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Highlights From the EVO VISIAN ICL EXPERTS SUMMIT 2017

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EVO Visian ICL: Medium- and Long-Term Results

Clincal efficacy, predictability, and safety with this lens are strong.

BY JOSÉ F. ALFONSO, MD, PHD

We have had a long road of success with the Visian ICL (STAAR Surgical). Starting our journey with this lens in 2002, we have continued to increase our surgical volume year over year, and this has paralleled many refinements in the procedure and in the technology itself. The latest models, the EVO and EVO+ Visian ICL, have a hole in the center of the optic, which has eliminated the need to perform a peripheral iridotomy. The addition of this KS-AquaPort* has been a tremendous boost in the efficiency of the procedure. In this article, I discuss the medium- and long-term follow-up with this lens and review the clinical efficacy, predictability, and safety.

BACKGROUND

At the Instituto Universitario Fernández-Vega, we offer patients several forms of refractive surgical correction, including clear lens extraction with multifocal and monofocal IOLs, PRK, femtosecond LASIK, and implantation of the EVO family of Visian ICLs. In our experience, it is best to tailor the procedure to the individual needs of our patients,

TABLE 1. EVO VISIAN ICL FOR MYOPIA: PREOPERATIVE DATA

	Mean	Range
Corneal thickness (µm)	534 ±33	441–660
Anterior chamber depth (mm)	3.32 ±0.26	2.80–3.91
Horizontal angle-to-angle (mm)	12.01 ±0.43	11.01–13.45
Photopic pupil (mm)	4.8 ±0.9	2.5–6.5
Mesopic pupil (mm)	6.7 ±0.9	4.5–8.5
IOP (mm Hg)	13.1 ±1.9	10–18

TABLE 2. EFFICACY AND SAFETY						
N = 186	Preoperative	1 month	3 months	1 year	2 years	3 years
UDVA		0.93 ±0.14 (0.40 to 1.00)	0.92 ±0.14 (0.40 to 1.00)	0.93 ±0.14 (0.40 to 1.00)	0.88 ±0.17 (0.40 to 1.00)	0.85 ±0.20 (0.40 to 1.00)
Sphere (D)	-7.95 ±2.91 (-17.50 to -2.50)	-0.10 ±0.31 (-2.00 to 0.50)	-0.11 ±0.32 (-2.00 to 0.50)	-0.12 ±0.32 (-2.00 to 0.50)	-0.22 ±0.37 (-2.00 to 0.50)	-0.29 ±0.41 (-2.00 to 0.50)
Cylinder (D)	-0.71 ±0.63 (-2.00 to +0.00)	-0.17 ±0.35 (-1.50 to 0.00)	-0.18 ± 0.35 (-1.50 to 0.00)	-0.17 ±0.35 (-1.50 to 0.00)	-0.15 ±0.32 (-1.50 to 0.00)	-0.16 ±0.32 (-1.50 to 0.00)
DCVA	0.95 ±0.13 (0.30 to +1.00)	0.97 ± 0.08 (0.50 to 1.00)	0.97 ±0.09 (0.50 to 1.00)	0.98 ±0.10 (0.50 to 1.00)	0.97 ±0.08 (0.50 to 1.00)	0.97 ±0.09 (0.50 to 1.00)
Efficacy		0.98	0.97	0.98	0.93	0.89
Safety		1.02	1.02	1.03	1.02	1.02

which, in many cases, ends up being the EVO Visian ICL. We have found that the sweet spot for the EVO Visian ICL can include patients under the age of 50 years with refractions ranging from 5.00 to -20.00 D. The key to ensuring safety with the procedure comes down mainly to three components: patient selection, selection of the proper ICL size, and lens vault evaluation and management.

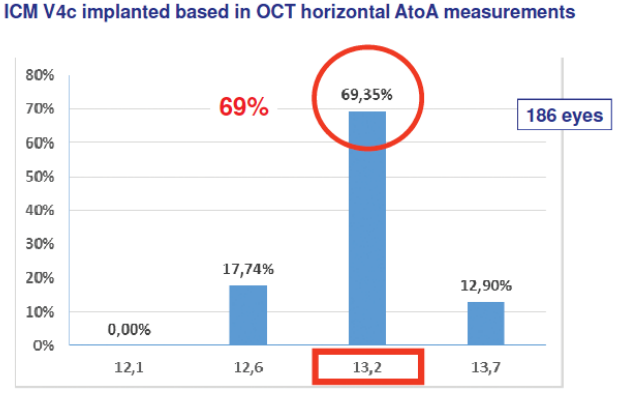

Figure 1. Sizes of the EVO Visian ICL implanted in the study.

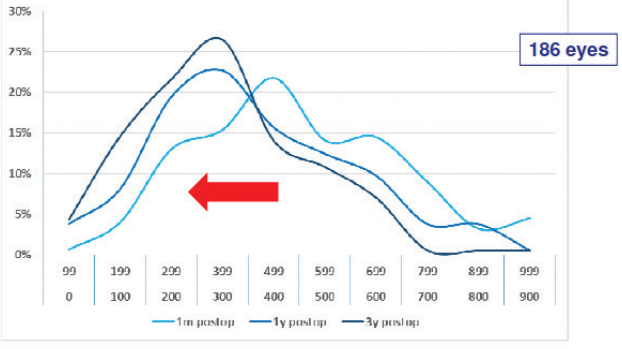

Figure 2. Evolution of vault from 1 month to 3 years postoperative.

Patient selection. The patient's ocular anatomy must safely support a phakic IOL. In short, the rules of thumb that we use include the following:

- Anterior chamber depth 3 mm or greater;
- Iridocorneal angle above grade 3;
- Crystalline lens rise below 500 µm;
- Angle-to-angle greater than 11 mm; and
- Pupillary diameter greater than 9 mm.

ICL size selection. Once an eye is deemed safe for phakic IOL implantation, the next step is to select the proper size of the implant. In our practice, this should be equivalent to the following: *ICL size = OCT horizontal angle-to-angle +1.0 mm.* In case of doubt, the larger the white-to-white, anterior chamber depth, or crystalline lens rise, the larger the ICL size.

Lens vault evaluation and management. When implanting the phakic IOL, follow these general rules: the larger the ICL size, the greater the vault and the larger the ICL power, the greater the vault.

STUDY DESIGN

In 2017, we decided to review data from 186 myopic eyes that received the EVO Visian ICL at our practice and had at least 3 years' follow-up. In total, 93 patients (63 women and 30 men) with a mean age of 30.4 ±5.4 years (range, 20†–45 years) were included in the study. Preoperative data can be found in Table 1.

Using the safety criteria described above, we selected the size of the EVO Visian ICL according to the OCT horizontal angle-to-angle measurements in each eye. In the majority of eyes (69.35%), a 13.2-mm EVO Visian ICL was implanted (Figure 1). Regardless of ICL size, we used the following surgical protocol:

- Day 1: Surgery on the first eye;
- Day 2: OCT of the first eye;
- Day 3: OCT of the first eye and surgery on the second eye;
- Day 4: OCT of the second eye; and
- Day 5: Standard exploration OCT of both eyes and database update by the optometrist.

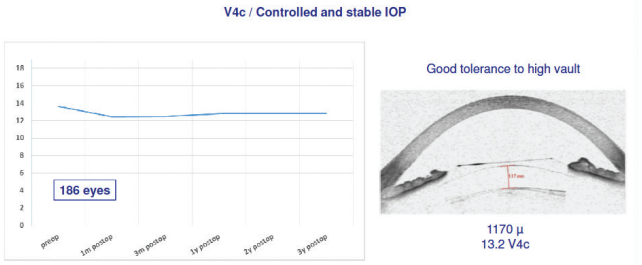

Figure 3. Eyes had a good tolerance to high vault, with controlled and stable IOP.

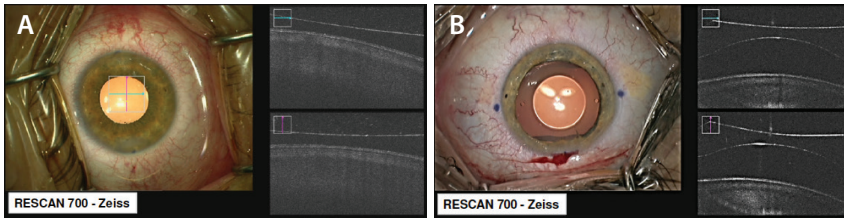

Figure 4. Intraoperative OCT.

Safety protocol

Vault	OCT microns	To evaluate	Attitude
0	< 100	Central touch	Monitor
1	100 - 250	Peripheral touch	
2	250 - 750		Right
3	750 - 1000	Iris / Pupil / Angle compromised	Monitor or Relocate (exchange if toric)
4	> 1000		Exchange

Figure 5. Safety protocol with the EVO Visian ICL.

RESULTS

Safety and efficacy. The safety and efficacy data, through 3 years of follow-up, can be found in Table 2. In short, the efficacy of the procedure ranged from 0.98 at 1 month postoperative to 0.89 at 3 years postoperative, and the safety remained consistent at 1.02 at 1 and 3 months and 2 and 3 years postoperatively. At 1 year postoperative, it was 1.03. This medium- and long-term follow-up confirms the safety and efficacy of the procedure.

Predictability. EVO Visian ICL implantation is also a predictable procedure, and our results supported this. At 1 month postoperative, 97.2% of patients were within ±0.50 D of intended correction and 99.4% were within ±1.00 D. At 1 and 3 years, 95.6% and 80.6% of patients, respectively, were within ±0.50 D of intended correction and 99.4% and 95.6%, respectively, within ±1.00 D.

Evolution of vault. Vault also remained relatively consistent through 3 years postoperative (Figure 2). At 1 month postoperative, the mean vault was 478 ±204 µm (range, 90–1,080 µm), with only 8% of eyes outside the recommended range. At 1 and 3 years, the mean vault was 411 ±193 µm (range, 60–990 µm) and 350 ±164 µm (range, 40–960 µm), respectively, with only 10% and 6% of eyes, respectively, outside the recommended range.

What is also impressive about our study results was that there was no incidence of anterior subcapsular cataract postoperatively. In fact, this extends well beyond the study data. Since we began implanting the EVO Visian ICL—the model with the KS-AquaPort—in 2011, we have had zero anterior subcapsular cataracts in the 1,957 eyes we have treated with this procedure. Prior to this time, with a previous generation of the lens, we had experienced anterior subcapsular cataract formation postoperatively in 21 of 1,531 eyes, for an incidence of 1.37%. When this number (21) is taken into context with the total number of ICLs we have implanted (4,596), the incidence of cataract formation is a mere 0.46%. Again, each and every case of cataract formation occurred with a previous generation of the Visian ICL.

IOP. We also looked at IOP over time and found that all eyes had a good tolerance to high vault (Figure 3). This, again, is likely related to the addition of the KS-AquaPort, as it restores a more natural flow of aqueous humor within the eye.

Endothelial cell loss. Our results also indicated that the amount of endothelial cell loss was controlled and stable across 3 years postoperative, from 2,700.39 cells/mm^2 at 1 month postoperative to 2,661.07 cells/mm^2 at 3 years postoperative.

CONCLUSION

In summary, our results have indicated that, with the correct vault of the EVO Visian ICL and the addition of the KS-AquaPort, the risk for cataract formation postoperatively is nearly eliminated. In order to ensure that the optimum vault is reached, we have found it useful to incorporate OCT with the Rescan 700 (Carl Zeiss Meditec).

When vault is low, we wait and monitor (Figure 4A), and when the vault is high, we rotate the EVO Visian ICL into a different position (Figure 4B). Our safety protocol is described in Figure 5. ■

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*The KS-AquaPort was named after and developed in cooperation with Kimiya Shimizu, MD, of Japan.
†Outside the age range approved in the EU

Booby Traps on the Road to Refractive Surgery

Recognizing tear film insufficiency and treating it adequately prior to scheduling surgery will lead to better postoperative outcomes and, ultimately, happier patients.

BY ERIK L. MERTENS, MD, FEBOPHTH

Dry eye disease (DED) is everywhere, and in fact it is the most frequently encountered disease state by eye care professionals. According to a 2013 Market Scope analysis,[1] more than 25 million people living in Europe suffer from DED. What is an even more staggering statistic is that these people spend about €3.2 billion annually in the European Union on medications and prescriptions that provide DED symptom relief. According to Market Scope, the global dry eye treatment market will reach $4.9 billion in 2022, with the highest rate of growth expected in China, India, and other emerging markets.

Given these statistics, it is no wonder that we see so many patients with DED. The presence of DED is not a contraindication to refractive surgery, however, as long as it is recognized and treated adequately prior to scheduling surgery. In this article, I will review the two most primary forms of DED and overview some of the best methods to treat the condition.

CATEGORIZE THE DED

Before you can recognize the presence of DED, you must understand the difference between the two primary forms, evaporative and aqueous deficient.

Evaporative DED. This form of DED, which is a lipid deficiency caused by meibomian gland dysfunction, accounts for roughly 86% of the DED patients you will see.[2] Evaporative DED occurs when the aqueous in tears evaporates at a faster than normal rate. The severity of the disease can range from mild to severe.

Aqueous deficient DED. This form of DED is more rare, as it only constitutes about 14% of the DED patients you will see.[2] In patients with aqueous deficient DED, aqueous generation from the lacrimal gland is insufficient to keep the eyes moist. The severity of the deficiency can range from a tear meniscus dimension of 0.2 to 0.0 mm. Treatments to maintain or increase tear volume should be considered in patients with tear meniscus heigh values ≤210 µm because they have a 4.65 relative risk ratio of developing severe corneal epitheliai disease (odds ratio = 5.59).[3]

DIAGNOSE THE DED

Diagnosing both evaporative and aqueous deficient DEDs requires both subjective and objective testing. Luckily for us, the Tear Film and Ocular Surface Society recently released its Dry Eye Workshop II (DEWS II) study,[4] which generated a global consensus on multiple aspects of DED, including an updated definition and classification system, a regimen for diagnosis of DED, and recommendations for pharmaceutical interventions for DED treatment (Figure 1).

The first and foremost step is to talk to each patient who walks through your door. A DED questionnaire such as the Standardized Patient Evaluation of Eye Dryness (SPEED) or Ocular Surface Disease Index (OSDI) are both appropriate and helpful tools to help identify patients with DED. Further, patients should be asked about what kind of medications they are on and have been on in the past, including antihistamines, decongestants, antidepressants, and glaucoma eye drops. Patients should also be assessed for any anatomical lid defects. Another important step in the analysis of patients for DED is to perform a systemic history, including Sjogren syndrome,

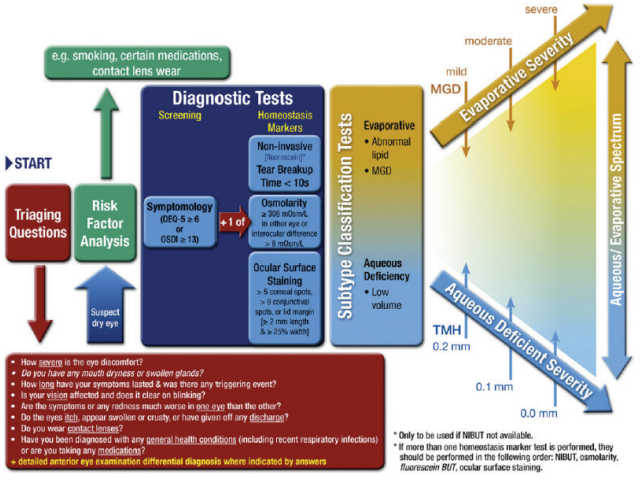

Figure 1. TFOS DEWS II flow chart.

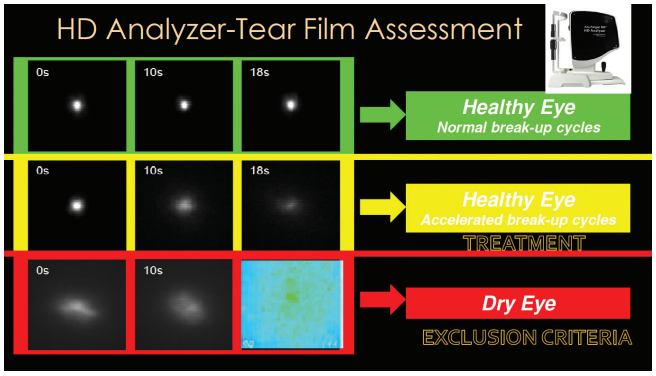

Figure 2. Tear film assessment with the HD Analyzer.

rheumatoid arthritis, rosacea, thyroid dysfunction, lupus, and hormonal changes.

In my office, I perform the following diagnostic testing in addition to the SPEED/OSDI patient questionnaires:

- Corneal and conjunctival staining with fluorescein, lissamine green, or rose Bengal;
- Tear film breakup time (TBUT);
- Schirmer test;
- Meibography;
- Tear osmolarity;
- Matrix metallopeptidase 9 (MMP-9) and interleukin-1 receptor antagonist; and
- Epithelial thickness mapping.

A DEEPER DIVE

Some of the diagnostic testing we have available today is more advanced than the staining, TBUT, and Schirmer tests that most of us are comfortable performing. These tests are still extremely relevant and important to perform, but other tests can help us to pinpoint the exact cause and severity of the DED.

Tear osmolarity. This is a relatively new innovation that can be useful to detect abnormal osmolarity or instability in the tear film. Normal tear osmolarity is 290 mOsms/L, but patients with DED will often present with an elevated reading (>308 mOsms/L), indicating loss of homeostasis. Likewise, the typical inter-eye difference in tear osmloarity is 2 mOsm/L; however, patients with DED who present with a difference of >8 mOsms/L have instability of the tear film. If the patient is symptomatic but presents with normal tear osmolarity, additional considerations include conjunctival chalasis, mild allergic conjunctivitis, and epithelial basement membrane dystrophy.

It should also be noted that patients who do not present with DED symptoms can still have hyperosmolarity, and performing a tear osmolarity test will help to identify such patients. According to a study of 9,216 patients performed by Sullivan et al,[5] 51% of patients had a normal osmolarity, meaning that the other 49% had some form of DED. Of the patients who did not report any symptoms of DED (n = 5,191), 47% had hyperosmolarity.

Tear film assessment. TBUT can be assessed thoroughly with the HD Analyzer (Visiometrics). This tool can not only differentiate between eyes with healthy and unhealthy tear films, but it can also differentiate between a healthy eye with a normal TBUT cycle and a healthy eye with an accelerated TBUT cycle (Figure 2). The HD Analyzer can also create an ocular scattering index, which can correlate with visual function.

Inflammation. As another indicator of DED, it is important that we test the ocular surface for inflammation. Identifying

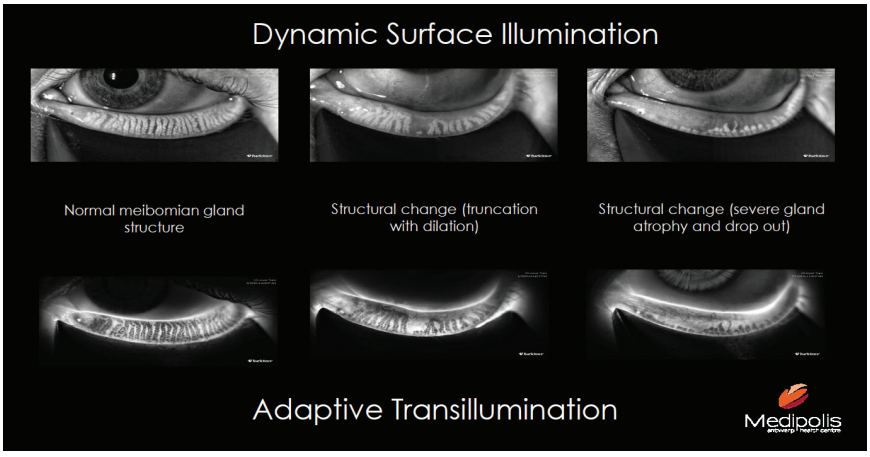

Figure 3. Dynamic surface illumination and adaptive transillumination help to assess the Meibomian gland structures.

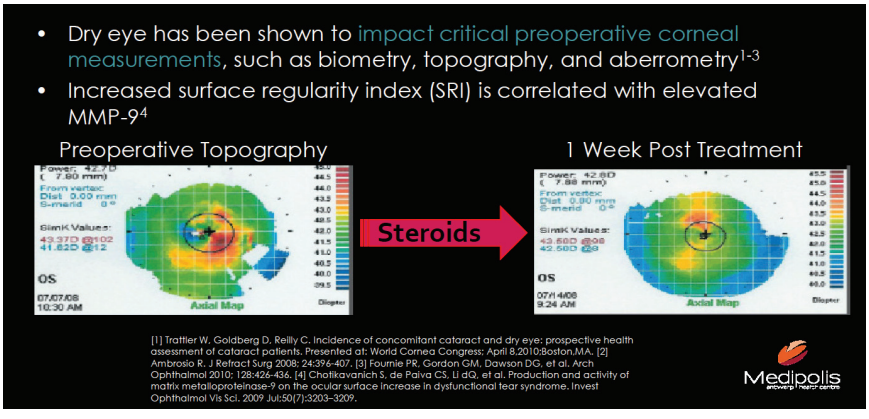

Figure 4. Depiction of how DED can impact preoperative corneal measurements: Preoperative topography (left) and repeat topography 1 week after prescribing treatment with steriods (right).

elevated MMP-9 levels guides our therapeutic decision making because it can help to predict what patients will respond to antiinflammatory therapy, and it can therefore help us to customize a treatment plan.[6] Traditional testing methods (TBUT, Schirmer, and even osmolarity) cannot predict what patients have inflammation, and therefore I use the RPS Inflammadry test (RPS).

In the presence of inflammation, many complications can occur if cataract or refractive surgery is attempted. These include less accurate presurgical measurements, leading to potentially worse visual acuity outcomes,[7] and exacerbation of DED severity and symptoms.[8]

PUTTING IT ALL TOGETHER

So why does diagnosing (Figure 3) and treating DED preoperatively matter? For starters, it will help you to ensure that your patients have the best shot at excellent postoperative outcomes (Figure 4). Specifically, leaving a patient hyperosmolaric prior to IOL implantation could result in a significant difference in IOL power, as indicated by Epitropoulos et al.[9] ■

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EVO Visian ICL Versus SMILE

In low to moderate myopes, the phakic IOL continues to hold many advantages over cornea-based refractive surgery procedures.

BY JIN ZHOU, MD

Surgical refractive correction has come a long way since its inception 30 years ago. Today, we can offer our patients a wide range of lens- and cornea-based refractive surgery procedures, including phakic IOL implantation, refractive lens exchange, LASIK, PRK, and small-incision lenticule extraction (SMILE).

With such a diverse pool of options to choose from, selecting the procedure that is right for each patient can sometimes be a daunting decision; however, in my clinic, we have great faith in the EVO Visian ICL (STAAR Surgical) and continue to expand our recommendations for its use to include low to moderate myopes.

A LONG, SUCCESSFUL HISTORY

Posterior chamber phakic IOLs like the EVO Visian ICL have a 20-year-long history. Clinical validations of safety, efficacy, stability, and predictability for moderate to high myopia and even extremely high myopia are well documented.[1,2] Likewise, the phakic IOL can offer many distinct advantages over other refractive surgery procedures. For starters, the Visian ICL has been shown to yield better simulated retinal image quality versus LASIK. In a study of 39 eyes, 20 that received the Visian ICL and 19 that underwent LASIK, mean postoperative coma was 0.17 and 0.37, respectively, and the mean total higher-order aberrations (HOAs) was 0.41 and 0.62, respectively.[3] In another study of 93 eyes, 46 that received the Visian ICL and 47 that underwent wavefront-guided LASIK, the ICL induced significantly fewer HOAs than LASIK. Further, in eyes with high myopia, contrast sensitivity improved significantly after implantation of the Visian ICL but deteriorated after wavefront-guided LASIK.[4]

Other studies have also shown that the toric Visian ICL performed better than conventional PRK in pre- to postoperative night driving simulator testing with and without glare.[5] In that study of 68 eyes, 27 that received the toric Visian ICL and 41 that underwent PRK, detection and identification of business and traffic signs and pedestrians, both without and with glare, was better in almost

TABLE 1. PRE- TO POSTOPERATIVE CHANGE IN NIGHT DRIVING SIMULATIONS WITH AND WITHOUT GLARE AFTER TORIC VISIAN ICL IMPLANTATION AND PRK

	Change in Feet ± SEM		Significance of Difference
	TICL	PRK*	
Detection (without glare)			
Business sign	3.3 ±4.8	1.8 ±3.7	0.81
Traffic sign	11.5 ±6.0	2.1 ±3.9	0.18
Pedestrian	9.4 ±5.7	-0.2 ±3.8	0.15
Average	8.1 ±4.8	1.2 ±2.8	0.20
Detection (with glare)			
Business sign	8.7 ±6.3	12.0 ±4.5	0.66
Traffic sign	1.7 ±6.2	-0.3 ±4.0	0.78
Pedestrian	18.4 ±10.1	0.3 ±4.5	0.11
Average	9.6 ±5.0	4.0 ±3.2	0.33
Identification (without glare)			
Business sign	27.2 ±7.7	-5.8 ±7.8	0.005
Traffic sign	24.6 ±9.3	-9.5 ±11.5	0.038
Pedestrian	36.2 ±6.8	-0.3 ±6.3	0.001
Average	28.1 ±7.2	-5.2 ±7.9	0.005
Identification (with glare)			
Business sign	24.7 ±7.0	5.8 ±9.9	0.12
Traffic sign	12.6 ±8.5	0.7 ±11.8	0.42
Pedestrian	46.0 ±11.0	1.0 ±8.3	0.001
Average	27.8 ±6.8	2.5 ±9.6	0.035

Abbreviations: TIC L= Toric Implantable Collamer Lens, SEM = standard error of the mean
*Negative number indicates that targets had to be closer after surgery (ie, postoperative performance was worse than preoperative).

every measure. In fact, some patients had to be closer to the object after surgery than they did before surgery to adequately see (Table 1), indicating that the postoperative performance was worse than the preoperative performance in those instances.

EXPANDING PATIENT OPTIONS

Laser vision correction has been shown as an effective means to treat low to moderate myopia, and it is a relatively mature and highly accepted course of treatment. On the other hand, the usefulness of phakic IOLs and SMILE in eyes with low to moderate myopia is not as well documented. In order to assess the EVO Visian ICL and SMILE as alternatives for the correction of low to

◆ UCVA after ICL and SMILE operations

VA after 6 months	EVO ICL	SMILE	t	p
UCVA	1.19±0.20	1.21±0.16	-1.86	>0.05
BCVA	1.22±0.11	1.23±0.13	-1.45	>0.05

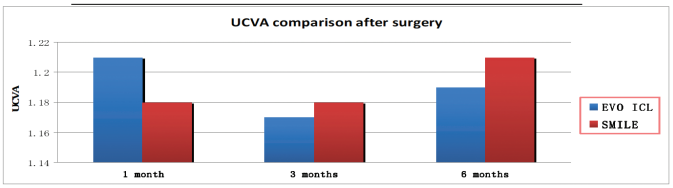


Figure 1. Postoperative UCVA and BCVA: EVO Visian ICL versus SMILE.

moderate myopia, my colleagues and I compared and evaluated the clinical outcomes and visual quality after phakic IOL implantation and SMILE for low to moderate myopia.

The sample size of our study included 124 eyes of 63 patients. A total of 75 eyes (38 patients) received the EVO Visian ICL, and 49 eyes (25 patients) underwent SMILE. The average age of patients was similar, at 24.3 ±4.1 years in the ICL group and 25.1 ±5.0 years in the SMILE group. All patients were available for at least 6 months of follow-up. The inclusion criteria were as follows:

- Spherical equivalent (SE) -1.00 to -6.00 D;
- BCVA ≥20/20;
- Anterior chamber depth ≥2.8 mm*;
- Endothelial cell density >2,500 cells/mm^2;
- No presence of inflammatory disease;
- No history of trauma; and
- No history of systemic disease.

No intra- or postoperative complications occurred at any point in the study, and all eyes had a normal IOP postoperatively. In the EVO Visian ICL group, the lens vault was stable through 6 months postoperatively.

At 1, 3, and 6 months postoperative, we evaluated UCVA, refractive error, total HOAs, total spherical aberration, and total coma, and we performed a quantitative assessment of visual acuity. By 6 months postoperative, UCVA and BCVA were similar between groups, with average UCVAs in the EVO Visian ICL and SMILE groups of 1.19 ±0.20 and 1.21 ±0.16, respectively, and average BCVAs of 1.22 ±0.11 and 1.23 ±0.13, respectively (Figure 1). Distance UCVA was also similar between groups at 6 months postoperative, with 100% of patients in both the EVO Visian ICL and SMILE groups achieving 20/20 and 71.8% and 73.8%, respectively, achieving 20/16 distance UCVA. More patients in the EVO Visian ICL group achieved 20/12.5, however (24.9% vs 18.8%).

When we evaluated postoperative SE, we found that it improved more substantially over time with the EVO

Refractive diopter after 6 months				
	EVO ICL	SMILE	t	p
Refractive diopter	0.002±0.08	-0.085±0.18	0.0415	<0.05

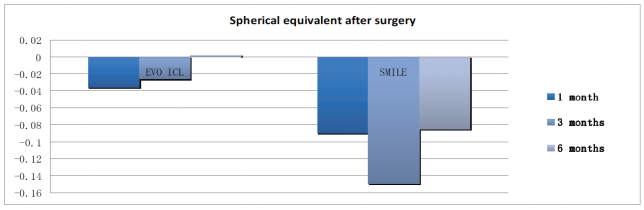
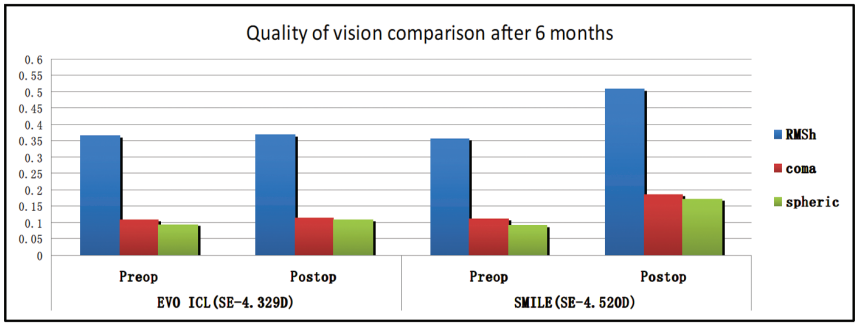


Figure 2. Postoperative spherical equivalent: EVO Visian ICL versus SMILE.

Visian ICL. By 6 months postoperative, SE in that group was 0.002 ±0.08, versus -0.085 ±0.18 in the SMILE group (Figure 2). We also found a higher level of refractive predictability in the ±0.50 D range, with 100% of eyes in the EVO Visian ICL group versus 93% in the SMILE group achieving this range.

The level at which root mean square HOAs, coma, and sphere increased postoperatively was also slightly higher in the SMILE group (Figure 3), indicating that the quality of vision with the EVO Visian ICL is better than with SMILE. In the quantitative assessment of visual acuity, 26% and 41% of patients in the EVO Visian ICL and SMILE groups, respectively, said that they noticed halos; 10% and 17%, respectively, said that they noticed glare; and 21% and 10%, respectively, said that they noticed starbursts. We used the iTrace (Tracey Technologies), simulated by single HOAs, to determine visual quality and found a corresponding relationship between the amount of spherical aberration (HOAs) and the decreasing visual quality.



Comparison of HOAs between EVO ICL and SMILE group at 6 months after operation

	EVO ICL	SMILE	t	P
RMSh	0.368	0.508	0.194	>0.05
coma	0.115	0.185	0.162	>0.05
spherical	0.108	0.172	0.042	<0.05

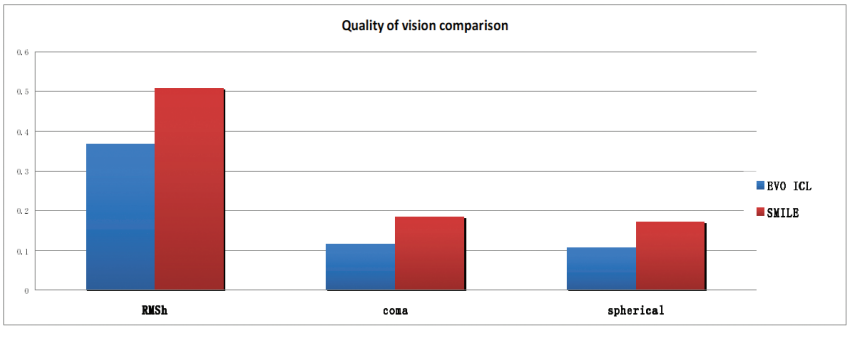


Figure 3. Comparison of quality of vision (top) and HOAs (bottom): EVO Visian ICL versus SMILE.

CONCLUSION

Using our results for grounds to expand the indications for the EVO Visian ICL, we now feel comfortable treating patients with low to moderate myopia with this surgical intervention. In our study, both the EVO Visian ICL and the SMILE procedures provided patients with good clinical outcomes, and both procedures were safe and efficacious. The stability and predictability were better in the EVO Visian ICL group, with 100% of patients achieving a correction within ±0.50 D of the intended refraction. The amount of HOAs was also much lower in the EVO Visian ICL group.

Although both procedures are equivalent in some aspects, I prefer the EVO Visian ICL and believe it is a valid choice for patients with low myopia, especially if the patient has poor preoperative distance BCVA, if the procedure is a second intervention, if the cornea is abnormal, or if the patient has any symptoms of dry eye disease. ■

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*Below the approved minimum in China for the EVO Visian ICL

EVO Visian ICL: 10 Years of Follow-Up

The recent ability to incorporate OCT into ICL size selection has helped to increase postoperative results even further.

BY KIMIYA SHIMIZU, MD, PHD

As the Director General of a relatively large hospital, I believe it is my responsibility to make sure that we have the very best procedures and technologies available to our patients. Part of that responsibility, however, is also to continually evaluate those procedures and technologies that we do offer our patients. If at any time one of them is underperforming, it is my responsibility to figure out why and, if it comes down to it, decide to eliminate its use in our hospital.

Over the years, I have amassed a great deal of experience with many cataract and refractive surgery procedures, and on occasion I have had to make the tough decision to stop performing a procedure or two. Below I describe those experiences and explain my rationale for the final decision, and I also share my experience with a technology that has, in my experience, stood the test of time as an outstanding refractive surgery procedure: phakic IOL implantation.

CORNEA-BASED REFRACTIVE SURGERY PROCEDURES

In 1997, I had the privilege of performing the first LASIK procedure in Japan. Initially, I was impressed: Patients experienced rapid recovery, I could perform the procedure bilaterally in a single session, and I only had to prescribe a short use of steroids postoperatively for patients. By 2000, the procedure was approved by the Japanese Pharmaceuticals and Medical Devices Agency. But over the course of the following 10 years, patient satisfaction with LASIK declined. I noticed that some of my patients complained about their clarity of vision and some also complained of an increase in their dry eye disease (DED) symptoms. I was not alone in my observations, and various studies supported the claims that LASIK could promote tear dysfunction due to the loss of goblet cells,[1] the induction of ocular surface inflammation,[2,3] and the damage caused to corneal trigeminal nerves.[4] By 2008, I had stopped performing LASIK and sought other methods by which I could correct my patients' refractive errors.

In 2010, I started to perform small-incision lenticule extraction (SMILE). Again I was impressed by the procedure, but I did notice some drawbacks including a slow return to visual acuity postoperatively due to an increase in ocular scattering brought on by the procedure. As this died down over time, visual acuity gradually recovered. However, I also experienced something called *interface fluid syndrome* in some of my patients, which I found can occur if IOP is underestimated preoperatively. By 2015, I stopped performing SMILE.

THE PHAKIC IOL

My experience with phakic IOLs began about the same time I performed the first LASIK procedure in Japan—1997. What immediately drew me to this lens-based refractive correction approach is the fact that it is removable (and therefore reversible) and also that it seemed to provide patients with visual results that were as good as if not better than LASIK. On the flip side, at that time, implantation of the Visian ICL (STAAR Surgical) also required me to perform a peripherial iridotomy (PI) to restore a more natural flow of aqueous humor. This two-step procedure also came with the risk for patient discomfort, ocular bleeding, and bullous keratopathy. Another concern that I had was regarding late-onset cataract formation, which I had heard from colleagues was a possibility.

But the more I thought about and performed the procedure, the more I was convinced of its potential to provide patients with maximal postoperative results. Around 2004, I pursued the idea of incorporating a central hole in the optic of the Visian ICL. This, I theorized, would eliminate the need for a PI and also the risk for cataract formation. This hole, the KS-AquaPort (Figure 1), eventually revolutionized the way that we could perform phakic IOL implantation.

In 2007, I implanted my first Visian ICL with the KS-AquaPort, and today I have more than 10 years of

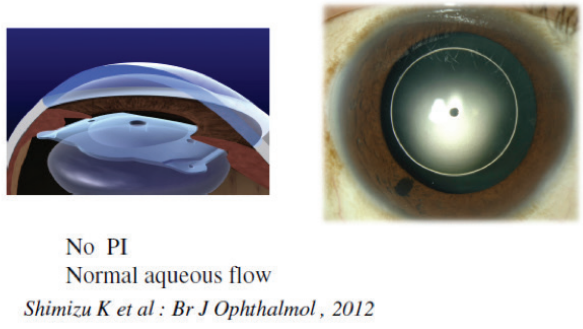


Figure 1. The EVO Visian ICL with the KS-AquaPort eliminates the need for a peripheral iridotomy.

SELECTING ICL SIZE

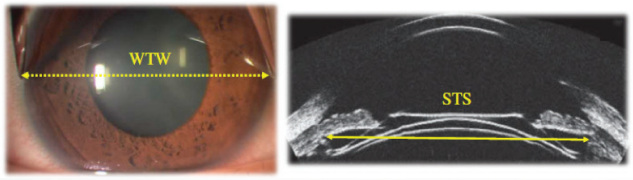
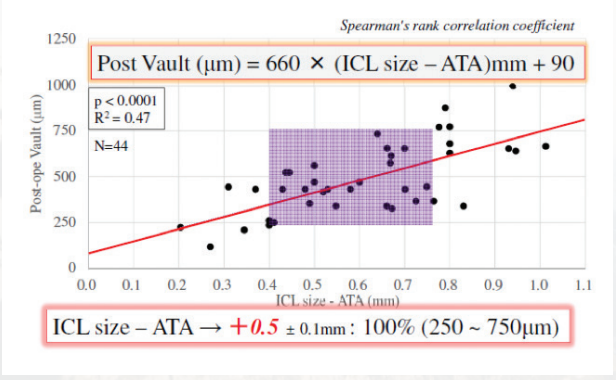


Figure 1. Historically, ICL size has been selected based on white-to-white (left) or sulcus-to-sulcus (right) measurements.



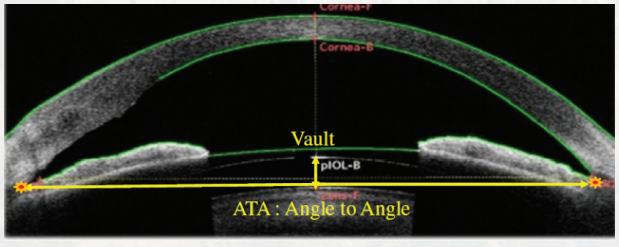


Figure 2. Another option to select ICL size is using angle-to-angle measurements as obtained by anterior segment OCT. The author has shown that angle-to-angle and vault are correlated (top). Angle-to-angle measurement with the CASIA 2 (Tomey; bottom).

Historically, selection of the size of the Visian ICL (STAAR Surgical) is determined by the eye's white-to-white or sulcus-to-sulcus measurement (Figure 1). Picking the proper size of the lens is important because it will ensure proper lens vault, which can be anywhere from 250 to 750 µm. Today, we can also use angle-to-angle measurements with an anterior segment OCT (AS-OCT) device to select ICL size. We have found this to be just as accurate if not more accurate than white-to-white measurements (Figure 2).

As part of our long-term, 10-year study on the EVO Visian ICL, we also looked at a subset of six patients (average age 34.4 ±5.9 years) to determine if horizontal or vertical fixation was the most accurate. In each patient, horizontal fixation was achieved in one eye and vertical in the other. What we found was that the mean angle-to-angle on AS-OCT was similar in both horizontal and vertical groups (11.84 ±0.51 vs 12.10 ±0.58 mm; *P* <. 003). Both fixation techniques had similar safety and efficacy indices (Figure 3), and both achieved refractive predictability within ±0.50 D of intended correction in 100% of eyes.

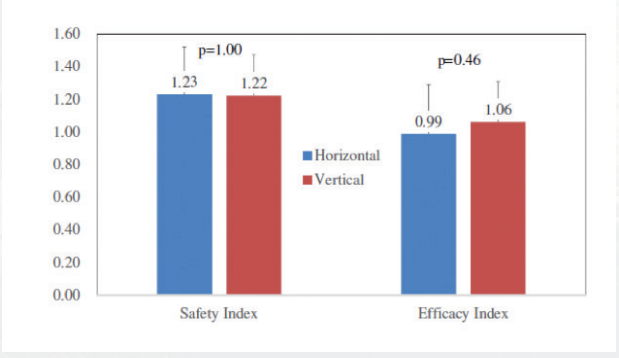


Figure 3. Safety and efficacy index for horizontal and vertical fixation of the EVO Visian ICL.

experience with this version of the lens, the EVO Vision ICL. In 2016, my colleagues and I published results of a 5-year comparative study, in which the EVO Visian ICL with the KS-AquaPort was implanted in one eye of patients and the standard Visian ICL was implanted in the other.[5] Since that time, we have also populated 10-year data of all cases of EVO Visian ICL implantation performed at the Sanno Eye Center and Kitasato University Hospital from 2007 to 2017. Our results are described below.

STUDY RESULTS

From 2007 to 2017, 292 EVO Visian ICLs were implanted in a total of 128 patients. The average age of patients was 34.7 ± 7.7 years (range, 20–54 years*), and the average spherical equivalent (SE) and manifest cylinder was -8.00 ±3.47 D (range, 0.50 to -23.75 D) and -1.23 ±1.26 D (range, 0.00 to -7.00 D), respectively. Of the EVO Visian ICLs implanted in this population, 129 were nontoric and 163 were toric.

A total of 130 eyes were available for 1-year follow-up. Fifty-one were available for 3-year follow-up, 34 for 5-year, 27 for 7-year, and seven for 10-year. The change in distance BCVA from 1-year to 10-year follow-up is shown in Figure 2. The change in SE from 1 week postoperative to 10 years postoperative was extremely stable, ranging from -0.20 at 1 week to -0.54 at 10 years (*P* = .35). Also stable was IOP, ranging from 13.4 mm Hg at 1 week to 14.2 mm Hg at 10 years (*P* = .56), and endothelial cell density, ranging from 2,740 cells/mm^2 at 3 months postoperative to 2,673 at 10 years postoperative (*P* = .06).

As expected, there were no early term complications in any case. In long-term follow-up through 10 years, there

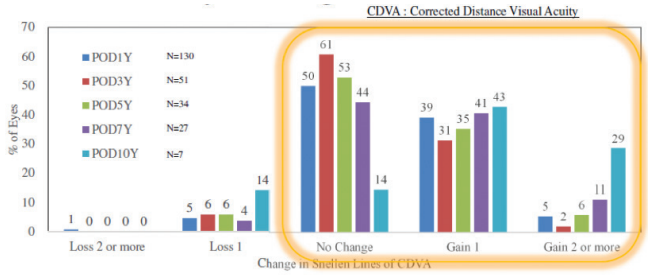


Figure 2. Change in distance BCVA from 1 year to 10 years postoperative.

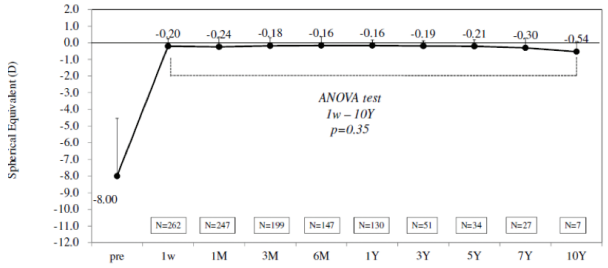


Figure 3. Change in spherical equivalent from preoperative to 10 years postoperative.

was no incidence of infection or cataract formation, and enhancement surgery was only required in four study eyes. Of those, exchange of the EVO Visian ICL was performed in two eyes and PRK enhancement in the other two.

CONCLUSION

Our results indicate that implantation of the EVO Visian ICL is a safe, efficacious, highly predictable procedure that provides patients with a stable refraction over long-term use. In the 10+ years of experience with this lens at our hospitals, we have had no complications. For those reasons, the EVO Visian ICL is my first choice in refractive correction for those patients who I feel are good candidates for the procedure. I am also highly encouraged by the recent advance of selecting ICL size using OCT technology (see *Selecting ICL Size*). ■

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*Outside the Approved age range in Japan

Proven Clinical Outcomes With the EVO Visian Toric ICL

The rotational stability of this lens after implantation is most impressive.

BY DAVID KANG, MD

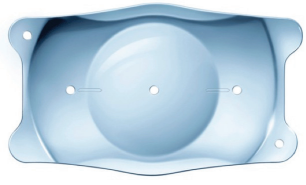

Figure 1. The toric EVO Visian ICL has inherent properties to aid in lens alignment to the 180° meridian.

The precise placement of any toric IOL is important. For every degree of misalignment, about 3% of the lens' cylindrical power is lost. A seemingly small rotational error of 3° can cause nearly a 10% loss of cylindrical effect. Luckily today, the art of toric IOL alignment has evolved, and now several tools can help us to further improve postoperative outcomes and fine-tune our surgical processes. Aligning the toric EVO Visian ICL (STAAR Surgical) in the posterior chamber is just as crucial to the final postoperative outcome as toric IOL alignment in the anterior chamber is. The lens is designed with the cylinder component placed within the optic in such a fashion as to allow the long axis of the EVO lens to remain implanted as close to horizontal (0–180° meridian) as possible. Based on the specific EVO/ICL lens ordered, the maximum rotation at the time of implantation will not exceed 22° from the 0° to 180° meridian. There are inherent properties built into the toric EVO Visian ICL that can aid in the alignment process, including two extended toric alignment markings etched onto the optic of the lens (Figure 1).

OBSERVATIONAL CASE SERIES

My colleagues and I recently performed a prospective

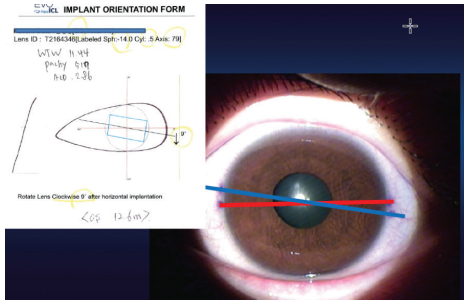

Figure 2. The implant orientation form, which helps the surgeon to properly align the toric EVO Visian ICL in the posterior chamber.

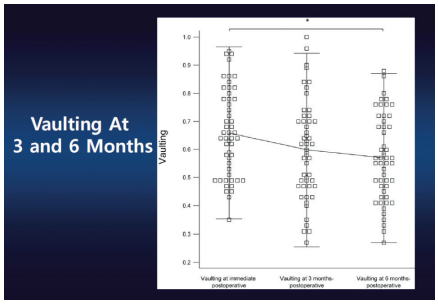

Figure 3. Vaulting of the EVO Visian ICL at 3 and 6 months postoperative.

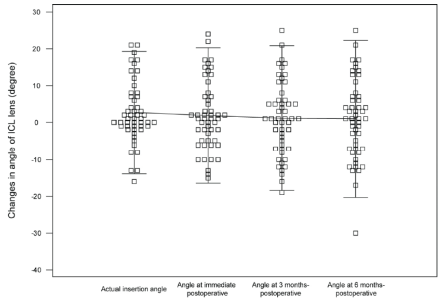

Figure 4. Changes (degrees) in angle of the Visian ICL lens.

observational case series on 51 eyes of 51 patients to determine the stability of the toric EVO Visian ICL. The average age of patients was 27 ±4.7 years (range, 19–38 years*), and the average refractive sphere, cylinder, and mean refractive spherical equivalent (MRSE) was -8.07 ±2.22 D (range, -14.87 to -4.50 D), -2.21 ±0.88 D (range, -4.63 to -0.87 D), and -9.18 ±2.39 D (range, -16.31 to -5.12 D), respectively. The mean flat and steep keratometric (K) values were 42.30 ±1.30 D (range, 39.50–45.00 D) and 44.50 ±1.50 D (range, 41.40–48.80 D), respectively. The average anterior chamber depth was 3.34 ±0.26 mm (range, 2.86–4.00 mm*), the average white-to-white was 11.56 ±0.30 mm (range, 10.51 ±12.42 mm), and the average sulcus-to-sulcus was 11.83 ±0.36 mm (range, 10.97–12.55 mm).

We used the 12.1 mm toric EVO Visian ICL in 11 eyes, the 12.6 mm in 37 eyes, and the 13.2 mm in four eyes. In all cases, manual markings were applied with a marker at the slit lamp, and up to 22° of rotation for the proper toric ICL alignment was allowed. This was determined by the toric EVO ICL implant orientation form (Figure 2).

RESULTS

Assessments included 6-month follow-up in all eyes. Retroillumination imaging was used to determine toric lens alignment. Lens vault immediately postoperative and at 3 and 6 months is shown in Figure 3. Both postoperative vaulting and AQD/valuting significantly decreased in a time-dependent manner ($P < .001$). The results of a multiple regression analysis showed that there was no explanatory variable relevant to the absolute degree of rotation, including postoperative vault.

At 6 months postoperative, 49% of the study population had a distance UCVA of ≥20/12.5, 86% of ≥20/16, 96% of ≥20/20, and 100% of ≥20/25. Also at this time point, 96% had gained at least 1 line of BCVA and 47% had gained at least 2 lines. No eyes lost any lines of BCVA.

When we looked at MRSE, 92% of eyes were within ±0.50 D of intended correction and 98% were within ±1.00 D. When we broke these numbers down more specifically, 98% were between -0.50 and 1.00 D of intended correction, 82% between -0.13 and 0.50 D, and 35% between 0.14 and 0.50 D. Furthermore, 90% of patients had no more than 0.50 D of refractive astigmatism at 6 months postoperative, and 98% had no more than 1.00 D. The majority of patients (59%) had no more than 0.25 D of refractive astigmatism at 6 months postoperative. Figure 4 details the tight spread of the changes in degrees in the angle of the toric EVO Visian ICL positioning from the actual insertion angle to the angles at immediately postoperative and 3 and 6 months postoperative. At our 6-month analysis, neither the lens rotation nor vaulting was associated with the intended angle of implantation; most of the rotations occurred immediately postoperative. Although the angle of the toric ICL showed no significant difference postoperatively ($P = .166$), the postoperative absolute degree of rotation showed a significant difference ($P = .009$). A post-hoc comparison demonstrated that the absolute degree of rotation at 3 and 6 months was significantly larger than that noted immediately postoperative ($P = .043$ vs $P = .023$, respectively). There was no significant difference between the absolute degree of rotation noted at 3 and 6 months postoperative.

We hypothesize that removal of the OVD and final lens positioning may be factors that contributed to rotation. From postoperative day 1 to postoperative month 6, the rotation of the toric EVO Visian ICL was negligible. The delta of the intended versus achieved angulation at 6 months postoperative was 2.79 ±1.83°. Therefore, the intended degree of rotation at implantation had no correlation with rotational stability. Further, rotational stability had no correlation with postoperative vault.

CONCLUSION

Our study indicated that implantation of the EVO Visian ICL, within 22° of the 0° to 180° meridian provides excellent visual results and rotational stability. We believe that this procedure is a safe, predictable, efficacious method of astigmatism correction in patients who are indicated for a phakic IOL. This option can provide patients with stable refractive outcomes, and it is our procedure of choice in the majority of our patients. ■

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- Financial disclosure: None

*The Directions for Use provides for an age range of 21 to 45 years and a minimum anterior chamber depth of 3.0 mm for patients in South Korea.

Expanding Patient Options With the EVO Visian ICL

Our clinical outcomes support the use of this lens in eyes with low myopia.

BY ALAA ELDANASOURY, MD, FRCS

I have been performing refractive surgery now for many, many years. When it comes to deciding what procedure is right for my patients, I consider all of the options that we have and select what I feel is the most ideal solution. In my experience, what makes the EVO Visian ICL (STAAR Surgical) the ideal refractive surgery procedure in so many cases is its efficacy, predictability, removability, and safety and its potential to help patients achieve excellent visual results postoperatively, including gained lines of distance BCVA. Implanting a phakic IOL like the EVO Visian ICL also accommodates patients' future needs and allows the best outcome both immediately and down the line when the patient requires cataract surgery.

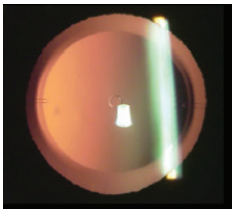

Figure 1. No incidence of cataract formation with the EVO Visian ICL.

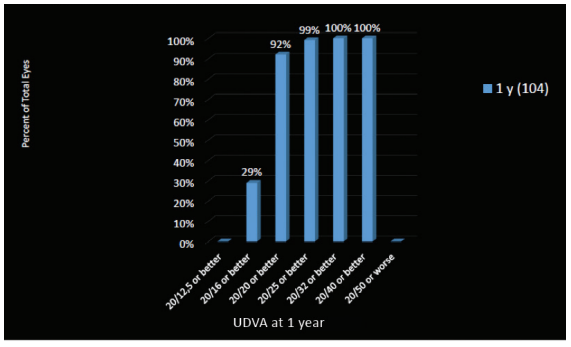

Figure 2. Cumulative distance UCVA from preoperative to 6 months postoperative.

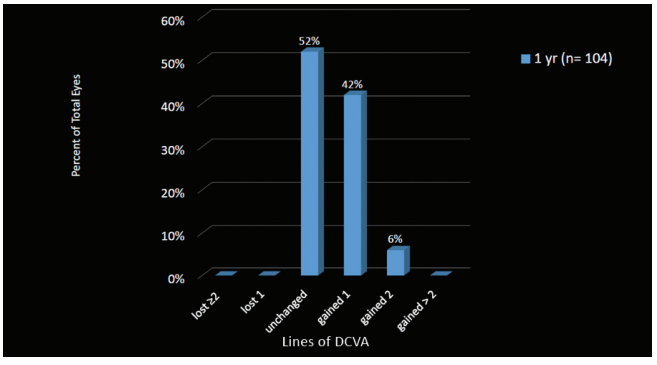

Figure 3. Change in distance BCVA at 1 year postoperative.

In the past, I tended to use the EVO Visian ICL mainly in eyes with high myopia and in some cases moderate myopia. Now, given recent data, I have expanded my recommendations with this lens to include eyes with low myopia as well. Given all of the properties of the EVO Visian ICL that make it an ideal solution for refractive correction, I am quite pleased to be able to offer this option to a wider range of patients.

A JOURNEY BACK

The evolution of the Visian ICL has been exciting, and with the latest EVO model, the company has now eliminated all of the barriers that have previously been raised about the use of phakic IOLs for refractive correction (Table 1) for my practice in Saudi Arabia.

Anterior subcapsular cataract. Even though the rate of anterior subcapsular cataract has always been relatively low (for example, in my experience 6.6% before 1997 and 0.5% between 2005 and 2015), it is now eliminated completely with the addition of the KS-AquaPort, a small hole in the center of the optic that helps to return the flow of aqueous humor to a more natural state (Figure 1). Since I have been using this version of the lens in 2015, I have not had one eye develop an anterior subcapsular cataract.

Sizing. Another area of concern for some has been selecting the adequate size of the lens. *(Editor's note: This topic is covered in the article beginning on page 10 of this educational material.)* But with each evolution of design, sizing has become increasingly easier.

Over the past decade, we compared many techniques for ICL sizing using different technologies including white-to-white (WTW) horizontal diamter, sulcus measurement with high-frequency ultrasound, and angle-to-angle diameter using anterior segment OCT. We concluded that using the WTW diameter is good enough in more than 95% of the cases. Using WTW diameter, our rate of ICL exchange due to improper sizing in the last 3 years was 1%.

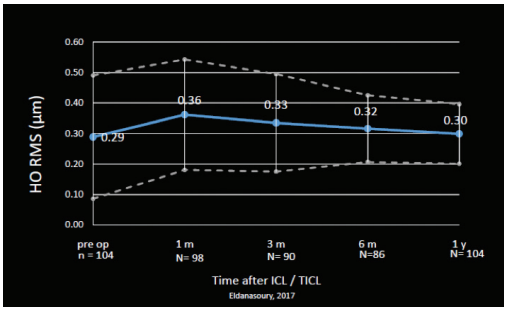

Figure 4. Root-mean-square of higher-order aberrations over time.

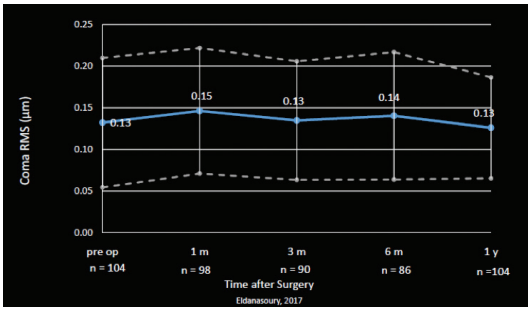

Figure 5. Root-mean-square of coma over time.

Optic size. With the introduction of the EVO+ Visian ICL, we are now able to better accommodate the ocular anatomy of patients with larger pupils. The latest model, the EVO+, has an expanded optical diameter up to 6.1 mm depending on lens power, which improves the quality of vision especially at mesopic conditions. With the the EVO Visian ICL design, the functional optical zone is larger than previous designs and is much larger than any laser vision correction procedure; this makes the superiority in quality of vision more significant when compared to laser procedures.

PATIENT OPTIONS

Now the EVO Visian ICL can be recommended for use in a wider range of patients. This is in part due to the updated design, which can accommodate patients with larger pupils, and also in part due to the fact that it can effectively treat lower amounts of myopia and astigmatism than previously attempted. We can also use the EVO Visian ICL across a wider age range, and bilateral surgery has become a routine practice.

Today I often use the lens in eyes that are good candidates for LASIK because I believe in the procedure, and I know that it truly offers my patients the closest to ideal refractive correction.

TABLE 1. EVOLUTION OF THE VISIAN ICL IN SAUDI ARABIA

	1997	2004	2015
1. Cataract	6%	<0.5%	~0.0%
2. Toric Design	Not available	Available	In stock
3. Loading and Injector	Poorly developed	Well developed	Reproducible
4. Surgical technique	Not reproducible	Reproducible	Reproducible
5. Alignment technique	Not needed	Less accurate	Accurate
6. Sizing	White-to-white	More understanding	Better sizing
7. KS-AquaPort	Not Available	Not Available	Introduced
8. Larger OZ (EVO+)	Not Available	Not Available	Available <-14.00 D

My colleagues and I recently performed a retrospective anaylsis of the EVO Visian ICL for the treatment of low myopia (-5.00 D or less). A total of 52 patients who underwent bilateral, same day surgery with the EVO Visian ICL or the toric EVO Visian ICL were included. The target refraction in all cases was emmetropia, and all eyes (N = 104) had a preoperative DCVA of 20/20 or better. At least 1-year follow-up was available for all patients.

The mean age of patients was 27.36 ±3.5 years (range, 18–35 years*), and the mean refractive spherical equivalent (MRSE), the mean sphere, and the mean cylinder were -3.43 ±0.80 D (range, -4.88 to -1.75 D), -3.09 ±0.89 D (range, -4.75 to -1.00 D), and -0.69 ±0.64 D (range, -3.25 to 0.00 D), respectively. At 1-year postoperative, the average deviation from intended correction was -0.17 ±0.22 D (range, -0.50 to 0.75 D). Cumulative distance UCVA and change in CDVA are shown in Figures 2 and 3. It is worthwhile to note that no eyes lost any lines of distance BCVA, 42% gained 1 line, and 6% gained 2 lines. Only one eye experienced lens rotation, which was due to an undersized lens being implanted. This lens was exchanged for one of adequate size at 3 months postoperatively; ICL exchange, when needed, is simple and safe to perform.

In the astigmatic eyes that received the toric EVO Visian ICL, the mean cylinder improved from -0.92 ±0.93 D preoperative to -0.33 ±0.46 D by 1 year postoperative. Further, the root-mean-square (RMS) higher-order aberrations and coma over time were relatively stable, and by 1-year postoperative, were back to preoperative levels (Figures 4 and 5).

CONCLUSION

Our recent results help to prove that the EVO Visian ICL is a viable option for refractive correction in a wider range of patients, including a wider distribution of ages and a wider distribution of refractive correction. I am now able to treat low myopes (below -5.00 D) with the EVO Visian ICL, and this is a welcomed evolution in patient care. I have complete confidence in the surgical reproducibility of the EVO Visian ICL, I have complete confidence in selecting the proper sizing of the lens, and I have complete confidence in the toric lens' design to ability to correct astigmatism. ■

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* This is outside the approved age range for Saudi Arabia

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