

# Management of Post-LASIK Corneal Ectasia With Intacs Inserts

## One-Year Results

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**Objective:** To prospectively study the effects of the use of Intacs microthin prescription inserts (Addition Technology Inc, Fremont, Calif) for the postoperative management of corneal ectasia resulting from laser in situ keratomileusis (LASIK).

**Methods:** In this prospective nonrandomized clinical trial, 10 eyes of 7 patients with post-LASIK corneal ectasia (2 men and 5 women) aged 33 to 46 years (mean  $\pm$  SD, 40.67  $\pm$  5.99 years) were included. The follow-up ranged from 6 to 24 months (mean  $\pm$  SD, 15.0  $\pm$  6.5 months). Two Intacs segments of thickness depending on the residual refraction of the patients were inserted in each eye.

**Main Outcome Measures:** Uncorrected visual acuity, best spectacle-corrected visual acuity, refractive outcome, and topographic findings after Intacs implantation.

**Results:** Intacs were successfully implanted in all eyes. Spherical equivalent error was statistically significantly

reduced after Intacs implantation (pre-Intacs, mean  $\pm$  SD:  $-4.81 \pm 3.24$  Diopters (D) (range,  $-13.75$  to  $-2.50$  D) to  $-0.96 \pm 2.93$  D (range,  $-8.75$  to  $2.50$  D) ( $P < .001$ ). Pre-Intacs uncorrected visual acuity was 20/100 or worse in all eyes (range, counting fingers to 20/100) while at the last follow-up examination, 9 (90%) of 10 eyes had uncorrected visual acuity of 20/40 or better (range, counting fingers to 20/20). Three eyes maintained the pre-Intacs best spectacle-corrected visual acuity while the rest of the eyes (7) experienced a gain of 1 to 2 lines. The mean difference between pre-Intacs and last follow-up best spectacle-corrected visual acuity was a gain of  $1.00 \pm 0.82$  lines.

**Conclusions:** Intracorneal ring segments implantation improved uncorrected visual acuity and best spectacle-corrected visual acuity in patients with post-LASIK ectasia. Even though the results are encouraging, concern still exists regarding the long-term effect of such an approach for the management of post-LASIK ectasia.

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A DECADE after the introduction of the laser in situ keratomileusis (LASIK) technique in refractive surgery, the initial enthusiasm was replaced by skepticism regarding the post-LASIK complications, which has led refractive surgeons to adopt a more conservative approach. Indications that limit potential candidates for LASIK, such as attempted correction, preoperative corneal pachymetry, topographic findings, pupil diameter, and tear film stability, have led to the institution of strict inclusion criteria.<sup>1</sup> Even though these criteria limit the number of LASIK candidates, they contribute to the reduction of postoperative LASIK complications, resulting in increased patient satisfaction and physician confidence.

During the last 5 years, there has been increasing concern regarding the occurrence of postoperative keratectasia. After LASIK, the cornea is structurally weakened, not only by the laser central stro-

mal ablation (depending on the attempted correction) but also by the creation of the flap itself. The postoperative alternations in these tectonically changed and weakened corneas could lead to the instability of the biomechanical forces of the cornea, resulting in post-LASIK ectasia. Since 1998, when Seiler<sup>2</sup> published the first article regarding this complication, we have not yet elucidated the exact pathophysiologic mechanism behind this phenomenon, but several mechanisms and factors are proposed to contribute to this post-LASIK complication.<sup>3-5</sup> Up to now, the therapeutic options for patients with post-LASIK ectasia were limited to spectacles and contact lenses,<sup>6</sup> and in the advanced stages, penetrating keratoplasty (PKP).<sup>7</sup> There is only one preliminary publication with limited data regarding the management of patients with cornea ectasia after LASIK with Intacs microthin prescription inserts (Addition Technology Inc, Fremont, Calif).<sup>8</sup>

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Intacs were initially used for the correction of low myopia.<sup>9-11</sup> The main advantage of Intacs is that, unlike excimer laser refractive techniques, they preserve corneal tissue while maintaining clarity in the central optical zone. In this way, Intacs may represent an interesting surgical alternative for patients with corneal ectasia after LASIK.

Several studies have demonstrated the efficacy of Intacs in correcting low myopia, while in keratoconic eyes, Intacs implantation has resulted in an increase in topographic regularity and in uncorrected visual acuity (UCVA).<sup>12,13</sup> The objective of our study was to prospectively evaluate the safety, efficacy, and optical effects of Intacs implantation in post-LASIK ectatic eyes.

## METHODS

The study included 7 patients (2 men and 5 women; 10 eyes), aged 33 to 46 years (mean  $\pm$  SD, 40.67  $\pm$  5.99 years) with post-LASIK corneal ectasia. Four patients developed bilateral ectasia, and the rest had unilateral ectasia. All patients gave their written informed consent in agreement with institutional guidelines according to the Declaration of Helsinki.

A complete ophthalmologic examination was performed preoperatively to exclude other ocular disease, and the preoperative and postoperative follow-up evaluations included UCVA, best spectacle-corrected visual acuity (BSCVA), manifest refraction, keratometric data, and corneal topography. Postoperative visits were scheduled for days 1, 3, 15, and 30, and every 3 months thereafter.

Ectasia was diagnosed by slitlamp appearance of corneal thinning, unstable topographical steepening (EyeSys Technologies, Houston, Tex, and TechnoMed C-Scan/Technomed GmbH; Technomed, Baesweilec, Germany), progressive corneal thinning in ultrasonic pachymetry (Corneo-Gage, Sonogage Inc, Cleveland, Ohio), decreased visual acuity, unstable refraction, and posterior corneal steepening (Orbscan Slit Scanning Topography/Pachymetry system; Orbtex Inc, Salt Lake City, Utah).

Each patient had undergone LASIK at least 12 months before (mean  $\pm$  SD, 47.08  $\pm$  36.86 months [range, 12-108 months]). Mean  $\pm$  SD preoperative spherical equivalent (SE) refraction was  $-11.23 \pm 3.11$  diopters (D) (range,  $-8.25$  to  $-18.00$  D); and mean  $\pm$  SD pachymetry was  $511.40 \pm 11.93$   $\mu$ m (range, 500 to 530  $\mu$ m). The pre-LASIK UCVA was uniformly poor at counting fingers (CF). Best spectacle-corrected visual acuity ranged from 20/40 to 20/20. The mean  $\pm$  SD attempted correction was  $-10.83 \pm 3.06$  D (range,  $-8.25$  to  $-18.00$  D). Intraoperative (after flap was lifted) ultrasonic pachymetry was used in all eyes to determined flap and residual corneal bed thickness. The mean  $\pm$  SD residual corneal stromal thickness after the creation of the flap and stromal ablation was  $240.00 \pm 49.21$   $\mu$ m (range, 175-325  $\mu$ m), while the mean flap thickness was  $129.00 \pm 22.77$   $\mu$ m (range, 90-170  $\mu$ m).

## SURGICAL PROCEDURE

Procedures were performed by 2 surgeons (I.G.P. and C.S.S.), and topical anesthesia was given. Two Intacs segments were inserted in the usual fashion used for low myopia correction (nasotemporally). The thickness of the Intacs was chosen based on the attempted correction (0.40 mm in 4 eyes, 0.35 mm in 3, 0.30 mm in 2, and 0.45 mm in 1). Using a diamond knife set at 70% of the corneal thickness at the incision site, a 0.9-mm radial incision was created, and 2 intrastromal corneal pockets were created using a pocketing lever, stromal spreader, and clockwise and anticlockwise dissection glides. Two tunnels (right

and left) were created using clockwise and anticlockwise dissectors under suction created by a vacuum centering guide. The 2 polymethylmethacrylate segments were implanted in the clockwise and counterclockwise tunnels, maintaining a space of 2.0 mm between their ends and 1.5 mm between the opposite edge of each segment and the edge of the incision. Because of the standard 7-mm optic zone diameter of the ring segments, Intacs segments inevitably ended up central and deep to the LASIK flap edge.

After the stromal pocket had been carefully washed with balanced salt solution, the incision was closed with a single interrupted 10-0 nylon suture. All procedures were uneventful, and no disruption of the LASIK flap occurred. Postoperatively, all eyes received antibiotic/steroid combination eye drops 4 times per day for 1 week. In addition, all patients were instructed to use preservative-free artificial tears frequently. The sutures were removed 2 weeks after surgery.

## STATISTICAL ANALYSIS

Group differences for continuous variables were tested using the unpaired and paired *t* tests. Results are presented as mean  $\pm$  SD. A *P* value less than .05 was regarded as statistical significance.

## FOLLOW-UP EVALUATION

All eyes were examined preoperatively. Postoperative visits were scheduled for days 1, 3, and 15, and every 3 months thereafter. Uncorrected visual acuity, BSCVA, and manifest refraction were measured. The follow-up ranged from 6 to 24 months (mean, 15.0  $\pm$  6.5 months).

## RESULTS

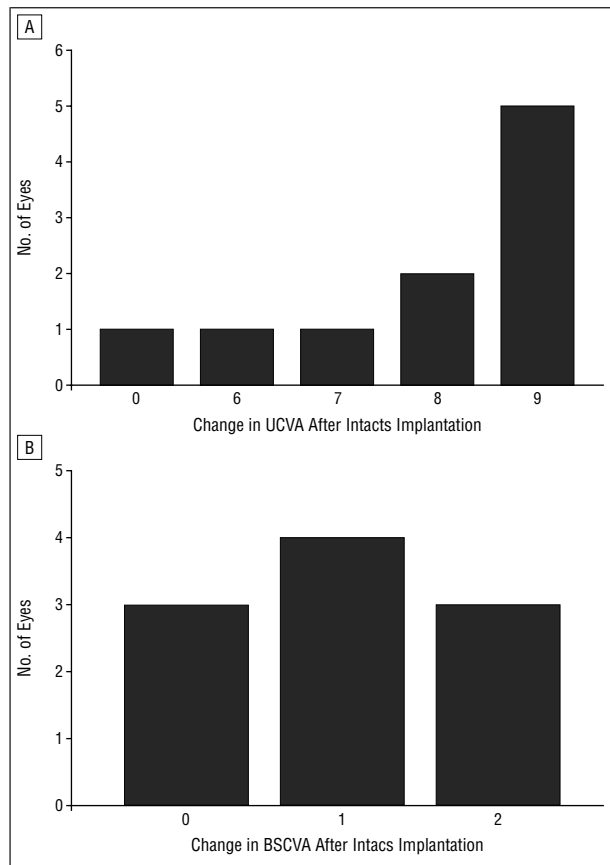
### VISUAL ACUITY

Pre-Intacs UCVA was 20/100 or worse in all eyes (range, CF to 20/100). At the last follow-up examination, 9 (90%) of 10 eyes had UCVA of 20/40 or better (range, CF to 20/20). Of the 10 eyes, 1 eye maintained the preoperative UCVA, while the rest (9 eyes) experienced a gain of 6 to 9 lines. The mean difference between preoperative and postoperative UCVA was a gain of 7.4 lines (range, unchanged UVA to gain of 9 lines) (**Figure 1A**).

Pre-Intacs BSCVA was 20/25 or better only in 2 (20%) of 10 eyes (range, 20/63-20/25) while after Intacs implantation, this was observed in 6 eyes (60%) (range, 20/50-20/20). Of the 10 eyes, 3 eyes maintained the pre-Intacs BSCVA, while the rest (7 eyes) experienced a gain of 1 to 2 lines (Figure 1B). The mean difference between pre-Intacs and last follow-up BSCVA was a gain of 1.00  $\pm$  0.82 lines (range, unchanged to gain of 2 lines). In all eyes (except one case in which there was a gain of 1 line and another one with a loss of 2 lines in BSCVA), there was a return to the pre-LASIK BSCVA after the Intacs implantation.

### REFRACTIVE OUTCOME

Preoperative and last follow-up mean values for spherical equivalent refraction revealed a statistically significant reduction (*P* = .001) from  $-4.81 \pm 3.24$  D (range,  $-13.75$  to  $-2.50$  D) to  $-0.96 \pm 2.93$  D (range,  $-8.75$  to 2.50 D) (*P* < .001), with a mean reduction value of  $3.85 \pm 1.32$



**Figure 1.** Change in uncorrected visual acuity (UCVA) (A) and best spectacle-corrected visual acuity (BSCVA) (B) between preoperative and the last postoperative follow-up. Intacs is manufactured by Addition Technology Inc, Fremont, Calif.

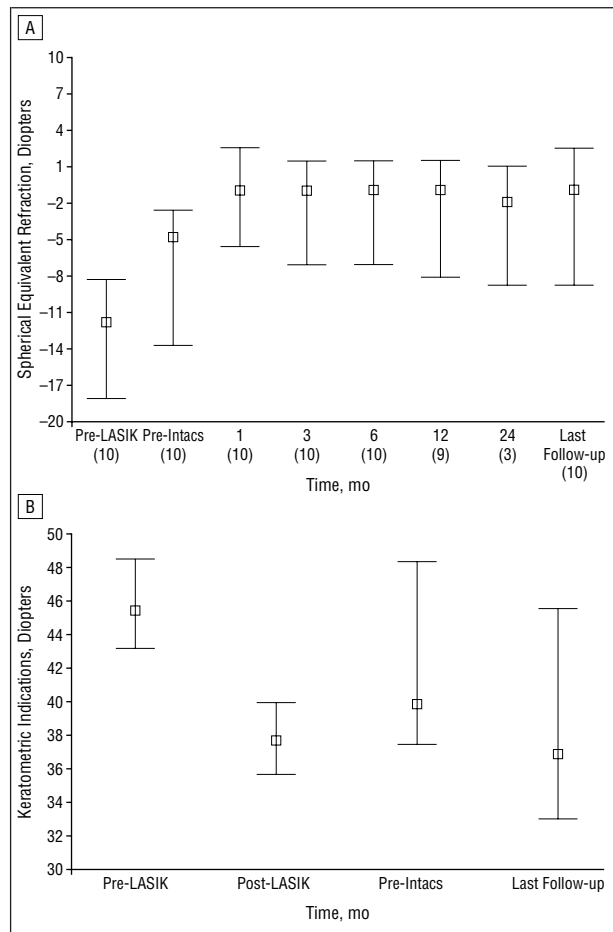
D (range,  $-6.75$  to  $-2.50$  D) at the last follow-up (**Figure 2A**). There was also a statistically significant difference between predicted corrections according to the nomogram of myopia ( $2.98 \pm 0.68$  D) compared with the correction achieved ( $3.88 \pm 1.30$  D) ( $P = .02$ ) after Intacs implantation (**Figure 3**).

#### TOPOGRAPHIC FINDINGS (KERATOMETRIC VALUES)

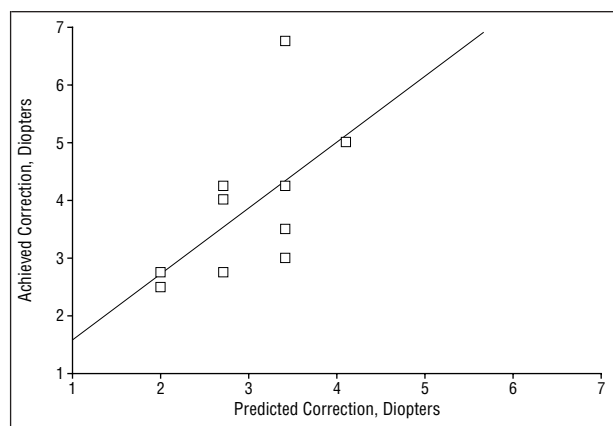
A significant reduction in keratometric values was found at the last follow-up examination. Mean preoperative keratometry from  $40.21 \pm 3.54$  D (range, 37.42-48.34 D) significantly changed to  $37.14 \pm 3.93$  D (range, 33.00-45.50 D) ( $P < .01$ ) at the last follow-up, with a mean reduction of  $3.07 \pm 0.77$  D (range,  $-4.42$  to  $-1.91$  D) (Figure 2B).

#### ADVERSE EFFECTS AND THEIR MANAGEMENT

In one eye with an advanced stage of ectasia (spherical equivalent refraction,  $-13.75$  D), between the third and the sixth month after Intacs implantation (0.45 mm), a decrease in the BSCVA (20/50-20/80) and an increase in topographic irregularity were observed (**Figure 4A-D**). The patient underwent LASIK with attempted correction of  $-12.50$  D (preoperative pachymetry was 530  $\mu\text{m}$  and residual corneal bed thickness after ablation was 180

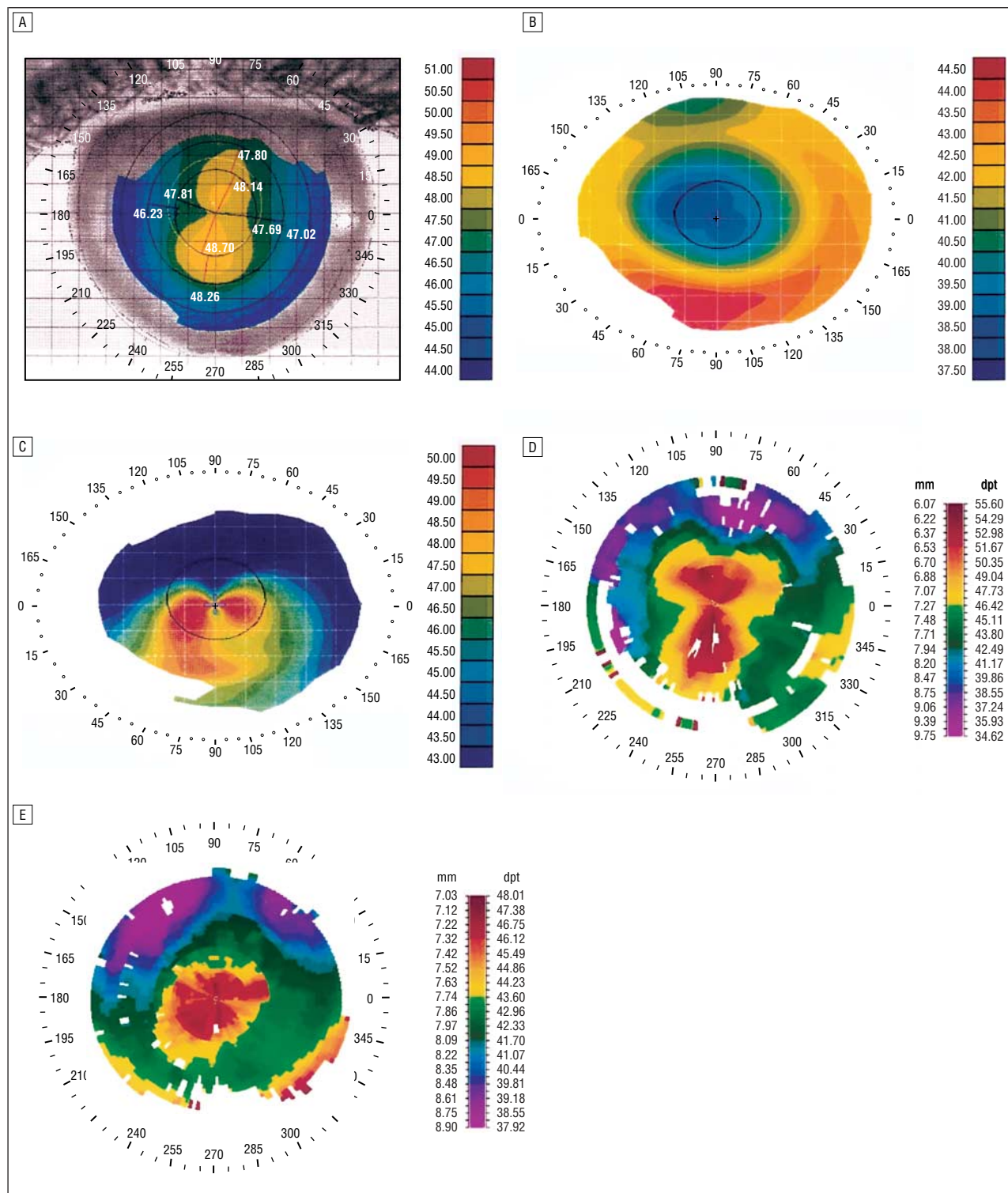


**Figure 2.** Mean spherical equivalent refraction (A) and keratometric values (B) after Intacs (Addition Technology Inc, Fremont, Calif) implantation. The error bars indicate 95% confidence intervals for the means. LASIK indicates laser in situ keratomileusis.



**Figure 3.** Correlation between attempted and predicted correction after Intacs (Addition Technology Inc, Fremont, Calif) implantation.

$\mu\text{m}$ ). We decided to move the segments and to advance them to bring them in contact and minimize the irregular astigmatism (**Figure 5**). Three months later, the patient had a remarkable increase in BSCVA (20/32), while a significant increase in the topographic regularity was found, which remained stable at the last follow-up, 10 months later (Figure 4E).



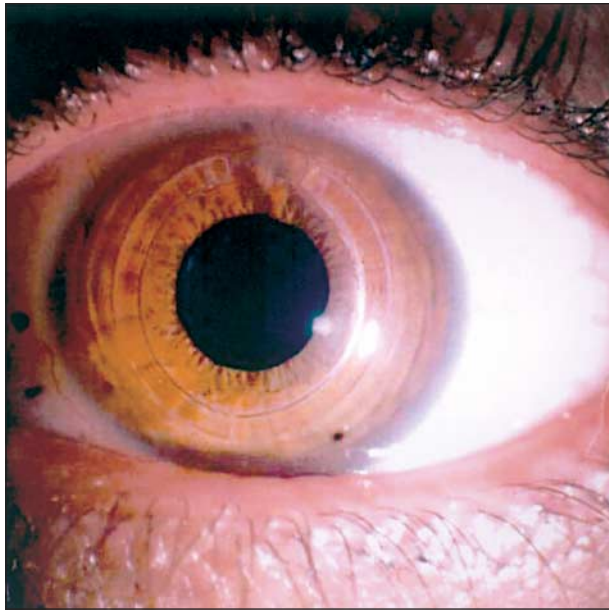
**Figure 4.** Preoperative (A), and postoperative topographies (B, 2 months after laser in situ keratomileusis (LASIK); C, 4 years after LASIK; D, 3 months after Intacs [Addition Technology Inc, Fremont, Calif] segments insertion; E, 10 months after segment replacement) of a case of left eye with post-LASIK ectasia.

## POSTOPERATIVE COMPLICATIONS

At 9 months, most eyes showed mild channel deposits at the inner edge of the segments. In 2 eyes, superficial mild wound site neovascularization was found after 9 months, which remained stable during the follow-up period and without any changes in VA or topographic findings.

## COMMENT

As refractive surgery gains worldwide acceptance for its safety, the number of refractive operations increases every year. The demands on patients and physicians are continuously increasing. In this concept, large retrospective and prospective studies are being held to establish



**Figure 5.** Slitlamp photograph of patient with post-laser in situ keratomileusis ectasia after Intacs (Addition Technology Inc, Fremont, Calif) replacement, with the inferior part in contact to minimize the induced astigmatism.

the results and efficacy of refractive surgery. With the increasing experience in the field of refractive surgery, several recommendations have been proposed to maximize the safety of refractive surgery.<sup>1</sup>

Over the last years, there has been increasing concern regarding the occurrence of corneal ectasia after LASIK. Even though corneal ectasia is a rather rare post-LASIK complication, it can have a profoundly negative effect on the refractive properties of the cornea. The cornea begins to thin and when the resultant irregular astigmatism cannot be corrected with gas-permeable contact lenses, PKP is necessary for visual rehabilitation.<sup>2-7</sup>

We first published our preliminary results of 3 post-LASIK ectatic eyes, in which Intacs were used to reduce the corneal steepening and astigmatism, and VA was improved in all eyes.<sup>8</sup> We described herein our relatively successful experience with Intacs in 10 eyes that demonstrated corneal ectasia after LASIK. After a mean follow-up of 1 year, an improvement in refractive outcome in all eyes was observed, with an increase in UCVA, BSCVA, and in topographic regularity.

An important finding is that in all eyes (except one case in which there was a gain of 1 line and another case with a loss of 2 lines of BSCVA), there was a return to the pre-LASIK BSCVA after the Intacs implantation. It seems that Intacs implantation in post-LASIK ectatic eyes could mechanically bring the post-LASIK ectatic cornea to a more normal state. Additionally, there was a statistically significant difference between the achieved and the predicted (according to the myopic nomogram) correction after Intacs implantation, demonstrating an enhanced effect of Intacs in the refraction of post-LASIK ectatic eyes. This finding could be explained by the reduction of the pachymetric findings of post-LASIK ectatic corneas, which allows Intacs to have a more pro-

nounced effect than in myopic eyes that have not undergone the operation.

We were surprised at the significant improvement of one patient who had an advanced stage of ectasia and underwent movement of the segments to bring them in contact with each other and to minimize the irregular astigmatism. These findings support the unpredictability of the effects of Intacs in the advanced stages of post-LASIK ectasia, and close follow-up of these patients is necessary to control and manage the possibly unpredictable results.

Our experience seems to show that even in cases where biomechanical factors in the cornea have been disturbed by prior surgery, the placement of Intacs may still provide favorable outcomes. The availability of a non-invasive, painless, rapid recovery procedure as an intermediate layover is very promising. Since long-term stability is a critical issue for any surgical intervention in ectatic corneas, it will be interesting to evaluate how Intacs affects corneal ectasia over a more extended follow-up period.

In conclusion, Intacs seem to offer a minimally invasive alternative treatment for post-LASIK ectatic eyes, especially in early stages of the disease when there are fewer topographic irregularities. Further follow-up and additional cases must be reviewed to draw final conclusions about the efficacy of this surgical technique in post-LASIK ectatic eyes.

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