Clinical Experience With Subcuticular Absorbable Staples for Wound Closure in Multiple Surgical Specialties

Observations of Improved Outcomes With Decreased Complications, Reduced Overall Costs and Increased Patient Satisfaction

Contributing Authors:

Contributing authors and additional commentary are listed below.

Summary

We have evaluated a proprietary absorbable subcuticular skin staple to observe its clinical performance in terms of safety, efficacy, wound healing, associated complications, cosmesis, patient satisfaction and clinician safety, as well as its overall cost-effectiveness in a range of surgical procedures in the following surgical specialties: Obstetrics, Gynecology, General, Transplant, Head & Neck (ENT), Breast, Oncology, Colo-rectal, Vascular, Thoracic, and Orthopedic surgery. Each of the contributing authors has used the absorbable subcuticular skin stapler for a minimum of 50 surgical procedures for at least a 2 year period. The subcuticular closures with absorbable staples were closely approximated and offer the clinical benefit of an interrupted closure with excellent skin eversion, no apparent inflammatory reaction, and a notably improved and faster wound healing with pleasing cosmetic results. We have experienced either no increase or a significant decrease in wound complications, including surgical site infections, hematomas, seromas and wound disruptions. In addition, many of the authors have observed a reduction in the recurrence of keloids and hypertrophic scars in patients with prior surgeries. We found the single operator closure technique to be simple, rapid and time-effective, saving significant operative and anesthesia times compared to suturing with closure times equivalent to percutaneous metal staples. The absorbable subcuticular staple eliminates the inconvenience, cost, anxiety and discomfort of percutaneous metal staple removal. Our experience with absorbable subcuticular staples has demonstrated improved clinical and economic outcomes with less-complicated, low maintenance wounds, resulting in a significant savings to the institution. The subcuticular stapler is a safety device, eliminating the risk of needlestick injuries. We have been especially pleased with the expression of patient satisfaction due to comfort, cosmesis and the convenience of this absorbable subcuticular closure modality, and we now routinely use the device in our surgical practice.

Background

The objectives of surgical wound closure are safe, efficacious, comfortable, cost-effective outcomes with minimal complications, good cosmetic results and a high degree of patient satisfaction. Although not given a high exposure in most operating suites, we have found that the choice of skin closure modality does have a significant effect on the clinical and economic outcomes of a surgical procedure. Prior to the introduction of the absorbable subcuticular skin stapler for the closure of longer incisions, clinicians only had the choice of a time-consuming subcuticular continuous suturing or a time-effective percutaneous interrupted metal skin stapling. The absorbable subcuticular skin stapler (INSORB® Absorbable Subcuticular Skin Stapler, Incisive Surgical, Inc., Plymouth, MN) provides a new alternative that combines the benefit of a rapid interrupted closure modality with the benefit of a subcuticular closure modality. This paper presents our experience and observations of clinical and economic outcomes associated with subcuticular absorbable staples in various procedures and surgical specialties. We evaluated this new skin closure modality to determine its efficacy, cost-effectiveness, safety and patient satisfaction in our various surgical practices, and now routinely use the device in our surgical procedures.

Materials and Methods

The absorbable subcuticular staples are comprised of a polylactide-polyglycolide co-polymer with an established history in wound closure. The polymer is broken down by hydrolysis and is essentially absorbed in 90-120 days. The dimensions of the U-shaped staple are 3.5mm x 5.0mm. There are hooks at the two distal ends to secure the dermal tissue.
The stapler is a sterile, single patient use device that contains 30 absorbable staples, sufficient to close up to a 21 cm incision. The device utilizes a novel method to precisely present the dermis and then place an absorbable staple in a horizontal, subcuticular, and interrupted fashion to provide a secure, well approximated and everted skin closure.

Absorbable Subcuticular Skin Staple & Stapler

Each of the contributing authors of this paper has used the absorbable subcuticular skin staples for more than 2 years in over 50 procedures in various procedures in the following specialties: Obstetrics, Gynecology, General, Transplant, Head & Neck (ENT), Breast, Oncology, Colo-rectal, Vascular, Thoracic, and Orthopedic surgery.

Observations

The absorbable staples provide secure and uniform wound closure with minimal wound complications, including wound separation, seroma, hematoma, infection, or other complications. Wound closure with absorbable staples eliminated the need for staple removal as required with percutaneous metal skin staples and the potential for 'railroad track' scars. Patients remark on the comfort and cosmetic result of the closure, particularly patients who have had previous surgical procedures with percutaneous metal skin staples. In addition, many of the authors have observed a reduction in the recurrence of keloids and hypertrophic scars in patients with prior surgeries.

Pfannenstiel Incision
(different patients)

INSORB Absorbable Subcuticular Staples

Closures with absorbable staples result in uniformly approximated and everted wound edges with secure interrupted staples and no percutaneous injury. These comfortable wounds heal quickly with little or no apparent erythema and inflammation and excellent cosmetic appearance. Many of the contributing authors have observed more rapid and improved wound healing with absorbable subcuticular staples.

Midline Incision

INSORB Absorbable Staples  Percutaneous Metal Skin Staples

Increased wound drainage is apparent with these closures, often seen as wetter dressing at the first dressing change. There is no apparent inflammatory response and this early drainage is likely permitted by the interrupted placement of these staples and the absence of compression as seen with percutaneous metal staples or continuous suture.

We have experienced either no increase or a significant decrease in wound complications, including surgical site infections, hematomas, seromas and wound disruptions. The rapid and efficient single operator closure technique reduces operative and anesthesia times compared to suturing and, with experience, equivalent to percutaneous metal skin staplers. We have found...
that the patients remarked that the absorbable skin staple closures were ‘comfortable’. Absorbable staples eliminate the inconvenience, cost, anxiety, and discomfort of staple removal.

**Discussion**

Subcuticular closure of wounds has been recognized as providing superior patient comfort and cosmetic results compared to metal staples that create uncomfortable percutaneous insult that can lead to infection and ‘cross-hatching’ scars, i.e., ‘railroad track scars’. Subcuticular suture closure is a time consuming technique that extends operative and anesthesia times. Further, a continuous suture closure is contraindicated in suspected contaminated wounds due to the risk of inoculation or spread of infection along a suture line, i.e., suture track infection. The absorbable subcuticular staples provided rapid, uniform, secure, and unnecessary trauma, discomfort, disquieting appearance, and inconvenient and sometimes painful metal staple removal. We have observed minimal inflammatory response to the subcuticular absorbable staples, which has been noted in other studies [1-7]. We consistently achieve precise approximation and pronounced wound eversion with the absorbable subcuticular staple that cannot be achieved with a continuous running suture. The literature clearly shows that “[b]ecause scars tend to retract over time, eversion of the wound edges at the time of closure promotes less prominent scarring” [8]. We believe an absorbable subcuticular skin closure provides precise approximation and wound eversion without wound edge tension which is essential to ensure primary healing and minimal scarring.

**Total Hip Arthroplasty**

- **INSORB Absorbable Subcuticular Staples**
- **Percutaneous Metal Skin Staples**

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**Conclusions**

Our clinical experience with the absorbable subcuticular stapling modality has demonstrated improved clinical outcomes, observed improved wound healing, reduced complications, increased patient satisfaction, and greater safety and efficiency with overall cost reduction for providers. The absorbable skin staple provides the clinical benefit of both a time-effective subcuticular skin closure modality and an interrupted skin closure modality, and has become our preferred method for routine skin closure.

1) “Following closure with subcuticular staples, the wounds demonstrated less infection, less inflammation, and acceptable cosmesis compared to subcuticular suture closure. Although the wound infection rate with subcuticular absorbable staples was similar to that of percutaneous staples, percutaneous staples cause peri-wound injury and inflammation, can be uncomfortable, and require removal that can be painful. These results suggest that subcuticular absorbable staples may be a superior alternative for the closure of skin incisions.” Piñeros-Fernandez A, Salopek LS, Rodheaver PF, Rodheaver GT. “The Influence of Skin Closure Modalities on Infection: A Comparison of Absorbable Subcuticular Staples, Continuous Subcuticular Absorbable Suture, and Percutaneous Metal Skin Staples in the Closure of Contaminated Wounds,” Journal of Long-Term Effects of Medical Implants, 22(2): 145-155 (2012).


3) “A resorbable subcuticular staple system can provide comparable wound closure to stainless steel staples following total hip replacement and may do so with less local discomfort or erythematous reaction.” Fisher DA, Bengero L, Clapp B, Burgess M: “A Randomized, Prospective Study of Total Hip Wound Closure With Resorbable Subcuticular Staples,” Orthopedics, September 2010.

4) “Although our experience is early and limited, we conclude that absorbable subcuticular staples are secure and effective, and preferable to metal staple closures even in renal transplant recipients receiving steroids and sirolimus.” Tellis V. “Renal transplant incision closure using new absorbable subcuticular staple device,” Clinical Transplantation, 2007: 21: 410-412 DOI: 10.1111/j.1399-0012.2007.00661.x.

5) “Incisional complications [in this IRB-approved study of 500 consecutive cesarean deliveries] were one hematoma, no seromas, and no wound disruptions. The overall surgical site infection rate of 1.2% varied with risk factors. These were low maintenance wounds that patients found comfortable and aesthetically pleasing. Absorbable subcuticular staples provide efficient and uncomplicated wound closures associated with a high level of patient satisfaction.” Shibley KA, Bion J, Brearley AM. “500 consecutive cesarean deliveries closed with subcuticular absorbable staples,” presented at the ACOG Annual Clinical Meeting, May 2012.


7) “[W]e conclude that absorbable subcuticular staples are secure and effective and are preferable to routine closures with percutaneous metal staple closures due to the patient stated preference and increased satisfaction.” Shibley, KA:“Skin closure with subcuticular absorbable staples in obstetric and gynecologic surgery is associated with increased patient satisfaction,” Incisive White Paper.

Contributing Authors/Additional Commentary:

K. Anthony Shibley, M.D., F.A.C.O.G., OBGYN Specialists, P.A., associated with the University of Minnesota/Fairview Health System, Edina, MN.

“Results presented at the Annual Meeting of the American College of Obstetricians and Gynecologists from a retrospective chart review of 500 consecutive cesarean deliveries closed with subcuticular absorbable staples found that incisional complications were one hematoma, no seromas, and no wound disruptions. The interrupted placement of the absorbable staples permits immediate post-operative drainage and avoid infection provoked by inoculation and contamination along a continuous suture line. The overall surgical site infection rate of 1.2% varied with risk factors. These were low maintenance wounds that patients found comfortable and aesthetically pleasing. Absorbable subcuticular staples provide efficient and uncomplicated wound closures associated with a high level of patient satisfaction.”

Scott D. Dreiker, M.D., M.S., F.A.C.O.G., South Shore Hospital, Weymouth, MA, Good Samaritan Medical Center, Brockton, MA.

“Since using INSORB, I have had a large reduction in incisional infections, serous drainage, skin dehiscence; and a significant increase in patient satisfaction, specifically from patients who had surgery w/ either subcuticular closure or percutaneous metal staples prior, then INSORB most recently. Initially I was concerned with the appearance and patient satisfaction with the acute look of the raised opposed edges, but after explanation and warning, I found excellent patient acceptance, as well as my own with the results as wound healing continued. The only issues I have had were less than 6 patients with one or more staples coming out of the skin, no other complications, half were gently removed with forceps, and the rest were allowed to stay, all with no adverse events. As the photos demonstrated, the healing and scarring is significantly improved compared to the percutaneous metal staples.”

Edward Ray, M.D., F.A.C.S., Duke Regional Hospital, Durham, NC.

“I have been using the INSORB device on many different procedures, but primarily abdominoplasty and thigh lifts. This dramatically reduces surgical time (thus more than paying for its use), and improves the cosmesis of the resulting scars. I am a strong believer in the INSORB stapler and have convinced many of my colleagues to use it as well!”

David L. Street, M.D., F.A.C.S., Oregon Surgical Specialists, Medford, OR.

“I am very pleased with the wounds. The INSORB [Stapler] saves a lot of office time in the post-op period and patients don’t complain of having staples removed. I use it all the time, especially on leg wounds from bypass surgery.”

Thomas G. Howell, M.D., District One Hospital, Faribault, MN.

“I have found the INSORB [Stapler] to be a time saver, as well as patient satisfier. In the transition from metal staples to INSORB, we found less prn analgesic usage in the hospital, thus having the potential for significant cost savings. We have had zero infections in over 5 years.”


“Not only does the INSORB device improve the cosmetic result, but I have seen a definite decrease in wound complications since utilizing this innovative technology. The product is easy to use and I am able to create value for patients, in addition to, saving time in the office since there is nothing to remove.”

Nate Nistler PA-C, Summit Orthopedics, St. Paul, MN.

“The INSORB Stapler has performed well with total knee and total hip arthroplasty closures. We have seen good cosmetic results and it has saved both surgical and clinical time. We have used the INSORB Stapler in approximately 100+ Orthopedic procedures with minimal wound complications. I am pleased with the product and will continue to recommend the product to other providers.”