Research

Force Modulating Tissue Bridges for Reduction of Tension and Scar: Finite Element and Image Analysis of Preclinical Incisional and Nonincisional Models

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Abstract

Background: Force modulating tissue bridges (FMTB) represent a new class of combined wound closure and scar reduction device designed to optimize the tension milieu of the healing wound.

Objectives: Engineering analysis and testing in both intact skin and incisional models was undertaken to assess changes in tissue tension associated with device placement and compare to standard suture closure.

Methods: Nonlinear, large deformation finite element analyses (FEA) were performed to compare the strains applied to tissues with sutures and FMTB. In the incisional model, a freshly euthanized Yorkshire pig received full thickness cutaneous incisions followed by alternating closure with sutures and FMTBs. FMTBs were also applied to intact adult human skin after pattern application. In each of the experiments, photographs were taken preapplication and postapplication and the resultant dot grid pattern changes were analyzed by image recognition algorithms to calculate applied strains.

Results: FEA indicate compressive stresses at the tissue:suture interface on the order of 4000 mmHg and 20 mmHg at the tissue:FMTB interface. Strain analysis of the sutures and FMTBs applied in the incisional lab testing indicated imposed strains on the tissues of around 40%, with FMTBs providing 10% more compression than sutures and 25% more compression between the applied devices ($P = 0.000057$). In the longitudinal study, tension reduction of the order of 30% was maintained over the treatment period of 10 days to verify device efficacy.

Conclusions: FMTBs provide wounds while simultaneously modulating skin tension and thus have the potential to improve scar appearance.

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Wounds and their subsequent scars can have a significant impact on the quality of life (QOL) of patients, both from the potential fear and pain of wound closure, and through the emotional and social impact of the resultant scar.[1-3] Self-consciousness and anxiety related to scars have roots in biological and social human evolution, as unflawed skin is an indicator of health. Even minor scars, when in visible locations, can negatively impact a patient's QOL,[4] and poor scar appearance can not only decrease patient satisfaction but may be a major trigger for the initiation of malpractice suits.[5,6] To combat scars, surgical procedures are designed to limited the visible impact of scars by a variety of techniques, including positioning scars in favorable, less visible locations, orienting scars parallel to Langer's lines, and reducing scar length (eg, minimally invasive or endoscopic techniques).[7,8] Patients may decline surgery altogether or be driven toward noninvasive treatments due to scar concerns. More than 180,000 scar revisions are performed in

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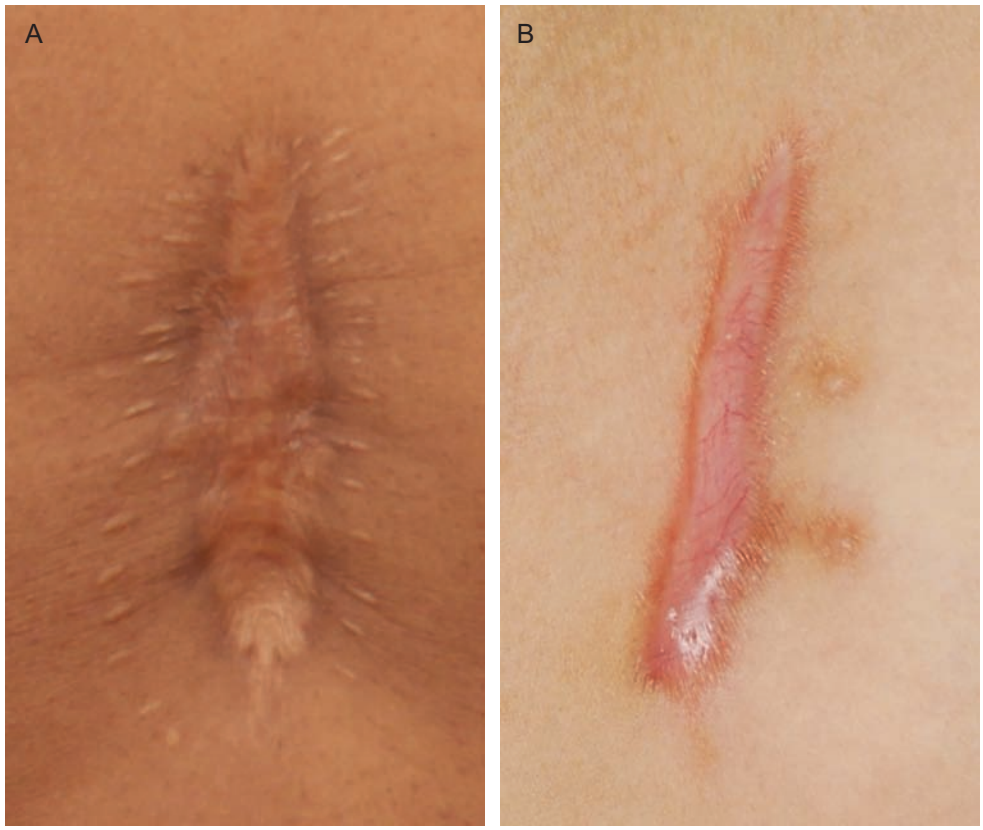


Figure 1. (A) Mature scar from closure with external sutures. The hash marks are related to high pressure at the tissue:suture interface which exceeds the perfusion pressure of the tissue. This results in an advancing line of tissue necrosis where the suture ultimately cuts through the compromised tissue, moving centrally, with healing laterally resulting in "railroad track" or "hash mark" scarring. In addition, once the sutures are removed, the tissue tension is exerted to the wound interface, which can lead increased scar burden. (B) Absorbable sutures can also actively contribute to scar formation. The dark lines inferior to the scar are secondary to superficial deep dermal sutures which have created hash mark scarring from underneath.

the United States on an annual basis,[9] leading to patient discomfort, lost productivity, and cost. It is therefore not surprising that significant efforts have been expended to develop pharmacological or device-based therapies to improve scar appearance, many of which are touted with little clinical evidence.

Given the profound impact of scarring, it is ironic that modern methods of cutaneous wound closure can actively contribute to scar formation. Transcutaneous sutures and staples penetrate the skin, exerting concentrated pressure points at the device:tissue interface that exceed tissue perfusion levels, thus inducing migrating zones of tissue necrosis leading to iatrogenic hash mark scarring (Figure 1A). Once these sutures or staples are removed, the native tissue tension, possibly accentuated by loco-regional swelling, is fully transmitted to the wound interface during a period when wound strength is low, potentially leading to scar widening, hypertrophy, or poor scar appearance. Tension on healing wounds produces chemical and neurological signals that can lead to increased scar formation via calcium channel mechanoreceptor mediated fibroblast proliferation and other mechanisms.[10,11] Foreign body granulomatous reactions to absorbable sutures may also contribute to scar formation.[12,13] More recently strategies have developed for "in plane" approximation of wounds, including tapes, skin adhesives, and a variety of skin adherent mechanical closure devices. While these types of devices eliminate the potential for hash mark scarring, they may not produce the force vectors necessary to evert wounds or to mitigate scar-inducing tissue tension. Furthermore, when mechanical devices are used to "pull together" wounds, distracting forces where the end of a rigid device interfaces with mobile skin can create a shear stress step off leading to skin irritation and blistering.

Force modulating tissue bridges (BRIJJIT, BRIJJITCo, LLC, Atlanta, GA) are a new class of noninvasive wound closure and tissue healing device developed to optimize control of the wound healing environment to promote optimal healing and scar characteristics. In order to meet these goals, the technology development was focused on the following requirements:

- Accurate wound alignment with sustained eversion.
- Reduction in wound tension forces below that of normal anatomical levels.
- Elimination of foreign body within the superficial layers of the wound.
- Noninvasive (no tissue penetration).
- Absence of shear force step off.
- Sustained adherence and function for seven days, with the ability to reapply afterwards to maintain tension reduction.

To characterize the tension reduction and eversion characteristics of FMTBs, engineering analysis was performed to assess the mechanical tension characteristics of human skin and the tension environment of intact and disrupted skin. Finite element analysis (FEA) was used both for technology development and to compare the 3-dimensional force environment of sutures and FMTBs in a computer simulation model. FMTBs were then applied in both incisional and nonincisional models in order to assess applied strains before and after application using image analysis.

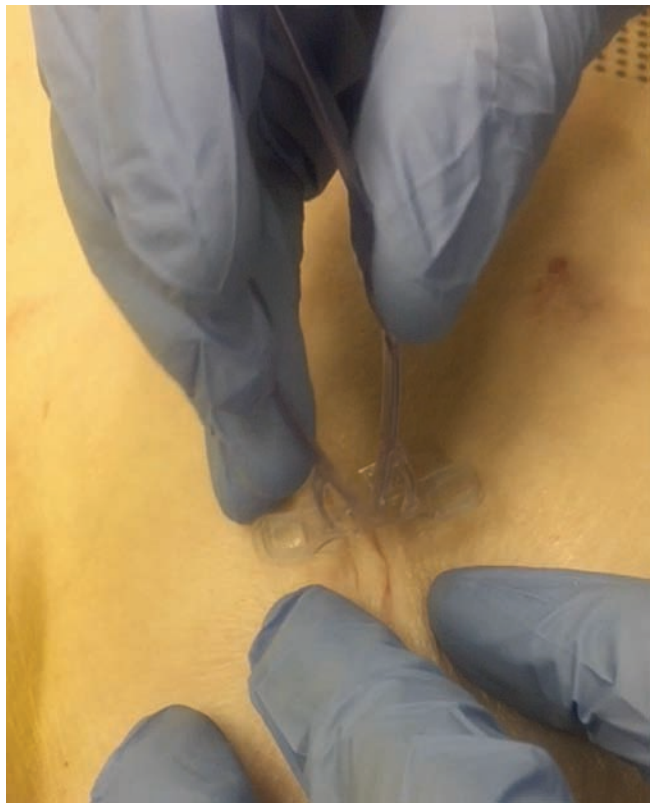
METHODS

Description of the Device

FMTBs are deformable nonplanar polymeric constructs that span a wound or scar in order to approximate and evert the tissue and to modulate the tissue forces. FMTBs have a backbone with a central spanning arch connected to lateral segments. The lateral segments include footplates for attachment to the patient's skin. Within the footplate is a stiffener layer that allows the footplate to extend partially under the arch. This extension, known as a medial strut, assists in application and alignment, but is flexible enough to promote eversion of the underlying tissues to which it is applied.

Figure 2 provides a series of images illustrating the device usage. FMTBs are provided on a custom loading tray with paired ridges. These ridges create a central depression in the tray which allows the medial strut to flex downward during device loading onto an applicator. This applicator has catch arms which are inserted into windows in the central arch of the backbone, and once engaged the devices are lifted off the loading tray, detaching the device from the peel liner to expose the underlying pressure sensitive adhesive. This mechanism of loading means that the device is immediately ready for use as the peel liner remains attached to the tray, eliminating the risk of loose liner material within the field.

To apply, the loaded applicator is squeezed to flex the backbone of the FMTB which the wound is held in approximation, either digitally or with forceps. As shown in Figure 2, the device is lowered onto the skin on either side of the wound, at right angles to the wound, and centered over the wound. The first point of contact is at the medial strut. As the squeeze on the applicator is relaxed, the struts move centrally, approximating and everting the skin due to the dual arcs of rotation of the strut and the backbone, while simultaneously allowing the skin forces lateral to the medial strut to distribute evenly (Figure 3, Video 1). This lateral force distribution mitigates the risk of a shear stress level step off, which can induce skin irritation and blistering.[14]



Video 1. Watch now at https://academic.oup.com/asj/article-lookup/doi/10.1093/asj/sjy079

Description of the Finite Element Analysis

FEA is a widely used technique for simulation and relies on numerical discretization of a complex geometry such that each finite element can have its own material properties and states. The governing physics, usually modeled by one or more differential equations, can then be applied to all the finite elements in incremental steps to simulate nonlinear material properties or large and dynamic changes to the system. Nonlinear, large deformation structural simulations were performed using SolidWorks 2017

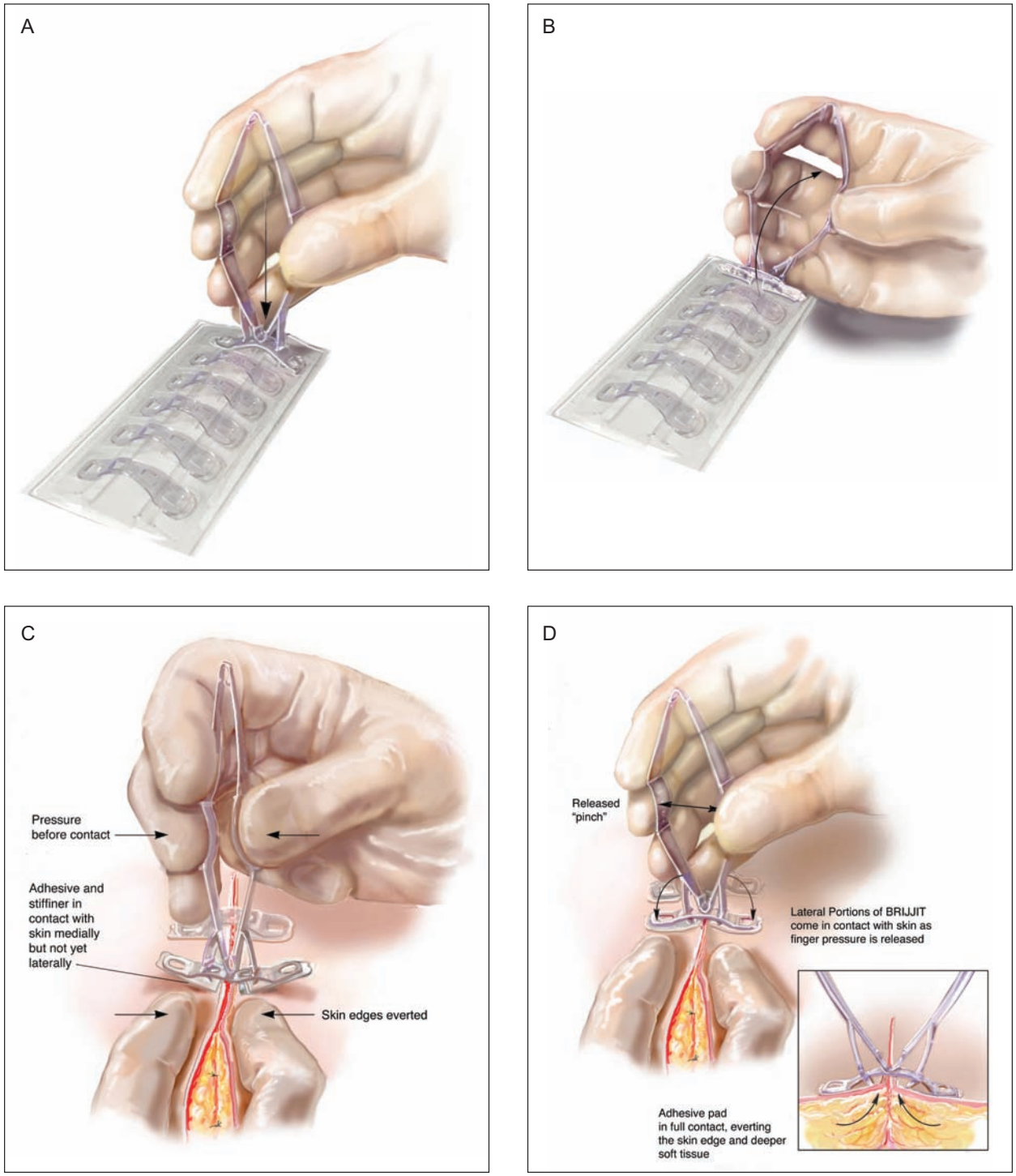


Figure 2. (A) The force modulating tissue bridges (FMTB) is loaded onto the applicator by inserting the catch arms into the central windows. The applicator is not compressed during the loading process. (B) To begin release of the FMTB from the loading tray, the attached applicator is pivoting to toward either end of the loading tray. (C) To apply, the wound is held in approximation either with the fingers, as shown, or with forceps. The applicator is compressed, bending (preloading) the FMTB, and the preloaded FMTB is centered over the wound and lowered. The medial struts will be the first points of contact on either side. (D) With gentle pressure applied, the applicator compression is relaxed, allowing the lateral sections to rotate into position. Inset: Relaxation of the applicator produces a rotational movement with downward lateral force, combined with a medical movement, to produce an upward and inward force vector at the wound interface. These transmitted rotational forces will produce eversion of the wound and mitigate tension of the superficial tissues. The applicator is now ready for removal. Figures reprinted with permission from BRIJJITCO, LLC (Atlanta, GA).

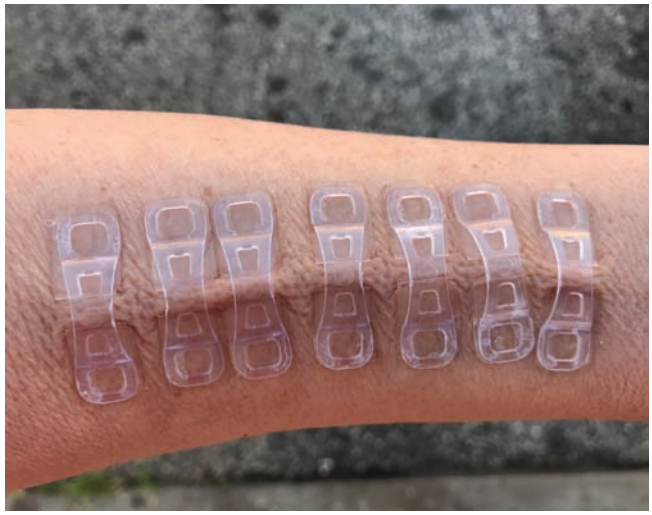


Figure 3. Force modulating tissue bridges applied to intact forearm skin. Eversion is clearly visible, as in reorientation of Langer's lines and changes in pore configuration, all of which are evidence of reduction of tissue tension levels.

SP2 (Dassault Systèmes SOLIDWORKS Corp, Waltham, MA). The details of the simulation methodology, including modeling of the biological tissues and device behavior, are provided in the Appendix (available as Supplementary Material online at www.aestheticsurgeryjournal.com). A quarter model was implemented using planes of symmetry on the longitudinal and transverse directions in order to reduce computation time. Figure 4(A-C) provides a series of FEA results corresponding to the final three steps illustrated in Figure 2. The results here are for an intact tissue model that also approximates the case for a closed wound. Figure 4A illustrates the FMTB near its neutral position when first being actuated by the applicator; a video of the application is available with the online version of this paper. The analysis indicates that a normal force of 6 N on the FMTB window provides for full application with an angle of inclination of 30° for the medial strut, as shown in Figure 4B. The applicator is designed to provide this force using a mechanical advantage to provide tactile feedback upon full device actuation while avoiding any fatigue by the end user.

The device is then lowered onto the tissue, with the forward edge of the medial strut making first contact. Figure 4B illustrates the stress and displacement when the medial strut first fully contacts the tissue. At this point, the medial strut has begun to provide compression to the contacted tissues. Figure 4C illustrates the stress and displacement when the device is fully installed. While stresses vary somewhat during application, the stresses applied to the tissues by the FMTB are very low, of the order of 20 mmHg. Eversion of the central tissue is predicted based on the lateral displacement of the underlying tissues by the FMTB. As later discussed, this compression not only maintains wound closure, but is also known to provide beneficial conditions to aid wound healing and prevent scarring. The amount of the tissue eversion can be adjusted by compressing the tissues for wound closure prior to FMTB application, and should be performed using the experience of the medical attendant as is current practice with sutures.

The amount of displacement and stresses within the underlying tissues are provided by design of the device and its usage as governed by the design of the applicator. Given that the polymers that constitute the FMTB device have higher modulus and strength than the underlying biological tissues, the residual stresses within the device after application provide adequate closure forces even when loadings are applied to the surrounding tissues. To demonstrate this behavior, a lateral displacement of 2 mm is applied to the tissue 10 mm away from the distal end of the FMTB. As shown in Figure 4D, it is observed that the resulting load is primarily distributed within the tissues outside of the FMTB and so compressive stresses remain within the central tissues that are protected by the FMTB. Similar analysis was conducted for sutures, as described in the Appendix. The results suggest two significant deficiencies related to sutures. First, the sutures provide a very high state of stress in the surrounding tissues. Compressive stresses of 5700 mmHg are predicted on the at the interface between the skin and the leading surface of the suture, two orders of magnitude higher than the FMTB which distributes the required closure force over a broad area of the tissues. Second, any forces applied to the surrounding tissues are transmitted directly to the tissue surrounding the suture and may inhibit wound healing; the analysis methodology and results provided in the Appendix suggest that sutures are not robust with respect to extraneous displacements of the surrounding tissues. This deficiency potentially explains at least part of the potential for wound dehiscence associated with wound closure utilizing suture-based techniques.

Description of the Incision and Wound Closure

All studies and analyses were performed between October 2016 and November 2017. The porcine study was completed at T3 Labs (Atlanta, GA), an Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACI)-approved facility under Institutional Animal Care and Use Committee (IACUC approval DN01P-TR). Incisions and wound closures were performed on a single Yorkshire pig, weighing 77.0 kg and recently euthanized (< 1 hour after a noninvasive, unrelated procedure) under deep anesthesia via potassium

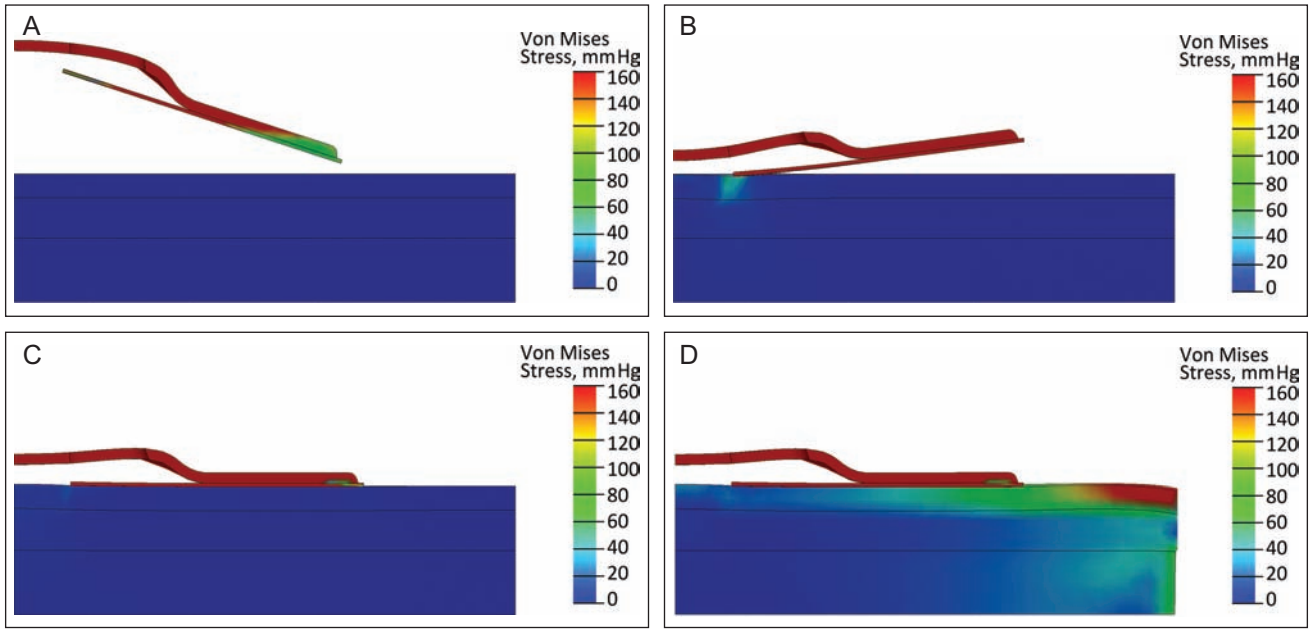


Figure 4. Finite element analysis results of the FMTB being applied to intact tissues at (A) start of application, (B) first contact, (C) full application, and (D) after skin displacement.

chloride infusion. The timing of application was chosen to prevent significant cooling of the specimen which might have inhibited adherence of the device. Prior to incision, a rectilinear grid of black dots was printed on a thin adhesive film and applied to the volar surface (chest and anterior abdomen). The dot radius was 2 mm with a pitch of 5 mm from dot center to center. Incisions were made to the volar surface (chest and anterior abdomen) parallel to midline (paramedian) with a length of 54 mm. Both straight line incisions and elliptical excisions of tissues was made to create a higher tension wound at varied orientations.

For each wound, a first suture was applied at the center of the wound according to standard practices using a curved suture needle and a USP #4 suture having a diameter of 0.2 mm. The suture extended approximately 3 mm on each side of the surrounding tissues. Additional sutures were then placed 15 mm on both sides of the first suture to provide a uniform wound closure. The sutures were then removed, and the tissues verified to return to their presuture locations. A first FMTB was then applied at the site of the first suture. In applying the FMTB, the tissues were first approximated with forceps. The FMTB was loaded onto the applicator and actuated to widen and rotate the FMTB medial struts, as shown in Figure 2. The FMTB was then pressed onto the tissue, contacting first at the inner edges of the medial struts, and then fully setting the footplates on the adjacent tissues. Two additional FMTBs were then placed on either side of the FMTB at the same locations of the second and third sutures. At each step of the lab session, photographs with a resolution of 3264 × 2448 pixels were taken at consistent camera viewpoint and lighting conditions.

Description of the Image and Strain Analysis

FMTB performance of wound closure relative to sutures was performed through image analysis. The images from the lab session were first rotated and cropped to center and align the grid pattern along horizontal and vertical axes. The preprocessed images were then imported into Matlab (Mathworks, Cambridge, MA) for analysis. The circular Hough transform (CHT) was applied to the dot grid in the images given expected dot diameters between 20 and 40 pixels. This algorithm was used due its known robustness in the presence of noise, occlusion, and varying illumination.[15] After automatic circle recognition, the identified dots were sorted by horizontal and vertical location and overlaid on the postprocessed images. Any falsely recognized dots were manually removed. Missing dots, most often due to partial or full occlusion, were manually placed using cross-hairs superimposed on the postprocessed images. Figures 5A and 5B, respectively, illustrate the recognized dot grids before and after the incision of the left anterior section.

The analysis then computed the elongations across the tissues given the relative change in position from one image to another. The elongation, also referred to as engineering strain, is defined as $\Delta L/L$ where L is a reference length

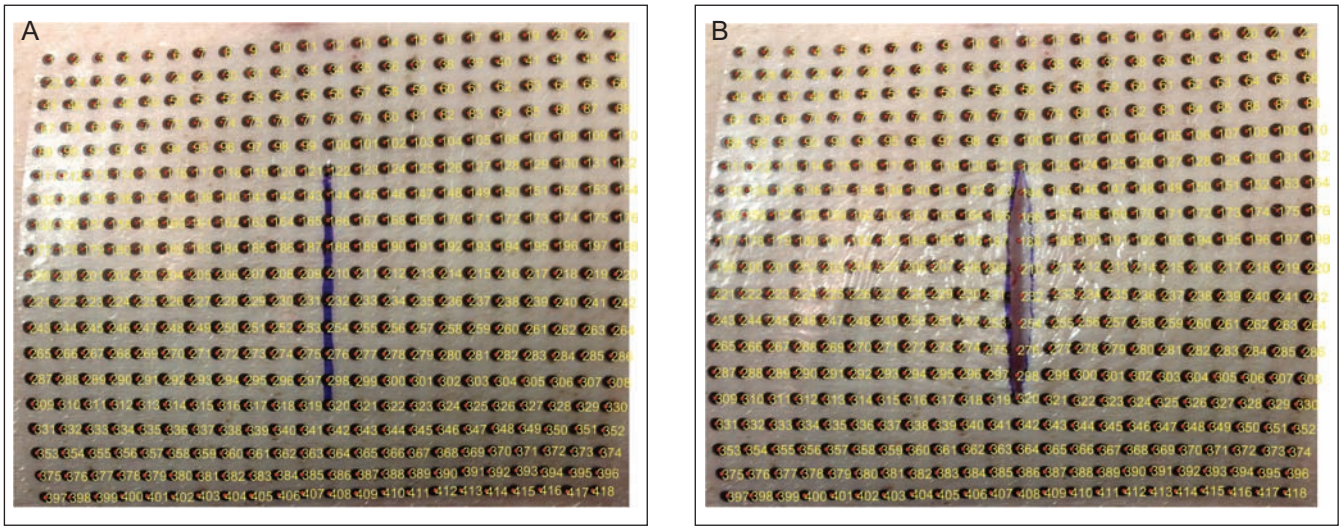


Figure 5. Recognized dot grids (A) before and (B) after incision of left anterior section.

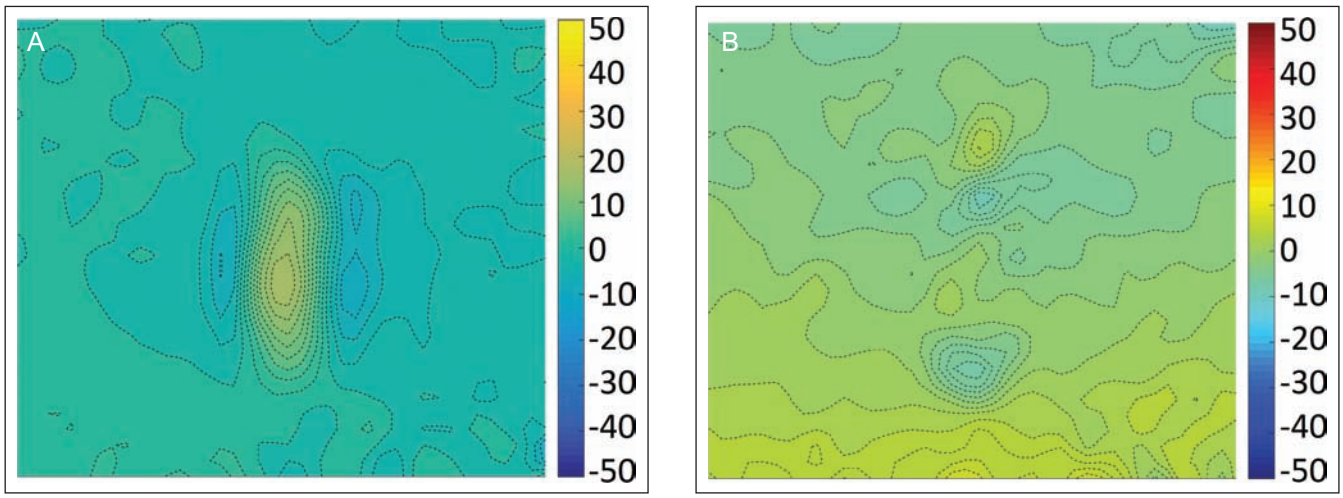


Figure 6. Tissue deformations of incision as analyzed by Figure 5B relative to Figure 5A. The plotted deformations are in the (A) transverse and (B) longitudinal directions.

and ΔL is the change in the reference length.* The elongation or strain may also be expressed as (L2-L1)/L1 where L1 and L2 represent an initial and subsequent length. For example, suppose that two dots were spaced at a distance, L, of 5 mm. If in a subsequent image the dots were found to have moved closer 1 mm (ΔL = -1 mm), then the strain would be computed as (4 mm-5 mm)/5 mm which equals −0.20 or negative 20%. The elongation is typically computed in both the longitudinal and transverse directions, with a focus on the results in the principle direction of loading. The computed strains across the finite dot grid were then interpolated using cubic functions to provide continuous contour plots of the strain field using Delaunay triangulation of the data.

Figures 6A and 6B are contour plots of the resulting strains in the (A) transverse and (B) longitudinal directions to the incision. Focusing on Figure 6A, it is observed that the incision imposes transverse elongations of the order of 20% at the center of the open wound, as indicated by the orange color at the center. Adjacent to the area of highest transverse elongation, there are larger areas of slight compression, as indicated by the light blue contours at left and

*Elongation and strain are similarly calculated but have slightly different meanings in the context of this application. Technically, strain refers to the state of the deformed material while elongation more generally refers to the relative deformation. At the wound surface, for example, the transverse strain may be very close to zero (since it is a free surface) even though the transverse elongation may be significant.

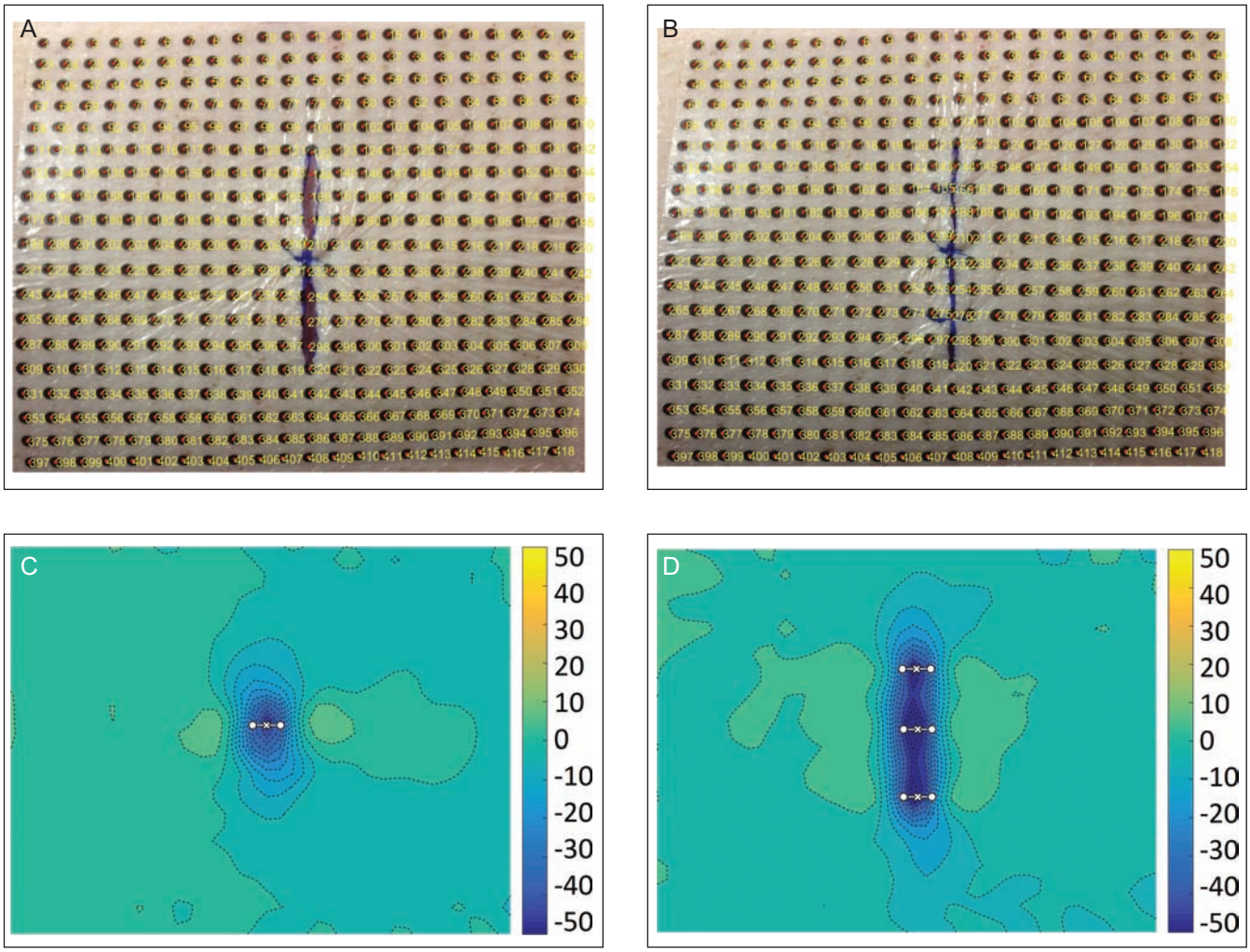


Figure 7. (A) One suture applied to the tissue shown in Figure 5B, (B) three applied sutures, (C) transverse strains from one applied suture, (D) transverse strains from three applied sutures.

right. These deformations taper off towards the end of the incision given the elliptical shape of the wound. Beyond and far from the incision, the transverse strains are near zero, as indicated by the green contours. The longitudinal strains are plotted in Figure 6B, and indicate much lower levels of displacement, though there are some significant local deformations at the ends of the incisions due to shortening of the wound length associated with the opening of the wound. The reason is that the length of the wound remains constant, so the opening of the wound to a finite width necessarily results in a slight shortening of the wound.

In both Figures 6A and 6B, there are some minor variations in the strain contours associated with small inaccuracies in the image analysis methodology; the inaccuracies are mostly due to slight changes in camera position or lighting, photographic preprocessing (rotation and cropping), and circle recognition. The standard deviation of these strains (which are expected to have a mean of 0 but were found to have a mean of 0.2%) was 1.9%. Accordingly, the computed strains are believed to be accurate to within 3.7% at the 95% confidence level. Given the relatively low magnitude of the longitudinal elongations depicted in Figure 6B relative to the transverse elongations plotted in Figure 6A, the subsequent results focus on the transverse elongations with discussion of longitudinal elongation as warranted. It should be noted that a benefit of this analysis approach is that the methodology allows direct comparison of any two images with consistent dot grids (eg, comparison of wound closure using sutures and FMTBs as later described).

RESULTS

Figures 7A and 7B provide the analyzed images of the closed incision using one and three sutures. Inspection of the images near the suture sites indicates a significant level of local strain. Specifically, the dots numbered 209, 211, 231, and 233 in Figure 7A show an elliptical shape with

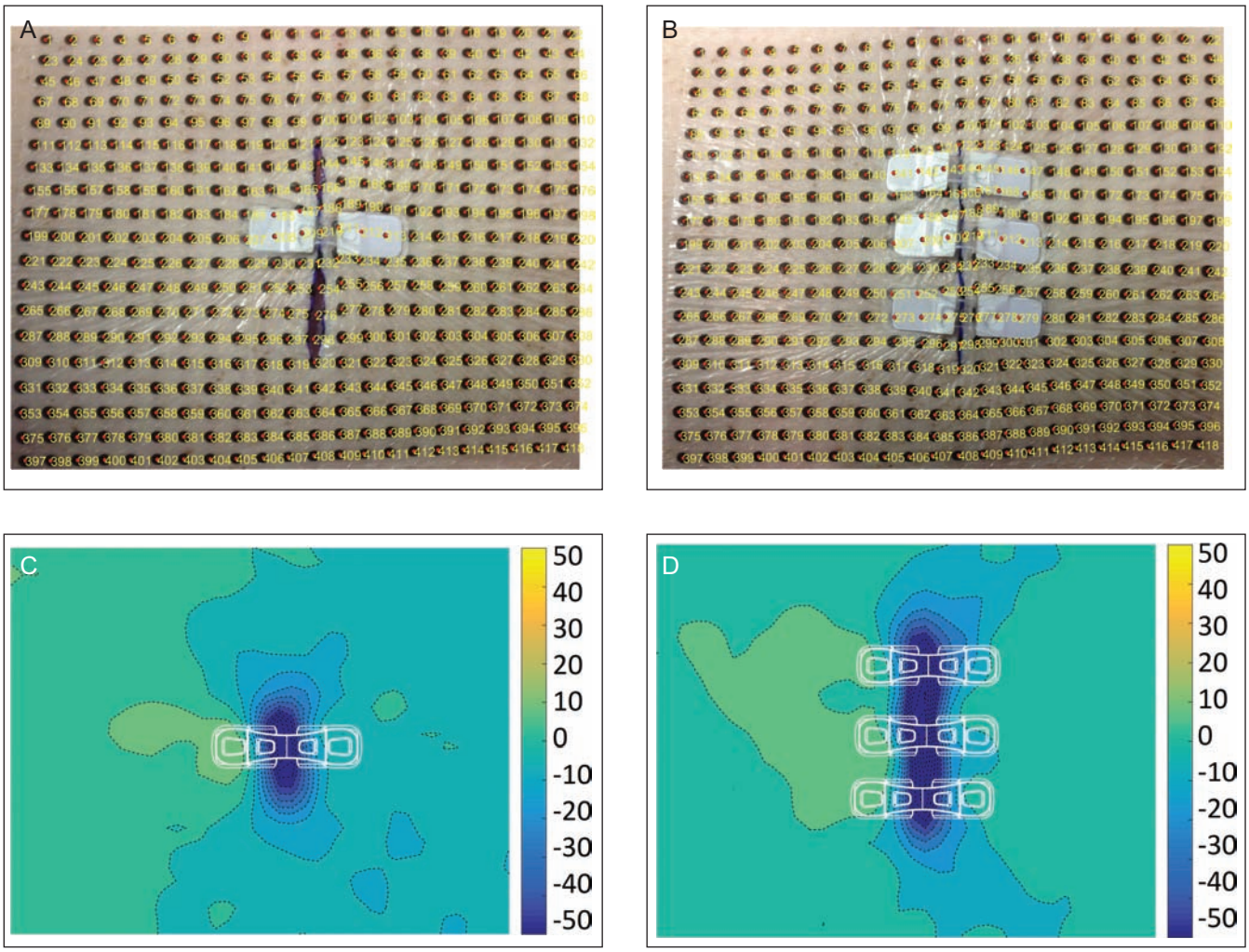


Figure 8. (A) One force modulating tissue bridges (FMTB) applied to the tissue shown in Figure 5B, (B) three applied FMTBs, (C) transverse strains from one applied FMTB, (D) transverse strains from three applied FMTBs.

significant strain towards the nearby end of the suture. Similar behavior is evidenced by the deformation of the circles and film near dots 165 and 167 as well as 275 and 276 in Figure 7B. This deformation behavior indicates that the tissues at the suture sites are undergoing significant local strain, concentrating stresses on the tissues that likely exceed tissue perfusion levels, thus potentially reducing healing rates or even inducing migrating zones of tissue necrosis and scarring.

Figures 7C and 7D provide the analyzed transverse elongation of the closed wounds shown in Figures 7A and 7B, relative to the open wound shown in Figure 5B. The suture is indicated by two connected circles with an "x" at the center. The analysis indicates that the suture provides full closure at the center of the wound with compressive strains of the order of 40% at the center of the suture. However, there are significant gradients in the nearby tissues, with low wound compression at distal positions of the wound. By placing additional sutures, more uniform closure is provided, as illustrated by the transverse strains plotted in Figure 7D. Here, a more uniform state of compression is provided with compressive strains between 40% and 50%. Tensile transverse strains, of the order of 10%, can be observed in the adjacent transverse tissues.

The sutures were then removed and the wound closed by the FMTBs as shown in Figures 8A and 8B. Examination of the tissues underlying the FMTBs indicates eversion of the wound along the length of the incision. The reason is that the approximation of the wound prior to FMTB application, followed by the inward closure of the FMTB's medial struts upon application, provides the required tissue support. Close examination of dots 231 and 233 in Figure 8A as well as dots 297 and 299 in Figure 8B indicate some local deformation of the tissues but not nearly as severe as that observed for the sutures illustrated in Figures 8A and 8B. The reason is that the FMTBs perform the wound closure

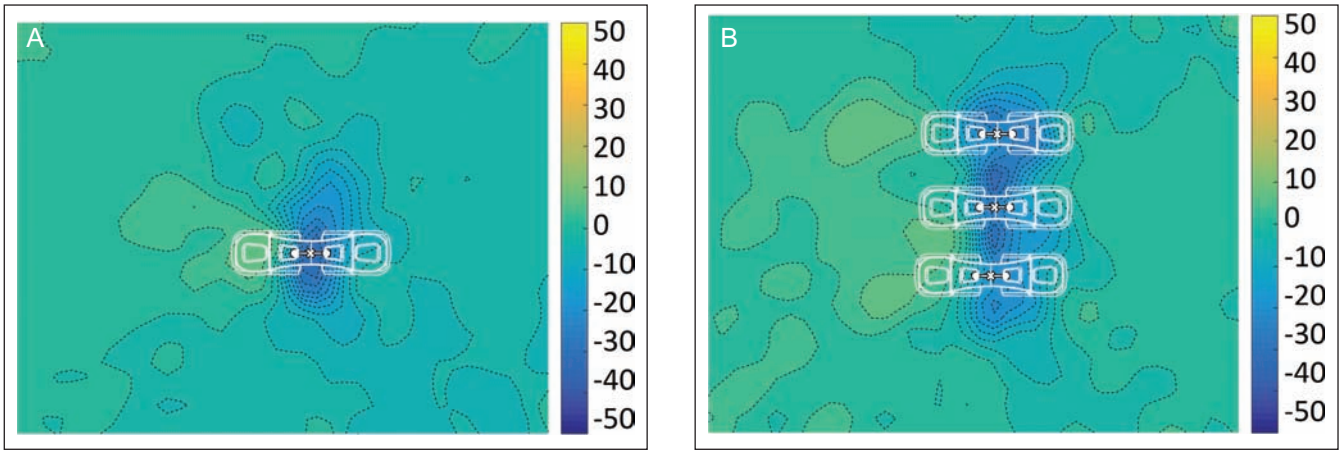


Figure 9. (A) Relative transverse strains applied by one force modulating tissue bridges (FMTB) relative to one suture, (B) relative transverse strains applied by three FMTBs relative to three sutures.

by distributing the applied stresses across a much larger area of the tissues. As such, the excessive local stresses associated with sutures may be avoided while providing a desirable level of compression and eversion at the wound closure interface.

The transverse strains applied by the FMTBs are shown in Figure 8C and 8D, which correspond to the deformation of the closed wounds shown in Figure 8A and 8B relative to the open wound shown in Figure 5B. In these figures, the outline of the FMTBs are superimposed on the contour plots at locations corresponding to Figure 8A and 8B. It is observed that the transverse strains applied by single FMTB, as shown in Figure 8C, are substantially greater than those provided by the single suture, as shown in Figure 5C. The reason is that the FMTB works on the underlying tissues across a larger area, providing more transverse compression across a greater width of the wound. The application of three FMTBs results in a uniform state of transverse compression as shown in Figure 8D. The transverse strains are consistently above 50% across the length of the wound. This larger and more uniform compression is enabled by the three FMTBs applying slight tensile strains to a larger area of tissues at distal locations transverse to the wound site.

The described analysis was also applied to directly compare the deformations of the FMTB relative to the sutures. Figure 9A plots the transverse strains of the single FMTB plotted in Figure 8C relative to the transverse strains of the single suture plotted in Figure 7C. A similar plot of the transverse strains of three FMTBs relative to the three sutures is provided in Figure 9B. In all cases, the FMTBs provide for greater wound compression than the alternative sutures. The additional compression provided by the FMTBs is approximately 15% at each of the suture locations. Furthermore, inspection of Figure 9B indicates that the use of three FMTBs provide for additional compression of approximately 25% between the closure devices relative to the use of three sutures. The reason is that the sutures provide a more localized closure of the tissues such that there is less tissue compression between the sutures. Figure 9B also explicitly shows the greater area of slight tension outside the FMTBs wherein the adjacent tissues are being drawn in to support the improved closure of the wound site. These tensile strains are very small, typically less than 10%, and so are not expected to provide discomfort or complications in use.

The statistical significance of the transverse strains applied by the three sutures and the three FMTBs was evaluated according to a paired-sample t test. The transverse strains for each set of devices were evaluated across the 40 mm length of the incision at 5 mm increments, yielding 9 evaluations of strain for each type of device. The mean and standard deviation of the imposed transverse strain for the three applied sutures were −21.9% and 10.4%; The mean and standard deviation of the imposed transverse strain for the three applied FMTBs were −55.4% and 15.5%. The paired-sample t test rejected the null hypothesis that the sutures and FMTBs were the same, with a probability (P value) of 0.000057.

To investigate the long-term performance of the FMTBs in human application, a longitudinal study of the FMTBs was performed. Prior to FMTB application, a dot pattern was first applied to a participant's forearm in the form of an inked tattoo (Inbox Ink, Inc., Toronto, Canada). The ink, based on genipa plant extract, is absorbed by skin to provide a high contrast image that develops over one day and has a duration of approximately two weeks. A series of eight FMTBs were then applied to the intact skin with a centerline pitch of 16 mm. Photos were taken prior to, during, and immediately after FMTB application as well as at subsequent intervals. The participant then went about their normal routine without any special treatment of the

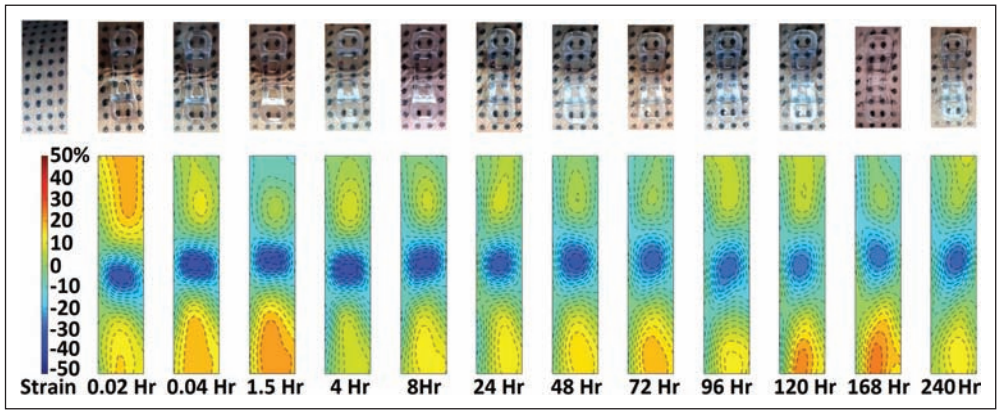


Figure 10. (Top) Photographed images prior to and after force modulating tissue bridges (FMTB) application, (bottom) relative transverse strains applied by the FMTB at various time intervals.

applied FMTBs; these participant activities included exercise and twice daily showers.

Figure 10 provides the photographed FMTBs and analyzed transverse strains across a ten-day span. The first FMTB was applied at 0.02 h. Tissue eversion is observed with compressive strains of the order of 20% to 25%. Second and third FMTBs were then applied on either side of the first FMTB and photographed at 0.04 h. It is observed that the compressive strains increased slightly to 30% to 35% given the adjacent FMTBs. The reason is that the adjacent FMTBs can draw the adjacent tissues across a larger area, and so provide some additional compression relative to a single FMTB. The participant then went for a vigorous run, with a photo taken at 1.5 h. It is observed that the transverse strains remained stable across the next four days, with some variation associated with camera angle and image recognition. Regardless, tissue eversion was observed with compressive strains remaining of the order of 20% to 25% throughout the duration of the study.

Figure 11 plots the vertical (transverse) strain as a function of time for the analyzed images. The error bars at each data point correspond to the standard deviation of the transverse strain within the FMTB. The results suggest that the FMTB provided constant compression to the underlying tissues, though there was a slight reduction in compression from 30% at the start to 20% at day 10; the increase in compression from day 7 to day 10 (corresponding to the two right-most points in Figure 9) is within the error of the analysis associated with image recognition. The underlying cause of the reduction is believed due to creep of the pressure sensitive adhesive between the footplate and tissues. The reason is that close inspection of the lower edge of the bottom footplate shows a downward displacement at 168 h relative to 0.02 h. We do not believe this decrease in decompression is problematic given the recovery time for most wound healing applications. In medical practice, more complicated cases should be followed up with examination and potential reapplication of the FMTBs to optimize scar therapy.

DISCUSSION

It has been well documented that tension on a healing wound leads to decreased scar quality beginning early in the healing process and can occur by a variety of mechanisms.[10,16] Embryonic wounds can heal without scars, and the native tissue tension within the embryo is significantly lower than that in the postembryonic period. Wound healing is a complex process, however it is possible that the low skin tension environment within the embryo is contributory to superior scarring.[17,18] The tissue layer which appears to be responsible for the production of excess scar is the dermis, and reducing tension at the dermal layer appears to be key in reducing hypertrophic and keloidal scars.[19,20] Therefore, topical devices that prevent mitigate dermal strain would be predicted to improve scar quality. Indeed, reduction of tension and skin eversion is associated with improved scarring at closure[21] and Gurtner et al[22] have shown that shielding of tissue tension does improve scar quality. Wound closure devices that similarly reduce tension within the dermal layer would be postulated to improve scarring. Since tension effects nocioceptor fibers, there is also the potential for decreased pain in the closed wound when tension reduction is realized.[10] Wound closure mechanisms that reduce tension, rather than induce zone of high tissue forces, such as sutures or staples, have the potential to improve scar quality, patient experience, and patient outcomes.

FMTBs were designed to accurately approximate cutaneous wounds and simultaneously to reduce tissue tension as a result of deformational changes within the devices. This mechanism of closure differs significantly from currently available mechanical wound closure devices which use a cable-tie mechanism (eg, TopClosure, IVT Medical, Ra'anana, Israel; Zipline, Zipline Medical, Inc., Campbell,

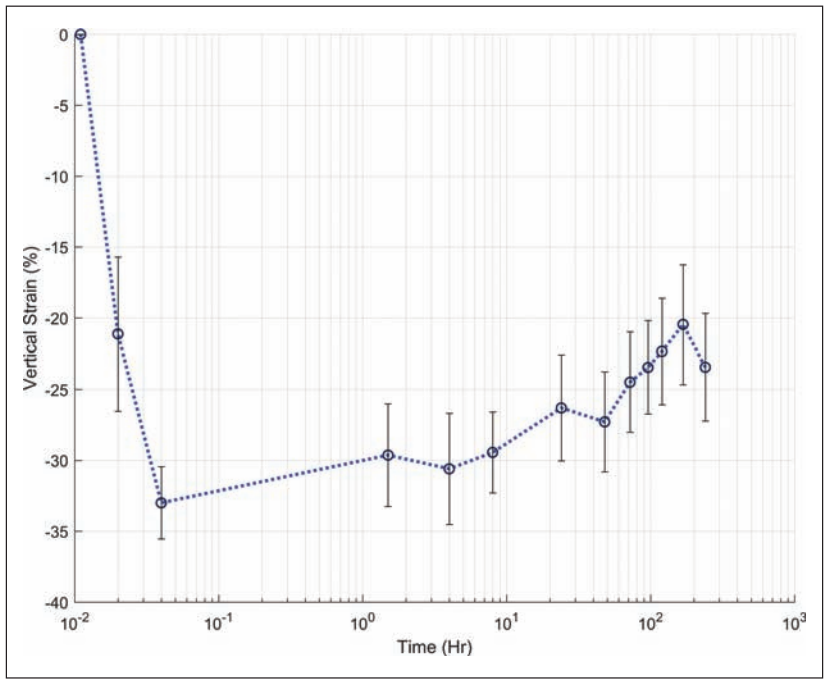


Figure 11. Transverse strains as shown in Figure 10 over time. Point A is the baseline strain prior to force modulating tissue bridges (FMTB) application. Point B is the immediate change in strain after placement of the FMTB being analyzed. Point C shows the additional strain reduction in the FMTB being analyzed immediately after placement of an adjacent FMTB.

CA, and DermaClip, DermaClip US LLC, Houston, TX) or linear strips (eg, Steri-Strips, 3M, Maplewood, MN). These devices approximate the wound with a linear element which has a centralizing force vector parallel to the skin but lying at are above the surface of the skin. As a consequence, they can produce a net downwardly directed force vector to the tissues resulting in inversion, rather than eversion, of the wound. FMTBs are designed to overcome this limitation by utilizing dual arcs of rotation (of the backbone and medial struts) to produce a medializing and rotational motion to the tissue which produces an upward (everting) force at the wound margin, as confirmed by finite element analysis. Furthermore, FMTBs were designed to be rapid to apply and to be easily (or passively) removed, to enhance surgical efficiency and patient comfort. Embrace (Neodyne Biosciences, Inc., Newark, CA) devices have been shown to reduce tension on wounds and improve scar appearance but are not applicable to wound closure.

Both the described analysis and lab testing suggest that the force-modulating tissue bridges (FMTBs) not only provide an improved healing environment, but also are significantly more robust than sutures. The tissue constitutive modeling presented in the Appendix suggests that a USP #4 suture having a diameter of 0.2 mm would provide compressive stresses of the order of 4000 mmHg to provide 0.1 N of closure force to 1 mm thick skin. In addition, the sutures provide a significant shear stress banding, as indicated by the elliptical shape of the locally distorted circular dots shown in Figure 7. By comparison, the shear stresses applied by the FMTB can be purposefully designed by controlling the tissue displacement and specifying an appropriate device:tissue interface with a relatively large medial strut. The same tissue constitutive modeling presented in the Appendix suggests that the shear stress applied to the underlying tissue by a FMTB with a footprint of 10 mm length by 10 mm width away from the wound area would be just 10 mmHg… a factor 400 times lower than that for the suture. The fact that the FMTB provides (1) lower stresses to (2) an area away from the wound site in (3) a noninvasive manner suggests a preferable wound closure concept strategy.

Still, the local stresses desired and imposed on the tissues near the closed wound site will vary by with the patient, device, skin thickness, anatomical location, and application technique. The medical practitioner should apply FMTBs based on their experience with sutures, using similar wound closure techniques and device spacing for the FMTBs as with sutures. The adhesives of the FMTBs are designed to release with exfoliation of the skin, such that the practitioner need only reapply the FMTBs in complicated cases where ongoing tension modulation is desired as a scar reduction strategy. As such, FMTBs provide significant potential cost benefits in regard to the avoidance of anesthetic, multiple visitations, and scar revision.

FMTBs represent a potential alternative to sutures, staples, adhesives, tapes, or other mechanical devices for

final-layer skin closure. Furthermore, since FMTBs reduce skin tension over time, they can theoretically be reapplied to closed, immature wounds during the healing period as a form of mechnomodulation scar therapy. The described FMTBs have been designed to be suitable for a wide range of applications in the surgical, emergency room, office, or home setting.

While this study does demonstrate that FMTBs can align wounds in a porcine model and reduce tension in the treatment zone, it does not assess changes wound healing per se nor changes in scarring as a result of tension reduction. Clinical trials are being designed to assess the impact of the FMTBs in wound closure and scar characteristics. The described FMTBs have been designed to be suitable for a wide range of applications. However, we recognize that the size and properties of FMTBs will vary by type of wound and wound site characteristics. The development of additional sizes and configurations of FMTBs could help optimize function in a wide range of applications. The testing model described will help inform the development of such modifications by validating the design appropriateness to the specific application parameters, such as anatomical location.

CONCLUSION

Force modulating tissue bridges reduce tension within closed wounds and intact skin, such as in a healing scar, thus potentially leading to improved scar aesthetics. Photometric analysis confirms finite element analysis predictions for tension reduction and without lateral sheer step off which could be a source of skin irritation or blistering.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

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Disclosures

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