Novel Adhesive Skin Closures Improve Wound Healing Following Saphenous Vein Harvesting

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ABSTRACT ***Background And Aims:*** **New techniques for skin closure that minimize tissue inflammation and avoid foreign material may decrease morbidity following saphenous vein harvesting. The 3M™ Steri-Strip™ S surgical skin closure system is a new, noninvasive method of wound closure, which consists of polymeric components coated with a pressure-sensitive skin adhesive. This prospective, randomized study was undertaken to compare the results of the noninvasive skin closure method to the traditional subcuticular skin closure technique on saphenous vein harvest sites.** ***Methods:*** **Twenty-six patients undergoing coronary artery bypass surgery with saphenous vein harvesting were prospectively randomized to skin closure using 3M Steri-Strip S Surgical Skin Closure System or subcuticular suture closure with a skin sealant. Wounds were evaluated on postoperative days 7 and 2l for erythema, edema, pain, cosmesis, and the time taken to close the incision.** ***Results:*** **Skin closure with 3M Steri-Strip S was significantly faster, resulted in significantly less erythema, edema, and significantly improved cosmesis.** ***Conclusions:*** **3M Steri-Strip S Skin Closure improves wound healing of saphenous vein sites, compared to traditional subcuticular skin closure techniques.** doi: 10.1111/j.1540-8191.2007.00563.x *(J Card Surg 2008;23:152-155)*

Although endoscopic techniques have reduced complications associated with saphenous vein harvesting during coronary artery bypass graft (CABG) surgery, pain, erythema, and cellulitis continue to result in significant postoperative morbidity. This contributes to longer postoperative recovery and increased medical costs. The techniques used to close the skin can contribute to this increased morbidity. Several studies have shown that intracutaneous suture techniques promote a localized inflammatory response which contributes to erythema, cellulitis, and superficial wound infections.[1,2] Skin closure techniques that avoid foreign material may minimize the inflammatory response that compromises wound healing.

The 3M™ Steri-Strip™ S Surgical Skin Closure is a new, noninvasive method of wound closure consisting of polyurethane pads and polymeric straps coated with a nonlatex pressure-sensitive, hypoallergenic skin adhesive. This study was, therefore, undertaken to determine whether the noninvasive Steri-Strip S Surgical Skin Closure would improve wound healing at saphenous vein harvest sites compared to the traditional skin closure using an absorbable running intracutaneous suture technique combined with a tissue sealant.

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Conflict of Interest: The source of all funds used to perform this study was from 3M Health Care, Minneapolis, MN. The Steri-Strip S Surgical Skin Closures used in this study were also donated by 3M Health Care. The authors had full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

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MATERIALS AND METHODS

The Steri-Strip S Surgical Skin Closure consists of strips of breathable, polyurethane pads and polymeric straps coated with nonlatex, pressure-sensitive, hypoallergenic skin adhesives. It comes in sizes from 10 to 100 mm and is color-coded and numbered to indicate the liner removal sequence. The adhesive film is comprised of two independent transparent parts; an adhesive pad and multiple interlocking filament straps attached to pulling tabs, which allow for more precise wound edge approximation. The adhesive pads are anchored to both sides of the wound and serve as a foundation for the filament straps (Fig. 1). The straps are then laid on top of the transparent pads and the wound edges are properly aligned (Figs. 2 and 3). The combination of adhesive pads and filament straps maximizes adhesion and allows for easier skin edge approximation. The pads and straps are left in place for 7 to 10 days, after which time it naturally sloughs off the skin. Since the pads and straps are transparent, the clinician can easily monitor the wound for erythema, edema, or signs of infection.

Twenty-six consecutive patients undergoing CABG surgery were enrolled in this prospective, randomized trial. Approval was obtained from the Boston

Figure 1. *Anchoring adhesive pads. Note: Clear adhesive pads are anchored to both sides of the wound and serve as a foundation for the filament straps.*

University Medical Center Institutional Review Board (Protocol #H-23711) and an informed consent was obtained from each patient. The inclusion criteria included all CABG patients undergoing harvest of a saphenous vein. Patients were excluded if they had diabetes mellitus, were known keloid formers, had allergies to skin adhesives, had an immunosuppressive disease, or required immunosuppressive medications. Patients who required perioperative anticoagulation or systemic or topical steroids were also excluded.

The night prior to surgery, patients received a phisohex scrub or shower, and received 1 gram of Cephazolin 30 minutes prior to the surgical incision and subsequently 1 gram every 8 hours for 48 hours following surgery. Randomization was performed using a computer-generated block schedule. Envelopes detailing the technique for closure of each saphenous vein harvest site were made available for each patient prior to skin closure. In the endoscopic techniques, a 3 to 4 cm incision was made in the distal thigh. Occasionally, a longitudinal incision was made in the leg to retrieve additional segments of vein. For the open technique, an incision was made parallel to the course of the saphenous vein to remove the desired length of conduit. Incisions were avoided across joint lines.

Figure 2. *Aligning the wound edges. Note: The filament straps are laid on top of the adhesive pads and the wound edges are aligned by pressing in the filament straps.*

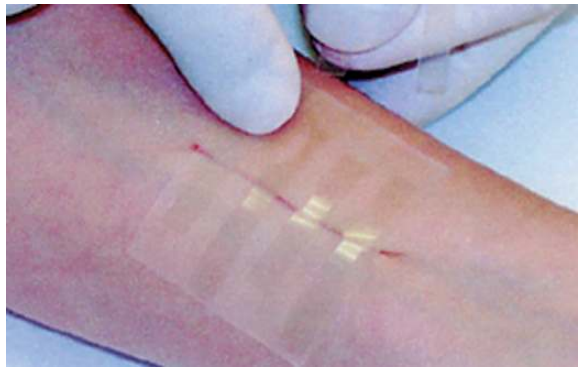

Figure 3. *Final skin approximation. Note: The wound edges are now approximated.*

All incisions had the subcutaneous layer closed with a 3-0 polyglactin (Vicryl, Ethicon, Inc., Somerville, NJ) suture. In one group of patients, the Steri-Strip S Surgical Skin Closure was used to close the skin using the technique described above (Figs. 1–3). All the investigators had undergone standardized training in the application of this device. The suture group had the skin closed using a running 4–0 polyglactin suture (Vicryl, Ethicon, Inc.) and a tissue adhesive, 2-octylcyanoacrylate (Dermabond, Ethicon, Inc.). All saphenous vein harvest sites were closed after complete reversal of heparin with protoamine.

Postoperative wound inspections were performed daily. Parameters of wound healing were measured on postoperative day 7 (or earlier if the patient was discharged) and on postoperative day 21 by nurse clinicians (CF, JT). The primary endpoints included: The Incidence of Infection (diagnosed as the presence of a positive wound culture); ERYTHEMA (0 = none; 1 = barely perceptible [minimal, faint]; 2 = mild [pink, covering most, but not all of the incision]; 3 = moderate [pink-red, covering the entire incision]; 4 = marked [bright red]; 5 = severe [deep red]); EDEMA (0 = none; 1 = slight [barely perceptible]; 2 = mild [slight raising at the edge of the wound]; 3 = moderate [raised 1 mm from the edge of the wound]; 4 = severe [raised greater than 1 mm and beyond the edge of the incision]); Pain (0 = none; 1 = barely noticeable; 2 = mild [slight irritation]; 3 = moderate; 4 = severe); Patient Satisfaction—Cosmesis (0 = excellent; 1 = very satisfied; 2 = neutral; 3 = disappointed; 4 = unacceptable); Incidence of Wound Separation. Secondary endpoints included The Need for Extra Visits for Wound Issues, and The Time Taken to Close the Incision.

Description data are shown as counts for categorical variables and mean plus/minus the standard deviation for continuous variables. Exact nonparametric Wilcoxon rank sum tests were used to test for statistical significance between the groups. Estimates of the central tendency for each group are presented in terms of medians with dispersion stated in terms of the minimum, 25th percentile, 75th percentile, and maximum. A two-sided statistical significance criterion of 0.05 was used for these analyses.

TABLE 1
Patient Profiles and Surgical Outcomes

	3M TM Steri-Strip	Suture
N	13	13
Male/female	13/0	12/1
Endoscopic harvest	12	12
Open harvest	1	1
Hospital length of stay (days)	8.4 ± 2.5	8.4 ± 1.8
30-day mortality	0	0
Myocardial infarction	0	0
Lost to follow-up	0	0

RESULTS

The patient profiles and surgical outcomes are summarized in Table 1. There were no 30-day operative mortalities or myocardial infarctions and no patient was lost to follow-up. One patient in each group underwent an open saphenous vein harvest.

None of the patients in either group developed a wound infection, or required extra postoperative visits for a wound problem. There were no wound dehiscences in either group. All Steri-Strip S Skin Closures had sloughed off the skin at the time of the 21-day postoperative evaluation.

The primary outcomes of pain, cosmesis, edema, and erythema are summarized in Table 2. Saphenous vein harvest sites closed using the Steri-Strip S Surgical Skin Closure had significantly less edema and erythema at 7 and 21 days postoperative, and were less likely to complain of pain early after surgery. Patients receiving this technique were also more likely to be satisfied with the cosmetic appearance of the wound compared to the suture technique. The Steri-Strip S Surgical Skin Closure resulted in a faster closure (6.45 ± 1.38 min vs. 9.00 ± 4.03 min; $p = 0.02$), then the suture technique.

CONCLUSIONS

Although skin closure with nonabsorbable suture is an established technique, it takes longer and increases local tissue reaction, which may impair and prolong wound healing. Karabay et al. compared the outcomes of intracutaneous versus transcutaneous suture techniques in 100 patients undergoing open-heart surgery.[1] Intracutaneous closures were performed with absorbable 4.0 dexon suture (United States Surgical Corp., Norwalk, CT) and 4.0 prolene nonabsorbable suture (Ethicon Inc.) was used for the transcutaneous technique. Following 6 weeks, the incidence of superficial wound infection was 2% for the transcutaneous suture versus 16% for the intracutaneous technique ($p = 0.016$). There were no deep infections. Although diabetes mellitus was an independent risk factor for the development of wound infections in all patients, the incidence of wound infections was higher in diabetic patients in the intracutaneous group compared to the transcutaneous technique ($p = 0.007$). Risnes et al. compared the incidence of wound infections in 300 open-heart surgery patients using either a 3.0 Monocryl reabsorbable nonfilament suture or a transcutaneous nonreabsorbable nonfilament suture, polyamid (Ethilone, 3.0; Ethicon, Inc.). The rate of superficial infections was significantly lower in the transcutaneous group (2.3% vs. 6.7%; $p = 0.01$) 6 weeks following surgery, although there was no difference in the rate of deep infections between the groups. These studies suggest that the type of wound closure plays an important role in wound healing. Intracutaneous suture techniques incite a local inflammatory response

TABLE 2
Primary Outcome—Pain, Cosmesis, Edema, and Erythema

	Median (Minimum, 25th Percentile, 75th Percentile, Maximum)		
	3M TM Steri-Strip N = 13	Suture N = 13	p Value*
Pain at 7 days	1 (0, 0, 1, 2)	1.5 (0, 1, 2, 2)	0.07
Pain at 21 days	0 (0, 0, 0, 1)	0 (0, 0, 1, 2)	0.29
Cosmesis at 7 days	1 (0, 0.5, 1, 2)	1.5 (1, 1, 2, 3)	0.008
Cosmesis at 21 days	0.5 (0, 0, 1, 1)	1 (0, 1, 1, 3)	0.02
Edema at 7 days	1 (0, 0, 1.5, 3)	2 (1, 1, 3, 4)	0.006
Edema at 21 days	0 (0, 0, 1, 2)	1 (0, 1, 2, 3)	0.02
Erythema at 7 days	1 (0, 0, 1, 3)	2.5 (1, 2, 3, 3)	0.0004
Erythema at 21 days	0 (0, 0, 1, 2)	2 (0, 1, 2, 4)	0.0004
Time-to-Closure (min)	6 (4.5, 6, 7, 10)	8.5 (4,7, 10, 20)	0.02

*Exact p Value from Wilcoxon rank sum test.

and may promote the passage of superficial bacteria such as staphylococous epidermidis just beneath the skin.[3] In transcutaneous suture techniques, the nonabsorbable suture is usually removed after 7 days, thus limiting the exposure of a foreign material in the skin. In contrast, nonabsorbable sutures remain in place for longer periods allowing for a greater opportunity to develop an inflammatory response or an opportunistic site for bacterial colonization.[4]

Adhesive skin closure devices eliminate foreign bodies in the intracutaneous layer, thus decreasing the incidence of bacterial colonization. However, they can result in wound dehiscence and have been associated with allergic reaction. It can be difficult to assess the correct tension needed to bring wound edges together, especially near joints and in larger incisions. The Steri-Strip S Surgical Skin Closure has several advantages compared to the other types of skin closures. The polyurethane and polymeric films are coated with a nonlatex, pressure-sensitive, hypoallergenic skin adhesive, thus decreasing the chance for skin sensitivity reactions. The device allows the surgeon to more accurately adjust tension and wound alignment by utilizing a series of interlacing filamentous straps, thus decreasing the chance for wound dehiscence. Since the filament straps are anchored to pads on either side of the incision, there is less tension along the wound edges. This leads to less edema, erythema, and a more satisfactory cosmetic result. The Steri-Strip S Surgical Skin Closure is faster then the traditional subcuticular closure and minimizes the chance for needle sticks to the clinician. The adhesive pads and filament straps are transparent, making it easier to observe the wounds for sign of infection. Application and removal of the pads and straps is painless.

There are several limitations to our study. The small sample size and exclusion of patients with diabetes mellitus did not allow for detection of differences in the incidence of wound infections between the groups. The short follow-up period limits the assessment of long-term scar formation. Although observers were blinded to the treatment groups on day 21, the presence of some strips on day 7 could potentially have lead to an early bias in favor of the Steri-Strip Closure technique. However, the criteria for inflammation were so exact that this was extremely unlikely to have occurred.

Despite these limitations, this study has demonstrated several potential benefits of the Steri-Strip S Surgical Skin Closure for closure of saphenous vein harvest sites. Steri-Strip S Surgical Skin Closure decreases the potential for wound dehiscence and its transparency allows for better monitoring of postoperative wounds. It is faster than subcuticular skin suture closure and results in less edema and erythema and a better cosmetic result. Studies are now underway to determine whether the Steri-Strip S Surgical Skin Closure will also prove to be beneficial for closure of larger sternotomy incisions in a larger cohort of patients, including those with diabetes mellitus, and corticosteroids, who are more susceptible to problems with wound healing.

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