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Evaluation of microMend wound closure device in repairing skin lacerations

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ABSTRACT

Background microMend, a novel microstaple skin closure device, may be able to close simple lacerations. This study aimed to evaluate the feasibility and acceptability of using microMend to close these wounds in the ED.

Methods This was an open-label, single-arm clinical study conducted at two EDs within a large urban academic medical centre. Wounds closed with microMend underwent assessments performed at days 0, 7, 30 and 90. Photographs of treated wounds were rated by two plastic surgeons using a 100 mm visual analogue scale (VAS) and a wound evaluation scale (WES), which has a best possible score of 6. Participants rated pain during application and both participants and providers rated their satisfaction with the device.

Results Thirty-one participants were enrolled in the study: 48% were female and the mean age of participants was 45.6 (95% CI 39.1 to 52.1). The mean wound length was 2.35 cm (95% CI 1.77 to 2.92), with a range of 1–10 cm. Mean VAS and WES scores at day 90 as evaluated by two plastic surgeons were 84.1 mm (95% CI 80.2 to 87.9) and 4.91 (95% CI 4.54 to 5.29), respectively. The mean pain score with application of the devices was 7.28 mm (95% CI 2.88 to 11.68) on a scale of 0–100 mm using VAS. Local anaesthesia was used in 9 patients (29%, 95% CI 20.7 to 37.3) of participants (of whom 5 required deep sutures). Ninety per cent (90%) of participants rated their overall assessment of the device as excellent (74%) or good (16%) at day 90. There were no serious adverse events in any participants in the study.

Conclusion microMend appears to be an acceptable alternative for closing skin lacerations in the ED, providing good cosmetic results, with high levels of satisfaction by patients and providers. Randomised trials are needed to compare microMend with other wound closure products.

Trial registration number NCT03830515.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Sutures and staples are commonly used to close lacerations in the ED, but can cause problems related to scarring, infections and also produce variable results depending on surgical skills.
⇒ Tissue adhesives are also used, but have limited tensile strength, can cause severe skin reactions and carry the risk of wound dehiscence.
⇒ microMend is a novel wound closure product, which comprises miniature staples (microstaples) attached to an adhesive backing.

WHAT THIS STUDY ADDS

⇒ The current study evaluated wound repair with microMend in 31 patients.
⇒ Wound evaluation scores provided by plastic surgeons at 90 days were similar to studies of suture and tissue adhesive.
⇒ Treating providers reported high satisfaction with speed, ease of use and cosmetic results.
⇒ Patients assessed the method as either excellent (74%) or good (16%) and reported minimal pain, with few requiring local anaesthesia unless multilayer closure or irrigation was required.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ microMend appears to be an acceptable option for would repair and should be further evaluated in controlled studies.

INTRODUCTION

Lacerations are one of the most common reasons for an individual to seek medical care in an ED, accounting for approximately 3.4% of ED visits annually in 2020.[1] The objectives of wound repair in the ED are to avoid infection and achieve high-quality aesthetic results.[2] Common skin closure techniques use sutures,[3] staples[4] and tissue adhesives,[5] each of which has specific indications and challenges. For example, both sutures and staples typically require the use of local anaesthesia and return clinic visits for removal,[6] which are factors associated with reduced patient satisfaction. Tissue adhesives are useful alternatives that produce similar cosmetic outcomes as sutured wounds[7 8] and can be applied more quickly.[9]

One approach in achieving better cosmetic outcomes include methods to distribute or decrease wound tension[10] by layered closures where appropriate,[11] advanced suturing techniques[12] and in the case of elective surgical planning, measurement of skin tension non-invasively a priori.[13] Wounds cared for in the ED are unlikely to benefit by these approaches due to limited time and lack of resources.

There are other adhesive tape-based wound closure devices[14 15] that are claimed to overcome the problems associated with current products by eliminating need for anaesthesia and reducing closure time in surgical wounds.[16 17] However, there is no evidence[18] to support their use in traumatic wounds.

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One new wound closure device is microMend, which contains a small array of miniature staples (microstaples) attached to a polyurethane backing, coated with acrylic adhesive, about the size and shape of a butterfly closure. The microstaples provide secure attachment to the skin and allow for safer and more uniform tensioning that is theoretically associated with better cosmesis. This is available for use in the USA and approved as a surgical staple by the Food and Drug Administration. While this device could have benefits to both ED patients and healthcare providers, it has yet to be evaluated clinically. We aimed to determine the ability of microMend to achieve satisfactory closure of lacerations and both patient and provider satisfaction in an open-label prospective clinical study. The authors hypothesise that microMend wound closure devices used for simple laceration repair in the ED will provide satisfactory aesthetic outcomes comparable to suture or wound adhesive and will result in minimal adverse events.

METHODS

Study design

This was an open-label, single-arm study, conducted at a large tertiary academic medical centre and a second academic affiliated community site in the USA between 1 August 2018 and 20 November 2019.

Participants

A convenience sample of participants was recruited daily from 07:00 to 12:00 hours when a study research assistant was available. Potentially eligible participants were identified through screening of electronic health records and referral from healthcare providers. Eligible participants were adults (≥18 years old) presenting to the ED with a laceration requiring skin closure who were accepting of an alternate wound closure device. Exclusion criteria included: inability to provide informed consent; allergy to adhesives or medical tape; wounds involving an extensor or flexor surface (eg, knee, elbow) or on concave areas of the face (eg, nasal sidewall, orbit); wounds under high tension or with a gap >1 cm between the wound edges; wounds with active bleeding; wounds in an area with significant body hair (eg, scalp) or an active skin disorder (eg, psoriasis, dermatitis, eczema) at the wound site. Healthcare providers were allowed to perform subcutaneous sutures for deep closures and these lacerations were still eligible for skin closure with microMend as long as the skin edges were <1 cm apart. The study was registered on ClinicalTrials.gov (NCT03830515).

Device application training

All lacerations were repaired by the treating healthcare provider. The healthcare providers (senior resident and attending physicians, and advanced practice providers) underwent training by watching a brief video demonstrating how to apply the device; they were also allowed to briefly practice (<5 min) with the device on artificial skin. To use the device, healthcare providers were instructed to: (1) clean and dry the wound as per practice, (2) manually approximate the wound edges, (3) attach one end of the device adjacent to the wound edge, (4) pull the other end across the wound to close it and (5) press down to attach the device to the skin (figure 1). Each individual device is designed to close 1.5 cm of wound length. Healthcare providers were allowed to choose the number of devices to obtain satisfactory closure. If more than one device was needed to close a wound, they were applied adjacent to one another along the entire length of the wound with no more than 1 mm separating adjacent devices. Providers were also advised not to shave hair as the product design precluded that necessity (figure 2). After application of the microMend device(s), the closed wound was covered with a non-stick gauze dressing. This device was not on the hospital formulary at the time and was not available outside of the study. The research assistant measured the length of the wound and elapsed time of the wound repair from the moment of wound cleansing to completed closure.

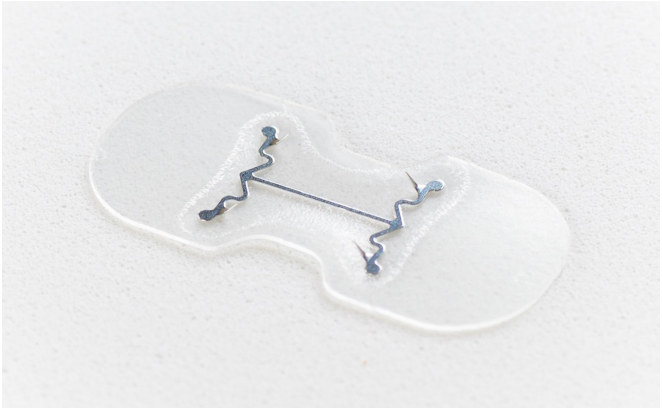

Figure 1 Magnified microMend device featuring miniature staples attached to a polyurethane backing, coated with an acrylic adhesive. The smaller version depicted has one row of staples on both ends whereas larger-sized devices have two rows of staples on both adhesive wings.

Variables and outcomes

Participants were followed prospectively for 3 months. Evaluations were performed at day 0, and at the time of device removal at day 6 (range: 5–7) for facial lacerations and day 8 (range: 7–10) for lacerations elsewhere on the body. Follow-up evaluations were then conducted 30 and 90 days after wound closure (figure 2). A minimum of two standardised digital photographs were taken of each wound at each follow-up visit. Surveys were used to evaluate both healthcare provider and participants' ratings of microMend and its use and outcomes. The healthcare provider performing the laceration repair rated their satisfaction with the device on a Likert scale (excellent, good, fair or poor) related to appearance of the closed wound, ease and speed of use of the microMend device and overall assessment. Participants rated the level of pain associated with application of the microMend device using a 100 mm visual analogue scale (VAS) (0=no pain, 100=worst possible pain).[5] Participants also rated the comfort on device removal and overall assessment of the wound repair using the same Likert scale.

Quality of wound healing and cosmetic results were rated independently by two plastic surgeons who reviewed the photographs digitally but were not involved in other aspects of the study such as wound closure procedures, data collection and analyses. They evaluated wound characteristics using a 100 mm VAS (0=worst possible scar, 100=best possible scar),[6] and a wound evaluation scale (WES) assessing six clinical variables (6=best possible score, 0=worst possible score) described previously.[19]

Statistical methods

Descriptive data are presented as means or percentages with 95% CI. The wound repair was considered acceptable if, a priori: (1) >80% of participants and healthcare providers were satisfied with the device (ratings of 'good' or 'excellent') and (2) the mean

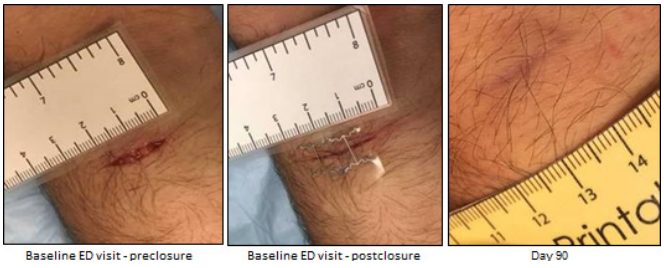

Figure 2 Representative wound before and after closure using the microMend device and the scar at 3 months.

of the two rater cosmesis ratings at 90 days were satisfactory (VAS >80 and WES >5). Agreement between the two surgeon raters was calculated for the initial and 90 days follow-up assessment for the VAS ratings, using Lin's concordance[20] correlation coefficient (CCC) with 95% CI, and with Cohen's weighted kappa (95% CI) for the WES scale. A sample size calculation was not performed given the unknown effect size of the intervention in this pilot study.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Thirty-six participants consented to participate in the study; however, five participants who were enrolled withdrew after consent because the healthcare provider decided to choose an alternative wound closure method. Thirty-one participants were included in the final analysis (figure 3). Demographics of study participants and wound characteristics grouped by blunt or penetrating trauma are shown in table 1.

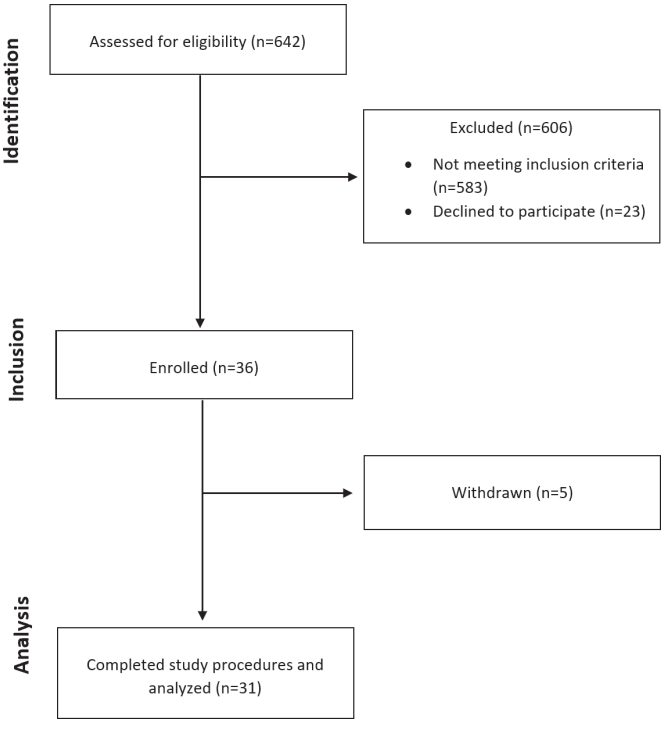

Figure 3 Flow diagram of determination of participant inclusion in study.

Table 1 Participants' demographic data (n=31) and characteristics of study wounds

Demographics			
Age, mean (95% CI), years		45.6 (39.1 to 52.1)	
Gender, female, n (%)		15 (48.4)	
Black/African-American, n (%)		3 (9.7)	
White, n (%)		25 (80.6)	
Other, n (%)		3 (9.7)	
Hispanic, n (%)		8 (25.8)	
Non-Hispanic, n (%)		23 (74.2)	
BMI, mean (95% CI)		26.2 (24.6 to 27.9)	
Wound type and location	**N (%)**	**Wound length, cm (mean (95% CI))**	**microMends used (mean (95% CI))**
Blunt trauma	23 (74.2)	1.92 (1.67 to 2.17)	1.61 (1.40 to 1.81)
Laceration site			
Scalp	3 (13.0)	2.17 (0.99 to 3.34)	
Face	5 (21.7)	1.70 (0.85 to 2.55)	
Forehead	10 (43.5)	2.03 (1.79 to 2.27)	
Extremity	4 (17.4)	1.73 (1.47 to 1.98)	
Extremity (skin tear)	1 (4.3)	2	
Local anaesthesia	4 (17.4)	1.60 (0.88 to 2.32)	
Deep sutures	2 (8.7)	1.75 (0.28 to 3.22)	
Penetrating trauma	8 (25.8)	3.73 (1.67 to 5.80)	3.13 (1.49 to 4.76)
Laceration site			
Extremity	8 (100)	3.73 (1.67 to 5.80)	
Local anaesthesia	5 (62.5)	4.37 (1.09 to 7.65)	
Deep sutures	3 (37.5)	6.28 (2.04 to 10.59)	

BMI, body mass index.

The mean wound length was 2.35 cm (95% CI 1.77 to 2.92), with a range of 1–10 cm. Wound closure was completed using a mean of 2.0 (95% CI 1.51 to 2.49) microMend devices. Blunt injury wounds were closed with 1.61 (95% CI 1.40 to 1.81) and penetrating injury wounds were closed with 3.13 (95% CI 1.49 to 4.76) devices (table 1). The overall mean time of device application was 3.9 min (95% CI 2.6 to 5.2). Participants reported the mean pain score on application of microMend as 7.28 (95% CI 2.88 to 11.68) on a 0–100 mm VAS.

Local anaesthesia was used in nine participants (29%; 95% CI 20.7 to 37.3) for placement of deep sutures (n=5) and wound irrigation (n=4). Proportionately more deep suturing and use of anaesthesia occurred in penetrating extremity wounds (table 1).

On the baseline ED visit, healthcare providers gave excellent or good ratings for the microMend device on the following: appearance of the closed wound (93%), ease of use of the microMend device (92%), speed of use of the microMend device as excellent (90%) and overall assessment of the device as excellent (51%) or good (39%).

Mean VAS of cosmesis at initial assessment was 37.3 mm (95% CI 31.9 to 42.7), and at 90 days the mean score was 84.1 mm (95% CI 80.2 to 87.9). Mean WES score at initial assessment was 1.45 (95% CI 1.11 to 1.79) and the 90-day WES mean was 4.91 (95% CI 4.54 to 5.29) (figure 4). At the initial assessment, the CCC for VAS was 0.15 (95% CI 0.03 to 0.28), at 90 days CCC was 0.35 (95% CI 0.17 to 0.51), kappa at initial assessment was 0.03 (95% CI −0.02 to 0.08) and at 90 days kappa was 0.30 (95% CI 0.09, 0.50).

Five participants (16.1%; 95% CI 11.6 to 20.4) experienced unintentional detachment of microMend devices before the

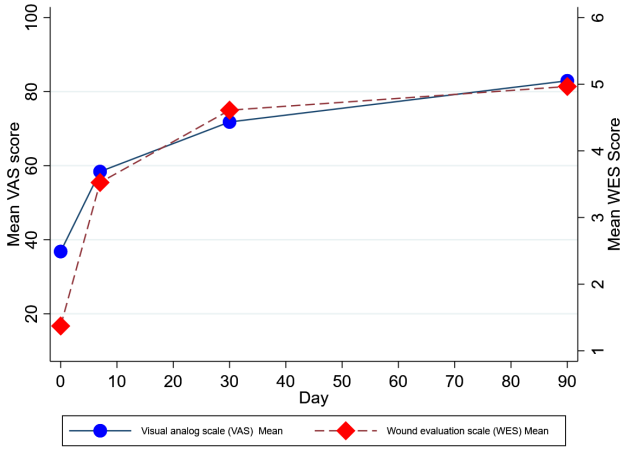

Figure 4 Mean visual analogue scale (VAS) and wound evaluation scale (WES) scores at 0, 7, 30 and 90 days postwound closure with the microMend device.

planned removal date; four participants had one device detach and one participant had two devices detach approximately 3 days after device application. Affected wound locations were on an extremity or the scalp/forehead and in four out of the five instances occurred during dressing changes. Serious adverse clinical outcomes including subsequent infection, dehiscence, sensitivity or allergic reaction to microMend and other adverse events were not reported in any participant in the study.

At the 7–10 days follow-up, participants rated their overall assessment, including device removal, as excellent (67%), good (29%) or poor (3.2%), the latter being a participant that had unintentional device removal. Participants rated their overall assessment of the device as excellent (74%), good (16%) or fair (10%) on the day 90 follow-up.

DISCUSSION

This is the first report of the use of a microstaple device to close lacerations in the ED. It suggests that the microMend device is an acceptable alternative for skin closure. Overall, participants had satisfactory cosmetic outcomes at 90 days as measured by VAS and WES scores (figure 4). Prior studies using VAS scores reported 73 mm at day 112[21] and 68 mm at day 90 following wound suturing, and 67 mm for tissue adhesive in the same study.[8] The length of wounds in these studies were on average 1.9 cm[21] and 2.3–2.5 cm,[8] respectively and thus comparable to 2.35 cm in the present study. The WES scores in the present study were slightly lower at day 90 compared with prior studies.[3] However, this may be attributable to the adjudication by plastic surgeons who in our experience grade wound cosmesis more stringently than emergency physicians, and have shown only moderate correlation with emergency physicians in VAS scores.[22]

The mean time of 3.9 min in device application compared favourably with that previously reported for staples compared with sutures,[23 24] and is similar to tissue adhesive (3.6 min),[8] a potential advantage in busy clinical settings. Beside the need for local anaesthesia for placing deep sutures and irrigation, no participant required other types of anaesthesia. Additionally, participants reported very low pain levels on application of the microMend device, also similar to tissue adhesive (7.2 mm).[8] This is due to the small dimensions and short length (1 mm vertical height) of the microstaples that do not penetrate into the deeper dermal layers where pain nerve fibres are located. Avoiding local anaesthesia and reducing pain are especially important in laceration repair in paediatrics, a clinical setting where microMend should be evaluated. Local anaesthesia however may still be needed for irrigation of contaminated wounds. In the one patient with a skin tear in the blunt trauma group (table 1), we found that microMend was particularly useful. A theoretical advantage exists since wound closure tension is reliant on both an adhesive bandage and an invasive point of entry tissue anchor (microstaple). By contrast, suture alone in thinned dermal tissue without supporting subcutaneous layers[25] bears the majority of suture tension which can easily tear and disfigure.

Device detachment was reported in five participants from either extremity or scalp locations, which may be due to failure to apply the device to a dry skin surface, inappropriate application of the microMend device, excessive mobility of wounds particularly near joints or patient factors such as dislodgement during dressing change outside of the ED. However, none of the five participants required return clinic visits for further management of their lacerations, and wound healing and cosmetic outcomes were satisfactory. Following the completion of this study, the manufacturer improved the adhesiveness of the tape supporting the microstaples which in hindsight could have possibly prevented some of these detachments.

The cost of microMend is US$13.50 per device, which is within a similar range of other wound closure methods such as Dermabond (tissue adhesive) which averages US$22. Suture costs US$6–10 and has incumbent supply costs and additional healthcare expenditures to remove them. Steri-Strips™ cost US$0.10–0.20 per strip.

Training was to some extent similar to the training imparted to trainees and mid-level providers in the application of Steri-Strips. The importance of pursing and aligning everted wound edges as the device is applied is a central tenet of using microMend successfully. The tension in the tape holding the microstaples could be readjusted by inserting the staples, followed by repositioning, in achieving optimal wound edge eversion. This is a distinguishing feature from wound adhesives if used in a wound with some degree of orthogonal tension where wound apposition and compression may be required as the adhesive polymerises.

The inter-rater reliability of the two plastic surgeons represented fair agreement[26] at the 90-day outcome assessment when compared with another study[26] that also involved showing adjudicating plastic surgeons' photographs post hoc. Our observation of improvement in inter-rater scores from day 7 after repair to 3 months later has been observed previously in other controlled ED wound care trials[7]; however, other studies at the time of suture removal reported higher kappa statistics.[3]

Limitations

This was a single-arm study and thus it is not possible to compare cosmetic outcomes, patient or provider satisfaction or relative costs in terms of equipment and time. An open-label randomised study comparing microMend with sutures or wound adhesive in clinical outcomes is required to determine the comparative safety, efficacy and potential economic benefits. However, the lack of a control group makes these outcomes difficult to assess. As this was an open-label, single-arm study design, there was an inherent bias in patient selection[27] for non-complicated wounds. Thus, there was a paucity of wounds longer than several centimetres in the study, largely due to healthcare provider and patient preferences for using existing standard of care repair methods for longer wounds. Although all images were obtained on the same camera, the photographs presented for VAS and

WES scoring were performed by several different research staff members in clinic settings with variable lighting conditions and this may have contributed to some differences in final image quality between participants. In addition, assessment of wound quality is subjective. To overcome this problem, others have proposed the use of automated assessment of wound healing using digital analysis of photographs. While such an objective measure would be appealing, no such tool is widely available.[22] An additional limitation is lack of long-term follow-up given that healing continues for several months after laceration repair. The final end point at 90 days postwound closure was based on previous reports that wound quality assessed after 3 months is a good indicator of long-term cosmetic outcomes.[3 7]

CONCLUSION AND FUTURE DIRECTIONS

Overall, this small and non-comparative study found that closure of lacerations with microMend yielded favourable cosmetic results, low participant reported pain, short application time and high levels of patient and provider satisfaction. The effectiveness and safety of the microMend device for laceration repair should be compared with other wound closure products (eg, sutures) in a broader range of patients in randomised trials.

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Contributors FB and GJ conceived the study and are the guarantors. TN, FB, SS, AA and GJ enrolled patients. FB and GJ conducted data analysis and interpretation of results. RAB performed follow-up on enrolled patients.

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Competing interests None declared.

Patient and public involvement statement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was approved by the site's Institutional Review Board (reference #401318). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information.

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