Safety and Efficacy of Midface-lifts With an Absorbable Soft Tissue Suspension Device

James Newman, MD

Objective: To evaluate the safety and efficacy of midface-lifting using an absorbable suspension device (Endotine ST).

Design: Prospective cohort of 10 consecutive adult female patients seen in a private practice who underwent isolated midface-lift without accompanying eyelid surgery or volume augmentation procedures in the setting of an accredited ambulatory surgical center. All patients underwent endoscopic-assisted midface-lifts with general anesthesia or intravenous sedation. Subperiosteal dissections of the midface were performed with fixation of the Endotine ST device to temporalis fascia. Objective and subjective criteria were recorded and photodocumented during the postoperative period at 1 week and 1, 3, and 6 months. Patient characteristics of erythema, tenderness, and pain were recorded with a visual analog scale. The patients and surgeon rated changes from the baseline condition and overall satisfaction with the procedure at 1, 3, and 6 months.

Results: All 10 patients completed the 6-month postoperative follow-up. Nine of the 10 patients had significant improvements in their aesthetic outcome. The most common objective symptom of malar sensitivity diminished significantly between the 1- and 3-month visits. One patient experienced a temporary paresis of the zygomaticofacial nerve that resolved at 3 months. There were no major complications of infection, extrusion, skin irregularities, or device removals.

Conclusions: Midface-lifting with the Endotine ST device provided significant elevation of the malar fat pad with improvement in facial contour. Safety of this surgical technique was comparable to that of midface-lifts in other published studies. Patient acceptance of the midface-lift using the Endotine ST device was favorable. Temporary tenderness over the malar area can be expected during the early postoperative period.

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THE NEED FOR ADDRESSING ptosis of the malar fat pad is recognized for total facial rejuvenation. A number of surgical techniques are used to add volume to the midface and to suspend the muscle, fat, and skin unit of the midface.[1-4] Challenges of midface-lifting include obtaining symmetrical results, the longevity of the procedure, and safety related to facial nerve injury and lower eyelid malposition.[3,5]

The midface can be suspended from 3 directions, including temple,[1,6] subciliary,[7] and lateral[8,9] approaches, with traditional face-lift incisions. The plane of the dissection can vary depending on the approach used and the extent of dissection. Whichever method is chosen, successful mobilization of the midface structures relies on release of the zygomatic- and masseter-retaining ligaments of the cheek.[10] Lateral approaches take advantage of adding significant lateral and posterior vectors to achieve improvements in the jowl and neck. Subciliary approaches take advantage of vertical vectors of lift with the ability to modify the nasojugal groove directly. The temporal approach has the advantage of using an access incision with very little morbidity and allows for vertical and oblique vectors of lift.

With the popularity of endoscopic-assisted brow-lifts and visualization advantages of using endoscopes, the midface can be elevated safely and effectively in the subperiosteal plane.[1,11] The extension or transition from the subgaleal plane to the subperiosteal plane is accomplished through the same temporal incision used in endoscopic-assisted forehead-lifts. Many of the same patients who present for forehead-lifts also exhibit early signs of midface aging with descent of the malar fat pad, lengthening of the lower eyelid, and deepening of the nasolabial and nasojugal grooves.

A novel biocompatible and bioabsorbable soft tissue fixation device (Endotine ST; Coapt Systems Inc, Palo Alto, Calif) has been developed to assist with the surgeon's desire for safe and reliable midface stabilization after dissection and release of the midface have been achieved. The size of the device is amenable to placement through endoscopic incisions. Because tines are used to engage soft tissue, there is no need for suture passes, which can be technically challenging and pose some risk of entrapment of nerves. The Endotine ST device is made of a polymer of polylactic and

Author Affiliation: Section of Facial Plastic Surgery, Department of Otolaryngology–Head and Neck Surgery, Stanford University Medical Center, Stanford, Calif.

Figure 1. The bioabsorbable midface suspension device (Endotine ST; Coapt Systems Inc, Palo Alto, Calif) platform and leash. The device is a copolymer of polylactic and polyglycolic acids.

Figure 2. Plane of dissection for midface surgery (A) and insertion of the device (B). A, DTF indicates deep temporalis fascia; ITF, intermediate temporalis fascia; STF, superficial temporalis fascia; and VII, cranial nerve VII. B, Engagement of the malar fat pad with the 4.5-mm tines of the device is shown in the inset illustration.

polyglycolic acids similar to the Endotine brow device and was approved by the US Food and Drug Administration for soft tissue suspension in 2003. The midface device has a 0.6-mm thickness with a platform that supports 5 angled 4.5-mm blunt-tipped tines (**Figure 1**). The Endotine brow device has been used in more than 25 000 procedures worldwide and has gained popularity among facial plastic surgeons.[12] I have had successful experience with the use of the Endotine brow device and decided to undertake a pilot study to evaluate the safety and efficacy of the Endotine ST midface device for endoscopic-assisted midfacelifts, with emphasis on patient acceptance and aesthetic outcome.

METHODS

From December 1, 2003, to November 30, 2004, 10 consecutive adult female patients provided informed consent for midfacelifts alone or in combination with endoscopic brow-lift surgery with the Endotine ST midface device. The study protocol was an approved institutional review board study (Mid-Lands IRB, Leawood, Kan). Patients received an in-depth description of the procedure and explanations regarding the nature of the Endotine ST device. The informed consent process and 10-page document related to the procedure itself and consent to participate in a clinical research study. Patients were asked to complete photographs and data questionnaires at their first postoperative visit and again at 1, 3, and 6 months after the procedure. Patients were asked to assess 3 physical characteristics of erythema, tenderness, and pain of their midface or cheek area after surgery by marking a visual analog scale. In addition, aesthetic satisfaction assessments were obtained at each postoperative visit to assess improvement from baseline appearance and overall satisfaction with the results of their midface surgery. The surgeon also completed an evaluation related to aesthetic improvement and any potential adverse events during the 6-month period.

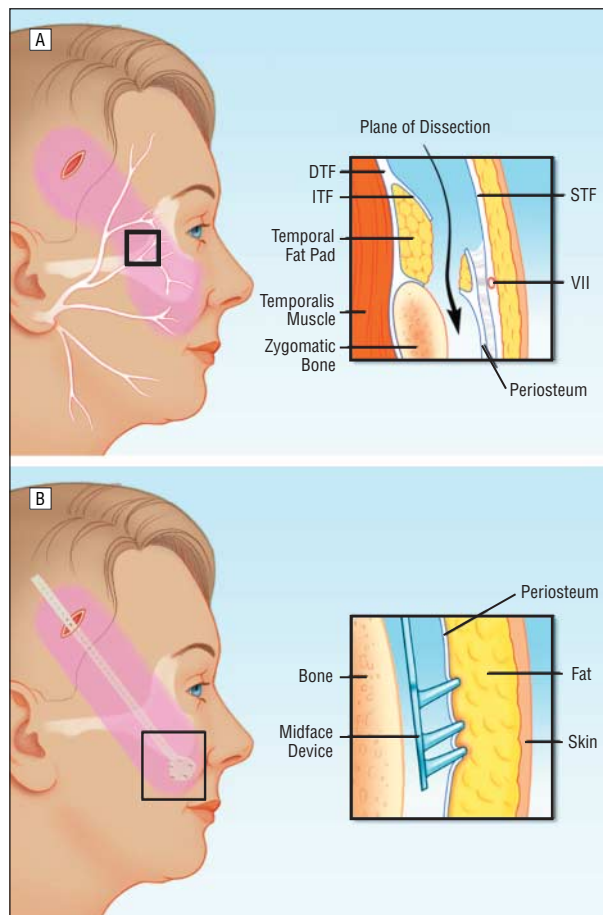All procedures were performed in an accredited ambulatory surgery center, with 8 patients receiving intravenous sedation and 2 receiving general anesthesia. Two access incisions were created when the midface-lift was performed as an isolated procedure, including 1 temple and 1 gingivobuccal incision. Additional forehead paramedian and central incisions were performed if a concurrent endoscopic brow-lift procedure was performed (3 of the 10 patients underwent brow-lifts). The temple incision was beveled along the shaft of the hair follicles and allowed for dissection below the temporoparietal fascia and just superficial to the superficial layer of the deep temporalis fascia (SDTF) layer as shown in **Figure 2**. A 30° sheathed endoscope was used to identify key landmarks, including the lateral orbital ligament, the medial zygomaticotemporal vein (sometimes referred to as the sentinel vein), and the lateral zygomaticotemporal vein, artery, and nerve. The SDTF is entered just above the zygomatic arch to ensure elevation of the periosteum and protection of the frontal branch of the facial nerve. The entry into the midface is made medial to the sentinel vein when a more vertical vector of lift is desired; when a more oblique vector is desired, the path of dissection is lateral to the sentinel vein and medial to the lateral zygomaticotemporal neurovascular structures (**Figure 3**). After the zygomatic arch is identified, the periosteum is then elevated along the arch and proceeds inferomedially on the zygoma and inferolaterally over the masseteric fascia. A 2.5×7.6-cm (1×3-in) cotton pledget soaked with local anesthetic (a combination of 2% lidocaine hydrochloride and 1:100 000 epinephrine bitartrate) is placed, and attention is then turned toward the lower midface dissection.
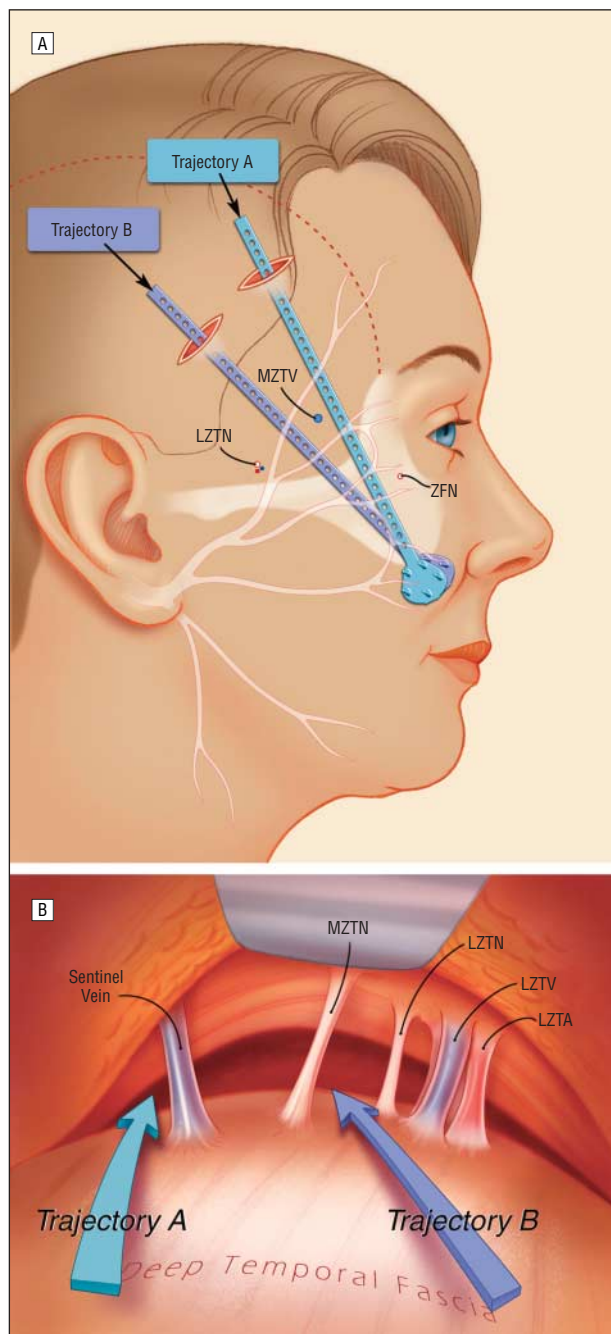
Figure 3. Entry into the midface. A, Vector trajectories of the device leash placed medial or lateral to the medial zygomaticotemporal (sentinel) vein. B, Endoscopic view of the neurovascular landmarks as the surgeon proceeds toward the midface. LZTA indicates lateral zygomaticotemporal (LZT) artery; LZTN, LZT nerve; LZTV, LZT vein; MZTN, medial zygomaticotemporal nerve; MZTV, medial zygomaticotemporal vein; and ZFN, zygomaticofacial nerve.

Figure 4. Severity scores (range, 0-10) of erythema, tenderness, and pain throughout the study period for all 10 patients.

After prepping the gingivobuccal area with povidone-iodine, a 1-cm radial incision is created in the canine fossa and a subperiosteal dissection is performed over the body of the maxilla and laterally over the masseteric fascia. Care is taken not to enter into the buccal space. The infraorbital nerve is identified and preserved. The superior limit of the dissection is to the orbital arcus marginalis; that of the medial dissection is to the piriform aperture. The superolateral dissection connects to the cottonoid where the zygomaticofacial nerve is seen and preserved. All named veins, arteries, and nerves were preserved in all patients. Preservation of the sentin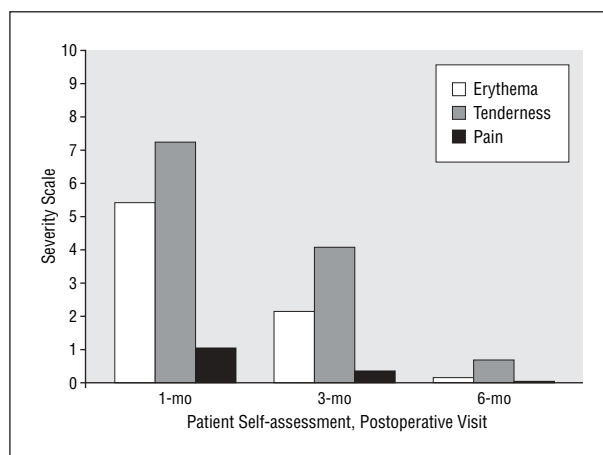el vein is enhanced by leaving a cuff of fascia around the body of the vein and avoiding excessive traction. Dissection in the subperiosteal plane allows for safe release of the zygomatic-retaining ligaments, and dissection over the masseter fascia allows for release of the masseter-retaining ligaments. Mobility of the midface was checked with finger palpation and even sweeping of the periosteal dissector. With this dissection there is usually minimal bleeding and the endoscope can easily visualize all of the structures described.

The fixation of the mobilized flap is then performed in 2 steps. The first step involves the insertion, deployment, and suture stabilization of the Endotine ST device. The device is shown in Figure 2 in proper position with beginning engagement of the periosteum, muscle layer, and malar fat pad. The paddle platform has 5 individual 4.5-mm blunt tines. In all 10 patients, the device was placed through a retrograde delivery to avoid trauma to the temporal venous system and to adequately visualize all of the neurovascular structures described. A 1.3-cm (0.5-in) Penrose drain was used to protect the Endotine ST device, as the leash was grasped by a curved clamp placed through the temporal incision. The Endotine ST device was then gently passed superiorly until the leash was clearly seen in the temporal incision. The engagement of the tines was then performed after assessing the proper vector of pull and location of engagement in the midface. The vector of pull was customized for each particular patient. When a more oblique vector was selected, the leash passed between the medial and lateral zygomaticotemporal veins. When a more vertical vector was chosen, the leash passed just medial to the medial zygomaticotemporal vein (Figure 3). The tines usually engaged the soft tissue within the bulk of the malar fat pad just lateral to the nasolabial groove. Care was taken not to have the engagement too superior over the body of the zygoma to avoid palpability of the device. Firm finger pressure is required to engage all 5 tines, with pressure being placed steadily until the visual confirmation of the engagement is checked. Manipulation of the leash then confirms the lifting and pulling effect achieved by the platform paddle and the engaged tines. The leash is then secured to the deep layer of the SDTF with a 2-0 polydioxone or 2-0 polyglactin 910 suture in a horizontal mattress fashion. Two sutures are placed on each leash to avoid excess tension through the SDTF layer.

The second part of the fixation occurs with the temporoparietal fascia and subcutaneous tissue just anterior to the hairline being secured to the SDTF layer. This maneuver creates a fold of skin that is balanced by an uneven series of suture bites to best approximate the dermal layers of temple skin. The temporal skin is quite tight after this maneuver, and care must be taken not to take bites of fascia too close to the path of the frontal branch of the facial nerve. After the skin edges are closed
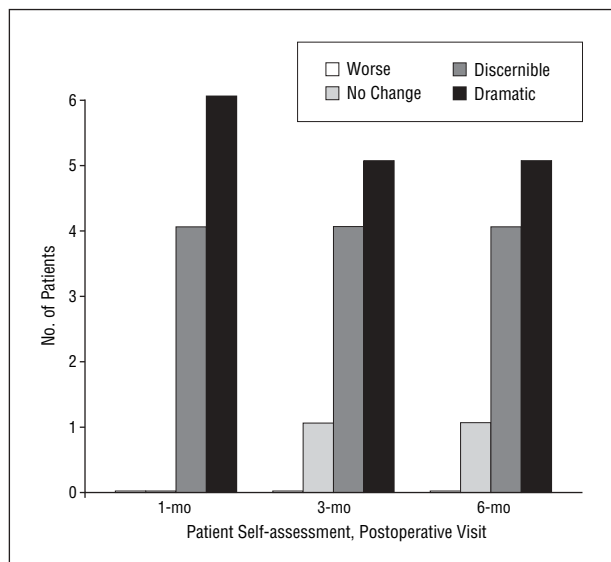
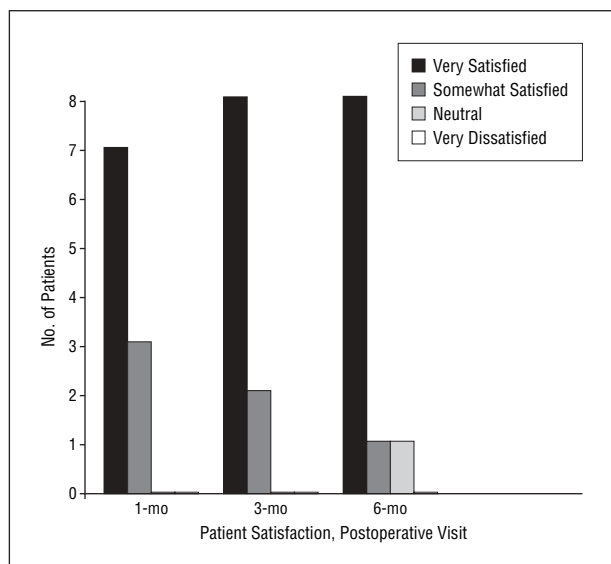**Figure 5.** Aesthetic improvement after surgery compared with the baseline condition as rated by the patients.

Figure 6. Overall satisfaction of patients with their procedure and aesthetic benefit during the study period.

Figure 7. Preoperative (A, C, and E) and 6-month postoperative (B, D, and F) frontal (A and B), oblique (C and D), and lateral (E and F) views of a patient. Improved contour of the midface mound and volume redistribution are seen.

with a 5-0 monofilament suture, the gingivobuccal incision is closed with 4-0 plain gut suture. The intraoral incision is left loose to promote any drainage. The overlying skin is taped with 2.5-cm (1-in) foam tape (3M Company, St Paul, Minn) to diminish edema of the skin and to help obliterate any potential air spaces in the dissected midface. When muscle bleeding or adequate hemostasis is a concern, a rubber band or a 0.6-cm (0.25-in) Penrose drain is placed through the intraoral incision for 24 hours. A 7.6-cm (3-in) cotton Kling dressing (Johnson & Johnson, Princeton, NJ) is applied for gentle compression with ice packs over the cheeks and temple for 48 hours.

RESULTS

All 10 women completed the study (mean age, 42.4 years). Eight patients underwent the procedure with intrave-

nous sedation and 2 with general anesthesia. The patient severity scores for erythema, tenderness, and pain are shown in **Figure 4** for the 6-month postoperative period. A significant improvement from baseline was rated by all patients at the 1-month visit. At the 3-month visit, 1 patient noted a decline to no significant change from baseline (**Figure 5**). Overall improvement was noted in 9 patients (90%) by the 6-month visit. One patient believed that her condition improved as swelling resolved between the 1- and 3-month visits. One patient believed that there was no significant improvement and that her condition returned to baseline by the 3-month follow-up visit (**Figure 6**). There were no complications of scarring, infection, alopecia, hematoma, salivary duct injury, allergic response, or prolonged tenderness. There was no visibility of the device or erythema over the de-

Figure 8. Preoperative (A, D, and G) and 4-month (B, E, and H) and 12-month (C, F, and I) postoperative frontal (A-C), oblique (D-F), and lateral (G-I) views of a patient undergoing endoscopic midface-lift.

vice platform or tips. One patient developed a facial nerve paresis limited to a zygomatic branch supplying the orbicularis muscle, which produced mild rounding of the lower eyelid for 6 weeks. This was noted by the surgeon and not the patient, with full resolution by the 3-month follow-up visit. This patient noted significant elevation of her midface tissues and was very satisfied with the results at the 6-month visit. Three patients have completed their 1-year anniversary postoperative visits, and their results and assessments are unchanged from their 6-month assessments.

The subjective changes of midface elevation and overall aesthetic improvement were rated by the surgeon and matched the patients' self-assessment changes from baseline. Three examples of the improvements in midface position are shown at 6 months and 1 year (**Figures 7**, **8**, and **9**).

COMMENT

The endoscopic-assisted midface-lift procedure can correct descent of the malar fat pad with redistribution of the volume in a more superior and oblique vector without the need for skin excision. Most of the aesthetic benefit from the procedure is volume redistribution over the malar prominence and is dependent on an adequate release of the retaining ligaments of the masseter and zygoma. As an isolated procedure, it does not correct nasolabial grooves or make much of an impact on the medial nasojugal groove. Results from this study are important because they show the improvements and limitations of simply mobilizing the midface and resuspending the malar fat pad. A solid and secure suspension is demonstrated through the 6-month follow-up with consistent and standard photography. Although this is a small

Figure 9. Preoperative (A and D) and 6-month (B and E) and 12-month (C and F) postoperative frontal (A-C) and oblique (D-F) views of a patient undergoing endoscopic midface-lift.

group of patients, it reflected the high level of safety of using the subperiosteal plane connecting to the subgaleal plane over the zygomatic arch. It was encouraging to see a low incidence of nerve weakness and significant edema compared with traditional suture-suspension midface-lifts. Also, there were no direct complications of canthal dystopia or ectropion because the lateral canthal attachment was left undisturbed, and no lower eyelid orbicularis disruption occurred. Because the temporal skin was also suspended and redraped, there was no significant widening of the intermalar distance, which has been seen cited with more aggressive subperiosteal dissections.[7]

The 2 main technical points for stabilizing the mobilized flap with the Endotine ST device include engaging the tines into the malar fat pad and securing the leash to the SDTF layer. The actual device is easy to deploy and position through the dissected plane. In the cases presented herein, an intraoral incision was always made to assist in adequate periosteal release and preservation of important neurovascular structures. This allowed for a retrograde passing of the narrow Endotine ST leash to the subgaleal pocket overlying the SDTF layer. The medial zygomaticotemporal vein and the zygomaticofacial nerve were preserved in all cases. This is important because it avoids potential vascular en-

gorgement of the temporal venous system, which can leave an unnatural appearance. The use of the endoscope and direct visualization from the gingivobuccal incision makes preservation of all sensory nerves relatively easy and reduces the chances of any postoperative dysesthesias.

Adequate engagement of the Endotine ST platform in the proper location is important. Care was taken to engage the tines over the thickest part of the malar fat pad just lateral to the nasolabial groove. Any engagement of the tines overlying the prominence of the zygoma could result in palpability of the tine tips and concerns about extrusion. This observation can be made by the surgeon intraoperatively and necessitates release and repositioning of the platform. Adjustability and repositioning are major advantages of using such a system, compared with traditional suture suspension. Because the tips of the tines are blunt, adequate digital pressure is required to engage the soft tissues. This is important because the more tissue is engaged, the more secure the grip and the more even the distribution of tension are. Second, obliteration of any potential space is ensured with adequate engagement to prevent a seroma or hematoma from forming. In the first 4 postoperative days, a layer of foam tape (3M Company) is applied over the skin to provide for gentle skin compression to cushion the cheek

skin and reduce localized edema over the Endotine ST–engaged tissues. Having adequate engagement and compression helped prevent any incidence of seroma, hematoma, and possible infection.

The second potential site of technical failure for the Endotine ST suspension device is at the fixation of the leash over the SDTF layer. If an inadequate suture is used or if one suture pulls through the fascia, loss of fixation can occur. A 2-0 long-term absorbable suture such as polydioxone ensures stability as the leash degrades in 4 to 6 months. If the surgeon chooses to use a permanent suture, a monofilament such as polypropylene is recommended because of its low reactivity to surrounding tissues. Two sutures for each leash of the Endotine ST device are recommended to decrease the incidence of tearing through the SDTF layer. This layer is thin, especially in women, and can tear if only one suture is used to secure the leash. A possible reason for the return to baseline in one of the patients may have been the tearing of the single suture placed for the leash to the SDTF. This suture is under a significant amount of tension during the first few weeks of the recovery period while the tissues remain swollen. Subsequently, using 2 sutures per side seems to have eliminated any early recurrence of malar pad descent.

The most commonly cited patient severity score was that for tenderness to palpation, which diminished to minimal levels by the 3-month follow-up. The polymer of the Endotine ST device is 82% polylactic acid and 12% polyglycolic acid. Animal studies show that the integrity of the Endotine ST copolymer diminishes by 6 months and simply crumbles into its base units and becomes totally absorbed by hydrolysis. The key to the longevity of these results is in the fact that a mobilized subperiosteal flap was repositioned in a more superior oblique vector, and new fibrosis occurs that secures the periosteum. Animal studies have shown that periosteum readheres to the bone within 6 to 8 weeks,[13] which is well within the period of tensile strength degradation of the Endotine ST copolymer.

After assessing the results of the study, patient satisfaction for the procedure remained high and low morbidity rates were encountered. For the technical job of suspending the soft tissues after mobilization, the Endotine ST device performed well. Three points can be emphasized from the overall aesthetic improvements for the midface-lift that were observed during this pilot study. First, the lack of improvement in the nasolabial groove is not surprising because the gliding of the overlying skin was not addressed and no volume was added to the depths of the groove or medial to it. Second, although the lower eyelid distance was reduced, the medial nasojugal groove was unchanged in all of the patients. To improve this area, a more superior medial vector is needed, similar to what can be achieved with lower eyelid approaches in combination with fat repositioning or implants. Third, the supraperiosteal or subgaleal plane that is used over the temporalis fascia is a valuable plane for redraping the submuscular aponeurotic system and skin. Several anchoring sutures are placed into the temporalis fascia and dermis to redrape the overlying temple skin and secure the SDTF layer. Extension of the supraperiosteal plane beyond the zygomatic arch is more technically challenging; often, branches of the facial nerve are visualized and protected with only a thin fibromuscular layer of the submuscular aponeurotic system. This type of dissection serves several experienced surgeons well,[14,15] but a higher incidence of orbicularis problems, canthal dystopia, and facial nerve paresis may occur for the inexperienced operator. Thus, with the subperiosteal approach, the excess skin may need to be addressed in the more advanced elastotic skin.

The endoscopic-assisted midface-lift with the Endotine ST device as an isolated procedure is appropriate for patients with midface ptosis and mild nasojugal and nasolabial grooves. Patients with associated brow ptosis will benefit the most because the same temporal incision can be used for both the midface-lift and an endoscopic-assisted browlift. These same patients will benefit from suspension of the malar fat pad, which will add about 1 hour of operating time, as no additional equipment setup is needed to complete the midface dissection. The adjustability and decreased risk of nerve entrapment to the overlying soft tissues makes the Endotine ST device another option for safe and secure stabilization of a properly mobilized midface.

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