

Phakic IOLs Outside the United States

When do I implant these lenses?

By John So Min Chang, MD



Phakic IOLs are becoming more popular in Hong Kong due to the prevalence of high myopia among Hong Kong Chinese.¹ Thirty percent of my Chinese LASIK patients have -8.00 D or more of myopia. When choosing

between LASIK and phakic IOLs, I generally offer the latter if the patient has a manifest refraction spherical equivalent of -10.00 D or higher. Currently, I am using the Visian ICL (STAAR Surgical, Monrovia, CA) and the AcrySof Phakic IOL (Alcon Laboratories, Inc., Fort Worth, TX; not available in the United States) for patients with less than 1.50 D of astigmatism, which I can easily correct intraoperatively with limbal relaxing incisions. I offer the Visian TICL (STAAR Surgical Company; not available in the United States) to patients with higher amounts of astigmatism. I also use the Artisan/Verisyse phakic IOL (Ophtec BV, Groningen, The Netherlands/Abbott Medical Optics Inc., Santa Ana, CA) in a limited patient population (between -20.00 and -25.00 D).

LASIK VERSUS PHAKIC IOLS

I perform wavefront-optimized LASIK with the Allegretto Wave Eye-Q excimer laser system (WaveLight Laser Technologie AG, Erlangen, Germany; available in the United States from Alcon Laboratories, Inc.) and the Zyoptix Aspheric algorithm on the Technolas 217z (Technolas Perfect Vision GmbH, Munich, Germany; not available in the United States).

Assuming adequate corneal tissue and a pupil that is not overly large, I seldom hear complaints about halo and glare when patients' myopia is below -10.00 D, but they are the chief grievances for higher corrections. In Hong Kong, most people do not drive, so night vision is a lesser concern. I therefore sometimes will correct as much as -12.00 D of myopia in this population. For patients from mainland China and other countries who drive at night, however, I begin recommending a phakic IOL rather than LASIK if their level of myopia exceeds -10.00 D.

I tell all high myopes that studies have shown that the Visian ICL provides better vision than LASIK to eyes with moderate and high myopia^{2,3} (Figure 1). If these patients insist on undergoing LASIK, I perform the procedure on

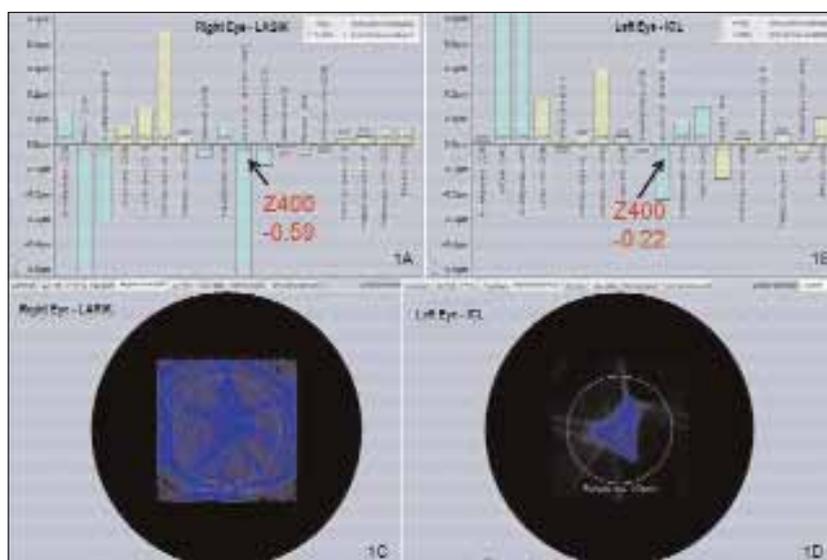


Figure 1. Postoperative higher-order aberrations (A and B) and point spread function (C and D) for a patient who underwent LASIK in his right eye and the implantation of a Visian ICL in his left eye. The amount of spherical aberration in the ICL eye was much lower than in the LASIK eye.

their nondominant eye first and ask them to test the vision in that eye at night. Those who are satisfied undergo LASIK on their dominant eye. Those who are not receive a phakic IOL in that eye.

CHOICE OF PHAKIC IOLS

The Visian ICL and TICL

Most high myopes have significant amounts of astigmatism as well. The Visian TICL is therefore my first choice among all of the phakic IOLs available in Hong Kong. The lens' high stability in the posterior chamber means that the refractive outcomes remain relatively unchanged after 1 week.⁴ With the Visian ICL and TICL, proper sizing is essential to attaining accurate refractive results and avoiding postoperative complications such as anterior subcapsular cataract. I therefore double-check the calculation to see if the size is marginal. If a 0.1-mm increase in the white-to-white measurement will result in a larger lens size, I will choose it. If I remain doubtful about the lens' size or concerned that the eye is too small, I will instead choose an AcrySof Phakic IOL.

AcrySof Phakic IOL

Although anterior chamber lenses always seem to give surgeons the impression of damage to the corneal endothelial cells, an ongoing multicenter study of the AcrySof Phakic IOL showed a slight reduction of 3.31% in central cell density 6 months after surgery. At 1, 2, and 3 years postoperatively, however, no further reduction in the mean, annualized, chronic loss in the central density of endothelial cells was reported (data on file with Alcon Laboratories, Inc.). This lens can correct myopia ranging from -6.00 to -16.00 D.

It is relatively easier to estimate the size for implantation of the AcrySof Phakic IOL than the Visian ICL, because the anterior chamber angle-to-angle diameter can be determined by anterior segment optical coherence tomography (OCT) (Visante OCT; Carl Zeiss Meditec AG, Jena, Germany). Although Alcon Laboratories, Inc., only requires a white-to-white measurement with the IOLMaster (Carl Zeiss Meditec AG) to calculate the lens' size, I believe that it is worthwhile to perform anterior

segment OCT as well.

Another advantage of the AcrySof Phakic IOL compared with a PCIOL is that the former requires no peripheral iridectomy. The lens can therefore be implanted in a single procedure. I find that the AcrySof Phakic IOL entails the shortest learning curve of all phakic lenses. Its disadvantage is the lack of a toric model, which the company may produce in the future.

Verisyse Phakic IOL

This iris-fixated phakic IOL is available on a rigid and a foldable platform. The rigid Verisyse lens is available in powers of up to -23.50 D (-14.50 D for the foldable version). I use the rigid lens for eyes with greater than 20.00 D of myopia, for which the Visian ICL and AcrySof Phakic IOLs are not available.

BIOPTICS

For the rare patient who is too myopic (≥ -25.00 D) or whose eyes are too small for the Visian ICL or AcrySof Phakic IOL, I rely on a bioptics approach to correct his or her residual astigmatism and myopia. I find that limbal relaxing incisions are reliable up to -2.00 D only. With a bioptics approach to correct astigmatism, I intentionally target myopia when placing the phakic lens in order to leave the eye with myopic astigmatism (eg, -3.00/+3.00 D or plano/-3.00 D). I find this method to be more accurate for correcting myopic versus hyperopic astigmatism.

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By Erik L. Mertens, MD, FEBO



My indications for phakic IOLs have changed significantly during the last couple of years with a shift toward lower myopia and hyperopia. I always use a phakic IOL to treat myopia of -8.00 D or more (provided the distance between the endothelium and the anterior surface of the crystalline lens is at least 2.8 mm) and hyperopia of

+4.00 D and higher. Phakic lenses are also my top choice in cases of dry eye disease; thin, flat (< 38.00 D), or steep (> 47.00 D) corneas; or suspected keratoconus. Moreover, I favor them for eyes at high risk of developing keratectasia. In recent years, I have also begun implanting the Visian ICL (STAAR Surgical Company, Monrovia, CA) in eyes that have no other option for refractive correction after previous refractive or cataract surgery. Four cases illustrate my practice and experience.

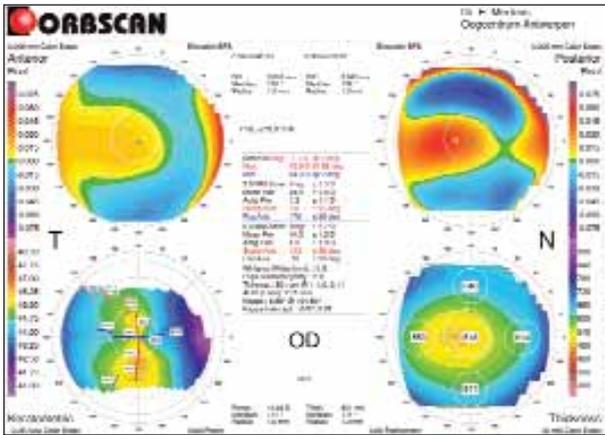


Figure 1. Asymmetric pattern in corneal astigmatism in the patient's right eye.

CASE No. 1

A good friend of mine with low myopia presented for a refractive surgery consultation. The refraction in her right eye was -3.25 -0.75 X 10 with a keratometry reading of 44.25/45.75 @ 82°. The refraction in her left eye was -3.25 -2.75 X 4 with a keratometry reading of 43.25/46.75 @ 92°. Pachymetry measured 501 μm OD and 510 μm OS.

At first glance, the patient appeared to be a perfect candidate for laser refractive surgery, but a closer evaluation of her corneal topography showed otherwise. Testing with the Orbscan Topographer (Bausch & Lomb, Rochester, NY) revealed asymmetric corneal astigmatism with a difference between her eyes of more than 1.00 D (Figures 1 and 2). Her corneas were therefore suspicious for forme fruste keratoconus and at high risk of developing keratectasia.

In 2004, I implanted a Visian ICL in the patient's right eye and a Visian TICL (STAAR Surgical Company; not available in the United States) in her left eye. At her last visit in late 2008, her UCVA measured 20/16 OD and 20/20 OS.

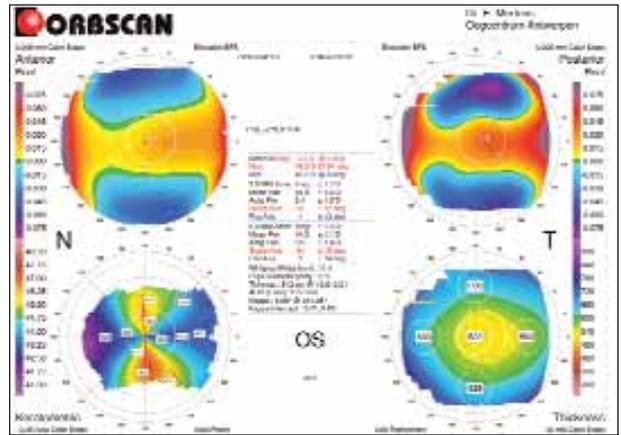
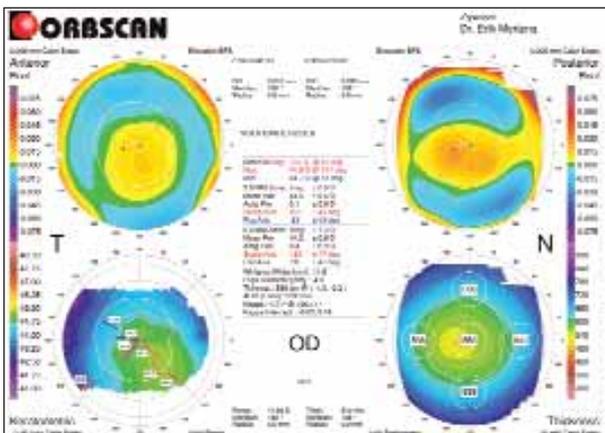


Figure 2. Orbscan topography of the patient's left eye shows a difference of more than 1.00 D in corneal astigmatism compared with her right eye.

CASE No. 2

A 22-year-old male presented with an increasing intolerance of his soft contact lenses. The refraction in his right eye was -6.75 -0.25 X 175 with a keratometry reading of 44.25/44.75 @ 90°. The refraction in his left eye was -6.50 -0.25 X 100 with a keratometry reading of 44.25/44.5 @ 82°. The mesopic pupil size was 7.0 mm bilaterally.

An evaluation of the anterior and posterior float on Orbscan topography showed no symmetry (Figures 3 and 4). The posterior elevation was 53.60 D OD and 54.00 D OS. In conjunction with the patient's dry eyes and large mesopic pupils, these measurements made me suspicious regarding the status of the corneas. In addition, the eyes also exhibited asymmetric astigmatism on the keratometric map (not corneal warpage because he had not worn his soft contact lenses for more than 3 weeks and no topographical changes had occurred in several consecutive months).

I decided to implant the Visian ICL bilaterally. Postoperatively, the patient attained a UCVA of 20/20 OU and a visual

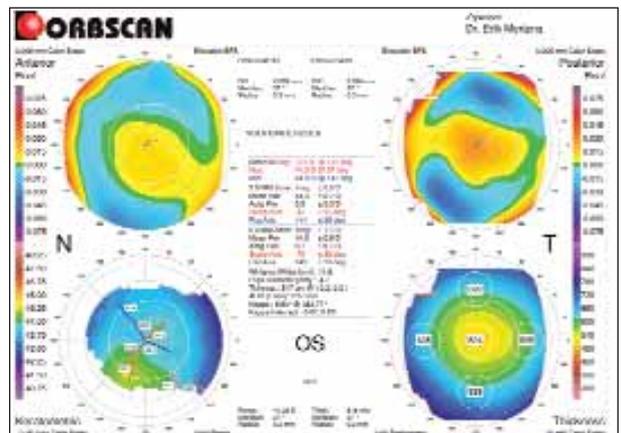


Figure 4. Keratometry of the patient's left eye shows a steep cornea inferiorly.

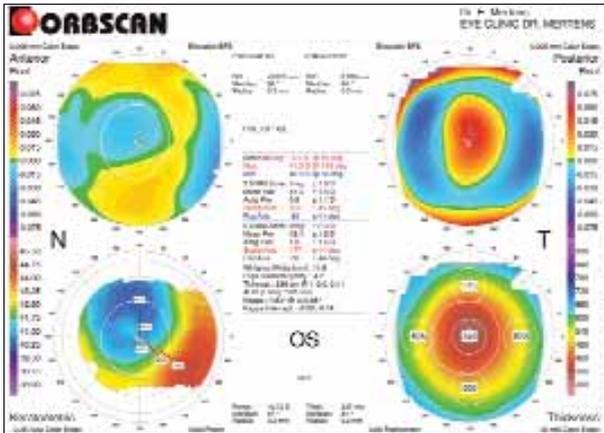


Figure 5. Very thin pachymetry reading due to prior laser refractive surgery.

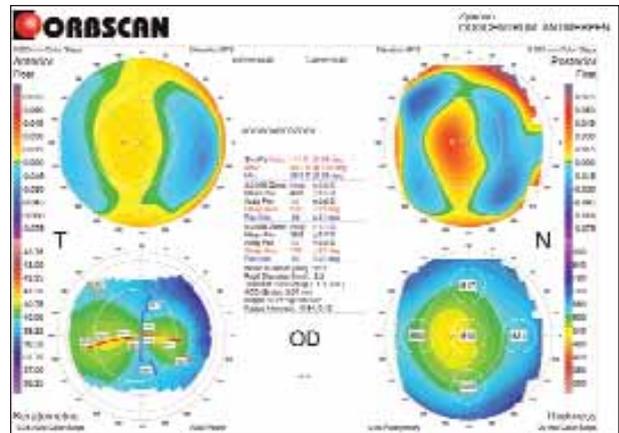


Figure 6. Clear against-the-rule astigmatism in the patient's right eye.

quality that provided him with clear night vision. Moreover, his eyes were no longer red, irritated, or dry.

CASE No. 3

A patient underwent several PRK surgeries in both eyes to treat myopia that initially measured -9.00 D. At the time of his presentation, the UCVA in his right eye was 20/32 with a significant compromise in the quality of his night vision. His left eye still had -1.50 D of myopia. Orbscan topography showed very thin corneas (Figure 5).

I implanted a -2.50 D Visian TICL (ICM120V4) in the patient's left eye in 2006. Two years later, his UCVA was 20/20.

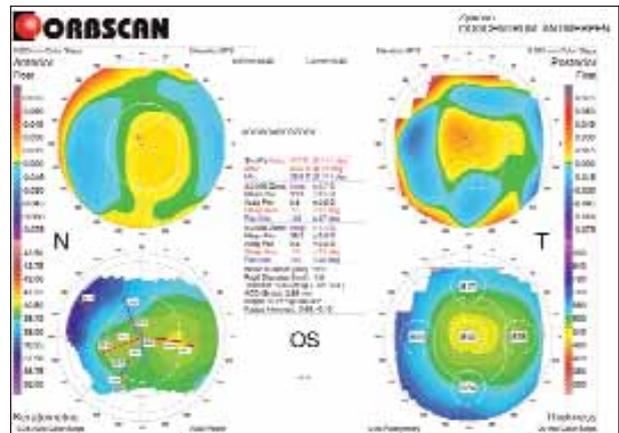


Figure 7. A small amount of corneal astigmatism is evident on the Orbscan map.

CASE No. 4

A 26-year-old male with a history of allergies presented for a refractive surgery evaluation. The refraction in his right eye was -4.50 -2.50 X 84 with a keratometry reading of 39.37/40.5 @ 173°. The refraction in his left eye was -4.5 -1.75 X 100 with a keratometry reading of 39.5/40.12 @ 13°. In mesopic lighting, his pupils measured 7.2 mm OD and 7.0 mm OS. Orbscan topography did not show any direct contraindications to refractive laser surgery (Figures 6 and 7).

I discussed with the patient the possibilities of LASIK, epi-LASIK, and the Visian TICL. Based on the flatness of his corneas and the difference between his corneal and refractive cylinder, my recommendation was the Visian TICL. I implanted the TICM125V4 in both of his eyes: -9.5 +3.0 X 174 OD and -8.5 +2.0 X 10 OS (Figure 8).



Figure 8. A slit-lamp photograph of an eye after implantation of the Visian TICL.

My cut-off for this IOL's implantation is a pupillary size of 7.5 mm for a correction of up to -8.00 D and 7.0 mm for corrections higher than -8.00 D.

CONCLUSION

The case examples presented herein illustrate a wide range of indications for phakic IOLs. Not every sur-

geon will agree with my approach. Based on my 17 years of experience with various phakic lenses and their growth to more than 25% of the refractive procedures performed in my practice, however, I am confi-

dent that the popularity of phakic IOLs will continue to rise.

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By Rudy M. M. A. Nuijts, MD, PhD, and M. Doors, MD



Iris-fixated phakic IOLs have been safely implanted since 1986 to correct myopia, hyperopia, and, later, astigmatism. These lenses provide stable and predictable visual results.¹⁻⁵ Briefly, the data on long-term safety showed a loss of more than two lines of BSCVA in only 0% to 2.6% of eyes.¹⁻⁵ Vision-threatening complications are rare (< 1%) with the current models of the Artisan/Verisyse (Ophtec BV, Groningen, The Netherlands/Abbott Medical Optics Inc., Santa Ana, CA) and Artiflex/Veriflex (Ophtec BV/Abbott Medical Optics Inc.; not available in the United States).³

The long-term effect of iris-fixated phakic IOLs on the corneal endothelium remains a point of discussion. The density of endothelial cells is known to decrease over time at a physiological rate of 0.6% per year in patients who are 18 years of age or older.⁶ Several short-term and a few recent longer-term studies have evaluated the loss of corneal endothelial cells after the Artisan's implantation, and they found an average rate of loss ranging from 0.7% to 11.7% over 3 years.^{1,7-13} Research has suggested that anterior chamber depths (measured from the epithelium) of at least 3.0 and 3.2 mm are an adequate safety measurement for implanting the Artisan and Artiflex IOLs, respectively.^{1,8,14} Other proposed criteria for maintaining a safe distance between the IOL and endothelium include a distance of 1.5 mm between the edge of the phakic lens and the endothelium¹⁵ and a distance of 2.0 mm between the center of the IOL and the endothelium.¹⁶ The importance of these measures was illustrated by Dr. Doors and colleagues.¹⁷ They reported that a shorter distance between the IOL's edge and the endothelium was associated with a higher loss of endothelial cellular density. This finding indicates the importance of yearly imaging of the anterior segment—as well as endothelial cell counts—among patients who have received phakic IOLs.

In our clinic, we use additional measures to ensure the safe and effective implantation of iris-fixated phakic IOLs. Patients must exhibit refractive stability for 2 years prior to receiving these lenses. Their pupillary size under mesopic lighting must be smaller than 7 mm for a 6-mm optic. Candidates must have no irregularities in their corneas, pupils, or irides and no history of glaucoma or of chronic or recurrent uveitis. Finally, a preoperative endo-

thelial cell count must demonstrate a density of at least 2,000 cells/mm².

Two case presentations will show how we are currently using iris-fixated phakic IOLs in our practice.

CASE No. 1. REFRACTIVE SURGERY

In 2008, a 42-year-old male presented for a refractive surgery consultation. His preoperative subjective refraction was -7.75 -1.25 X 30 OD and -8.00 -1.00 X 156 OS. Corneal topography was normal, and the central corneal thickness was 499 μ m OD and 504 μ m OS. Due to the patient's high refractive error and relatively thin corneas, we recommended the implantation of a phakic IOL. The preoperative endothelial cellular density was 2,384 and 2,352 cells/mm² in his right and left eyes, respectively. The patient consented to the procedure, and we implanted an Artiflex IOL with a spherical power of -9.00 D in both of the patient's eyes (Figure 1).

The Artiflex IOL has a convex-concave shape and a 6-mm optical zone. This three-piece lens consists of a flexible optic made of ultraviolet-absorbing silicone and two rigid haptics made of PMMA. The lens is available in dioptric powers of -2.00 to -14.50 (in increments of 0.50 D). This foldable IOL can be inserted through a smaller incision (3.2 mm) than the Artisan lens (5.2 or 6.2 mm, depending on the size of the optic).

Six months postoperatively, both of this patient's eyes had a UCVA of 20/20. Anterior segment optical coherence tomography showed adequate distances from the IOL to the endothelium and the crystalline lens in both of his eyes (Figure 2).



Figure 1. Slit-lamp photograph of an eye after the implantation of an Artiflex phakic IOL.



Figure 2. After the implantation of an Artiflex phakic IOL, anterior segment optical coherence tomography of the patient's left eye measured the distances from the IOL to the endothelium and to the crystalline lens.

CASE No. 2. AFTER PENETRATING KERATOPLASTY

Individuals with high astigmatism after penetrating keratoplasty (PKP) represent a special category of patients. In all such patients, the astigmatism has a regular and irregular component, but the former accounts for 82% of the total wavefront error.¹⁸ The iris-fixated Toric Artisan IOL (Ophtec BV; not available in the United States) treats the regular component. Manufactured by compression-molding technology, this single-piece PMMA lens has a convex-concave toric optic with a spherical anterior surface, a spherocylindrical posterior surface, and a 5-mm optical zone. The IOL is available in dioptric powers of -2.00 to -23.00 for myopia and +2.00 to +12.00 for hyperopia, with a cylindrical correction of 1.00 to 7.50 D.

A 72-year-old female underwent a triple procedure in her left eye (phacoemulsification, IOL surgery, and PKP) for Fuchs' endothelial dystrophy and cataract in 1998. In 2001, she presented to our clinic with a significant amount of corneal astigmatism, which could not be adequately corrected by glasses or contact lenses. Her BSCVA was 20/50 with a subjective refraction of -9.00 -6.00 X 165 (Figure 3). The endothelial cellular density measured 1,459 cells/mm² in her left eye.

This patient received a Toric Artisan lens with a spherical power of -8.50 D and a cylindrical correction of -5.50 D. The intended axis of enclavation was 165°. Six months after implantation (Figure 4), she presented with a UCVA of 20/40 and a BSCVA of 20/25 with a subjective refraction of plano -2.00 X 50. The actual axis of implantation was 158°, which might account for the slight undercorrection. The patient was very satisfied with the results. Her subjective satisfaction scores on a scale of 1 to 10 (with 1 really poor and 10 excellent) were 2 preoperatively versus 8 postoperatively. Eight years after receiving the phakic IOL, her cornea remained clear, and her BSCVA was 20/25 with a subjective refraction of -2.00 -2.50 X 130. The endothelial cell count had decreased to 589 cells/mm², which corresponded to a yearly loss of 7.5%.

The loss of endothelial cells does not stop after PKP

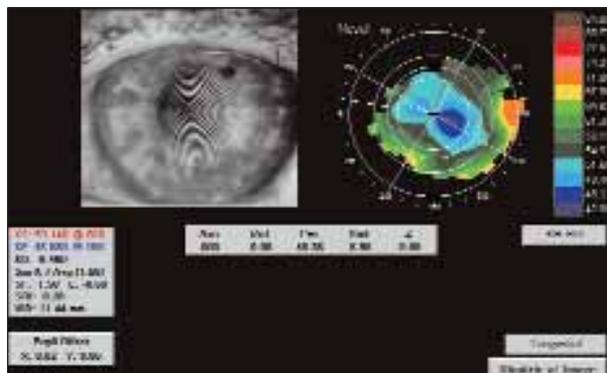


Figure 3. Preoperative topography of the patient's left eye 3 years after PKP.



Figure 4. This patient received a Toric Artisan phakic IOL 3 years after PKP.

and a phakic IOL's implantation.^{19,20} According to the Cornea Donor Study, the rate of loss is approximately 75% after 5 years, which may explain the ongoing decrease in endothelial cells after PKP. Cell counts of 600 cells/mm² 10 years after PKP are not unusual.^{21,22}

CONCLUSION

Anterior segment imaging and continued assessments of endothelial cell loss are crucial to guaranteeing the long-term safety of iris-fixated phakic IOLs. Certain groups of patients do not fit the usual inclusion criteria for these lenses, such as high astigmats who have undergone PKP and individuals with keratoconus. In our experience, iris-fixated phakic IOLs can produce highly satisfactory results in these patients and represent a viable treatment option. ■

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