CLOSURE OF SKIN WOUNDS WITH MICROMEND® WOUND CLOSURE DEVICE AFTER MOHS SURGERY

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ABSTRACT

Background: There is a need for new wound closure devices in dermatologic surgery that can address the limitations of sutures, which include time-consuming procedures and additional resources required to close wounds. An additional need is for devices that can provide tight and precise approximation of wound edges.

Objective: This purpose of this study was to evaluate the use of microMend to close skin wounds after Mohs micrographic surgery.

Methods and Materials: A prospective clinical study was conducted, in which 9 patients underwent surgical removal of 10 cutaneous malignancies. Deep dermal sutures were applied before superficial closure with microMend. Closure times, physician satisfaction with use and cosmetic outcome, and patient satisfaction were recorded.

Results: Eight surgeries were performed on the head and 2 surgeries on the trunk/extremities. Closure with microMend was much more rapid than reported with sutures. Both physicians and subjects rated the highest median levels of satisfaction for all parameters. The mean time for skin wound closure was 20 secs/cm. The median VAS score of cosmetic results on a scale of 0-100 was 86.

Conclusion: This study demonstrates microMend to be a safe and effective wound closure device. microMend has the ability to rapidly close wounds with excellent healing and cosmetic results. Both subjects and dermatologists reported high levels of satisfaction with the product.

Introduction

After removal of a skin lesion such as a cutaneous malignancy, reconstruction is performed to optimize the functional and cosmetic results. For the majority of procedures, sutures are used to relieve tension on the surgical wound. Although suturing has proven safe and effective, it requires surgical instruments to apply them, can be time consuming and requires extra staff, such as surgical assistants to cut sutures and provide other support, as well as additional costs for suture removal. In addition, scarring may occur due to a variety of causes. For example, if sutures are tied too tightly or remain in the skin for an excessive amount of time, strangulation of tissue and suture tracks may occur.[1,2] There is a strong need for new wound closure devices that can close a wound quicker than suturing with better approximation across a wound, more tension than tissue adhesive and better approximation of the wound edges than staples.

microMend® is a novel wound closure device that incorporates two arrays of miniature Microstaples with an adhesive backing that enables secure attachment to the skin (Figure 1). The microMend device is similar in shape and dimensions to a butterfly closure. However, in contrast to this product, the adhesive is largely replaced with arrays of Microstaples, which are designed to simulate the features of currently used medical staples on a micro-scale. microMend is able to anchor to the skin with superior holding strength to adhesive bandages. In previous porcine studies, microMend demonstrated similar tensile strength to sutures and excellent wound closure results in several surgical procedures.[3] A clinical study demonstrated the superiority of microMend over sutures when they were directly compared to one another in closing port site wounds associated with laparoscopic and robotic surgeries.[4]

This purpose of this study was to evaluate the use of microMend to close skin wounds after Mohs micrographic surgery.

Methods and Materials

Subjects

The procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 1983. Subjects were recruited from 3 out-patient medical dermatology practices located in Beverly Hills, CA, Encino, CA and Torrance, CA. Subjects referred for Mohs surgery of malignant cutaneous lesions were evaluated for study inclusion. Exclusion criteria included: allergies or reactions to lidocaine or epinephrine, active smoker, known pregnancy or lactating mother, or underlying immunodeficiency. Subjects who volunteered to participate in the trial were enrolled after written informed consent was obtained.

Study Design

Subjects underwent standard removal of their lesion via Mohs surgery or excision by two dermatologists. After the lesion was removed and the site documented to be free of cancer by the dermatologist, the subject was set up for wound closure. The dermatologist first marked the site for optimal wound closure and then anesthetized the site. Once the incisions were made and the wound edges were undermined (cutting of the fibrous septae that connect the skin to the

underlying fascia), electrocautery was used to achieve hemostasis. The deep dermal layers were approximated with absorbable 4-0 Vicryl sutures (Ethicon Inc., Somerville, NJ, U.S.A.). The wound area was then patted dry. Subsequently, microMend devices were used to approximate the superficial edges of the wound (Figure 2). A pressure dressing using Telfa was placed on the site and subjects were instructed to keep the area dry until self-removal in 24 hours. They were given instructions to keep the microMend in place for 1 week or until the devices detached from the skin (whichever was a shorter time). Subjects were advised to avoid any excessive exercise, heavy lifting, or swimming until their follow up appointment in 1 week.

Evaluation

At Day 0, the time of skin closure was measured from the placement of the first to the last microMend device. A physician observer rated the wound closure with regards to appearance, ease of use of product, speed of use of product and overall assessment from 1 (poor) to 4 (excellent). Subject's pain and stress with wound closure were evaluated by a medical assistant at the end of the procedure using the Visual Analog Scale (VAS) on a score from 0 (least possible) to 100 (worst possible). At one week after the procedure, the subject evaluated the surgical wound at their first return to the clinic. The subject rated the comfort of incisions, comfort of wearing the product, comfort when removed, appearance of the wound and overall assessment on a scale of 1 to 4: 1 (poor); 2 (fair); 3 (good); or 4 (excellent). Photographs were obtained at Day 0 and 1 month follow up. The photos at 1 month (Figure 3) were used to rate cosmetic results according to a 4-point satisfaction scale by an independent blinded observer: 0 (not satisfied), 1 (somewhat satisfied), 2 (satisfied), or 3 (extremely satisfied). The physician observer also evaluated the photos for the overall cosmetic outcome using the Visual Analog Scale (VAS), which rates results from a range of scores of 0 to 100, where the best possible result is rated 100 and the worst possible result is rated 0.[5]

Results

Nine subjects referred for Mohs surgery of malignant cutaneous lesions were recruited into the study (3 males and 6 females). The median age was 55 years old (range = 46 – 84). Eight subjects underwent surgery for a single lesion, while 1 subject underwent surgery for 2 separate lesions for a total of 10 sites. Eight surgeries were performed on the head and 2 surgeries occurred on the trunk/extremities. Nine of the surgical wounds were complex repairs and a rhombic flap was utilized for 1 repair.

The mean wound length was 3.1 cm and ranged between 1.9 – 4.2 cm. The mean time for skin wound closure was 76 seconds (range = 29-185 seconds). The average rate of closure was 3.3 cm/minute (range = 1.1-7.2) or 20 seconds/cm (range = 8-53) At Day 0, the dermatologist rated the median score for all of the measured parameters as 4: ease of use (range = 3-4), speed of use (range = 3-4), appearance of closed wound (range = 2-4) and overall assessment (range = 3-4). All subjects rated both pain and stress associated with microMend closure as 0.

At the first return clinic visit (one-week post-procedure), the median scores for all of the measured parameters, including comfort of incisions, comfort of wearing the product, comfort when removed, appearance of the wound and overall assessment by the subjects was 4

(excellent) with a range from 2-4 for each of these parameters. On a scale of 0-3 in terms of level of satisfaction with cosmesis, the physician observer was extremely satisfied (score of 3) and satisfied (score of 2) with 78 and 22% of the scars, respectively. The median VAS score of cosmetic results on a scale of 0-100 was 86 (range = 72-92).

There were no complications, such as wound hematoma, seroma, overlap of edges, separation of edges, or dehiscence, other than one subject who had a minor wound infection that was successfully treated with antibiotics.

Discussion

The purpose of this study was to ascertain whether the microMend wound closure device is an effective alternative to suture for patients undergoing Mohs surgery for cutaneous malignancies.

There are a number of attributes of microMend that contribute to excellent cosmesis. microMend provides a tight wound seal with close approximation along the entire wound length. This is in contrast to sutures, where wound gaps that occur in between sutures can result in scars. When the sutures are tied, they create focal points of tension that can lead to inflammation and scarring. In contrast, the combination of the Microstaples and adhesive backing provides even tension along the wound, which reduces the potential for inflammation and scarring. In addition, if sutures are tied too tightly, they can cause strangulation of tissue resulting in the classic railroad track appearance of scars. Finally, the ease of use of microMend reduces inconsistent outcomes due to the variability in surgical skills in closing wounds with sutures.

The physician observer gave the highest median rating for all measured parameters, including microMend's ease of use, speed of use, wound appearance, and overall assessment. Subjects gave the highest median rating for all measurements of microMend, including overall assessment as well as its comfort and wound appearance. Similarly, the physician observer gave the highest median rating for the cosmetic results. As another measure, the mean VAS score was 86. The range of VAS scores ranged from 72 to 92, which is above the threshold of 65 that reflects optimal cosmetic results as documented by Quinn et al.[6] In comparison to microMend, Sniezek et al[7] reported VAS scores of 66 and 68 using tissue adhesive (cyanoacrylate) and sutures, respectively, to close skin wounds in Mohs surgery.

To treat the growing number of skin cancers, there is a need for increased speed and efficiency in Mohs surgeries. In 2002, Bhatia et al. conducted a comparative study between staples and sutures.[8] They demonstrated that the average rate of closure with sutures was 51 seconds/cm and 25 seconds/cm for staples. Our study showed that closure with microMend (20 sec/cm) was as rapid as staples and much faster than sutures, which is the most common wound closure product used in dermatologic surgery. Given that the mean wound length in this study was 3.1 cm, an approximate time to superficial closure would translate to 155 seconds with sutures and 62 seconds with microMend. The time saved and its ability to be used to close wounds, including surgical incisions and lacerations, make microMend an attractive alternative to sutures.

We recognize a few limitations to this study. One is the lack of a comparator arm in the study. Given that most Mohs surgeries result in smaller skin wounds, it would not be practical to perform a split wound study where half of the wound was closed with a comparator, such as sutures, and the other half with microMend. In addition, the dermatologists performing the study determined that wound appearance, as well as comfort between sutures and microMend, would be difficult for the subject to measure differences in a small wound between two types of closure devices in a split wound study. We performed a single-center study, which makes it difficult to generalize our results between different clinical practices. However, the participation of surgeons with different levels of experience in this study has greater external validity and better represents those in practice. In this study, we only used 4-0 Vicryl sutures for the deep dermal layer to maintain consistency between wounds. Finally, wounds were assessed at 1-month post-procedure, which is too short of time for complete wound healing and to determine the final cosmetic result.

Despite these limitations, the implications of this study are valuable and applicable in routine practice for the dermatologic surgeon. Additional research on longer wound repairs in a side-by-side study with sutures with a longer follow-up period could be helpful to determine the efficacy of microMend in other dermatologic surgeries.

Conclusion

The modern day dermatologic surgeon has a wide armamentarium of wound closure materials. microMend has the ability to rapidly close wounds in Mohs surgery. Both subjects and dermatologists reported high levels of satisfaction with microMend. In addition, excellent wound healing and cosmetic results were demonstrated in the study. We conclude that microMend can serve as a valuable wound closure device in dermatologic surgery.

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TABLE

Table 1. Summary of Subject and Wound Characteristics

Subject Characteristics

No. of subjects	9
Male	3
Female	6
Age – median (range)	55 (46-84)
Skin photo types	I-III
Squamous cell cancer	2
Basal cell cancer	8

Wound Characteristics

No. of wounds	10
Forehead	1
Cheek	4
Lip	2
Clavicle	2
Arm	1
Mean length ± SD (cm)	3.1 ± .89
Range (cm)	1.9 – 4.2

FIGURES

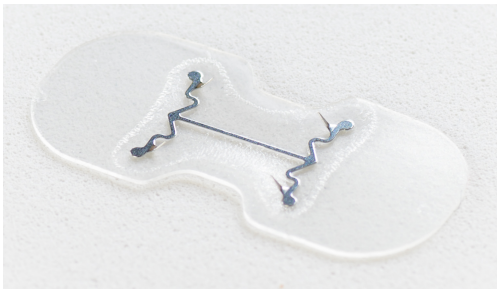

Figure 1. microMend wound closure device.

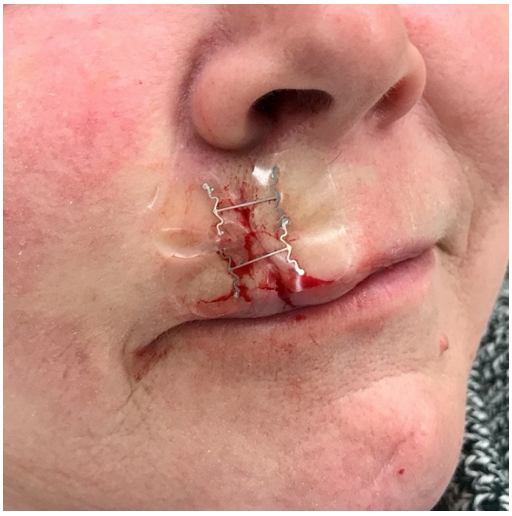

Figure 2. Surgical wound after placement of dermal sutures and microMend.

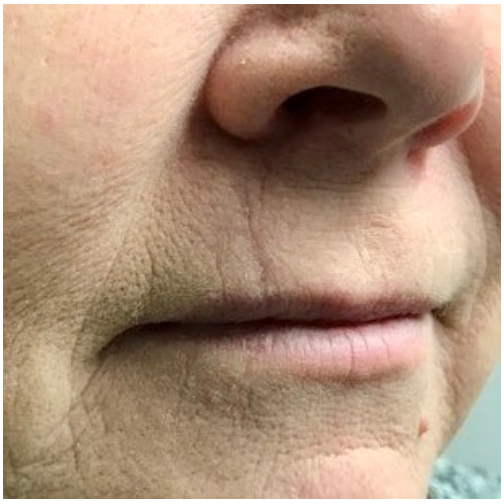

Figure 3. 1-month postoperative excision.