Cost Benefit Analysis of the SubQ It! Bioabsorbable Skin Closure System[1]

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Objective: This study reviews the costs and benefits of using SubQ It! for closing surgical incisions compared to conventional methods and devices.

Introduction: The expanding emphasis on outcomes and cost containment in health-care has stimulated the search for new technologies including improved methods for closing surgical incisions. The use of metal staples (estimated at 8 million procedures per year in the US) is under scrutiny to change to other modes of skin closure. This recommendation is based on several concerns including the higher overall health care system cost of returning to remove the staples which more than cancels the savings of time during surgery [1]. In addition there is an increased risk of wound infection with the metal staple. Figueroa, et.al. [2] in a 2013 study from the University of Alabama at Birmingham, compared surgical staples with subcuticular sutures after Cesarean delivery (one-third of all US pregnancies and the most common major surgical procedure performed in the US). The study showed that the cumulative risk of wound disruption or infection was 14.5% for staples and 5.9% for sutures (P=.008, relative risk 2.5, 95% CI 1.2–5.0). Similarly, Talat, et.al. [3] compared staples to subcuticular sutures after Coronary Artery Bypass Graphs and found significantly greater (P=0.05) rate of sternal wound infection with staples and overall better outcomes with subcuticular sutures.

Figure 1. Metal skin staplers pierce the external surface of the skin and must be removed.

The traditional alternative is subcuticular suturing with bioabsorbable material. These techniques require increased time, are technically challenging and include the risk of "needle stick". In addition this manual technique is particularly challenging for the short incisions used in Minimally Invasive Surgery (MIS) procedures. MIS now represents over 25 percent of surgeries in the US and is growing at a rate of 3-5% per year [4]. As metal staples are not acceptable to most patients and surgeons, many surgeons are using the hand suturing technique (see Figure 1) This requires working inside the small incisions to access the dermal layer (1-2 mm thick) without piercing the top surface, and maintaining good orientation of the edges when the suture is tied.

Figure 2. Subcuticular hand-stitch using bioabsorbable suture material.

As a result of the above issues other techniques such as skin adhesives, (e.g. 2-octyl cyanoacrylate) have been introduced by a number of surgical supply companies to close incisions (see Figure 3). These products are being increasingly used [5] due to perceived speed

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and simplicity offered in wound sealing. The adhesive procedure, however, holds the tissue together only at the epidermis and requires sub-dermal approximation to insure a durable closure. In addition the manufacturer recommends that the wound be manually held in apposition for approximately one minute for the glue to dry and secure the bond thus negating much of the time saved as compared to manual closure.

Figure 3 Dermabond® skin adhesive is applied above the incision.

Furthermore Harold et.al [6] studied 137 wounds of 48 patients comparing manually applied Vicryl® sutures to cyanoacrylate tissue adhesive and skin tape. With strong statistical significance, they reported that Cyanoacrylate tissue adhesive yields poor results with respect to both wound healing and pain. Vicryl (bioabsorbable) sutures provided superior results to the other methods in terms of scar formation and comfort with the only down-side being that hand suturing takes more time.

New Technology: The SubQ It! disposable stapler system is preloaded with ten (10) bioabsorbable fasteners that, due to its unique delivery device, has the ability to deploy the fasteners into small 5-15mm incisions as well as longer incisions (see Figure 4). Furthermore the design elements of the stapler allow the surgeon to precisely position the tissue, which can be challenging in closing MIS incisions.

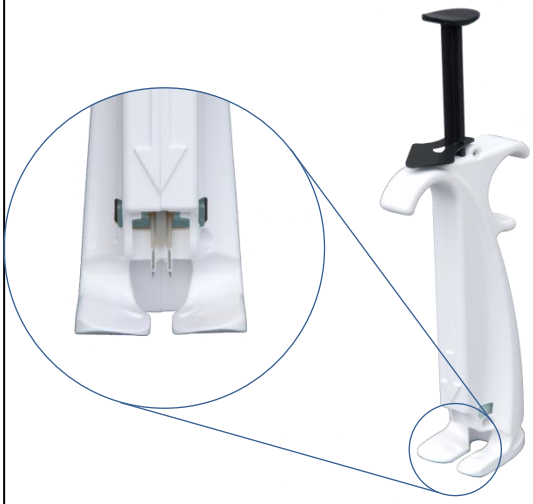

Figure 4. SubQ It! Stapler

Once the surgeon positions the two sides of the incision in the foot of the stapler, pressing the plunger delivers a fastener uniformly into the underside of the dermis. The fastener has two barbed legs connected by a flexible “bridge” (see Figure 5). The barbs engage in the dermis and the bridge holds the two edges in approximation by tension, similar to a traditional manual suture. Because the fastener is biodegradable and deployed subcutaneously, the staples do not need to be removed. The time to close the wound is comparable to using a metal stapler.

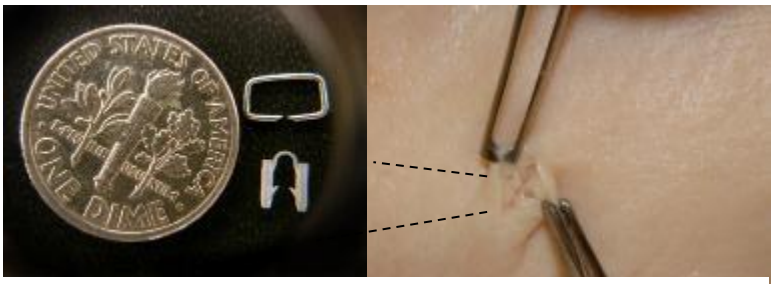

Figure 5. SubQ It! Fastener and standard surgical staple

Estimating Costs: The cost of the devices used for closing surgical incisions varies according to supplier contracts and quantities purchased. For purposes of this analysis the costs shown in Table 1 were taken from the referenced studies discussed below applied uniformly.

The times to close an incision used in Table 1 were obtained from Hargreaves [1] for manual stitches, skin adhesives and surgical staplers. Feese CA, et.al. [7] reported closing times for C-sections comparing metallic and absorbable staples. One of the dominant costs in this analysis is the Operating Room charge. According to a 2005 survey, OR time in the U.S. averaged $62/min (range: $22 to $133/min) [8], which does not include the anesthesia provider fee. Even using the minimum cost figure of $22/minute, the average savings of 5 minutes for SubQ It! shown in Table 1 provides over $100 in savings over manual sutures (the original reason for the widespread adoption of staplers). This significant savings still has a value to the surgeon and the hospital, and to the patient who doesn't need to return for the sole purpose of having the staples removed. The cost of an office visit for staple removal, whether borne by the patient, health insurance, or included in the surgeon's fee, is estimated at $200 [9] which does not include the cost to the patient for lost time or transportation.

Results: The results of the cost analysis are summarized in Table 1 and Figure 6. These data show that the cost of the devices is less significant than the costs incurred in using them. It also supports the observations discussed above that are discouraging the use of metal staplers. Therefore choice of the technology should consider factors other than the initial cost of the device.

Table 1. Cost estimates for closing incisions by various techniques

Method / Technology	Device Cost	OR Time (minutes)	OR Cost $62/min	Return/ Remove	Total
Bioabsorbable Sutures	$5	8.45	$524		$537
Metal Staplers	$9	2.76	$171	$200	$383
Adhesives	$24	4.49	$278		$307
SubQ It!	$40	3.51	$218		$261

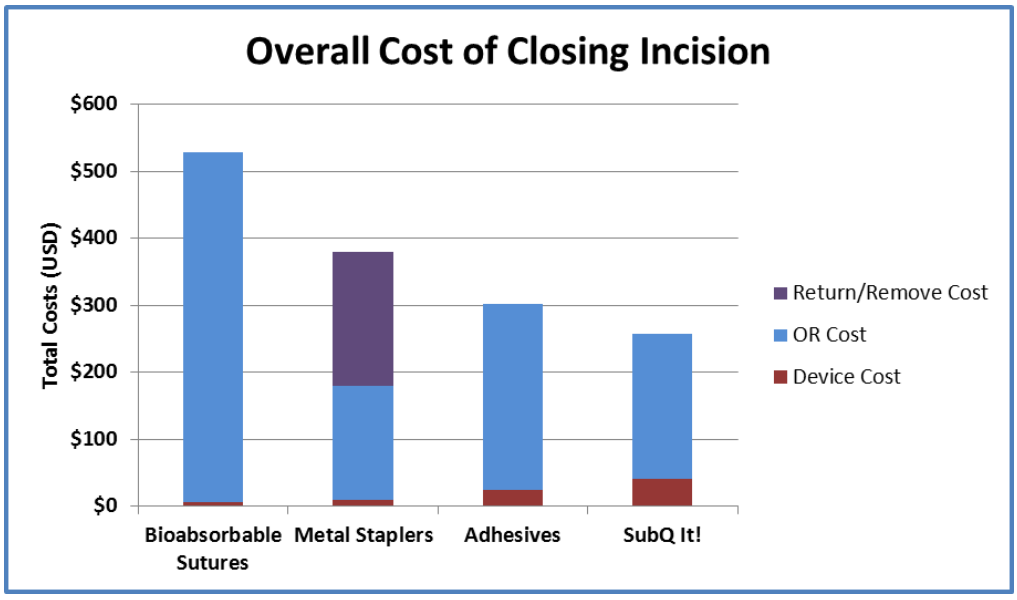

Figure 6. Cost comparison of different methods for closing incisions

Additional savings are expected to be demonstrated for SubQ It! due to a lower risk of infection/disruption versus Metal Staplers not shown in the analysis above. The costs of treating an infected incision can be thousands of dollars. Figueroa [2] showed that subcuticular sutures, unlike metal staples which violates the epidermis, have a significantly lower incidence of infection. Similar studies with SubQ It! are not yet available but SubQ It! has a risk profile similar to manual subcuticular sutures, so it is expected to have lower rates of infection resulting in further cost savings.

Nitsche, et.al reported a retrospective study of almost 200 patients comparing in-hospital analgesic use after cesarean section between patients who underwent skin closure with metal staples versus subcuticular absorbable polyglycolic acid staples (similar to SubQ It! fasteners). They found that the decreased use of ketorolac associated with the Subcuticular absorbable staples would result in a cost savings of approximately $200 per patient even after considering the higher cost of the absorbable staple device [10].

A very real but harder cost to quantify is needle stick injury. The Centers for Disease Control and Prevention (CDC) estimates that 24% of all sharps accidents involve suture needles [11]. Direct costs of accidental needle stick include (a) cost of baseline and follow-up laboratory testing of the exposed healthcare worker and testing the source patient, and (b) cost of post-exposure prophylaxis (PEP) and other treatment that might be provided. The CDC provides a workbook and a procedure [12] to use such costs to justify adoption of a new product that provides safeguards against sharps injuries such as SubQ It!

Discussion: Based on the above analysis the overall cost of SubQ It! is lower when comparing it to other conventional methods due to the time savings. If one completely discounts the value of time savings and considers only the cost of the SubQ It! stapler, it is more expensive per procedure by $15-28. However this cost is easily justified if incidence of infection, treatment for wound rupture, reduced analgesic use, and/or needle sticks is taken into account. These are not considered in Table 1 or Figure 6 but represent significant savings from only a few percentage points reduction in incidence.

In addition, SubQ It! offers qualitative benefits to both patients and surgeons. Patients have expressed relief in knowing that they will not need to return to have metal staples removed. Patients also appreciate the improved cosmesis associated with subcuticular closures versus the ‘railroad track’ scars of metal staples. In a study of fifty (50) patients on whom SubQ It! had been used, appearance of their scars as judged by the patient was 1.3 on the average (0-best, 10-worst) at the first post-op visit and 0.7 at the second visit [13].

A review of surgeons preferences, although anecdotal, reflects a pervasive trend away from the use of metal staplers (with a wry comment by one surgeon “unless it is after 6PM”). Surgeons benefit from using SubQ It! as it achieves the simplicity and time savings offered by metal staplers without the inconvenience of patients not being able to bathe while they are in place and having to return for staple removal. SubQ It! also provides the ease of use without the risk of rupture sought by surgeons who have tried skin adhesives. Surgeons who routinely do subcuticular dermal suture closure appreciate other features of SubQ It!. For example, being able to simultaneously raise both sides of the incision to assure alignment has significant benefits versus having to enter one side and then match it on the other. SubQ It! also offers the

surgeon excellent visibility and ease of placement in short MIS incisions and the flexibility to close longer incisions moving from one end to the other or from the middle out with complete freedom of placement.

Conclusions: The SubQ It! bioabsorbable skin closure system has lower overall costs when compared to conventional methods for closing surgical incisions. The benefits to the patient and surgeon are compelling and the device cost, while slightly higher than other devices, is justified by the savings in time and other related costs to make SubQ It! a cost effective product choice.

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