26

Laser Scleral Matrix Microexcisions (LaserACE/Erbium YAG Laser)

AnnMarie Hipsley, DPT, PhD and Marguerite McDonald, MD, FACS

The majority of the surgical techniques designed to address the issue of presbyopia involve a change in the optics of the eye, whether corneal or lenticular. In changing the eye's optics, there is a trade-off for all existing technologies, except accommodating IOLs, between providing near vision and sacrificing some aspect of distance vision (ie, acuity, contrast, or degree of visual disturbances). Moreover, to date, accommodating IOLs have failed to achieve consistent, clinically significant results.[1] Fibrosis of the lens capsule after cataract surgery and the significant changes in biomechanical alignment of the lens capsule, zonules, and ciliary muscle may prove to be significant hurdles in attempting a lenticular restoration of accommodation. A surgical procedure to restore the natural dynamic accommodation at the sclera would be considerably advantageous and could potentially preserve the existing geometry of the eye, preserve the optics of the eye, and eliminate the need for intraocular surgery in a younger eye with a clear lens that has no evidence of cataract.

In the 1980s, contributions of all relevant components of the accommodative system were identified, and changes in the elasticity of some of these components were described.[2] The sclera, a typical connective tissue, is relatively inelastic. However, its rigidity increases with age, suggesting there is some loss of plasticity in the tissue.[3] The fundamental premise of the laser scleral microexcisions procedure is that the restoration of this plasticity may provide some biomechanical advantage to the ciliary muscle and thus improve the ability to accommodate.

Anterior ciliary sclerotomy (see Chapter 25), an earlier scleral procedure, involved large radial excisions to effect a change in scleral biomechanics. The procedure was performed without any attempt to modify the healing process. Study results suggested that the technique had safety issues and that no significant change in accommodative ability was evident.[4] Later attempts involving insertion of collagen plugs suggested there was an accommodative effect, but it appeared transient.[5] The scleral microexcisions procedure novelizes that approach by using a laser to create precise microexcisions that are placed in a closely arranged, 2-dimensional array wherein the 2-dimensional array or matrix creates an area of "negative stiffness" in the scleral tissue. The microexcisions are filled with an antifibrotic collagen matrix to preserve the patency of the microexcisions and preserve the flexibility in the tissue matrix.

The Laser Scleral Microexcision Procedure: Restoration of Dynamic Accommodation

The procedure is a surgical technique utilizing an Er:YAG ophthalmic laser to perform scleral microexcisions in an attempt to restore dynamic

Pallikaris IG, Plainis S, Charman WN.
Presbyopia: Origins, Effects, and Treatment (pp. 219-224).

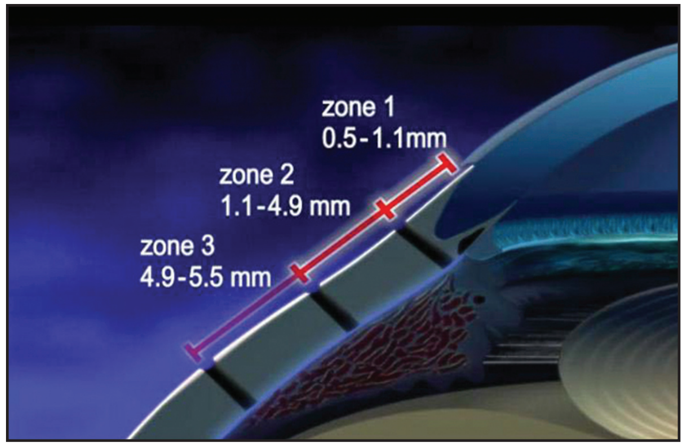

Figure 26-1. Schematic laser microexcision treatment zones.

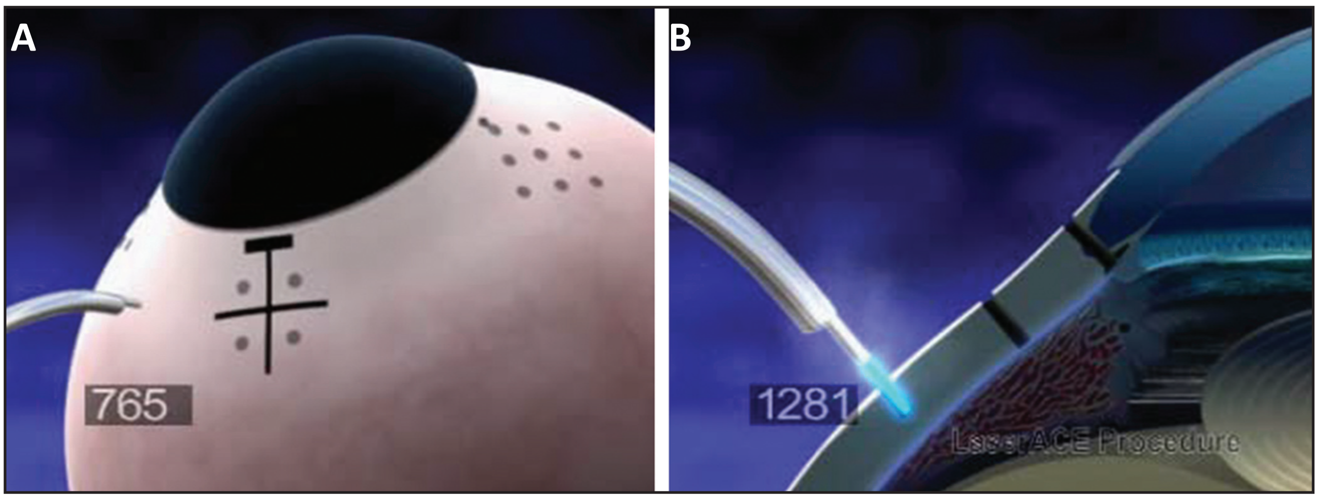

Figure 26-2. Matrix configuration and depth of the neopore microexcisions.

accommodation to the eye. The Er:YAG laser has an established safety profile and has been effectively used for scleral procedures for the treatment of glaucoma.[6] It operates in infrared at a wavelength of 2940 nm.

The nomogram used is based on patented mathematical calculations that treat the anterior globe in 3 specific critical zones.[7] The 3 zones are as follows (Figure 26-1):

1. Zone 1: Just distal to the corneoscleral envelope in the region of the limbus extending to the pars plana over the girth of the ciliary body.
2. Zone 2: The region of the sclera that begins just outside of the pars plana.
3. Zone 3: The region of the ora serrata and the origin of the anterior radial ciliary muscles.

The microexcisions are performed through the conjunctiva and are made to a depth of ~90% of the sclera. The laser creates an excision approximately 600-µm wide. Figure 26-2 shows the layout of the excisions. Four sets of 9 excisions are made on the oblique quadrants of the eye in the zones indicated above.

The surgery is bilateral, and it is an outpatient procedure typically taking between 10 and 15 minutes per eye. The eye is prepared with a topical anesthetic, and a small contact lens is inserted to protect the cornea. The matrix is marked at the 4 oblique quadrants, and the microexcisions are performed. The surgeon manually controls the depth of the ablation. After completion of the microexcisions, a proprietary collagen biomatrix filler is applied to the eye to fill the excisions, prevent fibrosis, and preserve the patency of the ablations. This collagen filler degrades naturally over time. A large-diameter 18-mm scleral contact lens is then applied to the eye, and multidose antibiotic and steroidal drops are instilled. By the next postoperative day, the excisions are difficult to detect, and by 1 week the eye has generally returned to normal. Figure 26-3 shows the surgical procedure in step-by-step illustrations (panels A through D).

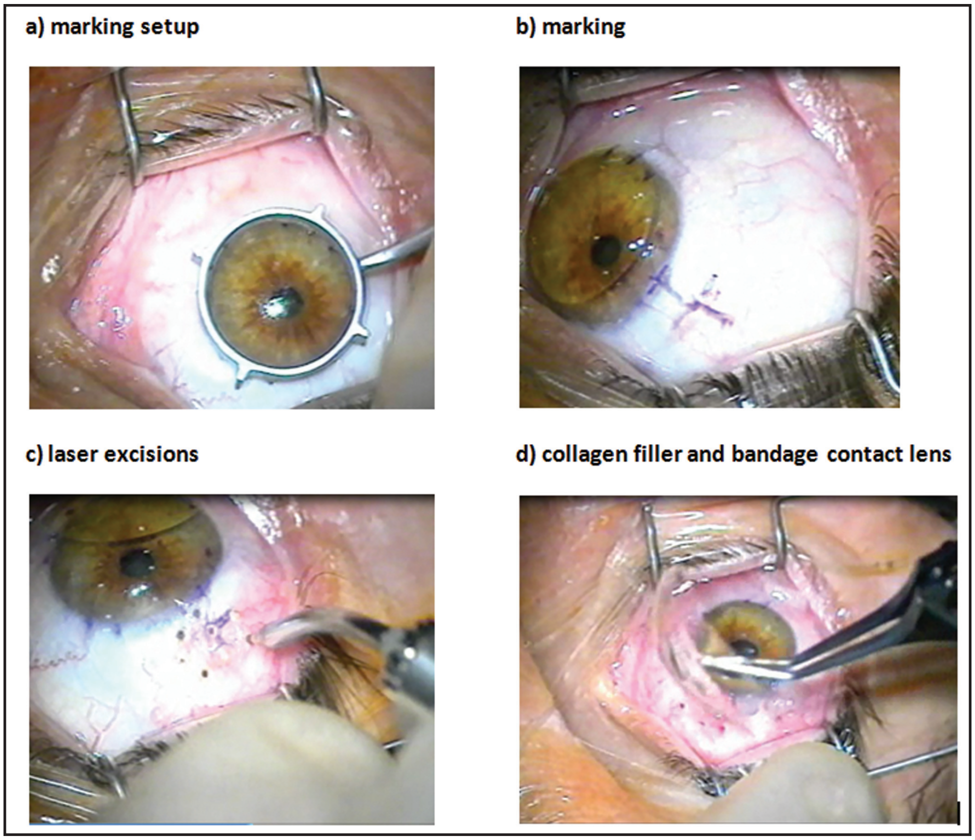

Figure 26-3. Steps in the laser microexcision procedure.

CLINICAL RESULTS

The important measures of success for any procedure to treat presbyopia (whether by restoring accommodation or through multifocal or aspheric corneal or IOL-related options) are as follows:

- □ The degree of accommodation (or pseudoaccommodation) achieved, as measured through intermediate and near vision when the patient is corrected at distance.
- □ The long-term efficacy of any change in near vision.
- □ The degree of visual disturbances introduced.
- □ The stability of distance vision after the procedure.

The early clinical trials of the laser scleral microexcisions procedure have been conducted using several iterations of the microexcision matrix, and the geometry of the matrix was modified for subsequent groups of patients based on results from the previous group. Measurements included pre- and postoperative refraction and objective measures of accommodation using the COAS aberrometer with dynamic stimulation aberrometry (AMO WaveFront Sciences, Albuquerque, NM) or the iTrace dynamic aberrometer (Tracey Technologies, Houston, TX). It is important that accommodative changes be objectively measured, as patient motivation and other factors can affect a patient's subjective range of accommodation (see Chapter 31). If a biomechanical change has been realized, objective accommodation will be measurably higher.

ACE Vision Group has 18-month follow up data on 67 presbyopic patients (134 eyes) who had a bilateral LaserACE procedure. The results show a significant increase in accommodative ability, a stable distance refraction and no increase in visual disturbances.

Figure 26-4 shows the change in refractive error over time for a small group of patients at one practice. Mean patient age was 50.4 ±3.9 years. Notice there is no change pre- to postoperatively except in the case of several hyperopic patients (preoperative data are positive in these cases). These patients appear to have a refractive error closer to 0 postoperatively, which is presumably a function of their restored ability to accommodate. Note that the slight variability over time is not unexpected and is likely the result of limited test-retest reliability. A statistical analysis of the refractive data for 13 eyes at 1, 6, 12, and 18 months

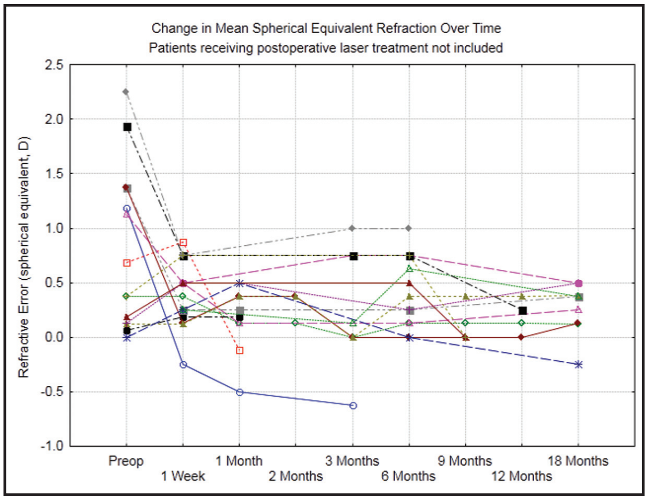

Figure 26-4. Refractive stability for distance vision.

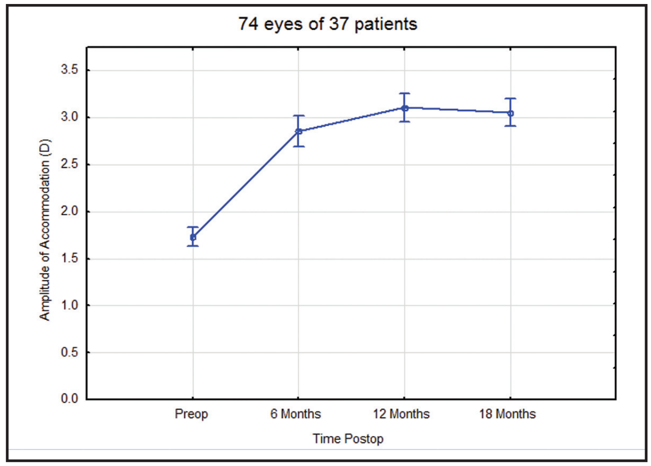

Figure 26-5. Average objectively measured accommodative amplitude preoperatively to 18 months postoperatively.

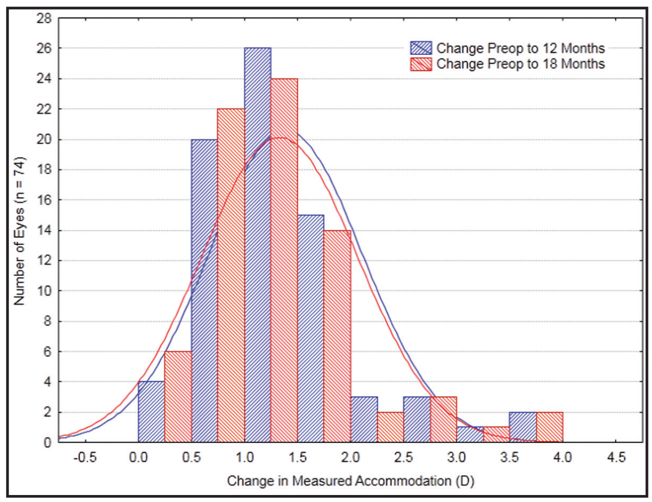

Figure 26-6. Histogram comparing changes in objectively measured accommodative amplitude at 12 and 18 months postoperatively.

showed no significant difference in mean spherical equivalent distance refraction (p=0.84). The average for all eyes was within ±0.25 D of emmetropia at all time points.

Figure 26-5 shows the average accommodative range measured for 74 eyes of 37 patients preoperatively to 18 months postoperatively, demonstrating stability at all postoperative time points. Mean patient age was 54.6 ±5.7 years.

Figure 26-6 contains a histogram of the change in objectively measured amplitude of accommodation preoperatively to 12 and 18 months postoperatively for the same group of eyes as in Figure 26-5. The accommodative effect is stable between the 2 time points, and the average increase in accommodation is between 1.25 D and 1.50 D. No patient lost any accommodative ability, nor did any patient lose any distance visual acuity, which suggests the visual results are safe for all patients and are effective for the majority of patients.

Figure 26-7 shows the cumulative reading ability in Jaeger notation before surgery and 18 months after surgery for 67 patients. Note that the improved reading performance was not at the expense of distance vision. Uncorrected distance vision was 20/20 or better in 75% of eyes preoperatively and in 88% of eyes 18 months postoperatively.

Critical features of the data collected to date include the following:

- There was no loss of accommodative ability, so all patients either retained their existing range of accommodation or demonstrated an increase in accommodative function.
- There was no change in best-corrected vision for any eye. This is in contrast to many competing technologies, particularly those involving increasing spherical aberration to provide a greater DOF.[8]
- There was no change in visual disturbances noted, in contrast to competing technologies.[9]

Summary

The laser scleral microexcision procedure involves the creation of a series of mathematically arranged microexcisions in the sclera over the ciliary body. Collagen filler is used to inhibit the healing response,

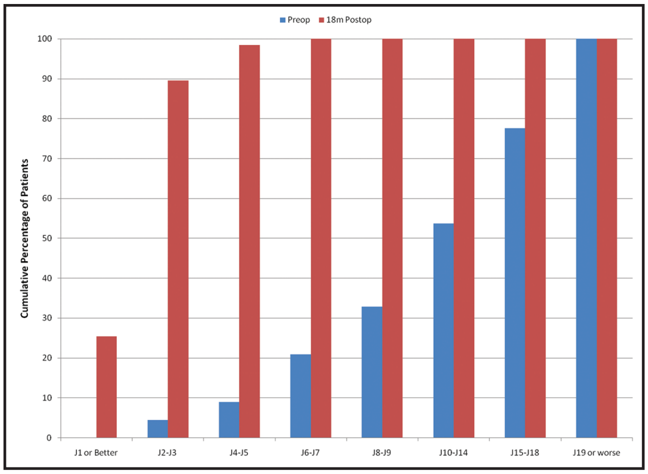

Figure 26-7. Cumulative near visual acuity (Jaeger) preoperatively (blue bars) and 18 months postoperatively (red bars).

ensuring that the excisions remain patent, as fibrosis across the excisions would negate the effect of the procedure. The premise of this procedure is that these microexcisions may increase the plasticity of the sclera and thereby increase the biomechanical efficiency of the ciliary muscle, restoring a degree of natural dynamic accommodation to the eye.

Early clinical results suggest the procedure is safe and effective. Distance visual acuity and visual disturbances were not affected, and the results appear stable to at least 18 months. The average increase in objectively measured accommodative range was 1.25 to 1.50 D. This appears to have a rejuvenation effect of approximately 5 to 10 years for early presbyopes.

The procedure is designed for restoring natural dynamic accommodation in emmetropic eyes. Patients who were emmetropic as a result of previous laser refractive surgery were included in the trials, and the procedure was equally effective for them. The potential exists for the procedure to be performed on post-LASIK or post-radial keratotomy patients who are slightly hyperopic with fluctuating vision. Restoration of some degree of dynamic accommodation may allow these patients to adjust to diurnal fluctuations in their refractive error.

The laser scleral microexcision procedure may also be used as an adjunct to other surgical and nonsurgical technologies to treat presbyopia. For instance, a limitation of monovision is that the range of tolerated difference between the near and distant correction appears to be approximately 1.00 to 1.25 D, which is insufficient for many patients' needs. If an additional 1.25 D was achieved with the microexcision procedure, patients would have an effective 2.50 D add when accommodating, which is sufficient for near work.

Additional studies on microexcision procedures for the restoration of dynamic accommodation include research into the mechanism of action of the procedure. Broader clinical trials to corroborate these early results are also under way. If similar results are achieved, this minimally invasive scleral procedure will be an attractive option for early presbyopes seeking to delay their need for reading spectacles.

REFERENCES

1. Menapace R, Findl O, Kriechbaum K, Leydolt-Koeppl CH. Accommodating intraocular lenses: a critical review of present and future concepts. *Graefes Arch Clin Exp Ophthalmol.* 2007;245(4):473-489.
2. Adler-Grinberg D. Questioning our classical understanding of accommodation and presbyopia. *Am J Optom Physiol Opt.* 1986;63(7):571-580. Erratum in: *Am J Optom Physiol Opt.* 1987;64(1):75.
3. Pallikaris IG, Kymionis GD, Ginis HS, Kounis GA, Tsilimbaris MK. Ocular rigidity in living human eyes. *Invest Ophthalmol Vis Sci.* 2005;46(2):409-414.
4. Hamilton DR, Davidorf JM, Maloney RK. Anterior ciliary sclerotomy for treatment of presbyopia: a prospective controlled study. *Ophthalmology.* 2002;109(11):1970-1976.
5. Malyugin B, Antonian S, Lohman BD. Anterior ciliary sclerotomy using collagen T-shaped implants for treatment of presbyopia. *Ann Ophthalmol* (Skokie). 2008;40(3-4):130-136.
6. Klink T, Schlunck G, Lieb WE, Klink J, Grehn F. Long-term results of Erbium YAG-laser-assisted deep sclerectomy. *Eye* (Lond). 2008;22(3):370-374.
7. Hipsley, AnnMarie inventor; ACE VISION GROUP INC, assignee. System and Method for Treating Connective Tissue United States patent US . 7, 871,404. Jan 18, 2011.
8. Jackson WB, Tuan KM, Mintsioulis G. Aspheric wavefront-guided LASIK to treat hyperopic presbyopia: 12-month results with the VISX platform. *J Refract Surg.* 2011;27(7):519-529.
9. Zhang F, Sugar A, Jacobsen G, Collins M. Visual function and patient satisfaction: comparison between bilateral diffractive multifocal intraocular lenses and monovision pseudophakia. *J Cataract Refract Surg.* 2011;37(3):446-453.