

## Reduced Best Spectacle-corrected Visual Acuity from Inserting a Thicker Intacs Above and Thinner Intacs Below in Keratoconus

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### ABSTRACT

**PURPOSE:** To report a case of decreased best spectacle-corrected visual acuity (BSCVA) 2 months after Intacs implantation.

**METHODS:** A 33-year-old woman with keratoconus and contact lens intolerance underwent Intacs surgery in the left eye at another institution. Two segments were used—a thinner one (0.25 mm) below the cone and a thicker one (0.35 mm) above the cone.

**RESULTS:** Two months postoperatively, the patient presented to our practice with BSCVA reduced from 20/20 to 20/30. The superior Intacs segment was explanted, the inferior segment was exchanged for a thicker one (0.35 mm), and collagen cross-linking with riboflavin treatment was performed. This resulted in visual, topographic, and refractive improvement with BSCVA returning to 20/20.

**CONCLUSIONS:** Single inferior segment Intacs may be more appropriate for paracentral and peripheral cones. Collagen cross-linking may help cause further flattening. Using asymmetrical segments, with the thicker segment above the cone, may increase distortions and result in loss of BSCVA. [*J Refract Surg.* 2007;23:93-95.]

A number of studies have been published with different Intacs configurations: single, double, asymmetrical, symmetrical, thicker above, and thicker below. Most studies report an improvement in best spectacle-corrected visual acuity (BSCVA) in the majority of patients but the degree to which this occurs is highly variable. Part of the problem is an imperfect understanding of corneal and Intacs biomechanics. Our own experience and the results of our published study<sup>1</sup> have led us to believe that a single segment thicker Intacs placed below produces the best results for peripheral or paracentral cones. We present a patient who had a reduction in BSCVA as a result of

undergoing double asymmetrical Intacs insertion with the thicker segment above.

### CASE REPORT

A 33-year-old woman was evaluated at an outside institution for consideration of Intacs (Addition Technology, Des Plaines, Ill) implantation. She was diagnosed with keratoconus 5 years previously and had been wearing gas permeable contact lenses since. Her father also had keratoconus. For 2 years she experienced increasing contact lens intolerance, and the lenses would fall out of her eyes on a regular basis. Artificial tears were not helpful. Because the patient had an active lifestyle, she found her symptoms to be disturbing. Her health was good and she was taking no medications.

Manifest refraction on initial examination was  $-6.75 +1.25 \times 130$ , with BSCVA of 20/20 in the right eye and  $-8.75 +1.50 \times 130$  with BSCVA of 20/20 in the left eye. Central corneal thickness readings were 494 and 493  $\mu\text{m}$  in the right and left eyes, respectively. Pupil size was 5.9 mm and 6.1 mm in the right and left eyes, respectively. Corneal topography showed paracentral cones in both eyes, displaced inferiorly with steepest Ks of 47.50 diopters (D) at  $114^\circ$  and 47.90 D at  $104^\circ$  (right and left eyes, respectively). Slit-lamp examination showed mildly ectatic corneas with no scarring. Fundus examination was normal. Because the left eye was dominant, Intacs implantation was planned for this eye.

The surgical technique consisted of making an incision in the  $130^\circ$  axis of astigmatism based on manifest refraction. Incision depth was 70% and a mechanical dissector was used to create the channels. Asymmetric segments were inserted—0.35 mm superiorly and 0.25 mm inferiorly. The technique of placing the thicker segment superiorly and thinner segment inferiorly has been described previously by other surgeons and is based on the theory that it will shift the cone centrally towards the optical center. A single suture was placed at the incision site.

Two months postoperatively, the patient presented to our practice with deteriorating vision in the left eye. She had not been fitted with a soft contact lens in the interim. Manifest refraction was  $-8.50 +2.50 \times 79$  yielding 20/30, representing a loss of 2 lines of BSCVA. Slit-lamp examination revealed a loose suture and healed double Intacs segments. Corneal topography showed an inferior paracentral cone (Fig 1).

Our proposed mechanism for loss of BSCVA was that the thicker superior segment caused excessive flattening above the cone (an area relatively flatter preoperatively). We explanted the 0.35-mm superior segment,

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*Dr Boxer Wachler is a paid consultant for Addition Technology, Des Plaines, Ill, and owns the trademark for C3-R. Dr Chan has no financial interest in the materials presented herein.*

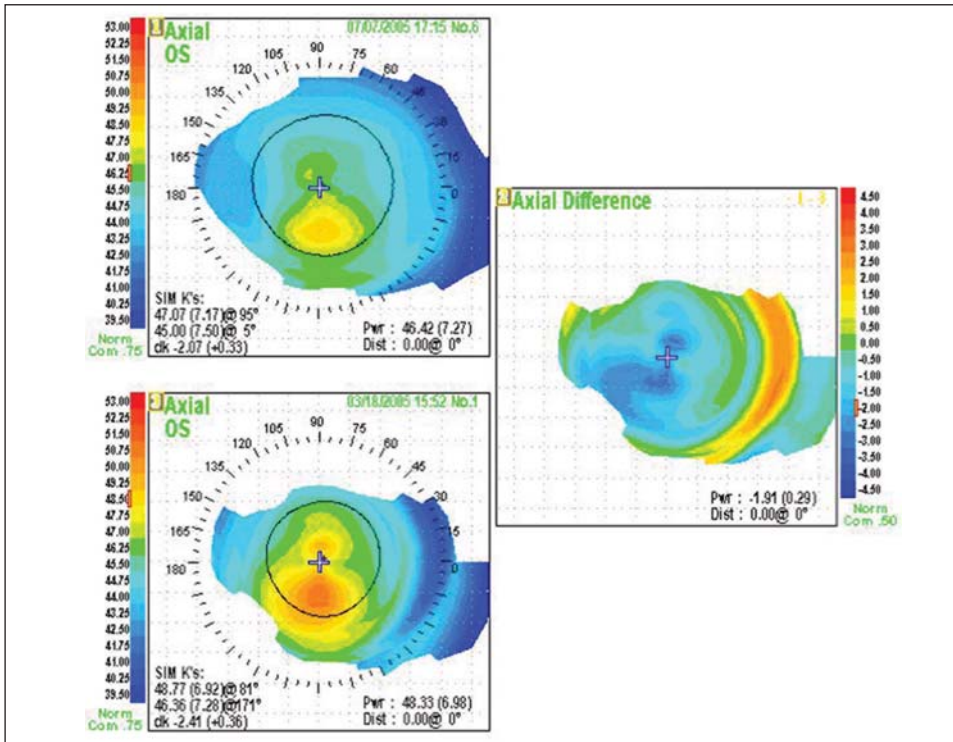
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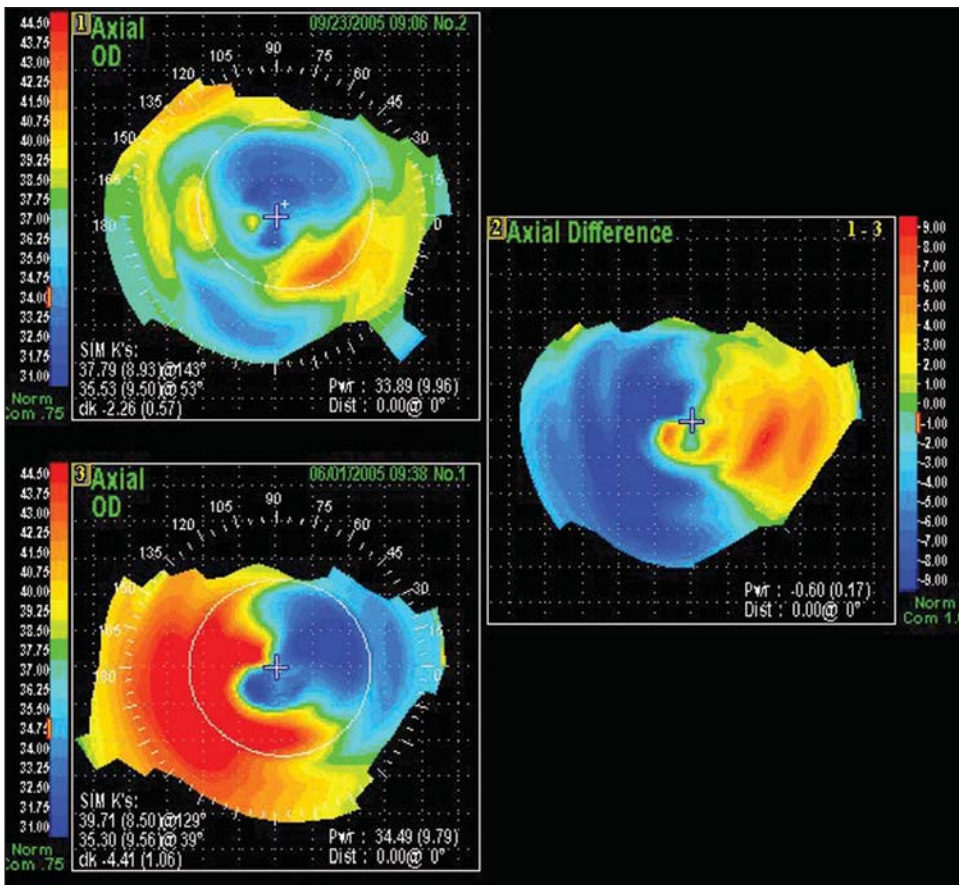
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**Figure 1.** Corneal topography of the left eye shows an inferior paracentral cone (**lower left**). Topography shows improvement after Intacs superior segment explanation, exchange of inferior segment, and collagen cross-linking treatment (**upper left**). Difference map showing marked flattening of the cone at 3 months after surgery (**right**).



**Figure 2.** Axial map (**lower left**) showing asymmetry of steep area below the meridian but relatively flat area above, which is inherent to keratoconus. Placement of an Intac in the area above will lead to further flattening and greater corneal asymmetry. Difference map (**right**) shows flattening of the cone with a single segment Intac and steepening of the flat area, resulting in a more normal looking axial map (**upper left**).

and the 0.25-mm inferior segment was exchanged for a 0.35-mm segment. The Intacs procedure was combined with corneal collagen cross-linking with riboflavin (C3-R) on the same day, as we have found this to augment flattening by the Intacs (Chan CK, Sharma M, Boxer Wachler BS, unpublished data, 2005). These procedures led to a marked topographic and refractive improvement (see Fig 1) at 3 months postoperatively. The manifest refraction was  $-5.25 + 0.75 \times 150$ , which returned BSCVA to 20/20. The difference map (see Fig 1) shows resolution of induced astigmatism. The patient was fitted with a soft contact lens and is satisfied with the result.

### DISCUSSION

In the United States, Intacs have been used for keratoconus since 1999 but controversy remains regarding the best technique for placement of segments. It has been our experience that a single segment works best for paracentral and peripheral cones, whereas a symmetrical double segment works best for central cones.<sup>1</sup> Our theory is that in peripheral keratoconus, the cone is oriented around a meridian of astigmatism, and there is a relatively steep area below the meridian and a relatively flat area above (Fig 2). Placement of a segment above the meridian in the flat topographic area exacerbates the topographic power asymmetry by causing further flattening. We have observed a unique coupling effect with implantation of a single Intacs segment in that superior steepening occurs, which improves corneal symmetry (see Fig 2). We describe this to our patients as a “beanbag effect”; that is, sitting on or flattening one end of the beanbag results in the other end popping up. Alio et al<sup>2</sup> recently demonstrated that using a single segment for inferior keratoconus and a double segment for keratoconus, which extends above the 180° axis, is effective.

We have also found that C3-R augments the effect of inferior segment Intacs (Chan CK, Sharma M, Boxer Wachler BS, unpublished data, 2005). Wollensak et al<sup>3</sup> demonstrated that flattening occurs with collagen cross-linking alone. We believe the primary reason for our patient’s improvement in BSCVA and corneal shape was the Intacs exchange, but C3-R may have added to the topographic and refractive improvements, along with the superior segment explantation.

The idea of using a thinner segment under the cone and a thicker one above to displace the cone towards the optical center is an intriguing idea. Asymmetrical segments in the opposite configuration (thicker segment below cone and thinner segment above cone) have been used previously and have shown to be effective.<sup>4-6</sup> To our knowledge, the results of the technique used in this report (thicker segment above cone and thinner segment below cone) have not been published in the literature.

In our patient, prior placement of a thicker segment above the cone resulted in loss of BSCVA and increase in manifest cylinder. Alio et al<sup>7</sup> recently reported another case where this approach resulted in loss of BSCVA and increased keratometric values, which was subsequently remedied by exchanging the two segments. There are a number of possible reasons why this technique may not produce optimal results: 1) shifting the cone centrally will shift an irregular part of the cornea into the visual axis. If the cone was a symmetrical sphere, this would have the effect of inducing myopia, but as it is an irregular shape, it will likely worsen distortions; and 2) the topography of a cone has two areas—a steep area below and a flat area above. Placing a segment in the upper half will further flatten an already flat area. Placing the thicker segment will flatten it further still and heighten the asymmetry.

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## Corneal Haze Following PRK With Mitomycin C as a Retreatment Versus Prophylactic Use in the Contralateral Eye

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### ABSTRACT

**PURPOSE:** To report photorefractive keratectomy (PRK) treated with mitomycin C (MMC) for previous corneal haze in one eye and PRK with MMC to prevent corneal haze formation in the fellow eye.

**METHODS:** A 40-year-old woman underwent PRK with MMC to treat previous corneal haze (secondary to previous PRK without MMC) for residual refractive error of  $+0.50 +0.25 \times 165$  in the left eye and PRK with MMC to prevent corneal haze in the right eye.

**RESULTS:** Postoperative slit-lamp examination revealed no haze in the right eye, but continued mild haze in the left eye.

**CONCLUSIONS:** Treatment with PRK and MMC for previous corneal haze is not as effective as primary PRK with MMC in preventing postoperative corneal haze formation. [*J Refract Surg.* 2007;23:96-98.]

Excimer laser photorefractive keratectomy (PRK) is a popular refractive procedure proven to be effective and safe for the correction of refractive errors.<sup>1</sup> However, postoperative corneal subepithelial scarring is a challenging complication following PRK, especially after high myopic corrections.<sup>2</sup> Stromal wound healing modulators have been used to minimize corneal haze formation, but limited efficacy is reported.<sup>3,4</sup>

Topical mitomycin C (MMC) was recently introduced as an adjunctive therapy for the treatment of

corneal haze after PRK.<sup>5,6</sup> We describe a 40-year-old patient who underwent repeat PRK with MMC application to treat corneal haze formation following previous PRK in one eye, and MMC to prevent corneal haze after PRK in the contralateral eye, which resulted in different outcomes.

### CASE REPORT

A 40-year-old woman presented at the Cole Eye Institute, Cleveland, Ohio for refractive surgery to correct manifest refractive error of  $-8.00 +2.50 \times 89$  and  $-8.75 +1.75 \times 91$  in the right and left eyes, respectively. Best spectacle-corrected visual acuity (BSCVA) was 20/20 in both eyes. Cycloplegic refraction was  $-7.50 +2.50 \times 92$  in the right eye and  $-8.25 +2.00 \times 90$  in the left eye. Preoperative keratometric readings were 43.25/45.12 @ 04 in the right eye and 43.00/44.75 @ 180 in the left eye. Ultrasonic pachymetry showed central corneal thickness of 545  $\mu\text{m}$  in the right eye and 551  $\mu\text{m}$  in the left eye. Corneal topography was normal in both eyes. Colvard infrared pupillometer (Oasis Medical, Glendora, Calif) showed pupil size of 5.2 mm in the right eye and 5.0 mm in the left eye. All preoperative tests were normal and there was no significant medical or ocular history. However, slit-lamp examination revealed anterior basement membrane dystrophy in both eyes.

The patient underwent uneventful PRK for distance correction in the left eye with the LADARVision 4000 (Alcon Laboratories Inc, Ft Worth, Tex) in January 2002. Alcohol removal of epithelium was completed and stromal photoablation was performed using a 6.0-mm optical zone with ablation depth of 96  $\mu\text{m}$ . Postoperatively, the patient was treated with prednisolone acetate 1% (Predforte; Allergan, Irvine, Calif), ketorolac tromethamine 0.5% (Acular, Allergan), and ciprofloxacin 0.3% (Ciloxan, Alcon Laboratories Inc) four times a day and a bandage contact lens (Soflens 66; Bausch & Lomb, Rochester, NY) was applied. The epithelial defect healed in 5 days and the bandage contact lens was removed. Ciloxan and Acular were discontinued 1 week postoperatively and Predforte was tapered over the next 3 weeks.

Two weeks after surgery, uncorrected visual acuity (UCVA) and BSCVA was 20/30 and 20/20, respectively, with residual refractive error of  $+0.50 +0.25 \times 165$ . Four weeks after PRK, the patient developed central subepithelial corneal haze (3+/4+) and BSCVA was 20/30 with manifest refraction of  $-1.25 +0.50 \times 175$ . Refractive error stabilized after 5 months, and the patient's left eye was surgically enhanced with PRK and an MMC 0.02%–soaked corneal sponge was applied intraoperatively for 2 minutes, followed by copious irrigation with balanced salt solution. The previ-

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ous postoperative regimen was followed and 3 months after enhancement UCVA and BSCVA improved to 20/25, with a manifest refraction of  $-0.50 +0.50 \times 155$ . However, the patient reported persistent symptoms of "cloudiness" due to mild residual central corneal haze in the left eye (Fig).

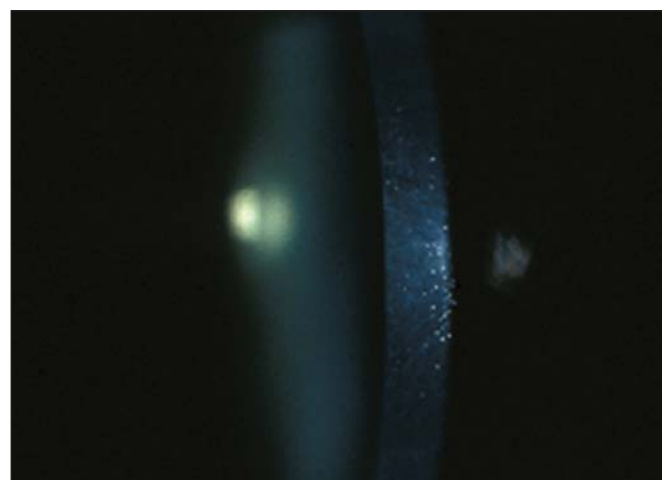
The right eye was treated for distance correction 4 months after the left eye with PRK and intraoperative application of MMC 0.02% for 2 minutes due to the increased risk of haze development. The postoperative regimen was the same as the contralateral eye and 2 weeks after the procedure BSCVA in the right eye was 20/20 with a manifest refraction of  $-0.75 +0.50 \times 95$ . Three months after surgery, UCVA was 20/20 with residual refractive error of  $-0.50 +0.50 \times 85$ , no haze visible on slit-lamp examination, and no postoperative symptoms in the right eye.

### DISCUSSION

Mitomycin C is a systemic chemotherapeutic agent, which is useful in ophthalmology. In some cases, topical application of MMC improved results of glaucoma surgery, pterygium excision, and treatment of conjunctival and corneal intraepithelial neoplasia.<sup>7,8</sup> Mitomycin C creates a potent cytostatic effect, blocking DNA and RNA replication and protein synthesis. As a consequence, MMC may inhibit cell mitosis, proliferation of corneal epithelial, stromal, and endothelial cells, conjunctival cells, and Tenon's capsule fibroblasts.<sup>9-11</sup>

Previous studies have reported good results with PRK and MMC application in preventing and treating corneal haze.<sup>5,6</sup> Majmudar et al<sup>5</sup> described the effectiveness of MMC 0.02% in treating corneal subepithelial fibrosis after debridement in five patients who underwent previous corneal refractive surgery. In addition, Vigo et al<sup>6</sup> reported significant improvement in corneal transparency in 31 eyes with preoperative haze when treated with MMC 0.02% solution for 2 minutes in association with a stromal scraping procedure. Good outcomes were also reported with prophylactic use of MMC. Carones et al<sup>12</sup> reported decrease in haze formation and more accurate refractive outcomes after prophylactic use of MMC 0.02% with PRK in 60 patients with spherical equivalent correction between  $-6.00$  and  $-10.00$  diopters.

To date, no controlled study has been performed comparing the efficacy of topical MMC in treating and preventing corneal haze formation after refractive procedures. It is hypothesized that, due to its antimetabolic properties, MMC inhibits fibroblast proliferation and differentiation, consequently blocking myofibroblast formation, which is the phenotype of the main keratocyte responsible for corneal haze.<sup>13</sup> Topical application of MMC



**Figure.** Slit-lamp photograph showing residual central corneal haze following PRK enhancement with mitomycin C.

has proven to block fibroblast replication in conjunctival tissue.<sup>9</sup> Additional evidence suggests that topical MMC induces keratocyte apoptosis and may also lead to myofibroblast death by inducing apoptosis and necrosis.<sup>14</sup>

Both mechanisms play a combined role, but in the presence of previously existing corneal opacification MMC may not completely eliminate haze due to an eventual persistence of myofibroblast cells. Maldonado<sup>15</sup> reported the presence of residual haze in the center of corneas treated with topical MMC for subepithelial scarring following PRK. It is possible that the antimetabolic effect of MMC, which blocks the formation of myofibroblasts and consequently prevents corneal opacification, is clinically more relevant than its cytotoxic effect inducing myofibroblast apoptosis and eliminating previous haze.

Possible toxic side effects are suspected as a consequence of MMC action on corneal tissue, possibly leading to endothelial and stromal complications. Chang<sup>16</sup> recently reported early endothelial edema following a single application of MMC in a rabbit model. In addition, Kim et al<sup>17</sup> described the importance of keratocyte death following PRK with MMC in an animal model, secondary to the apoptotic effect on the stromal keratocytes. No human complications have been reported, but long-term follow-up is required to establish its complete safety. Further studies are necessary to definitively describe the mechanisms of MMC on the cornea.

This report does not make a definitive conclusion, and additional studies are necessary to fully understand the mechanism of MMC action on corneal tissue, as well as its benefits, limitations, and possible side effects. However, clinical outcome does suggest a higher efficacy of MMC in preventing corneal haze than in treating previous corneal opacification. It is possible that MMC works more efficiently in blocking fibroblast

replication, thereby avoiding their formation, than in eliminating previously formed myofibroblasts, especially among cells located more posteriorly in the stroma. Our findings are consistent with preliminary results of a randomized experimental study performed in rabbits comparing the efficacy of topical MMC in preventing corneal haze formation versus treatment of previous corneal haze.<sup>18</sup>

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Corneal Ectasia After Hyperopic LASIK

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ABSTRACT

**PURPOSE:** To report two cases of corneal ectasia, which developed after hyperopic LASIK.

**METHODS:** Preoperative pellucid marginal corneal degeneration was observed in patient 1. Patient 2 had no preoperative risk factors.

**RESULTS:** Patient 1, a 47-year-old man, developed corneal ectasia in his right eye 6 months after unilateral hyperopic LASIK. Preoperative manifest refraction was +2.00 +1.50 × 178 in the right eye and +1.00 sphere in the left eye. Corneal thickness was 585 μm and 575 μm (right and left eye, respectively). Preoperative topography of the right eye demonstrated inferior steepening in the far periphery, suggestive of early pellucid marginal corneal degeneration. Patient 2, a 35-year-old man, developed corneal ectasia in his right eye >3 years after bilateral LASIK. Preoperative manifest refraction was +2.50 sphere and +3.25 sphere (right and left eye, respectively), and corneal thickness was 556 μm in both eyes. Preoperative topography was normal in both eyes with no evidence of asymmetry, steepening, or irregularity.

**CONCLUSIONS:** Corneal ectasia can occur after hyperopic LASIK in patients with or without recognized preoperative risk factors. Although uncommon, patients with pellucid marginal corneal degeneration can have hyperopic refractions and are at high risk for developing corneal ectasia after LASIK. [*J Refract Surg*. 2007;23:98-102.]

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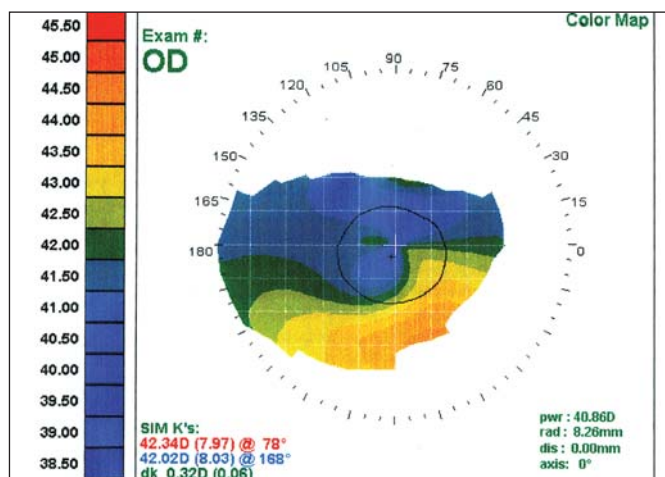
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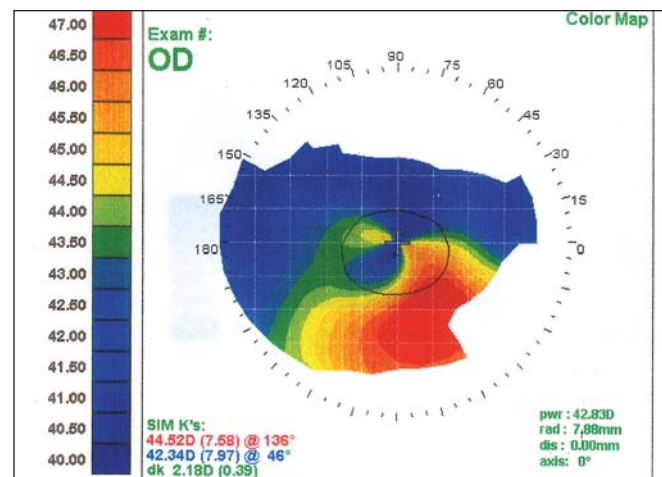
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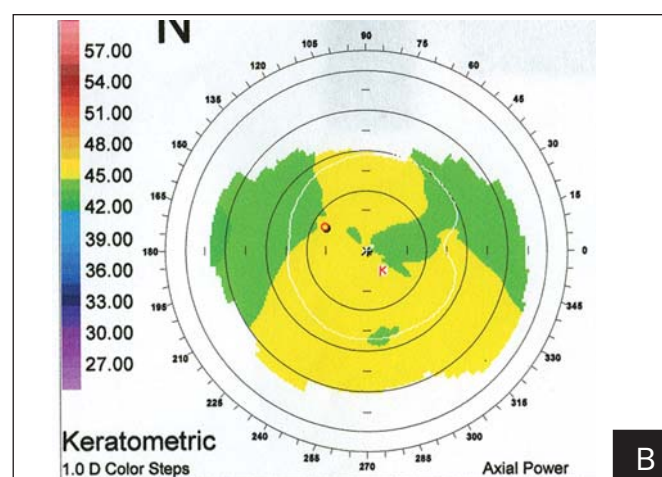
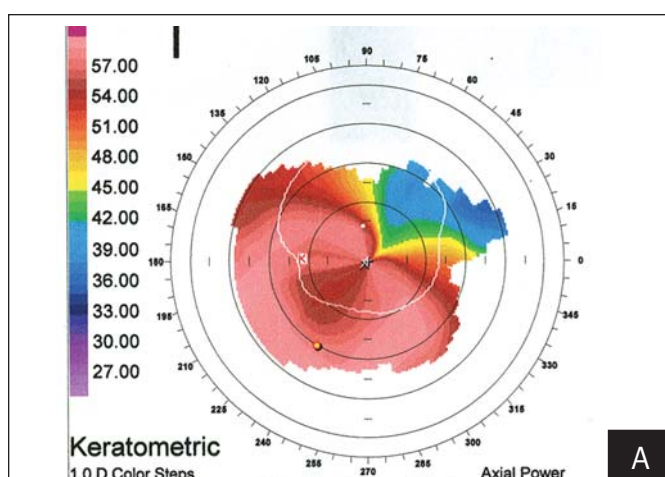
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**Figure 1.** Patient 1. Preoperative topography of the right eye demonstrates superior flattening and inferior steepening with the highest power in the far inferior periphery, which is suggestive of pellucid marginal corneal degeneration. Note that SimK values demonstrate only 0.30 D of corneal astigmatism.



**Figure 2.** Patient 1. Topography of the right eye 6 months postoperatively shows significant inferior steepening of 47.00 D, which is >5.00 D in the corresponding region of the superior cornea, signifying corneal ectasia after LASIK. The area of steepening corresponds to the steep region that was present preoperatively.



**Figure 3.** Patient 1. **A)** Topography of the right eye 5 years postoperatively. Inferior steepening >59.00 D with >10.00 D of corneal steepening compared to the corresponding region of the superior cornea, signifying advanced corneal ectasia after LASIK. **B)** Normal topography of the left eye (no surgery) with no evidence of inferior corneal steepening and <0.30 D of corneal astigmatism by SimK measurements.

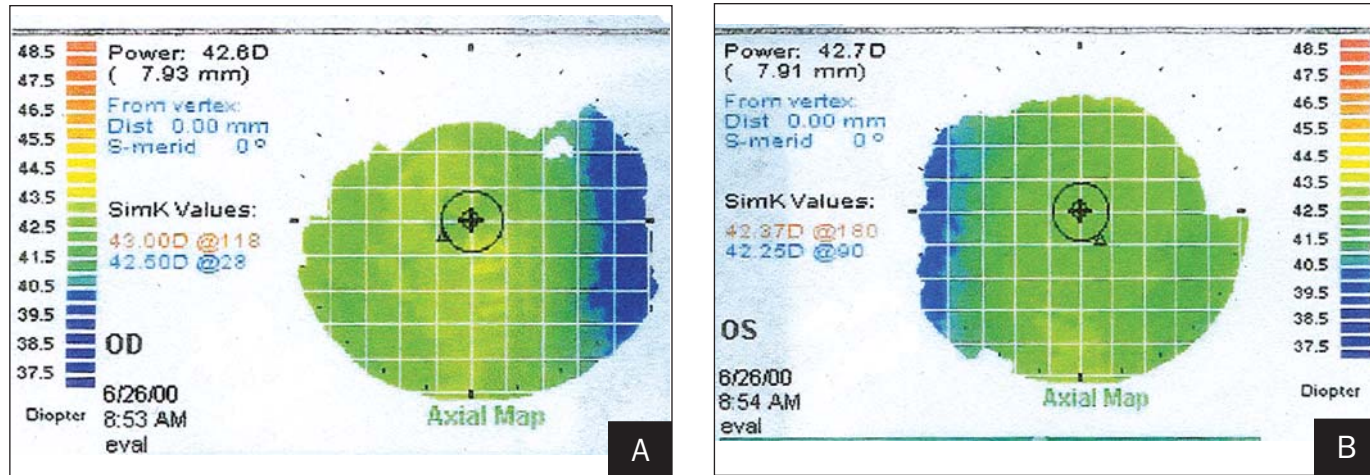
Corneal ectasia after myopic LASIK was first reported in 1998 and has been well documented in the literature.<sup>1-4</sup> Identified risk factors include high myopia, low preoperative corneal thickness, low residual stromal bed thickness, and abnormal topographies, including forme fruste keratoconus<sup>3,4</sup> and pellucid marginal corneal degeneration.<sup>5,6</sup> This is the first report in the literature of corneal ectasia occurring after hyperopic LASIK. Two cases of ectasia after hyperopic LASIK are presented: one case occurred in a patient with no recognized risk factors, and the other occurred in a patient with topographic findings of pellucid marginal corneal degeneration.

## CASE REPORTS

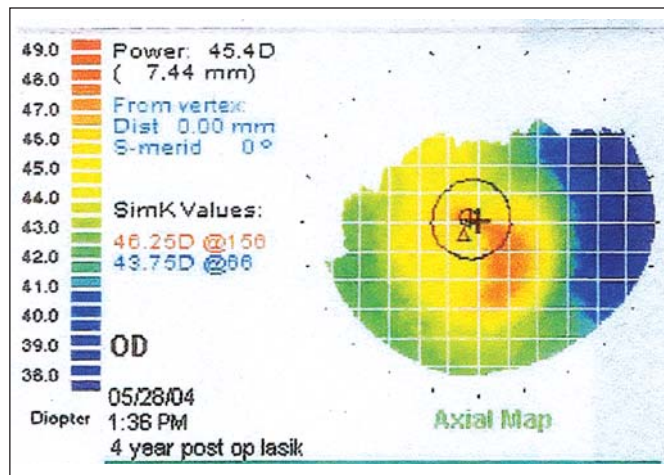
### PATIENT 1

A 52-year-old man presented in 2005 requesting surgical correction of the refractive error in his right eye following LASIK, which had been performed 5 years previously at an outside facility. Preoperative best spectacle-corrected visual acuity (BSCVA) was 20/20 in both eyes with a manifest refraction of +2.00 +1.50 × 178 in the right eye and +1.00 sphere in the left eye. Corneal thickness was 585 μm and 575 μm (right and left eye, respectively). Preoperative corneal topography in the right eye demonstrated superior flattening and inferior steepening in the far periphery (Fig 1). The remainder of

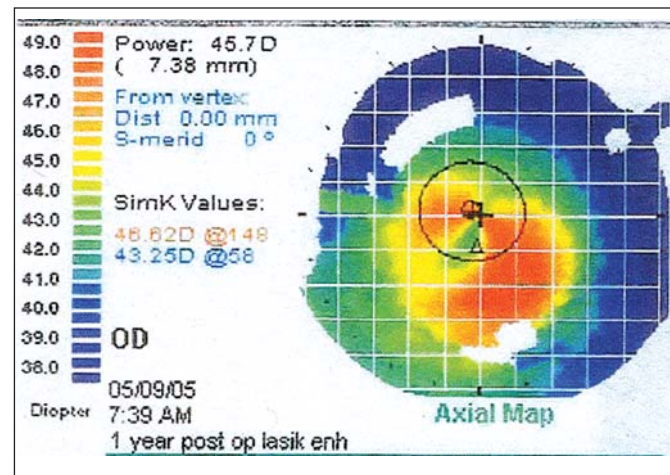
## Reports



**Figure 4.** Patient 2. Preoperative topography of the **A)** right and **B)** left eyes was normal with no evidence of steepening, irregularity, or asymmetry between eyes.



**Figure 5.** Patient 2. Topography of the right eye 4 years postoperatively shows increased inferior steepening with a skewed radial axis. The steepest point inferiorly is  $>47.00$  D with approximately 4.00 D of increased corneal steepening compared to the corresponding region in the superior cornea, signifying early corneal ectasia after LASIK.



**Figure 6.** Patient 2. Topography of the right eye 5 years after initial surgery and 1 year after enhancement shows increased inferior corneal steepening with more pronounced skewing of the radial axis. The steepest point inferiorly is  $>49.00$  D with  $>8.00$  D of increased corneal steepening compared to the corresponding region of the superior cornea, signifying progression of corneal ectasia.

the examination was normal. The patient underwent uneventful LASIK in the right eye in December 2000 with the VISX excimer laser (VISX, Santa Clara, Calif). No other specific surgical details were available for review.

Six months postoperatively, the patient complained of blurred vision in the right eye. Uncorrected visual acuity (UCVA) was 20/70, BSCVA was 20/25 with a manifest refraction of  $-0.25 +3.25 \times 006$ , and topography showed significantly increased inferior corneal steepening (Fig 2). The patient was diagnosed with corneal ectasia after LASIK in 2002 and fitted with a rigid gas permeable contact lens in the right eye.

The patient first presented to our institution in October 2005 seeking alternatives to the contact lens correction of his right eye. At this time, BSCVA was

20/80 in the right eye with a manifest refraction of  $-8.00 +7.75 \times 140$ . Central corneal thickness measured 532  $\mu\text{m}$  and 573  $\mu\text{m}$  (right and left eye, respectively) by ultrasound pachymeter. Topography demonstrated advanced corneal steepening in the right eye, and was normal in the unoperated left eye (Fig 3). Confocal microscopy revealed a flap thickness of 154  $\mu\text{m}$  and a residual stromal bed of 290  $\mu\text{m}$  at the thinnest point inferonasally. The patient was informed of the findings and elected to continue wearing the rigid gas permeable contact lens.

### PATIENT 2

A 35-year-old man presented for refractive surgery evaluation in June 2000 at an outside facility. Preop-

erative BSCVA was 20/15 in both eyes with a manifest refraction of +2.50 sphere in the right eye and +3.25 sphere in the left eye. Corneal thickness was 556  $\mu\text{m}$  in both eyes. Preoperative topography was normal bilaterally with no evidence of asymmetry, steepening, or irregularity (Fig 4). The remainder of the examination was normal. The patient underwent uneventful LASIK in the left eye in July 2000, followed by uneventful LASIK in the right eye in August 2000. A nasally hinged flap was created with a 180- $\mu\text{m}$  plate in both eyes (the brand of microkeratome used was not recorded). A VISX laser was used to perform the ablations, with a 5.5-mm optical zone. Planned ablation depth was 31  $\mu\text{m}$  and 36  $\mu\text{m}$  (right and left eye, respectively).

The patient initially did well, achieving 20/20 UCVA bilaterally, but in December 2003, 40 months postoperatively, he complained of blurred vision in the right eye. Uncorrected visual acuity in the right eye was 20/30 and 20/20 in the left eye, and BSCVA in the right eye was 20/20 with a manifest refraction of  $-0.50 +2.00 \times 137$ . By May 2004 UCVA had fallen to 20/70 in the right eye, and BSCVA was 20/25 with a manifest refraction of  $-0.75 +2.25 \times 155$ . Topography demonstrated mild inferior steepening with a skewed radial axis (Fig 5). The patient underwent enhancement at an outside facility in May 2004 with a planned ablation of 14  $\mu\text{m}$ . He again did well initially, but by May 2005 UCVA dropped to 20/50, and BSCVA was 20/25 with a manifest refraction of  $-1.00 +2.25 \times 140$ . Topography demonstrated increased inferior steepening (Fig 6). During the past year, visual acuity has continued to decline, rigid gas permeable contact lens fitting has been unsuccessful, and the patient is considering penetrating keratoplasty.

### DISCUSSION

Corneal ectasia after myopic LASIK has been well described in the literature<sup>1-4</sup>; however, to our knowledge, the two cases described represent the first report of ectasia after hyperopic LASIK. The first patient displayed subtle evidence of pellucid marginal corneal degeneration preoperatively, but the second patient had no apparent preoperative risk factors. Whereas most reported ectasia cases have recognizable preoperative risk factors, ectasia developing after myopic LASIK in patients without apparent risk factors has been reported.<sup>7,8</sup>

Pellucid marginal corneal degeneration is an ectatic disorder, typically characterized by bilateral inferior thinning and against-the-rule corneal astigmatism.<sup>9,10</sup> Classic topographic features of pellucid marginal corneal degeneration include superior flattening with rapid increase in corneal power inferiorly, with the greatest steepening in the far periphery between 4 o'clock and

8 o'clock.<sup>11</sup> Although this patient exhibited topographic changes suggestive of early pellucid marginal corneal degeneration, manifest refraction in the affected eye was hyperopic with only 1.50 D of astigmatism. The majority of patients with pellucid marginal corneal degeneration have myopia and  $>5.00$  D of astigmatism.<sup>10,12</sup>

Corneal ectasia has been reported following LASIK in individuals with pellucid marginal corneal degeneration preoperatively<sup>6,13</sup>; however, all of these patients had significant myopic refractions, and most had at least 3.00 D of astigmatism. Ambrosio and Wilson<sup>5</sup> also reported two cases of patients presenting for refractive surgery evaluation with early pellucid marginal corneal degeneration. Both cases had myopic astigmatism and more pronounced topographic changes than our case.

In a recent review by Sridhar et al,<sup>10</sup> all reported cases of pellucid marginal corneal degeneration had topographic evidence of bilateral disease. In contrast, the patient in our report had no obvious evidence of pellucid marginal corneal degeneration in the non-operated eye, with a normal keratometric map and spherical refraction; however, inferior corneal thickness as measured by the Orbscan II (Bausch & Lomb Inc, Salt Lake City, Utah) was only 5  $\mu\text{m}$  thicker than central thickness (570  $\mu\text{m}$  centrally and 575  $\mu\text{m}$  inferiorly). In normal subjects, average inferior corneal thickness measurements are more than 60  $\mu\text{m}$  thicker than average central corneal thickness measurements.<sup>14</sup> With hyperopic LASIK, central corneal steepening occurs as a result of peripheral corneal ablation. Thus, in patients with pellucid marginal corneal degeneration, treatment of hyperopia results in tissue removal at the thinnest, weakest portion of the peripheral cornea.

Corneal ectasia can occur after hyperopic LASIK in patients with or without apparent preoperative risk factors. Although rare, patients with pellucid marginal corneal degeneration can present with subtle topographic changes and hyperopic refractive errors. These individuals are at increased risk for corneal ectasia after LASIK.

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## Removal of an Intracorneal Hydrogel Implant for Hyperopia After LASIK

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### ABSTRACT

**PURPOSE:** To report a case of intracorneal hydrogel lens implantation for hyperopia after repeat LASIK surgery.

**METHODS:** A 34-year-old man underwent intracorneal lens im-

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plantation following two LASIK procedures for correction of hyperopia.

**RESULTS:** The decentered intracorneal lens was removed due to ocular pain and inflammation, epithelial ingrowth under the corneal flap, and high order aberrations. Pain and inflammation resolved, and corneal stability was regained >6 months after removal of the lens.

**CONCLUSIONS:** Intracorneal lenses may require explantation if previous laser ablative procedures fail to correct refractive errors. [*J Refract Surg.* 2007;23:102-104.]

Whereas corneal procedures for correction of myopia have reached a high level of safety, predictability, and efficacy, good clinical outcome for hyperopic patients continues to be problematic. This is not attributed to the safety of the interventions, but rather to the optimum design of ablation profiles yielding a stable and predictable refractive outcome.<sup>1</sup> In addition, the techniques used continuously undergo investigational efforts, which has led to a number of proposed procedures and devices. Refractive challenges include predictably steepening the corneal profile. Implantation of intracorneal lenses has been suggested as an alternative to excimer laser ablation. The idea of placing a refractive device within the corneal stroma dates back to almost half a century.<sup>2</sup> It has recently taken a fresh impetus with the development of a transparent, high-water-content hydroxyethyl methacrylate (Nutrapore; Anamed Inc,\* Lake Forest, Calif) lens that has proven to be well tolerated intracorneally.<sup>3,4</sup> A lenticule-shaped implant is made from this hydrogel and placed under a LASIK flap. Adhesion forces ensure a stable position centered in the optical zone without further fixation. Additional support is given to the central and near peripheral cornea to increase corneal curvature and thus enhance refractive power. This device is proposed for the correction of hyperopia and for enhancement of previous refractive stromal procedures, such as LASIK.

Earlier experimental investigations and clinical studies report safety and tissue compatibility.<sup>2,5</sup> We present a case that describes the clinical course of a patient who received an intracorneal lens after repeat LASIK.

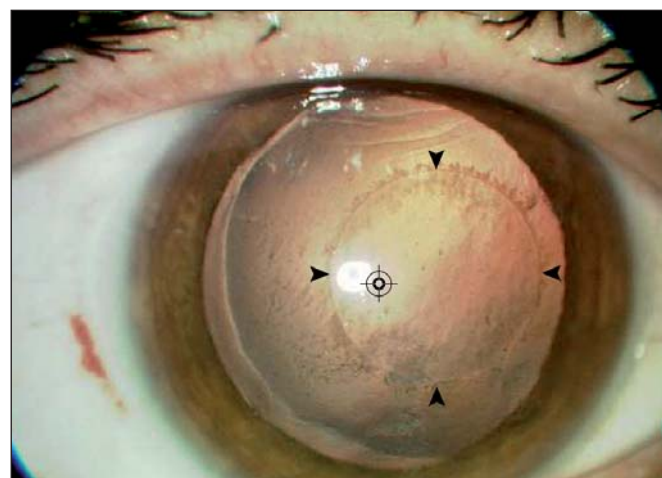
### CASE REPORT

A 34-year-old man underwent LASIK on the right eye for hyperopia of +3.25 diopters (D) (astigmatism -0.25 D @ 150°). A superior hinged flap was created, using a standard microkeratome, and excimer laser ablation was performed, but no subjective improvement was noted postoperatively. Retrospectively, it is

not possible to identify the reason for the procedure's refractive failure, as technical problems with the settings of the laser machine were not obvious. With the refractive effect absent, no evidence was found for resulting ocular problems. Weeks later, a second LASIK procedure was performed following a re-lift of the initial corneal flap. Again, it did not yield a relevant refractive change. Because the refractive effect was unsatisfactory, the corneal flap was re-lifted once more and an intracorneal lens (PermaVision, Anamed Inc) was implanted. After re-lifting the flap with a round microspatula, the bed was rinsed with 0.9% sodium chloride and the device laid onto the corneal stromal surface within the bed by sliding sideways from the specially provided spoon. Centration was secured by subjective medial position relative to the patient's miotic pupil to align the optical center of the lens with the optical axis of the eye. Finally, the flap was laid back onto the stromal surface and flattened over the bed with the lens. Decentration of the intracorneal lens occurred 1 week postoperatively, which necessitated re-lifting of the flap a third time to reposition the lens.

After implantation of the intracorneal lens, the patient complained of an increasingly burning ache in the eye with decreased visual acuity. Three weeks after implantation, best spectacle-corrected visual acuity (BSCVA) was 2/10 and objective refraction was +3.25 D, thus unaltered from starting values. Slit-lamp examination revealed marked delineation of the superficial flap with grayish contours. Epithelial ingrowth islets were detected covering approximately one-eighth of the entire flap area, concentrated in the lenticular periphery. In addition, regionally condensed hazy opacity was noted, particularly in the inferior hemisphere, with the implant decentered superionasally (Fig). Corneal topography revealed central depression. Refraction was  $-2.00 -1.00 \times 65^\circ$ . Because topical steroid administration over 4 weeks did not alleviate symptoms, the lens was removed. The flap was lifted with a blunt spatula without encountering major tissue resistance at the peripheral circumference. The lens was explanted from the stromal bed with forceps and the interface was carefully polished using a sharp, hockey knife followed by 0.9% sodium chloride rinsing. This was done to remove debris and epithelial cells evident under the slit-lamp microscope. The flap was then rolled back and correct position secured by application of a bandage contact lens for 48 hours.

Twenty weeks postoperatively, the patient recovered with BSCVA of 0.4 and refraction of  $+6.00 -3.25 \times 82^\circ$ . Corneal topography showed a discrete central flattening of the surface with higher order aberrations that exceeded the mathematical capacities of the digital kera-



**Figure.** Slit-lamp photograph showing superionasal decentration of the intracorneal lens implant with accumulated undefined cellular ingrowth and debris under the corneal flap around the edge of the device. The center of the cornea (target) and edge of the implant (arrows) are indicated.

tometer (Oculus Instruments, Wetzlar, Germany). The highly irregular microgeometry of the corneal surface appeared bipartite in two sections. A relative crater had formed around the center and to the edge of the flap, with an irregular peripheral rim. Ocular burning pain from postoperative dry eye syndrome persisted, which was of greater discomfort to the patient than the refractive fault. Slit-lamp examination showed a residual depression in the former place of the intracorneal lens with epithelial islets in the periphery of the interface. These signs gradually receded over 8 months postoperatively, with the central mark disappearing and lessening of dystopic epithelial and intrastromal opacities. Topographic readings confirmed microscopic flattening of the intracorneal lens footprint with marked higher order aberrations persisting. Tear film secretion was severely impeded as noted with a 17-mm difference in Schirmer testing and patient complaints of persistent dry eye.

## DISCUSSION

We report a case of uncomplicated LASIK for mild hyperopia without refractive improvement. Because repeat LASIK did not improve refraction, an intracorneal lens was implanted under the initial superficial flap. Recurrent lens decentration, presence of massive interface debris, and patient discomfort necessitated removal of the implant, which alleviated the optical problems but left the patient with lasting discomfort.

We cannot identify why the initial excimer laser procedure did not produce refractive correction, as the technical parameters were without difficulty. We suggest that the subsequent intracorneal lens implantation

failed because calculation of the needed lens power could not be made with sufficient precision due to stromal haze and previous LASIK interventions. Decentration of an intracorneal lens has been previously reported,<sup>6</sup> but does not impede the general notion of safety, predictability, and efficacy of such a device. It could be speculated that previous intrastromal ablation and repeated lifting of the flap had interfered with its biomechanical stability, leading to less tight intrastromal adhesion. Additional patient interference by rubbing of the eye cannot completely be ruled out. The optical results from decentration of the lens can be compared to those arising from decentered ablation zones in laser ablative operations, with the difference being the rim of the lens further adds to secondary optical straying. In this case, opacities crystallized at the circumference of the lens, thus worsening visual acuity.

The degree of lasting surface irregularities is somewhat surprising and may be attributable to a number of different factors. First, repeated lifting of the flap with possible exertion of some mechanical stress, particularly upon the outer margin, is thought to compromise the biomechanical stability. Second, the insertion and recentration of the lens into this jeopardized environment may not contribute positively to the formation of a geometrically even corneal surface. Third, the efforts to remove sticky corneal debris from either side of the stromal bed may have acted as an additional ablative procedure. Furthermore, neuronal axon sprouting to repair the denervated flap seems to have been severely impeded by the fivefold lifting of the lamella, and possibly by the intracorneal lens itself. It remains unclear why a depression of the central corneal surface persisted, even with the intracorneal lens in place.

Based on observations in this case, objections regarding tolerability of the methacrylate lens in the stroma can not be argued. However, the issues that arose

in this patient relating to efficacy and safety of the device merit consideration. Recurrent lens decentration, interface debris and cell accumulation, and refractive failure with massive subjective discomfort raises the question whether implantation of the device into a non-virginal interface may be appropriate.<sup>7</sup> Also, residual aberrations after removal of the device may not be attributed to the device itself, but rather stem from the entire sequence of surgical, laser ablative, and re-correctional procedures. Complications may have occurred due to the series of manipulations, which traumatically altered corneal integrity. Intracorneal lenses may evoke a difficult clinical course if a previous laser ablative procedure fails to correct refractive errors.

Patients and surgeons should be aware of the possible limitations of an intracorneal implant as an adjunctive reparative tool in refractive surgery, particularly when prior interventions have failed to correct refractive errors.

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