New INTACS SK Implantation in Patients With Post–Laser In Situ Keratomileusis Corneal Ectasia

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Abstract: In this case series, 2 patients with post–laser in situ keratomileusis corneal ectasia were included. Patients were treated with new intrastromal corneal ring segments, INTACS SK (severe keratoconus or steep "K") (Addition Technology, Inc, Des Plaines, IL) implantation. Two segments were inserted without any intraoperative or postoperative complications. Three months after the procedure, uncorrected visual acuity was improved in both patients from counting fingers preoperatively to 20/40 and 20/50, respectively. Best spectacle–corrected visual acuity improved from 20/40 to 20/32 and from 20/50 to 20/40. Manifest refraction improved from $-8.75/-5.00 \times 125$ and $-14.25/-6.50 \times 33$ preoperatively to $-5.50/-2.25 \times 125$ and $-8.25/-1.50 \times 15$ with an improvement in topographic findings. One year postoperatively, uncorrected visual acuity, best spectacle–corrected visual acuity, and topographic findings remained improved. In conclusion, new INTACS SK might be able to improve visual acuity in patients with post–laser in situ keratomileusis corneal ectasia.

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Keratectasia is a condition in which the cornea progressively thins and steepens, producing myopia, irregular astigmatism, and loss of best spectacle–corrected visual acuity (BSCVA). This corneal disorder has been reported as a serious complication after refractive surgery, more often associated with laser in situ keratomileusis (LASIK) surgery.[1,2] The exact incidence of post-LASIK ectasia remains still unknown. Several parameters, such as high myopic corrections, thin corneas, and residual corneal bed thickness less than 250 μm, represent major risk factors for this condition.[3,4]

Post-LASIK corneal ectasia treatment options depend on the severity of the condition. For patients in whom spectacles cannot improve visual acuity and rigid gas permeable contact lenses are not well tolerated, there is a series of minimal invasive procedures available, before deciding to perform keratoplasty, such as collagen cross-linking[5] and INTACS.[6,7]

INTACS (Addition Technology, Inc, Des Plaines, IL) are intrastromal corneal ring segments that were first used and approved by the Food and Drug Administration for the correction of moderate to mild myopia [−1 to −3 diopters (D)].[6] Recently, their application has been extended in the treatment of keratoconus and post-LASIK ectasias. INTACS can reshape the abnormal cornea, by an arc-shortening effect that flattens the cornea, neutralizing or minimizing topographic abnormalities and consequently improving visual acuity.[7] It is considered a safe and minimal invasive procedure because there is no tissue removed or manipulation of the central optical zone. The new INTACS SK (severe keratoconus or steep "K") are implanted in a smaller zone (6 mm) and the segment profile is elliptical, whereas in the previous INTACS model, optical zone was 6.8 mm and segment profile was hexagonal. INTACS SK have 2 available sizes, 0.400 and 0.450 mm to address severe ectasia.

The purpose of this case series is to evaluate the visual outcomes after INTACS SK implantation in 2 patients with corneal ectasia after myopic LASIK.

CASE 1

A 34-year-old woman presented to our institute with iatrogenic ectasia in the left eye 5 years after LASIK. Right eye had no signs of post-LASIK ectasia. A comprehensive ophthalmic examination was performed, revealing that uncorrected visual acuity (UCVA) was counting fingers (CF) and BSCVA was 20/40 ($-8.75/-5.00 \times 125$) in the left eye. Preoperative central corneal thickness was 473 μm and preoperative K readings were 54.28 and 49.62 D. Corneal topography revealed a progressive abnormal astigmatic pattern consistent with corneal ectasia.

CASE 2

A 26-year-old woman presented to our institute with iatrogenic ectasia in the right eye 4 years after LASIK. Left eye had signs of post-LASIK ectasia as well. A comprehensive ophthalmic examination was performed, revealing that UCVA was CF and BSCVA was 20/50 ($-14.25/-6.50 \times 33$) in the right eye. Preoperative central corneal thickness was 384 μm and preoperative K readings were 64.43 and 56.84 D. Corneal topography revealed a progressive abnormal astigmatic pattern consistent with corneal ectasia.

Both patients underwent intrastromal corneal ring segments implantation (INTACS SK; Addition Technology, Inc). They were appropriately informed and gave written informed consent in accordance with institutional guidelines, according to the Declaration of Helsinki.

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SURGICAL PROCEDURE

Surgical procedure was performed under topical anesthesia. Two INTACS SK (Addition Technology, Inc) segments were inserted. The thickness of the segments was 0.400 mm for the first and 0.450 mm for the second patient. Using a diamond knife set at 70% of the corneal thickness (350 μm at the incision site), a 0.9-mm radial incision was made 6 mm from the center of the cornea along with the steep meridian. Two tunnels (right and left) were created using clockwise and counterclockwise dissectors (Addition Technology, Inc) under suction created by a vacuum centering guide. The 2 polymethyl methacrylate 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. INTACS SK segments ended up central and deep to the LASIK flap edge, creating a central optic zone of 6.0 mm between them.

After the stromal pocket had been washed carefully with balanced salt solution, the incision was closed with a single interrupted 10-0 nylon suture. The procedure was uneventful, and no disruption of the LASIK flap (nasally hinged) occurred (Fig. 1).

Patients wore a bandage contact lens for 3 days after surgery and received antibiotic and steroid combination eyedrops 4 times daily for 1 week. In addition, patients were instructed to use preservative-free artificial tears frequently. The suture was removed 2 weeks after the procedure.

Three months after the procedure, UCVA showed significant improvement in both patients from CF preoperatively to 20/40 and 20/50. BSCVA improved from 20/40 to 20/32 and 20/50 to 20/40 with manifest refraction from $-8.75/-5.00 \times 125$ to $-5.5/-2.25 \times 125$ and from $-14.25/-6.50 \times 33$ to $-8.25/-1.50 \times 15$.

One year postoperatively, UCVA and BSCVA remained unchanged and topographic findings remained improved (Fig. 2). Deposits on the inner aspect of the rings are evident 1 year postoperatively (Fig. 1B).

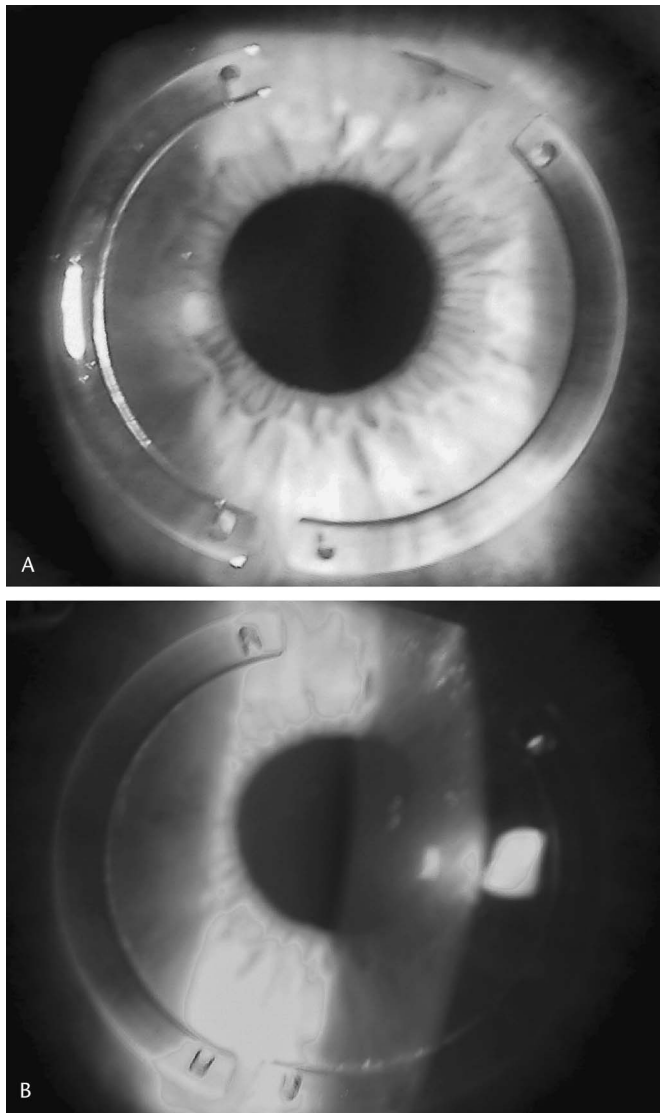

FIGURE 1. Slit-lamp photograph after INTACS SK (Addition Technology, Inc) implantation 2 weeks after surgery (A) and 1 year after surgery (B).

DISCUSSION

Iatrogenic ectasia is one of the most severe sight-threatening complications recurring after LASIK surgery.[1,8,10] The exact incidence of post-LASIK ectasia remains still unknown. If spectacle correction and rigid gas permeable contact lenses cannot improve visual acuity, other minimal invasive techniques like intracorneal ring segments implantation and collagen cross-linking can be performed before penetrating keratoplasty.

In this case series, one of the first published case series in the literature, we present 2 patients with post-LASIK ectasia treated with the new INTACS SK. After segments implantation, there was a significant improvement in visual outcomes (UCVA and BSCVA) and topographic findings that remained stable during the 1-year follow-up. No subjective symptoms were mentioned (foreign body sensation, glare, or halos), and no intraoperative or postoperative complications occurred.

Kamburoglu et al[11] reported that in a comparative study between INTACS SK and INTACS implantation in patients with advanced keratoconus, refractive results and K readings seem to be better improved in INTACS SK implanted eyes when compared with INTACS. INTACS SK are implanted in 6 mm zone, whereas the previous INTACS were implanted in 6.8 mm. This characteristic offers the possibility of increasing the possible effect of the new INTACS SK (in comparison with the previous model) and avoiding segment interference with the edges of the LASIK flap.

Intracorneal rings implanted at a smaller diameter zone (5 mm) than INTACS SK are Kera rings. Theoretically, these rings might have a greater effect than SK because they are placed more centrally, but the procedure is most probably more difficult because they are implanted in thinner corneal areas.[12] Additionally, Kera rings, implanted at a 5 mm zone, possibly produce greater glare and halos because they are placed close to the pupil edges. It is extremely difficult to predict if INTACS

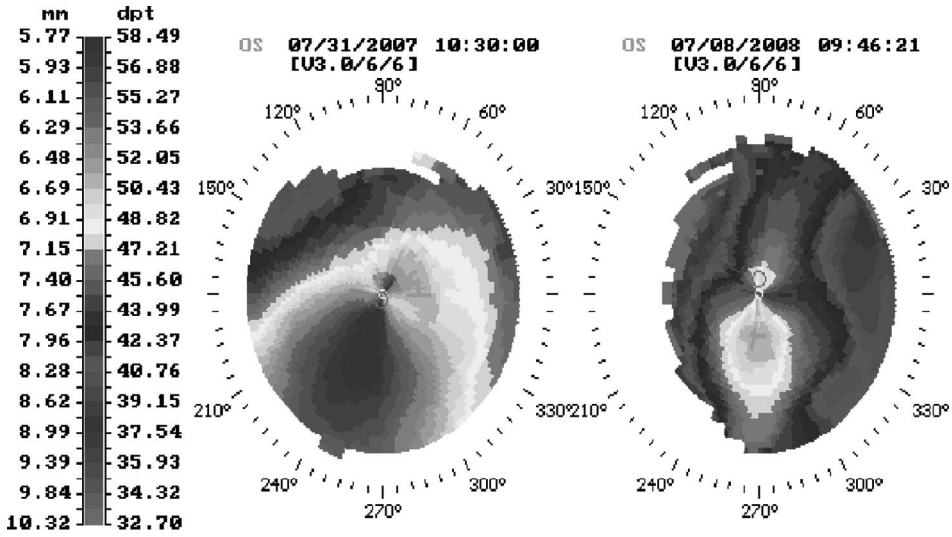

FIGURE 2. Preoperative (left) and postoperative (12 months later) topography of a left eye with post-LASIK ectasia after intrastromal corneal ring segments implantation (INTACS SK; Addition Technology, Inc).

SK present greater safety and efficacy than Kera rings, and a larger comparative study might be useful to have sufficient data and accurate results.

Furthermore, the segment profile of the new INTACS SK is elliptical, not hexagonal as the previous model. Because light scattering is amplified on objects with sharp angles, this new feature may eliminate subjective symptoms like halos or glare.

In conclusion, new INTACS SK could improve visual acuity in patients with post-LASIK corneal ectasia. Further studies are needed to draw conclusions about the efficacy and safety of this new model of INTACS in patients with corneal ectatic diseases.

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