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Cataract & Refractive Surgery Today

Highlights From the

EVO VISIAN ICL EXPERTS SUMMIT 2019

TABLE OF CONTENTS

- 2 Immediate Sequential Bilateral EVO Surgery**
The Medipolis protocol.
 By Erik L. Mertens, MD, FEBOPhth
- 10 Rhegmatogenous Retinal Detachment Risk: Refractive Lens Exchange Versus EVO**
Advice from a posterior segment surgeon.
 By Frank Kerkhoff, MD, PhD
- 5 20 Years of Visual Freedom With the Visian ICL**
The advantages of this phakic IOL can last for 20 years or more.
 By Tobias H. Neuhann, MD, FEBOS-CR
- 13 Indications for EVO Visian ICL in Low Myopia**
Expand your refractive practice by offering both laser vision correction and phakic IOLs.
 By Barbara Leyskens, MD
- 7 My Paradigm Shift in Refractive Surgery**
I now operate an ICL-only practice.
 By Yoshihiro Kitazawa, MD

Immediate Sequential Bilateral EVO Surgery

The Medipolis protocol.

BY ERIK L. MERTENS, MD, FEBOPHTH



I am a big believer in implanting posterior chamber phakic IOLs for the correction of refractive errors. Compared with laser vision correction, phakic IOLs can correct a larger range of refractive errors,¹ especially in myopia and astigmatism correction; provide the largest functional optical zone and have a lower risk of endothelial and anterior chamber angle complications than anterior chamber phakic IOLs²; are less likely to contribute to dry eye disease than LASIK³; and can be surgically removed. Phakic IOLs can also be performed in patients who are not candidates for laser vision correction due to corneal irregularity, a thin cornea, or excessive dry eye.⁴

Over the years, my protocol for performing phakic IOL implantation has evolved, and for more than 3 years now I perform immediate sequential bilateral implantation of the EVO Visian ICL (STAAR Surgical).

RATIONALE FOR IMMEDIATE BILATERAL SURGERY

The advantages of bilateral simultaneous cataract surgery are well documented.⁵ First, stereopsis is not disrupted, meaning patients do not have a long neural adaptation process with their new visual system. Second, patients achieve faster visual rehabilitation after immediate sequential bilateral cataract surgery than if two separate procedures were performed, giving them a more rapid return to normal life. Third, there is not only a time saving for the patient due to reduced postoperative visits but there is also a cost saving, as the cost to perform only one surgery is significantly less than that to perform two separate procedures. Fourth, patients must comply with only one eye drop instillation regimen instead of two. Lastly, there are fewer general anesthesia risks since patients only undergo one procedure.

It seems reasonable, then, that the benefits of immediate sequential bilateral phakic IOL implantation would carry

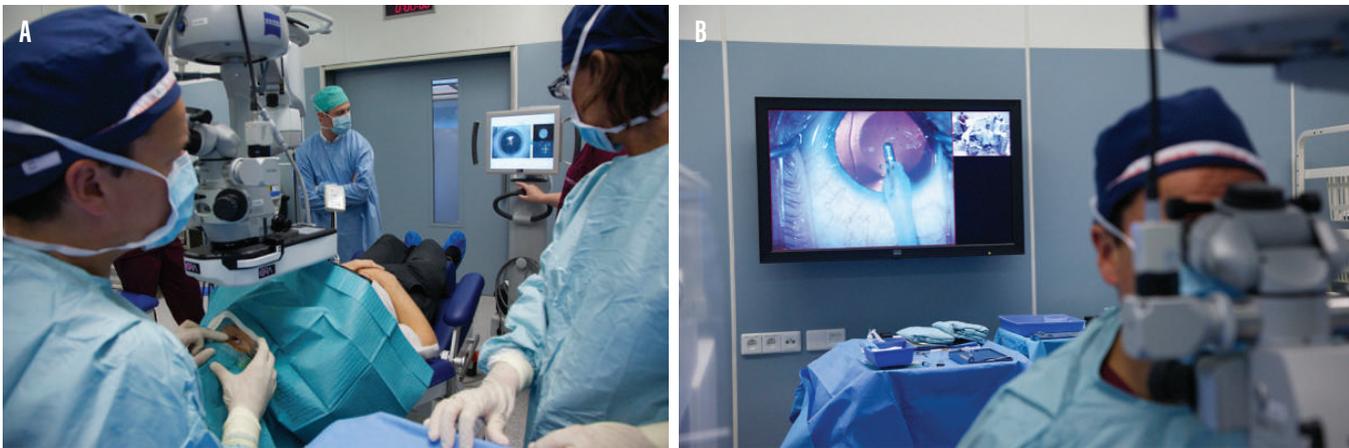


Figure 1. Dr. Mertens performs an immediate sequential bilateral phakic IOL implantation procedure (A,B).

those same benefits I just outlined. In our experience, which includes more than 1,468 Visian ICL lenses implanted in patients bilaterally (Figure 1), we have found this to be true.

ARGUMENTS AGAINST THE PROCEDURE

Perhaps the biggest argument against the use of immediate sequential bilateral eye surgery techniques is indeed the risk of endophthalmitis, which comes with the devastating consequence of possible loss of all light perception. In cataract surgery, the incidence of endophthalmitis has been reported to be between 0.13% and 0.7%.⁶ In phakic IOL surgery, that risk is even lower. Reporting on results from three separate studies that included 17,954 phakic IOL surgeries, Allan et al found that the incidence of endophthalmitis after immediate sequential bilateral phakic IOL implantation was 0.0167%.⁷ None of the patients included in this dataset who contracted endophthalmitis lost their vision.

Other considerations in immediate sequential bilateral phakic IOL implantation include accurate lens sizing, IOP control, and deciding whether or not it is necessary to obtain information from the first eye surgery before proceeding with surgery in the second eye.

PREVENTION IS KEY

The key to successful immediate sequential bilateral phakic IOL implantation—and immediate sequential bilateral cataract surgery for that matter—is prevention of endophthalmitis. We use a systematic approach to any bilateral eye surgery, including immediate sequential bilateral phakic IOL implantation, that starts with treating each eye as a separate procedure. This means that we use different operating tables and product batch numbers for each eye. It also means that we change our gloves and gowns between the procedures in the first and second eyes.

Other steps in the Medipolis protocol for immediate sequential bilateral phakic IOL implantation are described here.

We apply povidone iodine 10% to the eyelid and povidone iodine 5% to the ocular surface 15 minutes before surgery and again 3 minutes before we begin the procedure. We also apply povidone iodine 5% to the eye immediately after surgery. This practice has been shown to reduce the risk of endophthalmitis after cataract surgery⁸ as well as after intravitreal injections.⁹

During surgery, we instill intracameral cefuroxime 1 mg/0.1 cc (Aprokam, Thea) within 2 minutes of creating the three-step, 2.6-mm main incision and one paracentesis. Again, this practice has been shown to reduce the risk of endophthalmitis.^{10,11} One hour after surgery, we do an IOP check and give the patient acetazolamide 250 mg by mouth. We do not administer any miotic agents in immediate sequential bilateral phakic IOL implantation procedures.

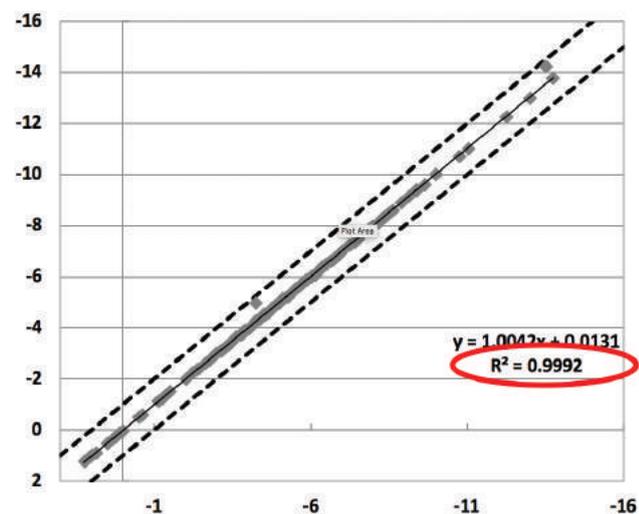


Figure 2. Attempted versus achieved refractive results in 1,468 EVO Visian ICLs implanted in immediate sequential bilateral phakic IOL procedures.

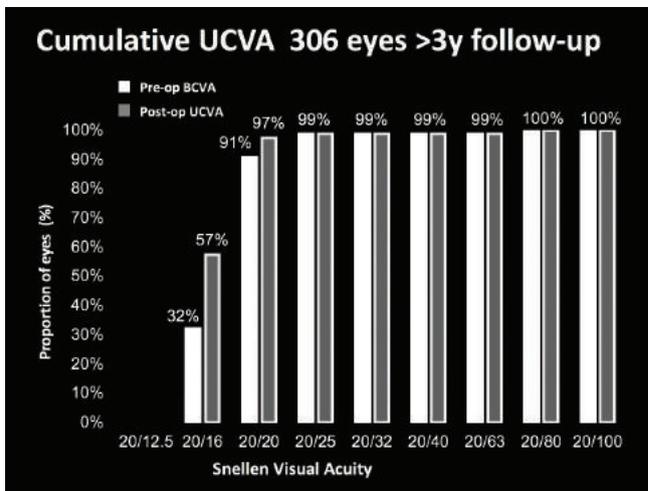


Figure 3. Cumulative UCVA in 306 eyes with more than 3 years of follow-up after immediate sequential bilateral phakic IOL implantation.

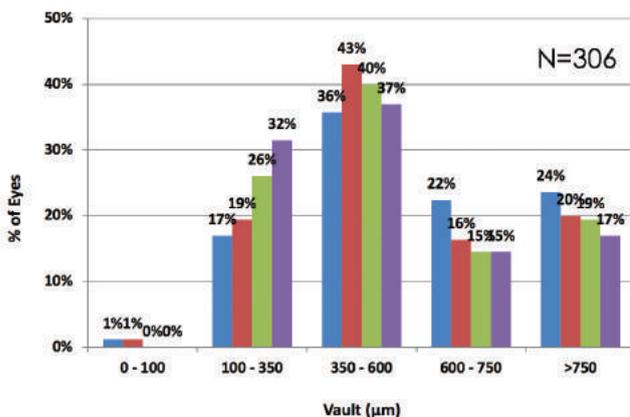


Figure 4. Postoperative vault at 1, 3, 6, and 12 months postoperatively. Key: blue = 1 month, rust = 3 months, green = 6 months, and purple = 12 months

WHY WAIT?

With a strong endophthalmitis prevention protocol in place, we also wanted to determine if it made a difference in the postoperative predictability if we did not use information from surgery in the first eye for surgery in the second eye. In other words, would the immediate sequential bilateral procedure still produce the same predictability as a procedure that incorporated information from how the first eye responded to phakic IOL implantation, or would the predictability suffer? Figure 2 shows the attempted versus achieved refraction in our series of 1,468 EVO Visian ICLs implanted in a sequential bilateral technique (unpublished data). Of these, 306 had more than 3 years of follow-up. These results clearly show that immediate sequential bilateral phakic IOL implantation boasts excellent predictability.

With these excellent predictability results, I ask this: Why wait to perform surgery on the second eye? We have the

same predictability after immediate sequential bilateral phakic IOL implantation as we do after standard phakic IOL implantation surgery in which surgery is delayed by several weeks between eyes. Further, in those 306 eyes with more than 3 years' follow-up, 97% achieved 20/20 UCVA postoperatively, 99% achieved 20/25, and 57% achieved 20/16 or better (unpublished data, Figure 3).

We do, however, acknowledge the importance of checking the position of the Visian ICL's haptics and vault intraoperatively to ensure the best predictability and postoperative results. Factors that can influence vault height include sulcus-to-sulcus diameter,¹² pre- and postoperative accommodation during testing,¹³ power of the ICL,¹⁴ and lens rise.¹⁵

The vault in the group of 306 eyes at 1, 3, 6, and 12 months postoperatively is seen in Figure 4.

CONCLUSION

In the end, only the patient can decide for himself or herself if immediate sequential bilateral phakic IOL implantation is the right choice. It is our job to educate patients, to provide thorough informed consent, and to ease patients' fears about sequential bilateral phakic IOL implantation. In our practice, the majority of patients now choose this option, and we have seen many benefits for them and also for our workflow. ■

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20 Years of Visual Freedom With the Visian ICL

The advantages of this phakic IOL can last for 20 years or more.

BY TOBIAS H. NEUHANN, MD, FEBOS-CR



I was the first surgeon worldwide to implant both the toric Visian ICL (STAAR Surgical) and the toric EVO+ Visian ICL, in 1999 and 2016, respectively. But I began using the Visian ICL in 1995 before I had the

distinguished honor of implanting that first toric Visian ICL. In this article, I share my long-term experience with the ICL, and I recount the case of one patient in whom I had implanted the lens bilaterally more than 20 years ago. This patient was happy with her decision in 1999, when the procedure was performed, and she was happy with her decision in 2019, when she had the implants removed to undergo laser cataract surgery performed by my son, Raphaël.

BACKGROUND

Toward the end of 1998, a 49-year-old* woman came to my clinic and inquired about refractive surgery. She was intolerant of contact lenses and wanted freedom from her spectacles. Upon routine examination, the refraction was -8.00 D in her right eye and -8.50 D in her left. BCVA in both eyes was 20/20. Endothelial cell count in her right and left eyes was 2,800 and 2,900 cells/mm², respectively, and pachymetry readings were 580 and 577 μm, respectively, in those same eyes. The white-to-white measurements were 12.1 and 12.0 mm in her right and left eyes. She had no other ocular pathologies.

At that time, I determined that the patient was a potential candidate for excimer laser surgery, which is what she had come in seeking, but I explained to her that she was also a good candidate for the Visian ICL. After sharing with the patient the benefits of both procedures, she decided to proceed with Visian ICL implantation. The target in this case was slight myopia.

In January 1999, I implanted a -10.00 D IC2020- ICL in her right eye, followed by implantation of a -9.00 D ICM125V2 Visian ICL in her left eye in a separate procedure 1 week

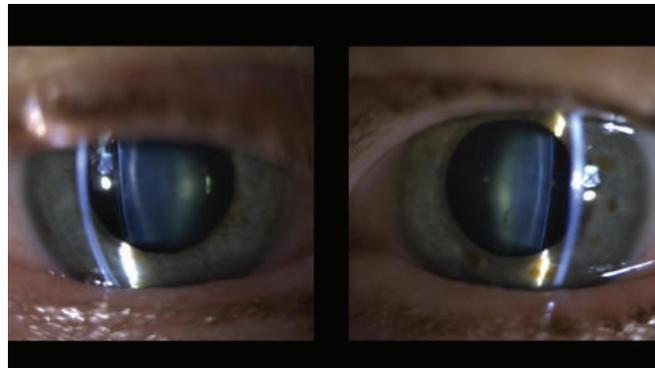


Figure 1. The patient's eyes at the slit lamp in 2019.

later. Postoperative refraction in the patient's right and left eyes was -0.75 -0.25 @ 165° and -0.50 -0.25 @ 200°, respectively. BCVA in both eyes was 20/15. She was spectacle independent.

At all of her follow-up appointments, the patient relayed that she was extremely happy with her results. She always told me that it was the best decision and investment that she made. Her last visit with me was in 2006.

IN NEED OF CATARACT SURGERY

Fast forward 20 years, in 2019, when this same patient returned to inquire about the possibility of gaining improvement in her vision, which had recently started to deteriorate. She was now 70 years old, and she had a cataract in both eyes (Figure 1). She was hoping to restore the same vision that the Visian ICL implants had given her for the past 20 years.

Figure 2 depicts that nothing uncommon was found during the diagnostic examinations in 2019. Of note, endothelial cell density at 20 years after Visian ICL implantation was minimally decreased. Refraction was -1.00 -0.75 @ 081° in her right eye and -1.50 -0.25 @ 122° in her left. UCVA was 20/40 in both eyes.

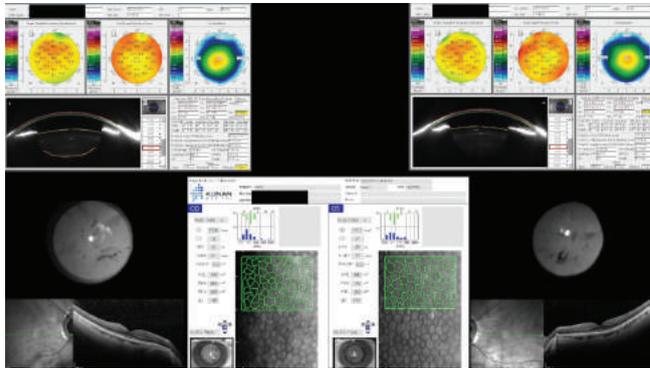


Figure 2. Diagnostic examinations prior to the patient's cataract surgery procedure.

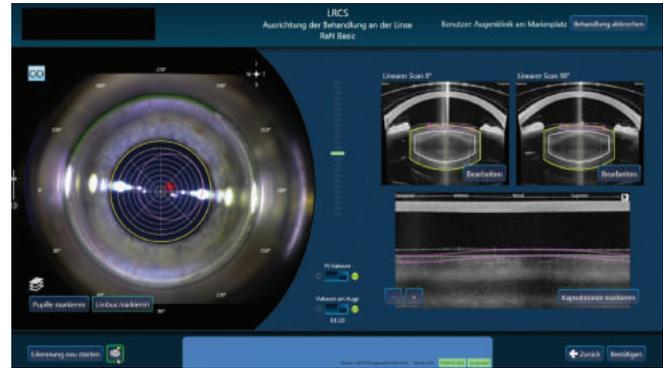


Figure 3. Laser cataract surgery is performed.

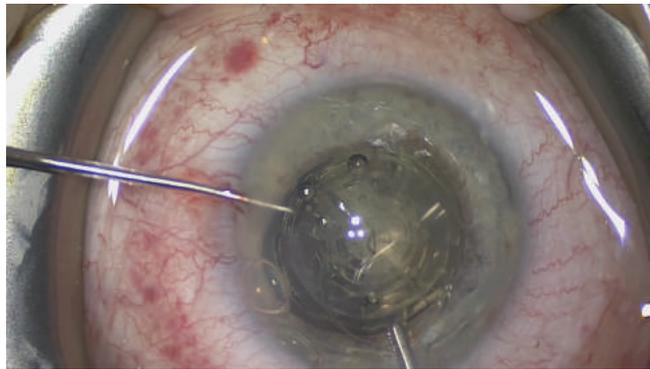


Figure 4. The Visian ICL is explanted.



Figure 5. The explanted Visian ICL.

It was decided that the best procedure to perform was femtosecond laser-assisted cataract extraction with Vision ICL explantation. The goal was now to aim for monovision (Figure 3).

We used the Barrett Universal II formula to determine a target of -1.50 D in her nondominant right eye while calculating the left eye for distance.

First, the Victus femtosecond laser (Bausch + Lomb) was used to create the 4.5-mm capsulotomy on the lens apex and fragment the nucleus. The Visian ICL had full contact with the lens surface; however, it did not alter the detection of the laser. Further, there was no excess gas formation between the human lens and the Visian ICL, meaning that the fragmentation of the lens was not altered.

ICL EXPLANTATION

After the laser portion of the procedure, the Visian ICL was carefully explanted (Figure 4). First, OVD was injected between the human lens and the ICL. Bubbles from the femtosecond laser also assisted in producing space between these two surfaces, which made it easier to inject OVD between the lenses. With slow and careful manoeuvres, the Visian ICL was moved in front of the iris and then explanted with a pair of forceps. After low power phaco and subsequent steps of the cataract surgery procedure were

performed, a +14.50 D EyeCee One IOL (Bausch + Lomb) was then successfully implanted in the right eye.

On postoperative day 1, refraction was -1.25 -0.25 @ 65°.

After surgery, we took a close look at the explanted ICL. It was interesting to see that the end of the haptics were slightly bent upward (Figure 5). The lens was perfectly clear, with no pigment, blood, or fibrosis on the surface of the lens to disturb the clarity of the material.

CONCLUSION

The Visian ICL has many competitive advantages over laser vision correction,¹ and these advantages can last 20 years or more. Further, even after 20 years of implantation in the human eye, this patient's Visian ICL remained clear and free from surface debris that could disturb the clarity. ■

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* This information represents data from the author's medical practice. The Directions for Use during that time indicated an age range of 21-45 years. This age range has since been approved for patients 21-60 years within the EU.

My Paradigm Shift in Refractive Surgery

I now operate an ICL-only practice.

BY YOSHIHIRO KITAZAWA, MD



I have a long and rich history with refractive surgery. I was an early adopter of PRK in 1991 and of LASIK in 1996. I have performed more than 50,000 of these procedures. I have also performed epi-LASIK, LASEK, and more than 20,000 cataract surgeries. And, in addition to all of this, I have probably implanted the most phakic IOLs in all of Japan. This is my story of how my approach to refractive surgery shifted away from the excimer laser and toward a lens-based approach. In fact, nowadays, my refractive surgery practice is 100% phakic IOLs, namely the EVO Visian ICL (STAAR Surgical).

NEGATIVE NEWS CYCLE FOR LASIK

Several years ago, after a negative news cycle in Japan in which LASIK patients spoke out against the procedure, a trend away from LASIK began to emerge in our country. Reports of decreased visual acuity and predictability in high myopia, halos and glare, and dry eye disease circulated around the country, and as a direct result the ophthalmology community saw a decline in LASIK volume.

About that same time, in 2013, the Consumer Affairs Agency urged caution when considering LASIK. The Japanese government agency reported having received 80 health-related complaints such as loss of vision, eye soreness, and headaches since 2009, and consumers were worried. That is when Japan saw an even more drastic downturn in laser vision correction rates.

In March 2014, the EVO Visian ICL with the KS-AquaPORT® was approved for use in Japan by the Japanese Ministry of Health, Labour and Welfare. At that time, I was practicing at Kobe-Kanagawa Eye Clinic, and I had just started implanting the Visian ICL in patients with moderate myopia. Prior to that point, I had mainly used the lens for patients who were in the high to extremely high myopia range (Figure 1).

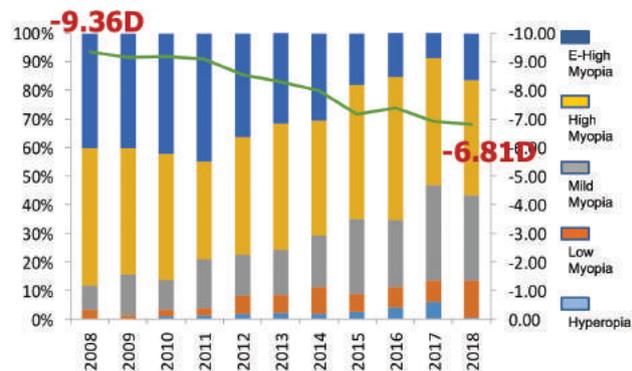


Figure 1. The range of myopia in patients who received a Visian ICL under Dr. Kitazawa's care at Kobe-Kanagawa Eye Clinic between 2008 and 2018.

With the decline in LASIK volume and because of my increasing confidence in the EVO Visian ICL, I slowly started to expand my indications to include low and mild myopia patients. By 2018, the average degree of myopia in my EVO Visian ICL patients was -6.81 D.

CURRENT TREND IN JAPAN

The current trend toward phakic IOL implantation for refractive correction is based on increased awareness among the surgeons and among our patients. It also correlates to complication rates with other refractive surgery procedures.

Surgeon awareness. Other surgeons in Japan also started recognizing the benefits that phakic IOLs provide. In a 2019 survey of Japan Society of Cataract and Refractive Surgery (JSCRS) members, 57.4% of respondents indicated that they offered phakic IOLs in their practices. That number was up from about 30% in 2009 (Figure 2A). Further, 65.3% indicated that they believe phakic IOLs will be the most useful refractive surgery procedure in the future (Figure 2B), and 22.6% said it was the option they would choose for their own eyes (Figure 2C).

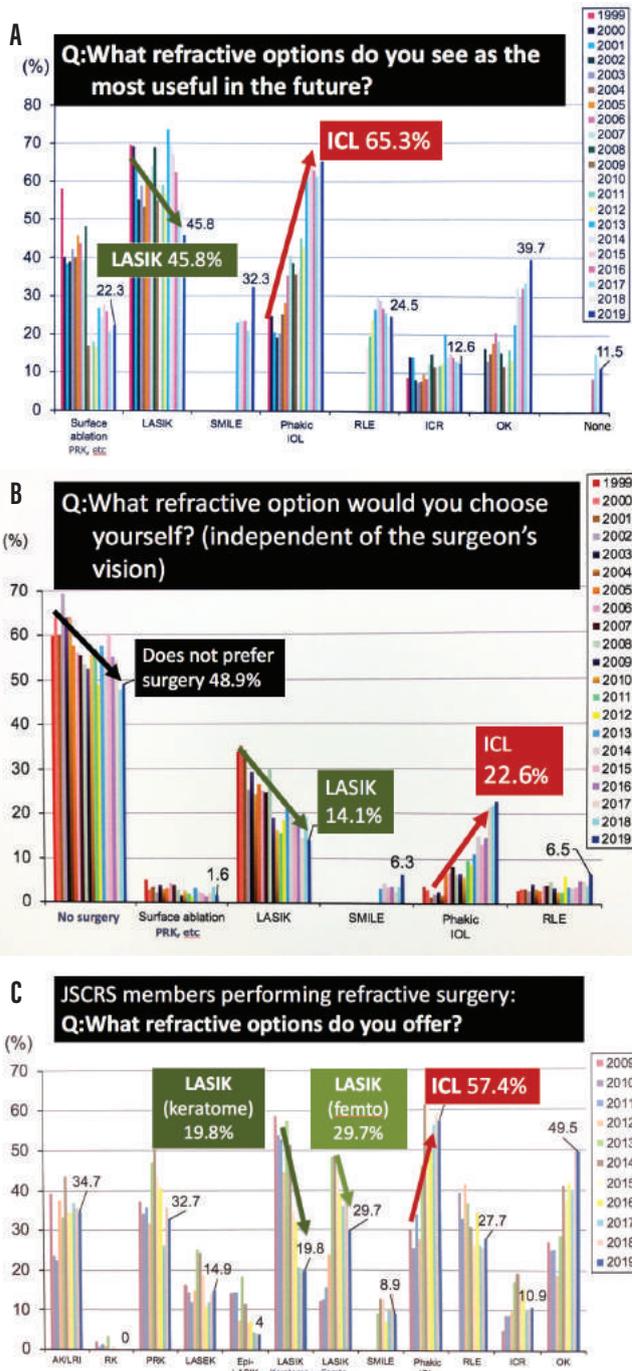


Figure 2. Percentage of refractive surgeons in Japan who offer phakic IOLs in their practice (A), who believe it is the most useful refractive surgery option in the future (B), and who said it was the option they would choose for their own eyes (C), from 2009-2019.

The peer-reviewed literature also shows the trend toward increased recognition of phakic IOLs among Japanese surgeons. It also indicates that surgeons now offer phakic IOLs to even more patients in the lower diopters of myopia. The Japan ICL Study Group performed a multicenter study

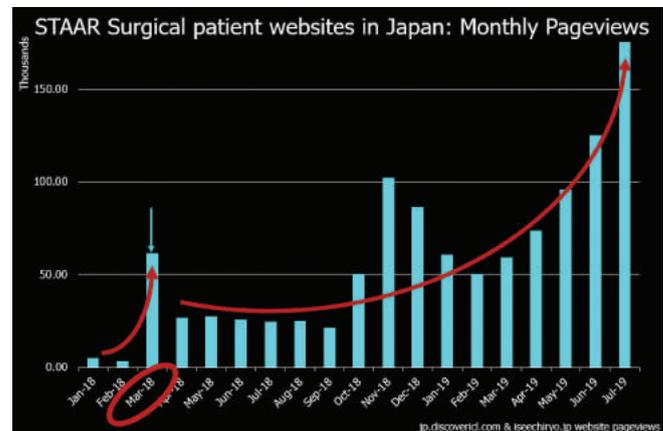


Figure 3. Number of page views on STAAR Surgical's patient website in Japan.

to compare low-to-moderate myopia patients with high myopia patients.¹ They concluded that the EVO Visian ICL performed just as well in low-to-moderate myopia as it did in high myopia at all timepoints in the 12-month follow-up.

Based on this study, the JSCRS submitted a request to the Japanese Ophthalmological Society (JOS) to modify the surgical indication criteria for the recommended use of phakic IOLs such as the EVO Visian ICL. In 2019, the JOS modified its guidelines for the indication of the EVO Visian ICL to start at -3.00 D instead of -6.00 D.

Patient awareness. Over the years, we have seen an increase in the number of patients coming into our offices asking for a phakic IOL such as the EVO Visian ICL. The largest increase was seen countrywide after a famous Japanese singer, producer, and actress underwent EVO Visian ICL implantation at my clinic. This famous Japanese personality has 2.7 million followers on Twitter. After she announced her surgery on that social media platform in March 2018, there was an instant and dramatic rise in the number of people visiting the STAAR Surgical website in search of more information on the EVO Visian ICL (Figure 3). The increase has since continued. Her Twitter post was liked by 16,292 individuals and retweeted 2,205 times.

Complication rates of other procedures. Another reason for the increased acceptance of phakic IOLs across Japan is that complications with other procedures have become more relevant, especially after the Consumer Affairs Agency reported its findings.

I've performed about 45,000 LASIK surgeries since 1996, and most have had excellent results. However, in that time, some patients have experienced complications such as infection, keratectasia, laser decentration, and epithelial ingrowth after the enhancement surgery. It is for those reasons that I stopped performing LASIK in 2018.

I also used to implant other phakic IOLs, and I implanted the Artisan IOL (Ophtec) in 2,513 eyes. However, this lens

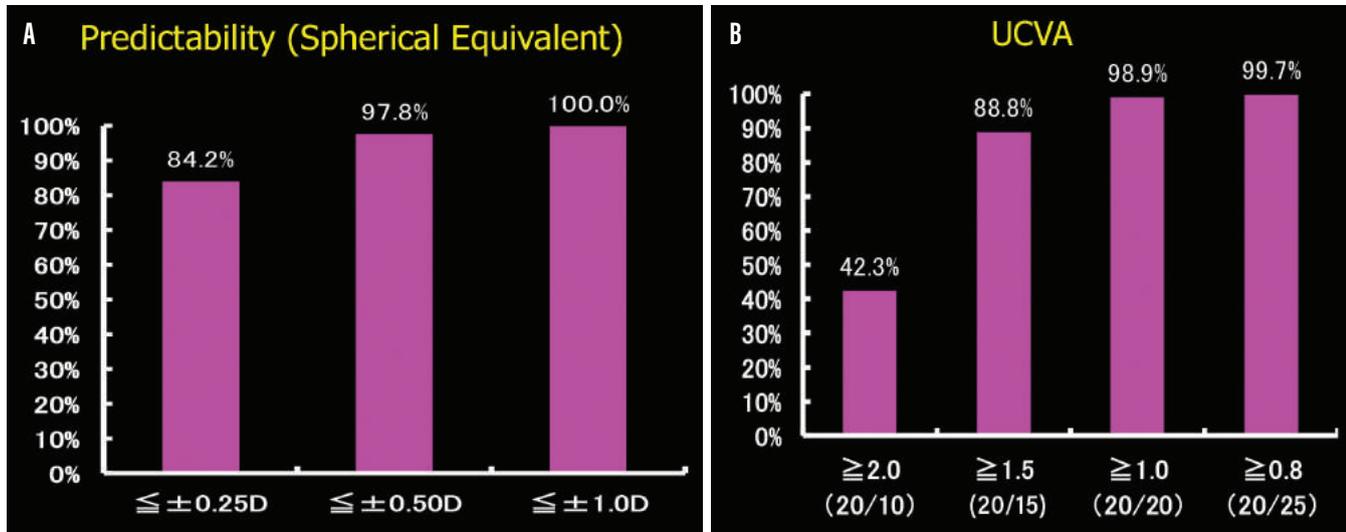


Figure 4. Predictability (A) and UCVA (B) with the EVO Visian ICL.

had to be explanted in 1.8% of all eyes due to endothelial cell loss. For this reason, I stopped doing Artisan surgery in 2015.

CAPITALIZING ON THE TREND

When it comes to refractive surgery, patients seem to be willing to pay a premium price to select a safer and more reliable procedure, which in my opinion is phakic IOL implantation. And recently the EVO Visian ICL has a superior brand image compared to LASIK.

Based on the safety of the EVO Visian ICL, the recognition among Japanese doctors that this is an excellent option for the correction of refractive errors, and an increased patient awareness due to recent celebrity surgery and other factors, I decided to open an EVO Visian ICL-only refractive surgery practice in Tokyo, the first of its kind in Japan. The Sapia Tower Eye Clinic Tokyo opened in February 2019, and it is located right in front of Tokyo station.

My clinic is on the 7th floor. When patients enter, our staff welcomes them warmly in the reception area. The space from the entrance to the examination area and the consulting room is open. There is a large glass wall overlooking the OR, which is dimmed during surgeries. Families of the patients can watch surgery from the observation space.

EARLY CLINICAL RESULTS

My surgical volume began with approximately 100 procedures performed in March 2019 and reached a cumulative total of more than 650 procedures by August 2019. Our early clinical results with the EVO/EVO+ Visian ICL at Sapia Tower Eye Clinic Tokyo are excellent.

We recently evaluated the clinical results of 361 eyes of 183 patients (mean age, 32.2 ± 7.6 years) operated from February to June 2019. The mean preoperative spherical equivalent refraction was $-6.97 D$, and about 40% of patients were in the low and mild myopic range.

At 1-month postoperative, we measured subjective refraction, uncorrected and best corrected visual acuity, predictability, safety and efficacy index, and complications. Mean subjective sphere and cylinder were 0.15 ± 0.25 and -0.38 ± 0.24 , respectively. Spherical equivalent was -0.04 ± 0.24 , UCVA was 1.67 (0.51 logMAR), and BCVA was 1.85 (0.62 logMAR). The safety and efficacy indices were 1.15 ± 0.19 and 1.03 ± 0.20 , respectively. Predictability and UCVA are shown in Figure 4.

CONCLUSION

The EVO Visian ICL is a mainstream refractive option and the procedure I believe in for my patients. I expect that ICL-only practices will become commonplace and that this implant will help refractive surgeons worldwide compensate for the loss of volume in their laser refractive surgery practices. ■

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

Rhegmatogenous Retinal Detachment Risk: Refractive Lens Exchange Versus EVO

Advice from a posterior segment surgeon.

BY FRANK KERKHOFF, MD, PHD



I've worked as an anterior and posterior segment surgeon for the past 20-plus years, and I have been performing refractive lens exchange (RLE) and phakic IOL implantation for the past 9 years. During my time in

practice, I have noticed a trend in the age demographics of patients who desire spectacle independence; today's patients are interested in achieving this goal at an earlier time in their lives.

This has caused an increase in the volume of cataract extraction and RLE procedures we perform. Given my unique perspective as an ophthalmologist who performs not only cataract and refractive surgery but also retina surgery, I understand that RLE and even cataract surgery could have potential large implications for the posterior segment, including posterior vitreous detachment (PVD), disturbing floaters, and rhegmatogenous retinal detachment (RRD).

With that in mind, in patients of presbyopic age (40–55 years) who desire spectacle independence, is it better to replace the human lens during a RLE procedure, or is it better to leave the human lens intact and implant a phakic IOL such as the EVO Visian ICL (STAAR Surgical)? The major concern for either procedure, from the point of view of a posterior segment surgeon, is RRD. The most common type of retinal detachment, an RRD occurs when a retinal tear leads to fluid accumulation and separation of the neurosensory retina from the underlying retinal pigment epithelium.

WHEN DOES RRD OCCUR?

According to the literature, RRD is most frequently related to PVD, and only a small number of RRDs happen without a PVD occurring first.¹⁻⁶ The risk of RRD can increase after

cataract extraction depending on the age of the patient and on vitreous loss during cataract surgery¹; however, various studies have also concluded that implantation of a phakic IOL does not induce PVD, and the rate of RRD does not seem to increase after surgery.⁷⁻¹¹

In fact, several of these studies have shown that the rate of RRD after cataract surgery, just as with RLE or phakic IOL implantation, is merely part of the natural disease state of eyes with high myopia.^{7-9,11} In relation to cataract surgery, the general risk of any eye with myopia for RRD depends on age, axial length/level of myopia, gender, vitreous status, and lattice degeneration. It is also related to surgical factors such as technique and intraoperative complications.¹

RISK FACTORS

Let's take a closer look at each of these factors.

Age. What the literature has taught us is that the younger the age of the patient at the time of PVD, the greater the chance for RRD. This is because younger eyes have a larger vitreous base and tighter vitreous-retina connections. Yonemoto et al created an algorithm for the anticipated age of PVD development, which is $Y = 0.91x + 60.93$, where Y is onset age of the PVD and x is the refractive error (Table 1).¹²

TABLE 1. ALGORITHM FOR THE ANTICIPATED AGE OF PVD DEVELOPMENT

Emmetropia	61 years
2.00 D myopia	59 years
6.00 D myopia	55 years
10.00 D myopia	52 years
17.00 D myopia	45 years

Refractive Error	Yearly Risk
Hyperopia and Emmetropia	0.004%/year
Mild Myopia (-1.00 to -4.75 D)	0.020%/year
Moderate Myopia (-5.00 to -9.75 D)	0.070%/year
High Myopia (> -10.00 D)	0.080%/year
Extreme Myopia (> -15.00 D)	Unknown

Axial length/level of myopia. We also know that, with higher myopia, comes a greater risk for RRD after cataract surgery. Böhringer et al reported on the yearly risk for RRD among men and women, assuming a lifespan of 80 years and according to their level of myopia at the time of cataract surgery (Table 2).¹³

Gender. The risk of RRD is 2.5 times greater in men than in women.^{14,15}

Lattice degeneration. In this disease, the peripheral retina becomes atrophic due to inadequate blood flow; tears, breaks, or holes can develop. Approximately 8% to 10% of all eyes have lattice degeneration, and 20% to 30% of all RRDs are related to this. The lifetime risk of RRD in patients with myopia and lattice degeneration is higher than in myopic patients without lattice degeneration (Table 3).¹⁶

High-risk groups. The risk for RRD after cataract surgery is highest among the following groups: younger patients,² men,^{14,15} patients presenting with lattice degeneration or vitreous loss,¹⁶ and patients with high axial length (ie, high myopia).^{13,17-19} We must remember that, in most myopic cases, but especially in men without visible PVD and lattice degeneration, the risk of RRD is still high. In fact, RRD risk increases 13- to 25-fold after cataract surgery.¹ If vitreous loss occurs, the risk increases even more.

Refractive Error and Lattice Degeneration	Risk
Sphere -3.00 to -5.00 D without lattice	1.2%
Sphere -3.00 to -5.00 D with lattice	12.1%
Sphere > -5.00 D without lattice	2.2%
Sphere > -5.00 D with lattice	35.9%

PRESBYOPIC MYOPIC CORRECTION AND A NEW CALCULATOR

So how does this research relate to presbyopic myopic correction with phakic IOLs? The RRD risk does not increase after the implantation of an EVO Visian ICL.⁷⁻¹¹ We must counsel all patients in these groups, regardless of what procedure is chosen, of the higher risk of RRD after surgery. However, for the correction of myopia and/or presbyopia in patients without a PVD and up to the age of 55, I would prefer and recommend an EVO Visian ICL over RLE.

Today's cataract and refractive surgeons have a plethora of lenses available, including toric, multifocal, trifocal, and extended depth of focus. It is important for surgeons to perform an RRD risk profile for every patient presenting for cataract surgery or RLE. An effective RRD risk profile, one that can help the ophthalmologist estimate the risk of vitreous loss during intraocular surgery, should include the elements discussed above.

I see many colleagues struggle with explaining the increased risk of RRD after cataract surgery. Using the summary of the RRD risk factors outlined above, and with the help of an epidemiologist, I created a calculator to help surgeons evaluate the risk of RRD in patients presenting for cataract surgery and RLE (Figure). It can also be used to

A
Figure. Examples of the FYEO-Medical RRD Risk Calculator (A,B).

help explain these risks to their patients. This calculator is available at <https://fyomedical.nl/retinal-detachment/>.

CONCLUSION

The risk of RRD after EVO Visian ICL implantation is not higher than the risk after cataract surgery or RLE. In order to keep our patients safe, it is crucial that surgeons perform an effective RRD risk profile on every patient who presents for cataract surgery, RLE, and even phakic IOL implantation. One tool to help with this is the FYEO-Medical RRD Risk Calculator. I prefer an EVO Visian ICL in any patient up to age 55 who does not present with PVD, but I always double check the patient's candidacy with the calculator. ■

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Indications for EVO Visian ICL in Low Myopia

Expand your refractive practice by offering both laser vision correction and phakic IOLs.

BY BARBARA LEYSSENS, MD



People today are used to having choices. In fact, in mostly every facet of our lives, we are overwhelmed by choices. This seems like it should be a good thing. However, the more choices a person has, the harder it

can be to decide what is best. Likewise, the more complex choices are, the harder it can be to make a decision.

This is known as choice paralysis, and it can affect our patients' ability to make decisions about their surgical options.

AVOIDING CHOICE PARALYSIS

Each patient is unique, and therefore each patient's visual preferences are unique. Offering a variety of procedures to fit the unique needs of our patients is crucial to the success of a practice. But the options must be presented in a way that does not induce the negative effects of choice paralysis.

In our private refractive surgery practice, with the same five refractive surgeons since 2011, we offer both lens- and cornea-based options for refractive correction, and we base our procedure of choice on patients' refractive errors, ocular examination, and occupation. Between 2011 and 2015, we used traditional indications for phakic IOL surgery with the EVO Visian ICL (STAAR Surgical) and a more traditional surgical pathway of ICL surgeons versus corneal surgeons.

Traditionally, eligible patients for ICL surgery are those with high myopia (-6.00 D or greater), pachymetry under $470 \mu\text{m}$, suspicious topography, stable keratoconus, and low residual stromal thickness.^{1,2}

OPTIMIZING THE DECISION-MAKING PROCESS

From 2011 to 2015, we used a two-step decision-making process depending on the myopia of the patient. If the myopic patient was younger than 50 years old* and had myopia of -6.50 D or greater, he or she was seen by

TABLE. TOTAL EVO VISIAN ICL NUMBERS

Two-Step System (Past)	One-Step System (Present)
2012: n=106	2016: n= 134
2013: n= 84	2017: n= 130
2014: n= 96	2018: n= 216
2015: n= 160	2019: n= 188 (last data July 2019)
Total n= 450 (average 111/year)	Total n= 668 (average 186/year)

the implant surgeon for the preoperative evaluation. If the patient was a good candidate, the implant surgeon scheduled him or her for intraocular surgery with implantation of the EVO Visian ICL. Patients with less than -6.50 D of myopia were scheduled for a preoperative evaluation with the laser surgeon.

In 2016, we transitioned to a one-step decision-making process: All surgeons perform ICL surgery and laser vision correction. So, every myopic patient who is younger than 50 years has a preoperative evaluation by a surgeon who performs both techniques.

Since that time, we have seen a rise in ICL implantations due to selecting less-traditional eligible patients with low (< -3.00 D) and moderate (< -6.00 D) myopia with the following conditions:

- Dry eye disease;
- Risk factors for retinal detachment;
- High regular astigmatism (> -3.00 D); and
- Low residual stromal thickness.

We also implant the EVO Visian ICL at the patient's request and if a patient wants quick visual recovery instead of the typically slow and painful recovery after PRK (if quick recovery laser treatments like SMILE or femtosecond LASIK were not options).

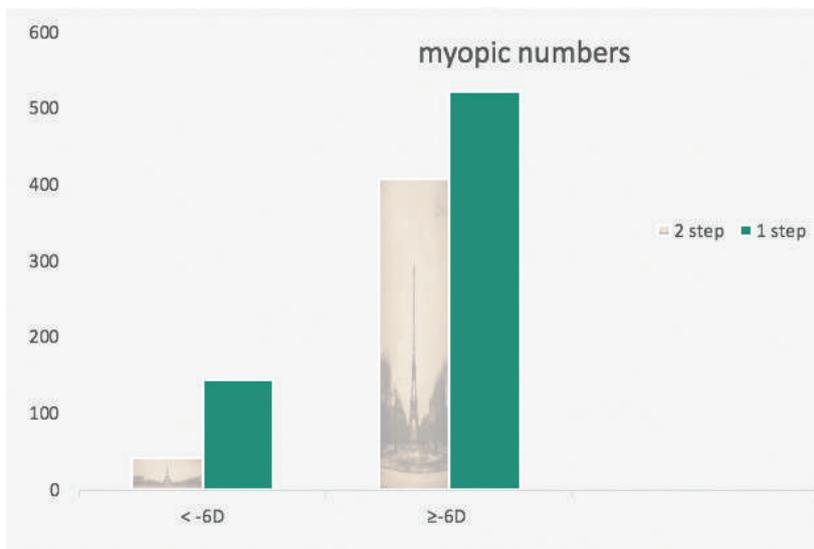


Figure 1. Number of EVO Visian ICL procedures performed in low to moderate (< -6.00 D) and high (≥ -6.00 D) myopia procedures using the two-step and one-step decision-making procedures.

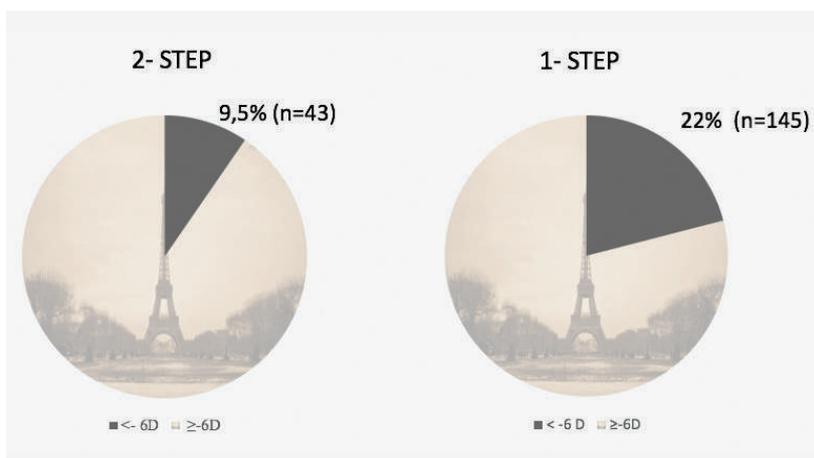


Figure 2. ICL numbers in low versus high myopia.

Today, we continue to use the one-step decision-making process with a less-traditional method of patient selection for phakic IOLs. It has worked well for us, and it has allowed us to grow our practice tremendously. (More on this later.)

PATIENT CHOICE

When patients ask specifically for the EVO Visian ICL, we honor their wishes as long as they are good candidates for the technology. We believe that there should be greater emphasis on the shared responsibility between patients and health professionals when deciding what surgical option is the best. Therefore, we always discuss the pros and cons of the procedure—even when patients have already made up their minds.

Pros. The pros of the EVO Visian ICL include its removability, decreased risk of dry eye as compared with laser vision correction procedures,³ and quicker visual recovery compared with PRK.⁴ Further, the procedure can be performed with an immediately sequential bilateral implantation technique, similar to bilateral laser vision correction procedures.

Cons. The cons of EVO Visian ICL include the routine risks that come along with any intraocular procedure, the financial choices relating to the cost of the lens, and, in some cases, patients' occupation or hobbies. In those cases, we advise, if possible, a surface ablation or SMILE procedure.

GROWTH IN THE PRACTICE

As I alluded to earlier, we have seen tremendous growth in our practice since transitioning to a single-step, less traditional decision-making process. In the two-step system, we were performing about 111 EVO Visian ICL procedures per year. In the one-step system, we now perform about 186 procedures per year (Table and Figure 1).

We have also grown the number of EVO Visian ICL procedures we have performed in patients with low and moderate myopia. With our two-step decision-making process, only 9.5% of our procedures were performed in patients with low myopia. But once we transitioned to the one-step decision-making process, that number grew to 22% (Figure 2).

Giving patients the shared responsibility and always discussing the different surgical options is an honest way to start your refractive business. In return, your private refractive practice will also grow through positive word-of-mouth recommendation.

CONCLUSION

Simplifying our decision-making process for refractive surgery procedures has helped us to grow our overall patient volume, and both ICL procedures and laser vision correction procedures have grown. It has also helped us to become more comfortable performing EVO Visian ICL implantation in patients with low-to-moderate myopia—a population that we previously preferred to perform laser vision correction procedures.

We strongly believe that patients and health professionals have a shared responsibility in deciding upon

surgical procedures. It is our duty to thoroughly discuss the pros and cons of any procedure with patients and to help them make the most educated decisions possible. ■

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**This information represents data from the author's medical practice. The Directions for Use during that time indicated an age range of 21-45 years. This age range has since been approved for patients 21-60 years within the EU.*

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