Improving the Healing Environment in Orthopedic Surgery with Brijjit® Force Modulating Tissue Bridges

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Background

Wound complications in orthopedic surgery can be a source of significant patient morbidity, re-operation, and increased cost of care. Superficial wound dehiscence can progress to open wounds or infection of bone, prosthetic hardware, and/or joint spaces. Even when minor, open wounds can lead to increased office visits or after-hours calls and reduced patient satisfaction.

While patient risk factors for wound complications (e.g. diabetes, smoking, steroid use, etc.) are well documented,[1-3] tension on the closed incision is known to be a significant source of wound healing complications and contributor of poor scar outcomes.[4,5] Ironically, concentrated force transmission from sutures or staples actively contribute to open wounds as a result of tissue compression focused by their small surface area[1,6-10] Such forces can be in the order of 4000 mmHg, far exceeding tissue perfusion pressures, leading to decreased perfusion at the wound site, focal necrosis, and delayed wound healing/open wounds.[6,8,11,12] Once such traditional closure devices are removed (or dissolve), the tension forces directly impact the immature, vulnerable scar and may lead to poor scar outcomes including scar widening, prolonged redness, and pathologic scar by a variety of mechanisms.[13] Tension offloading of the closed incision can improve both clinical and aesthetic outcomes.[14,15]

BRIJ Medical's Brijjit® Force Modulating Tissue Bridges (FMTB) are first-in-class non-invasive wound closure and support devices designed to offload tension both immediately at closure and over time. Strain mapping has demonstrated strain reductions of 25% or more in the healing area. Due to the large tissue contact area, device-induced tissue forces are reduced by approximately 400X compared to sutures.[11] The devices typically stay in place for 10 days to 3 weeks, depending on the body area, extent of motion, and patient skin characteristics. Approximately 15,000 surgical cases have been performed using the devices, with two clinical trials in plastic surgery showing an 89-91 percent decrease in delayed wound healing/open wounds as well as smaller initial scars (RCT).[16,17]

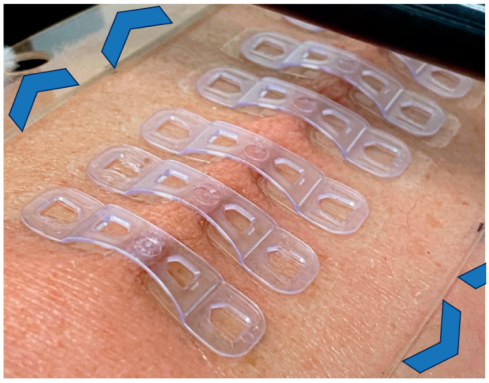


Figure 1: Brijjit devices placed on intact volunteer skin and subjected to a distracting tensile force > 30 Newtons. This high tension level results in visibly decreased perfusion of the skin lateral to the devices, however the treatment zone underneath the central arch remains tension free, evidenced by maintained eversion, with good maintenance of perfusion (evidenced by color).

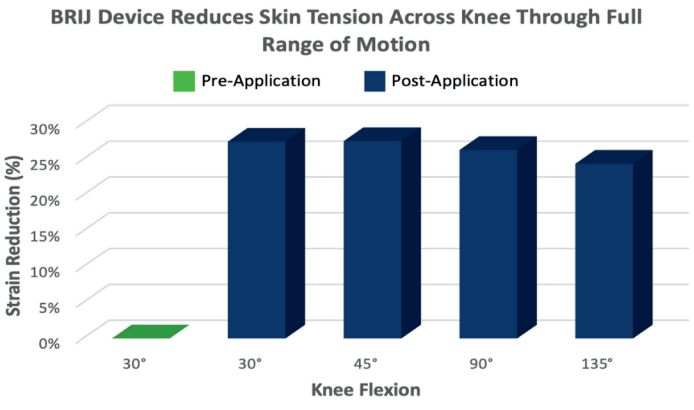
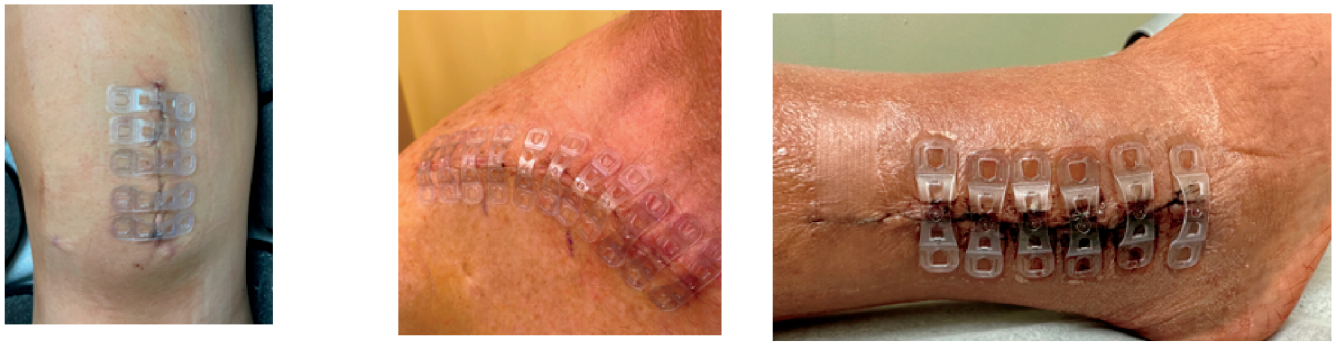


Figure 2: Strain reduction with Brijjit devices compared to unprotected skin. Devices were placed on volunteers at 30 degrees of flexion (neutral). Observed strain offloads were maintained in the range of 25% with increasing flexion.

Clinical Case Series

An initial series of orthopedic surgical procedures using the Brijjit devices was completed by Dr. John Andrew Grotting of Synergy Orthopedic Surgeons in San Diego, California. Thirty consecutive patients (mean age 29.7 years; range 14-56 years) underwent 45 procedures with application of Brijjit devices at wound closure. Incision locations were the anterior knee (n=24), lateral knee (n=2), anterior thigh (n=1), anterior shoulder (n=1), posterior shoulder (n=1), elbow (n=2), and ankle (n=1). Procedures included 13 ACL reconstructions (B2B=2, quad tendon=10, with meniscus=3), revision quadriceps (n=3), MPEL (n=3), knee PL Comer/Biceps femoris repair (n=1), ORIF patella (n=1), patellar tendon repair with osteophyte excision (n=1), shoulder CC ligament repair (n=1), trapezius transfer (n=1), elbow tendon repair (n=1), elbow arthroscopy with ROH and triceps repair (n=1), and ORIF ankle (n=1).

There were zero incidences of infection, wound breakdown, adverse skin reaction (e.g. blister, allergic reaction), or other complications in this small patient cohort. All patients tolerated the devices well with no complaints. 28/30 patients had adherence of all applied devices until ten to fourteen days post-op when they were removed. In two patients with a history of keloids an additional application of brijjits was used after removal of the operative application. 2/30 patients (6.7%) had a limited number of placed devices (1/8, 3/8) with premature detachment (1/8 and 3/8), but with no wound healing complications resulting. These occurred in some cases where arthroscopic infusion was used, with fluid dispersal into the soft tissues potentially decreasing initial device adherence. While the use of a tackifier (e.g. Mastisol®, Eloquest Healthcare, Ferndale, MI) is not routinely required when placing Brijjit devices, in instances where interstitial fluid accumulation is significant (e.g.arthoscopy, tumescent fluid infusion), application to the adhesive zone prior to Brijjit device placement can significantly increase strength of adherence.[18]



Examples of Brijjit BP100 device placement in orthopedic surgery

Summary:

This series demonstrates that Brijjit devices can be successfully utilized in a variety of orthopedic surgical procedures of both the upper and lower extremities. Such tension offloading could provide security during post-procedural physical therapy by mitigating motion-induced ischemia[19] and early return to physical activity while the immature scar is protected. If cooling/ice therapy is desired, it can be incorporated with the Brijjit devices in place, as lab testing in volunteers shows that the device function is maintained with icing.[18]

References:
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