

## Evaluation of a Subcutaneous Bioabsorbable Fastener for Closing Incisions<sup>1,2</sup>

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**Objective:** The goal of this study was to assess patient outcomes after closing incisions in a variety of procedures with the SubQ It! bioabsorbable skin closure system.

**Background:** The SubQ It! disposable stapler system is preloaded with ten (10) bioabsorbable fasteners and has the ability to deploy its fasteners into small 5-15mm incisions as well as longer incisions (see Figure 1). Unique design elements of the stapler allow the surgeon to precisely position the tissue, especially important in closing MIS incisions. Once the surgeon positions the two sides of the incision in the foot of the stapler, pressing the plunger delivers a fastener into the underside of the dermis. The fastener has two barbed legs connected by a flexible “bridge” (see Figure 2). 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.

**Methods:** The SubQ It! skin closure system was assessed in two studies by seven (7) participating surgeons at the Northern Vermont Regional Hospital. The first study included twenty-two (22) patients and a second study had twenty-eight (28) patients. The study protocol provided inclusion criteria that encouraged use in a large variety of surgical procedures. Surgeons offered the closing technique to their patients and obtained informed consent prior to surgery. Altogether sixteen (16) different procedures were performed; eight (8) laparoscopic and eight (8) “other” procedures having longer incisions (see Table 1).

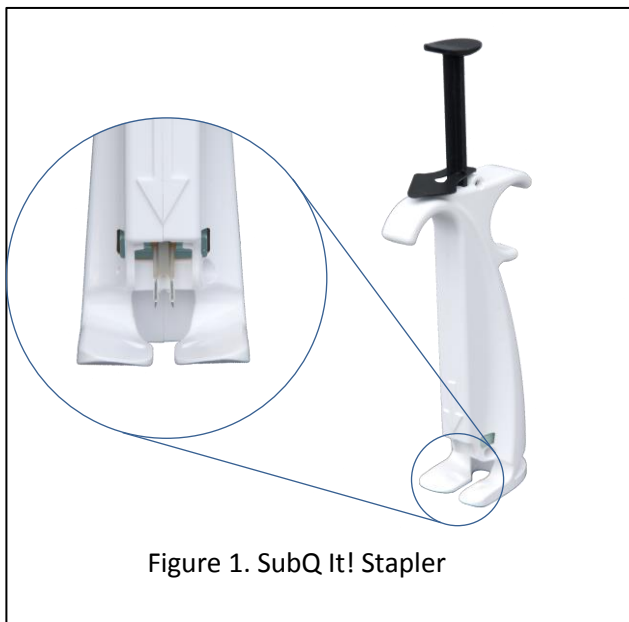


Figure 1. SubQ It! Stapler



Figure 2. SubQ It! Fastener and standard surgical staple

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<b>Table 1. Sixteen (16) Different Procedures</b>	<b>Number Patients</b>
<b>Laparoscopic Procedures</b>	
Femoral Lymph Node Biopsy	1
Laparoscopic Inguinal Herniorrhaphy	2
Laparoscopic Cholecystectomy	10
Laparoscopic Ventral Herniorrhaphy	5
Laparoscopic Nissen Fundoplication	1
Laparoscopic Umbilical Hernia Repair	1
Laparoscopic Assisted Vaginal Hysterectomy	2
Laparoscopic Tubal Ligation	4
<b>Other Procedures</b>	
Carotid Endarterectomy	1
C-Section	4
Inguinal Herniorrhaphy (Left and Right)	8
Exploratory Laparotomy	1
Breast Lumpectomy	1
Infusion Port Placement	3
Thyroid Lobectomy	1
Umbilical Herniorrhaphy	5
<b>Total</b>	<b>50</b>

Photographs were taken prior to dressing the wound and at follow-up visits 1 and 6 weeks after surgery (see Appendix A and B). Patients rated wound pain and appearance using an analog scale for each incision (0=no pain, 10=worst pain imaginable; 0=looks great, 10=looks terrible). Physicians rated each incision at the same time points using the Hollander wound evaluation scale<sup>3</sup> (HWES 0-6 scale, where 6 is a perfect score).

**Results:** Altogether the SubQ It! stapler was used to close 116 incisions using 457 bioabsorbable fasteners. Results from the two studies were in good agreement (see Table 2). Seventeen percent (17%) of the incisions had some bleeding / wetting of the dressings. Two percent (2%) of patients reported infection at any time post-surgery. Wound separation was noted in 2% of the incisions. Pain at its worst averaged 4.6 (0=no pain, 10-worst) and decreased to 1.4 at time of the first post-op visit and to 0.4 at the second visit. Appearance 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.

<sup>3</sup> Hollander JE, Singer AJ, Valentine S, Henry MC. Wound registry: Development and validation. *Ann Emerg Med.* 1995;25(5):675-685

Table 2.	Study 1		Study 2		Combined
Number of Surgeons	6		6		7
Number of Patients	22		28		50
Laparoscopic cases	11		15		26
Other cases	11		13		24
Number of Incisions	56		60		116
Number of Fasteners	229		228		457
Days to PO#1	12		13		13
Bleeding	24%		12%		17%
Infection	3%		2%		2%
Wound Separation	3%		2%		2%
Worst Pain	4.5		4.7		4.6
Pain at Post Op #1	1.4		1.3		1.4
Appearance at PO#1	1.3		1.1		1.3
HWES Score at PO#1	5.4		5.8		5.6
Days to PO#2	30		42		37
Pain at Post Op #2	0.5		0.3		0.4
Appearance at PO#2	0.7		0.5		0.7
HWES Score at PO#2	5.6		5.9		5.7

Physician scores of appearance using the HWES averaged 5.6 (0-worst, 6-best) at the first post-op visit and 5.7 at the second visit (see Figures 3 and 4).

**Conclusions:** Pain appeared acceptable as it related to the procedure performed. Drainage and incidence of infections were comparable to other subcuticular wound closure methods. Final overall appearance and HWES scores were excellent. Although developed for closing short laparoscopic incisions, the SubQ It! subcuticular skin closure system has the potential to be applied in a broad range of skin closures.

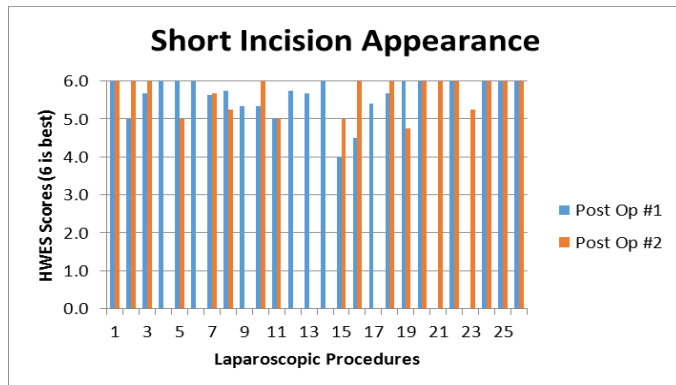


Figure 3. Hollander Wound Evaluation Scores (6 is best) for 26 laparoscopic procedures.

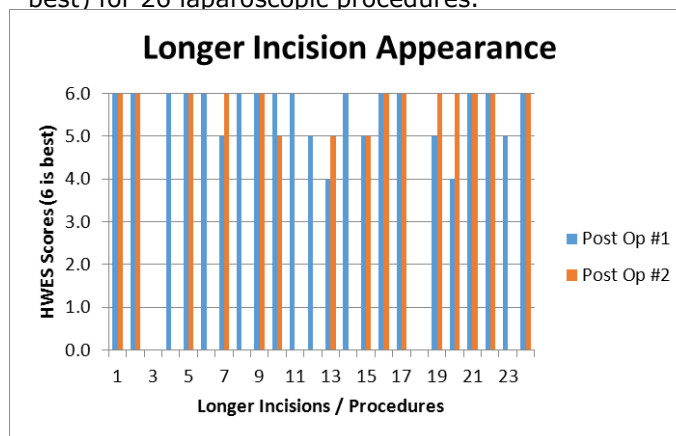


Figure 2. Hollander Wound Evaluation Scores (6 is best) for 24 other general surgical procedures.

## Appendix A – Laparoscopic Incisions



Laparoscopic Ventral Herniorrhaphy



11 days



47 days



Laparoscopic Cholecystectomy



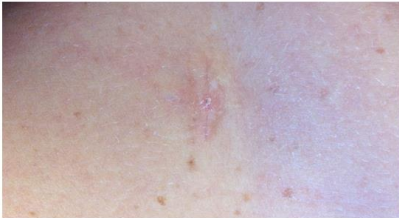
22 days



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**



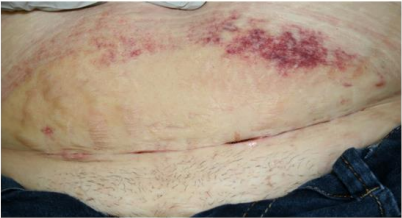
**15 days**



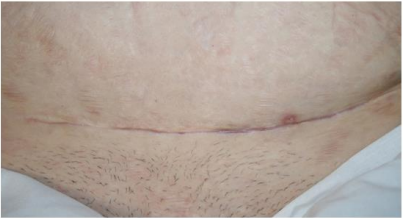
**42 days**



**C-Section**



**7 days**



**42 days**



**Left Inguinal Hernia**



**15 days**



**48 days**