on 3 mm centers. There are non-perforated lanes along the longitudinal edge (and along the center of wider dressings). It is available in widths up to 4” and various lengths up to 15 feet. Photo 1 shows different configurations of the dressing. Photo 2 and Photo 3 are micrographs showing the 1 mm channels and the micropores formed by the cellulose fibers.

MDS also contains an Agglutinant with Natural Marine Extract™. The Agglutinant is a topical skin adhesive comprising isopropyl alcohol and partially hydrogenated rosin. MBET Health recommends applying it to the skin before attaching the dressing under circumstances where additional adhesion might be advantageous. The Natural Marine Extract™ is in the form of lyophilized crystals from extracts from various marine animals and botanicals include sea abalone and sea cucumber. Such marine sources are well known to contain compounds of potential medicinal benefits.^{1,2} MBET Health provides Natural Marine Extract™ in various forms, and suggests that it supports the healing process. With MDS, the Natural Marine Extract™ crystals are suspended in the agglutinant.

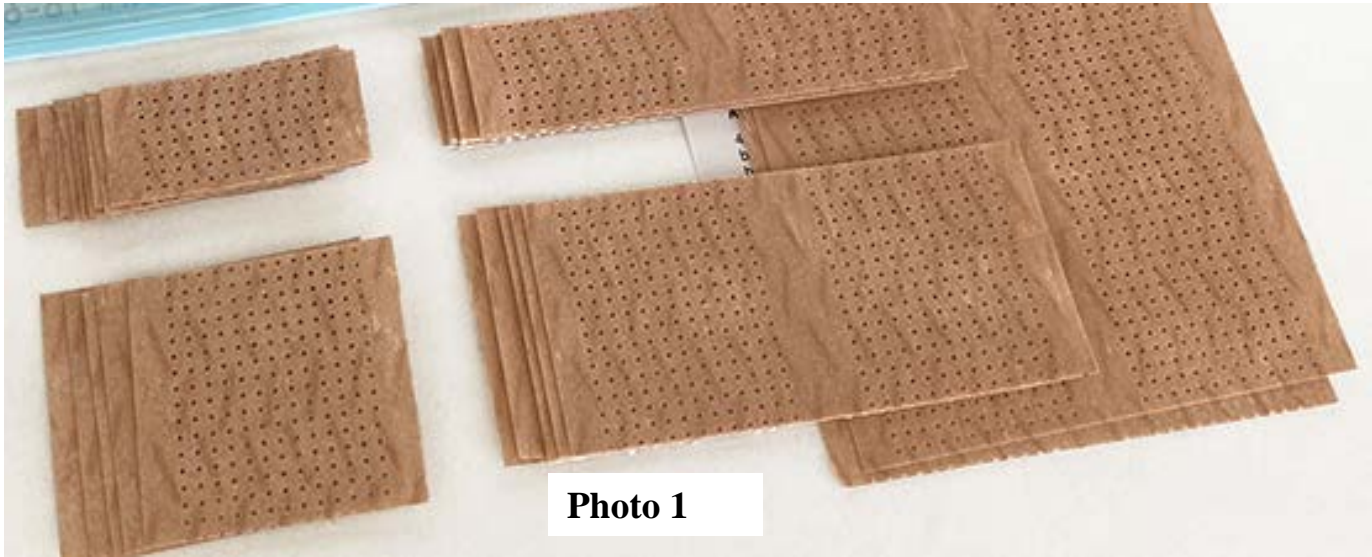


Photo 1

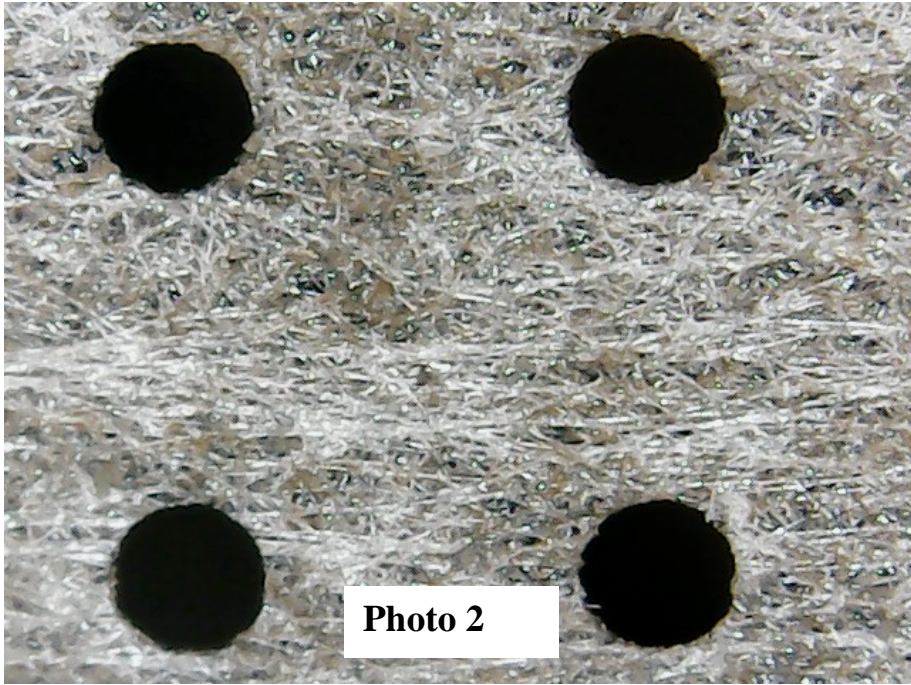


Photo 2

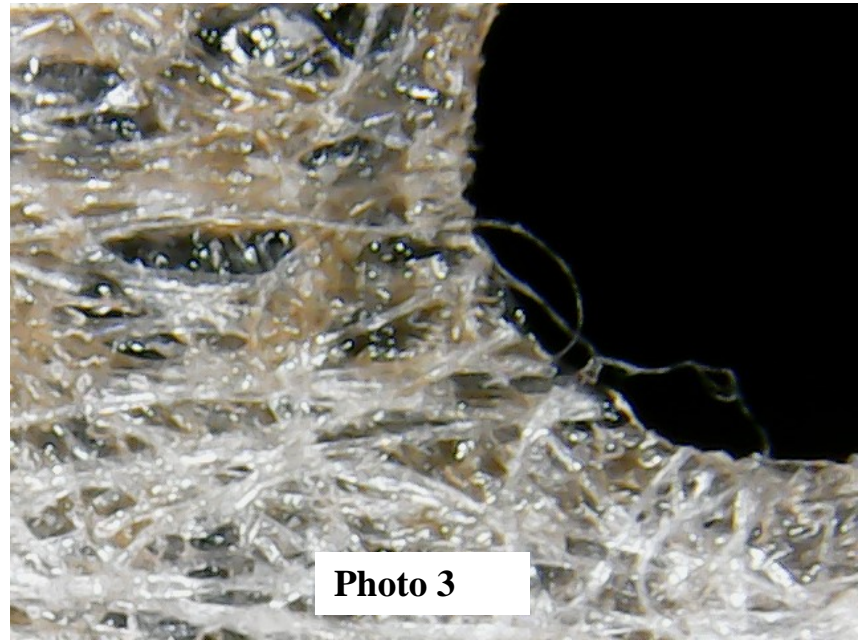


Photo 3

RESULTS

This study focuses on patients seen in our clinic for excision of non-melanoma skin cancer (and electrodesiccation and aluminum chloride treatment) and the follow-up wound care in elderly patients. The medical records of more than 100 such patients were reviewed including 72 patients who received MDS post excision care and 21 patients who received conventional wound care (i.e. BAND-AID with regular changes) as described in “Material and Methods”. Except for the subset analyses, in each case, n=72 for the MDS group and n=21 for the Control (BAND-AID) group.

Four related parameters of wound healing were examined, namely (1) Time in days to healing (Figure 1); (2) Percentage of wound healing by 21 days (Figure 2); Healing rate expressed as mm² per day averaged over 21 days (Figure 3); and healing rate expressed as mm across the width of the wound per day (Figure 4). Irrespective of the healing indicia analyzed, in each case there was a substantial increase in healing speed using the MDS system as compared to the tradition standard of care (i.e. BAND-AID®).

The results shown in Figure 1 – 4 are summarized in Table I. Here we see that the differences between MDS and the standard of BAND-AID® group were highly significant. Moreover, the MDS healing was accelerated by 46%, 64%, 44%, and 44%, respectively.

These data were further analyzed with respect to the location of the wound, namely (1) arm, (2) head, face, and neck, (3) leg, and (4) trunk. As shown in Table II, healing was accelerated in the MDS group irrespective of the location of the wound (from 34% to 47%)(where acceleration = (C days – MDS days X 100%)/MDS days). This difference was not due to the age or gender of the patients, which were not significantly different.

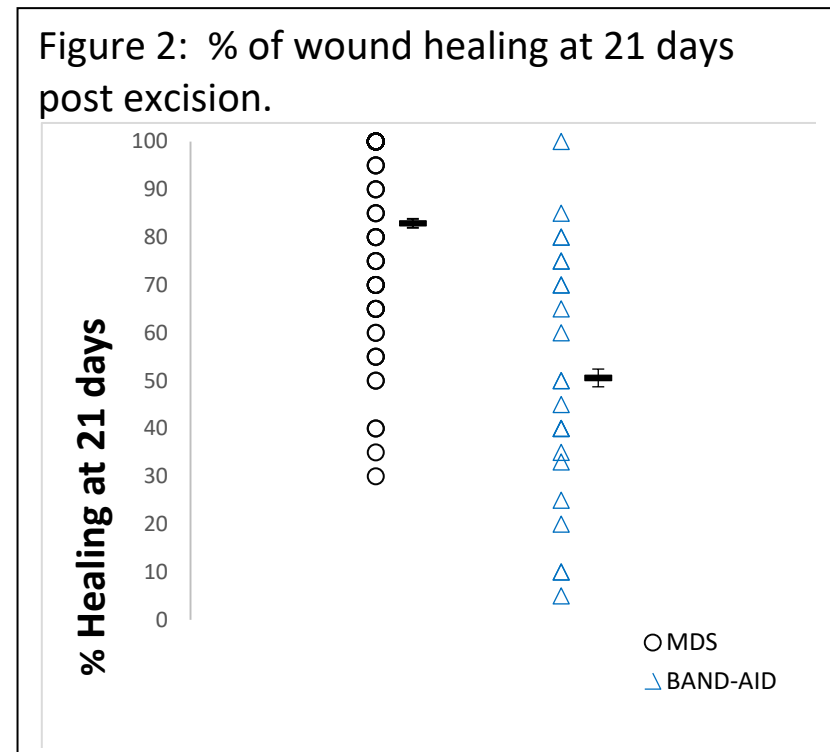
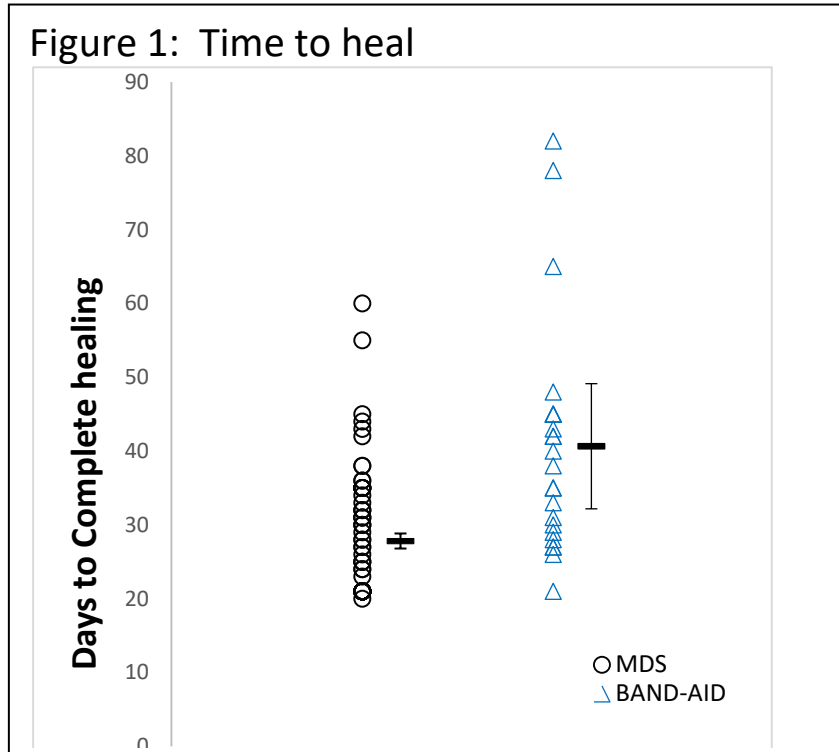


Figure 3: Healing rate (mm²/day).

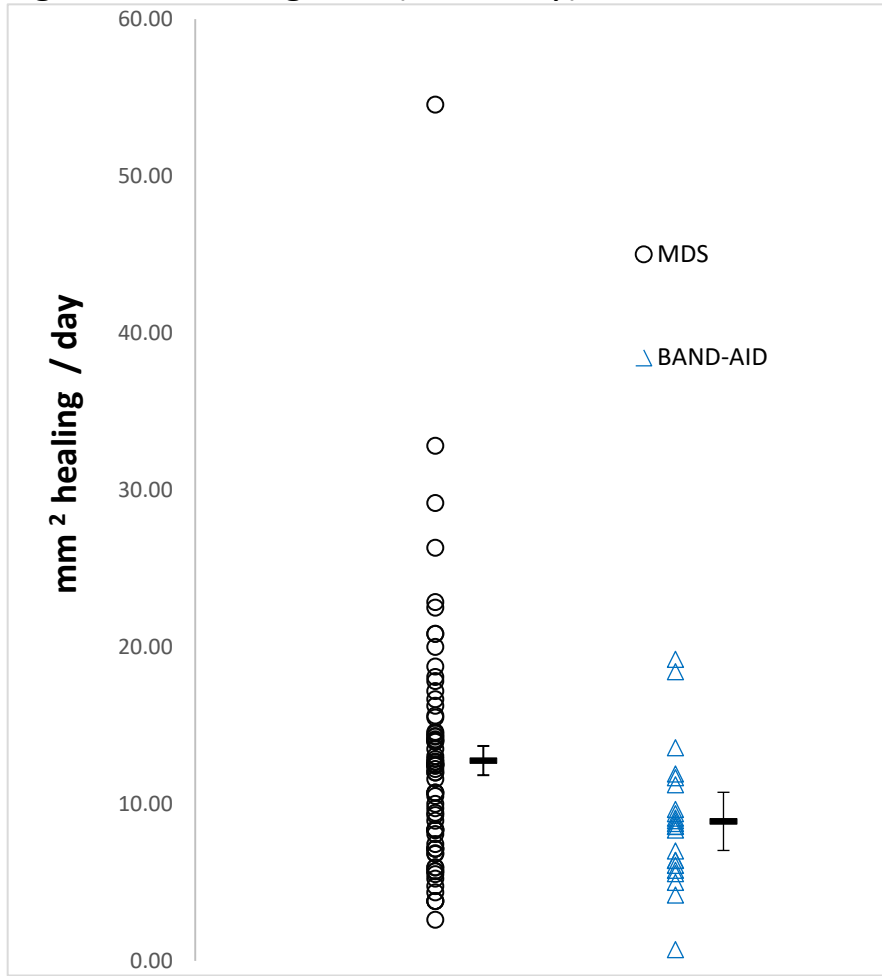
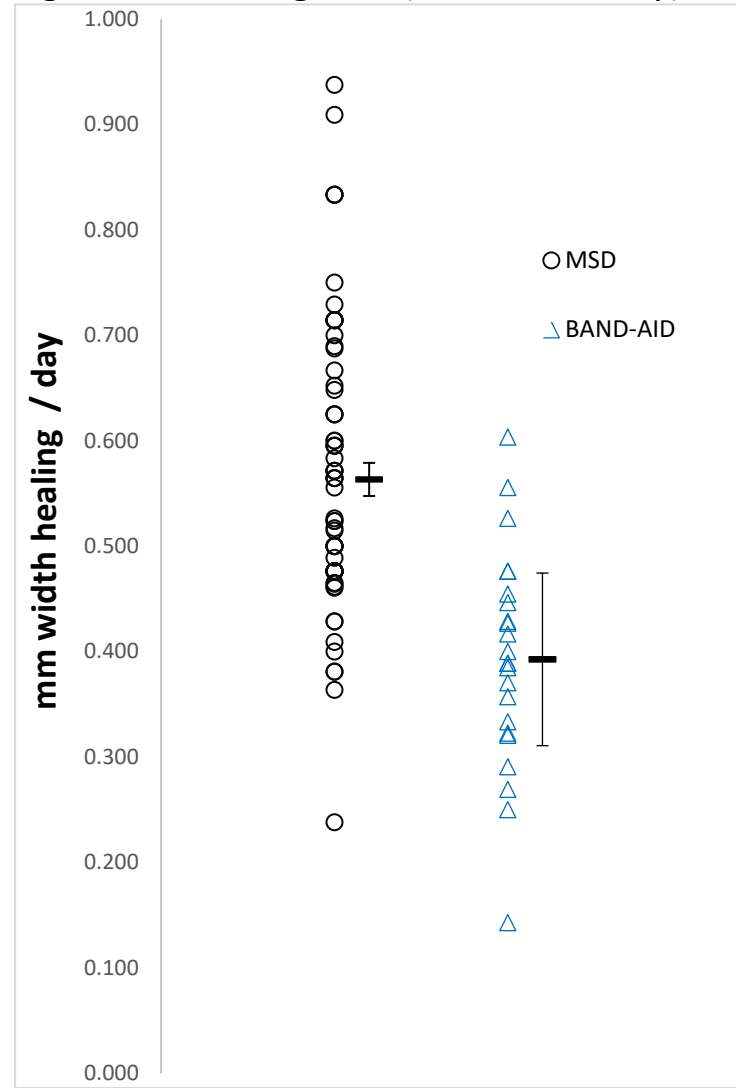


Figure 4: Healing rate (mm width/day).



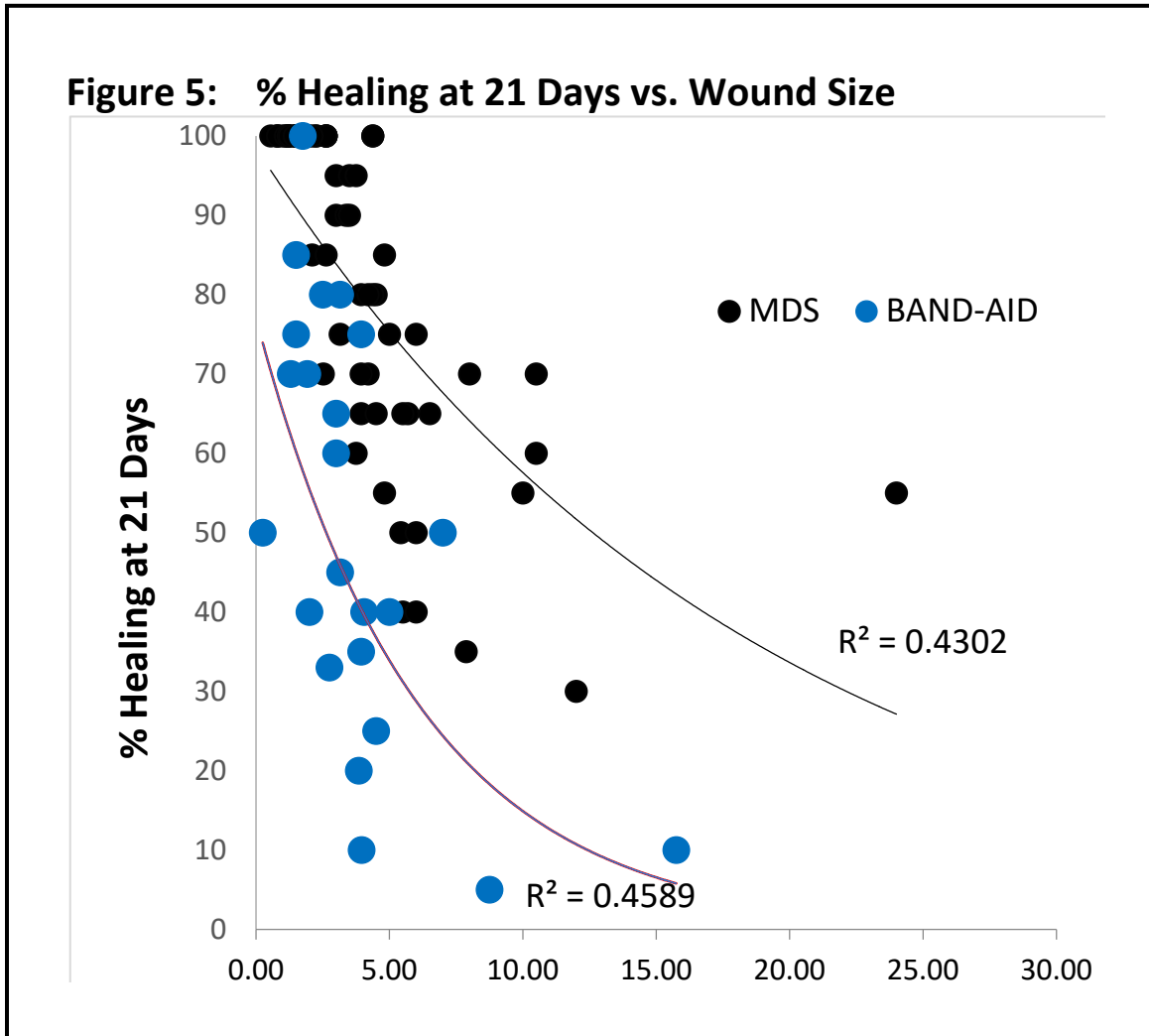
**Table I: Summary of Healing indicia
MDS vs BAND-AID**

Healing Indicia	MDS	BAND-AID
Time to healing (days)		
mean	27.8	40.6
SE	1.01	3.3
acceleration	46%	
P value	<0.001	
% Healing at 21 days		
mean	82.9	50.6
SE	2..3	5.5
acceleration	64%	
P value	<0.001	
Healing width mm/day		
mean	0.56	0.39
SE	0.017	0.022
acceleration	44%	
P value	<0.001	
Healing mm²/day		
mean	12.8	8.89
SE	0.92	0.88
acceleration	44%	
P value	0.01	

**Table II: Healing Time: Analyzed by
Location**

	MDS		BAND-AID	
	age	Healing time (days)	age	Healing time (days)
Arm				
n	12		6	
mean	77.3	24.1	76.5	34.7
SE	3.7	1.4	4.3	3.0
acceleration		34%		
Head				
n	23		8	
mean	76.7	27.5	81.8	37.6
SE	2.1	1.4	4.2	4.9
acceleration		36.9%		
Leg				
n	13		8	
mean	75.3	35.8	70.1	47.9
SE	2.3	2.7	3.1	7.4
acceleration				47.1%
Trunk				
n	14		1	
mean	75.1	28.9	89	43
SE	3.5	2.8		
acceleration		42.3%		

The data were also analyzed by % healing at 21 days versus the size of the initial wound (in cm²). These results are shown in Figure 5. Here, as expected, the larger wounds were less healed by 21 days than the smaller wounds. Indeed, there was a significant correlation between size and healing. However, there was a significant difference between the MDS and the control group, where MDS healed more quickly for all wound sizes. Indeed, whereas only one patient in the control group was 100% healed by 21 days, many patients with wounds as large as 5 cm² were 100% healed by 21 days.



This is a 72 year old patient who had previous skin cancer excisions and radiation treatment over his scalp. He had an excision of non-melanoma skin cancer eight weeks earlier and had minimal healing of his wound. MDS was applied. Photo 4 below was taken before MDS (Panel A), upon application of MDS (Panel B), and of the same area 21 days (Panel C).



Photo 4 – Panel A



Photo 4 – Panel B



Photo 4 – Panel C

Discussion

The average life span in the United States was 50 years in 1920, while 100 years later it is 82. In our elderly, the thickness, strength and elasticity and fibrocytes and capillaries nourishing the skin has decrease proportionately. Thus, not only the propensity to injury has increased but the ability to heal the injuries has decreased as well. Wound dressings have not evolved to meet this growing need. Wound care in the elderly present the dermatologist with special challenges. Besides protracted healing time, the elderly are especially susceptible to skin tears and ecchymosis from simply changing a wound dressing.^{3,42} Thus, using a breathable, 21-day stay-in-place dressing which stabilizes not only the wound but the surrounding skin may set a new standard of care.

If a wound has tremendous amounts of exudate, all existing dressings (other than MDS), even the absorbent ones, must be changed frequently. The common practice of applying and frequently replacing traditional adhesive dressings typically cause disruption of the wound with inflammation, bleeding, irritation and skin breakdown of the surrounding skin. Many of these elderly patients require caretakers, usually family, to help change dressings. The trauma of dressing changes is not only painful but it is also the source of anxiety for the patient and caregiver.

We have found that, instead of “keeping the wound dry and changing the bandage every day,” to avoid maceration, which are the directions of most wound preparations, with MDS water immersion (e.g. sponge rinsing, shower) cleans the wound and dissolves the marine extract crystals in a time release manner. In our experience, MDS generally stays adhered to the skin for three to four weeks and then falls of when the wound is healed or close to it.

COVID-19 has magnified the vulnerability of elderly skin to pressure injuries and the lack of medical technology to deal with it. The unfortunate paucity of nursing staff in long term care and skilled nursing facilities has caused the Wound Healing Society and Wound Source Fact Sheet to change the standard of care for pressure injuries - increasing the time intervals between in person visits by nurses and decreasing dressing changes. Indeed, Dr, John Armstrong, director of three skilled nursing facilities in Tampa, Florida estimates that there will be an increase of pressure injuries of two to three times.

Unfortunately, the present wound dressing technology has a maximum period between changes of 7 days. Obviously the 21-day dressing of MDS changes this paradigm, not only protecting and helping to heal Stage 1 and Stage 2 wounds but protecting the surrounding precarious skin.

Similar to the study presented here, we have had re/during/after MDS on a second and superficial third degree burn.



Photo 5

Conclusion

Our results showed superior healing using the 21-day breathable, stay-in-place dressing with marine extracts. It also showed reduced signs of surrounding skin disruption and pain as compared to traditional bandages. These results may be due to wound stripping that occurs with bandage changes in the control group, as well as the air breathability and liquid permeability of 21-day dressing. Moreover, the marine extracts may have been responsible for the decreased skin xerosis and micro-fissures in surrounding areas which can cause inflammation, bacterial colonization and slow wound healing. We have also used 21-day dressing for skin tears, second and early third-degree burns, ecchymoses, pressure injuries and their prevention with remarkable success. This dressing has no wound size limitations and can be used on entire limbs for such problems as burns and bullous disease. We predict that the MDS product will have a substantial impact on a wound care and its associated financial burden exceed \$25 billion.⁵

Conflict of interest. Dr. Lewis has a financial interest in MBET Health but received no financial support for this study other than a gratis supply of MDS.

References

1. Se-Kwon Kim, Marine Nutraceuticals: Prospects and Perspectives. B CRC Press, 2013; 464 Pages. ISBN 978-1-4665-1351-8
2. Gerstein AD, Phillips TJ, Rogers GS, Gilchrest BA. Wound healing and aging. *Dermatol Clin.* 1993;11(4):749-757.
3. Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. *Surg Clin North Am.* 2015;95(1):103-114.
4. Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. *Wound Repair Regen.* 2009;17(6):763-771.
5. Mazliadiyana M, Nazrun A, Isa N, Optimum Dose of Sea Cucumber (*Stichopus Chloronotus*) Extract for Wound Healing. *Med & Health.* 2017;12(1):83-89.