

Evaluation of a Novel Absorbable Subcuticular Skin Stapler In General Surgery

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Summary

We have evaluated a novel absorbable subcuticular skin stapler to determine its clinical performance in terms of safety, efficacy and cosmesis in carotid endarterectomy and hernia repair procedures. Our experience included over 100 surgical patients. The resultant incisional closures were observed immediately post-surgery and generally at one week and three week follow-up visits. The absorbable staples demonstrated equivalent efficacy compared to our standard closure methods. Typical closures were closely approximated with good eversion and no apparent inflammatory reaction. We found the use of the device to be simple and comfortable and time-effective. In addition, the use of the absorbable subcuticular skin staples eliminated the cost, patient discomfort and inconvenience associated with post-operative removal of metal skin staples. Visible cutaneous erythema and other signs of inflammation were not observed in our patients. Overall, our patients expressed a high degree of satisfaction with the absorbable staple closure.

Introduction

The objectives of surgical wound closure are safe, effective healing with good cosmetic results. Effective time utilization of health care professionals in the surgical suite and post-operatively can be a determining factor in the selection of a closure modality. A number of incisional closure techniques are available, including a variety of suture materials, metal skin staplers, tissue glues and adhesive dressings. We evaluated this new mechanical skin closure modality to determine its effectiveness in our surgical practice.

Materials and Methods

We utilized a new absorbable subcuticular skin stapler (INSORB®|20 Subcuticular Skin Stapler, Incisive Surgical, Inc., Plymouth, MN) to close hernia repair and carotid endarterectomy incisions at Gaston Memorial Hospital (Gastonia, NC).

The stapler is a sterile, single patient use device that contains 20 absorbable staples. The device utilizes a novel method which precisely presents the dermis and then places an absorbable staple in a horizontal, subcuticular, and interrupted fashion to provide a secure well-approximated, everted closure. The absorbable staples are made of a polylactide-polyglycolide co-polymer with an established history in wound closure. The staple design features a U-shaped curvature with cleats at the two distal ends to secure the subcuticular tissue.



INSORB®|20 Subcuticular Skin Stapler
INSORB Absorbable Staple
INSORB|1 Forceps

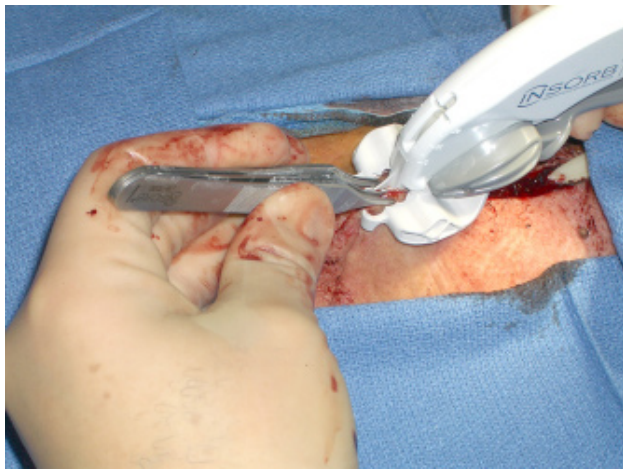
We utilized a proprietary double Adson forceps (INSORB|1 Forceps) which allows a single clinician to both approximate the skin and fire the stapler. This is unlike other stapler techniques which require a surgical assistant. The technique involves placing the forceps onto the shelves of the nose of the stapler over a designated tissue capture zone. As the stapler lever is advanced, the tissue is compressed into a 'capture' zone. Two surgical needles are then advanced into the capture zone to create a precise 'bite' of dermis on both sides of the incision simultaneously deploying a staple horizontally into the subcuticular tissue. The cleats of the staple secure the tissue. The absorbable staples were placed at approximately 6 mm intervals. Standard adhesive strips or transparent adhesive dressings were used on the closure for wound protection.



Carotid Endarterectomy Closure

A novel closure technique is utilized for the placement of the absorbable staples. Using a 'double-' Adson forceps that features preferential spring forces, we grasp just 2mm of one tissue edge with the weaker spring arm, and then grasp 2mm of the opposed edge with the stronger spring arm. We then lift the forceps to allow the introduction of the stapler, mate the forceps with the stapler, and fire the stapler. This represents a true "one-person" closure technique.

We have found that it is helpful to close both apices at the beginning of the closure to ensure ease of placing the final staple.



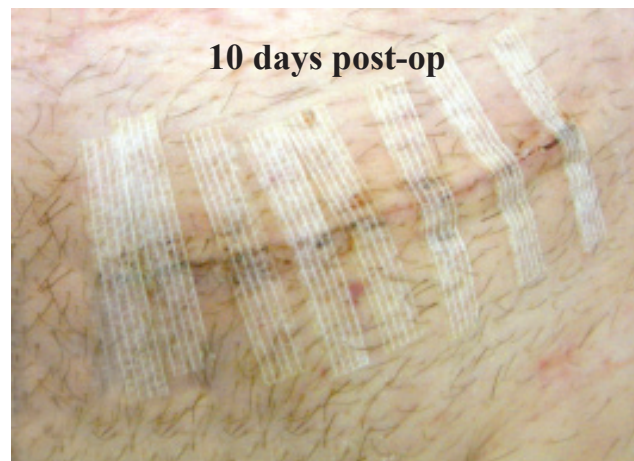
Carotid Endarterectomy Closure

Results

We studied the use of this new absorbable stapler and forceps in hernia repair and carotid endarterectomy procedures. The device is ergonomically-designed, and simple to use. We found that, with experience, closure times with the subcuticular skin stapler closely approximated closure times with a metal skin stapler, and was significantly faster than subcuticular suture closures. The use of the absorbable subcuticular skin staples resulted in a very uniform, interrupted, everted skin closure that eliminated the percutaneous insult associated with metal skin staples. The observed short-term cosmesis of the absorbable staple skin closures was superior to the resultant cosmesis of metal staple skin closures.

We have had experience with over 100 patients with absorbable subcuticular staples and have observed no infections, hematomas or seromas to date. Further clinical experience is necessary to determine if this experience may be due to the interrupted nature of the absorbable staple closure, staple material and design, or other factors.

The absorbable subcuticular staples demonstrated equivalent efficacy compared with metal skin staples and subcuticular suturing. We found a remarkable decrease in skin irritation over the incisional areas closed with absorbable subcuticular skin staples compared with metal skin staple closures. The use of the absorbable staples eliminates the cost, patient discomfort and inconvenience associated with the post-operative removal of metal skin staples. Patients have remarked of their satisfaction with regard to comfort and cosmesis of their wounds.



Hernia Repair Closure

Conclusions

It has long been understood in the medical community that the optimal incisional closure technique results in minimal tension on the wound edges with good eversion and approximation. In addition, productivity in the surgical suite, as well as on the hospital floor and clinic, is a subject of increasing interest. Lastly, we have experienced an increased sophistication in our patients as they become better informed of surgical options, including skin closure modalities.

Use of the absorbable subcuticular skin stapler resulted in a uniform, symmetric, everted skin closure. Our clinical results indicate that the incisional closure is equivalent to metal skin staples and subcuticular suturing with respect to efficacy. We found that the speed of the subcuticular stapler is significantly faster than subcuticular suturing, reducing operative and anesthesia times. Use of the absorbable staples resulted in low maintenance wounds, and eliminated the cost, patient discomfort and inconvenience associated with post-operative removal of metal staples. Our patients expressed a high degree of satisfaction with the wounds closed by the absorbable staples.

Our initial experience suggests that the use of the absorbable subcuticular skin stapler results in a high degree of patient satisfaction and is a reasonable alternative to metal skin staples and subcuticular suturing.