Preliminary Report

The Endotine: A New Biodegradable Fixation Device for Endoscopic Forehead Lifts

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Background: *No single technique for fixation of the scalp after endoscopic forehead lift is universally accepted, and complications such as alopecia and regression of elevation have been reported with all techniques.*
Objective: *This report describes the preliminary results of a study of the Endotine 3.5 forehead device (Coapt Systems, Inc, Palo Alto, CA), a new biodegradable fixation device.*
Methods: *The Endotine 3.5 device consists of a post on the deep side for anchoring it in the skull and five tines on the superior side for engaging the deep scalp tissues. It was tested in 9 patients, with postoperative follow-up ranging from 6 to 8 months. The surgeon evaluated the device for difficulty/ease of use, palpability, postsurgical pain, and wound healing.*
Results: *The Endotine 3.5 device produced a secure fixation without problems or complications, although it was often palpable with moderate degrees of sensitivity. It could be applied in less than 2 minutes per side.*
Conclusions: *Our preliminary findings indicate that the Endotine 3.5 forehead device provides rapid, secure fixation without the complications associated with other fixation techniques. After patients reported that it was still palpable up to 24 weeks after implantation, a second-generation polymer that dissolves more rapidly was fabricated. Further studies are under way to evaluate long-term efficacy.* (Aesthetic Surg J 2003;23:103-107.)

The forehead lift (elevation of the forehead and brow) is becoming recognized as an essential element in the rejuvenation of the aging face. According to statistics compiled by the American Society for Aesthetic Plastic Surgery,[1] between 1997 and 2002 the number of forehead lifts increased by 19%, from 55,009 in 1997 to 65,284 in 2002.

The reasons for this increased interest in brow lifting are multiple. Cosmetic surgeons are increasingly aware of the need to evaluate all facial features as a unit rather than considering only the cheek, neck, and eyelids. The proper positioning of the forehead and brow is an essential component in the overall synergy of the face. Furthermore, the limited goal of elevation of low brows has been supplanted by the need to improve forehead rhytids and muscle imbalance, as well as to correct upper-eyelid aesthetics and lateral temporal laxity.[2,3] Finally, the advent of less invasive endoscopic techniques has rendered the procedure less traumatic and more precise, leading to greater patient acceptance and reduced morbidity.

Generally the components of brow lifting include adequate release, intraoperative brow elevation and shaping, tension-free fixation of the desired position, and postoperative tissue relaxation/stretching. Surgical release, brow aesthetics, and postoperative tissue relaxation/stretching are well accepted by most surgeons. However, outcomes and, specifically, methods of fixation remain controversial. Multiple and diverse techniques continue to be advocated by various authors, and no single technique has completely satisfied the demands of surgeons.

This report describes preliminary results with the use of the Endotine (Coapt Systems, Inc, Palo Alto, CA), a biodegradable device that can suspend the forehead and requires only 1 or 2 minutes for application. Further, it allows necessary adjustment or correction during surgery with a simple procedure and may be used for the aesthetic shaping of the brow curvature and arch.

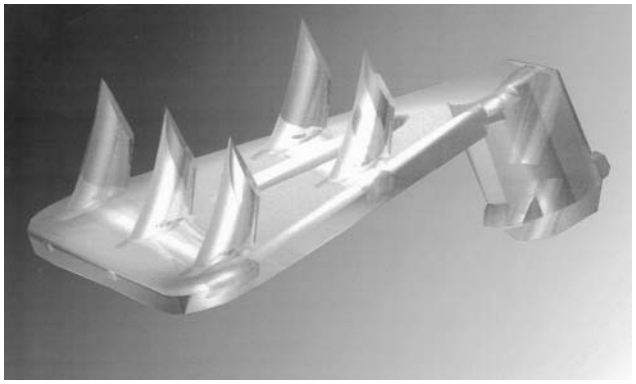

Figure 1. *Configuration of the Endotine device. Reprinted with permission from Coapt Systems, Inc. Copyright © 2002 by Coapt Systems, Inc.*

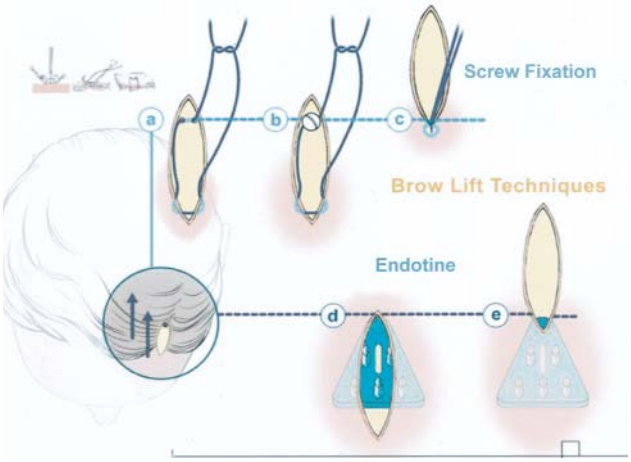

Figure 2. *Graphic illustration of difference between standard screw fixation and use of the Endotine device. Reprinted with permission from Coapt Systems, Inc. Copyright © 2002 by Coapt Systems, Inc.*

Patients and Methods

Between January 2002 and March 2002, 9 patients underwent Endotine fixation for endoscopic forehead lifts under a protocol administered and approved by the institutional review board of Mid*Lands (Leawood, KS). The patient group comprised 8 men and 1 woman, ranging in age from 35 to 55 years (mean age 48 years). All patients were treated under general anesthesia as outpatients. Three patients underwent endoscopic brow lifts as a sole procedure and 6 had adjunctive facial cosmetic procedures.

The Endotine 3.5 forehead device tested in this study consists of a polylactide homopolymer designed with 5 tines (each 3.5 mm long) on the superior surface for engaging the deep scalp tissues and a 4.25-mm post on the deep side for setting into a cranial bone hole (Figure 1). After a 4.25-mm hole was drilled in the outer table of the skull, the device was inserted and the scalp elevated to the desired position. The scalp was then pressed firmly onto the tines to engage the periosteum and galea (Figure 2). The time required for insertion of the device, from the initial drilling in the outer table to scalp fixation, was 60 to 90 seconds.

Results

The surgeon (W.G.S.) was asked to assess difficulty of dissection, drilling of the outer hole, insertion of the Endotine device, skin closure, and ease of instrument use (Table 1). The implants were judged palpable but not distinct during 3 months of follow-up (Table 2). Several patients with thin scalps complained of pain with pressure; the implant was removed from one of these patients. Postsurgical pain was evaluated on a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = moderately severe, 4 = severe) and averaged 0.7 (Table 3). Mild inflammation was seen only at the suture line. No other complications or side effects were noted. The surgeon's assessments of overall outcome ranged from "very satisfied" to "somewhat satisfied" (Table 4). Typical results are shown in a male and a female patient (Figures 3 and 4).

Discussion

There is considerable debate among surgeons using endoscopy as to the most effective fixation technique in brow lifting and the time required for fixation techniques to suspend the forehead until natural adherence takes place between the periosteum and the outer table of the skull. McKinney and Sweiss[4] argue that the periosteum attaches in a very short time and maintain screw suspension for just 3 to 5 days. Most authors who advocate the use of metal screws or pins remove the hardware in 10 to 14 days. Romo et al[5] conducted a histologic study of the fixation of periosteum to bone in rabbits and concluded that periosteal adherence to calvarium requires at least 6 weeks and complete adherence occurs by 12 weeks. Eaves et al[6] believe that it takes 42 to 60 days for adhesion to plateau. All surgeons agree that the type of fixation is only one of the critical elements in permanent brow elevation. Complete release of the supraorbital periosteum and permanent weakening of brow depressor muscles are necessary as well. The force of gravity also influences later descent of the brow.

A less explored area of brow lift outcomes involves the dynamic relationship of the galea to the underlying periosteum. An adherent periosteal layer on the cranium may not necessarily assure an elevated galea and overlying skin. The Endotine 3.5 device is designed to secure periosteum and galea, in contrast to fibrin glue, which presumably affects only periosteal adherence to bone.

Table 1. Assessment of difficulty with Endotine 3.5 forehead device

Patient	Difficulty*				Ease of use/ instrument assessment†
	Dissection	Drilling	Endotine	Skin closure	
1	1	2	1	1	2
2	1	1	1	1	1
3	1	2	2	1	2
4	1	1	1	1	1
5	1	1	1	1	1
6	1	1	1	1	1
7	1	1	1	1	1
8					1
9	1	1	1	1	1
Average	1.0	1.3	1.1	1.0	1.2

*1 = no; 2 = yes

† 1 = no problems encountered; 2 = problem identified but easily corrected; 3 = significant problem; 4 = unable to implant device

Table 2. Postoperative palpability of implant

After surgery	1 month	3 months	6 months	12 months
3	2	2	3	
3	3	3	3	
3			3	
2	3	3	3	
3	2	2	2	
3	3			
2	3		3	
2	3	2		
2	3			
2.6	2.8	2.4	3.0	

1 = no palpability; 2 = palpable but not distinct; 3 = distinct sharp or edge palpability; 4 = tine penetration through scalp

Table 3. Postsurgical pain assessment (mm)

After surgery	1 month	3 months	6 months	12 months
0	0	0	0	
0	2	0	0	
0			0	
0	0	0	0	
3	0	0	0	
3	1			
0	0		0	
0	0	0		
0	0			
0.7	0.4	0.0	0.0	

0 = none; 1 = mild; 2 = moderate; 3 = moderately severe; 4 = severe

Further research is necessary to unravel the myriad influences that affect the forehead subjected to surgery. Several authors have observed that regression of the initial brow elevation observed at surgery occurs in the postoperative period. Eaves et al[6] noted that the tissue around the fixation device gives way and loosens. McKinney and Sweiss[4] measured brow elevation in 24 randomly selected patients and noted that immediate intraoperative pupil-to-brow elevation of 6 to 7 mm did not persist but, rather, descended 2 to 3 mm during follow-up. Troilius[7] presented an extensive series of measurement comparisons of subperiosteal versus subgaleal brow lifts. He concluded that the subperiosteal lift achieves more permanent fixation because the entire inelastic periosteum adheres to bone. The subgaleal elevation consists of galea and frontalis muscle, both of which are elastic and can stretch and glide back toward their original positions. Multiple and diverse methods of fixation of the forehead after endoscopic lifts have been described. Morello[8] stated that the three most important factors in endoscopic brow lift are "fixation, fixation, and fixation." He noted that historically, endoscopic brow lifts were performed without fixation or products that provided temporary fixation, such as external taping and bolsters, Reston foam, or elastic wraps. However, complications of scalp necrosis and alopecia occasionally

Table 4. Surgeon's overall assessment

After surgery	1 month	3 months	6 months	12 months
1	1	1	1	
1	1	1	1	
1			1	
1	1	1	1	
1	1	1	1	
1	1			
1	1	1	1	
1	1	1		
1	1			
1.0	1.0	1.0	1.0	

1 = very satisfied; 2 = somewhat satisfied; 3 = neither satisfied nor dissatisfied; 4 = somewhat dissatisfied; 5 = very dissatisfied

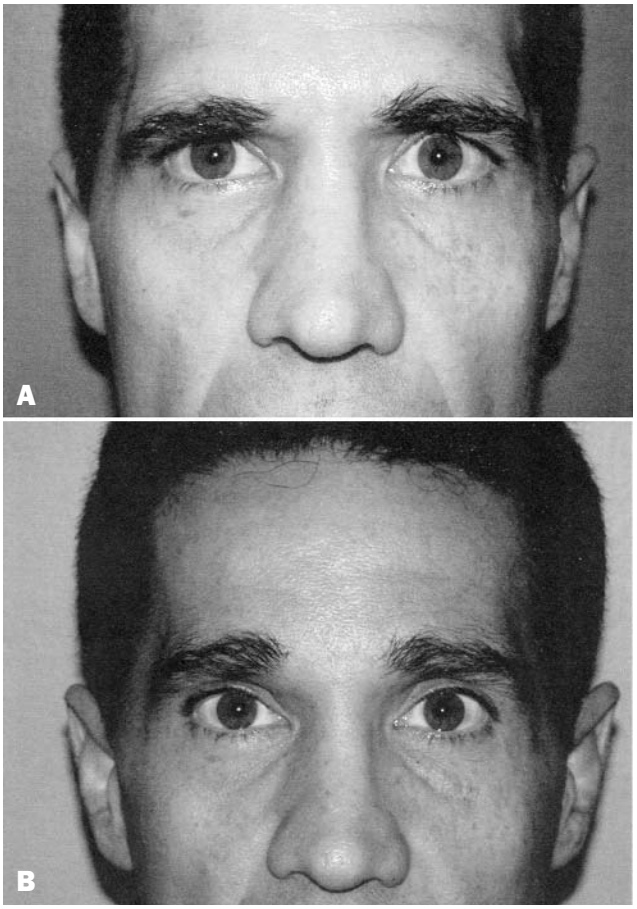

Figure 3. A, *Preoperative view of a 45-year-old man.* **B,** *Postoperative view 3 months after endoscopic brow lift.*

occurred, and long-term brow position was unpredictable because the full correction was not maintained over time.

Several methods of suspension that do not involve anchoring to bone have been described. These include scalp excision, V-Y advancement, and the use of fibrin glue. Vasconez and de la Torre[9] used 3 staples to close the endoscopic entrance wound and 3 staples approximately 4 cm behind this site. They then suspended the anterior staples posteriorly with a 3-0 nylon suture and maintained the suspension for 3 to 5 days. Hamas[10] has described a method of plication of the galea that involves 6 suspension sutures. The resulting overlying skin roll flattens in 3 to 6 weeks. Several authors have advocated the use of cortical tunnels in the outer table, using a power drill to fashion the tunnel, through which sutures may be fastened.

Multiple procedures have been described that involve placing hardware in the form of metal screws, pins, or plates in the outer table of the skull. Chasen[11] preferred percutaneous screws to internal permanent microscrews or plates. Swift et al[12] used 2-mm cortical titanium miniscrews and staples behind the screws. Daniel[13] advocated a 13 to 15 × 1.5-mm screw with 4-mm thread plus staples that are kept in place 3 to 4 weeks. He applied maximal upward tension to the scalp during screw application.

Complications and side effects reported from external wires, pins, and screws include alopecia and regression of position. In a survey of 570 plastic surgeons and a total of 3475 endoscopic forehead lifts, Elkwood et al[14] recorded that the most common complication was alopecia, which occurred in 2.94% of cases. Chasen[11] concluded that a significant incidence of alopecia occurs around screw sites. He also observed that patients are often dissatisfied with the visual effect of the screw protruding from the head, as well as with the pain at the screw site. Swift et al[12] reported a 25% incidence of small (5- to 8-mm) areas of alopecia at the screw-fixation sites. Daniel and Tirkanits[15] reported a 15% incidence of transitory alopecia around the screws. Lorenc[16] advocated the use of cortical tunnels to secure the forehead flap to the skull in order to place wound tension below the level of the hair follicles.

More recently, the use of permanent internal fixation devices has been advocated. Permanent metallic miniscrews such as the Mitek anchor are attached to the overlying periosteum with sutures. Bioabsorbable miniscrews made of Lactosorb or polylactic acid have also been used; as with the metallic miniscrews, sutures are used to tether the devices to the overlying tissue.

The Endotine 3.5 device can be rapidly applied and provides secure multipoint fixation. It can be easily adjusted or changed in the intraoperative or postopera-

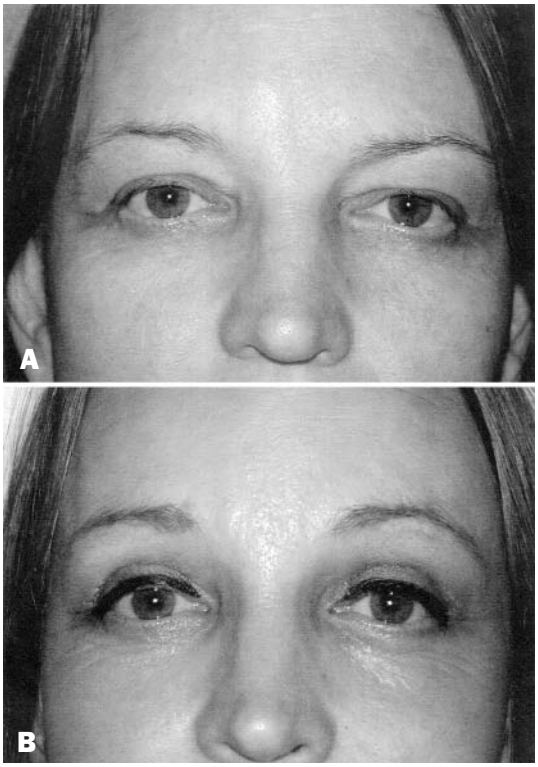

Figure 4. A, *Preoperative view of a 47-year-old woman.* **B,** *Postoperative view 3 months after endoscopic brow lift and upper blepharoplasty.*

tive period and allows aesthetic elevation and arching of selective brow elements. The multitine fixation prevents loosening and release of the scalp that is seen with single-suture fixation and thus may provide more stable, longer-lasting fixation of the brow position, reducing regression or relaxation of the suspended upper face. Studies are under way to evaluate its long-term efficacy. Internal fixation with the Endotine device has not been associated with the alopecia seen with the use of percutaneous pin or staple techniques.

The polylactic acid used in the Endotine 3.5 device is a well-known polymer used extensively in bioabsorbable devices, including maxillofacial applications. Although the initial polymer composition appeared to soften through water intake in approximately 12 weeks in porcine models, most patients reported that the devices were still palpable up to 24 weeks after implantation. In light of these reports, a thinner second-generation polymer that dissolves more rapidly has been fabricated. The Endotine 3.5 device is currently recommended only for patients with a comparatively thick scalp, at least 5 to 6 mm.

Conclusion

Preliminary findings indicated that the Endotine 3.5 forehead device provides fast, secure fixation without the complications associated with other fixation techniques. After most patients reported that the device was still palpable up to 24 weeks after implantation, a second-generation polymer that dissolves more rapidly was fabricated. ■

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