

## CLINICAL TECHNIQUES & TECHNOLOGY

# The use of bioresorbable staples for mucoperichondrial flap coaptation in septoplasty

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*Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.*

Coaptation of the mucoperichondrial flaps at the conclusion of septoplasty has been a challenge since the procedure was introduced in 1882 by E. F. Ingals.<sup>1</sup> The purpose of coaptation is to reduce the dead space between the flaps and facilitate healing. If dead space persists, a septal hematoma may form that can lead to complications such as abscess formation and separation of the blood supply from the cartilage. Occasionally, this can result in a septal perforation and/or a “saddle-nose” deformity.

Before the 1980s, mucoperichondrial flap coaptation was accomplished with nasal packing. In addition to being quite uncomfortable and dreaded by most patients, nasal packing, although effective, was occasionally associated with complications such as infection or toxic shock syndrome. In the 1980s, it became common to avoid nasal packing after septoplasty by performing a quilting suture technique to provide flap coaptation. Although suturing reduces serious complications such as toxic shock syndrome, it has created its own set of complications and challenges.<sup>2,3</sup> Visual limitations, inability to align mucosal tears, needle and suture breakage, and damage to the lateral nasal wall have all been attributed to suturing of the nasal septum. There is also a considerable learning curve associated with the intranasal suturing technique.

We present a new nasal septal stapling system (The ENTact septal stapling system: ENTrigue Surgical Inc, San Antonio, TX) that uses bioresorbable staples to align and coapt the mucoperichondrial flaps developed during septoplasty.

## DEVICE DESCRIPTION

The septal stapler (Fig 1) is composed of two arms. One houses the bank of eight staples and the other is a counter tension arm. Each individual arm is inserted into one of the nasal cavities. The trigger mechanism of the stapler has two



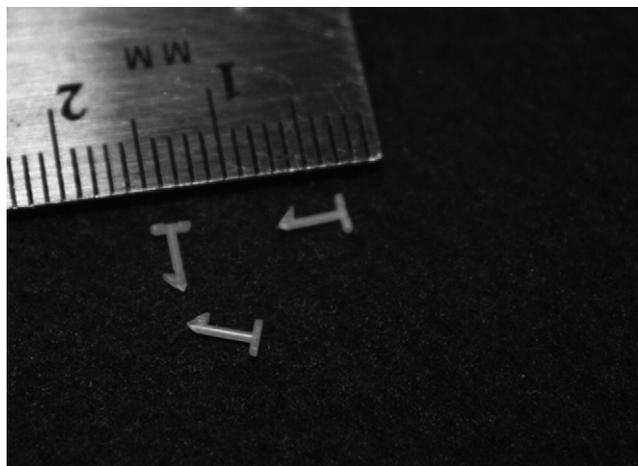
Figure 1 ENTact septal stapler.

distinct actions: 1) to bring the arms together to grasp the septal tissue, and 2) to drive the staple through the mucosal flaps, with or without cartilage. The purpose of the first action is to grasp the septal tissue for accurate placement of the staple and to create a counter-tension pocket for the precise staple insertion. This action may also give the added benefits of re-approximating tears in the septal mucosa and for the repair of septal perforations. With the second action, a guiding needle pierces the tissue and enables the staple to penetrate the entire flap and hold the tissues in proximity. The arms of the septal stapler measure 7.5 cm, which is sufficient to reach the face of the sphenoid.

## SEPTAL STAPLES

The staples (Fig 2) are composed of absorbable polylactide-co-glycolide (PLG), the same copolymer found in Vicryl sutures. This family of polymers, which includes polylactic acid (PLA), polyglycolide acid (PGA), and their copolymers PLG, has an extensive history of use in medical applications without major biocompatibility problems.<sup>4</sup> In addition to their use in sutures, PLA, PGA, and PLG materials have been used throughout the musculoskeletal system in ophthalmic, maxillofacial, and dental sites and as vehicles for

Received November 10, 2008; revised December 18, 2008; accepted December 22, 2008.



**Figure 2** Staple implants.

controlled release of drugs and other bioactive agents. This family of aliphatic polyesters has a long history of use in human beings and has been studied more extensively than any of the other bioresorbable polymers. These biopolymers degrade into products that are naturally found in the body and can be readily eliminated through normal physiologic pathways. The septal staples are designed to degrade in 3 to 6 weeks with minimal tissue reaction.

## DISCUSSION AND CONCLUSION

Although septoplasty is a generally well-tolerated procedure, the coaptation of the mucoperichondrial flaps has been a challenge. Many diverse methods for coaptation have been proposed and include packing, suture, and even the use of fibrin glue. All of these methods have drawbacks and complications that make them suboptimal.

The stapler has many potential advantages over both packing and suture, which include a reduction of time needed for closure. The stapler has been designed to gently but securely approximate the tissue with the use of point fixation rather than tightly gathering the tissue as is usually the case with the suture technique. Point fixation may be associated with reduced tissue edema and may promote a more natural healing than occurs with the tissue-gathering technique. The stapler is designed to allow both direct and endoscopic visualization of its placement.

Complications of the septal-suturing technique, such as needle or instrument damage of the lateral wall, as well as the occasional needle or suture breakage may be eliminated

with the nasal septal stapler. Because the arms of the stapler are able to reach the entire length of the nasal septum, this technique may produce a more complete closure of the mucoperichondrial flaps than can be attained with the suture technique. The dual action of the trigger allows for precise staple placement as well as manipulation of the septal mucosa for approximation of mucosal tears. The PLG polymer staples may safely and effectively coapt the nasal mucosal tissues with minimal to no tissue reaction. An ongoing IRB-approved clinical trial is currently underway to determine to what extent the potential advantages of using a septal stapler may be achieved in clinical practice.

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## FINANCIAL DISCLOSURES

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