

Prospective, Randomized, Blinded Study of a New Wound Closure Film Versus Cutaneous Suture for Surgical Wound Closure

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BACKGROUND Wound closure devices include sutures, tissue adhesives, adhesive strips, and staples. Recent studies suggest no differences between various tissue adhesives and sutures for dehiscence, infection, and satisfaction when assessed by patients or surgeons. To date, no studies have investigated ClozeX (Clozex Medical LLC, Wellesley, MA, USA), a novel adhesive strip, for closure of surgical incisions.

OBJECTIVE To compare surgical wounds repaired with ClozeX versus suture.

METHODS A prospective, randomized study was conducted, in which 15 patients with surgical incisions were allocated to closure with ClozeX on half of the wound and monofilament suture on the other half. Physician satisfaction with blinded assessment, patient satisfaction, complication rates, and closure times were recorded.

RESULTS Application with ClozeX was faster than with suture ($p = .007$). There were no complications in either group. Sixty-nine percent of the patients gave ClozeX a higher satisfaction score ($p = .02$). More physicians were satisfied with the ClozeX half than with the suture half ($p = .007$).

CONCLUSIONS This pilot study demonstrates ClozeX to be a safe and effective closure device. The cosmetic outcome seems to be at least as good as simple running suture. Physicians and patients were generally more satisfied with ClozeX. No difference was found in the rate of dehiscence or infection between the groups.

This study was funded by Clozex Medical LLC, Wellesley, Massachusetts.

Thousands of patients undergo surgical excision of benign and malignant cutaneous lesions each year. For the majority of excisions, sutures are used to relieve tension on the surgical wound and to evert the wound edges.¹⁻³ Although wound closure with sutures is safe and effective, it requires specialized instruments, is time consuming, operator dependent, and requires a subsequent visit for suture removal. If sutures are tied too tightly or left

in for an excessive amount of time, strangulation of tissue and suture tracks may occur.⁴ Sutures also carry the risk of a needlestick. In the United States, it has been estimated that there are between 600,000 and 800,000 needlestick injuries per year.⁵ Approximately 50% of needlesticks are caused by suturing needles.⁶

ClozeX (Clozex Medical LLC, Wellesley, MA, USA) is a new, commercially available, wound

closure adhesive film. This film comprises two independent parts, each with an adhesive underside and multiple interlocking filaments attached to pulling ends. The pulling ends allow for wound edge approximation.

Recent studies suggest no significant differences between tissue adhesives and suture for dehiscence, infection, and satisfaction when assessed by patients or surgeons.⁷⁻¹¹ To date, no study

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has compared ClozeX versus suture for repair of surgical wounds.

Methods

Patients referred for excision of benign and malignant cutaneous lesions were evaluated for study inclusion. Exclusion criteria included locations subject to high tension, sites of cosmetic importance, and areas with poor adhesive potential. Specifically, these sites included the genitalia, mucous membranes, joints, scalp, and face. Patients with known allergy to adhesives were also excluded. After obtaining investigational review board approval and written consent, 15 patients with surgical wounds measuring greater than 4.5 cm in length were included in this prospective study.

Following removal of the lesion by surgical excision, hemostasis was attained by electrocoagulation. For all patients, subcutaneous sutures (polyglactin 910) were applied to relieve tension, close dead space, and appose wound edges. Before superficial closure, the area was cleaned with hydrogen peroxide solution and dried. Each surgical wound was then marked at midline into two halves (Figure 1). Based on a predetermined randomization schedule, half of the wound received a running stitch with 4-0 prolene, and the remaining half was closed with ClozeX (Figure 2). Lastly, bacitracin with a standard dress-



Figure 1. Surgical wound after placement of deep buried sutures. Surgical wound is marked at midline into two halves.

ing was placed over the suture half.

The location and length of each wound and the time required for epidermal skin closure were recorded. The recorded time included only the time required to apply ClozeX and the simple running suture. Patients were instructed to keep their wounds clean and dry for at least 24 hours

after surgery. All investigators had undergone standardized training on the application of ClozeX.

At the 2-week postoperative and 4- to 6-week postoperative visits, surgical sites were evaluated by a physician for erythema, swelling, infection, hematoma, seroma, pruritus, serous drainage, overlap of edges, separation of edges, wound dehiscence, hypertrophic scar, keloid, hypersensitive scar,



Figure 2. Surgical wound after placement of running suture and ClozeX.



Figure 3. Scar 1-month postoperative excision. The suture half (A) and ClozeX half (B) are indicated.

and track marks. Photographs of the surgical sites were taken at the 4- to 6-week postoperative visit (Figure 3).

Photographs of the scars were evaluated by a panel of 13 blinded examiners (10 dermatology residents, 1 Mohs fellow, and 2 Mohs

surgical attending). The examiners were asked to determine whether one half of the scar looked cosmetically better than the other. The examiners were also asked to rate each half of the scar according to a four-point satisfaction scale (i.e., concerning the appearance of each half of the

scar, are you: (0) not satisfied; (1) somewhat satisfied; (2) satisfied; or (3) extremely satisfied).

The judgment of the patient was also recorded at the 4-week postoperative visit according to a similar four-point scoring scale.

Statistical Analysis

The sign test was used to test differences calculated from paired data (such as the time needed for suture/ClozeX or patient satisfaction for suture/ClozeX). The binomial test was used in all analyses involving percentage of patients/physicians satisfied with the 4- to 6-week outcome to test whether the percentage was significantly different from 50%. The κ -statistic was calculated to assess inter-rater reliability for the independent examiners.

Results

In this pilot study, a total of 15 patients (age range, 18–87 years; nine males and six females; skin photo types I–IV) with 15 surgical wounds were enrolled. The wounds were distributed over the chest ($n = 4$; 27%), back ($n = 5$; 33%), arm ($n = 3$; 20%), and leg ($n = 3$; 20%). The mean incision length was 5.7 cm, and ranged between 4.6 and 13.5 cm (Table 1).

Closure with ClozeX was faster than with simple running suture. The median suture time was 127 seconds longer than that of ClozeX application. Statistically,

TABLE 1. Summary of Patient and Wound Characteristics

Patient characteristics	
No. of patients	15
Mean age (years)	53
Range (years)	18–87
Male	9 (60%)
Female	6 (40%)
Skin photo types	I–IV
Wound characteristics	
No. of wounds	15
Chest	4 (27%)
Back	5 (33%)
Arm	3 (20%)
Leg	3 (20%)
Mean length \pm SD (cm)	5.7 \pm 1.8
Range (cm)	4.6–13.5
Placement of ClozeX	
Superior	2 (13%)
Inferior	7 (47%)
Lateral	5 (33%)
Medial	1 (7%)

this difference in time for skin closure between the two studied groups was significant ($p = .007$).

Early Follow-Up

Follow-up occurred at 14 days in all 15 patients (100%). No complications were seen with any of the wounds. There were no instances of wound hematoma, seroma, infection, overlap of edges, separation of edges, or dehiscence in either group. One patient, however, had an allergic contact dermatitis to bacitracin ointment over the suture half. Several of the suture halves exhibited increased inflammation and erythema, whereas ClozeX caused less tissue reaction.

Four- to Six-Week Follow-Up

Four- to six-week follow-up was performed on 13 patients (87%). Again, there were no complications with any of the wounds. Furthermore, there were no instances of hypersensitive or pruritic scar, hypertrophic scar, or keloid in either group. Track marks, however, were seen in two of the suture halves.

Blinded Physician Evaluation

The panel of blinded examiners evaluated digital photographs of scars taken during the 4- to 6-week follow-up visit. There was good agreement between the examiners. The percentage of examiners who rated the ClozeX half as cosmetically superior was 66%, while 14% thought the

suture half was superior, and 20% rated the two halves as appearing equal (Figure 4).

The percentage of examiners completely satisfied (score of 3) with the ClozeX half was 40% versus 17% with the suture half. When combining satisfied and completely satisfied percentages together (scores 2 and 3), 78% of physicians were satisfied with ClozeX versus 36% satisfied with suture (Figure 5). Overall, more physicians were satisfied with the ClozeX half than with the suture half ($p = .007$).

Patient Questionnaire

Thirteen (87%) of 15 patients completed the patient questionnaire at the 4- to 6-week postoperative visit. Although subjective, the patient's perception is extremely important. Nine (69%) of the patients gave ClozeX a higher satisfaction score. The median difference between patient rating of ClozeX and suture (ClozeX suture) was 1 ($p = .02$). Five (39%) of the patients were completely satisfied with ClozeX, while none of the patients were completely

satisfied with the suture half ($p = .0003$). Overall, 11 (85%) of the patients were either satisfied or completely satisfied (scores 2 and 3) with ClozeX (Figure 6).

Discussion

The purpose of this pilot study was to ascertain whether ClozeX is an effective alternative to suture for patients undergoing surgical excision. This study demonstrated that ClozeX decreased the time required to close surgical wounds by approximately 2 minutes. Whether this difference translates into tangible cost benefits is harder to determine. The cost of a 2.5 mm ClozeX device is \$11, whereas the cost per package of prolene suture is \$8. Factors such as needlestick costs, follow-up visits, and operating time need to be considered.

The most significant outcome of effectiveness of wound closure is dehiscence. In this study, there were no cases of dehiscence in either the ClozeX or standard suture halves. As application of ClozeX in areas of high tension such as around joints was ex-

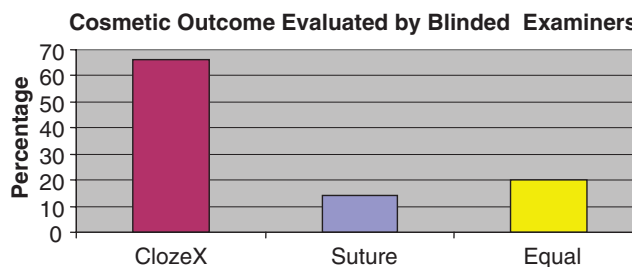


Figure 4. Percentage of examiners who rated the ClozeX[®] half as cosmetically better, the suture half as better, or both halves as equivalent.

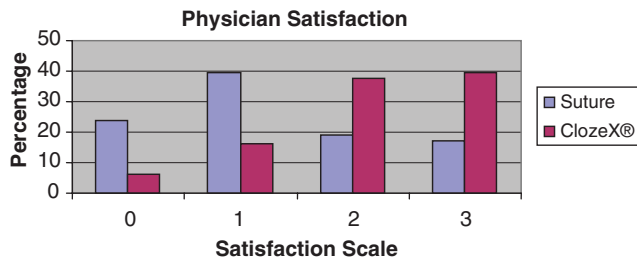


Figure 5. Blinded physician evaluations of scars 4 to 6 weeks postoperative excision. Scars are scored from 0 (not satisfied) to 3 (completely satisfied).

cluded from our investigation, this will need to be addressed in future studies.

Consistent with the overall low infection rates reported in the dermatologic surgery literature,¹² there were no cases of infection in either study group. Our clinical assessment for infection at 2 and 4 weeks postoperatively included evaluation for redness, swelling, purulent discharge, pain, increased skin temperature, and fever.

Cosmetic result is an important outcome of wound repair for the patient and dermatologic surgeon. Study bias was reduced by having assessments performed by independent examiners blinded to the study group. Parameters for cos-

metic outcome included assessing for step-off borders, contour irregularities, wound margin separation, edge inversion, excessive inflammation, railroad tracking, and presence of hypertrophic scars. Overall, both patients and physicians were more satisfied with the ClozeX half.

The decision to use simple running sutures was based on its allowance for quicker placement and more rapid reapproximation of wound edges, compared with other techniques. Theoretically, less scarring occurs with running sutures because fewer knots are made.¹³ Other suture techniques that would be acceptable and possibly yield superior cosmetic results in these locations include vertical mattress suture to maxi-

mize wound eversion and horizontal sutures for wounds under high tension. For wounds under minimal tension, running subcuticular suture would have been ideal for cosmetic comparison as there is no crosshatching.¹⁴

Analysis of our experience with ClozeX has several limitations. The statistical power of our study is limited by sample size and a potentially short follow-up period for scar assessment.¹⁵ In addition, restrictions from utilizing a panel of blinded examiners include substituting live patient follow-ups for digital photographs, demonstrating agreement between examiners, and incorporating potentially less than ideally skilled examiners. The limitations of our study design underscore the need for a larger study with a longer follow-up period to further validate our results.

Conclusion

This pilot study demonstrates ClozeX to be a promising surgical wound-closure device. The cosmetic outcome seems to be at least as good as simple running suture. Through evaluation by blinded physician assessment of digital photographs and patient questionnaires, we conclude that physicians and patients were generally more satisfied with ClozeX.

Importantly, no difference was found in the rate of dehiscence or infection between the groups.

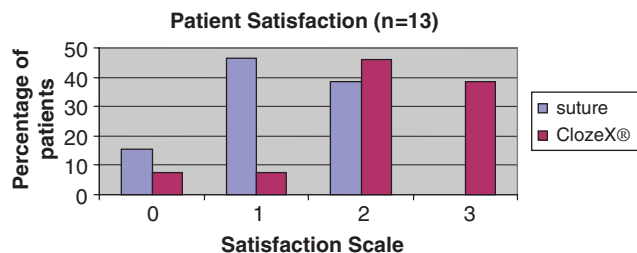


Figure 6. Patient evaluations of scars 4–to 6 weeks postoperative excision. Scars are scored from 0 (not satisfied) to 3 (completely satisfied).

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