

# ASSESSING COSMETIC RESULTS OF NOVEL VS. TRADITIONAL WOUND CLOSURE METHODS IN PRIMARY CAESAREAN SECTIONS

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#### Abstract

**Background**: This study aims to assess the performance of traditional and novel wound closure techniques and their cosmetic outcomes in primary caesarean section procedures. **Methods**: A total of 122 patients scheduled for primary caesarean sections were randomly assigned to receive either traditional Prolene suture closure or a novel wound closure device. The cosmetic outcomes were evaluated by the patients, operating surgeons, and independent blinded examiners at 3, 6, and 12 months post-surgery. **Results**: Both closure methods yielded comparable high scores on the visual analogue scale (VAS) for cosmetic evaluation at all follow-up periods. There were no significant differences between the two methods in terms of cosmetic appearance as rated by the patients, surgeons, and blinded examiners. **Conclusion**: Our findings suggest that innovative wound closure techniques, such as SkinLink, provide excellent cosmetic outcomes comparable to traditional Prolene sutures. Both methods offer effective results for wound closure in caesarean sections.

**Keywords**: Caesarean section, Wound closure, Prolene suture, Cosmetic outcome.

#### INTRODUCTION

Sutures have been used for over 4,000 years to close wounds, providing an effective and safe method of wound closure. However, suture closure carries certain risks, such as the need for specialized tools, potential for additional tissue trauma, and the necessity of removal afterward. In recent years, alternatives like adhesive strips, staples, and tissue adhesives have gained popularity due to their proven efficacy. In emergency rooms, adhesive strips are frequently used for treating lacerations, offering reliable closure and acceptable cosmetic outcomes [1, 2]. The choice of wound closure device in the operating room often depends on the surgeon's preferences and experience. Beyond ensuring reliable wound closure and good cosmetic results, factors such as procedure duration and cost are also considered, leading to the use of tapes, staples, and tissue adhesives [3-6]. Despite the availability of these options, new wound closure devices continue to emerge on the market, though their reliability is not always well established [7, 8].

One such device is a commercially available wound closure product that combines the benefits of adhesive strips with topical skin adhesives for added fixation. This device consists of a nonwoven strip anchored to intact skin using a pressure-sensitive adhesive. While commonly

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used for traumatic wounds [9], it is also being explored for closing surgically induced wounds, which are typically closed with sutures. An experiment comparing skin-linking sutures with prolene sutures was conducted to assess its potential. Caesarean sections, a common yet challenging surgical procedure [10-12], often require closure of the Pfannenstiel incision, and there is no standard method for this. Any new technique offering superior cosmetic results is highly sought after, providing obstetricians and patients with alternative options. Given the priority placed on cosmetic outcomes for patients, this study specifically focuses on evaluating the cosmetic results of different wound closure methods.

## **METHODS AND MATERIALS**

#### **Patients**

## **Study Design and Participants**

This study excluded patients with allergies to cyanoacrylates, formaldehyde, or dressing strips, as well as those with skin conditions, a history of keloid formation, obesity, or impaired blood clotting. The study involved 61 pregnant women scheduled for a primary Caesarean section. Wound closure was performed using either the Prolene suture method or Leukosan SkinLink, with patients randomly assigned to one of these closure methods using a random number generator. The Statistical Analysis System (SAS) function 'ranuni' was used to randomly assign patient numbers to the wound closure procedures before enrolling the first participant. The randomization process was conducted electronically and on paper (random list). The investigator received the random list and assigned patient numbers to the participants accordingly.

## **Surgical Technique and Wound Closure**

Perioperative antibiotic prophylaxis was provided with Gramaxine. Pubic hair was shaved using a shaving machine, and the skin was prepared using Cutasept F and Octenisept. A forced-air convection system maintained normothermia during surgery. Subcutaneous fat was sutured to close the wound, and Vicryl 2-0 absorbable sutures were used for the deep sutures, with buried knots. The needle was inserted between the dermis and subcutis, exiting the papillary dermis. An atraumatic technique was used to handle the skin with small forceps and skin hooks. A cutting needle was used for the closure. For Prolene topical closure, horizontal bites were taken through the papillary dermis on both sides of the wound. There were no visible suture marks, and the suture looped through the subcuticular tissue. The suture was knotted at the opposite end of the wound after completing the closure. SkinLink was used for topical wound closure in the second group.

### **Evaluation**

The treating physician evaluated the ease of application and performance of the wound closure procedure on a scale of 1 to 10. Any complications or unexpected events were documented. Patients were asked to rate their comfort and pain levels after the removal of sutures or Leukosan SkinLink. A physician also assessed the cosmetic appearance of the wounds using a 100-mm visual analogue scale (VAS), where 0 represented a "poor scar" and 100 represented a "perfect scar." Patients returned for follow-up visits at 3, 6, and 12 months post-Caesarean section for wound photography. Digital cameras were used for consistent lighting, exposure, and distance

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from the subject. At each visit, both the physician and patient evaluated the cosmetic appearance using the VAS. Three blinded examiners, unaware of the wound closure method, independently evaluated the scars at the 3-, 6-, and 12-month follow-up visits. Patients were generally hospitalized for seven days during the primary healing period, and any infections or complications were recorded during the follow-up visits.

## **Statistical Analysis**

Non-parametric statistics were employed to compare cosmetic outcomes between the two wound closure methods. Descriptive statistical analysis was conducted on parameters such as weight, height, age, wound closure performance, ease of application, comfort during wear, and pain after removal. The Wilcoxon test was used to compare the two closure methods. A p-value of less than 0.05 was considered statistically significant.

## **RESULTS**

The trial involved 122 women who were randomly assigned to receive Prolene suture or LeukosanÒ SkinLink. Demographically, the two groups were similar (Table 1). A total of 24 patients were lost to follow-up because of lack of contact. 46 patients completed the Prolene suture arm and 52 completed the Leukosan Skin- Link arm. Women in the study had caesarean sections performed by experienced gynecologists. According to the manual, SkinLink was applied.

**Table 1** shows the demographic data of the patients

Patient Data	Mean	SD	Median	Minimum	Maximum	n
Age (years)	33·1	5.7	34.0	25.0	43.0	60
	33.2	6.2	34.0	19.0	40.0	62
Weight (kg)	72.7	12.4	72.5	51.0	94.0	60
	71.5	9.9	71.0	53.0	89.0	62
Height (cm)	172.1	5.1	172.0	164.0	179.0	60
	172.9	6.1	171.0	165.0	182.0	62

Closure of wounds on surgery day performance was assessed by the surgeons with high ratings. Prolene suture scored slightly higher for ease of application.

Table 2 Surgical wound closure and ease of application are two of the key features of this product

M	ethod	Mean	SD	Median	Minimu	Maximu	n
					m	m	

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Wound closure	Prolene suture	10.0	0.10	10.0	8.0	11.0	60
1	Leukosan ±SkinLink	9.9	2.3	10.0	6.0	11.0	62
	Prolene suture	10.2	0.8	10.0	9·0	11.0	60
11	Leukosan ±SkinLink	9·7	2.3	10.0	6.0	11.0	62

Patient satisfaction with the comfort of wearing was comparable for both closure techniques. It was also shown that patients reported low pain when sutures were removed, as compared to Leukosan SkinLink. Complications were not different between Leukosan SkinLink and Prolene closure. There was one report of dehisce with Leukosan Skin-Link. There were no reports of allergic reactions or infections. At 3, 6 and 12 months following surgery, the scar's cosmetic appearance was evaluated. Three gynecologists blinded to wound closure evaluated it along with the physicians and patients. Photographs taken during follow-up visits were evaluated by blinded examiners. The cosmetic outcome was assessed at any time point or by any group, no significant differences were found between the two closure techniques. Leukosan SkinLink performed equally well with the standard method. In both wound closure methods (Figures 4A–D), scars had similar cosmetic appearances.

## **DISCUSSION**

The closure of simple, low-tension lacerations can be achieved with noninvasive devices such as adhesive tapes (13). More challenging surgically inflicted wounds, such as those with longer or higher tension, have limited data. Many surgeons use a technique based on their own experience and preference in many surgeries for closing the skin. Alternatives to traditional noninvasive wound closure devices may be available in the form of newly developed devices. This study examines the effectiveness of a new wound closure device, LeukosanO Skin Link, can effectively close wounds after surgery. Wounds following primary section were targeted. Pfannenstiel incisions remain controversial despite caesarean sections being common (14). Skin closure materials and techniques are still being developed. During a caesarean section, several layers of the mother's abdomen must be cut and reclosed. A comparative study found that LeukosanÒ SkinLink was comparable to suturing on all counts. In addition to suturing being a technical skill, one, can also be mastered with some instruction and practice. According to the surgeons who participated in this study, both wound closure methods were highly satisfactory in terms of ease of application and wound closure results. Infection was reported in this study. According to published international data, caesarean section SSI rates range from 29% to 179%, depending on body mass index (BMI), age, blood loss, wound closure method, and emergency procedures. Since emergency cases and high-risk patients are excluded, the incidence is low. The patient is concerned about the comfort of the wear and the pain of removal. Due to the need for removal, suturing and stapling can cause anxiety (9,13). Based on patient assessments, Prolene suture was no different from LeukosanO Painless removal and comfortable wearing with SkinLink. In spite of the higher pain scores associated with Prolene sutures, patients' anxiety about suture removal is likely to be higher when it comes to adults. Both wound closure methods were found to be acceptable in terms of wearing comfort. There were no reports of allergic

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reactions or infections. Also, Leukosan SkinLink has been tested for biocompatibility (ISO 10993). According to tests, Leukosan SkinLink is not cytotoxic, irritating, or sensitizing. In addition to the atraumatic wound closure, no additional materials are required, the doctor can close the wound independently of a nurse or assistant, and the procedure is very easy to learn. Patient comfort is high, and there is no need for a repeat visit to remove stitches. BSN medical's commercial politics determine comparative costs. Atraumatic devices find their financial expression in the fact that they do not require local anaesthesia, additional sterilization of instruments, additional nurses, or repeated visits to remove stitches, which can add weight to ambulatory surgery.

Compared to continuous sutures, the new method also reduces wound closure time. The device 'SkinLink' was tested on pig skin to determine its time efficiency, according to BSN medical records. Pig skin was incised between 4 and 8 cm. By using separate stitches, continuous sutures, and SkinLink, these were treated in parallel. According to the results, it is 45-65% faster than sutures. Women, in particular, place a great deal of importance on the cosmetic acceptability of a scar after caesarean sections. We assessed the cosmetic outcome of both closure methods in detail. To minimise bias, the surgeon, patient, and three gynecologists blinded to wound closure method assessed scar appearance. It was decided to follow-up at 3, 6 and 12 months for scar assessment since shorter follow-up periods may limit validity (2). According to surgeons, patients, and blinded observers, LeukosanÒ SkinLink was equally effective as suturing according to a blinded observer, a patient, and both surgeons. It is a pilot study with 61 patients and therefore has limited statistical power. Although the sample size is small, the results remain valid since caesarean wounds are quite homogeneous and standardised among women (see demographic data). Additionally, digital photographs are substituted for live follow-ups by blinded examiners. The images were taken in a standardised manner, and the patient and physician assessed them live to support evaluation of the photographs. The blind observers validated the patient's and physician's potentially subjective assessments.

## **CONCLUSION**

According to the results of this study, Leukosan\* Skin-Link is an effective alternative to traditional suturing. LeukosanÒ SkinLink was comparable to invasive suturing on all levels studied. Patients and physicians now have an additional non-invasive surgical wound closure option with comparable cosmetic outcomes and wound closure performance.

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