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Comparison of Leukosan SkinLink with surgical suture for traumatic laceration repair

A randomized controlled trial

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Abstract

Background: Leukosan SkinLink (LS), which combines non-woven textile strips and tissue adhesive, offers the advantage of atraumatic treatment while effectively shortening the procedure time. We hypothesized that wound closure would be faster with LS than with surgical suture (SS) and the wound infection and dehiscence would be similar.

Methods: A prospective, open label, single-center, randomized controlled trial was performed. Between November 2014 and April 2016, 49 patients with traumatic lacerations who presented to the emergency department were eligible for study inclusion.

Results: The mean wound closure time was significantly lower in the LS group than in the SS group (1.48 ± 0.2 seconds vs 8.8 ± 3.6 minutes, $P < .001$). After adjusting the wound closure time according to the lacerations length, the time remained significantly lower in the LS group than in the SS group (1.0 ± 0.8 seconds vs 5.03 ± 2.5minutes, $P < .001$). During follow-up for 14 days, no significant differences in dehiscence and wound infection were observed between the 2 groups.

Conclusion: Wound closure was approximately 4minutes faster with LS and there were no differences in wound infection and dehiscence rates. Thus, the LS could be used as a timesaving suture technique for acute traumatic lacerations in emergency department (ED).

Trial registration: ClinicalTrials.gov NCT02333877

Abbreviations: ED = emergency department, LS = Leukosan SkinLink, SD = standard deviation, SS = surgical suture.

Keywords: lacerations, randomized controlled trial, surgical tape, tissue adhesive

1. Introduction

Traumatic lacerations are common acute wounds in patients visiting the emergency department (ED). Surgical suture (SS) has been widely used to repair traumatic lacerations as it promotes wound healing and reduces scars.[1–3] Although SS is safe and effective, the procedure is time-consuming and operator-dependent. Therefore, several alternative materials for wound closure, such as tissue adhesives (skin glue) and surgical tapes, have been recently used because the methods are easy to learn and are time-saving.[4] The currently used tissue adhesives are 2-octylcyanoacrylate (Dermabond; Ethicon, Inc., Somerville, NJ) and n-butyl-2 cyanoacrylate (Histoacryl; B. Braun, Ann Arbor, MI). However, these adhesives can seep into the wound and cause dehiscence or hematoma in improperly everted wounds. The use of surgical tapes, such as Steri-Strips (3M Deutschland GmbH, Neuss, Germany), is another easy alternative approach for wound closure. Nevertheless, the theoretical disadvantages of surgical tapes are that they frequently fall off, have lower tensile strength than SS, have the highest rate of dehiscence and cannot get wet.[5–7]

Leukosan SkinLink (LS; BSN medical GmbH, Hamburg, Germany) is a non-invasive, 2-component skin closure system, combining non-woven textile strips and a tissue adhesive (n-butyl-2-cyanoacrylate). One previous study reported that the tissue adhesive proved superior to Steri-Strips but inferior to stapled closure.[8] The tissue adhesive of the LS has therefore benefits to supplement these disadvantages of Steri-Strips, because the tissue adhesive reinforces the structure and strength of the textile strips (Fig. 1).

No previous randomized controlled trial has compared LS with SS for acute traumatic lacerations. The present study aimed to compare LS with SS for acute traumatic lacerations in the setting of a randomized controlled trial. We hypothesized that wound closure would be faster with LS than with SS and the wound infection and dehiscence would be similar.

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HK and WK have contributed equally to this study.

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All authors declare that they do not have any potential conflicts of interest.

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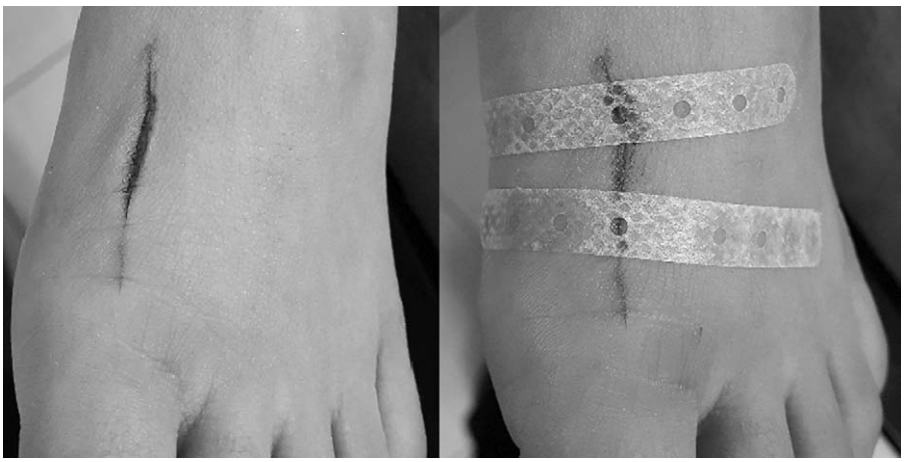

Figure 1. Leukosan SkinLink. The tissue adhesive was applied on the strips rather than directly on the wound.

2. Materials and methods

2.1. Study design

We performed a randomized controlled trial to evaluate the outcomes of LS and SS. The study was performed at Hallym University Kangnam Sacred Heart Hospital between Jan 2015 and April 2016. Written informed consent was obtained for all participants. The local ethics committee approved this trial on November 27, 2014 (IRB No.: 2014–11–152). This trial was registered in Clinical Trials before initiation. (Clinicaltrials.gov: NCT02333877).

2.2. Participants

Between Jan 2015 and April 2016, 49 patients with at least 1 traumatic laceration (SS group: n=18, LS group: n=31) were eligible for enrollment at Hallym University Kangnam Sacred Heart Hospital in South Korea.

The inclusion criteria were age 18 to 75 years, presence of a partial thickness laceration (defined as "laceration limited to the epidermis and superficial dermis"), generally good health without systemic abnormalities, agreement to return for a 14-day follow-up. The exclusion criteria were previous diagnosis of diabetes mellitus, peripheral vascular disease, or bleeding disorders; history of keloid formation or scar hypertrophy; and allergy to cyanoacrylate compounds or formaldehyde (Fig. 2).

2.3. Interventions

Random numbers were generated by a sequence generator (http://www.random.org). These numbers were printed on slips of paper and were placed in translucent boxes. Suture sets were numbered with numbers corresponding to the slip numbers, and the sets contained SS or LS material. The study nurses were asked to select a translucent box, and the suture set with the corresponding number was selected. The physician opened the suture set just before beginning the procedure.

In the SS group, after rinsing the wound, lidocaine was applied near the wound. After injection of a local anesthetic, simple interrupted skin suture with nylon (4-0, 5-0, 6-0) was performed. Deep suture was not used.

In the LS group, after rinsing and drying the wound, adhesive textile strips were applied perpendicular to the wound. The wound edges were everted with fingers assisted by forceps. Adhesive adjunct was not used. The tissue adhesive was applied on the strips rather than directly on the wound.

After skin closure, semi-occlusive dressing using foam was applied to the wound. Prophylactic oral antibiotics were used for all patients for 5 days. The suture and LS were removed at postoperative day 14.

At short-term follow-ups, patients were evaluated for wound outcomes (postoperative days 2, 7, 14). The observers (senior resident of emergency medicine or emergency physician) were blinded to the identity of the physicians who performed the wound closures.

2.4. Equipment and materials

In the SS group, 10% povidone-iodine (Q&Q, Pharm Co., Ltd., Seoul, South Korea; Huons Co., Ltd., Seongnam-si, South Korea; Ailee Co., Ltd., Busan, South Korea.) was used for wound sterilization on the skin edges and 2% lidocaine (Lidocaine HCL injection; Huons Co., Ltd., South Korea) was used for local anesthesia. Non-absorbable suture material (3-0 to 6-0 Nylon, Blue, Ailee Co., Ltd., South Korea) was used for wound closure. In the LS group, LS was used for wound closure. In both the groups, Allevyn adhesive (Smith & Nephew, London, UK) was used for semi-occlusive dressing.

2.5. Outcomes

The primary outcome was the wound closure time which could compare timesaving efficiency between both the groups.[9,10] The wound closure time was defined as the time required only for primary closure, excluding the time of general wound care, including cleansing and local anesthesia. In the LS group, the wound closure time was defined as the time from everting the wound edges to the physician saying, "finished" after applying the tissue adhesive. In the SS group, the wound closure time was defined as the time from applying local anesthetics to the physician saying, "finished" after completing the simple interrupted suture.

The secondary outcomes were wound dehiscence and infection. Wound dehiscence was assessed as <1, 1–2, and >2 mm. Wound infection was assessed according to erythema, edema, pain, and temperature using a 4-point scale for each.[11] One or more points defined as wound infection.

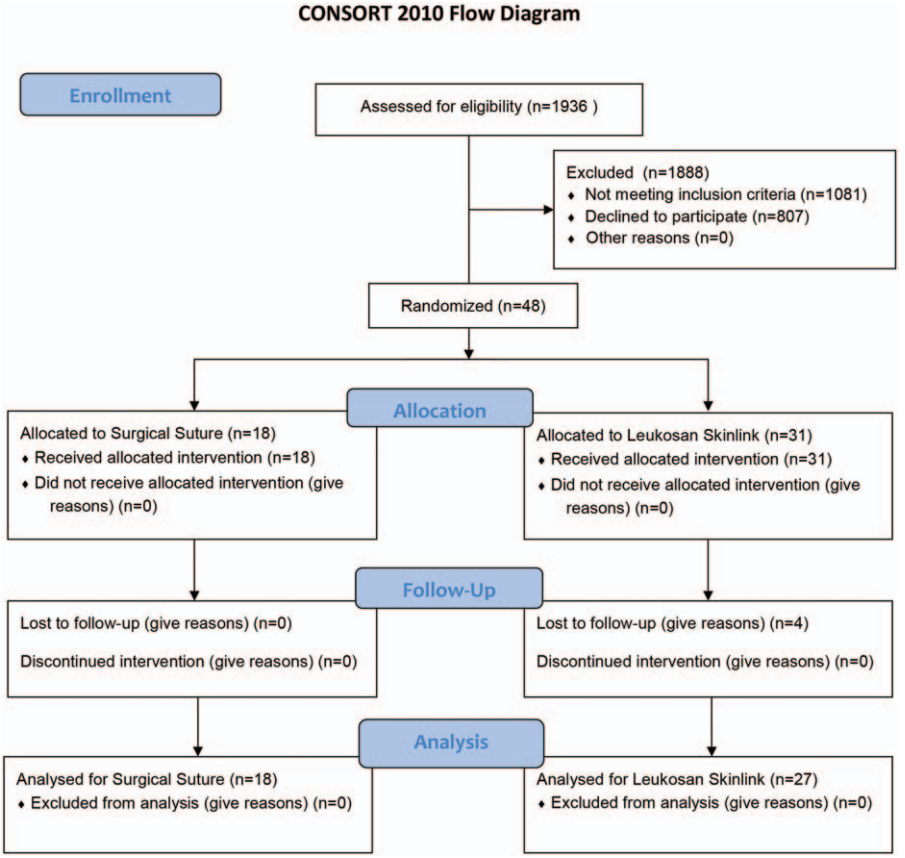

Figure 2. Flow diagram.

2.6. Statistical analysis

The sample size was calculated based on our informal study on the wound closure time. The wound closure time (mean ± SD) in that study was as follows: LS group, 4.0 ± 1.7 minutes and SS group, 5.9 ± 2.0 minutes. To detect 2 minutes difference in wound closure time, at least 17 patients for each group were needed. Hence, we estimated that 24 patients would be adequate for each group, with a 30% dropout rate and a power of 0.8.

We generated descriptive statistics and presented them as frequencies and percentages for categorical data and means with standard deviations for continuous data.

To compare the wound closure time between the LS and SS groups, the Mann–Whitney *U* test (nonparametric data) or independent *t* test (parametric data) was used for continuous variables. The Fisher exact test was used to compare categorical variables, such as dehiscence. The data were compiled using a standard spreadsheet program (Excel; Microsoft, Redmond, WA) and analyzed using the Statistical Package for the Social Sciences (SPSS) 20.0 KO for Windows (SPSS Inc., Chicago, IL). A *P*-value <.05 was considered statistically significant.

3. Results

3.1. Characteristics

One thousand nine hundred thirty-six patients were assessed for eligibility and 1888 patients were excluded (not meeting inclusion criteria: 1081, declined to participate: 807). Forty-nine patients with traumatic laceration (SS group: n = 18, LS group: n = 31) were eligible for enrollment (Fig. 2).

The most common mechanism of injury was knife. The mean laceration length was significantly greater in the SS group than in the LS group (1.9 ± 0.7 cm vs 1.2 ± 0.5 cm, *P* = .001). All other baseline variables were similar between the 2 groups (Table 1).

3.2. Initial outcomes

The mean wound closure time was significantly lower in the LS group than in the SS group (1.4 ± 0.2 minutes vs 8.8 ± 3.6 minutes, *P* < .001). However, wound length was about 0.7 cm longer in the SS group as shorter wound length could contribute to shorter wound closure time, we adjusted wound closure time according to the wound length. After adjusting the wound closure time according to the laceration length, the time remained significantly lower in the LS group than in the SS group (1.0 ± 0.8 seconds vs 5.0 ± 2.5 minutes, *P* < .001) (Table 2).

3.3. Follow-up

Over the 14-day follow-up, no significant differences in dehiscence and wound infection were observed between the 2 groups (Table 2).

4. Discussion

To our knowledge, this is the first randomized controlled trial comparing LS with SS for acute traumatic lacerations. In this study, we found that LS was faster than SS and that the adverse events were similar between LS and SS.

Table 1

Baseline patient characteristics.

	Surgical suture (n = 18)	Leukosan SkinLink (n = 31)	*P*-value
Age, y	41.7 ± 15.3	36.2 ± 12.7	.18
Female	9 (50.0)	16 (51.6)	.91
Mechanism of injury			N/A
Knife	8 (44.4)	16 (51.6)	
Glass	6 (33.3)	4 (12.9)	
Can	0 (0)	3 (9.7)	
Scissors	2 (11.1)	2 (6.5)	
Others	2 (11.1)	6 (19.4)	
Location of laceration			N/A
Finger	6 (33.3)	27 (87.1)	
Hand, except fingers	7 (38.9)	1 (3.2)	
Upper arm	0 (0)	0 (0)	
Lower arm	1 (5.6)	0 (0)	
Upper leg	2 (11.1)	2 (6.5)	
Lower leg	2 (11.1)	0 (0)	
Unknown	0 (0)	1 (3.2)	
Laceration length, cm	1.9 ± 0.7	1.2 ± 0.5	.001*
Depth of laceration			N/A
Superficial	0 (0)	2 (6.5)	
Partial thickness	18 (100)	29 (93.5)	
Gross contamination	0 (0)	0 (0)	N/A
Foreign body identified	0 (0)	0 (0)	N/A
Initial tenderness (VAS)	3.1 ± 2.6	3.1 ± 2.1	.84*

Categorical values are presented as number (%).

Continuous variables are presented as mean ± SD. These variables were assessed with the independent *t* test. N/A = not available.

* Calculated with the Mann–Whitney *U* test.

The ideal method of wound closure should be simple, safe, rapid, and painless; prevent bacterial growth; and result in optimal cosmetic appearance of the scar.[12] The LS procedure does not require the use of anesthesia and is painless. Additionally, the procedure is easy to learn. Furthermore, a reinforced tension-free effect is obtained with topical adhesives and there is no effect on epithelialization. These characteristics of LS are consistent with the characteristics of an ideal method of wound closure. Nevertheless, there have been no clinical studies on LS, except for 1 prospective observational study in the ED and 1 randomized study in the operating room.[13,14]

Published studies for tissue adhesives and surgical tapes concentrate solely on the repair of surgical incision wounds in the operating room and not on acute traumatic wounds in the ED.[15,16] Bleeding and infection are more likely to occur in traumatic wounds than surgical incision wounds; therefore, the efficacy and safety of LS identified in previous studies on surgical incision wounds cannot be extended to traumatic wounds.[17–19] In the limited small study, the rate of short-term adverse events was similar to sutures.

A previous study reported that the cosmetic outcome of wounds closed with the SS was dependent on the level of training.[12] In contrast, the experience of practitioners with tissue adhesives was found to not affect the cosmetic outcome of wounds closed with octylcyanoacrylate.[12] In a previous study, the wound closure time was lower with surgical tapes, such as Steri-Strip S, than with the SS, and the complication rates were equivalent.[20] Hence, we believe that less experienced practitioners could use LS easily and safely as the procedure is similar to that for surgical tapes and octylcyanoacrylate.

4.1. The present study had some limitations

First, the patient follow-up was limited to 14 days, although cosmetic outcomes, such as dehiscence, were evaluated after 3 months or 1 year in several studies. Therefore, the outcomes of our study do not reflect long-term cosmetic outcomes.

Second, the patients were from South Korea; therefore, it might not be possible to generalize the findings to patients from other countries/regions. Further studies with a long-term follow-up and wide patient representation are needed to overcome these limitations and obtain robust results.

Third, lines of minimal tension were not considered in this study. We also think that lines of minimal tension could affect cosmetic outcome. However, the cosmetic outcomes of LS were similar with those of SS. Hence, minimal tension lines have minimal effect on cosmetic outcomes in this study.

Fourth, the study was under-powered to detect meaningful differences in safety outcomes and had sample imbalance between both the groups. We assumed that this imbalance between both the groups was caused by considering high dropout rate in calculating sample size. Nevertheless, we believed that this imbalance did not significantly affect the results. It was because most baseline variables were similar between both the groups as shown in Table 1.

In conclusion, wound closure was approximately 4 minutes faster with LS and there were no differences in wound infection and dehiscence rates. Thus, the LS could be used as a timesaving suture technique for acute traumatic lacerations in ED.

Author contributions

Conceptualization: Wonhee Kim, Gu Hyun Kang, Yong Soo Jang, Hyun Young Choi, Jae Guk Kim, In Young Kim.

Table 2

Outcomes.

	Surgical suture (n = 18)	Leukosan SkinLink (n = 27)	*P*-value
Initial outcome			
Wound closure time (min)	8.8 ± 3.6	1.4 ± 0.2	< .001
Wound closure time after adjusting for laceration length (s/cm)‡	5.0 ± 2.5	1.0 ± 0.8	< .001*
Follow-up (14 days)			
Dehiscence	2 (11.1)	0 (0)	.15†
Wound infection	0 (0)	0 (0)	N/A

Categorical values are presented as number (%).

Continuous variables are presented as mean ± SD. The variables were assessed with the independent *t* test. N/A = not available.

* Calculated with the Mann–Whitney *U* test.

† Calculated with the Fisher exact test.

‡ Calculated using the following formula: wound closure time (s)/laceration length (cm).

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