Comparing the Tolerability of a Novel Wound Closure Device Using a Porcine Wound Model

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Objective: To compare the tolerability and mechanical tensile strength of acute skin wounds closed with nylon suture plus a novel suture bridge device (SBD) with acute skin wounds closed with nylon suture in a porcine model.

Approach: Four Yucatan pigs each received 12 4.5 cm full-thickness incisions that were closed with 1 of 4 options: Suture bridge with nylon, suture bridge with nylon and subdermal polyglactin, nylon simple interrupted, and nylon simple interrupted with subdermal polyglactin. Epithelial reaction, inflammation, and scarring were examined histologically at days 10 and 42. Wound strength was examined mechanically at days 10 and 42 on *ex vivo* wounds from euthanized pigs.

Results: Histopathology in the suture entry/exit planes showed greater dermal inflammation with a simple interrupted nylon suture retained for 42 days compared with the SBD retained for 42 days ($p < 0.03$). While tensile wound strength in the device and suture groups were similar at day 10, wounds closed with the devices were nearly 8 times stronger at day 42 compared with day 10 ($p < 0.001$).

Innovation: A novel SBD optimized for cutaneous wound closure that protects the skin surface from suture strands, forms a protective bridge over the healing wound edges, and knotlessly clamps sutures.

Conclusion: This study suggests that the use of a SBD increases the tolerability of nylon sutures in porcine acute skin wound closures allowing for prolonged mechanical support of the wound. For slow healing wounds, this may prevent skin wound disruption, such as edge necrosis and dehiscence.

Keywords: wound closure, acute wound, surgical wound, device, suture bridge

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INTRODUCTION

CUTANEOUS WOUND CLOSURE is the most common medical procedure in the United States, and of the 50 million annual inpatient surgeries in the United States, ~20 million require repair of the skin.¹ Nonabsorbable sutures made of nylon or polypropylene are most commonly used to close

the cutaneous level of wounds.² Sutures are considered better than adhesives and sealants for preventing wound dehiscence in some studies,³ and may pose less infection risk than nonabsorbable staples.⁴ However, a large study recently showed that use of an acrylate adhesive over dermal absorbable sutures may

reduce wound infection and dehiscence compared with absorbable sutures alone.⁵ Nonabsorbable suture materials and methods have not been optimized to overcome challenges that can lead to cutaneous disruption of the surgically closed incision, including pressure necrosis and surgical wound dehiscence (SWD).

SWD is the splitting open of a previously closed surgical incision site. Annually in the United States, SWD is estimated to occur in ~3% of cesarean sections⁶ and hip arthroplasty⁴; and in 9% of saphenous vein graft sites,⁷ 10% of breast reduction surgeries,⁸ and 30% of limb amputations.⁹ While SWD can be superficial or deep, few studies distinguish between the two. SWD is costly, with estimates ranging from \$1,200¹⁰ for minor wound dehiscence cared for in the community in Australia, and between \$14,000 and \$28,000 for inpatient minor and major wound dehiscence in the United States.¹¹ In the United States, postoperative abdominopelvic wound dehiscence has been adopted as a surrogate hospital safety and quality indicator for adults (PSI 14) and pediatrics (PDI 11) because it impacts patient morbidity, length of hospital stay, and readmission rates.¹²

The purpose of closing a wound is to provide external support until the wound has regained adequate inherent strength. If supports are removed or fail before a wound gains sufficient inherent strength, then the wound reopens, creating a SWD. Depending on the bodily location of the closed incision, common practice is to remove nonabsorbable sutures between 5 and 14 days to prevent skin overgrowth of the sutures.¹³ However, by 10 days skin wound strength is only 5% of that of uninjured skin,^{14,15} and even less for slow-healing wounds,¹⁶ leaving the wound weak and vulnerable to reopening. Additionally, commonly used absorbable sutures placed in the deep dermis fail to provide wound strength at day 10.¹⁷ Thus, optimal mechanical support of wounds, especially slow-healing wounds, using traditional suturing devices and methods is limited.

For acute wounds to heal, the four phases of wound healing must occur in the right sequence, at the right time, for the right duration, and at the right intensity. Slow-healing wounds are out of step with this sequence, often getting stuck in the inflammatory phase.¹⁶ Slow-healing wounds are a result of a host of risk factors, including age over 65, anemia, diabetes, diagnosis of cancer, chronic obstructive pulmonary disease, hypertension, malnutrition, obesity, and vascular disease, and use of steroids or tobacco. Wounds under high tension, or of greater length or depth, that are

infected or have had prior radiation are also slower to heal.^{18,19}

CLINICAL PROBLEM ADDRESSED

Surgical wounds closed by primary intention that are at risk of delayed healing might benefit from prolonged mechanical support by nonabsorbable suture. However, using current suturing methods, nonabsorbable suture can become ingrown and irritate the wound before sufficient inherent strength of the wound is achieved.²⁰ As well, suture strands lying on top of the skin can apply too much pressure to the healing wound edges causing pressure necrosis, especially for wounds closed under tension or for wounds that experience significant postoperative edema. Pressure necrosis is thought to be a critical factor in the development of wound dehiscence.²¹ The purpose of this study was to compare the tolerability of surgical skin wounds closed with nylon suture plus a novel suture bridge device (SBD), in the experimental group, and with surgical skin wounds closed with nylon suture only, in the control group, in a porcine model for up to 42 days. Given that most wound strength acquisition occurs between 2 and 6 weeks postoperatively,¹⁴ we also examined how much stronger the wound would be at 6 weeks than 10 days using the SBD and document any adverse effects of the SBD on the skin. Suture bridges have been successfully and extensively used in laparotomy closures, where they encircle skin, muscle, and fascia in a mass closure,²² and in attempts to close large cutaneous defects over time.²³ However, there has been little use of such devices to prolong the effective lifespan of nonabsorbable sutures in the skin. Current devices are large and bulky, making them less appropriate for most wound closures. The SBD tested in this study has been optimized for skin wound closures. The results of this study suggest that the use of a SBD optimized for the skin increases the tolerability of nylon sutures in porcine surgical skin wound closures. For slow-healing wounds, prolonged mechanical support of the wound may prevent SWD.

MATERIALS AND METHODS

The SBD tested in this study is a novel suture bridge that interfaces between the skin and the suture, lifting the suture away from the skin, thus preventing it from compressing the healing wound edges. In contrast, simple interrupted sutures (SIS) have an extracutaneous portion of suture that presses on the wound edge. The device used in this study has two skin contact portions connected

by an elevated nonskin contact traversing member that is positioned over the incision (Fig. 1). The elevated traversing member lifts the suture away from the wound edge and forms a void into which wound eversion can protrude without pressure from the device. The SBD has a living hinge with an upper arm that clamps down upon a lower arm and the suture strands (Fig. 1). The latch system at the ends of the arms locks the sutures in place by utilizing an interference fit between the two arms. The surgeon has the option of relying solely on the clamping mechanism of the SBD or tying a knot before engaging the clamp. An aluminum mold was manufactured (Proto Labs, Maple Plain, MN) and used for injection molding SBDs using random copolymer polypropylene. The devices used for this study were sterilized with ethylene oxide for 1 week before the study.

Yucatan white miniature hairless pigs were chosen for this study due to their similarity to human skin.²⁴ Four, 3-month-old, ~15 kg, female Yucatan pigs were sourced from Sinclair Bio Resources, LLC, and housed singly at Oregon State University's Laboratory Animal Research Facility for the duration of the study. The experimental design and methods were approved by the Oregon State University Institutional Animal Care and Use Committee.

Each pig was premedicated with Xylazine (30 mg intramuscular) and induced with ketamine

(100 mg intramuscular). After endotracheal intubation they were maintained on isoflurane 2% in oxygen. After sterile preparation, twelve 4.5 cm full-thickness cutaneous incisions were performed on the dorsum of each pig, 8 cm apart (Fig. 2), each with a new sterile scalpel blade. The 12 incisions were randomly allocated to be closed in four ways: (1) SBDs secured with nylon, (2) SBDs secured with nylon and polyglactin subdermal sutures, (3) Simple interrupted cutaneous sutures using nylon, and (4) Simple interrupted cutaneous sutures using nylon and polyglactin subdermal sutures. Surgical wounds closed with devices and secured with nylon (Vicryl™; Ethicon, Somerville, NJ) each received four SBDs placed 10 mm apart. This resulted in suture exit and entry wounds every 5 mm along the wound. Surgical wounds closed with SIS each received eight SIS using 3-0 nylon (Vicryl; Ethicon) and spaced 5 mm, consistent with routine clinical practice.²⁵ Thus, there was equal number and spacing of suture entry and exit wounds in all closures. The incisions closed with subdermal 3-0 polyglactin sutures (Vicryl; Ethicon) had 4 SIS with buried knots, placed 10 mm apart to mimic clinical practice. The pigs were given buprenorphine (0.45 mg) intramuscularly and carprofen (66 mg) subcutaneously at the end of the procedure for analgesia. A nonadhesive dressing (Tegaderm™, 3M, St./Paul, Minneapolis) was applied over the wounds postoperatively and kept in place for the first 3 days of healing. Incisions were monitored for the absence/presence of device and excessive inflammation or dehiscence.

In the two day 10 pigs, all cutaneous nylon sutures and suture bridges were removed immediately before testing. The subdermal polyglactin (Vicryl; Ethicon) sutures were left intact in all

Figure 1. SBD in an open configuration (A) and in a closed configuration clamping on suture (B). SBD, suture bridge device.

Figure 2. SBD applied to a porcine skin incision model showing wound eversion into the recess without compression of wound edge skin. To see this illustration in color, the reader is referred to the web version of this article at www.liebertpub.com/wound

incisions. In the day 42 pigs, all wounds destined for mechanical testing had cutaneous interrupted sutures removed at day 10 to mimic clinical practice. The SBD device remained on the incisions for day 42 pigs and was removed only before mechanical testing. In the day 42 pigs, wounds destined for histology testing, cutaneous SIS were removed from one half of the wound at day 10 and half were retained for the entire 42 days. All SBDs were retained for the entire 42 days and removed before testing.

Two pigs were humanely euthanized at day 10, and two pigs were humanely euthanized at day 42, by a sedative of telazol-ketamine-xylazine (0.025 mL/kg) intramuscularly, followed by an intravenous dose of pentobarbital (0.5 mg/kg). All remaining SBDs and sutures were removed before mechanical testing or histopathology processing. Incisions for histopathology were removed *en bloc* and immersed in 10% neutral buffered formalin at a ratio of 1:10. Incisions used for mechanical testing were removed *en bloc*. Before mechanical testing, all sutures and SBDs were removed. The tensile specimens excluded the peripheral 1–2 mm of each end of the wound to ensure that no intact skin was tested. Up to 8 mm of nonload-bearing subcutaneous fat was left in place so as to not damage the skin. Approximately 4 cm of skin on each side of the incision was retained to allow gripping of the skin in tensile testing grips. Specimens were wrapped in saline-soaked gauze until mechanical testing.

After complete formalin fixation, all skin samples were sectioned perpendicular to the incision. Sections were taken directly under the skin contact portions of the SBDs, halfway between the suture entry/exit planes, and through suture entry/exit planes for both the experimental and control groups. Sections were processed for routine histopathology, sectioned at 4 μ m, and stained with Hematoxylin and Eosin.

Slides were evaluated by a single board-certified veterinary anatomic pathologist using an Olympus BX46 microscope. Measurements were taken with an Olympus SC100 Digital Camera with CellSens entry. Slides were marked over points of device contact, 6 mm either side of incision. Skin, peripheral to the device on the same section, was used as an internal control and is hereafter referred to as normal skin.

Skin sections were evaluated for morphological changes, including width of the stratum corneum (indicator of hyperkeratosis), presence of parakeratosis (abnormal keratinization), width of the epidermis excluding the stratum corneum (measure

of epidermal hyperplasia), frequency of keratinocyte death, number of intraepithelial lymphocytes (cell mediated inflammation), width of dermal scar, and inflammation.

For hyperkeratosis, the width of the stratum corneum was measured at the incision, beneath points of device contact, and in normal skin. Measurements were an average of two measurement points. Parakeratotic hyperkeratosis was defined by retained nuclei in the stratum corneum and was defined as absent or present within two 10 $\times$ fields that were measured 6 mm lateral to the incision (beneath points of device contact). For epidermal hyperplasia, averaged epidermal width (excluding stratum corneum) and number of mitotic figures in two 10 $\times$ fields were measured at the incision, 6 mm lateral to the incision, and in normal skin. Keratinocyte death was defined as hypereosinophilic and shrunken keratinocytes, measuring 6 mm lateral to the incision and in normal skin (a length of 12 mm for each site). The number of intraepithelial lymphocytes was counted in a total of two, 20 $\times$ fields from either side of the incision, and in normal skin. The width of the scar was measured at the epidermal junction and for maximal width. Maximal dermal and epidermal inflammation was assigned a semiquantitative score over the entire area of interest, with 0 = none, 1 = mild, 2 = moderate, and 3 = severe, and based on the density of leukocytes (neutrophils, macrophages, lymphocytes, plasma cells, and eosinophils). Corneal exudate was defined as either absent or present (degenerate leukocytes within or above the stratum corneum). This was measured at the incision and beneath points of device contact.

Mechanical testing was performed for both 10- and 42-day wounds within 6 h of tissue harvesting. For each group ($n=4$), tensile wound strength testing was performed using a computer-controlled servo-hydraulic Instron 8501 universal testing machine with a calibrated 5 kN capacity load cell (Instron Corporation, Norwood, MA). A 4 cm by 8 cm rectangular piece of skin was harvested and did not include any intact skin at the edges of the incision. Similar to other studies,²⁶ samples were gripped using serrated rectangular (50 mm wide, 25 mm tall)-faced grips. Load was applied perpendicular to the wound using a constant displacement rate of 40 mm per minute. Force (N) was normalized to the length (mm) of the incision and not to the cross-sectional areas due to nonload-bearing subcutaneous fat. Temperature and relative humidity were maintained at 24°C $\pm$ 1°C and 32% $\pm$ 2%, respectively. The lengths of the sample wounds were measured and the wound breaking

forces were normalized by wound length to calculate a breaking strength with units of Newtons per millimeter (N/mm).

For histopathology data, normality was assessed using the Shapiro–Wilk test. For two-level ordinal and continuous variables, a two-sample independent *t*-test was performed on normally distributed parameters and the Mann–Whitney U test on non-normal parameters. The Kruskal–Wallis H test was performed on non-normal ordinal variables of greater than two levels. Chi-square tests with Fisher's exact adjustment were used for categorical parameters. The alpha level was set at 0.05 for all analyses, and two-tailed tests of significance are reported. All analyses of histopathology data were performed in STATA version 13.1 (StataCorp. 2014; College Station, TX). Statistical analysis of mechanical tensile strength data was conducted using unpaired, two-tailed *t*-test. Analysis of strength data was performed using Statgraphics Centurion XVII software (Statpoint Technologies, Inc. Warrenton, VA) with $p < 0.05$ considered statistically significant.

RESULTS

All pigs tolerated the device, with no adverse reactions or incisional complications during the study period. There were no infections or other complications clinically observed in any of the wounds. Devices were easily installed, during which there was immediate wound eversion into the eversion recess, but no skin contact of wound edges to the device. There were no complications with device removal at days 10 or 42. At device removal, there was no gross evidence of ulceration,

adhesions, or inflammation on the skin at days 10 or 42.

When comparing histology of wounds with SIS and SBD retained for the entire 42 days, there was significantly more dermal inflammation in the plane of suture entry/exit with nylon SIS than with SBD group ($p < 0.03$). Using a scale of one being mild inflammation and three being severe inflammation, the mean of the SIS group was 2.5 (range 2–3), equaling moderate-to-severe inflammation, whereas the mean of the SBD group was 1.5 (range 1–2) indicating mild-to-moderate inflammation (Fig. 3). There was no significant difference between hyperkeratosis, epidermal hyperplasia, and mitotic activity at the incision, 6 mm lateral to the incision, or normal skin between the SIS and SBD groups at both 10 and 42 days. For keratinocyte death and lymphocyte exocytosis, there was no significant difference between skin beneath the footplates and normal skin, and between the SIS and SBD groups at both day 10 and 42. There was no significant difference for width of scar or inflammation between the two groups either. All wounds closed with polyglactin had granuloma formation around this material. Coagulation necrosis or infarction was not identified in the dermis or epidermis of any pigs at either 10 or 42 days.

Strength results are reported as mean (standard deviation). Wounds closed with SBDs plus polyglactin were on average 8.0 times stronger ($p < 0.0001$) at day 42, 18.4 N/mm (1.1), compared with day 10, 2.3 N/mm (0.3). Wounds closed with SBDs without polyglactin were on average 7.4 times stronger ($p < 0.0001$) at day 42, 20.8 N/mm (2.3), compared with day 10, 2.8 N/mm (0.2). As we previously reported, there was no statistically significant effect of the use of a

Figure 3. Routine histopathology of skin at 42 days, with simple interrupted suture alone (A) showing marked inflammatory response versus SBD (B) showing mild inflammatory response ($p < 0.03$). The asterisk (*) marks the dermal scar, defined by fibroblast hypercellularity. Arrows mark the suture exit point. To see this illustration in color, the reader is referred to the web version of this article at www.liebertpub.com/wound

dermal polyglactin suture on mechanical strength using either the SBD or nylon SIS. Wounds closed with SIS (removed at 10 days) plus polyglactin were 9.4 times stronger ($p < 0.0001$) at day 42, 27.2 N/mm (4.2), compared with day 10, 2.9 N/mm (0.5). Wounds closed with SIS (removed at 10 days) without polyglactin were on average 8.7 times stronger ($p < 0.0001$) at day 42, 26.2 N/mm (42.0), compared with day 10, 3.0 N/mm (0.3).

DISCUSSION

This study compared the tolerability and mechanical tensile strength at days 10 and 42 of surgical skin wounds closed by primary intent with nylon suture plus a SBD with surgical skin wounds closed by primary intent with nylon suture using SIS in a porcine model. There was no difference in histology or tensile strength between the SBD and SIS groups at day 10. These findings suggest that the SBD does not obstruct normal wound healing for healthy wounds in a porcine model.

Within the SBD group, there was a 7.4–8.0-fold improvement in tensile wound strength from day 10 to 42. This is consistent with reported animal wound healing curves, also suggesting that the SBD does not obstruct normal wound healing. For example, Garden *et al.*²⁷ examined the ratio of wound strength from days 10 to 42 after removing sutures at day 7 in 2-month-old female Pitman-Moore pigs and found a 13-fold increase. Similarly, Forrester *et al.*²⁸ examined the ratio in wound strength acquisition from days 7 to 42 of incisional wounds repaired with suture in Sprague Dawley rats and reported a 10-fold increase.

When comparing the tensile test results, it is important to note that the procedures of the groups were only identical up to 10 days since the SIS sutures were removed for the 42-day samples to mimic common clinical procedures. In contrast, the SBD group sutures were left in for the full 42 days to simulate the anticipated clinical procedures. Because of the different procedures after 10 days, the SBD group wounds from this study still had open suture holes after 42 days, whereas the SIS group wounds were fully healed. The open suture holes are stress concentrators that are assumed to weaken the wounds. Accordingly, when we compared the strength of the SIS group wounds with suture removed at day 10 and left to heal until day 42 with the experimental group day 42 strength data, the SBD group wounds were 27% ($p < 0.05$) weaker. Regrettably, we did not mechanically test wounds in which SIS were retained for the entire 42 days since that would have required two ad-

ditional pigs and is inconsistent with most common clinical practice. However, fair strength comparisons can only be made across studies for the 10-day results, where results of a two-way ANOVA test revealed that there was no statistically significant difference between the strength of wounds closed with the SBD group versus SIS group at day 10 ($p = 0.24$). The equivalent strength after 10 days and the strength increase from 10 to 42 days suggests the device likely will have no negative effect on wound strength once the device is removed and the wound is fully healed.

At day 42, the SBD group had significantly less inflammation than wounds in which the SIS was retained for 42 days. In particular, we observed less inflammation in the planes of the suture entry and exit points at day 42 in the SBD group compared with the SIS group. This might be the result of a less hypoxic or better perfused wound environment.²⁹ Clinically, it is well known that too tight of sutures can strangulate a wound²⁵; the mantra in suturing technique being to “approximate not strangulate.” The SBD displaces compressive forces of suture away from the healing wound edges and over a greater surface area alleviating pressure from the sutures that could strangulate the wound.

Altogether, these results suggest that there is a clinical tradeoff: prolonging suture provides mechanical support to the wound to withstand external forces but slightly reduces the rate of healing. While the SBD might not be appropriate for all wounds, it has the potential to help patients at greater risk for wound complications. Non-absorbable suture remains the best option for closing wounds at risk for delayed healing. Tissue adhesives are contraindicated in patients at risk for delayed wound healing as well as for incisions over high tension and high friction areas.² And, in cases of orthopedic surgeries⁴ and saphenous vein graft sites,⁷ cutaneous wound closure with nonabsorbable staples is associated with a significantly higher incidence of superficial site infections than nonabsorbable sutures.

Future research should examine how long the SBD should be kept in a wound to minimize the probability of SWD but maximize inherent wound strength. This will need to be examined for various locations of the body and in various patient populations. Furthermore, the SBD would benefit from additional mechanical investigation, including examination of different suturing patterns, determination of optimal bite size, and device size and design for minimizing pressure near the fragile wound edge.

INNOVATION

Surgeons routinely prolong nonabsorbable sutures in slow-healing wounds by staggering their removal over time. The SBD in this study could eliminate staged suture removal and prevent some cases of SWD that result from premature suture removal. The results of this study demonstrate that prolonging nonabsorbable sutures in the skin with the SBD resulted in less epidermal inflammation compared with sutures alone, and resulted in an eight-times increase in tensile wound strength from day 10 to 42. The SBD in this study is a novel device designed specifically for challenging postsurgical skin wound closures.

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KEY FINDINGS

- Leaving SIS in for more than 10 days is proinflammatory.
- Using a suture bridge that lifts suture off the skin, protects the healing wound edges, and disperses pressure away from the healing wound toward healthier tissue can decrease the inflammatory response of sutures in the skin.
- Using a suture bridge for 42 days is tolerable and results in healed wound strength consistent with healthy wound healing trajectories.
- Using a suture bridge can prolong mechanical support of a wound without the risk of skin growing over the sutures.

Oregon State University. She has clinical and research expertise in soft tissue surgery and surgical oncology. **Jen Akeroyd, PhD, RN**, is cofounder of JULVIA Technologies, Inc. **Duncan S. Russell, BVMS, DACVP**, is Assistant Professor at the Department of Biomedical Sciences, Carlson College of Veterinary Medicine, Oregon State University. **Bria L. Robertson, Honors BS**, Mechanical Engineering, was a graduate student at the Department of Materials Science, School of Mechanical, Industrial, and Manufacturing Engineering, Oregon State University. **Jamie J. Kruzic, PhD**, is Professor and Deputy Head of School at the School of Mechanical and Manufacturing Engineering, University of New South Wales (UNSW), Sydney. **William Lear, MD**, is a Board-Certified Dermatologist and fellowship-trained Mohs Surgeon, and director of the Silver Falls Dermatology Mohs Fellowship program. He has completed more than 15,000 Mohs cases. Dr. Lear presents both locally and nationally, and is actively engaged in research on surgical materials. He has authored numerous peer-reviewed publications and a textbook chapter for *Surgery of the Skin*. He is cofounder of JULVIA Technologies, Inc.

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Abbreviations and Acronyms

SBD = suture bridge device
 SIS = simple interrupted sutures
 SWD = surgical wound dehiscence