

Summary

All established, conventional tissue fasteners—sutures, staples and staple variants—work mechanically, transferring tensile force to and from the living tissue by physical interlocking. That is, the force-receiving/delivering surfaces consist of some projection perpendicular to the force direction. Direct compressive, or ‘normal’, force is borne by tissue as pressure equaling the transmitted force divided by the area of that perpendicular projection. Due to that pressure, closures of incisions or wounds too often fail.

The risk varies with the kind of tissue. Soft noncollagenous tissues tolerate only mild holding pressure (e.g., liver, fat, and muscle—whether uterine, cardiac, or skeletal); even stronger tissues disintegrate under excessive pressure (e.g., stitches reconnecting the slender tendon of a forcefully contracting muscle). Substantial mortality and disability follow, across many surgical disciplines, from dehiscence (the bursting apart or splitting open) of a sutured abdominal wound, to peripartum uterine rupture after fibroid myotomy or prior cesarean, to unsuccessful repairs of diverse tissues after blunt trauma, to disrupted heart valve replacements in ‘normal’ (unscarred) annuli. Each may be lethal.

The FiberSecure works differently, employing a myriad of very fine, independent, continuous filaments, essentially parallel to the separating force. The filaments serve both (1) as a large-interface substrate (or ‘scaffold’) for adherent new tissue formation within the substance of one or more existing living tissues, and (2) as tension members to directly hold that existing living tissue to another living tissue. It thus exploits the remarkable tissue-prosthetic ingrowth seen in *ex vivo* tissue culture “bioreactors”, but harnesses that phenomenon to achieve durable bonding with one or more living tissues inside the body. FiberSecure’s tows (unbraided bundles) of filaments are drawn through the living tissue, where each becomes in effect a slender embedded bioreactor extending through the tissue interstitium. This allows adjacent cells, particularly fibroblasts, to ingrow and adhere, facilitated by already-present tissue factors to generate protein fibers (collagen, fibronectin) strongly adhering and coupling both to the filaments and to the physical framework of the tissue itself, the ‘extracellular matrix’. Basic studies by Davila¹ and Bruck² indicate that very small fibers (Bruck’s were 5 microns, Davila’s were 50 microns) allowed themselves to be ‘captured’ by a collagen envelope compatible with the immediately adjacent blood supply. In the FiberSecure, each individual filament extends without interruption across boundaries to the second tissue for similar bonding. We confirmed this in three additional experiments, at three separate institutions, each with a different device and different animal model for a different end—but every one relying on this same operating principle^{3 4 5 6}.

Thus, FiberSecure transfers load not by normal force but by interface shear, and calculated resistance to disruption should be the product of (a) contact area, (b) tissue pressure, and (c) frictional coefficient. FiberSecure’s contact area is nearly 200 times that of a conventional suture, because the same small mass is comprised instead of thousands of fine independent filaments, rather than a tight braid or monofilament. Thus the other two factors can remain very, very small (only existing baseline interstitial tissue pressure and low coefficient of friction) and still be sufficient to sustain impressive loads. The principle is the familiar mechanism by which plant roots can hold tenaciously, even when in very soft soil. Pressure exacerbation in bearing tissue—proportional to the distracting force and inescapable in normal-force coupling—no longer exists.

Moreover, risk of fatigue failure is avoided due to a combination of factors:

- (a) the multitude of filaments,
- (b) the mechanical continuity of fibers with no inter-material junctions, and
- (c) extremely small radii of individual filaments (reducing bending stress component)
- (d) expected material stress well under 5% of ultimate strength.

Accelerated testing (10 million cycles at load far exceeding expectations) is confirmatory.

The problem: unreliability of conventional closure materials and methods in the absence of organized collagenous tissue

It is the near-universal conclusion from clinical surgical experience^{7 8 9 10 11} that reliable wound closure requires healthy collagenous structures in which to place sutures, and techniques soundly capturing those structures.

Not all patients with wounds though, either operative or traumatic, are so fortunate as to have strong collagenous structures bounding their defects. Sometimes trauma or infection has destroyed usually reliable

abdominal fascia. There may be compromise secondary to other comorbidities, such as obesity or diabetes. Other tissues, even when normal—myometrium,^{12 13} unscarred cardiac valve annuli,^{14 15} for example—are endowed with far less well developed fascia than is normal abdominal musculature.

Muscle is a prime example, especially when needed repair is a cut across, rather than along and parallel to, muscle fibers. Though suturing muscle alone is deceptively simple technically, repeated experience shows it notoriously unreliable. Without fascia, they come apart. Tie loosely, and muscle fibers spread, separating the wound. Tie tightly, and necrosis follows so that sutures cut through, separating the wound. Many come apart; others leave a progressively enlarging, bulging, sac in the form of a disabling incisional hernia. Clinically significant complications follow^{16 17}. Laparotomies dehisce (burst apart or split open). Uteri rupture during pregnancy and labor subsequent to fibroid myomectomy or previous caesarian section. Heart valve suture-fixations leak. Needed myocardial mass is lost to scarring by the mechanical necessity of wide buttressed sutures in left ventriculotomy closure. This experience indicates that without organized collagenous support, soft tissues, including—but not limited to—skeletal, cardiac and smooth muscle, lack sufficient mechanical strength and integrity to reliably withstand distracting forces in the conventionally closed surgical or traumatic wound. In those wounds initially intact, poor local mechanical support of sutures may then leave that tissue vulnerable to compressive obliteration of local blood flow with subsequent loss of even that meager mechanical integrity.

Existing techniques to partially mitigate some of these difficult wounds have serious limitations, and few circumstances in which they can be applied. In the abdominal wall, added healing time can be provided by widely placed, full-thickness skin-to-peritoneum penetrating, retention sutures that add strength initially but cannot be safely left beyond a few days¹⁸. Prosthetic meshes^{19 20 21 22} may be anchored to strong fascial sutures further from wound edge than the direct reach of sutures, but do not eliminate the need for sound anchoring somewhere. Worse, there is sometimes no sound tissue in which to anchor, even remotely. And temporary support can only benefit if closure strength develops in reasonable time.

The principle of the FiberSecure

The basic element of the FiberSecure is a bundle of several hundred to a few thousand fine polymer fibers (in this case 2250 12- μm polyester (PET) fibers) swaged into the heel of a conventional straight needle (**Figure 1**).

The principle of FiberSecure is illustrated below (**Figure 2** right side). Every tiny increment of interface between a myriad of fine fibers and tissue produces a force to counter disruption. The cumulative disruption-resisting force sums to match or exceed that of the conventional closure device (suture shown at left; staple mechanism is the same). Yet the tissue stress induced by the force is both profoundly different and far less with FiberSecure. *Compressive*—blood-flow-reducing—stress is replaced



Figure 1. Close-up of the FiberSecure, a tow (unbraided bundle) of twelve-micron polyester fibers, converging into the heel of a needle.

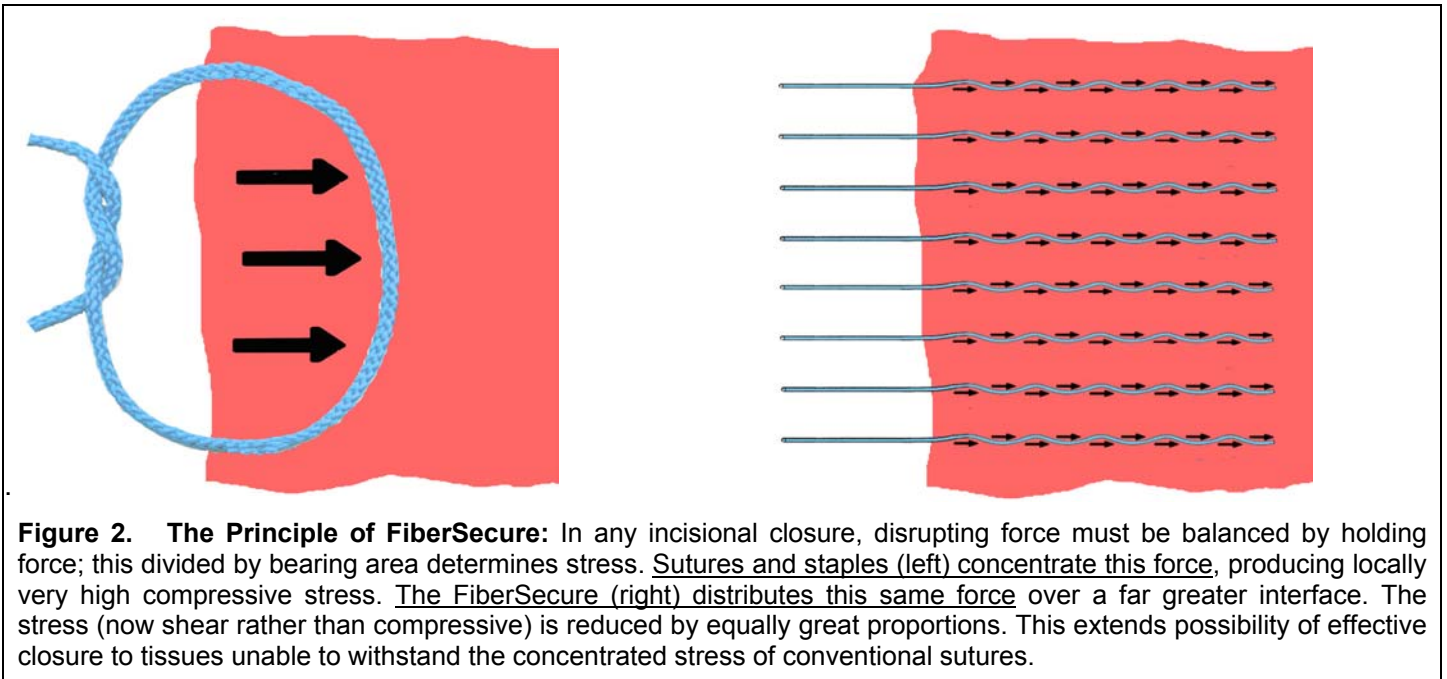
by less-damaging *shear* stress. Far more important, however, is the tremendous reduction in total magnitude of tissue stress induced. The practically achievable bearing area for the FiberSecure is dramatically greater than that of the suture or staple—and thus induced stress is reduced by a similarly dramatic proportion.

The research that led to FiberSecure initially targeted the challenge of harnessing skeletal muscles for circulatory power. This was accomplished with a tissue-to-prosthesis coupler (termed MyoCoupler) that incorporates FiberSecure bundles. Next, tendon-deprived muscles were re-attached with an orthopaedic variant (OrthoCoupler) and then fascia-deprived muscle incisions were closed to demonstrate the general/plastic surgical version (FiberSecure). In each test—leg, abdominal, or back muscles; goats, minipigs, rabbits, or dogs; for 2 weeks to 12 months; 189 implants overall; 6 surgeons (3 specialties) in 4 institutions—the experimental device has outperformed suture controls, consistently exceeding even intrinsic muscle tear strength³⁻⁶.

Here is a brief description of two of those studies. In one orthopedic study, the semitendinosus (hamstring) tendon was removed bilaterally in eight goats. Left sides were reattached with the experimental device and

right sides were reattached using the Krackow stitch with #5 braided polyester sutures. Tested at 60 days post-surgery, suture control pulled out at 120.5 ± 68.3 N, whereas the FiberSecure-based experimental device held until muscle tear at 298 ± 111.3 N (mean \pm SD). Another, ongoing wound-closure study is demonstrating FiberSecures' efficacy in cross-fiber incisions in the external oblique muscle of Sinclair miniature swine. To date, in one-month experimental closures all (64/64) closures tested stronger than the muscle (area beyond the repair) itself. In each of these studies, muscle tear strength was in every instance reached with the fiber-muscle composite produced in healing still soundly intact.

Also, *in vitro* testing has shown the fatigue strength of the fiber bundles themselves (tested to over 10^7 cycles) to be over 168 N/mm² (168 MPa), whereas the maximal contraction strength of a muscle is only 0.15 N per mm² of largest cross-sectional area²³. Since the device-to-muscle size ratio is consistently between 1% and 2%, this provides a safety factor against fatigue of more than 10 (that is, $1\% * 168 / 0.15 > 10$).



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