Brow Fixation with the Endotine Forehead Device in Endoscopic Brow Lift

R. Laurence Berkowitz, M.D., Daniel I. Jacobs, M.D., and Paul J. Gorman, M.D.

Campbell, San Jose, and Palo Alto, Calif.

Background: The Endotine Forehead device (Coapt Systems, Inc., Palo Alto, Calif.) is an implantable bioabsorbable fixation device designed to provide intuitive, multipoint, distributed tension and repeatable and predictable brow fixation during endoscopic and open browplasty. The purpose of this study was to evaluate early results in a series of endoscopic brow lift cases using the Endotine Forehead device.

Methods: Two versions of the Endotine device were used in this study. One was composed of polylactic acid, and the other was a smaller version consisting of 82/18 L-lactide/glycolide). In a consecutive series of endoscopic brow lift cases, preoperative and postoperative standardized photographs were taken in the Frankfort horizontal plane and three measurements were compared: midpupil to superior brow, midpupil to hairline, and lateral canthus to superior brow.

Results: A total of 21 patients (19 women and two men) underwent endoscopic browplasty. Photographs were obtained preoperatively and 54 to 174 days postoperatively. Brow elevation measurements were obtained postoperatively. No significant adverse events were encountered in the follow-up period.

Conclusion: The Endotine Forehead device provides significant and reproducible brow elevation, with no significant adverse events, as measured at three points in

excess of 14 weeks postoperatively. (*Plast. Reconstr. Surg.* 116: 1761, 2005.)

Surgical elevation of the forehead and brow for aesthetic improvement of the upper third of the aging face has been performed for nearly 100 years.¹ Open techniques traditionally relied on skin resection and brow repositioning to achieve desired results. These coronal approaches involve well-known negative sequelae, including paresthesias, numbness, scar widening, and alopecia, in addition to drawbacks with suboptimal tissue fixation and difficulty controlling brow shape.^{2,3} With the advent of minimally invasive techniques for facial aesthetic surgery in the early 1990s, surgeons began performing brow lifts without skin excision through much smaller incisions.^{4,5}

The development of endoscopic browplasty highlighted the importance of tissue fixation, as opposed to excision (which was merely a method of fixation), as a key factor in the success of the operation.⁶ Indeed, difficulty obtaining predictable tissue fixation was rapidly identified as a shortcoming of the endoscopic brow lift procedure.³ Various tools and techniques were developed in attempts to provide secure fixation, including Mitek anchors (Mitek Worldwide, Norwood, Mass.), bone tunnels, microscrews, percutaneous fixation posts, Kirschner wires, fibrin glue, and miniplates, and in some cases, no fixation was used.^{7–13}

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From private practice, the Department of Plastic and Reconstructive Surgery, Kaiser Permanente, and Department of Clinical Affairs, Coapt Systems, Inc. Received for publication June 8, 2004; revised November 22, 2004.

Dr. Berkowitz has served as a consultant and Medical Advisor to Coapt Systems and holds company stock options. Dr. Jacobs is founder and currently a director of the company, and holds company stock options. Dr. Gorman has served as Director of Clinical Affairs for the company.

Many of these techniques are thoroughly discussed by Rohrich and Beran.⁶

To date, most fixation techniques have relied on a single point of fixation (i.e., one suture loop passed through tissue and secured, or a single percutaneous post serving as a tissue dam). A new absorbable device (Endotine Forehead; Coapt Systems, Inc., Palo Alto, Calif.), designed to distribute tension over multiple points of fixation, has recently been introduced. The device is composed of a bioabsorbable copolymer and consists of a platform, a post, and a series of five tines projecting from the platform. During use, the post is inserted into a small hole in the outer table of the cranium and the device is seated firmly against bone (subperiosteal). The untethered scalp/ forehead tissues are then lifted and suspended through tine penetration of the periosteum.

Early work has shown that the Endotine Forehead device provides rapid, predictable, and secure fixation without complications.¹⁴ This report provides as detailed description of brow fixation, with preoperative and postoperative brow height measures, in a series of 21 patients.

PATIENTS AND METHODS

Between April of 2002 and September of 2003, 21 patients underwent an endoscopic brow lift (all procedures were performed at a single site by Dr. Berkowitz) with Endotine Forehead fixation. The first 15 patients (group 1, 14 women and one man) received the original Endotine device, which was made of a polylactide homopolymer and consisted of a 1-mm-thick platform and tines that projected 3.5 mm from the platform (Fig. 1). One device

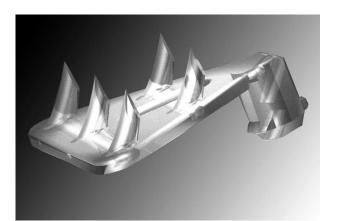


FIG. 1. Original Endotine Forehead device.

was implanted on each side, anterior to the coronal suture and medial to the temporal fusion line, beneath hair-bearing scalp (Fig. 2). The original device required drilling a cranial hole to 4.25 mm.

Group 1 patients underwent a series of concomitant procedures, detailed in Table I). The remaining six patients (group 2, five women and one man) received the next-generation device (embodied in a much smaller total mass), composed of L-lactide/glycolide (82: 18), a more rapidly absorbing polymer. Five of them received the 3.0 version (tines projecting 3 mm from the platform) and one received the 3.5 version (tines projecting 3.5 mm from the platform). The cranial drill hole in this group was limited to 3.95 mm. These six patients also underwent additional procedures, also detailed in Table I. Placement of the device was identical in both groups.

Full-size, 1:1, standardized black-and-white photographs (Frankfort horizontal plane) were taken of each patient 4 to 6 weeks before surgery. An additional set of photographs was taken postoperatively. The postoperative photographs included at least one image with a scale (cm and mm) to validate measurement accuracy. From a horizontal line drawn through the medial canthi, the following three measurements were taken from each side of the before and after images (Fig. 3):

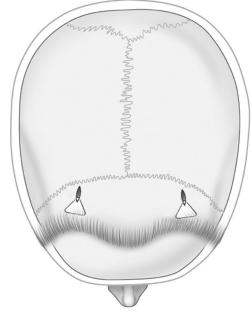


FIG. 2. Device placement.

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TABLE I Concomitant Procedures for Group 1, Group 2, and Both Groups Combined

	EBL	EMFL	BUEB	BLEB	FL	NL	CA	PEL
Group 1	15	7	1	7	2	2	0	4
Group 2	6	4	1	1	4	4	1	0
Combined	21	11	2	8	6	6	1	4

EBL, endoscopic brow lift; EMFL, endoscopic midface lift; BUEB, Bilateral upper eyelid blepharoplasty; BLEB, bilateral lower eyelid blepharoplasty; FL, face lift; NL, neck lift; CA, chin augmentation; PE, periorbital erbium laser.

- 1. On a perpendicular line passing through the midpupil to the superior margin of the eyebrow (hereafter referred to as the "superior brow")
- 2. On a perpendicular line passing through the midpupil to the hairline
- 3. On a perpendicular line passing through the lateral canthus to the superior brow

The measurements were recorded and compared.

RESULTS

Twenty-one patients were evaluated, with follow-up ranging from 54 to 174 days (average follow-up, 102 days, or 14.6 weeks). There were no reports of pain, device extrusion, device removal, numbness, paresthesias, or alopecia. No additional surgery was required to revise or maintain the desired result. Table II shows raw measurement data for the midpupil and lateral canthus to superior brow distances. Group 1

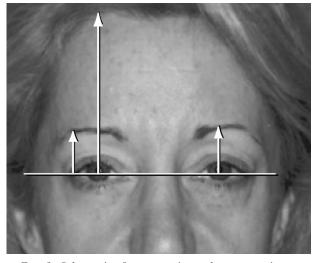


FIG. 3. Schematic of preoperative and postoperative measurements.

patients (n = 15) received elevations averaging 4.3 to 4.8 mm (range, 1 to 13 mm) (Table III). A representative patient result is shown in Figure 4. Group 2 patients (n = 6) received elevations averaging 3.5 to 5.0 mm (range, 1 to 8 mm) (Table IV). A representative patient result is shown in Figure 5. The combined group (21 patients) received elevations averaging 4.2 to 4.8 mm (range, 1 to 13 mm) (Table V).

DISCUSSION

The long-term efficacy of endoscopic brow lift has been a subject of debate. Others have used brow height change as a marker for success, with results ranging from approximately 2 mm to more than 6 mm and, in some cases, 10 to 12 mm.^{12,15,16} Maximum brow height elevation alone is often not the operative goal, as predicting brow height change is limited by the surgeon's inability to predict the effect of frontalis muscle relaxation. Other factors, including brow shape and overall aesthetic balance, must be considered when assessing outcomes. However, dissatisfaction with the endoscopic brow lift procedure is often related to suboptimal vertical height change. As such, assessing measurable differences in preoperative and postoperative brow height does provide an objective standard among multiple factors used to evaluate brow lift outcomes.

Many believe that a key factor in achieving a prolonged and stable lift is the extent to which effective fixation is maintained. The shortterm methods (taping, percutaneous screws, and so on), in addition to poorly distributing the tensile forces, do not provide support throughout the critical early healing period. Studies have shown that it can take up to 6 weeks for elevated periosteum to re-adhere to underlying bone, and some advocate maintaining fixation for at least 6 to 8 weeks postoperatively.^{7,17,18} Other factors influence outcome, including weakening of brow depressors and the extent of periosteal, orbicularis, and restraining ligament release along the orbital rim.

The Endotine device provides effective fixation during healing. The multipoint fixation concept appeared to successfully provide several points of contact to distribute the postoperative regressive forces over a broader surface area than single-point fixation. Average elevations of 4.2 to 4.8 mm, as measured across

TABLE II

Raw Measurement Data for Midpupil and Lateral Canthus to Superior Brow Distances

Patient Midpupil to Su			erior Brow (r	bw (mm) Lateral Canthus to Superior Brow (ms			(mm)	POD	
Preoperative Left Right	perative	Postoperative		Preoperative		Postoperative			
	Right	Left	Right	Left	Right	Left	Right		
1	19	17.5	24	22	18	18.5	22.5	23	161
2	26	23	30	28	26.5	23	30	27	84
3	19	16	26	24	20	18	27	27	60
4	23	22	25	24	22	21	24	24	131
5	19	15	28	28	19	17	27	27	105
6	25	25	29	29	26	25	30	28	106
7	24	21	26	24	24	24	26	26	129
8	21	20	22	21	21	21	23	24	118
9	26	26	30	31	30	28	34	33	54
10	27	26	30	30	29	29	30	31	174
11	26	21	28	24	24	25	27	26	89
12	24	21	28	25	24	23	29	26	139
13	17	16	25	23	17	19	25	26	103
14	23	24	28	27	25	25	29	29	104
15	22	19	27	24	19	19	26	25	81
16	22	22	27	30	25	25	30	33	88
17	26	24	30	27	26	24	28	27	88
18	20	20	25	25	19	21	24	25	84
19	21	19	28	26	21	21	30	29	82
20	25	21	27	23	26	22	28	24	77
21	23	21	24	26	22	24	25	27	168

POD, postoperative day.

three points bilaterally, were obtained. The three points were chosen because they reveal measurable vertical change over three regions. The devices were well tolerated by the patients, and none required removal. Use of the device was intuitive and rapid.

Patient follow-up did not exceed 6 months in this study. The device material used in group 1 is known to absorb slowly (well over 12 months), while group 2 received devices composed of a copolymer that is fully resorbed, in vitro, within 12 months. In both cases, device integrity is maintained well beyond the critical healing period, thus providing mechanical fixation until sufficient biological fixation has taken place.

The original device was offered with 3.5-mm tines to ensure the tines would penetrate the periosteum. The current Endotine Forehead device is available with 3.0-mm tines, in addi-

TABLE III Group 1 Patient Results (n = 15 patients)

Measurement		Left			Before vs After p		
	Before	After	Difference	Before	After	Difference	
Midpupil to superior brow							
Mean (SD)	22.7 (3.13)	27.1 (2.37)	4.3 (2.29)	20.8 (3.61)	25.6 (3.02)	4.8 (2.88)	0.000
Median	23.0	28.0	4.0	21.0	24.0	4.0	
Min., max.	17.0, 27.0	22.0, 30.0	1.0, 9.0	15.0, 26.0	21.0, 31.0	1.0, 13.0	
Midpupil to hairline							
Mean (SD)	76.1 (5.40)	80.7 (5.59)	4.6 (2.03)	75.7 (5.26)	80.3 (4.83)	4.6 (2.15)	0.000
Median	76.0	81.0	5.0	77.0	80.0	4.0	
Min., max.	67.0, 87.0	71.0, 93.0	2.0, 8.0	67.0, 84.0	71.0, 88.0	1.0, 9.0	
Lateral canthus to superior brow							
Mean (SD)	23.0 (3.97)	27.3 (3.09)	4.3 (2.27)	22.4 (3.68)	26.8 (2.65)	4.4 (2.58)	0.000
Median	24.0	27.0	4.0	23.0	26.0	4.0	
Min., max	17.0, 30.0	22.5, 34.0	1.0, 8.0	17.0, 29.0	23.0, 33.0	1.0, 10.0	

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FIG. 4. Preoperative (left) and postoperative day 60 (right) images.

tion to 3.5-mm tines, to accommodate surgeons' wishes for a lower profile device, with less material volume, that maintains adequate periosteal penetration. The device insertion post was shortened with the second generation to reduce material volume and decrease bonedrilling depth without compromising device anchoring. There have been no reported cases of cranial penetration resulting in a cerebrospinal fluid leak.

There was no evidence of numbness, paresthesias, or alopecia associated with use of this device. The absence of alopecia may be due to relatively less tension in a given tissue unit due to multiple points of suspension. This phenomenon provides for diminished local tissue compression and may provide an improved healing environment with subsequent positive effects on scar formation.

Recent reports have indicated that the number of endoscopic brow lift cases is declining and that practitioners find the open (coronal) approach more effective for obtaining brow-lifting goals.^{19,20} The Endotine Forehead device may allow a return to the more minimally invasive endoscopic approach by providing a simple, effective, and predictable solution to the problem of brow fixation in endoscopic browplasty.

TABLE IV Group 2 Patient Results (n = 6 patients)

Measurement		Left			Before vs After p		
	Before	After	Difference	Before	After	Difference	
Midpupil to superior brow							
Mean (SD)	22.8 (2.32)	26.8 (2.14)	4.0 (2.19)	21.2(1.72)	26.2 (2.32)	5.0(2.28)	0.000
Median	22.5	27.0	4.5	21.0	26.0	5.0	
Min., max.	20.0, 26.0	24.0, 30.0	1.0, 7.0	19.0, 24.0	23.0, 30.0	2.0, 8.0	
Midpupil to hairline							
Mean (SD)	73.0 (6.99)	76.5 (6.60)	3.5(1.05)	73.0 (7.27)	77.3 (7.87)	4.3 (2.07)	0.000
Median	74.0	78.0	3.5	74.5	77.5	4.0	
Min., max.	62.0, 82.0	67.0, 85.0	2.0, 5.0	62.0, 81.0	66.0, 89.0	2.0, 8.0	
Lateral canthus to superior brow							
Mean (SD)	23.2 (2.93)	27.5 (2.51)	4.3 (2.66)	22.8 (1.72)	27.5 (3.21)	4.7 (2.66)	0.000
Median	23.5	28.0	4.0	23.0	27.0	3.5	
Min., max.	19.0, 26.0	24.0, 30.0	2.0, 9.0	21.0, 25.0	24.0, 33.0	2.0, 8.0	

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FIG. 5. Preoperative (*left*) and postoperative day 82 (*right*) images. Note the use of scale to validate measurements.

TABLE VCombined (Groups 1 and 2) Patient Results (n = 21 patients)

		Left					
Measurement	Before	After	Difference	Before	After	Difference	Before vs After p
Midpupil to superior brow							
Mean (SD)	22.8 (2.86)	27.0 (2.26)	4.2 (2.21)	20.9 (3.15)	25.8 (2.79)	4.8 (2.67)	0.000
Median	23.0	27.0	4.0	21.0	25.0	4.5	
Min., max.	17.0, 27.0	22.0, 30.0	1.0, 9.0	15.0, 26.0	21.0, 31.0	1.0, 13.0	
Midpupil to hairline							
Mean (SD)	75.2 (5.89)	79.5 (6.05)	4.3(1.85)	74.9 (5.84)	79.4 (5.80)	4.5(2.07)	0.000
Median	76.0	80.0	4.0	77.0	80.0	4.0	
Min, Max	62.0, 87.0	67.0, 93.0	2.0, 8.0	62.0, 84.0	66.0, 89.0	1.0, 9.0	
Lateral canthus to superior brow							
Mean (SD)	23.0 (3.63)	27.4 (2.88)	4.3 (2.31)	22.5 (3.20)	27.0 (2.76)	4.5(2.54)	0.000
Median	24.0	27.0	4.0	23.0	27.0	4.0	
Min., max.	17.0, 30.0	22.5, 34.0	1.0, 9.0	17.0, 29.0	23.0, 33.0	1.0, 10.0	

R. Laurence Berkowitz, M.D. 3803 S. Bascom Avenue Campbell, Calif. 95508 rlberkowitz@gmail.com

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