

Nine-year Follow-up of a Posterior Chamber Phakic IOL in One Eye and LASIK in the Fellow Eye of the Same Patient

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ABSTRACT

PURPOSE: To compare the long-term results (9 years) of LASIK in one eye and phakic intraocular lens (implantable contact lens [ICL]) implantation in the fellow eye of the same patient.

METHODS: A patient with high myopia underwent LASIK with a MEL 60 excimer laser in one eye (spherical equivalent refraction -9.75 diopters [D], 5-mm optical zone with no transition zone) and phakic intraocular lens (STAAR Collamer implantable contact lens [ICL]) implantation (spherical equivalent refraction -9.50 D) in the fellow eye.

RESULTS: At 9 years postoperatively, the mean spherical equivalent refraction was -1.00 in the eye with the ICL and -1.75 D in the eye that underwent LASIK. During the first 6 postoperative months in the LASIK eye, refraction regressed, but remained stable during the remainder of follow-up. Uncorrected visual acuity was 20/25 in the eye with the ICL and 20/30 in the LASIK eye, whereas best spectacle-corrected visual acuity was 20/20 in both eyes. Less night vision problems (glare and halos) were experienced in the eye with the ICL compared to the LASIK eye. Although the patient initially preferred the LASIK procedure, at last follow-up 9 years postoperatively, increased overall satisfaction was reported for the eye with the ICL compared to the LASIK eye.

CONCLUSIONS: Nine years after treatment of high myopia with the ICL and LASIK in the same patient, better quality of vision, stability, and satisfaction score were achieved in the eye with the ICL compared to the eye that had undergone LASIK. No long-term sight-threatening complications were found during follow-up. [*J Refract Surg.* 2007;23:935-937.]

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Many different parameters must be considered when deciding whether a patient is a good candidate for refractive surgery. Refractive error, patient age, corneal pachymetry and topography, scotopic pupil size, and fundus examination as well as the patient's needs and psychological profile are the main criteria for choosing the proper treatment.

For high myopic corrections, surgeons have to choose, according to the patient's preoperative profile, between keratorefractive (surface or intrastromal) and intraocular procedures (phakic intraocular lens [IOL] implantation or clear lens extraction). Possible complications in high myopic corrections after keratorefractive techniques include corneal ectasia, myopic regression, poor quality of vision in scotopic conditions, and haze,¹ whereas intraocular procedures, despite better optical results,² are more invasive and may result in endothelial cell loss and elevated intraocular pressure.^{3,4}

Few comparative studies between implantable contact lens (ICL) and LASIK exist.⁵⁻⁹ Two prospective, randomized clinical trials have been reported^{8,9}; however, follow-up was ≤ 3 years. As long-term evaluation is essential for any procedure, we report 9-year follow-up in a patient who participated in a prospective, randomized, comparative clinical study of LASIK and phakic IOL implantation for the correction of high myopia.

CASE REPORT

A 21-year-old woman presented for refractive surgery evaluation in 1997. Uncorrected visual acuity (UCVA) was count fingers in both eyes. Preoperative best spectacle-corrected visual acuity (BSCVA) was 20/20 with refraction of $-9.25 -0.50 \times 85$ in the right eye and 20/20 with refraction of $-9.50 -0.50 \times 125$ in the left eye. Scotopic pupil size was 6 mm in both eyes. Central corneal thickness was 496 μm in the right eye and 506 μm in the left eye. Intraocular pressure was 11 mmHg in both eyes. The patient had no family history of keratoconus. Keratometry was 42.29/43.15 in the right eye and 42.39/43.32 in the left eye (Fig). Ophthalmic examination found no anterior or posterior segment abnormality.

The patient was included in a prospective, randomized, comparative clinical study between LASIK and phakic refractive lens implantation. The patient was fully informed of the possible intra- and postoperative complications and gave written consent in accordance with institutional guidelines and the Declaration of Helsinki.

On July 27, 1997, the patient underwent LASIK in the left eye and 1 month later underwent ICL implantation (posterior chamber hydrogel collagen plate phakic IOL; STAAR Collamer ICL [STAAR Surgical AG,

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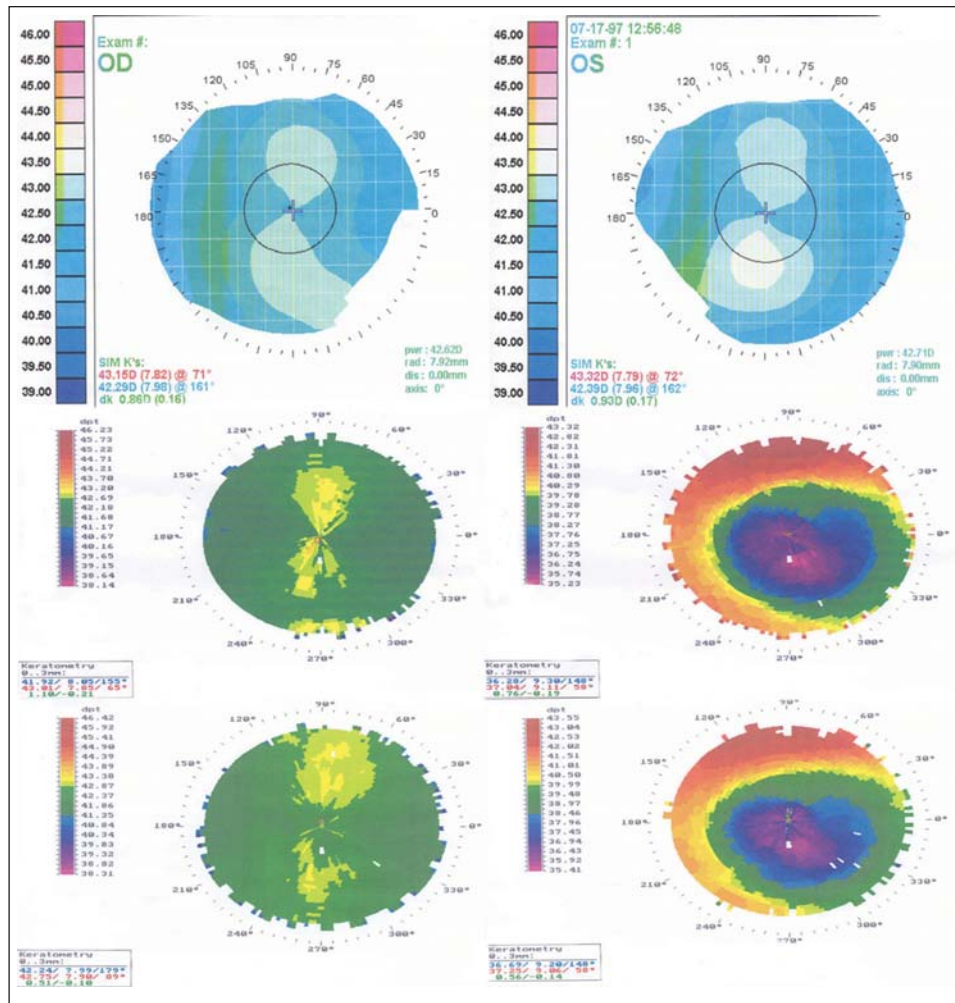


Figure. Top) Preoperative, middle) 5-year, and bottom) 9-year postoperative topographies after left) ICL implantation in the right eye and right) LASIK in the left eye.

Nidau, Switzerland]; ICM 120V2, size 12 mm) in the right eye. The procedures were randomized according to a coin flip.

Laser in situ keratomileusis was performed with the MEL 60 excimer laser (Aesculap Meditec, Heroldsberg, Germany) after a nasally hinged flap of 139 μ m (intraoperative pachymetry) was made by the Flapmaker microkeratome (Refractive Technologies Inc, Cleveland, Ohio). The attempted correction was -9.50 D at the 5-mm optical zone, with no transition zone (estimated maximum ablation depth 87 μ m), leaving a residual corneal stromal bed thickness of 280 μ m.

Lens power calculations were performed by STAAR Surgical AG on the basis of the following variables: 1) manifest and cycloplegic refractions for a vertex distance of 12.0 mm; 2) keratometry; 3) corneal thickness; and 4) anterior chamber depth. The size of the ICL was chosen by STAAR according to the patient's horizontal corneal diameter (white-to-white) measured with a caliper.

Procedures in both eyes were uneventful. At 1-month

postoperative follow-up, UCVA was 20/25 (BSCVA 20/20 with $-0.25 -1.50 \times 160$) in the right eye (ICL) and 20/25 (BSCVA 20/20 with $-0.25 -1.50 \times 115$) in the left eye (LASIK). Refraction regression occurred in the first 6 postoperative months in the LASIK eye (UCVA 20/30, BSCVA 20/20 with $-1.00 -1.50 \times 120$), which remained stable for the duration of follow-up. No statistically significant alterations were found regarding the visual acuity or refraction in the ICL eye during follow-up.

Best spectacle-corrected visual acuity was 20/20 in both eyes at all postoperative examinations (no gain or loss of Snellen lines). Slit-lamp and fundus examinations of both eyes were unremarkable. The corneal topographic appearance revealed anatomical stability in both eyes (see Fig).

Binocular vision was not affected by the different surgical procedures (keratorefractive and intraocular). At last follow-up 9 years postoperatively, the patient reported increased overall satisfaction with the eye implanted with the ICL compared to the LASIK eye,

due to superior UCVA, stability, and less night vision problems (glare and halos).

DISCUSSION

Laser in situ keratomileusis and phakic refractive IOL implantation are the most commonly used procedures for the correction of large degrees of ametropia, especially in young patients. In high myopic corrections (>10.00 D), predictability, efficacy, stability, and safety of LASIK has been reported to be low.¹⁰ Moreover the quality of vision is poor due to the need for smaller attempted optical zones,⁵ the significant decrease in photopic or mesopic contrast sensitivity,^{11,12} and the increase of spherical aberration³ postoperatively. On the contrary, phakic refractive IOL implantation, despite the potential damage to endothelial cells,^{3,4} is a theoretically reversible technique, does not affect the natural prolate shape of the cornea, and contrast sensitivity can be preserved or even improved.^{11,12}

In previous comparative studies of the two procedures with follow-up of up to 3 years,^{8,9} eyes that underwent phakic refractive IOL implantation had better UCVA and more eyes gained BSCVA lines compared with eyes that underwent LASIK. In this report, better UCVA and stability of residual refractive error with less glare and halos were noted in the eye with the ICL compared to the eye treated with LASIK. The more intense night vision problems in the LASIK eye can be explained by the small attempted optical zone of 5 mm (smaller than the patient's scotopic pupil size) and the absence of a transition zone. Overall, the patient preferred the ICL eye due to better stability and quality of vision.

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Fifteen-year Follow-up After LASIK: Case Report

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ABSTRACT

PURPOSE: To present 15-year follow-up of one of the first LASIK-treated patients.

METHODS: A 40-year-old woman underwent LASIK in the left eye for myopia in July 1991.

RESULTS: Fifteen years after LASIK, spherical equivalent error was statistically significantly reduced from preoperative $-8.75 -3.75 \times 025^\circ$ to postoperative $-4.25 -2.75 \times 010^\circ$. Six months postoperatively, refractive and topographic stability was obtained and remained stable during follow-up with no significant changes between interval mean time ($-3.75 -3.00 \times 020^\circ$ 6 months postoperatively to $-4.25 -2.75 \times 010^\circ$ 15 years postoperatively). No early or late postoperative complications

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were observed, and confocal microscopy revealed a regenerated nerve plexus and normal cornea. However, increased scattering and presence of debris were observed at the flap interface even after 15 years. Despite moderate predictability (residual refractive error) and small optical zone, the patient was satisfied with final outcome.

CONCLUSIONS: One of the first LASIK-treated patients was presented 15 years after surgery. LASIK in this patient had low predictability, although refractive and topographic stability occurred after the sixth postoperative month. No long-term, sight-threatening complications were identified during follow-up. [*J Refract Surg.* 2007;23:937-940.]

Fifteen years have passed since the first published case series of human eyes after LASIK.¹ Although LASIK is a more invasive procedure than photorefractive keratectomy (PRK) and the cornea is exposed to more possible risks (eg, flap-related complications and ectasia),^{2,3} it changed the trends in refractive surgery and has become the most popular refractive technique for the correction of ametropia⁴ over the past decade.

To our knowledge, there are few long-term postoperative LASIK studies, and none exceed 6 years' follow-up.⁵⁻⁷ We present one of the first LASIK-treated patients who participated in the first worldwide LASIK trial in Crete, Greece, 15 years after unilateral surgery using a first-generation microkeratome and excimer laser.

CASE REPORT

A 40-year-old woman underwent LASIK in the left eye for myopia in July 1991. Ocular history was unremarkable. Preoperative examination included slit-lamp microscopy, uncorrected visual acuity (UCVA), Snellen best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions, intraocular pressure (IOP), corneal topography (Corneal Analysis System version 2.104; EyeSys Laboratories Inc, Houston, Tex), and optical pachymetry of the central cornea. Uncorrected visual acuity was counting fingers in both eyes. Best spectacle-corrected visual acuity was 20/32 with $-7.00 -1.25 \times 149^\circ$ in the right eye and 20/100 with $-8.75 -3.75 \times 025^\circ$ in the left eye. Central keratometric measurement was 43.88/44.95 D and 43.75/46.25 D in the right and left eye, respectively. Central corneal thickness was 534 μm and 530 μm in the right and the left eye, respectively.

The patient was fully informed regarding the experimental nature of the procedure, as well as possible intra- and postoperative complications, and gave written informed consent in accordance with institutional guidelines and the Declaration of Helsinki.

The eye was anesthetized with topical oxybuprocaine hydrochloride 4 mg/mL eyedrops (Novesin 0.4%;

CibaVision, Embrach, Switzerland [formerly Dispersa AG, Hettlingen, Switzerland]), one drop every 5 minutes for a total of three drops before surgery. Peribulbar anesthesia was then administered (2 to 4 cc lidocaine hydrochloride 20 mg/mL [Xylocaine 2%; AstraZeneca, Sodertalje, Sweden]). A Barraquer eyelid speculum (Katena Products Inc, Denville, NJ) was placed, and the eye was cleaned with normal saline. A nasally based, 150- μm thick corneal flap was made with a Draeger's lamellar rotor keratome (Storz Instruments GmbH, Heidelberg, Germany) using a 0.15-mm spacer. This rotor keratome was semiautomatic and operates with a rotational mode of its blade. During microkeratome suction fixation, IOP was raised to 60 mmHg.

Following formation of the corneal flap, the microkeratome with its suction ring was removed and the flap reflected nasally. The corneal bed was ablated with a 193-nm excimer laser (MEL 60; Carl Zeiss Meditec, Heroldsberg, Germany), beam fluence at the cornea of 220 mJ/cm² and a firing rate of 20 Hz, with a 5-0 mm ablation zone. We used the PRK algorithm that was programmed with the machine. No astigmatic correction was performed, and attempted correction was 10.00 D (estimated maximum ablation depth of 83 μm). The automated 4.9-mm diameter, computer-controlled, contracting iris diaphragm of the unit, with its incorporated suction ring, was placed on the corneal bed and the intended correction was entered into the module. Before ablation, beam quality was checked on photographic paper.

After excimer laser ablation, the bed was irrigated with normal saline for approximately 5 to 10 seconds. The corneal bed and inner surface of the flap were dried with an air pump, and the corneal flap was reflected back to its original position. At the end of the surgery, 3 mg tobramycin 0.3% and 1 mg dexamethasone 0.1% (Tobradex; Alcon Laboratories Inc, Ft Worth, Tex) and tropicamide 1 mg/mL eye drops (Mydriaticum; Novartis Ophthalmics AG, Basel, Switzerland [formerly Dispersa]) were instilled. One milliliter of 40 mg of methylprednisolone acetate was injected into the sub-Tenon's space, and a therapeutic bandage soft contact lens was used for 48 hours after surgery. The entire procedure was performed under the excimer laser surgical microscope.

The patient was examined every 24 hours for the next 5 days. The patient received antibiotic/steroid combination eye drops 4 times a day for 4 weeks. The early postoperative course was uneventful.

Follow-up was scheduled at 1 day, 2 weeks, 1, 3, and 6 months, and 1 year postoperatively. Full refraction, slit-lamp, and topographic examination (Corneal Analysis System for the first postoperative year and last follow-up with the Technomed C-Scan [Technomed GmbH, Baesweiler, Germany]) were performed at each visit.

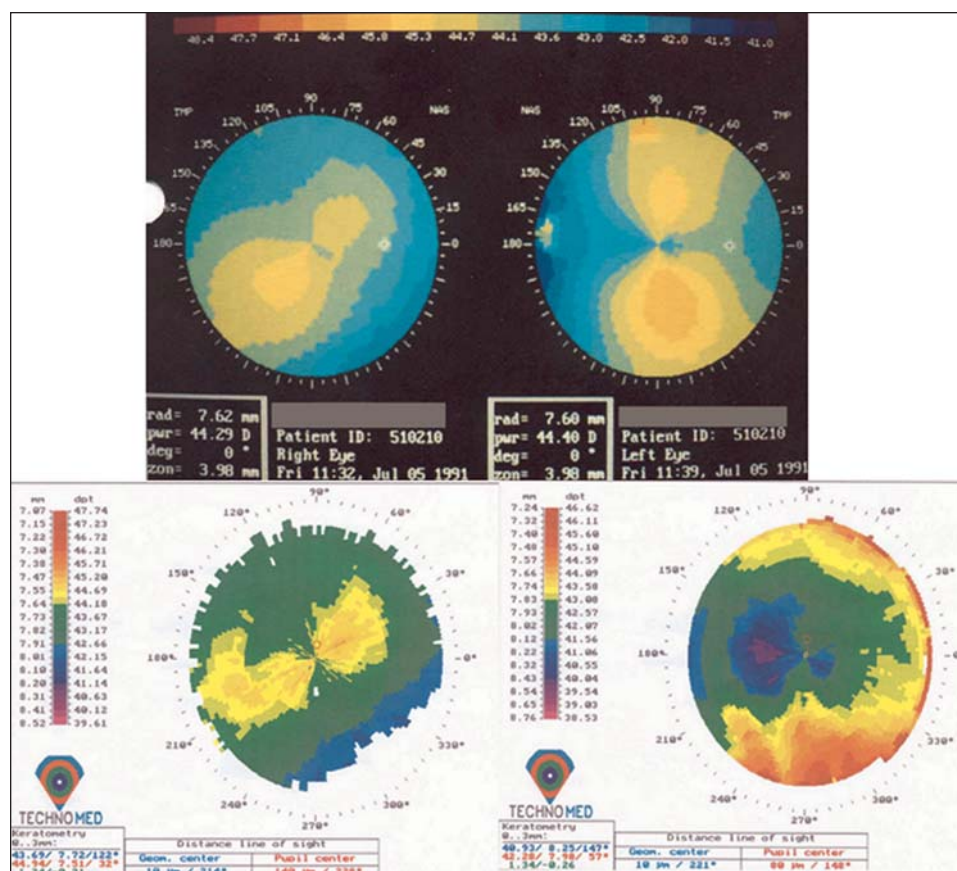


Figure 1. Topography showing preoperative (top left) right untreated eye, (top right) LASIK-treated left eye, and at last follow-up 15 years after LASIK, (bottom left) untreated right eye, and (bottom right) LASIK-treated left eye.

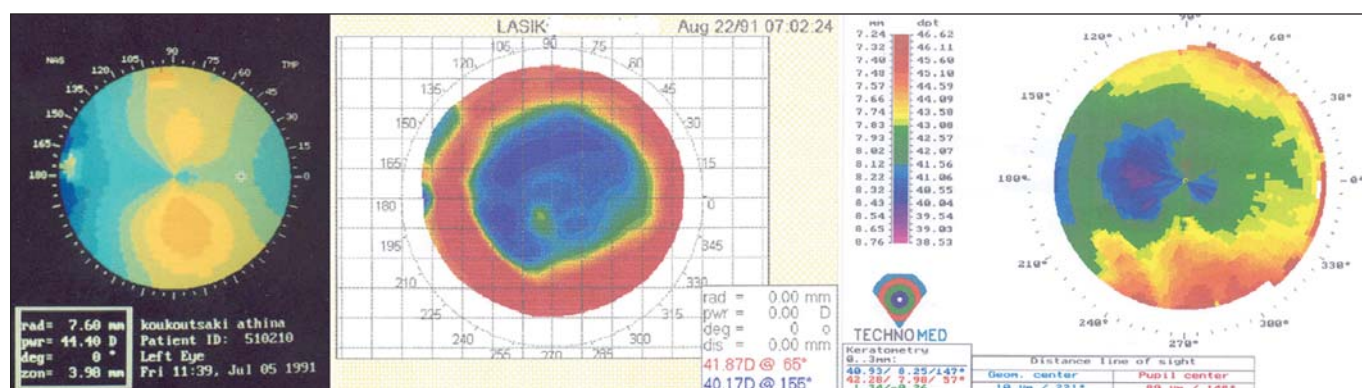


Figure 2. Topography shows (left) preoperative, (middle) 2 months postoperative and (right) last follow-up 15 years after LASIK.

RESULTS

Six months postoperatively, UCVA was counting fingers and BSCVA was 20/80 with $-3.75 -3.00 \times 020^\circ$ in the left eye. Manifest refraction, UCVA, BSCVA, and topographic findings were stable during the next 6 months. Fifteen years later, UCVA was counting fingers in both eyes. Best spectacle-corrected visual acuity was 20/32 with $-7.75 -1.50 \times 130^\circ$ in the right eye and 20/80 with $-4.25 -2.75 \times 010^\circ$ in the left eye, and topographic stability was observed (Figs 1 and 2).

Confocal microscopy analysis was performed with a modified confocal scanning laser ophthalmoscope

(HRT II Rostock Cornea Module; Heidelberg Engineering Inc, Vista, Calif). Qualitative evaluation of the images was performed with special attention directed at the subepithelial nerve plexus and flap interface. Corneal images revealed a normal epithelium with flat superficial cells, polygonal intermediate cells, and cylindrical basal cells. Images of the subbasal and subepithelial nerve plexus exhibited a regenerated nerve plexus that appeared normal with slightly increased tortuosity (Fig 3A). Keratocytes' bright nuclei against a dark background were observed just anterior to the flap interface (Fig 3B), whereas keratocyte activation,

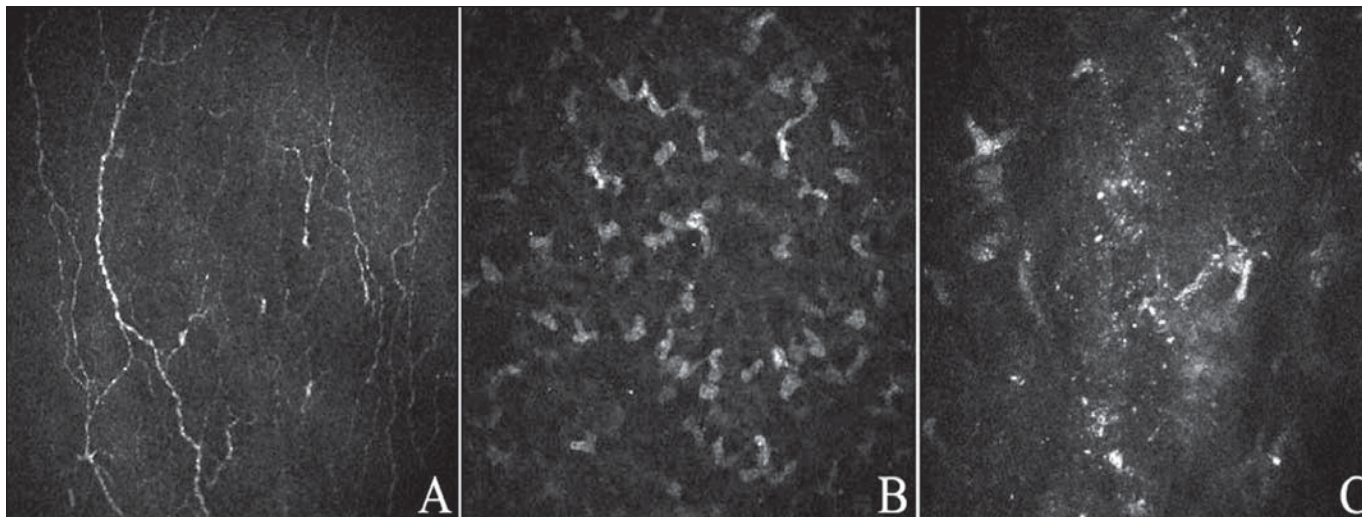


Figure 3. Confocal scanning laser microscopy images demonstrate **A**) regenerated subepithelial nerve plexus, **B**) anterior stroma with increased keratocyte density and activation, and **C**) increased scattering and highly reflective particles at the flap interface.

increased scattering, and highly reflective particles were observed at the flap interface (Fig 3C). Keratocyte density at the anterior flap seemed higher compared to the deeper stromal layers.

On a current overall satisfaction scale of 1 to 5, the patient was considered to be happy with the results (score of 4).

DISCUSSION

Fifteen years have passed since the first published case series of human eyes treated with LASIK,¹ although long-term follow-up studies of LASIK-treated eyes do not exceed observation over 6 years.⁵ During these years, an impressive improvement in microkeratome and excimer laser technology has led to significant decrease in intraoperative and early postoperative complications. Despite these improvements, long-term postoperative complications, with a major interest in the possible effects of such an invasive technique on ocular structures, has not yet been investigated.

In the present case report, long-term complications were not observed. Refractive and topographic stability were achieved 6 months after LASIK treatment. Previous long-term follow-up studies of myopic LASIK have shown moderate refractive predictability and stability in attempted higher corrections.⁵⁻⁷ Similarly, we found moderate predictability in the refractive outcome with a trend for refractive and topographic stability after the sixth postoperative month despite the large attempted correction (-10.00 D) and estimated residual corneal stroma (<300 μm). Furthermore, increased scattering and

presence of debris was observed at the flap interface even after 15 years.

Unexpectedly, the patient was satisfied with the final outcome despite considerable residual compound myopic astigmatism. We believe patients with high degrees of ametropia and amblyopia (such as the patient in the current study) are more receptive to such outcomes.

To our knowledge, this is the longest (15 years) LASIK follow-up case report in the literature. Late postoperative complications related to the surgery were not observed; conversely, refractive stability was observed after the sixth postoperative month.

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Bilateral Keratectasia After Photorefractive Keratectomy

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ABSTRACT

PURPOSE: To report the clinical features, management, and outcome of a patient who developed bilateral ectasia after photorefractive keratectomy (PRK).

METHODS: Case report of a 35-year-old man who underwent bilateral PRK. Preoperative uncorrected visual acuity was 20/200 in the right eye and 20/100 in the left eye. The patient's history was unremarkable and he denied a family history of ocular disorders.

RESULTS: Two weeks after surgery, the patient presented with loss of visual acuity in both eyes. Uncorrected visual acuity was 20/80 in the right eye and 20/200 in the left eye. Objective refraction could not be obtained. Slit-lamp microscopy showed corneal thinning in both eyes. After examining the patient's family, his sister was found to have clinical and topographic keratoconus.

CONCLUSIONS: Ectasia is a rare complication of PRK. We report the occurrence of bilateral ectasia after PRK in a patient with asymmetric bowtie topographies. We recommend that refractive surgery, even surface techniques such as PRK, be avoided in patients with a family history of keratoconus. [*J Refract Surg.* 2007;23:941-943.]

The first case of ectasia development after LASIK was reported in 1998, and it was not until after 2000 that a significant number of cases had been described.¹ Keratectasia after excimer laser is a potentially devastating complication with visual morbidity that, in some cases, requires penetrating keratoplasty.^{2,3} The etiology and biomechanical changes that induce keratectasia after refractive surgery are unknown.⁴ Possible risk factors for the development

of ectasia following excimer laser have been identified in the literature^{2,5,6} and include high myopia, reduced preoperative corneal thickness, reduced residual stromal bed after laser ablation, and asymmetrical corneal steepening (forme fruste keratoconus), but none of these characteristics definitively predict development of ectasia. Ectasia can develop in eyes with no identifiable risk factors.^{2,5,6}

Holland et al⁷ reported cases of ectasia after photorefractive keratectomy (PRK) due to retreatment or unrecognized keratoconus.

Malecaze et al⁸ recently reported a case of corneal ectasia after PRK in a patient with forme fruste keratoconus. Koch⁹ suggested that data be reported for patients who develop keratectasia after excimer laser; therefore, we report a patient who developed bilateral corneal ectasia after uneventful PRK with asymmetric bowtie topography and suspicion for forme fruste keratoconus in the right eye.

CASE REPORT

A 35-year-old man underwent refractive surgery in August 2005. He had not worn soft contact lenses for 4 months. Ocular history was unremarkable. Initially, he denied family history of ocular disorders, particularly keratoconus. Uncorrected visual acuity (UCVA) was 20/200 in the right eye and 20/100 in the left eye. Best spectacle-corrected visual acuity (BSCVA) was 20/20 with $-3.00 -1.50 \times 20$ in the right eye and $-3.00 -2.00 \times 160$ in the left eye. The patient's refraction was stable.

Preoperative central corneal thickness was 497 μm in the right eye and 511 μm in the left eye, and the peripheral corneal thickness was 626 μm and 647 μm , respectively. Central keratometry was 43.25/45.00 in the right eye and 43.25/45.50 in the left eye. Preoperative topography with the Orbscan II (Bausch & Lomb, Rochester, NY) is shown in Figures 1 and 2. The anterior elevation map shows 7.85 mm/43.00 diopters (D) with a differential of 0.014 in the right eye and 7.81 mm/43.20 D with a differential of 0.012 in the left eye. The posterior elevation map shows 6.15 mm/54.80 D with a differential of 0.021 mm in the right eye and 6.14 mm/54.90 D with a differential of 0.026 mm in the left eye. Because of asymmetry of the astigmatism, forme fruste keratoconus was suspicious, mostly in the right eye. No clinical signs of keratoconus were found on slit-lamp examination.

Bilateral PRK was performed uneventfully, removing 8.0-mm diameter of corneal epithelium with an excimer laser (Technolas 217; Bausch & Lomb) after 30 seconds of 30% alcohol exposure. The attempted correction was $-3.00 -1.50 \times 20$ in the right eye

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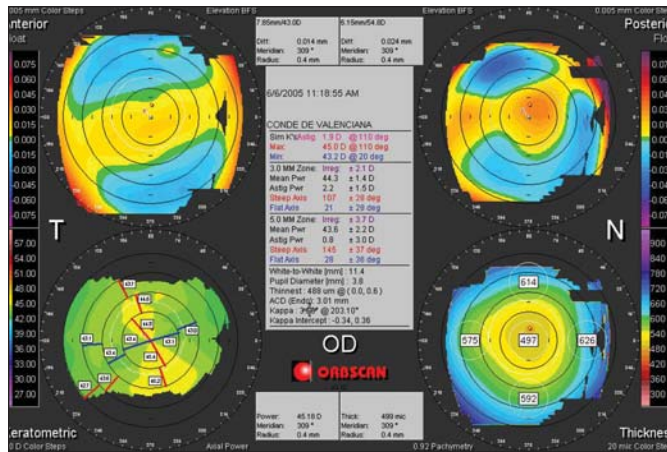


Figure 1. Preoperative topography of the right eye.

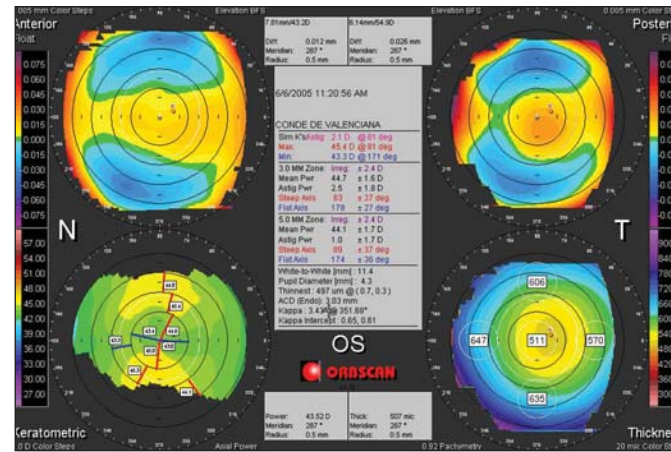


Figure 2. Preoperative topography of the left eye.

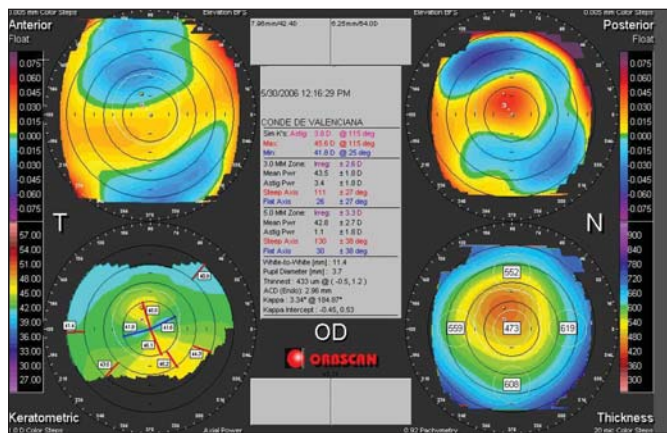


Figure 3. Topography of the right eye 9 months after photorefractive keratectomy.

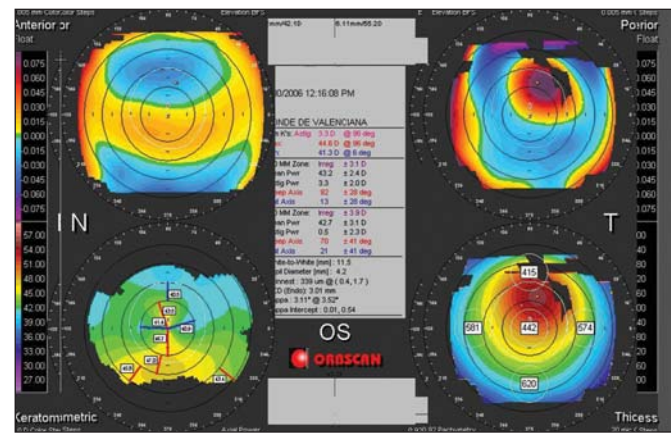


Figure 4. Topography of the left eye 9 months after photorefractive keratectomy.

and $-3.00 -2.00 \times 165$ in the left eye. The ablation zone diameter was 5.0 mm and 5.5 mm, respectively. The calculated total ablation depth was 67 μ m in the right eye and 70 μ m in the left eye. After 5 days, the epithelium was fully recovered and the soft contact lenses were removed. Uncorrected visual acuity was 20/50 bilaterally.

Two weeks after surgery, the patient experienced loss in visual acuity in both eyes. Uncorrected visual acuity was 20/80 in the right eye and 20/200 in the left eye. Objective refraction was impossible to obtain. Slit-lamp examination showed corneal thinning in both eyes. The patient was required to wear rigid contact lenses to achieve a final BSCVA of 20/25 in both eyes.

Six months after surgery, topographic findings were consistent with the diagnosis of corneal ectasia after PRK. Nine months after PRK, UCVA was 20/70 in the right eye and 20/80 in the left eye. We found a scissoring reflex on retinoscopy, corneal thinning, and mild prominent corneal nerves in both eyes. Both topographic and clinical findings (Figs 3 and 4) persisted

with the diagnosis of keratectasia in both eyes. Best spectacle-corrected visual acuity with rigid contact lenses was 20/20 bilaterally.

DISCUSSION

Corneal ectasia after PRK is extremely rare. In our case, the patient did not have tangible risk factors except for asymmetric bowtie topographies.

Ectasia after LASIK has been described to occur within weeks and up to 45 months after the primary surgery.¹⁰ Our patient presented only 2 weeks after surgery with findings consistent with ectasia. One possibility for ectasia-like findings is that the healing of corneal epithelium during the early postoperative period may result in an artificial and temporary hyperflattening of the corneal contour¹¹; unfortunately, we did confirm the diagnosis of ectasia after PRK in our patient.

Photorefractive keratectomy has proven to be a safe, simple, and effective procedure to correct low to moderate myopia, and with proper patient selection can be considered safer compared to other refractive proce-

dures.^{12,13} Alio et al¹² reported few complications after PRK in 3000 eyes. Over the past few years, mitomycin C treatments have gained popularity to reduce haze and allow greater surface ablations.^{14,15} Using our case as an example, refractive surgeons should be aware of the possibility of corneal ectasia occurrence in low myopia, low ablation, and with enough residual stromal bed after ablation even when a corneal flap is not performed.

After clinical ectasia presented in our patient, we further questioned him regarding other risk factors. He advised he was a habitual eye rubber in both eyes since childhood. As Comaish et al⁶ proposed, surgeons should be aware of the potential for development of progressive keratectasia after excimer laser in chronic eye rubbers.

Binder¹⁰ recommends investigating clinical or topographic evidence of keratoconus or forme fruste keratoconus in a family history before evaluating the ablation used. After the ectasia occurred, we examined the patient's family and found a sister with clinical and topographic keratoconus. Some surgeons avoid performing refractive surgery in patients with a family history of keratoconus. As proposed by Rabinowitz,¹⁶ we considered family history an important risk factor in the algorithm to prevent ectasia. Therefore, we recommend avoiding refractive surgery, even surface techniques such as PRK, in patients with a family history of keratoconus.

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