

Bioabsorbable Fasteners for Laparoscopic Incisions^{1,2}

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Objective: The objective of this work was to develop a skin stapler suitable for closing short laparoscopic incisions using a technique comparable to the “Set-back Buried Dermal Suture”.

Background: The Set-back Buried Dermal Suture (SBDS), first published by Jonathan Kantor in 2010 [1], is an interrupted vertically applied suture that captures the dermal tissue on the deep surface away from the incised edge (see Fig. 1).

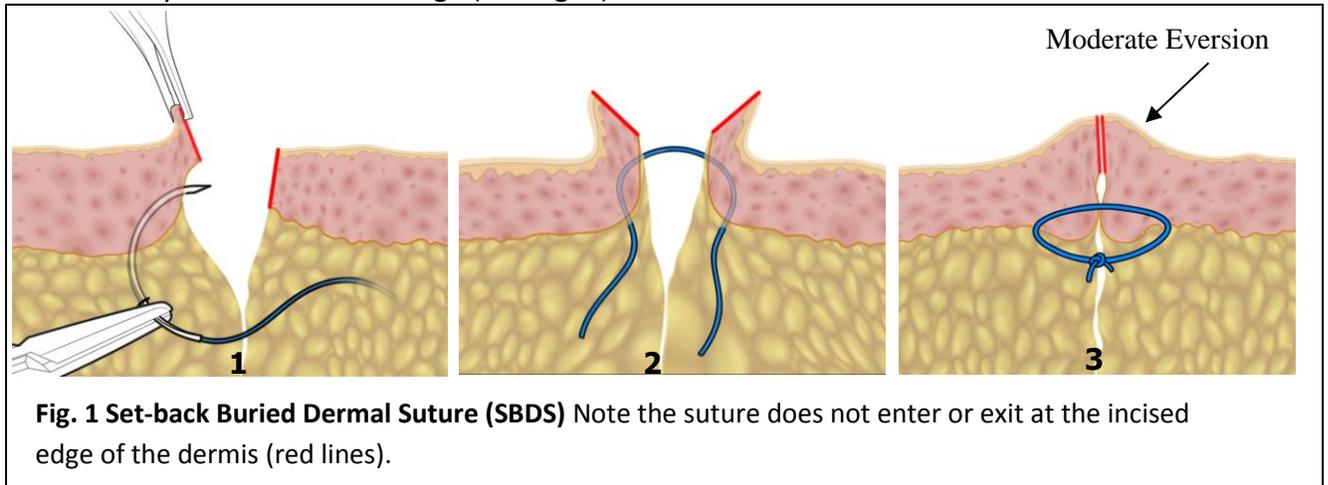


Fig. 1 Set-back Buried Dermal Suture (SBDS) Note the suture does not enter or exit at the incised edge of the dermis (red lines).

This manual suture technique provides strength to close the incision by capturing the dermal tissue away from the incised edge. An elegant study of this procedure was conducted by Wang et.al. [2], in a prospective, randomized study using a split-wound/split scar model where the patient serves as their own control. Highlights of the manual technique include:

- aggressive minimization of dead space
- encourages wound eversion
- minimizes tension across the epidermal component
- knot buried in the subcutaneous tissue

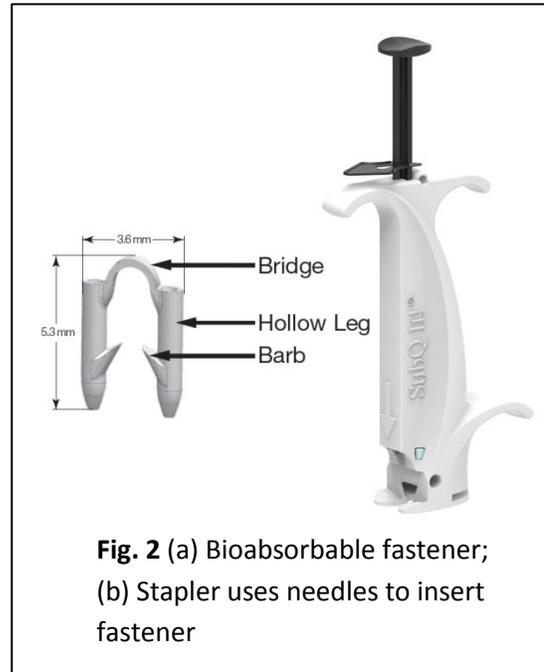
The study showed this new procedure provided superior wound eversion and better cosmetic outcomes with fewer spitting sutures when compared to the more common Buried Vertical Mattress Suture (BVMS) technique where sutures penetrate the incised edge.

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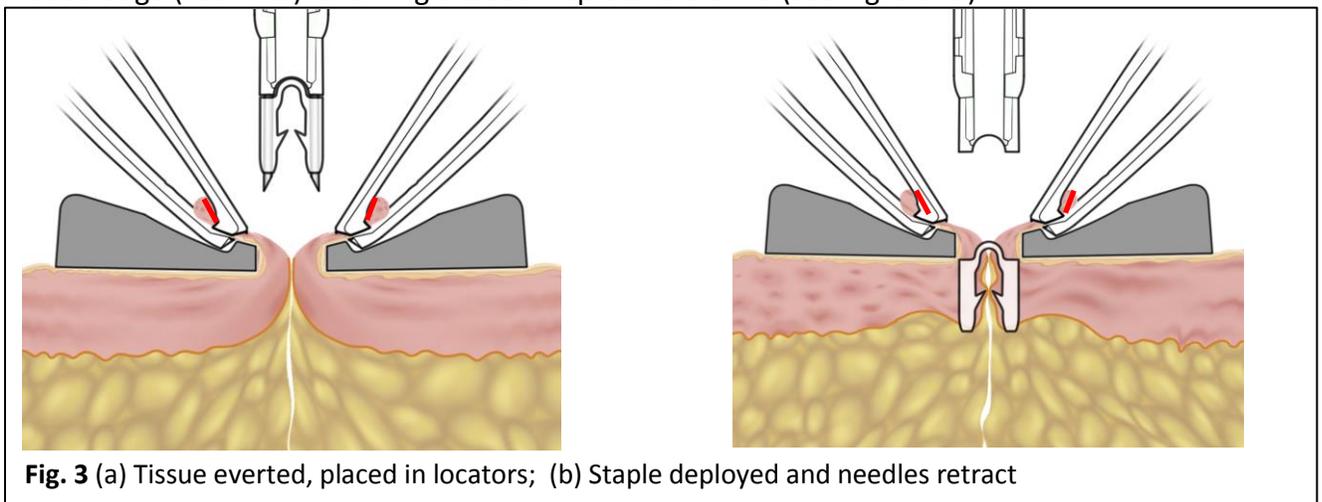
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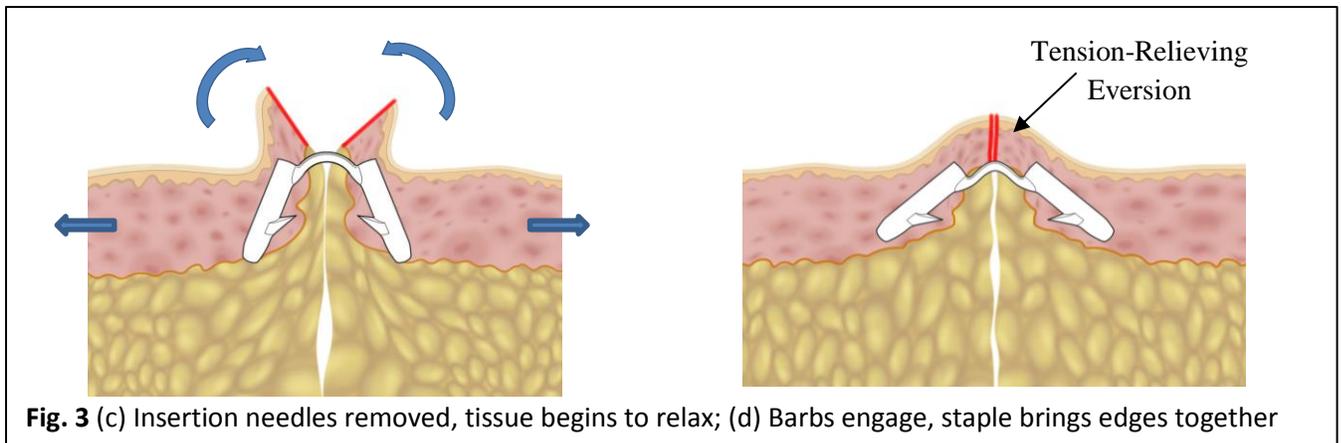
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Methods: The SBDS technique is time consuming and requires a higher level of skill to be done correctly. Prior to Kantor's publication we began development of a skin stapler, now called SubQ It!, which coincidentally incorporates the SBDS technique. We first developed a flexible bioabsorbable fastener in the shape of a horse-shoe that is deployed by a specially designed stapler (see Fig. 2). The SubQ It! fastener is molded from polylactic-co-glycolic acid (PLGA), a well-known biodegradable material, which has been used in widespread medical applications. The design of the fastener uses barbs to engage the dermal tissue with a flexible bridge connecting the barbed legs. The concept of holding tissue with barbs is similar to the mechanical technique of barbed sutures except that the barbs of the SubQ It! fastener are at fixed locations and oriented to oppose each other. When the incision is placed under tension, the bridge straightens and the barbs hold the two sides of the incision together.



The SubQ It! stapler incorporates the salient features of the set-back technique as illustrated in Figure 3 which shows an incision in cross section. As in the manual technique, forceps lift the tissue to expose the sub-surface of the dermal tissue. With SubQ It!, however, two forceps lift the two edges of the incision simultaneously and are placed in forceps locator indentations to precisely position the tissue. In this position the needles enter the dermis just back from the incised edge (red lines) following the technique of the SBDS (see Fig. 3 a -b).





In Fig. 3 (c) the stapler and forceps have been removed so that the tissue can begin to relax. As the tissue pulls back the barbs of the staple engage and the shape of the staple begins to flatten. As the wound further relaxes the staple opens up angularly but due to the distance set-back from the incised edge, the tissue remains moderately everted (see Fig. 3 c-d).

The SubQ It! fastener does not require tying of knots. The knots of manual interrupted sutures crush some tissue leading to local ischemia and a reparative response of the tissue. Mechanical tension on the wound has been identified as a leading cause of hypertrophic scarring [3]. The barbs of the SubQ It! fastener engage the tissue without a crushing action and are relatively far from the incised edge, where the vascular bed is undisturbed, minimizing the body's reaction to the suture. In one case of a tertiary C-section where two previous incisions had hypertrophic reactions, the SubQ It! closure resulted in a normal scar [4].

Results: Studies were performed using porcine tissue to determine the strength of the SubQ It! closure. Incisions were closed with only one SubQ It! fastener and then each incision was pulled and the force to rupture recorded. The results (see Fig. 4) met our minimum strength

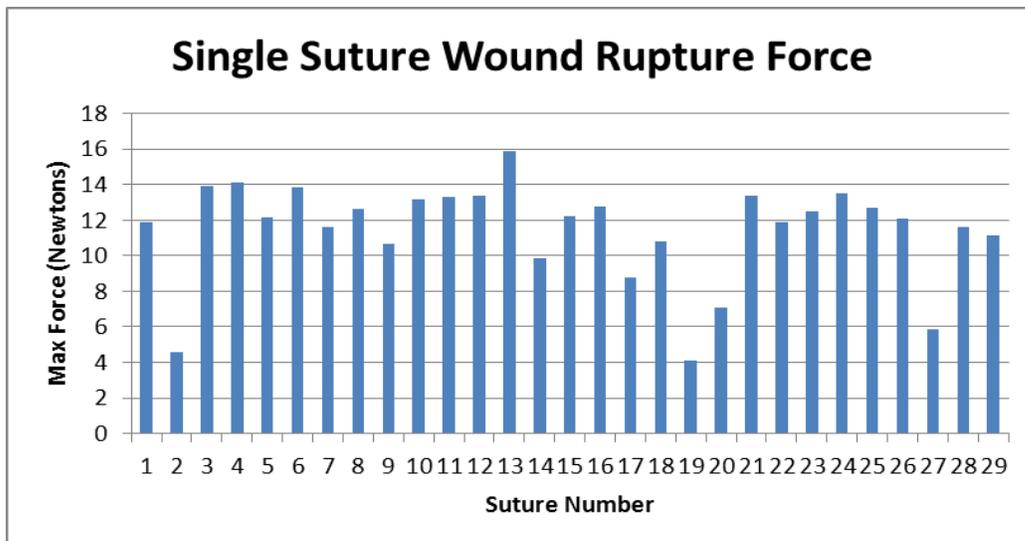


Fig. 4 Force applied to rupture incisions held by only one SubQ It! fastener.

requirement of 2 Newtons in all cases with the minimum being 4.08 Newtons and the average strength being 11.43 Newtons (95% Confidence 10.35 - 12.51Nt).

Since the SubQ It! fasteners are independent each additional fastener adds approximately 10 Newtons (1 kg) of holding strength to the closure (Fig 5).

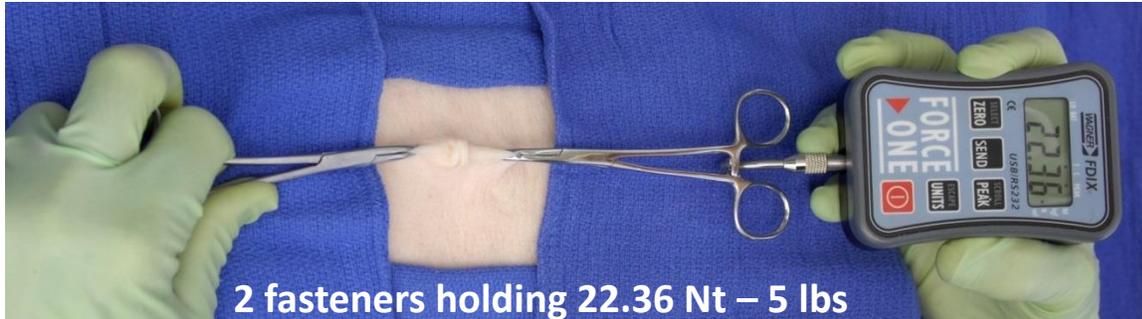


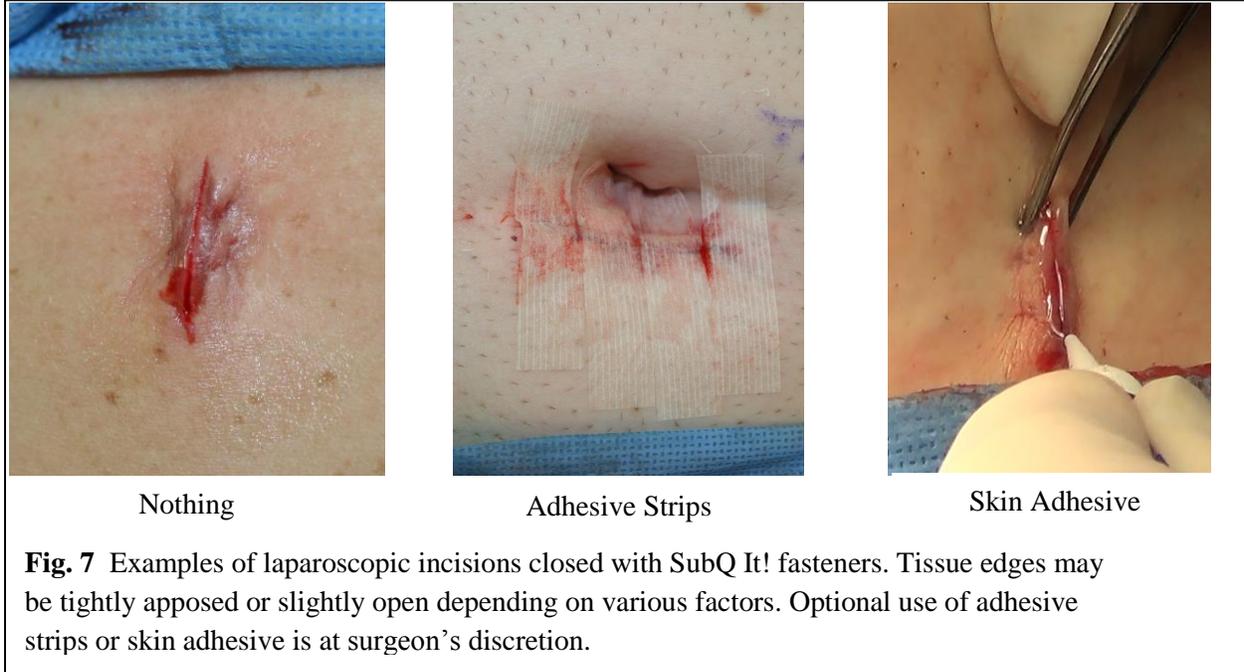
Fig. 5 Force to rupture incision closed with two (2) SubQ It! fasteners measures 22.36 Newtons or about 2x the strength of a single fastener.

When the SubQ It! stapler was cleared by the U.S. FDA, we began using it on a variety of surgical cases. Short incisions, such as used in Minimally Invasive Surgery (MIS) procedures reported here, are the primary application of the device. We found that SubQ It! can be used even in 5mm trocar incisions because the fastener is delivered vertically. MIS incisions can be secured with a single SubQ It! fastener, but the ease and added security of having two fasteners makes this our recommended practice.

SubQ It! brings the edges of the incision together with moderate eversion as Wang [2] demonstrated (see Fig. 6). If additional edge treatment is desired SteriStrips or Skin Adhesive are preferred (see Fig. 7) over subcuticular sutures to avoid having suture material at the incised edge.



Fig. 6 (a) Laparoscopic Trocar Incision on day of surgery, and (b) after 47 days of healing



Summary and Conclusion: The SubQ It! system mirrors the Set-back Buried Dermal Suture (SBDS) technique which has been shown in its manual application to provide superior healing conditions and cosmesis compared to the commonly used BVMS technique. SubQ It! further improves on the manual procedure by not using knots thereby potentially reducing reparative response of the tissue and improved healing. In addition SubQ It! reduces the procedure time and the skill level needed to perform this technique in short laparoscopic incisions by incorporating the operating principles into a stapler that delivers a bioabsorbable fastener vertically into the smallest incisions. We conclude that SubQ It! provides rapid secure apposition and excellent cosmetic results. For our future direction we recommend additional trials to confirm findings associated with the SBDS technique that we expect will be demonstrated by the SubQ It! stapler:

- Reduced rate of infections compared to metal staples or continuous subcuticular sutures [5]
- Fewer incidences of suture “spitting” [2]
- Lessened hypertrophic reactive responses [3]
- Low incidence of wound separations [6]
- Improved cosmesis compared to metal staplers and skin adhesives [7]

References:

1. J. American Academy Dermatology, 2010 Feb, pg 352-353, "Letters to the Editor", Kantor, Jonathan
2. J Am Acad Dermatol, 2015 April, 72(4), 674-680, "Set-back versus buried vertical mattress suturing: Results of a randomized blinded trial", Wang AS, Kleinerman, R, Armstrong, AW, Fitzmaurice, S, Pascucci A, Awasthi S, Ratnarathorn M, Sivamani R, King TH, Eisen DB.
3. Med Hypotheses, 2008 Oct; 71(4): 493-500. doi 10.1016/j.mehy.2008.05.020. Epub 2008 Jul 9, "Keloid and hypertrophic scarring may result from a mechanoreceptor or mechanosensitive nociceptor disorder", Ogawa R.
4. Singer, S., M.D. "Case Study: Use of SubQ It! in Keloid-sensitive patient", 2018, on file.
5. J Long Term Eff Med Implants, 2012;22(2), "The influence of absorbable subcuticular staples, continuous subcuticular absorbable suture, and percutaneous metal skin staples on infection in contaminated wounds" Pineros-Fernandez A, Salopek LS, Rodeheaver PF, Rodeheaver G.
6. J Dermatol Surg Oncol. 1992 Sept; 18(9): 785-95, "A review of sutures and suturing techniques", Moy RL, Waldman B, Hein DW.
7. Obstet Gynecol Sci. 2018 Jan; 61(1); 79-87, doi: 10.5468/ogs.2018.61.1.79. Epub 2018 Jan 9, "Cosmetic outcomes of cesarean section scar; subcuticular suture versus intradermal buried suture, Yang J, Kim KH, Song YJ, Kim SC, Sung N, Kim H, Lee DH.