A randomized, controlled study comparing the cosmetic outcome of a new wound closure device with Prolene suture closing caesarean wounds

Sven Juergens, Carolin Maune, Fatima Kezze, Thorsten Mohr, Katrin Scheuer, Peter Mallmann


ABSTRACT
A prospective, randomised study was conducted to compare the wound closure performance and cosmetic outcome of caesarean section wounds closed with traditional Prolene suture or a new wound closure device (Leukosan® SkinLink). Sixty-one patients referred to primary section were allocated to wound closure with either Leukosan® SkinLink or Prolene suture. Cosmetic outcome as the primary measure was evaluated by the patient, the surgeon as well as by independent examiners blinded to the method of wound closure. Evaluations were recorded at 3, 6 and 12 months following wound closure. Both methods of wound closure scored equally high on the visual analogue scale for cosmetic evaluation at the 3-, 6- and 12-month follow-ups as assessed by the patient, surgeon and the blinded observers. The study has shown that innovative methods for wound closure compared with traditional methods such as suture providing excellent cosmetic results represent a valid alternative to physician and patient for surgical incisions.

Key words: Caesarean section • Cosmetic outcome • Leukosan® SkinLink • Suture • Wound closure

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INTRODUCTION

Suturing has been the standard form of wound closure for over 4000 years. Although wound closure with sutures is effective and safe, it bears certain disadvantages: it requires specialised instruments and skilled operators, creates additional trauma and requires removal. Lately, wound closure devices such as staples, adhesive strips and tissue adhesives have also proved feasible and safe for skin closure. Non invasive wound closure devices such as adhesive strips and tissue adhesives in particular are increasingly used for repair of traumatic lacerations in children and adults in emergency rooms, offering reliable wound closure as well as acceptable cosmetic results (1–4). In the operating room, wound closure is often more challenging and the use of the closure devices enabling optimal wound repair is dependent on the preferences and experiences of the surgeon. Although reliable wound closure and cosmetic outcome are the main focus, duration of wound closure and costs are additional factors that are considered. Therefore, surgical tapes, staples and tissue adhesives as alternative methods have also entered the operating room (5–10).

In addition to the established wound closure devices, innovative products are still entering the market whose reliability still has to be proved (11,12). Leukosan® SkinLink (BSN medical GmbH, Hamburg, Germany), a commercially available wound closure device, represents such an innovative system for wound closure, combining the advantages of wound closure strips and topical skin adhesives for additional fixation. Leukosan® SkinLink consists of perforated, non woven textile strips coated with pressure-sensitive adhesive and a surgical adhesive (N-butyl-2-cyanoacrylate) which additionally anchors the strips to the intact skin on either side of the wound. In addition to repair of traumatic wounds, Leukosan® SkinLink is suitable for closing surgically inflicted wounds. As these types of wounds are most commonly closed using sutures, a study was designed to compare wounds closed with either Leukosan® SkinLink or Prolene suture. Caesarean sections were chosen as this is a common, yet challenging surgery with no agreed standard on operative techniques and materials to be used (13–16). The ideal method of closing the skin following a Pfannenstiel incision has not been established yet and any new technique providing an excellent cosmetic outcome is welcomed to provide women and their consulting obstetrician with alternative choices. As the cosmetic result is of utmost importance for the patient, the study is focussed on the evaluation of the cosmetics.

MATERIALS AND METHODS

Following the institutional ethical board approval (Ärztekammer Hamburg, Germany, Ref. no. 2754), between June 2007 and March 2009, pregnant patients referred for primary section were evaluated for study inclusion. Informed consent was obtained from all patients who were included in this study.

Patients

Exclusion criteria included the following: known allergy to cyanoacrylates, formaldehyde or dressing strips and patients suffering from impaired wound healing, dermatoses, keloid formation, adipositas, impaired blood clotting or diabetes. Sixty-one pregnant women who were to undergo primary section were included in this study. They were then randomly allocated for topical wound closure with either Prolene suture or Leukosan® SkinLink using a computer-generated randomised number system.

Before inclusion of the first patient, patient numbers were allocated randomly to one of the wound closure procedures by a validated Statistical Analysis System (SAS) (program components) program using the SAS function ‘ranuni’. The allocation was fixed electronically and as paper printout (random list). The random list was handed over to the investigator. Patients who were included in the study were assigned the next lower patient number. The wound closure was performed according to the procedure as given by the random list for the respective patient number.

Surgical technique and wound closure

For peri-operative antibiotic prophylaxis, we used gramaxine. The skin preparation included Cutasept® (BODE Chemie GmbH, Hamburg, Germany), Octenisept® (Schülke & Mayr GmbH, Norderstedt, Germany) and shaving...
of the pubic hair using a shaving machine. Normothermia was achieved by a forced-air convection warming system.

The surgical technique entailed the placement of deep sutures in the subcutaneous fat. When placing deep sutures, absorbable Vicryl 2-0 was used. The knot was buried. In addition, a subcuticular (subdermal) suture was placed by inserting the needle at the junction of the dermis and the subcutis. The needle curved upwards and exited in the papillary dermis. Atraumatic skin-handling technique with instruments such as skin hooks and small forceps was used. A cutting needle was the needle of choice.

For topical closure with Prolene, the running subcuticular was placed by taking horizontal bites through the papillary dermis on alternating sides of the wound. No suture marks were visible. The suture was looped through the subcuticular tissue by successively passing through the opposite sides of the wound. The knot was tied at the opposite end of the wound by knotting the long end of the suture material to the loop of the last pass that was placed. Topical wound closure with Leukosan® SkinLink was performed according to the manual.

Evaluation
Following surgery, wound closure performance as well as ease of application were assessed by the treating physician using a scale ranging from 1 to 10 (1 at one end representing an unsatisfying closure or difficult application and 10 at the opposite end representing very good closure or very easy application). Complications and unexpected events were documented by the treating physician. On the day of suture or Leukosan® SkinLink removal, the patient was asked to assess the wearing comfort and the pain on suture or Leukosan® SkinLink removal. In addition, the wounds were judged for cosmetic appearance by the physician using an approved 100-mm visual analogue scale (VAS) (17), which stated that 0 at one end represented a ‘poor scar’ and 100 at the opposite end represented a ‘perfect scar’. Patients returned to have their wounds photographed at 3, 6 and 12 months following caesarean section. Photographs were taken using a digital camera in a standardised manner as regards distance from the subject, lighting and exposure. At each visit, the cosmetic appearance was evaluated by the patient as well as the physician using the 100-mm VAS.

The photographs of the scars taken at the 3-, 6- and 12-months’ postoperative visits were then also presented to three examiners blinded to the method of wound closure who independently evaluated the photographs using the VAS.

Generally, patients who underwent caesarean section remained under inpatient surveillance for 7 days, covering the primary wound healing time; wound healing in this period of time is duly recorded. Enquiries about other potential infections after this period were made in the follow-up visits at 3, 6 and 12 months. As definition for surgical site infection (SSI), the guidelines of the ‚Nationale Referenzzentrum für Surveillance von nosokomialen Infektionen‘ by Robert-Koch-Institut were applied.

Statistical analysis
Non parametric statistics were only used for the comparison of the cosmetic results. Descriptive statistics was carried out for the following parameters indicated in Tables 1 and 2: demographic data (age, weight and height), wound closure performance, ease of application, wearing comfort and pain on removal. Statistical analysis comparing the two methods of wound closure was carried out with Wilcoxon test. Significance was ascribed to a P-value < 0.05.

RESULTS
A total number of 61 women were initially entered into the trial and by random allocation, 30 were treated with Prolene suture and 31 with Leukosan® SkinLink. Both groups were demographically similar (Table 1). Twelve patients were lost to follow-ups throughout the time because of lack of contact. Of the 49 patients who completed the study, 23 were in the Prolene suture and 26 in the Leukosan® SkinLink arm. All patients in the study had their caesarean section performed by experienced gynaecologists. Application of Leukosan® SkinLink was performed as described in the user’s manual.

On the day of surgery, assessment of wound closure performance by the surgeons resulted
SkinLink was also not satisfying to the method of wound closure. The blinded examiners evaluated digital photographs taken during the follow-up visits independently. No significant difference between the two closure technique was found at any time point or for any group assessing the cosmetic outcome (patient’s assessment at 3, 6 and 12 months post surgery). It was evaluated by the physicians, the patients as well as a group of three gynaecologists blinded to the method of wound closure. The blinded examiners evaluated digital photographs taken during the follow-up visits independently. No significant difference between the two closure technique was found at any time point or for any group assessing the cosmetic outcome (patient’s assessment at 3, 6 and 12 months post surgery).

As regards complications, no difference was found between Leukosan® SkinLink and Prolene closure. One single case of dehiscence was reported for Leukosan® SkinLink. No allergic reaction or infection was reported.

The cosmetic appearance of the scar was evaluated at 3, 6 and 12 months post surgery. It was evaluated by the physicians, the patients as well as a group of three gynaecologists blinded to the method of wound closure. The blinded examiners evaluated digital photographs taken during the follow-up visits independently. No significant difference between the two closure technique was found at any time point or for any group assessing the cosmetic outcome (patient’s assessment at 3, 6 and 12 months post surgery: \( P = 0.08, P = 0.42 \) and \( P = 0.32; \) physician’s assessment: \( P = 0.71, P = 0.72 \) and \( P = 0.33; \) assessment blinded observers: \( P = 0.64, P = 0.26 \) and \( P = 0.07; \) Figure 3A–C). Leukosan® SkinLink scored equally high as the standard method (Figure 3A–C). The cosmetic appearance of the scars was comparable for both methods of wound closure (Figure 4A–D).

### Table 1: Demographic patient data

<table>
<thead>
<tr>
<th>Patient data</th>
<th>Treatment</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Prolene suture</td>
<td>32.1</td>
<td>4.7</td>
<td>33.0</td>
<td>24.0</td>
<td>42.0</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Leukosan® SkinLink</td>
<td>32.2</td>
<td>5.2</td>
<td>33.0</td>
<td>18.0</td>
<td>39.0</td>
<td>31</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>Prolene suture</td>
<td>71.7</td>
<td>11.4</td>
<td>71.5</td>
<td>50.0</td>
<td>93.0</td>
<td>30</td>
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<tr>
<td></td>
<td>Leukosan® SkinLink</td>
<td>70.5</td>
<td>8.9</td>
<td>70.0</td>
<td>52.0</td>
<td>88.0</td>
<td>31</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>Prolene suture</td>
<td>171.1</td>
<td>4.1</td>
<td>171.0</td>
<td>163.0</td>
<td>178.0</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Leukosan® SkinLink</td>
<td>171.9</td>
<td>5.1</td>
<td>170.0</td>
<td>164.0</td>
<td>181.0</td>
<td>31</td>
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</tbody>
</table>

### Table 2: Wound closure performance and ease of application as assessed by the surgeon at the day of surgery

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
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</thead>
<tbody>
<tr>
<td>Wound closure performance</td>
<td>Prolene suture</td>
<td>9.0</td>
<td>0.9</td>
<td>9.0</td>
<td>7.0</td>
<td>10.0</td>
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<tr>
<td></td>
<td>Leukosan® SkinLink</td>
<td>8.9</td>
<td>1.3</td>
<td>9.0</td>
<td>5.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Ease of application</td>
<td>Prolene suture</td>
<td>9.2</td>
<td>0.7</td>
<td>9.0</td>
<td>8.0</td>
<td>10.0</td>
</tr>
<tr>
<td></td>
<td>Leukosan® SkinLink</td>
<td>8.7</td>
<td>1.3</td>
<td>9.0</td>
<td>5.0</td>
<td>10.0</td>
</tr>
</tbody>
</table>

**Figure 1.** Wearing comfort as assessed by the patients before discharge from the hospital.

**Figure 2.** Pain experienced by the patients on removing either Leukosan® SkinLink or Prolene.
New wound closure device SkinLink

Figure 3. Assessment of the cosmetic appearance of the wound closed with either Leukosan® SkinLink or Prolene. Evaluation of cosmetic results by the surgeon (A), patients (B) and blinded examiners (C) at 3, 6 and 12 months post surgery.

DISCUSSION

Non invasive wound closure devices such as adhesive tapes and topical adhesives are ideal for closure of simple, low-tension lacerations (1). Regarding the use of the non invasive wound closure devices for more challenging surgically inflicted wounds such as higher tension or longer wounds, data are limited. For many surgeries, the ideal method of closing the skin is not established and surgeons appear to choose a technique based on their individual experiences and preferences. New devices for wound closure entering the market may represent effective alternatives to the traditional non invasive wound closure devices.

This study aimed to investigate whether one of these new wound closure devices, Leukosan® SkinLink, is a reliable alternative for wound closure following surgery. As target wounds, wounds following primary section were chosen. While caesarean section is a common procedure performed on women worldwide, the ideal method of closing the skin following a Pfannenstiel incision remains controversial (13,16). A great variety of materials and techniques are used for skin closure and there is still a need to identify which provide the best outcomes for women (15,16). In addition, wounds following caesarean section are challenging as it is a surgery during which several layers of the mother’s abdomen need to be cut and need to be closed again.

The results of this study show that Leukosan® SkinLink was comparable with the invasive method of suturing in all aspects investigated. Similar to suturing, which is a technical skill, application of Leukosan® SkinLink also requires some instruction and practice. The surgeons in this study had proficiency in both methods of wound closure and their assessment showed high satisfaction with both methods regarding ease of application and wound closure performance.

In this study, infection was reported. Generally, international published SSI rates vary from 2.9% to 17.9% for caesarean section, depending on body mass index (BMI), age,
blood loss, method of wound closure and emergency procedures (18) As patients with high risk criteria and emergency cases were excluded, the low incidence is within range (of the limited number of cases).

Wearing comfort and pain on removal are important to the patient. Invasive methods such as suturing and stapling are known to produce anxiety because of the need for removal and stapling in particular has been reported to cause postoperative discomfort (9,13). In this study, patient assessment showed no difference between Prolene suture and Leukosan® SkinLink for pain on removal and wearing comfort. Although higher pain scores could be expected for Prolene suture, it is likely that the anxiety in relation to suture removal is exaggerated at least in relation to adult patients. In regard to wearing comfort, the study showed that both methods of wound closure are valid options. No allergic reaction or infection was reported. In addition, Leukosan® SkinLink is a medical device for which testing has been conducted in accordance with biocompatibility tests (ISO 10993). Testing certifies that Leukosan® SkinLink is not cytotoxic, not an irritant and not a sensitizer.

The benefits of Leukosan® SkinLink are atraumatic wound closure (no local anaesthesia required, no additional punctures to wound edges), no additional materials required (no surgical instruments and no resterilisation), doctor can close wound without the help of nurse/assistant and there is a quick learning curve. No repeat visit of patient to remove stitches is required and there is a high patient comfort.

We put no attention to comparative costs as they depend on the commercial politics of BSN medical, (data on file at BSN medical). However, it can be claimed that the benefits of this atraumatic device find their financial expression, for example, no cost for local anaesthesia, no resterilisation of additional instruments, no additional nurse/assistant and no repeat visit of patient to remove stitches, which gain more weight in ambulatory surgery.

In addition, the new method is time-saving for medical team: compared with continuous sutures and separate stitches, SkinLink is shortening wound closure time. To test the time efficiency of the device ‘SkinLink’, the developers conducted tests on pig skin, data on file at BSN medical. Incisions of 4–8 cm were made on pig skin. These were then treated in parallel, using separate stitches, continuous sutures and using SkinLink. The results indicate that using SkinLink is ~45–65% faster than using sutures on identical wound sites.

Cosmetic acceptability of a scar is an important outcome of wound repair for the patient and surgeon and caesarean section in particular represents a surgery following which the appearance of the scar is highly important to women. Therefore, focus was laid to assess in detail the cosmetic outcome as achieved by the two closure methods. In this study, the cosmetic appearance of the scar was assessed by the surgeon, the patient as well as by three gynaecologists blinded to the method of wound closure in order to minimise bias. For scar assessment, follow-up visits at 3, 6 and 12 months post surgery was chosen as shorter follow-up periods are often discussed to limit study validity (2,16). At any follow-up, Leukosan® SkinLink provided equally high cosmetic results to suturing as assessed by the surgeon, patient and blinded observers.

The study design incorporates the following limitations: the statistical power of the study is limited by sample size of 61 patients and therefore has the character of a pilot study. However, as wounds inflicted by caesarean section represent a quite homogenous and standardised type of wound and the women patients also represent a rather homogenous study group (see demographic data) the outcome of the study is still valid despite small sample size. In addition, restrictions from using blinded examiners include substituting live patient follow-ups for digital photographs. However, photographs were taken in a standardised manner and photograph evaluation was supported by the live assessment by the patient itself and the physician. In turn, the potentially subjective assessment by patient and physician who were not blind to the technique used was confirmed by the blind observers enabling overall a reliable evaluation.

CONCLUSION

Overall, this study clearly shows that the new wound closure device Leukosan® SkinLink represents a valid alternative to traditional suturing for surgically inflicted incisions. Leukosan® SkinLink was comparable with the invasive method of suturing in all aspects
New wound closure device SkinLink investigated. The cosmetic outcomes as well as wound closure performance were comparable for both techniques, leaving patients and physicians with an additional non invasive option for wound closure in the operating room.

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