An Innovative Advance in Non-invasive Wound Closure: A New Paradigm

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ABSTRACT Injury is the leading health and readiness threat to the armed forces, with two million instances per year; therefore, innovating wound care solutions can help improve readiness. The DermaClip Skin Closure Device is a new, non-invasive, painless, and easy-to-apply wound closure device that does not require either needles or painful anesthesia injections or create additional damage to the wounded area. The efficacy of the device was tested in a 120-patient trial, composed of 60 experimental cases and 60 control cases. The trial of the DermaClip device demonstrated the device's efficacy in meeting the needs of clinical applications. Additionally, the experimental group had no adverse events in the product safety test. The efficacy of the device coupled with the features of ease of use and limited requirements for application make this a wound closure device particularly applicable to the emergency and battlefield setting.

INTRODUCTION

Injury is undisputedly the leading health and readiness threat to the armed forces.[1] A major portion of injuries to the warfighter involves cutaneous wounds requiring closure. Therefore, the search for a superior cutaneous wound closure device that can be efficiently and effectively used both in the field and in a hospital setting to treat cutaneous injuries as well as to expedite surgical closures has significant importance.[2] Recent observational studies indicate that the DermaClip device may fulfill that role.

Much has been written regarding the use of sutures, staples, and adhesives ("traditional closure methods") in wound closure. Previous studies, as well as in practical experience, with each of those traditional closure methods, demonstrate both positive and negative attributes. One study assessed patients' satisfaction with traditional closure methods and reported no significant difference between suture and staple closure media,[3] although Stockley and Elson[4] and Singh et al[5] reported that staples were invariably more painful to remove than sutures, an observation previously cited in the non-orthopedic literature.[6–8] Some authors have suggested that the time-saving benefits of staples might have a psychological effect on surgeons and theater staff, particularly after a long operation.[4,9,10] Given the lack of difference in the incidence of superficial wound infection,[11] and the limited empirical evidence for patients' or surgeons' preference, there is insufficient evidence to justify the use of staples over sutures.

Studies related to the use of glues further cloud the evidence. Gupta and Singh et al reported an advantage for glue over staples in wounds smaller than 10 cm but also referenced the significantly increased cost.[12] Also, most studies advocating the use of glues were done in patients anesthetized or having had local anesthetic. Along with the increased expense and need for anesthesia, there is a possibility of a severe allergic skin reaction that may last for weeks.

The subject of this article is a new, non-invasive, painless, needle-free, and easy-to-apply wound closure device that neither requires anesthesia injections nor creates additional damage to the wound area. The development of the DermaClip device addresses issues associated with traditional closure methods, rendering the device superior to those methods. A study of the DermaClip device was performed in China and is presented herein with an analysis of the potential implications of the use of the device in emergency and combat settings.

The DermaClip device itself is composed of two pieces of adhesive joined by a polypropylene bridge. The device is simple in design but quite advanced as a wound closure device.

The DermaClip device is applied to the approximated edges of a wound and is closed by pulling the polypropylene tabs in opposing directions until a "click" is heard, indicating that the device is locked. As the device closes, the angled faces of the polypropylene bridge encounter each other and create a lifting action of the wound edges, putting the viable dermis on each side of the wound into contact.

In other words, the design creates eversion of the skin edges on closure – eversion being the result a skilled surgeon seeks to accomplish – as it is widely believed that wound eversion is essential for minimizing scarring because it maximizes the chance for proper epidermal approximation and avoids the potential for inversion. Additionally, because the device is applied to the approximated edges of the wound,

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FIGURE 1. Pad of five regular DermaClip devices.

FIGURE 2. Pad of three large DermaClip devices.

wound alignment is maintained without forceping or other skin manipulation.

The device currently comes in two sizes, regular and large (Figs 1 and 2). The regular device is 11 mm in width, whereas the large device is 20 mm in width. Multiple devices can be used for larger wounds. Once the wound edges are in satisfactory apposition and the devices are closed, the excess tabs are removed and dressing is applied. The full process is as simple as "Place" (Fig. 3), "Pull" (Fig. 4), and "Clip off the Tabs."

MATERIALS AND METHODS

Per Chinese State Food and Drug Administration ("CFDA") Order No. 5, for a new, sterile wound closure device to be used in the operating room, the non-inferiority hypothesis must be tested in a randomized, parallel-controlled clinical verification trial. Based on the sample size calculation, the DermaClip device control groups were 60 and 60 patients, respectively. Therefore, a total of 120 patients were recruited in this study. For this purpose, two hospitals (the 2nd Hospital of Xuzhou Medical College and the Army 254th Hospital) were invited to participate in the study, with 60 cases completed at each hospital.

The physicians performing the study recorded the enrolled patients' chief complaints, professional examination results, and accessory examination findings. All patients were required to meet the inclusion criteria and voluntarily sign the informed consent form. Based on the visiting sequence, the patients were assigned to either the DermaClip device group (experimental

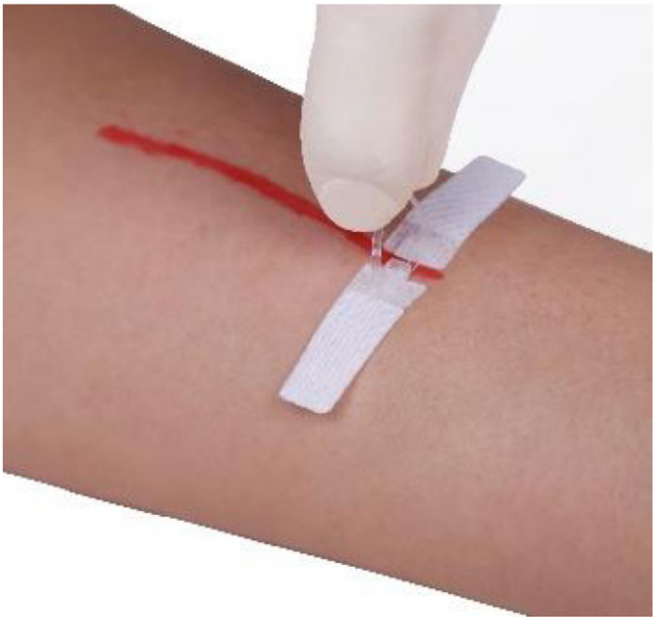

FIGURE 3. Place device on wound.

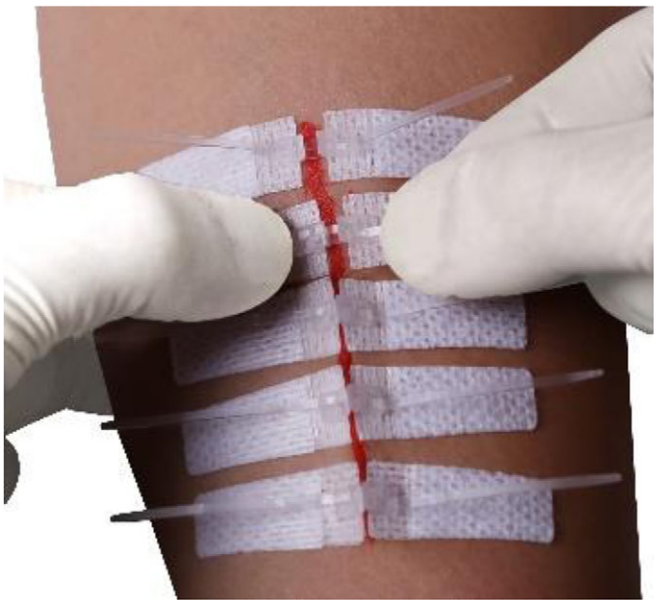

FIGURE 4. After all devices applied, pull wound closed.

group) or the control group using a random numbers table for skin wound closure. The experimental group used regular-sized DermaClip devices and the control groups' wounds were closed with a Beijing Aitekang Medical Co., single-use sterile surgical seam-free zipper, a common-use, CFDA-approved wound closure device in the Chinese surgical community.

All the enrolled patients met the inclusion criteria, including signing the informed consent form, and did not have any of the exclusion criteria (Table I). The investigators completed the Case Report Form and carefully reported the disease conditions and treatment of each subject. In this clinical trial, the subjects' vital signs were tested before use, immediately after

TABLE I. Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1. Age 18–75 yr.	1. Refuses to participate in this trial or to sign the informed consent form.
2. Men or women.	2. Has a coagulation abnormality.
3. An open wound (trauma first aid or war trauma) or a surgical incision that needs to be closed.	3. Has a mental disorder.
4. Able to participate in this trial on a voluntary basis and sign the informed consent form.	4. Has severe liver, kidney, blood, and/or immune disorder.
	5. Is critically ill and therefore not able to accurately evaluate the effectiveness and safety of the device.
	6. Has poorly controlled blood sugar.
	7. Has an infectious incision or a skin disease around the incision.
	8. Has other conditions that are deemed unacceptable for this trial per scrutiny by the investigators and medical staff.

use, and 1 wk after use. The patients' evaluations and corresponding indicators during the applications were recorded. The complications and adverse reactions were also recorded during the observation period, which was up to 2 wk after treatment. The medical institution undertaking the clinical trial completed the CRF per the findings of the clinical trial.

The first group consisted of 60 admitted obstetric and gynecology patients. They were randomly divided into two groups of 30 patients, half having their wound(s) closed by the control method and half with the DermaClip device.

The second group consisted of 60 patients admitted with a diagnosis of some type of trauma. The patients were randomly divided into two groups, half having their wound(s) closed with a control method and half being closed with the DermaClip device.

The demographics of all the patients in both groups can be found in Table II.

STATISTICAL ANALYSIS

Non-related third-party statisticians performed the statistical analysis on the trial data and submitted a "Statistical Analysis Report on the Clinical Trial of Medical Devices" in China. The data from these reports submitted by each of the two medical institutions – Test Report by 2nd Hospital of Xuzhou Medical College and Test Report by Army 254th Hospital, respectively – were then aggregated for further analysis, and a "Summary Report on the Clinical Trial of Medical Devices" was submitted. This summary report of the combined trial sites was approved by the CFDA, making DermaClip legal for manufacture, sale, and use in the Chinese market and in Chinese hospitals.

For this article, the original Chinese data were reviewed by US-based, non-related, third-party statisticians to confirm the outcomes of the study based on the protocol. Minor discrepancies in statistical analysis were found; however, none of those discrepancies had any material impact on the results. This article uses the statistical analysis of the US-based statisticians.

Demographic variables and baseline characteristics for the study included gender, age, weight, allergy history, previous disease history, and wound length. Continuous variables were summarized with descriptive statistics (mean, standard deviation, number of non-missing observations, median, 25th percentile, 75th percentile, minimum, and maximum) within each treatment group, whereas categorical variables were summarized using frequency counts and percentages within each treatment group. Treatment group comparisons were made with two-sample *t*-tests assuming unequal variances for continuous variables and with a χ^2 test for categorical variables.

The primary effectiveness endpoint of the study was the healing rate. Counts and percentages of healed subjects were computed by treatment group, and a non-inferiority test was conducted by comparing the lower limit of the 95% confidence interval of the healing rate differences to the non-inferiority margin of $\delta = 0.10$.

Secondary effectiveness endpoints included ease of use, postoperative care evaluations, and scar results. These endpoints were summarized using frequency counts and percentages of each response. Treatment group comparisons were made with an exact Wilcoxon rank-sum test on the numerically coded responses (i.e., 1 = unsatisfied to 5 = excellent).

Safety was analyzed via pre-treatment and post-treatment vital signs, presence of allergies, wound infections, and adverse events/reactions. Continuous variables were summarized with descriptive statistics within each treatment group, whereas categorical variables were summarized using frequency counts and percentages within each treatment group. Treatment group comparisons were made with two-sample *t*-tests assuming unequal variances for continuous variables with a χ^2 test for categorical variables.

The analysis of demographics and safety was based on the safety analysis set, which was defined as all randomized subjects who underwent at least one treatment session. The analysis of primary and secondary effectiveness was based on the full analysis set, which included all randomized subjects. All hypotheses were conducted at a two-sided α=0.05 level of significance. All data analyses used SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

When comparing the experimental and control groups with regard to age, weight, and sex demographic data, there was no statistically significant difference in the baseline of clinical

TABLE II. Demographic Data and General Information

Subject	Description	Experimental Group	Comparison Group	Statistics	*p*-Value
Age	*N* (miss)	60 (0)	60 (0)	$t = -1.01$	0.3145
	Mean ± SD	37.72 ± 13.88	40.25 ± 13.59		
	Median	35	36.5		
	Q1 ~ Q3	27.00 ~ 43.00	30.00 ~ 49.50		
	Min ~ Max	18.00 ~ 73.00	18.00 ~ 75.00		
Weight	*N* (miss)	60 (0)	60 (0)	$t = 1.50$	0.1368
	Mean ± SD	69.32 ± 10.06	66.22 ± 12.47		
	Median	69	66.5		
	Q1 ~ Q3	63.50 ~ 75.5	60.00 ~ 74.00		
	Min ~ Max	50.00 ~ 95.00	39.00 ~ 90.00		
Gender	*N* (miss)	60 (0)	60 (0)	$\chi^2 = 0.1500$	0.6985
	Male – *N* (%)	21 (35.00%)	19 (31.67%)		
	Female – N (%)	39 (65.00%)	41 (68.33%)		
Allergy history	*N* (miss)	60 (0)	60 (0)	—	—
	No – *N* (%)	60 (100.00%)	60 (100.00%)		
	Yes – *N* (%)	0 (0.00%)	0 (0.00%)		
Previous history	*N* (miss)	60 (0)	60 (0)	—	—
	No – N (%)	60 (100.00%)	60 (100.00%)		
	Yes – *N* (%)	0 (0.00%)	0 (0.00%)		
Wound Length	*N* (miss)	60 (0)	60 (0)	$t = -0.60$	0.5488
	Mean ± SD	5.82 ± 2.86	6.13 ± 2.91		
	Median	5.00	6.00		
	Q1 ~ Q3	3.50 ~ 8.00	3.00 ~ 8.00		
	Min ~ Max	1.00 ~ 12.00	1.00 ~ 10.00		

trials. Comparisons were also made between the experimental and control groups' allergy history, medical history, and wound length, which found no statistical difference (Table II).

In comparing the experimental group and the control group with regard to success in wound healing, there were no statistically significant differences between the two groups, each with 60 cases. The 95% confidence level of the difference of the level 1 healing rate between the experimental group and the control group was evaluated by using the clinical evaluation data. The experimental and control groups both had 100% level 1 healing rate (level 1: "Initial healing is excellent without any adverse reaction"), so the absence of variability in each treatment group makes it not possible to compute a comparison against the non-inferiority margin or a confidence interval. Therefore, the effectiveness of the experimental product could be considered to meet the needs of clinical applications.

In the secondary evaluation of clinical efficacy evaluation indicators for the experimental group and the control group, ease of operation, postoperative care, and scar results were compared, and the results were not statistically significant (i.e., there were no statistically significant treatment group differences detected in the data).

In the clinical safety evaluation, safety analysis showed that the test group and control group products performed without skin allergies, no wound infection, and no adverse events (Tables III and IV).

CLINICAL TRIAL CONCLUSION

The clinical trials were carried out per the requirements of the program for clinical validation. Each hospital completed a total of 60 cases to verify each of the cases, the experimental group and control group (120 total cases), for after-use wound healing, ease of operation, postoperative care, scarring, and adverse reactions. The results were compared with each other, but the healing rate of the primary outcome was 100% in both the experimental and the control groups. According to the protocol, a 95% confidence interval in the difference in rates would be computed in order to compare against the non-inferiority margin. Because the proportions are 100% in each group, there is no variability, so the confidence interval cannot be computed. However, it can be considered that the effectiveness of test products meets the needs of clinical applications given the 100% outcome and performance equivalent to that of the control. The same is true for the clinical safety evaluation, as both the experimental and the control groups had no adverse events. Therefore, the test product safety is in line with the clinical use requirements.

DISCUSSION

Historically, there have been accepted methods before the introduction of the DermaClip device. Interrupted sutures consisting of a single loop through the skin and subcutaneous tissues have existed since ancient Egypt first reported 5,000 yr ago.[13] Sutures have several advantages – they can be mastered with some training, and they can be adjusted to maintain wound eversion. Wound eversion is important to the final appearance of the healed scar, as wounds that are not everted can become inverted or indented.[14]

More recently, staples and skin glues have become accepted wound closure methods, popular across a wide

TABLE III. Clinical Effectiveness Evaluation Index and Adverse Events

Subject	Description	Experimental Group	Comparison Group	Statistics	*p*-Value
Wound closing (at 1 mo)	*N* (miss)	60 (0)	60 (0)	n/a – no variance	n/a – no variance
	Level I (%)	60 (100.00%)	60 (100.00%)		
	Level II (%)	0 (0.00%)	0 (0.00%)		
	Level III (%)	0 (0.00%)	0 (0.00%)		
Adverse event (at 1 mo)	*N* (miss)	60 (0)	60 (0)	n/a – no variance	n/a – no variance
	No – *N* (%)	60 (100.00%)	60 (100.00%)		
	Yes – *N* (%)	0 (0.00%)	0 (0.00%)		
Scar result (at 1 mo)	*N* (miss)	60 (0)	60 (0)	$S = 3519.0$	0.4826
	Excellent (%)	4 (6.67%)	5 (8.33%)		
	Satisfied (%)	50 (83.33%)	52 (86.67%)		
	Fair (%)	6 (10.00%)	3 (5.00%)		
	Poor (%)	0 (0.00%)	0 (0.00%)		
	Unsatisfied (%)	0 (0.00%)	0 (0.00%)		
Postoperative care (at 2 wk)	*N* (miss)	60 (0)	60 (0)	$S = 3630.0$	1.0000
	Excellent (%)	59 (98.33%)	59 (98.33%)		
	Satisfied (%)	1 (1.67%)	1 (1.67%)		
	Fair (%)	0 (0.00%)	0 (0.00%)		
	Poor (%)	0 (0.00%)	0 (0.00%)		
	Unsatisfied (%)	0 (0.00%)	0 (0.00%)		
Easy to use	*N* (miss)	60 (0)	60 (0)	$S = 3770.0$	0.2475
	Excellent (%)	9 (15.00%)	4 (6.67%)		
	Satisfied (%)	47 (78.33%)	52 (86.67%)		
	Fair (%)	4 (6.67%)	4 (6.67%)		
	Poor (%)	0 (0.00%)	0 (0.00%)		
	Unsatisfied (%)	0 (0.00%)	0 (0.00%)		

TABLE IV. Safety Evaluation (1 wk After Treatment)

Subject	Description	Experimental Group	Comparison Group	*p*-Value
Allergic reaction	*N* (miss)	60 (0)	60 (0)	—
	No – *N* (%)	60 (100.00%)	60 (100.00%)	
	Yes – *N* (%)	0 (0.00%)	0 (0.00%)	
Wound infection	*N* (miss)	60 (0)	60 (0)	—
	No – *N* (%)	60 (100.00%)	60 (100.00%)	
	Yes – *N* (%)	0 (0.00%)	0 (0.00%)	
Other adverse reaction	*N* (miss)	60 (0)	60 (0)	—
	No – *N* (%)	60 (100.00%)	60 (100.00%)	
	Yes – *N* (%)	0 (0.00%)	0 (0.00%)	

range of procedures and applications. Although many advances have been made in widely available methods of wound closure, no single solution optimized closure speed, safety, ease of use, and outcomes. All traditional closure methods have shortcomings: sutures involve sharps, take a high level of skill, and are slow to apply; staples puncture the skin, are painful, and leave track scarring; and glues are messy, are not ideal for long wounds, can fail prematurely, and can sometimes cause severe and problematic allergic reactions.[15]

Finding the best closure method and material will result in a better understanding of the method's contribution to complications, the patient's reported satisfaction for cosmetic results and absence of pain, and the discomfort reported through the removal of sutures and staples. However, the current data do not support naming a single method as the best. Multiple studies spanning decades have examined the clinical outcomes of skin closure techniques in gynecologic, vascular, and orthopedic surgery.[3] These studies often found contradictory results as to the best method and material to use for skin closure. Therefore, despite multiple studies, there is no definitive answer to this question, and it remains unclear as well whether there is an inherent difference in cosmetic result between wounds closed with sutures, staples, or glues.[16,17]

The development of the DermaClip device was the result of taking pre-existing knowledge of the shortcomings of traditional closure methods and attempting to formulate a solution addressing the issues presented. To formulate the solution, the pre-existing information was analyzed by two experienced surgeons with the goal of designing an answer to the shortcomings of traditional closure methods, resulting in the development of a concept for a wound closure device that would perform without the limitations of traditional closure methods. Partnering with an engineer, they jointly developed a wound closure device unlike, and distinguishable from, existing

methods. The outcome is a simple but medically elegant wound closure device, the DermaClip device.

The study presented demonstrates that the DermaClip device is a reliable alternative to more traditional wound closure methods with advantages that potentially make it a preferred method of wound closure in many instances. Use of the device avoids the pain and time associated with local anesthesia injections as well as the pain associated with suture and staple removal inasmuch as the device can simply be pulled off the wound. The cosmetic result is improved because application of the device involves no cross-hatching, as do sutures or staples, and the design of the device to evert the wound edges on closure avoids wound inversion or dimpling. The speed of application in any providers' hands can be as fast as staples and, certainly, faster than sutures, and the incidence of superficial infection is decreased compared with staples.[15]

As for glues, the DermaClip device can be used on large as well as small wounds, a problem for glues in the absence of mesh. The device does not burn on unanesthetized wounds, as do glues. The device is easy to use, unlike the problems with glues, which can be difficult to handle and must be used quickly before they dry prematurely, often difficult issues both in a field environment and in a hospital setting.

For the injured warfighter, the DermaClip device can be quickly applied in the field and easily removed once the injured warfighter reaches the forward base or rear base hospital without any puncture wound injury associated with removal of sutures and staples. The length of the skin laceration or wound does not matter. If the injury does not warrant evacuation, the device can be removed by the injured warfighter once healing has occurred.

Because the DermaClip device is easy to apply, training on this device is measured in minutes and does not necessarily require a medical background to apply and close the device effectively. For the warfighter, application can easily be incorporated into the warfighter's training, allowing the warfighter to tend to himself or a fellow warfighter on smaller, superficial injuries that might otherwise require a medic or corpsman to close. And with the closure of the device, the wound is closed.

Multiple benefits of this wound closure device have been demonstrated. First, the device works on the approximated wound edge, so the viable dermis on each side of the wound is put into contact with proper alignment. It is well established that wound healing is a process that begins very rapidly,[18] so holding proper wound approximation facilitates the initiation of the healing process. This re-approximation, among other things, allows for re-establishment of blood flow allowing increased oxygenation, which, in turn, increases the presence of neutrophils and, theoretically, decreases the likelihood of infection.

Second, because the DermaClip device utilizes a broad adhesive pad along the approximated wound edge, the device avoids the focal trauma to the skin and surrounding soft tissue caused by interrupted sutures or staples, or the trauma to the wound edge tissues caused by continuous subcutaneous sutures.[19] The adhesive pads help disperse the tension of wound closure along a large area of the skin, unlike other traditional closures that grab the skin and focus the force of closure on the puncture points. This is especially important for diabetics and for those with radiation damaged skin, whose skin quality may often be extremely poor and susceptible to trauma from stapling or suturing, along with the gripping of the skin with forceps. Additionally, this is important to the retired warfighter and to Veterans Hospitals, as geriatric skin has the same qualities. The DermaClip technology, in avoiding physical manipulation of the skin, causes less trauma and is less likely to cause necrosis of the wound edges.

Third, because each device is an independent segment, the DermaClip device is nimbler than many of its newer competitors when treating wound that are not straight. The multiple sizes of the DermaClip device provides flexibility for the medical provider closing the wound (Figs 5 and 6).

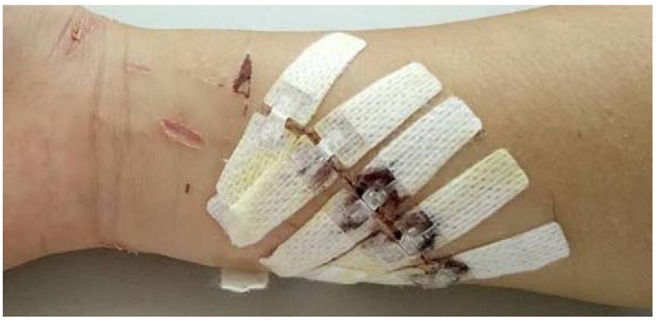

FIGURE 5. DermaClip usage on traumatic arm injury with wound.

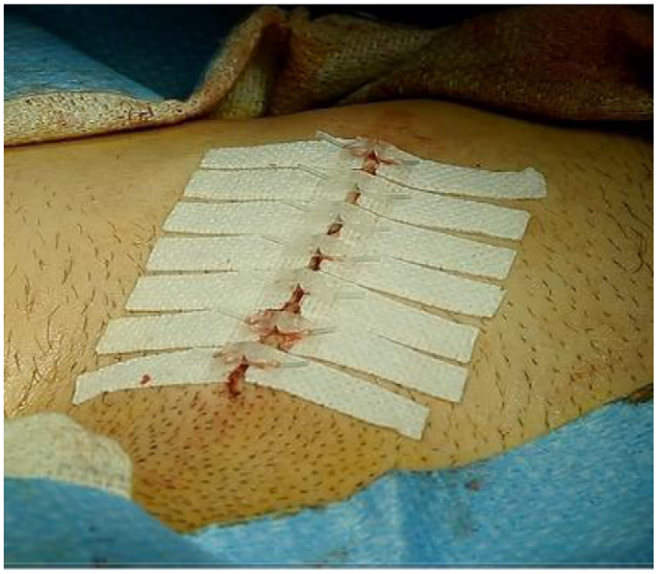

FIGURE 6. DermaClip usage on straight abdominal closure.

Fourth, controlled wound edge approximation puts viable tissue layers into contact with each other, achieving the initiation of regeneration of the injured tissue layer-to-layer and minimizing collagen formation, which minimizes scarring. The reality is that eversion has never been demonstrated to improve wound healing in a randomized control trial. In view of this, many physicians believe that eversion is unnecessary. Conversely, equally many surgeons believe that wound eversion is beneficial and is a desirable goal to be achieved in wound closure. Although still debated, what is known, and agreed upon, is that inversion of a wound causes dimpling of the scar – a most uncosmetic and, therefore, most undesirable result. Because it is known that there will be a certain percentage of atrophy and contraction of the wound edge, not starting out with an everted wound would likely result in an inverted scar.

It should be emphasized that wound edges will atrophy and the wounds will contract. If the closure does not evert, the final wound would certainly have, in a significant percentage of the cases, scar inversion.[20] Further, other skin closure techniques can cause focal trauma to the skin, surrounding soft tissue, or wound edges tissues, whereas DermaClip, by its design, avoids this. In summary, the easiest way to avoid inversion is eversion, and an easy, fast, and cost-effective way to ensure eversion of the wound is to employ a device that is designed to effect eversion on every closure.

The DermaClip device has been used on tens of thousands of patients. In its usage in China, a 3-inch incision was closed in under 3 min by physicians who had been shown the proper technique of application. The wound was observed to be cosmetically satisfactory, equivalent to any other means of closure, and healed by the time the device was removed, approximately just over 1 wk after application.

The study indicated that DermaClip has obvious benefits for the physician and the patient: specifically, a simple, quick, and efficient wound closure. However, there are situations where these features are of even greater value: specifically, where wound closures are of urgent or emergent nature, exactly the types of situations experienced by the military. In an emergency room or on the battlefield, confronted by multiple traumatized patients or casualties, instead of having to manipulate glues, staples, or sutures, the skin is cleansed with an astringent, allowed to dry, and then the DermaClip device is applied quickly, allowing attention to be directed to more urgent injuries. Anyone who has been in the field at night trying to suture a wounded warfighter can appreciate the benefit of a suture-less wound closure system that requires no anesthesia. Because there is no additional trauma to the skin in either pulling off the device or re-applying it, the DermaClip device can serve as an effective temporary closure device.

In non-battlefield-type settings like the emergency room, medical assistants rather than doctors and nurses can treat patients who require simple skin closure of their wound. There is no anesthesia required, no needles, and importantly no risk of needle-stick injury. Minor injuries that were always the last to be tended to in the emergency room can now be treated quickly and the patients discharged from the emergency room without consuming the time of the doctors and nurses.[21]

Additionally, skin tears are particularly common and are even more frequently seen among those receiving long-term corticosteroid therapy and among the elderly, who tend to have fragile skin.[22] This patient demographic has a high occurrence among retired warfighters, a patient population served by Veterans Administration Hospitals. For category I tears (without tissue loss), the standard care is approximation of the wound edges with surgical tapes, sutures, staples, or glue. The area is then covered with a non-adherent dressing. In one study, the healing rate of skin tears with the use of this treatment was 66% compared with 33% with the use of a thin-film dressing.[23] Category II skin tears (partial tissue loss) and category III skin tears (complete tissue loss) are managed with absorbent dressings.

The DermaClip device was utilized in an urgent care facility to determine efficacy on elderly patients. Figures 7 through 9 show an example of a successful closure at this facility using the DermaClip device on an elderly patient with fragile skin suffering from a skin tear; the wound was successfully closed and healed without risking additional damage with the introduction of sutures or staples (Figs 7–9).

In the operating room, once the fascia (or subcutaneous layer, if surgeon's preference) is completed, skin closure can be done by simply applying and closing the DermaClip devices. In this regard, DermaClip has completed an IRB-approved study closing cesarean sections at a major east coast teaching hospital where the DermaClip device replaced all dermal suturing for closure of the incision (Fig. 10).

CONCLUSION

The development of the DermaClip non-invasive skin closure device has been a major stride in removing many of the vagaries of skin closure in emergency and battlefield environments, in routine closure of wounds under standard conditions

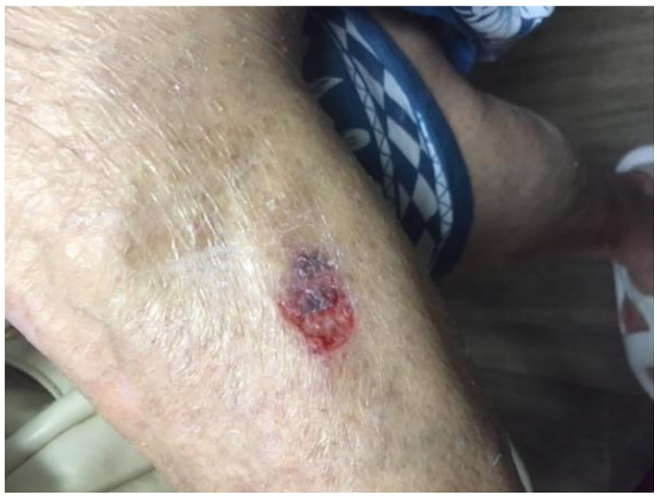

FIGURE 7. Wound at time of treatment.

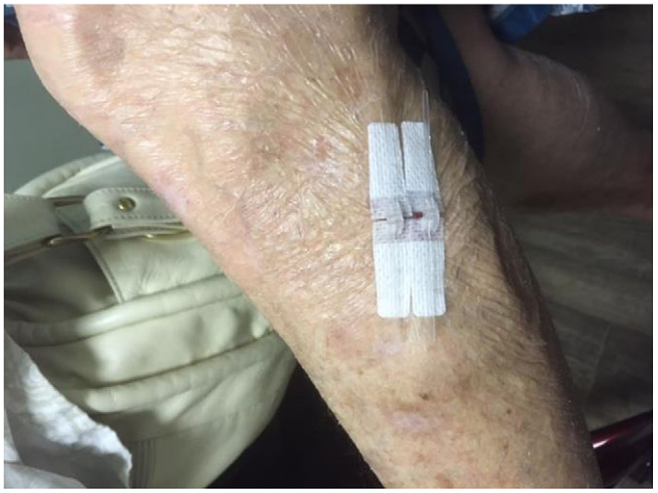

FIGURE 8. Closure on day of treatment.

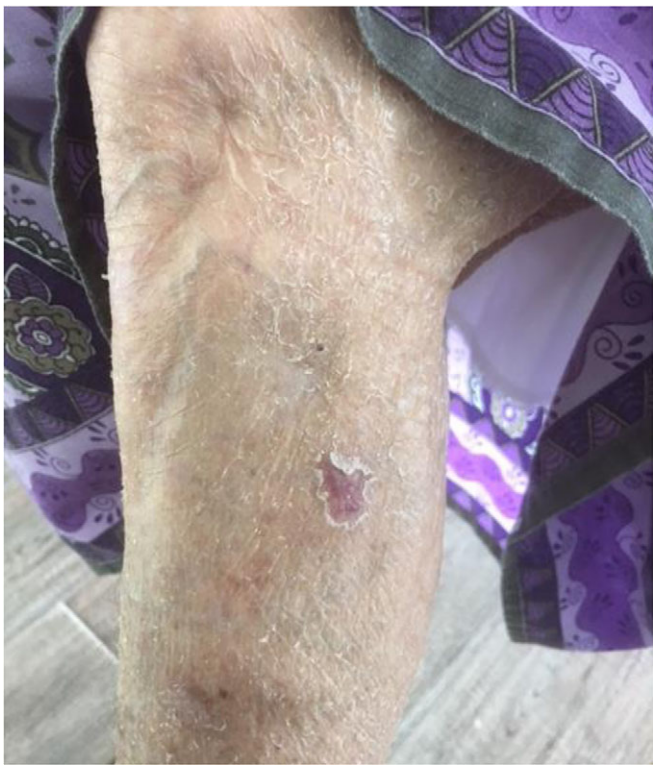

FIGURE 9. Four weeks after treatment.

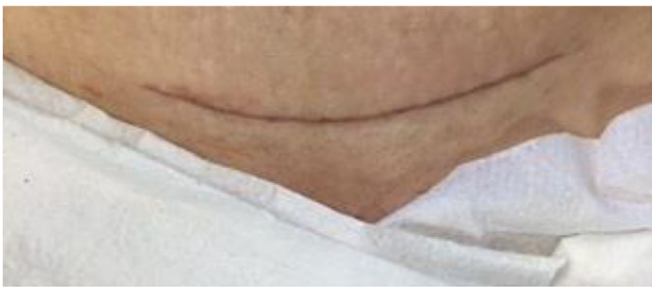

FIGURE 10. Six weeks after C-section closure.

and in closure of incisions in operating room environments. The authors believe that this painless, rapid, effective device requiring no anesthesia has the potential of becoming the standard of care in settings that require rapid wound closure especially under adverse conditions. Further studies are underway to identify the situations, with its obvious advantages, that will be most appropriate and cost-effective.

PRESENTATIONS

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