# SubQ It! History and Use

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The traditional approach for closing incisions in human skin is to manually apply 'skin stitches' using needles and suture material or metal staples. Historically the suture material was non-absorbable such as silk or polypropylene. In recent times the trend has favored subcuticular closing using bioabsorbable, materials made from polyglycolic acid/polylactate/co- polymers [1]. There are many reviews of the various materials and techniques suggesting criteria for selecting the suture material and the best procedure for applying [2]. The decision largely depends on the surgeon's training and personal experience. However there are accepted premises that everyone upholds:

1 – Compared to continuous sutures, interrupted sutures are less likely to develop infections around the suture material [3]

2 - The further the suture material is from the surface the less likely the suture will "spit"

3 – Minimize tissue damage from clamping, cauterizing or crushing (such as with knot tying)

4 - Good eversion of skin edges leads to a more esthetic scar [4] [6]

To these I have added that capturing deep dermal tissue so that the pulling forces are away from the incised edge mitigates risk of edge separation [5] and possibly a more esthetic final scar.

For these reasons I <u>do not use</u> the classic approach of subcutaneous plus running subcuticular sutures shown in Fig 1.

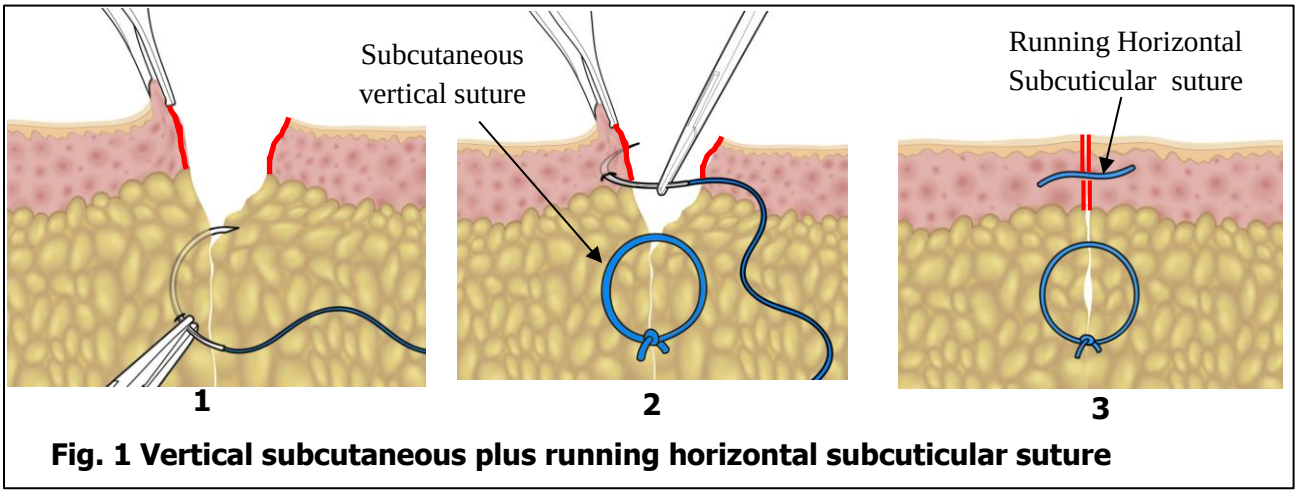



**Fig. 1 Vertical subcutaneous plus running horizontal subcuticular suture**

The alternate 'gold standard', the buried vertical mattress suture (BVMS), is shown in Fig. 2. This technique meets more of my requirements as these sutures are interrupted and provide some eversion by the way they capture dermal tissue.

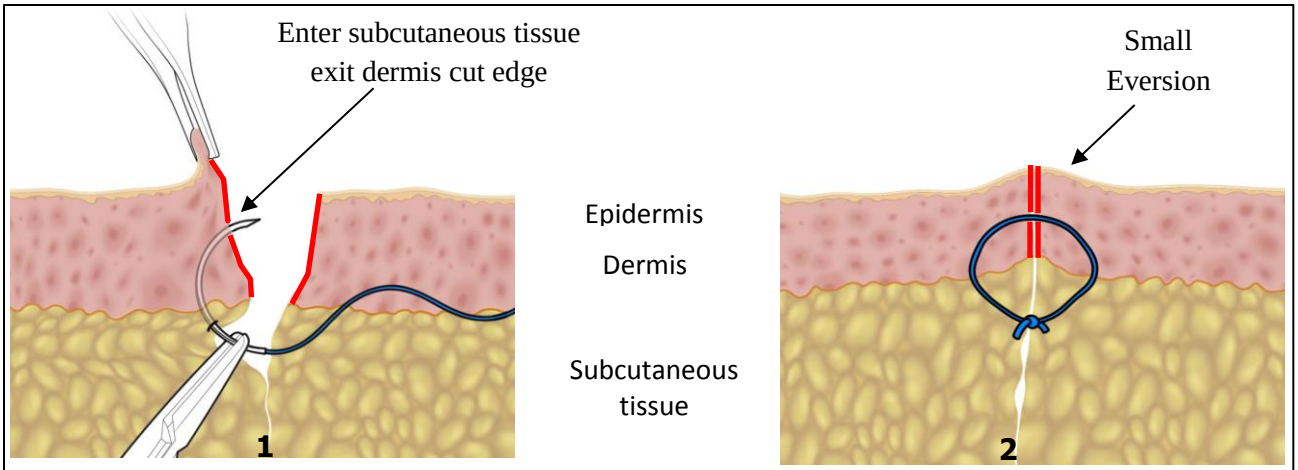



**Fig. 2 Buried Vertical Mattress Sutures (BVMS)**

Instead of these procedures, I use a skin closure technique that I first learned as a student with Dr. Robert Gross at Children's Hospital in Boston and later as pediatric surgery fellow with Dr. Judson Randolph at Children's Hospital National Medical Center in Washington, DC. I believe that the impetus for developing this technique was the universal aversion of the pediatric patient to having sutures removed.

This technique uses a bioabsorbable suture that is placed vertically; entering the underside of the dermal tissue away from the cut edge (outlined in red in Fig. 3) and passing through the dermis starting and ending in the subcutaneous layers with the knot buried in the subcutaneous tissue.

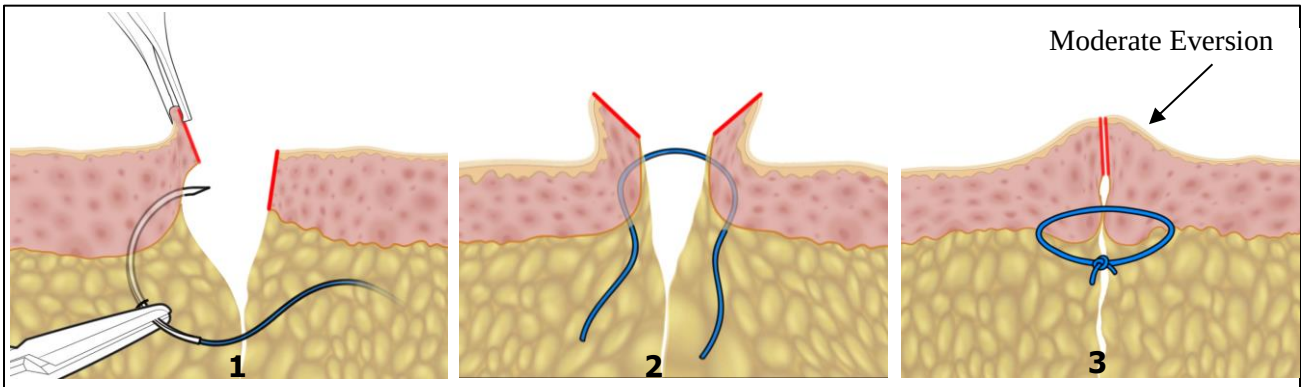



**Fig. 3 Set-back Buried Dermal Suture (SBDS)**

The interrupted sutures, when placed uniformly along the incision, provide excellent strength, good position of the skin edges and moderate eversion to provide first intention healing with excellent cosmesis. In Feb, 2010, Jonathan Kantor, MD, MSCE from Jacksonville, FL, U.S.A. wrote a letter to the editor of the Journal American Academy of Dermatology describing this exact procedure [7]. He called it the "set-back buried dermal suture" stating that it was described by him for the first time in the

literature which to my knowledge is correct. Drs Gross and Randolph only taught it to their students. Dr. Kantor noted that the set-back buried dermal suture permits aggressive minimization of dead space, encourages wound eversion, minimizes tension across the epidermal component of the wound, and because the sutures reside in the reticular dermis, there is less risk of suture spitting.

An accompanying editorial response from a respected senior surgeon and scholar was very favorable, but those of us using this technique had only our experience to rely on until October, 2013 when Dr. Wang and colleagues presented at the American Society for Dermatologic Surgery Annual meeting in Chicago, IL (later published online August 14, 2014) [4]. Wang emphasized that "in contrast with other methods, the set-back suture does not enter or exit from the wound edge. Instead, it both enters and exits from the underside of the superficial subcutis parallel to the skin surface when held in a vertical orientation. The importance of this paper is that Wang, et.al. studied the exact procedure that I have used and is the basis for the SubQ It! stapler and showed in a prospective, randomized study that compared to the standard BVMS technique this new procedure showed **superior wound eversion** and **better cosmetic outcomes** with **fewer spitting sutures**. In summary, it meets all of the premises that I described earlier.

An excellent video of Kantor's Set-back Buried Dermal Suture (SBDS) can be seen here:

https://www.youtube.com/watch?v=9XOTVZfSdtE

A summary of the three different techniques in terms of the 5 performance premises is shown in the table below:

| Performance based Premise | Conventional Subcuticular Suture | Buried Vertical Mattress (BVMS) | Set-Back Buried Vertical (SBVS) |
|---|---|---|---|
| 1. Interrupted reduces risk of infection | ✗ | ✓ | ✓ |
| 2. Away from surface to avoid spitting | ✗ | ✗ | ✓ |
| 3. Minimize tissue damage | ✓ | – | ✓ |
| 4. Good eversion | ✗ | ✗ | ✓ |
| 5. Capture deep dermal for strength | ✗ | – | ✓ |

When I began development of what we now call the SubQ It! Bioabsorbable Skin Closure System, it was clear to me that we wanted use the Set-back Buried Vertical Suture technique. This was before Kantor had published and given it this name so my biomedical engineering colleagues code-named it GRD for Gross, Randolph and Danielson (see Fig. 4a). Using the concepts that I learned from Gross and Randolph, the engineers first developed the staple, a flexible bioabsorbable device that could do the job of the suture.

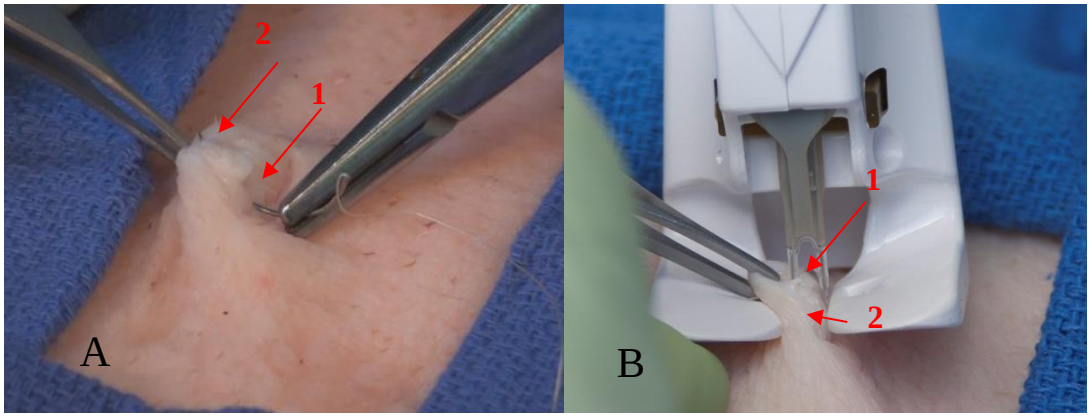



**Fig 4a** – Demonstration of GRD suture technique: needle inserted at 1 and exits at 2.
**Fig 4b** – SubQ It! fastener inserted at 1 and barbs engage at 2 (shown here on one side only for demonstration purposes).

We measured and painstakingly reproduced the geometry of the manual technique in a stapler using surgical needles inserted through the legs of the staple to pierce the dermis and install the staple (Fig. 4b). To obtain this result with SubQ It! the surgeon uses Adson forceps to grasp tissue from both sides of the incision simultaneously. As in the manual technique, the forceps lift the tissue to expose the sub-surface of the dermal tissue. The forceps are placed in forceps locator indentations to precisely position the tissue so that the needles enter the dermis just back from the cut edge.

The drawings in Fig. 5a – 5d show the incision in cross section to demonstrate how SubQ It! works. To minimize the mass of plastic in the wound, the staple has hollow legs connected by a tiny flexible bridge. Specially shaped needles are inserted through the legs which provide the strength and sharpness to pierce the dermis and deploy the SubQ It! fastener. After insertion, the needles are retracted leaving the staple in place.

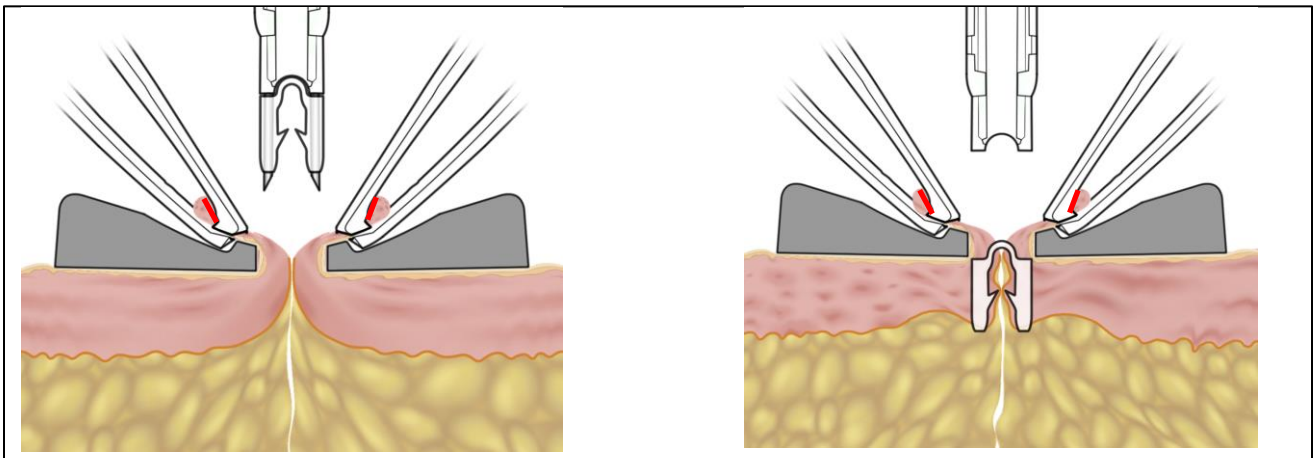


**Fig. 5 (a) Tissue everted, placed in locators; (b) Staple deployed and needles retract**

In Fig. 5 (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 and the tissue rotates to place the skin edges in apposition.

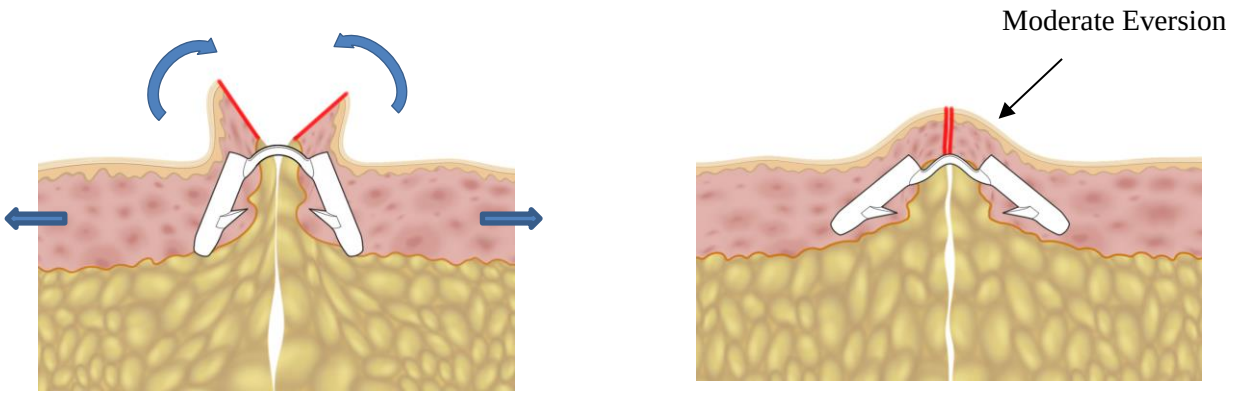



**Fig. 5 (c) Stapler removed, tissue begins to relax; (d) Barbs engage, staple brings edges together**

Comparing Fig. 5(d) with the manual GRD suture of Fig. 3 shows the similarity in concept. The SubQ It! meets all of my initial requirements. Additionally the SubQ It! fastener does not use knots. The knots of the manual suture unavoidably will crush the tissue that it is opposing, leading to local ischemia and more of a reparative response of the tissue. Mechanical tension on the wound has been identified as a leading cause of hypertrophic scarring [8]. The barbs of the SubQ It! fastener engage the tissue without a crushing action and are relatively far from the cut edge, where the vascular bed is undisturbed, minimizing the body's reaction to the suture.

For the SubQ It! staple to perform as designed subdermal closure is not necessary and actually hinders the designed function of the staple. Approximation of the subcutaneous fat to close dead space is appropriate at the surgeon's discretion - but sutures should be placed 1-2cm below the skin surface. SubQ It! fasteners work best when the edges of the incision remain separated approximately 1cm (see Fig. 6 left photo). This is because the correct functioning of the SubQ It! fastener requires the natural pull-back of the tissue to engage the barbs. Further relaxing and pulling back of the tissue by the staple serves to rotate the skin edges together as shown in Fig.6.

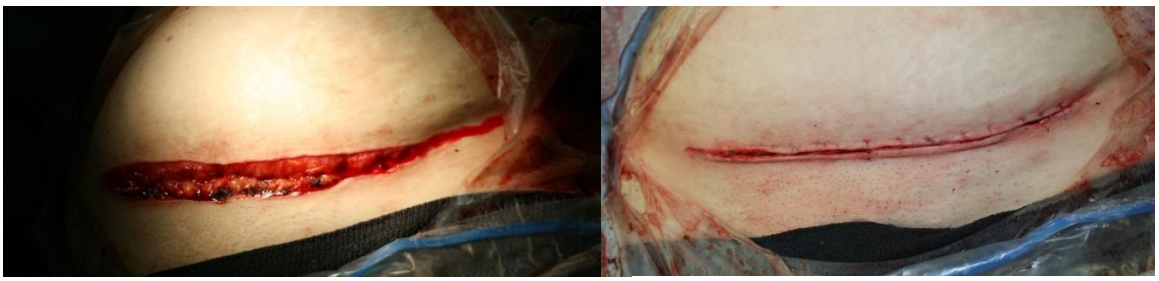


Fig. 6 C-section with previous scar removed

Immediately after closing with SubQ It!

SubQ It! fasteners should be placed approximately 1 cm apart in a regular pattern to give the most uniform distribution of forces to the closure. Because of the vertical orientation of the deployment additional staples can be added as needed to the closure. If there is no interference from subcutaneous stitches the amount of eversion is determined by the surgeon according to how much tissue is grasped in the Adson forceps.

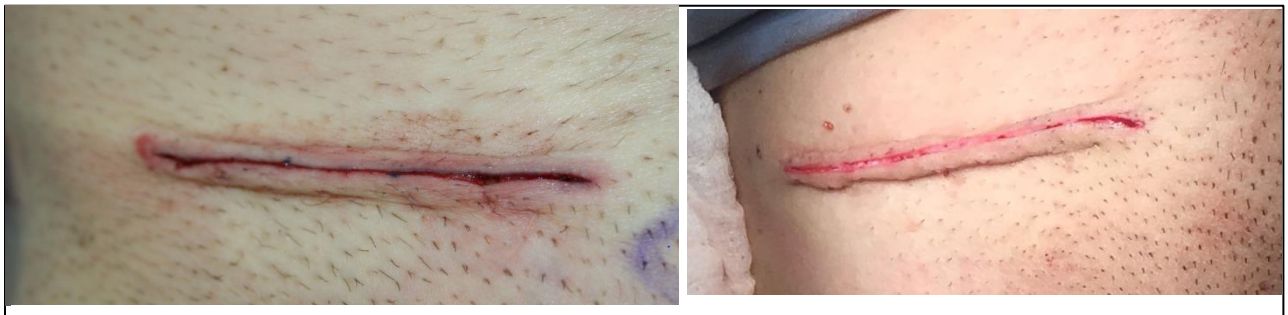


Fig. 7 Control of eversion (a) grasp 2-3 mm = Moderate eversion (b) 4-5mm = More eversion

Finally I want to discuss the strength of the SubQ It! closure that allows it to replace both the subcutaneous sutures and the subcuticular sutures with a single course of staples. Subcutaneous sutures are not needed for strain relief because every SubQ It! fastener independently engages the very strong dermal tissue (Fig. 8). Each staple that is placed adds approximately 10 Newtons (1 kg) of holding force to the closure (Fig 9).

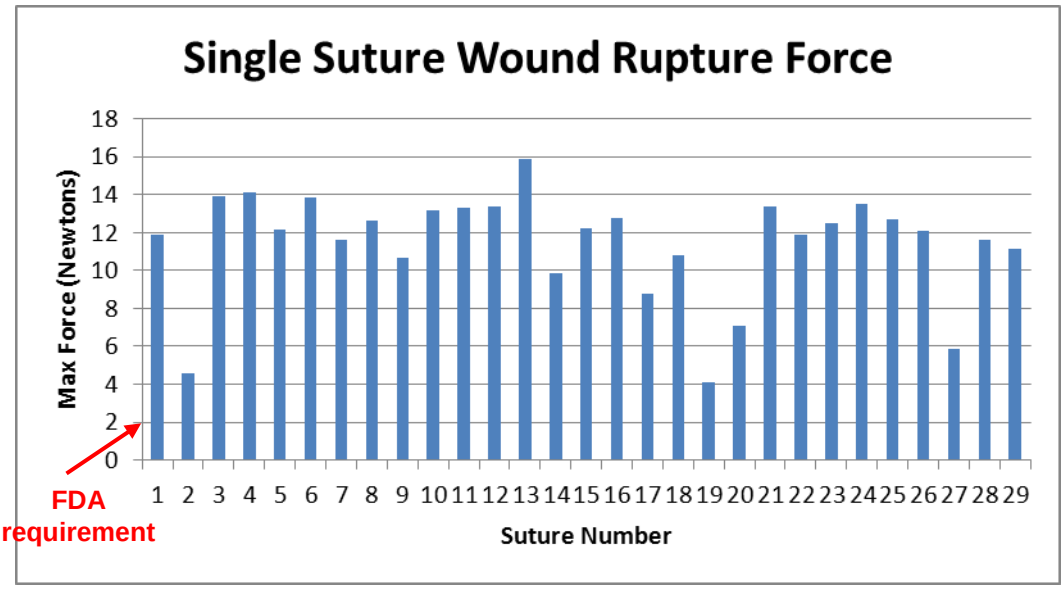



Fig. 8 Force to rupture wound when closed with a single SubQ It! fastener

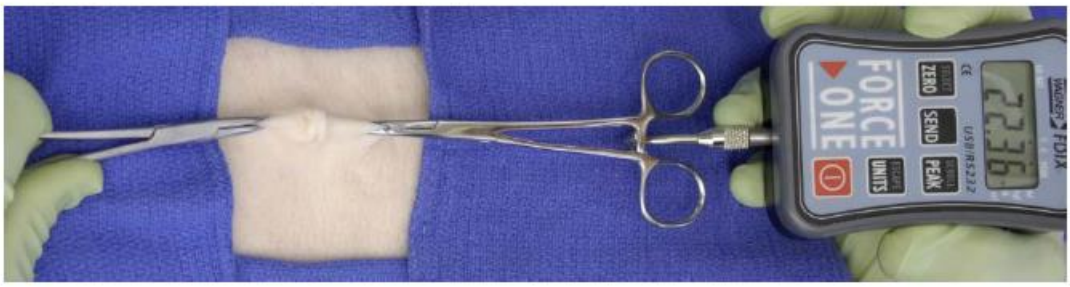
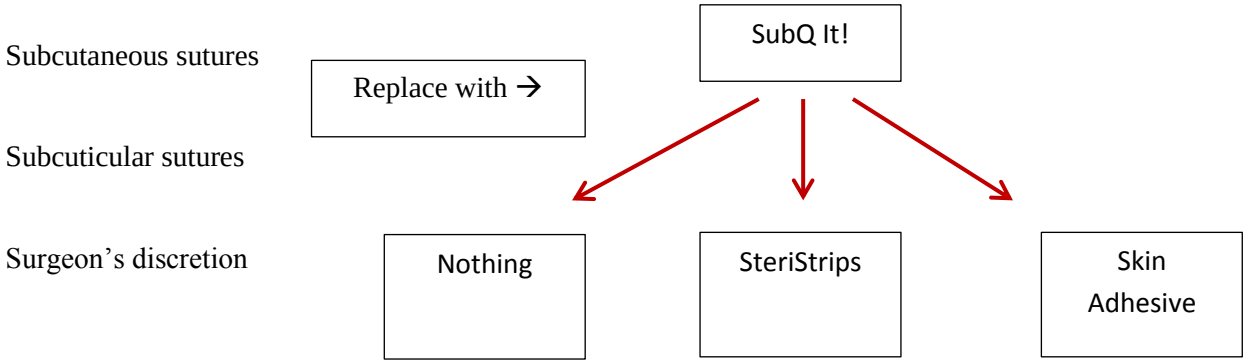



Fig. 9 Strength is additive. Two (2) staples hold 22.36 Newtons

Furthermore, additional subcuticular sutures are not needed for edge apposition because the SubQ It! brings the edges together as the tissues pull back (with superior cosmesis as Wang demonstrated). If additional edge treatment is desired, SteriStrips or Skin Adhesive may be used (see Fig. 9).




Nothing

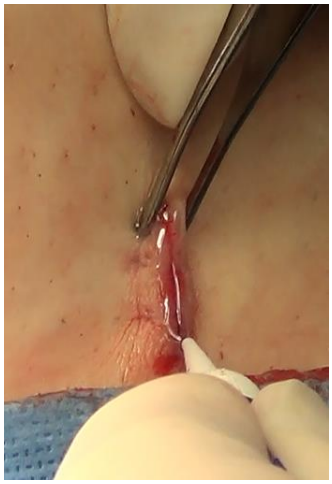
SteriStrips

Skin Adhesive

Short incisions such as used in Minimally Invasive Surgery (MIS) can also be closed with SubQ It! as the staple is delivered vertically.

Nothing

SteriStrips



Skin Adhesive

Once the SubQ It! stapler was approved by the U.S. FDA, I began using it on a variety of surgical cases. My colleagues and I have had excellent results on both laparoscopic (see Appendix A) and longer incisions (see Appendix B) [9]. There is a learning curve for first-time users but once you and an assistant have used it a few times, I think you will find it an excellent addition to your surgical procedures.

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Excellent video of Kantor’s set-back (GRD) suture

https://www.youtube.com/watch?v=9XOTVZfSdtE

## Appendix A – Laparoscopic Incisions

Laparoscopic Ventral Herniorrhaphy

11 days

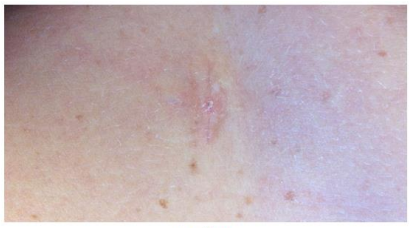
47 days

Laparoscopic Cholecystectomy

22 days

45 days

Laparoscopic Cholecystectomy



22 days

45 days

Laparoscopic Cholecystectomy

16 days

44 days

Laparoscopic Cholecystectomy

15 days

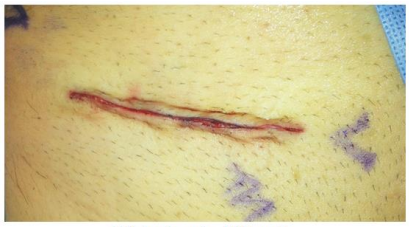
47 days

## Appendix B – Longer Incisions

Femoral Lymph Node Biopsy

8 days

44 days

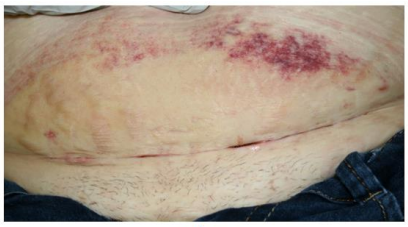


Right Inguinal Hernia

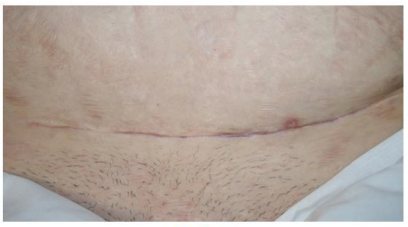
15 days

42 days

C-Section



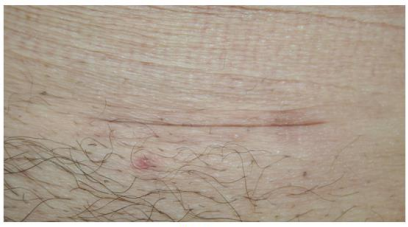
7 days



42 days

Left Inguinal Hernia

15 days



48 days