# Bitoric Laser In Situ Keratomileusis for the Correction of Simple Myopic and Mixed Astigmatism

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***Objective:*** To evaluate the safety and efficacy of bitoric laser in situ keratomileusis (LASIK) for the correction of simple myopic and mixed astigmatism.

***Design:*** Retrospective, single-center, and noncomparative case series.

***Participants:*** Eighty-six eyes of 56 patients were analyzed for this study. Six-month and 1-year follow-up data were available on 86 eyes and 72 eyes, respectively. Eyes were divided in two groups according to the type of astigmatism: myopic astigmatism with low sphere ($< -2$ diopters) and mixed astigmatism. The range of astigmatism was 1.25 to 7.5 diopters.

***Intervention:*** LASIK was performed using the Automated Corneal Shaper (ACS) microkeratome (Bausch & Lomb, Claremont, CA) to create a cornea flap using the 130- or 160-micron thickness plate. A bitoric mid-stromal ablation was performed using the Nidek EC-5000 excimer laser (Nidek Company, Gamagori, Japan).

***Main Outcome Measures:*** Uncorrected visual acuity, manifest refraction, and best spectacle-corrected visual acuity were the parameters measured preoperatively and at months 1, 3, 6, and 12.

***Results:*** At the last visit, an uncorrected visual acuity of 20/20 or better was achieved in 77% and 68% of the myopic and mixed astigmatism groups, respectively. Ninety-two percent of all eyes had a mean spherical equivalent within $\pm$ 0.50 diopter of emmetropia. A mean decrease in the vectorial magnitude of the astigmatism of 94% and 91% was achieved for those eyes with myopic and mixed astigmatism, respectively. There was no loss of best spectacle-corrected visual acuity. In two eyes, the axis of the positive cylinder was misaligned.

***Conclusion:*** Bitoric LASIK is an effective procedure to correct myopic and mixed astigmatism. Eighty-five percent of the eyes achieved an uncorrected visual acuity of 20/25 or better and had a final cylinder of 0.5 diopter or less. It is a safe operation, because no eyes lost any lines of best spectacle-corrected visual acuity. Longer follow-up may be needed to assess these results. *Ophthalmology 2001;108:303–308 © 2001 by the American Academy of Ophthalmology.*

Excimer laser refractive surgery has evolved from simple myopic ablations to cylindrical and elliptical myopic astigmatic ablation patterns on the central cornea. Annular peripheral ablations that steepened the central cornea to treat hyperopia were introduced later.[1–3] Because the central ablations to treat myopic astigmatism induce a spherical hyperopic shift, a special cylindrical ablation was designed to treat simple myopic astigmatism and prevent the hyperopic shift.[4] Alió et al[5] first reported the clinical results of such treatments. The first report of excimer laser surgery for the correction of mixed astigmatism involved the use of a toric ablation to flatten the steep meridian, in combination with a hyperopic ablation to compensate for the residual hyperopic sphere.[6] More recently, a new ablation profile was introduced to correct hyperopic astigmatism by steepening the flat meridian. This pattern has also been used in combination with myopic spherical ablation to treat mixed astigmatism. The initial reports from this combination to treat mixed astigmatism have shown encouraging clinical results.[7]

In 1997, we designed a new ablation pattern to treat mixed astigmatism and simple myopic astigmatism using laser in situ keratomileusis (LASIK). This ablation pattern consisted of flattening the steep meridian doing a cylindrical ablation, in combination with a paracentral ablation over the flat meridian to steepen it. The technique was later named "bitoric LASIK." Its rationale was to provide the largest optical zone to prevent visual symptoms, to compensate for the hyperopic shift induced by doing toric ablation over the steep meridian, and to prevent the need to use spherical ablation to compensate for the residual myopia when doing toric ablation over the flat meridian, therefore decreasing the

Originally received: October 24, 1999.
Accepted: August 29, 2000. Manuscript no. 99453.

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Presented in part at the American Academy of Ophthalmology annual meeting, Orlando, Florida, October, 1999.

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Published by Elsevier Science Inc.
ISSN 0161-6420/00/$–see front matter
PII S0161-6420(00)00498-X

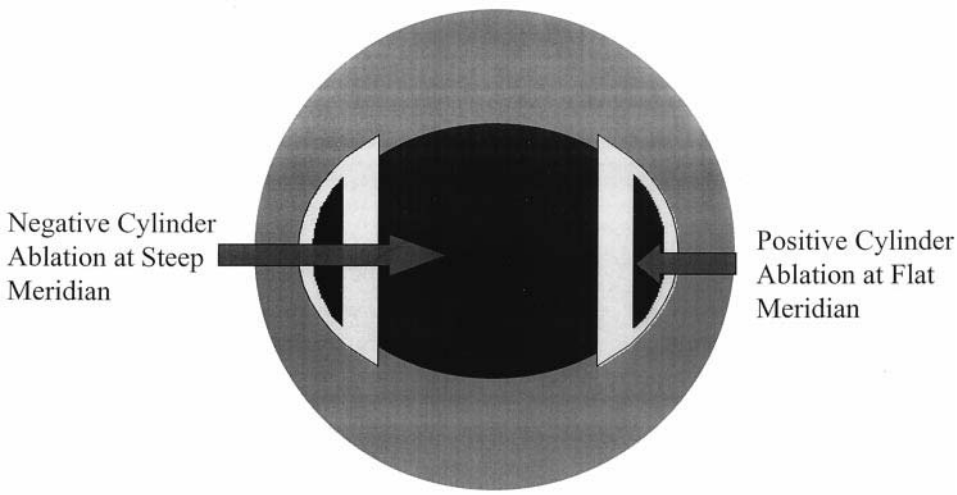


**Figure 1.** Bitoric ablation.

amount of tissue ablation. A formula was developed to calculate the percentage of toric ablation that should be used, and the preliminary results were published.[8]

Herein we are reporting, to our knowledge, the first long-term study on bitoric LASIK.

## Patients and Methods

Eighty-six eyes of 56 patients were treated with LASIK for the correction of myopic and mixed astigmatism. Toric ablations were always performed in both steep and flat meridians. All surgeries were performed by one surgeon (AC) between May 1997 and May 1998 at Codet Instituto de Oftalmología, Tijuana, México. Stromal ablations were done using the Nidek EC-5000 excimer laser (Nidek Ltd, Gamagori, Japan).

An elliptical ablation was used to flatten the central cornea in the steep meridian, and a "half-of-a-circle" paracentral ablation was used to steepen the central cornea at the flat meridian (Fig 1). The cylindrical ablation, which flattens the steep meridian, has the characteristic of inducing a hyperopic shift of approximately 33%. The paracentral ablation, which steepens the flat meridian, primarily affects this meridian and therefore does not induce any change in the spherical component of the refraction. On the other hand, with astigmatic keratotomy (AK), by placing incisions along the steepest meridian, depending on the length and optical zone used, a coupling effect is achieved. We found that this coupling effect is different when doing laser toric ablations, where basically no coupling effect occurs. When treating myopic astigmatism, the goal is to flatten only the steep meridian and therefore to correct all the astigmatism by matching the keratometric readings of the steep meridian to the preoperative readings of the flat meridian. Nevertheless, when using the cylindrical ablation, because most of the ablation occurs in the center of the cornea, the overall cornea is flattened (including the flat meridian), and, therefore, consecutive spherical hyperopia occurs. On the other hand, we found that when using the positive cylinder ablation over the flat meridian, the keratometric readings of this flat meridian matched those of the steep meridian, whereas the keratometric readings at the steep meridian remained the same. After considering these facts, we devised a formula to calculate the amount of cylinder to be corrected in each meridian (Fig 2). The formula design allows the surgeon to use cylindrical corrections only, because the spherical component is neuturalized by treating only the astigmatic components in the steep and flat meridians.

Inclusion criteria for the study consisted of myopic or mixed astigmatism of 1.25 to 7.5 diopters with a spherical component of −1.75 to +4.00 diopters. Most cases were simple myopic (spherical component of the refraction being "zero") and mixed astigmatism, with a few cases of compound myopic astigmatism with a very low spherical component (< −2 diopters), where bitoric ablation was needed to prevent the induction of hyperopia.

Patients were over 18 years of age with no history of systemic collagen vascular disease. All eyes had regular, symmetric, and orthogonal astigmatism demonstrated by corneal topography, central corneal thickness of more than 500 microns, and normal ocular examination. Patients with ocular hypertension or glaucoma were excluded.

Emmetropia was the target in all eyes. Uncorrected and best-corrected visual acuity was tested using a Snellen chart, and the examiners were instructed to test down to a visual acuity of 20/15.

### Laser Calibration

The Nidek EC-5000 excimer laser was calibrated and operated as described in the user manual. At the beginning of each operating day, the laser was calibrated by performing an ablation over a

$$C_{Myo} = \frac{|S + C|}{1.33}$$

$$C_{Hyp} = |C| - C_{Myo}$$

$C_{Myo}$ = negative cylinder, S = sphere, C= total cylinder
$C_{Hyp}$ = positive cylinder

**Figure 2.** Bitoric LASIK formula.

polymethyl methacrylate (PMMA) plate. We used the following routine: (1) −3.00 ± 0.25 diopters myopic ablation using a 5.0-mm ablation optical zone and 40-Hz repetition pulse. This calibration allowed setting the appropriate laser energy. (2) +3 ± 0.25 diopter hyperopic ablation using a 5.5-mm optical zone and 7.5-mm transition zone, 34-Hz repetition pulse, 1.0 PMMA/cornea ratio, and 0.45 seconds for sphere/cylinder rate.

After lensometry reading over the PMMA plate of −3.00 diopters and +3.00 diopters, respectively, we proceeded to enter the refractive data into the laser computer. We used a two-stage data entry program. The first stage consisted of the data entry of the plus cylinder (targeted to correct the flat meridian). The data of the minus cylinder (targeted to correct the steep meridian) was entered at the second stage. The ablation optical zone used for both steep and flat meridian treatments was 5.5 mm, and the transition zone used was 7.5 mm, also for both ablations.

### Surgical Technique

The eye that was to be operated on was prepared and draped, and topical anesthesia was achieved using two drops of 0.5% tetracaine. A wire lid speculum was placed, and the cornea was marked using the Chayet Corneal Marker (Katena Products, Denville, NJ). The Chiron Automated Corneal Shaper (Bausch and Lomb Surgical, Claremont, CA) was used to perform lamellar keratotomy using a flat, nonadjustable suction ring. The microkeratome was sterilized and assembled by technical personnel and tested by the surgeon before each operation. The suction ring was applied to the eye, and intraocular pressure was checked using a pneumotonometer (Mentor, Santa Barbara, CA) until 99.5 mmHg of intraocular pressure was achieved. The microkeratome head was engaged into the suction ring and then moved forward over the cornea to create a corneal flap 8.5 to 9.0 mm in diameter, using the 130- or 160-micron plate, depending on the preoperative corneal thickness. The 160-micron plate was typically used.

Once the microkeratome was reversed and removed, the Chayet LASIK drain (Becton Dickinson and Company, Waltham, MA) was placed over and around the cornea over the suction ring and the flap was lifted and reflected nasally to allow for the excimer laser midstroma ablation. Before starting the treatment, the head position was checked to prevent incorrect treatment alignment. All ablations were performed with the suction ring (without vacuum) acting as a mechanical fixator to facilitate centration of the ablation. Toric ablation over the flat meridian was done first and followed immediately using a multistage program by the steep meridian toric ablation.

After laser treatment was finished, the flap was rolled onto the bed using the Vidaurri LASIK canulae (Becton Dickinson and Company, Waltham, MA), and the flap was allowed to dry for about 1 minute. Before removal of the lid speculum, one drop of Garamicine (Schearing, Mexico City, Mexico) and one drop of Voltaren (Ciba, Mexico City, Mexico) were placed in the eye. The flap position was verified by a surgeon with slit-lamp microscopy approximately 20 minutes after surgery. The patient was subsequently discharged with a plastic eye protector taped in place.

### Postoperative Medications

The patient was instructed to use one drop of Tobradex (Alcon Laboratorios, Mexico City, Mexico) in the eye that was operated on four times daily for 4 days. Artificial tears were recommended as needed.

### Postoperative Examinations

Postoperative examinations were done at 24 hours, week 1, and at 1, 3, 6, and 12 months. Slit-lamp and uncorrected visual acuity (UCVA) examinations were done at days 1 and 7. UCVA, manifest refraction, best spectacle-corrected visual acuity (BCVA), and slit-lamp examination, were done at months 1, 3, 6, and 12.

Table 1. Preoperative Values for Gender, Age, Spherical Equivalent, Spherical Component, and Cylinder

| | |
|---|---|
| Male | 61% |
| Female | 39% |
| Mean age | 32 |
| Mean spherical equivalent | −1.08 (±1.17) |
| Mean spherical component | +0.53 (±1.17) |
| Mean cylinder | −3.75 (±1.37) |

### Laser in Situ Keratomileusis Enhancement

LASIK enhancement was performed for the correction of any residual refractive error that caused dissatisfaction to the patient. This was usually done when the UCVA was 2 or more lines worse than the preoperative BCVA and when the residual astigmatism was greater then 0.75 diopter.

Enhancement was allowed after the 3-month examination for undercorrections, and after 6 months for overcorrections.

### Outcome Measures and Statistical Analysis

Statistical evaluation was performed as follows: all data were entered into a personal computer using a spreadsheet program (Microsoft Excel 7.0; Microsoft Corp., Seattle, WA). The surgically induced refractive change was assessed by vector analysis using a technique previously described.[9] The changes were calculated based on the change in refractive astigmatism at the corneal plane. Statistical analysis was performed using StatXact (Cytel Software Corp., Cambridge, MA). A two-tailed Student's *t* test was used to evaluate differences between the mixed and the myopic astigmatism groups; *P* less than or equal to 0.05 was considered significant.

## Results

### Study Population

Ninety-seven eyes of 62 patients received bitoric LASIK from May 5, 1997, to May 31, 1998. Data from 11 eyes of 6 patients were not available either at 6 months or 1 year, because the patients lived a long distance away from our clinic. Therefore, we analyzed data from the 86 eyes of 56 patients who were seen at 6 months or 1 year. Data were available at 1 year on 72 of 86 eyes and at 6 months on 14 of 86 eyes.

Table 1 shows the demographics and preoperative values for mean spherical component, mean spherical equivalent, and mean cylinder.

Eleven of the 86 eyes (13%) received one enhancement.

The results reported are from the last visit, 84% (72 eyes) from year 1, and the remaining 16% (14 eyes) from month 6.

### Visual Acuity

Preoperative BCVA was 20/20 in 56 eyes (65%). Despite the fact that 30 of 86 eyes (35%) had a preoperative BCVA of 20/25 or worse, all eyes were included in the analysis of postoperative UCVA. At the last visit, UCVA was 20/20 or better in 62 eyes

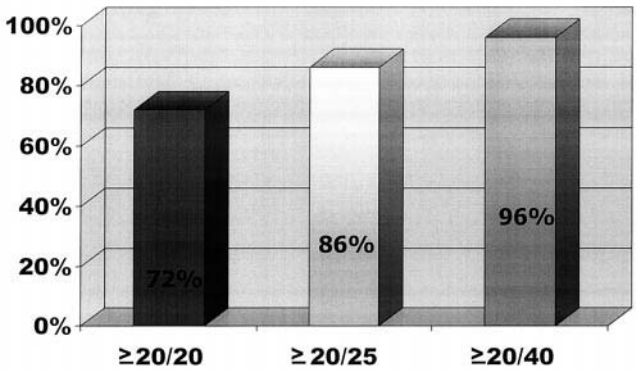


**Figure 3.** Uncorrected visual acuity for all eyes (n = 86) at the last postoperative visit.

(72%), 20/25 or better in 74 eyes (86%), and 20/40 or better in 83 eyes (96%; Fig 3).

Of the 86 eyes, none lost more than 1 line of best spectacle-corrected visual acuity, and 22 eyes (25%) gained 1 or more lines of best spectacle-corrected visual acuity (Fig 4).

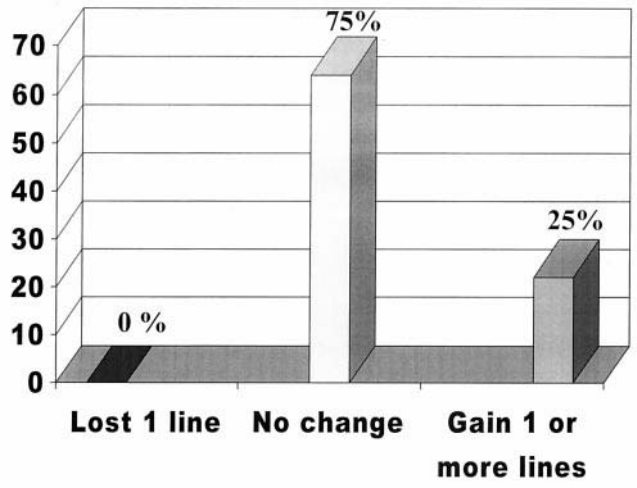


**Figure 4.** Postoperative change in lines of best spectacle-corrected visual acuity (n = 86).

## Predictability

At the last visit, 79 eyes (92%) had a mean spherical equivalent refraction within ±0.50 diopter of emmetropia, and 86 eyes (100%) within ±1.00 diopter of emmetropia.

Seventy-eight eyes (91%) had a spherical component of ±0.5 diopter, and 83 eyes (97%) had a spherical component within ±1.00 diopter. Three eyes had a spherical component between +1.25 and +1.75 diopters.

Table 2 shows results for myopic astigmatism and mixed astigmatism separately, before enhancements and at the last postoperative visit.

Before LASIK, the cylinder for all 86 eyes at the corneal plane was −3.75 ± 1.37 diopters (range, −1.25 to −7.50 diopters). At the last follow-up visit after bitoric LASIK, the mean cylinder at the corneal plane was −0.30 ± 0.4 diopter (range, 0 to −1.25 diopters). There was a mean reduction in corneal scalar astigmatism from 3.75 to 0.30 diopters, a 92% decrease in astigmatism magnitude. Vector analysis of astigmatism after bitoric LASIK demonstrated a surgically induced refractive cylinder of −3.45 ± 1.28 diopters. The mean achieved vector magnitude was 96% of intended. The achieved correction in the spherical component was 87%. The mean axis shift in refractive astigmatism was 9 ± 20 degrees after bitoric LASIK, and the mean achieved vector axis difference from the intended manifest refractive astigmatism axis was 1 ± 2 degrees.

Seventy two eyes (84%) had a postoperative cylinder of −0.5 diopter or less, 82 eyes (95%) had a postoperative cylinder of −1.00 diopter or less, and all eyes had a postoperative cylinder of −1.25 diopters or less.

## Mixed Astigmatism

In the mixed astigmatism group, the preoperative mean cylinder at the corneal plane for all 47 eyes was −4.02 diopters, and the standard deviation was 1.2 (range, −1.5 to −6.25 diopters). After bitoric LASIK, the mean cylinder at the corneal plane was −0.35 ± 0.42 diopter (range, −1.25 to 0.0 diopters). There was a mean reduction in scalar astigmatism from 4.02 diopters preoperatively to 0.35 diopter postoperatively, a 91% decrease in astigmatism magnitude. Vector analysis of astigmatism after bitoric

Table 2. Comparison of Bitoric LASIK for Eyes with Myopic Astigmatism and Mixed Astigmatism

| | | | | | | **Postoperative** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Preoperative* | | | | | *3 Months (No Enhancement)* | | | | | *1 Year (with Enhancement)* | | | | |
| | *Mean (SD)* | | | *BSCVA* | | *Mean (SD)* | | | *UCVA* | | *Mean (SD)* | | | *UCVA* | |
| **Reference Error** | *SE* | *SPH* | *CYL* | *≥20/20* | *≥20/40* | *SE* | *SPH* | *CYL* | *≥20/20* | *≥20/40* | *SE* | *SPH* | *CYL* | *≥20/20* | *≥20/40* |
| Myopic astigmatism n = 39 (E = 3/39) | −1.82 (±0.85) | −0.42 (±0.54) | −3.4 (±1.48) | 74% | 97% | −0.14 (±0.26) | 0.06 (±0.30) | −0.44 (±0.40) | 74% | 97% | −0.07 (±0.28) | 0 (±0.27) | −0.2 (±0.28) | 77% | 97% |
| Mixed astigmatism n = 47 (E = 8/47) | −0.43 (±0.99) | 1.31 (±0.95) | −4.02 (±1.22) | 57% | 94% | −0.06 (±0.58) | 0.18 (±0.58) | −0.49 (±0.46) | 57% | 93% | 0.07 (±0.38) | 0.25 (±0.40) | −0.25 (±0.40) | 68% | 98% |

BSCVA = best spectacle corrected visual acuity; CYL = cylinder; E = no. enhancement; SD = standard deviation; SE = spherical equivalent; SPH = sphere; UCVA = uncorrected visual acuity.

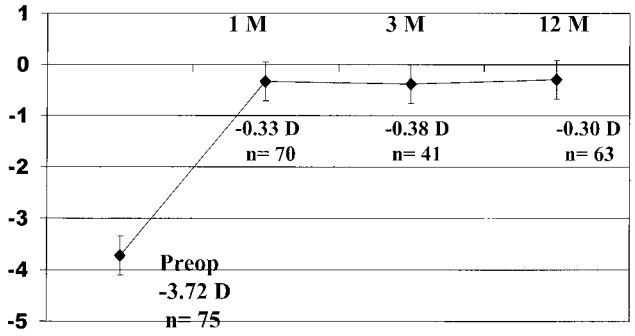


**Figure 5.** Stability of cylinder correction.

LASIK demonstrated a surgically induced refractive cylinder of −3.73 ± 1.14 diopters in the mixed astigmatism group.

### Myopic Astigmatism

In the myopic astigmatism group, the preoperative mean cylinder at the corneal plane for all 39 eyes was −3.4 ± 1.46 diopters (range, −1.25 to −7.5 diopters). Postoperatively, the mean cylinder at the corneal plane was −0.22 ± 0.29 diopter (range, −1.0 to 0.0 diopter). There was a mean reduction in scalar astigmatism from 3.4 diopters preoperatively to 0.22 diopter postoperatively, a 94% decrease in astigmatism magnitude. Vector analysis of astigmatism after bitoric LASIK showed a surgically induced refractive cylinder of −3.12 ± 1.35 diopters in the myopic astigmatism group.

The mean achieved vector magnitude was 91% of intended in the mixed astigmatism group and 94% in the myopic astigmatism group; these results were not statistically significantly different ($P > 0.5$).

In both groups, the mean axis shift in the refractive astigmatism was 9 degrees after bitoric LASIK, and the mean achieved vector axis difference from the intended manifest refractive astigmatism axis was 1 degree.

### Stability

The study of refractive stability included 75 eyes that had only one treatment and for whom complete data were available at postoperative examinations at months 1 and 3, and year 1. Preoperative mean cylinder of these eyes was 3.72 diopters (± 1.42); mean cylinder at 1 month was −0.33 diopter (± 0.36), at 3 months was −0.38 diopter (± 0.38), and at year 1 was −0.30 diopter (± 0.37; Fig 5). Regression of mean cylinder was 0.05 diopter from 1 to 3 months and 0.08 diopter from 3 months to 1 year.

### Complications

The complication rate of the 86 eyes included in the study was evaluated. No irregular flaps, free caps, dislocated flaps, or clinically significant epithelial ingrowth were observed. In two eyes of two different patients (2%), the axis of the positive cylinder was misaligned 90 degrees because of an error in the data input into the laser computer. In both cases, the cylinder misalignment was less than 2 diopters, and after the 3-month follow-up, both eyes received an enhancement procedure. At the 1-year follow-up, refraction in both cases was plano, with a UCVA of 20/20.

## Discussion

The surgical correction of myopia and compound myopic astigmatism with LASIK became very popular a few years ago, with excellent results being reported in the literature.[10–12] More recently, results from LASIK for hyperopia, although less favorable than those for myopia, have also been reported.[13] The other remaining refractive errors are simple myopic, mixed, and hyperopic astigmatism.

The treatment of hyperopic astigmatism became possible with a newer ablation profile, where tissue is removed with the excimer laser along the paracentral area, steepening the flat meridian. This steepening of the flattest meridian causes very little or no effect over the spherical component of the refraction. Argento et al[7] reported results of using such treatment in 1997. UCVA of 20/25 or better was achieved in 65% of simple hyperopic astigmatism with a 2.86-diopter decrease in vectorial magnitude.[7]

Simple myopic astigmatism has been traditionally treated using a special ablation pattern consisting of a cylindrical ablation, where the steep meridian is more selectively treated using a narrower profile, to prevent the hyperopic shift seen when using the elliptical ablation during compound myopic astigmatism. In an early study, Alió et al[5] reported their results of photo astigmatic keratectomy in 46 eyes with a mean preoperative simple myopic astigmatism of −2.5 diopters. Postoperatively, the mean residual manifest cylindrical correction at 12 months was −0.50 diopters.[5] Our results for the treatment of simple myopic astigmatism compare favorably. Our mean preoperative cylinder was −3.4 diopters, and we achieved a mean reduction to −0.20 diopters. Although we could not compare the percentage of eyes achieving a UCVA of 20/20 or better (Alió et al, data not available), 77% of the eyes operated on with our technique were able to achieve a UCVA of 20/20 or better. In addition, it is our impression that by using bitoric ablations, a larger optical zone is achieved, and therefore we found patients had fewer complaints of night symptoms compared with our previous experience using the narrower cylindrical ablation pattern (4.5 × 6.0 mm) for the treatment of simple myopic astigmatism.

Surgical correction of mixed astigmatism has been a significant challenge for refractive surgeons over the last two decades. We previously published the results of astigmatic keratotomy for the treatment of mixed astigmatism.[14] AK has the advantage that while flattening the steep meridian, a favorable coupling effect is achieved with a consequent steepening of the flattest meridian in the same proportion. Therefore, AK has been considered an adequate treatment for mixed astigmatism. With AK, we achieved a mean cylinder reduction of 72% at the 6-month follow-up; in comparison, we achieved a 91% reduction using bitoric LASIK in the current study. In addition to the improved results with bitoric LASIK, we also found this technique to be easier, more reliable and more stable than AK. Since the introduction of bitoric LASIK to our practice in May 1997, we have abandoned AK for the treatment of congenital astigmatism, and we are now occasionally using it to treat pre-existing corneal astigmatism during cataract surgery.

Another way of treating mixed astigmatism is by using a cylindrical ablation over the central cornea steep meridian in combination with hyperopic spherical ablation to treat the hyperopic spherical component of the refraction in addition to the induced hyperopia resulting from the cylinder abla-

tion over the steep meridian. Dausch et al[6] reported their experience using this approach to treat hyperopic and mixed astigmatism. In their study, five eyes with mixed astigmatism were reported, and they thought that this technique was effective. Although we could not find any other studies with similar treatments to correct mixed astigmatism, our earlier limited experience using this approach resulted in undercorrection of both the sphere and the cylindrical component with unsatisfactory results. In addition, more stromal tissue is removed using this technique. We therefore abandoned this technique for the correction of mixed and hyperopic astigmatism.

When the positive cylinder ablation was introduced, another alternative for the treatment of mixed astigmatism came into practice. The cylinder is corrected by steepening the flat meridian, and the remaining myopic sphere is treated with a myopic spherical ablation. Argento et al[7] published their results with this combination using a spot-scanning excimer laser. They had an initial overcorrection of the cylinder, and at 6 months the decrease in vectoral magnitude of the cylinder was 103%. In comparison, our results indicate a decrease in vectoral magnitude at the last visit of 91%. Because most of our patients had with the rule astigmatism, we use a slightly conservative algorithm by using, during calibration, a sphere/cylinder factor of 0.45, which is lower than the 0.60 factor that was recommended by the manufacturer.

Vinciguerra et al[15] theorized that treating astigmatism by splitting the correction over the flat and steep meridian has the advantage of conservation of tissue and improved optics. Although we agree with this statement, a comparative study of bitoric ablation versus the combination of positive cylindrical ablation and myopic spherical ablation may be needed to assess this observation.

Our results indicate that bitoric LASIK is an effective procedure that provides individuals increased independence from optical corrective devices. Eighty-five percent of the eyes in our study achieved an uncorrected visual acuity of 20/25 or better and had a final cylinder of 0.5 diopter or less. The formula and algorithm used proved to be accurate.

We found that bitoric LASIK is a safe procedure. There was no loss of best spectacle-corrected visual acuity. The only complication seen was axis misalignment because of confusion derived from using a different axis for each meridian ablation. These two cases occurred during our early experience with this technique. We recommend special attention with proper axis alignment when using any type of toric ablation. Software programs that simplify and confirm data input for bitoric ablations should help prevent this problem in the future.

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