A Novel Bioabsorbable Device for Facial Suspension and Rejuvenation

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To evaluate the safety and efficacy of a novel bioabsorbable suspension device made of a polymer of polylactic acid and polyglycolic acid (Endotine Ribbon), we performed a retrospective multi-institutional case study of 21 patients who underwent minimally invasive or open rhytidectomy with the use of the device in an ambulatory surgery center setting. Twelve patients had an excellent result, 7 a good result, and 2 a fair result. Early complications were corrected with technical modifications. Patient satisfaction was high. The Ribbon is a safe and effective adjunct for performing both minimally invasive and open rhytidectomy and cervical lifting. *Arch Facial Plast Surg. 2009;11(2):129-135*

After nearly a century of technique-driven improvements in surgical outcomes, the field of facial plastic surgery is facing a paradigm shift in favor of technology-driven outcome improvements. Although surgical technique will continue to be the foundation of optimal rejuvenative surgery, laser technologies, radiofrequency and other transcutaneous energy delivery devices, injectable materials, and absorbable bioimplants will occupy a growing role in most successful practices. Many of these techniques are compatible with a minimally invasive approach, which affords limited tissue dissection, the possibility of local anesthesia, reduced postoperative edema, and, therefore, reduced recovery time, while still offering superior rejuvenation to select patients.

Many novel "minimally invasive" procedures, although initially very exciting, do not stand the test of time because of unacceptable complication rates, suboptimal long-term results, or patient dissatisfaction. Suture-based suspension systems, for example, experienced a recent surge in interest owing to their ability to be placed via minimally invasive incisions and approaches, while offering excellent suspension. Unfortunately, long-term results with these systems were disappointing, and suture removal was extremely difficult.[1]

Absorbable implants are particularly attractive to patients in that they offer superb suspension during rejuvenative facial surgery and resorb slowly and completely, allaying patients' fears about the potential long-term appearance of permanent implants. Implants made of bioabsorbable polymers have a long history of clinical utility, having been used in craniofacial surgery and trauma surgery for more than 15 years.[2]

A recently introduced polymer ribbon made of polylactic acid and polyglycolic acid (PLA/PGA) (Endotine Ribbon; Coapt Systems, Palo Alto, California) is a promising new tool for cosmetic surgeons to use in minimally invasive surgery and is a useful adjunct for improvement of cheek/jowl and neck contour in open face and neck procedures. This report describes the device and illustrates its use in improvement of contour and definition of the face and neck.

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METHODS

DESCRIPTION OF THE DEVICE

The device consists of a slender, 16-cm-long, 5-mm-wide, and 0.25-mm-thick ribbon of PLA/PGA polymer. There are 17 rows of double

Figure 1. The polymer ribbon (Endotine Ribbon; Coapt Systems, Palo Alto, California), showing 17 rows of double tines with a long leash made from polyglycolic and polylactic acid.

Figure 2. The polymer ribbon in the protective housing. The "keel" allows it to be easily deployed or reinserted into the housing.

2.5-mm-high tines, with holes between the tines every 4.6 mm (**Figure 1**). The proximal one-third of the device constitutes the "leash," which has no tines and serves as the area for fixation. For minimally invasive procedures, a protective sheath is used to direct and place the device in the proper location and orientation and is then removed to expose the tines (**Figure 2**). The device loses its mass strength in approximately 3 months and is bioabsorbed completely in approximately 9 to 12 months. It is not anticipated that there will be regression or re-descent of the tissue elevation at this point because (1) there has been true tissue dissection, separation, and suspension; (2) fibrosis develops around and through the holes in the device, connecting the underlying superficial muscular aponeurotic system (SMAS)/fascia or platysma to the overlying skin; and (3) SMAS/fascia or platysma held in a shortened position for 3 to 5 months undergoes shortening and fibrosis. Thus, the bioabsorbable ribbon provides temporary mechanical fixation until biological fixation occurs.

MINIMALLY INVASIVE SURGICAL TECHNIQUE

The PLA/PGA polymer ribbon may be inserted in a minimally invasive approach that is effective for neck lifting. When a minimally invasive approach is chosen, the patients are administered local anesthesia with 1% lidocaine with 1:100 000 epinephrine in the postauricular sulcus, followed usually by the addition of tumescent solution (500 mL of isotonic sodium chloride solution, 0.5 mL of 1:1000 epinephrine, 6 mL of sodium bicarbonate, and 25 mL of 1% lidocaine) to the neck. Intravenous or oral sedation may also be administered. Cervicomental liposuction may be performed. The postauricular incision is then made and a subcutaneous flap is elevated over the mastoid. The platysma–cutaneous ligament is divided and dissection is then performed directly superficial to the platysma. A subcutaneous tunnel is created with narrow scissors or dissecting forceps. Careful attention must be paid when the tunnel is created so that its course stays inferior to the angle of the mandible and approaches the midline of the neck. The PLA/PGA ribbon is then advanced through the tunnel and is disengaged from its protective housing once the anterior limit of the dissected pocket is reached. The device is engaged with the platysma by means of gentle external manual pressure while simultaneous superolateral traction is applied to the device. The "tail" of the leash is then sutured to the mastoid fascia with a single interrupted 3.0 polydioxanone (PDS) suture once appropriate elevation has been achieved (**Figure 3**). Any excess of the leash is then cut behind the suture, and an additional 4.0 nylon suture is used for device fixation. At this point, the cervicomental angle is once again critically appraised, and an additional ribbon may be inserted inferior to the initial placement if additional definition is judged appropriate. An elliptical excision of postauricular skin is then performed according to the degree of skin laxity and age of the patient (**Figure 4**). The skin is then closed. Drains are not used.

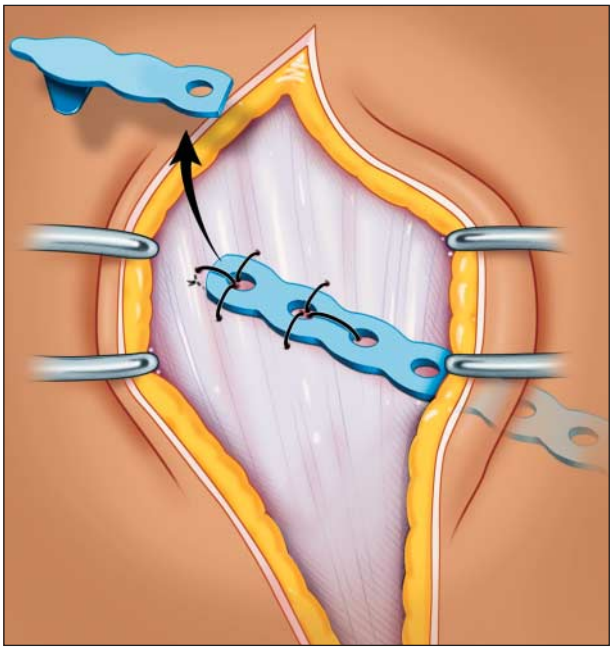

Figure 3. Fixation of the device to the fascia after removal of excess length of the leash.

OPEN SURGICAL TECHNIQUE

Because of its low profile and ease of insertion, the PLA/PGA ribbon may be used in a variety of open surgical techniques. When used with open neck lifting, the ribbon is placed against the platysma after complete surgical exposure is obtained and SMAS plication and/or elevation has been performed. The anterior aspect of the device is sutured to the ipsilateral anterior platysma with a 3.0 PDS suture (**Figure 5**). The housing is removed and the device is engaged against the platysma with gentle external manual pressure performed at the same time that steady superolateral traction is applied to the device. The leash is then sutured to the mas-

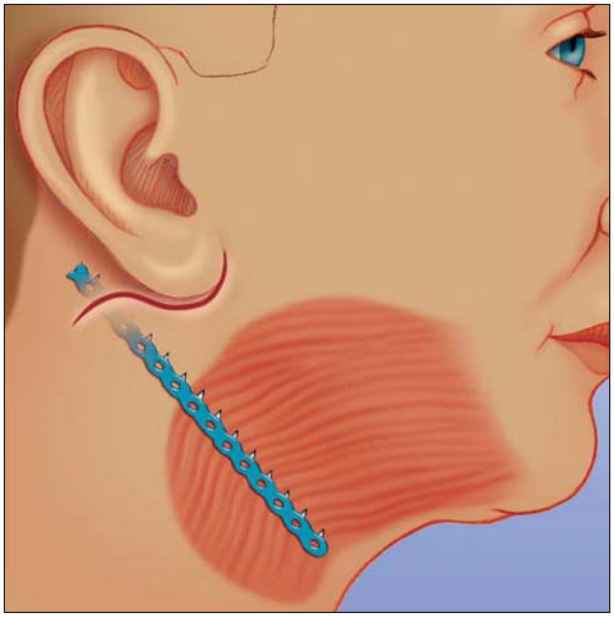

Figure 4. Placement of the ribbon against the midplatysma through a minimal-access incision behind the auricle.

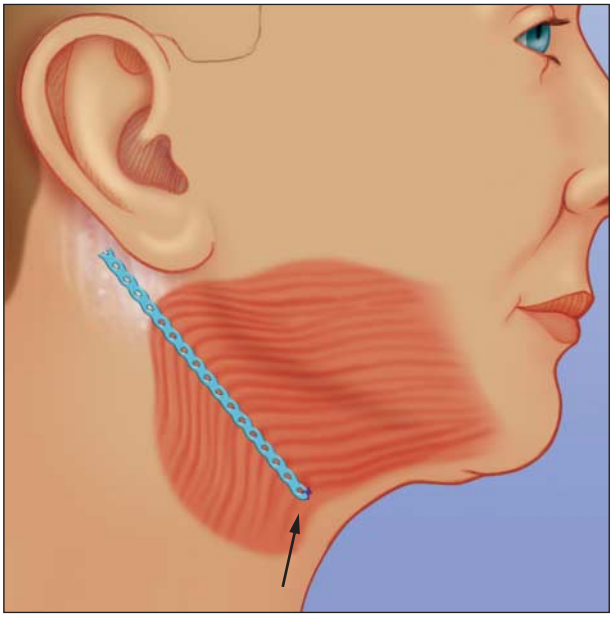

Figure 5. Posterosuperior traction on the ribbon to tighten the platysma, define the jawline, and rejuvenate the neck. Notice the anchoring stitch on the anterior aspect of the device (arrow).

toid fascia with a single 4.0 nylon suture. Once again, care is required to ensure that the device is not seated superior to the angle of the mandible; otherwise, it may become palpable or cause discomfort to the patient. The 3.0 PDS suture used for anterior anchoring is then used to imbricate the platysma over the device in a running back-and-forth fashion and is ultimately sutured to the mastoid fascia. Just as with the minimally invasive technique, an additional ribbon may be anchored inferiorly for additional neck contouring.

In a fashion similar to that in the neck, the devices may be placed in the face for additional SMAS elevation. After complete elevation of the skin and SMAS plication, imbrication, and elevation in a traditional skin-and-SMAS–type rhytidectomy, the anterior aspect of the PLA/PGA ribbon is secured to the SMAS just superior to the jowls with a 3.0 PDS suture. The device is then deployed from its housing. With gentle external manual pressure, the tines are engaged against the SMAS and superolateral traction is applied (**Figure 6**). Once ideal elevation of the SMAS is achieved, the tail of the device is sutured to deep temporal fascia with a 4.0 nylon suture. The SMAS is then imbricated over the device in a running fashion by using the initial 3.0 PDS suture, such that the device will be nonpalpable. A second device may be placed near the nasolabial fold for additional SMAS elevation.

INDICATIONS FOR USE AND PATIENT SELECTION

Although the PLA/PGA ribbon is certainly a useful adjunct in SMAS elevation during open skin-and-SMAS–type rhytidectomy, we have found it particularly helpful for additional cervicomental definition during open cervical lifting and during all minimally invasive neck-lifts. As with any implantable devices, patient selection and preparation are essential. Patients with minimal subcutaneous fat may report palpability of the device, particularly if it is used in the face. To date, we have not had patients mention problems with the device in the neck. Patients with thicker skin and heavier features may benefit more from the device because of the extra elevation it offers.

The ideal patient for the minimally invasive procedure has experienced advanced aging in a particular part of the face. The patient is seeking restoration of facial harmony without requiring full-face rejuvenative surgery. These patients are usually in the fourth to fifth decades of life and wish to limit the amount of recovery time.

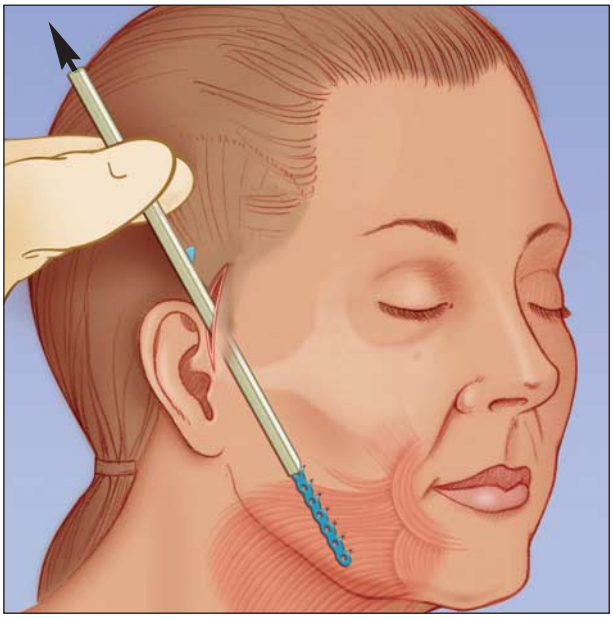

Figure 6. Jowl elevation performed via a temporal hairline incision.

Patients undergoing open surgical rejuvenation may benefit from the addition of the PLA/PGA ribbon if they seek greater definition of the cervicomental angle and jowls than would be possible during a skin-and-SMAS–type rhytidectomy. A patient with anterior cervical banding, which is not amenable to treatment via a lateral approach, will have unsatisfactory results with only a lateral approach using the ribbon.

RESULTS

To date, 21 patients with at least 6 months of follow-up have undergone minimally invasive or open facial reju-

Table. Demographic Data on All Patients Included in the Study

Patient No./ Sex/Age, y	Procedure Type	Follow-up, mo	Ancillary Procedures	Complications	Result
1/F/53	Minimally invasive face and neck	19.75	None	None	Good
2/M/69	Open neck	14.00	None	Implant release	Fair
3/M/54	Open face and neck	7.50	4-Quadrant blepharoplasty, endoscopic brow-lift, hair grafts	None	Good
4/F/48	Minimally invasive face	8.25	None	None	Excellent
5/M/56	Open face and neck	9.50	4-Quadrant blepharoplasty and hair grafts	None	Excellent
6/F/59	Open face and neck	6.75	None	None	Good
7/F/60	Open face and neck	10.00	4-Quadrant blepharoplasty and rhinoplasty	None	Excellent
8/F/51	Open neck	9.50	4-Quadrant blepharoplasty	None	Excellent
9/F/48	Minimally invasive neck	10.00	None	None	Good
10/F/51	Open face and neck	8.75	None	None	Excellent
11/F/76	Minimally invasive neck	6.75	Poly-L-lactic acid injection	Implant release	Fair
12/F/48	Minimally invasive neck	12.25	Cervical liposuction	None	Excellent
13/F/54	Minimally invasive neck	9.00	None	None	Excellent
14/F/53	Minimally invasive neck	13.50	None	None	Excellent
15/F/48	Minimally invasive neck	15.50	Cheek-lift	None	Good
16/M/48	Minimally invasive face and neck	13.75	Lower blepharoplasty	Facial device palpable	Good
17/F/58	Open neck	10.50	None	None	Excellent
18/F/60	Open face and neck	7.25	None	None	Good
19/F/63	Open face	11.25	None	None	Excellent
20/F/62	Minimally invasive neck and face	14.00	Lip augmentation	None	Excellent
21/F/45	Minimally invasive neck-lift	12.25	Chin revision	None	Excellent

venation with the PLA/PGA ribbon. Standard preoperative and postoperative photographs of the patients were taken, and results were judged according to the degree of neck and/or jowl elevation. Demographic data are provided in the **Table**. Eleven underwent minimally invasive face and/or neck lifting with the PLA/PGA ribbon, 3 underwent open neck lifting procedures, and 7 underwent open face and neck lifting with the ribbon. Results were graded by the surgeons as a whole as excellent, good, fair, or poor. Twelve cases were judged excellent, 7 cases were judged good, and 2 cases were judged fair. Complications included 1 case in which the device was palpable that resolved spontaneously and 2 cases of implant release. These occurred in patients treated by 2 of us (G.S.K. and D.B.A.) early in our experience with the PLA/PGA ribbon. In both cases the patients noted the development of a sudden lump in their necks in the second postoperative month. On examination, implant release was immediately noted, and the implants were removed via small transverse neck incisions with the patients under local anesthesia; the wounds healed uneventfully. Despite these complications, the patients were satisfied, and neither the surgeon nor the patient noted any asymmetry or contour irregularity at follow-up. **Figure 7** and **Figure 8** illustrate the preoperative and postoperative appearances of patients judged appropriate for treatment with the PLA/PGA ribbon lift (patients 1 and 10).

COMMENT

Following the introduction of the first bioabsorbable brow-lift anchor in 2003 (Endotine Forehead; Coapt Systems), a series of bioabsorbable fixation devices have been developed to aid in facial aesthetic surgery.[3] The devices consist of a polymer of various formulations of PLA and PGA, each formulation designed to be bioabsorbed at different time intervals, providing for mechanical fixation until biological fixation occurs. These devices have now found positive acceptance in the plastic surgery community.[4-10]

Effective, minimally invasive treatment of the aging neck has a history of significant exploration and innovation. Techniques involving direct excision of excess skin and subcutaneous fat with platysma plication have been repeatedly described. Recently, Biggs and Steely[11] reported on the T-Z-plasty, Miller[12] described direct excision with Z-plasty, and Zins and Fardo[13] described an "anterior-only" approach with or without skin excision. Although some of these approaches may be met with success, they suffer from lack of lateral suspension. The minimally invasive neck lifting approach with the PLA/PGA ribbon offers a true minimally invasive technique with or without a need for platysmaplasty.

Any implantable device used for long-term suspension of facial structures must by necessity rely on the normal biological mechanisms of wound healing for ultimate success. As evidenced by the failure of multiple suture-based suspension systems, face-lifting techniques not relying on the development of scar tissue and tissue fibrosis will ultimately fail. The composition of the PLA/PGA ribbon was engineered with this goal in mind. The device is resorbed slowly, causing minimal tissue toxic effects. However, the device must elicit a low degree of inflammation to stimulate tissue fibrosis. The composite PLA/PGA polymer has been used extensively in facial rejuvenation as well as in mandible reconstruction, and adverse effects have been minimal.[14]

Several aspects of the device are interesting and efficient from a bioengineering and minimally invasive surgical perspective. Primarily, minimally invasive surgical

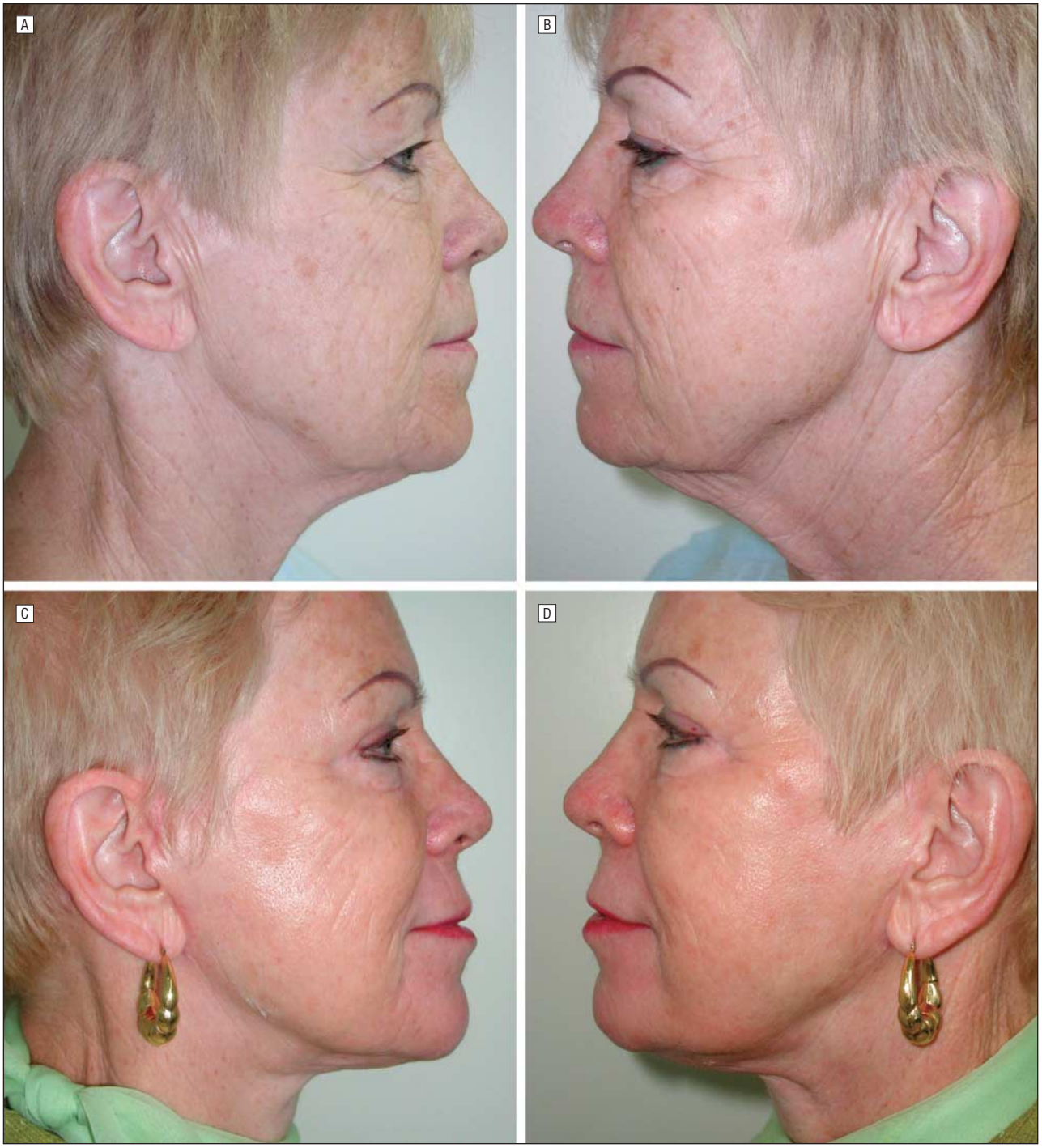

Figure 7. Patient 1. Right (A) and left (B) preoperative photographs and right (C) and left (D) 8-month postoperative photographs of a patient who underwent a cervical polymer ribbon lift without adjunctive procedures.

techniques performed with minimal tissue undermining offer the advantage of minimal tissue edema, faster recovery times, and the potential for local anesthesia with or without sedation. Disadvantages may include less dramatic rejuvenation and a shorter duration of efficacy. Such outcomes have been encountered with many of the suture-lifting techniques that have undergone experimentation during the past decade.

The PLA/PGA ribbon offers improvement over suture-lifting techniques in a variety of ways. Primarily, through its 17 rows of double mini-tines, it permits secure fixation to the SMAS and/or platysma along two-thirds of the device, thereby preventing the puckering that may be seen with suture fixation. Furthermore, because of the secure fixation obtained with the device, mobilization or tearing of the ribbon from the underlying SMAS and/or platysma, a common occurrence with suture fixation, is avoided. The PLA/PGA ribbon also benefits from a low profile, permitting placement in narrow pockets with minimal tissue undermining.

The length of the ribbon device allows it to be inserted under a long bridge of tissue, extending its tissue

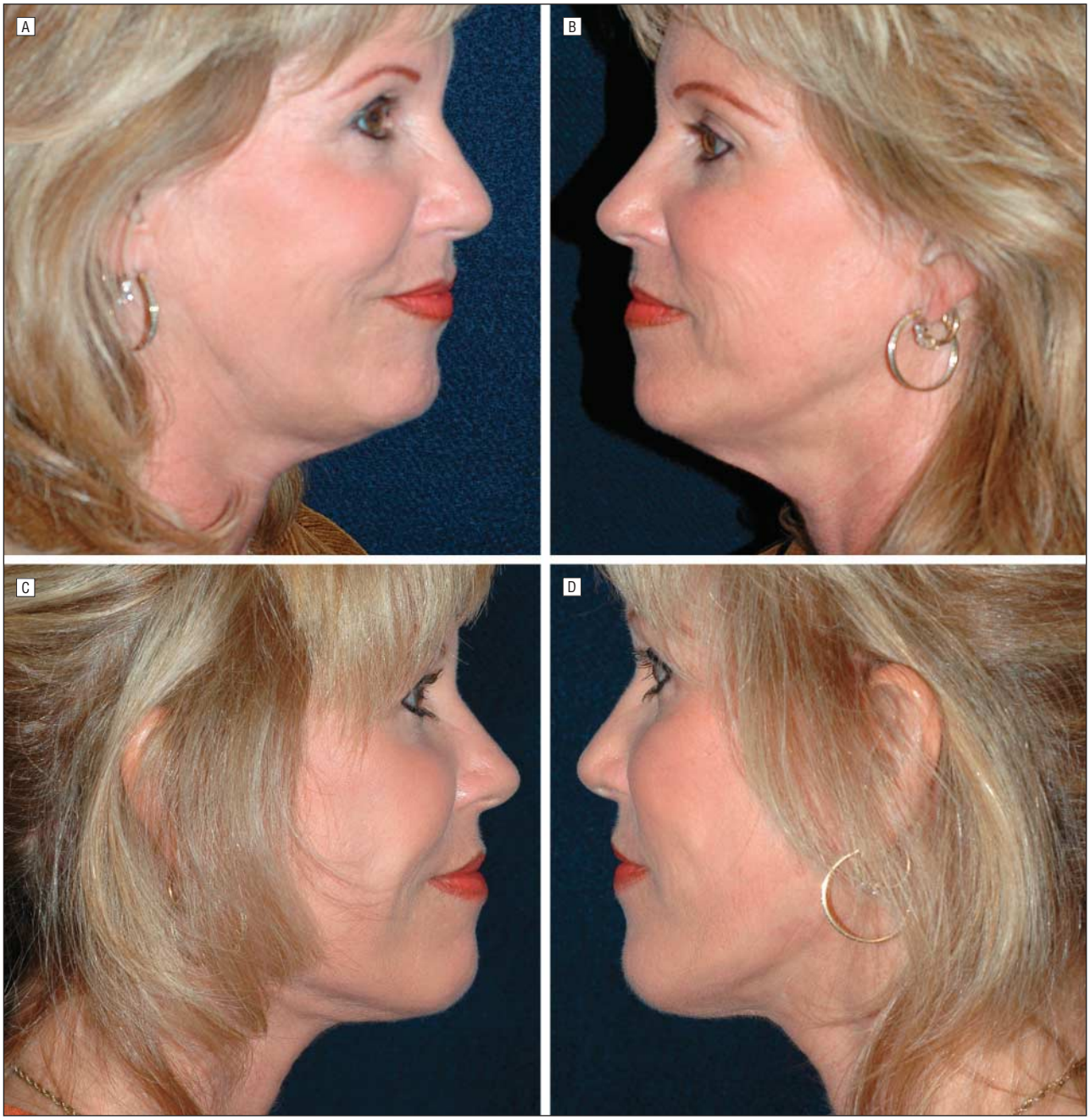

Figure 8. Patient 10. Right (A) and left (B) preoperative photographs and right (C) and left (D) 6-month postoperative photographs of a patient who underwent a cervical polymer ribbon lift in conjunction with open face- and neck-lift.

effects a long distance from its point of fixation. In this manner, it resembles a midface device (Endotine Midface ST; Coapt Systems). Moreover, the device is easily trimmed by cutting away either some of the tines or some of the leash, permitting a custom fit for particular clinical indications. In this manner, the device is easily removed from its housing and just as easily replaced in it.

The most important question regarding the efficacy of this type of bioabsorbable suspension device is the duration of the lift provided by the device. To date, there have been multiple reports on the duration and effectiveness of other devices with this mix of polymers. Effective suspension and a long duration of effectiveness have been noted in these cases.

The complications noted in this series must be mentioned. Each of the patients experiencing a complication underwent surgery early in this series, and these experiences led to important modifications in the surgical technique. Weakening of the suspension sutures was recognized as the cause of the device failure. Therefore, in all subsequent cases, the ribbon was anchored with a permanent suture, and no further premature device failures were noted. As well, the single case of palpability of the device led us to recognize that extra care was required for patients with relatively thin subcutaneous tissue. Therefore, both patient selection and technical modifications were made, such that treatment of patients with little subcutaneous fat was avoided and

the SMAS was imbricated over the device in all subsequent cases, and no further patients reported device palpability.

In conclusion, the bioabsorbable suspension ribbon tested in this study (the Endotine Ribbon) is a safe and effective device that may be used for SMAS elevation and/or for providing extra definition to the jowl and cervicomental angle in open or minimally invasive techniques.

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