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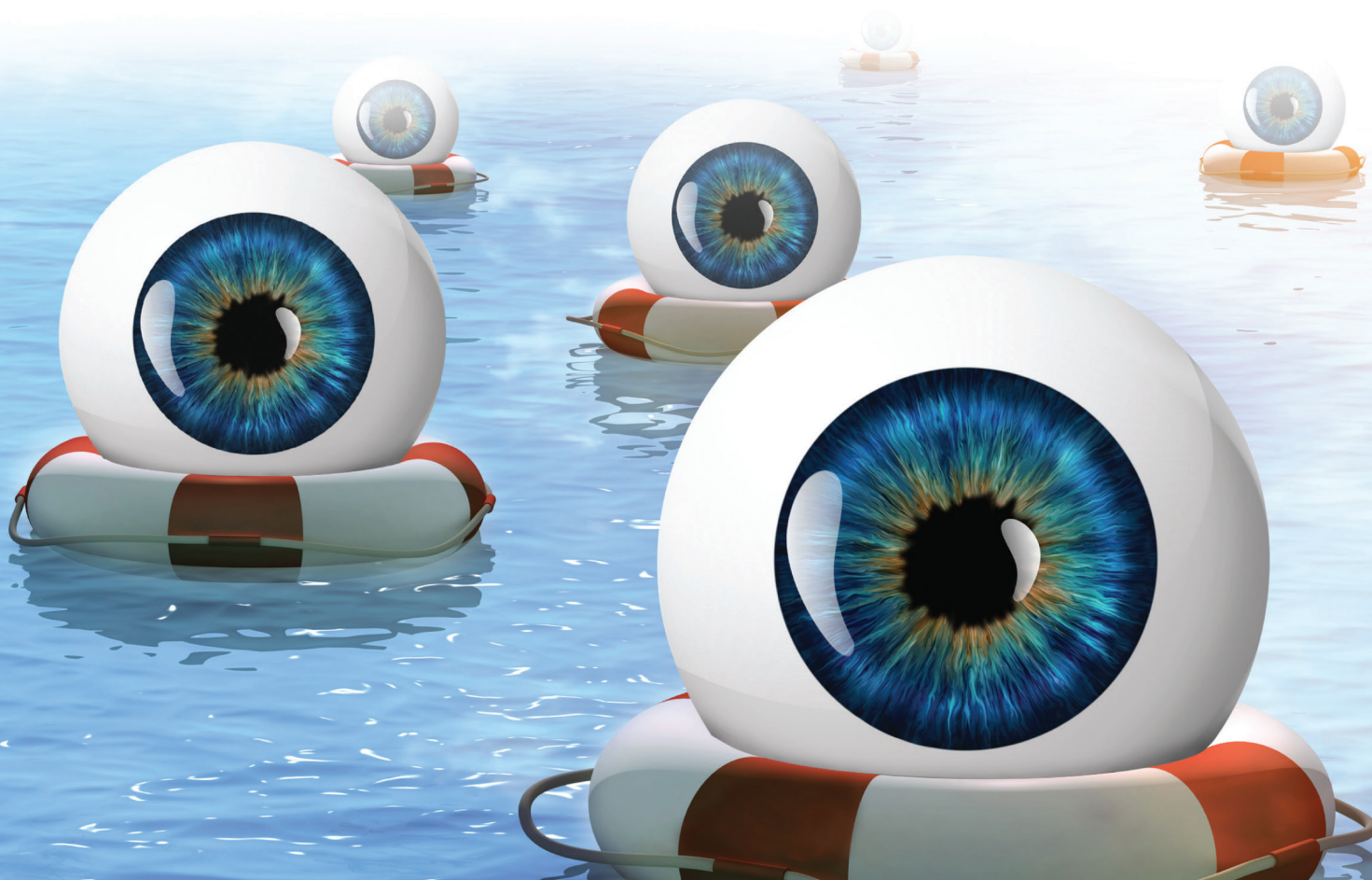
CRST EUROPE

Cataract & Refractive Surgery Today

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Preserving the Cornea for the Future



Highlights From the Visian ICL
Experts Meeting 2014

Why I Chose the Visian Phakic Posterior Chamber Lens for Myself

Any technology that is good enough for patients should be good enough for surgeons.

BY SHERIF EISSA, MD, FRCS

I have performed cataract and refractive surgery in Egypt for many years, but I have been a patient only once—when I decided to have the Visian Toric ICL (STAAR Surgical) implanted to correct my myopic astigmatism. The reasons for my decision and my experience are described in detail below.

Preoperatively, my refraction was -4.25 $-3.25 \times 15^\circ$ (BCVA 20/20⁻²) OD and -5.00 $-2.25 \times 175^\circ$ (BCVA 20/20⁻¹) OS. I had a moderate degree of myopia and astigmatism in both eyes, and my topography showed corneal steepening indicative of forme fruste keratoconus in my right eye (Figure 1A) more than in my left (Figure 1B).

MY CHOICES

Why didn't I choose surface ablation? If a patient came to me with this exact refraction and topography, I would recommend against corneal refractive surgery. Because of the safety, excellent predictability, and quality of vision with a posterior chamber phakic IOL compared with surface ablation, I quickly decided that it was the best treatment plan for me.

Why didn't I choose an anterior chamber phakic IOL? This type of phakic IOL was not an option, as I had stopped implanting these lenses in my own patients more than 5 years ago and was still explanting them in some eyes. Within the past 10 months, I had seen five cases of spontaneous disencapsulation of iris-fixated phakic IOLs, and, within 1 week, I explanted three more due to endothelial decompensation. (It is well known that phakic IOLs that use an iris fixation technique cause the most damage to the endothelium, with 8.3% at 4 years to 9% endothelial cell loss after 5 years.¹)

Regarding visual outcomes with a posterior chamber phakic IOL like the Visian ICL, excellent functional vision is highly likely.

Why did I choose the Visian ICL CentraFLOW (V4c) and not the V4b? This, too, was a simple decision: A laser iridectomy is no longer required with the CentraFLOW, thereby eliminating the pain associated with that procedure. Furthermore, aqueous flow is more natural and physiological with the CentraFLOW's KS-AquaPORT* technology, and there may be less risk for endothelial cell loss and cataract formation. The

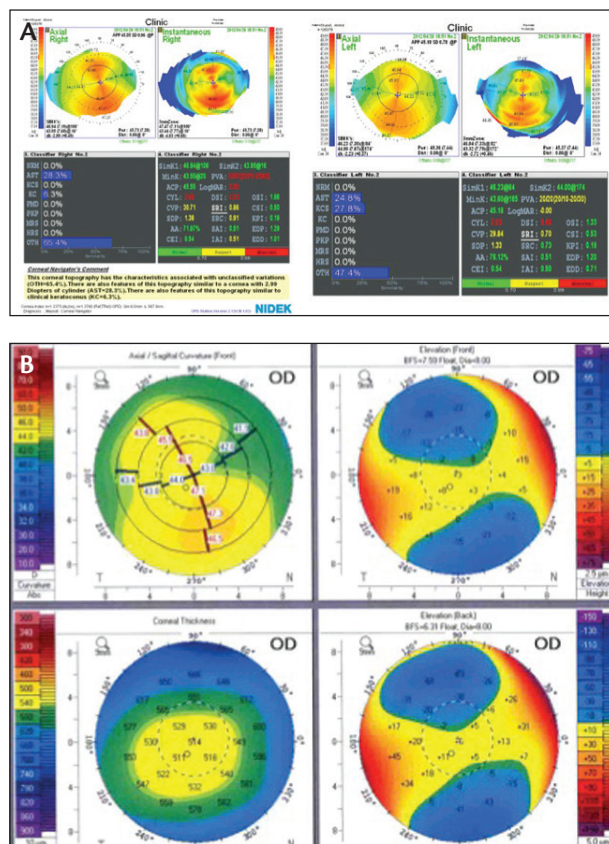
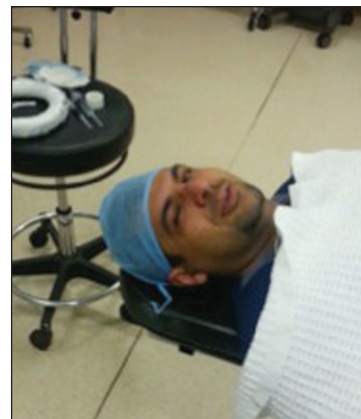


Figure 1. Preoperative topography showed corneal steepening indicative of forme fruste keratoconus in Dr. Eissa's right eye (A) more than in his left (B).

Visian ICL family has a proven track record and is made of biocompatible Collamer material, composed of collagen and copolymer material, that ensures biocompatibility with the eye.

Figure 2. Dr. Eissa being prepped for surgery.



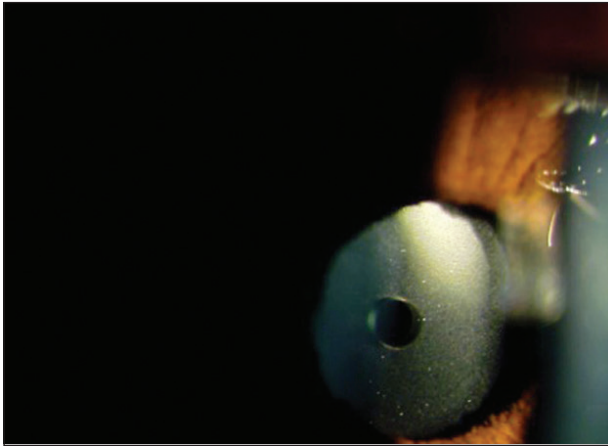


Figure 3. Postoperative day 1: The Visian ICL in situ.

SURGICAL EXPERIENCE

Surgery was scheduled for March 2014 (Figure 2). Although I had done the same procedure more than 300 times before—always coaching my patients that it only takes 2 minutes and is pain-free—I felt that sense of stress that my patients must feel. My blood pressure was displayed on the monitor: 175/115.

We started with my right eye; being under topical anesthesia, I was able to hear every single instruction given by the surgeon to the scrub nurse. After asking for the lens to implant, I heard the surgeon asking for MacPherson forceps, and I concluded that he quickly explanted, reloaded, and reimplanted it into the eye. This part of the procedure was not painful.

On the other hand, as I experienced, tucking the foot-plates of the Visian ICL behind the iris can be painful, and I now know to reassure patients during this step.

OUTCOMES

On postoperative day 1 (Figure 3), my subjective refraction was 20/20. At 6 months postoperative, my UCVA was 20/20, and my manifest refraction was +0.50 -0.50 X 27° OD and -0.50 -0.50 X 160° OS. Compared with my preoperative endothelial cell counts of 3,026 mm² OD and 3,087 mm² OS, at 6 months postoperatively they were 2,873 and 2,857 mm², respectively. The Pentacam (Oculus Optikgeräte) showed a vault of 610 μm (Figure 4).

Quality of vision has been excellent. The most important thing for me is night vision, and I am happy to say that I have had no significant issues with glare. My mesopic pupil diameter is 5.71 mm, and, unlike anterior chamber phakic IOLs, the larger optic size of Visian ICL, beside being closest to nodal point, is not sensitive to scotopic pupil size.

The only side effect that I have experienced is the presence of airy ring halos around the point source of light (Figure 5); however, it does not hinder vision and, as I now tell patients preoperatively, I assume it may be due to the diffractive effect of the KS-AquaPORT.

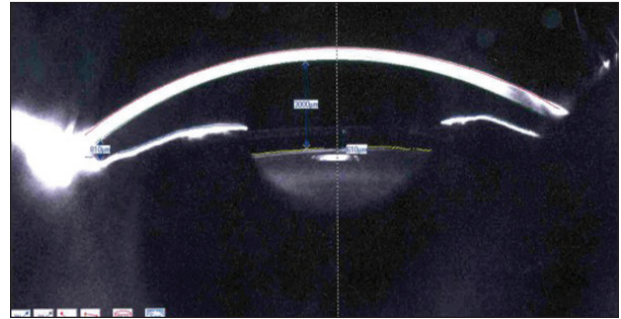


Figure 4. At 6 months postoperative, the ICL had a vault of 610 μm.



Figure 5. Airy ring halos around point sources of light may be caused by the diffractive effect of the KS-AquaPORT without hindering vision.

Because I had moderate dry eye preoperatively, I sporadically use artificial tears, especially if the weather is cold or I am working a long day in the operating room.

CONCLUSION

Now that I have the Visian ICL, I can relate to my patients and show them that I fully believe in this technology. As the Visian ICL continues to evolve and patients continue to ask about it, I can proudly say I have it implanted in my own eyes.

Like any patient, I took my decision to undergo refractive correction seriously. I know it was the right decision, because what is good enough for my patients should be good enough for me. ■

Sherif Eissa, MD, FRCS, is a corneal consultant at Magrabi Asser-KSA, in Saudi Arabia. Dr. Eissa states that he has no financial interest in the products or companies mentioned. He may be reached at drsjesus3@hotmail.com.



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**The KS-AquaPORT was named after and developed in cooperation with Kimiya Shimizu, MD, of Japan.*

Three-Year Results With the Visian CentraFLOW (V4c)

CentraFLOW technology represents one of the biggest advancements in refractive surgery in this decade.

BY JOSÉ F. ALFONSO, MD, PhD

In the past 12 years, my colleagues and I have implanted more than 3,500 Visian ICLs (STAAR Surgical). The evolution of the Visian technology is important, because various updates in design have helped us to reduce the surgical trauma we induce. Below is an overview of our experience with the Visian ICL, from our first introduction to the technology in 2002 to present day.

When we began using the Visian ICL V4, we relied on Orbscan topography (Bausch + Lomb) for size calculations and performed an Nd:YAG laser iridotomy 1 week before surgery. Four years later, we discovered that, for our practice, angle-to-angle measurement with the Visante OCT (Carl Zeiss Meditec) was the preferred approach. In 2010, the V4b, with an expanded diopter range, was introduced; at that time, we switched to performing an iridotomy at the end of ICL implantation.

The latest model, the Visian ICL CentraFLOW (V4c), is the most important evolution, as CentraFLOW technology has eliminated the need for an iridotomy altogether. We began using this technology in 2011 and have implanted more than 1,500 CentraFLOW ICLs to date.

PERSONAL PREFERENCES AND EXPERIENCE

Because we now have the ability to obtain more constant vault on postoperative day 1, we schedule second-eye surgery in the same week as the first eye. Therefore, ICL surgery, for us, is a 1-week procedure.

Regarding postoperative evaluation, we prefer optical coherence tomography (OCT) to Orbscan in the measurement of the anterior segment, as anterior chamber depth (ACD) and horizontal angle-to-angle are essential for not only ICL size calculations but also for postoperative vault control.

Taking into account our preference for OCT measurements, our general approach is to select the ICL that is equal to the angle-to-angle measurement plus 1 mm (Figure 1). When in doubt, ACD, lens power, and crystalline lens rise can aid in selecting the lens size.

We are currently conducting a study of the

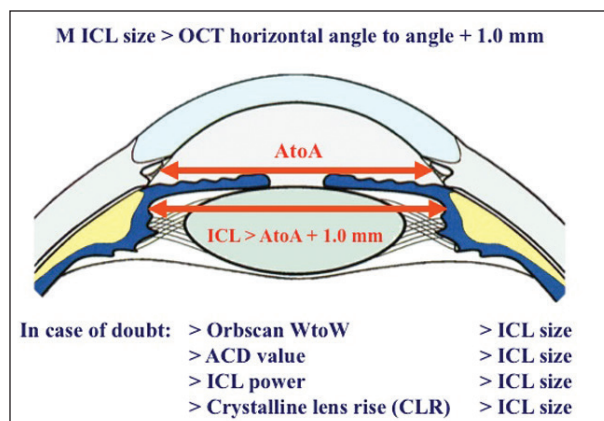


Figure 1. The author selects the ICL size that is equal to the angle-to-angle measurement plus 1 mm.

n=174	Sphere	Cylinder	K.Cyl	UDVA	DCVA
Preop	-8.10 ± 2.55 (-17.50 to -2.50)	-0.73 ± 0.64 (-2.50 to 0.00)	0.95 ± 0.56 (0.00 to 2.00)		0.96 ± 0.1 (0.4 to 1.0)
Postop	-0.09 ± 0.25 (-1.00 to +0.50)	-0.12 ± 0.27 (-1.25 to 0.00)	0.59 ± 0.43 (0.00 to 1.50)	0.94 ± 0.10 (0.5 to 1.0)	0.99 ± 0.05 (0.6 to 1.0)

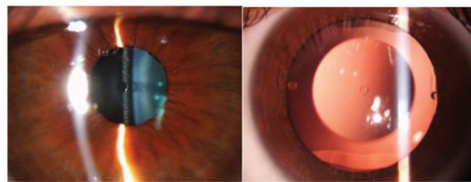


Figure 2. Preoperative measurements and 2-year postoperative results.

Visian ICL CentraFLOW in 174 eyes of 87 patients with myopia (see *Myopic ICL V4c Study*); follow-up at this time is 2 years. Based on the horizontal angle-to-angle measurements, the eyes in our study fell into four categories of ICL lens size: 12.1, 12.6, 13.2, and 13.7 mm; however, we avoided implantation of the 12.1-mm CentraFLOW to avoid the risk of a vault of 0. The most frequently implanted size was 13.2 mm, which was used in 61.5% of patients.

RESULTS

Preoperative measurements and 2-year postoperative results for the 174 eyes included in our study are

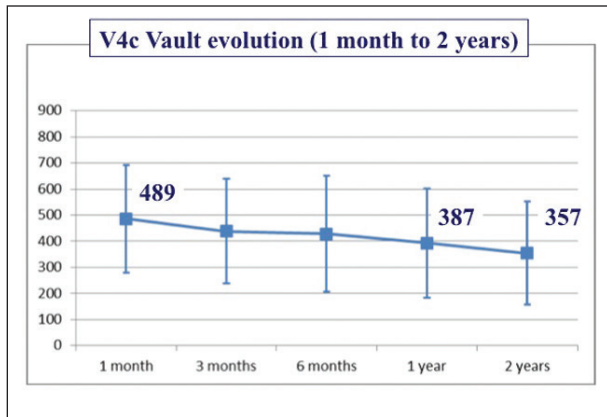


Figure 3. Decrease in vault: After 1-year postoperative, the vault had decreased by approximately 100 μm ; by the second year, it had decreased by another 30 μm .

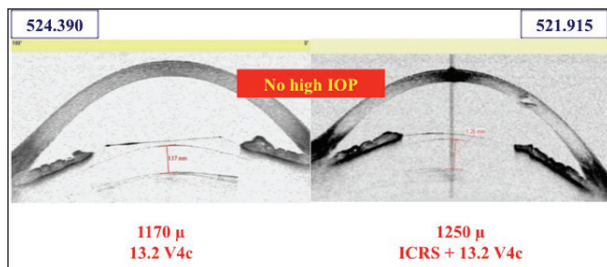


Figure 4. Higher vault is well tolerated with the V4c.

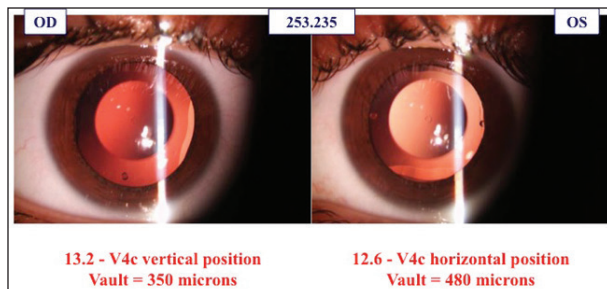


Figure 5. The Visian ICL CentraFLOW can be rotated from a horizontal into a vertical position.

found in Figure 2. Of particular note, emmetropia was achieved in most cases. Predictability was also excellent, with more than 95% of eyes within ± 0.50 D of intended correction. Regarding safety, all patients achieved the same or better distance BCVA than before surgery.

In the first month postoperatively, the mean vault value was 489 μm . The percentage of eyes with low and high vaults was 1% and 3%, respectively; however, at 2-year follow-up, the mean value decreased and the number of eyes with a vault of 0 had increased to 6%. If analyzed over a continuum, we can see that the vault decreases around 100 μm during the first year and

MYOPIC ICL V4c STUDY

Myopic ICL V4c Study / 2014-09

Selection criteria: Myopic ICL / Bilateral surgery
At least two years follow-up
No ocular pathology associated

174 eyes of 87 patients
64 females and 23 males
Mean age: 30.0 ± 4.7 (20 to 40) years

Mean preop. pachymetry:	534 ± 38	(441 to 630)
Mean preop. ACD:	3.31 ± 0.26	(2.80 to 3.98)
Mean preop. A-A:	12.01 ± 0.43	(11.09 to 13.41)

Mean preop. photopic pupil:	4.7 ± 1.0	(2.0 to 7.0)
Mean preop. mesopic pupil:	6.5 ± 0.9	(5.0 to 9.0)

Mean preop. IOP:	13.1 ± 1.9	(10 to 18)
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another 30 μm in the second (Figure 3). No cataracts have been observed in these 174 eyes.

In terms of endothelial cell loss, the V4c values are 0.7% at 1 year postoperative and 1.5% at 2 years, which is within physiological limits.

ADVANTAGES OF THE CENTRAFLOW TECHNOLOGY

Higher vaults are well tolerated with the V4c and do not cause IOP complications (Figure 4). This is because the continuous flow of aqueous humor through the hole avoids angle closure. This feature also gives us more time to exchange the ICL, in the rare event it is indicated.

The second advantage is that, because we no longer have to perform an iridectomy, we can rotate the Visian ICL CentraFLOW into a vertical position. This is especially useful in patients who have high vault of the ICL (Figure 5). We have performed this procedure in only 0.6% of cases. Logically, rotation is not possible with toric Visian ICL lenses.

CONCLUSION

In our experience, the Visian ICL CentraFLOW fulfills the classic requirements of refractive surgery, especially regarding safety. We believe that the epicapsular design of the Visian ICL with CentraFLOW technology represents one of the biggest advances in refractive surgery in this decade. ■

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Optical Quality After Visian ICL CentraFLOW (V4c) Implantation

Even when the lens is decentered postoperatively, vision can be excellent.

BY SANG YOUP HAN, MD

With today's modern premium IOLs, centration is key. If the lens is not perfectly centered over the pupil, the patient can have a poor refractive result that sometimes may require explantation. We recently set out to see if the same issue—centration—is as important with the latest in the line of Visian ICLs, the CentraFLOW (STAAR Surgical). This model's central port, KS-AquaPORT, is designed to facilitate fluid flow and eliminate the need for an iridotomy.

In an attempt to evaluate our clinical outcomes with the CentraFLOW ICL, we compared patients' optical qualities according to the degree of decentration of the Visian ICL and also evaluated postoperative UCVA and BCVA, distance visual acuity, refractive error, IOP, central vault, and adverse events. A total of 94 eyes of 48 patients were included; mean age was 25.6 ± 6.7 years and the mean preoperative spherical equivalent (SE) was -8.58 ± 2.08 D.

To determine the optical quality in the presence of decentration of the CentraFLOW ICL, we defined the degrees of decentration according to how far the KS-AquaPORT of the Visian ICL was decentered from the pupil center. Patients were broken into three groups: those in which the lens was decentered by 1 hole diameter ($n=46$), those in which the lens was decentered by more than 1 but less than 2 hole diameters ($n=42$), and those in which the lens was decentered by more than 2 but less than 3 hole diameters ($n=6$; Figure 1).

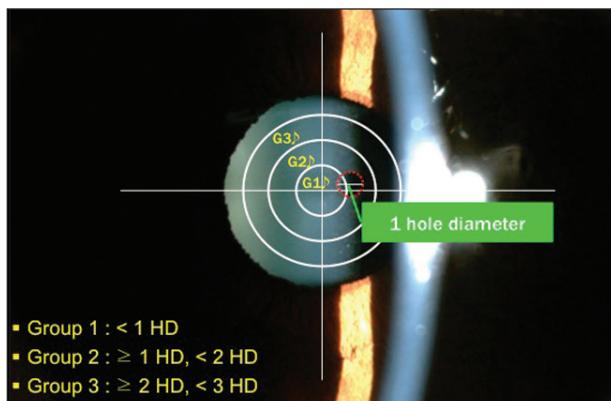


Figure 1. Eyes were broken into three groups according to how far the KS-AquaPORT of the Visian ICL was decentered from the pupil center.

RESULTS

When looking at the entire patient population, the average SE was 0.34, 0.30, and 0.27 D, at postoperative week 1 and months 1 and 2, respectively (paired t-test; $P=.00$). UCVA at these same time points was 1.03, 1.07, and 1.06, respectively (paired t-test), with an efficacy index of 1.07 (ratio of postoperative distance UCVA to preoperative distance BCVA) and a safety index of 1.08 (ratio of post- to preoperative distance BCVA).

Regarding the entire patient population, IOP decreased from 14.42 mm Hg preoperatively to 13.31 mm Hg at 3 months postoperatively. This confirms the central port in the Visian ICL is functioning as expected. The mean postoperative vault of the Visian ICL CentraFLOW was 631 ± 239.2 μ m (Figure 2).

When postoperative results were analyzed in each of the three groups, we found that UCVA (Figure 3), SE (Figure 4), IOP, optical quality (Figure 5), and higher-order aberrations (HOAs; Figure 6) were similar regardless of the centration of the Visian ICL. The

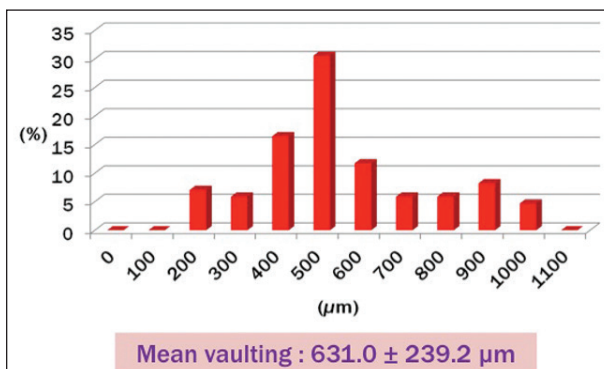


Figure 2. Mean postoperative vault at 3 months postoperatively.

	Group 1	Group 2	Group 3	p-value
1 wk	1.03 \pm 0.16	1.04 \pm 0.12	1.00 \pm 0.14	0.83
1 mo	1.02 \pm 0.14	1.11 \pm 0.18	1.08 \pm 0.20	0.06
3 mo	1.02 \pm 0.13	1.09 \pm 0.18	1.08 \pm 0.20	0.09

* UCVA : Uncorrected visual acuity

One way ANOVA

• Group 1 : within 1 hole diameter
 • Group 2 : within 2 hole diameter
 • Group 3 : within 3 hole diameter

Figure 3. Postoperative UCVA.

	Group 1	Group 2	Group 3	p-value
1 wk	0.28±0.24	0.38±0.21	0.50±0.40	0.12
1 mo	0.24±0.27	0.35±0.16	0.38±0.29	0.08
3 mo	0.21±0.27	0.32±0.19	0.38±0.29	0.06
* SE : spherical equivalent One way ANOVA ■ Group 1 : within 1 hole diameter ■ Group 2 : within 2 hole diameter ■ Group 3 : within 3 hole diameter				

Figure 4. Postoperative spherical equivalent.

RMS* (μm)	V4 ICL	Group 1	Group 2	Group 3	p-value	Reference*
Total HOA†	0.18±0.08	0.13±0.05	0.18±0.10	0.16±0.05	0.02	0.32
Coma	0.10±0.07	0.07±0.05	0.00±0.07	0.09±0.05	0.13	0.18
Trefoil	0.13±0.08	0.08±0.05	0.13±0.10	0.10±0.03	0.03	
Spherical aberration	0.01±0.03	0.02±0.03	0.02±0.04	0.02±0.03	0.98	0.09
* RMS : Root mean square † HOA : Higher order aberration One way ANOVA ■ Group 1 : within 1 hole diameter ■ Group 2 : within 2 hole diameter ■ Group 3 : within 3 hole diameter Reference* : J Cataract Refract surg 2013;39:242-9						

Figure 6. Postoperative higher-order aberrations.

CentraFLOW group illustrated equal or lower HOA values compared to the previous V4 version with no central port. One difference between groups, however, was the level of vault: Patients in group 3 experienced the most vault ($752.6 \pm 327.5 \mu\text{m}$), and patients in group 2

	Group 1	Group 2	Group 3	p-value
OSI*	0.82±0.56	0.94±0.76	1.07±1.17	0.57
MTF† cut off	33.42±9.20	34.13±9.51	32.74±11.94	0.91
Strehl ratio	0.19±0.06	0.18±0.05	0.19±0.07	0.61
* OSI : Ocular scatter index † MTF : Modulation transfer function One way ANOVA ■ Group 1 : within 1 hole diameter ■ Group 2 : within 2 hole diameter ■ Group 3 : within 3 hole diameter				

Figure 5. Postoperative optical quality.

experienced the least ($585.9 \pm 207.7 \mu\text{m}$); in group 1, the average vault was $657.4 \pm 251.9 \mu\text{m}$.

CONCLUSION

Implantation of the Visian ICL CentraFLOW with the KS-AquaPORT was effective and safe for the correction of myopia and provided stable IOP outcomes, without the need for iridotomy. Additionally, good visual acuity was achieved, regardless of the level of ICL decentration. ■

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Dry Eye and Laser Vision Correction

Who is at risk for moderate to severe dry eye after LASIK?

BY KIMIYA SHIMIZU, MD

I first studied the effects of LASIK in 1997, after I had noticed patients struggling with flap-related troubles including infections, diffuse lamellar keratitis, epithelial ingrowth, irregular astigmatism, and, most commonly, dry eye. I subsequently stopped doing LASIK in 2008 because these complications were not only problematic right after surgery, but they continued for a long time afterward.

THE EFFECTS

The most overwhelming side effect of LASIK for patients' everyday activities is dry eye. Common symptoms of dry eye include irritated, gritty, scratchy, or burning eyes; foreign body sensation; excess watering; and blurred vision. Patients who suffer from this condition

have either an insufficient amount or a poor quality of tears to lubricate and nourish the ocular surface. Dry eye can also affect visual quality. Although common and often chronic in older adults, dry eye is also seen in the younger population, especially in those who use computers, tablets, and smartphones extensively. The effects of dry eye are compounded in patients who undergo LASIK, and oftentimes laser vision correction is contraindicated in those with a history of the disease.

Let's look at a typical example: A 25-year-old woman opted for LASIK about 5 years ago. Preoperatively, her Schirmer test, tear breakup time (TBUT), and fluorescein score were indicative of dry eye; however, she underwent LASIK treatment any-

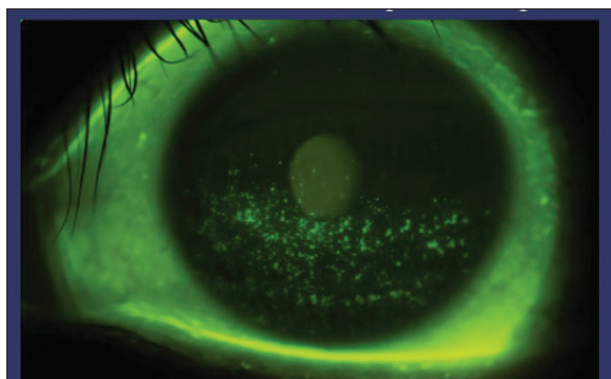


Figure 1. The patient's TBUT was 2 seconds and her Schirmer test score was 3 mm.

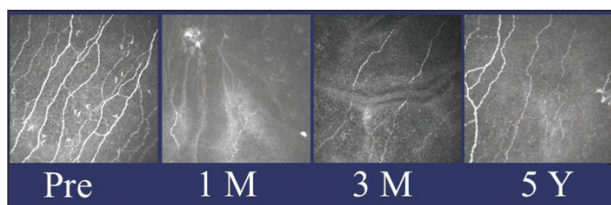


Figure 3. Subbasal nerve damage after LASIK: The presence of dry eye due to the cutting of the trigeminal nerve is noted on confocal microscopy at 1 and 3 months and 5 years.

way. Five years after surgery, the patient's TBUT was 2 seconds, and her Schirmer test showed a score of 3 mm (Figure 1).

Results are similar across different LASIK populations. For instance, we showed that 18% of patients required the use of eye drops preoperatively, compared with 78% at 5 years after LASIK (personal data). We also showed that the average TBUT fell from 9.1 seconds preoperatively to 4.2 seconds at 5 years postoperatively. Using the NEI-RQL patient questionnaire, patients' symptoms of dryness decreased from an average of 89.7 preoperatively to an average of 81.7 at 5 years postoperatively.¹

THE CAUSE

What causes this post-LASIK tear dysfunction? According to several published studies,²⁻⁷ flap creation can trigger a loss of goblet cells, ocular inflammation, and subbasal nerve damage (Figures 2 and 3). With LASIK, the main cause of dry eye is the latter. Between 3% and 59% of patients will report some level of dry eye after LASIK,^{8,9} with decreased tear production and increased neurotrophic effects of the epithelium.¹⁰

We have also studied the change in subbasal nerve density after LASIK, noting a decrease of 60% after just 1 year, and found that LASIK affected the ocular surface and damaged corneal subbasal nerves, triggering dry eye symptoms.

COMPARATIVE STUDY OF LASIK VS ICL

During a comparative study between the results of LASIK versus those after implantation of the Visian ICL (STAAR

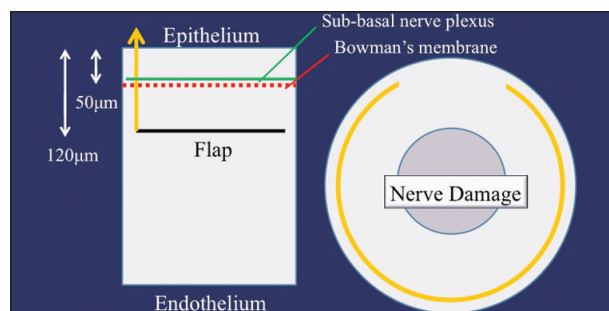


Figure 2. Nerve damage due to the flap-making process.

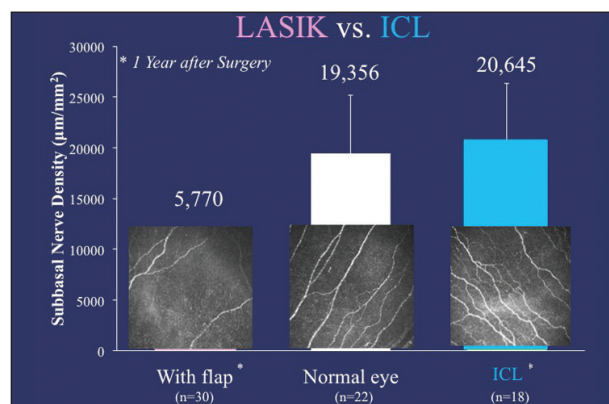


Figure 4. Subbasal nerve density had decreased by 60% in the LASIK group but remained the same in the ICL group.

Surgical), we noted that, 1 year after surgery, subbasal nerve density decreased by 60% in the LASIK group (n=30) but, in the ICL group (n=18), remained the same (Figure 4). Additionally, TBUT did not change in the ICL group.

In this same study, about 80% of LASIK patients needed eye drops, compared with approximately 20% of ICL patients.

For these reasons, we decided to completely cease the performance of LASIK in favor of Visian ICL implantation. ■

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