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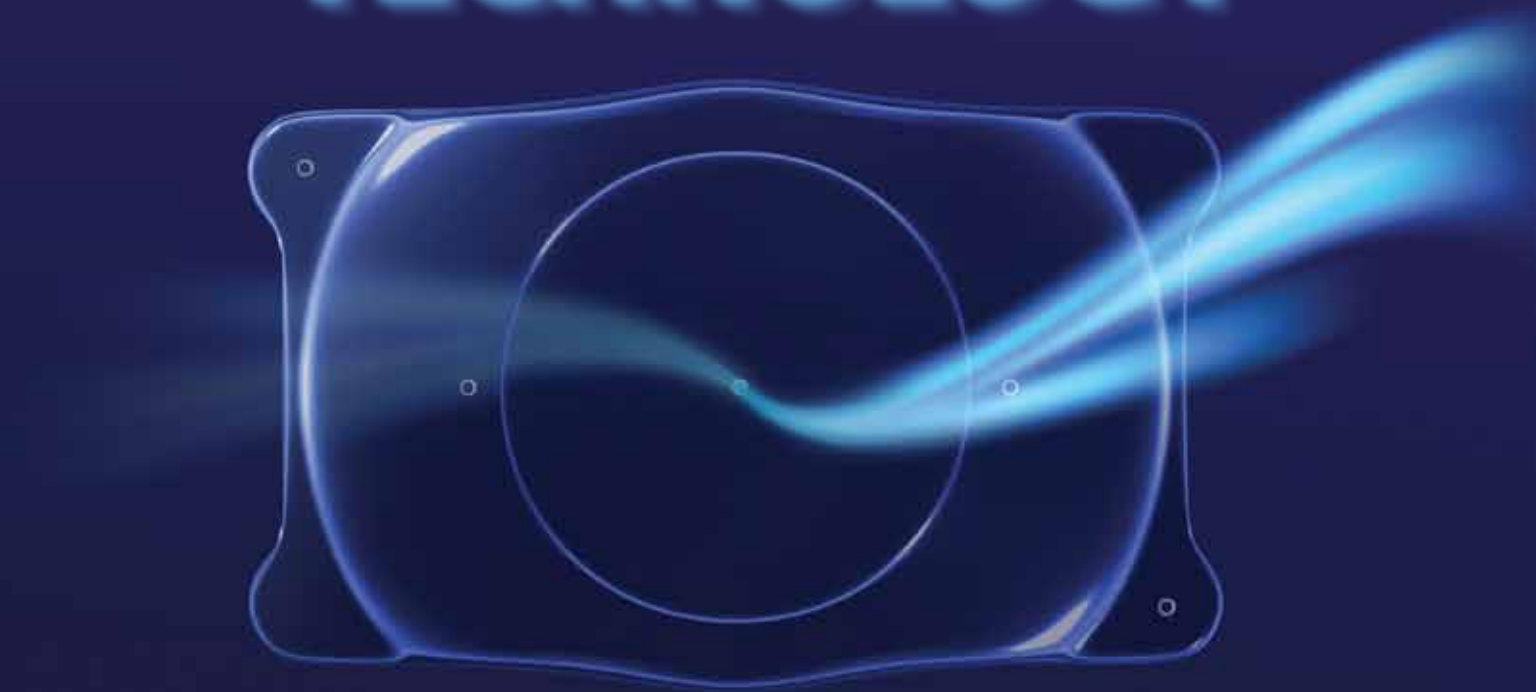
NEW OUTCOMES: VISIAN ICL CENTRAFLOW TECHNOLOGY



Highlights from the Ninth Annual Visian ICL Experts Symposium, September 2012

The Visian ICL Design: An Evolution 20 Years in the Making

Footplates, increased posterior curve, and CentraFLOW technology—the hallmarks of ICL evolution.

BY ROBERTO ZALDIVAR, MD

The first model of the Visian ICL (STAAR Surgical) was introduced exactly 20 years ago, and I had the pleasure of being among the first surgeons to implant it. Since this time, many evolutions in the lens' design have occurred, including changes to the fit and shape of the lens (Figure 1), and I have continued to implant the ICL in many of my patients with great success. Below is an overview of not only the changes made to the Visian ICL in the past 20 years but also my experience with the lens over this time.

FLASH FORWARD

Today, the latest model of the Visian ICL is the V4c. This lens includes a 360-µm KS-Aquaport* located in the center of the optic, which is designed to restore a more natural aqueous flow and eliminate the need for an iridotomy after implantation. This approach is not a new idea, however, as I originally suggested creating a hole in the middle of the optic for this specific purpose back in 1994. Just as with all good things, it comes to those who wait. Twenty years later, my idea is now a reality.

Other changes to the Visian ICL design also occurred since its introduction in 1993, mostly due to experience with the technology and improvement of our surgical techniques. Some of the larger milestones include introductions of the hyperopic ICL in March 1994 and the toric ICL in 2001. Additionally, in September 1994, STAAR added haptics to the lens design. Although the curve of the posterior face of the lens was always the same (11.3), the size of the haptics could change depending on the power of the lens. This latest innovation from STAAR, the KS-Aquaport, is another game changer because it means that we no longer have to perform an iridotomy after implantation.

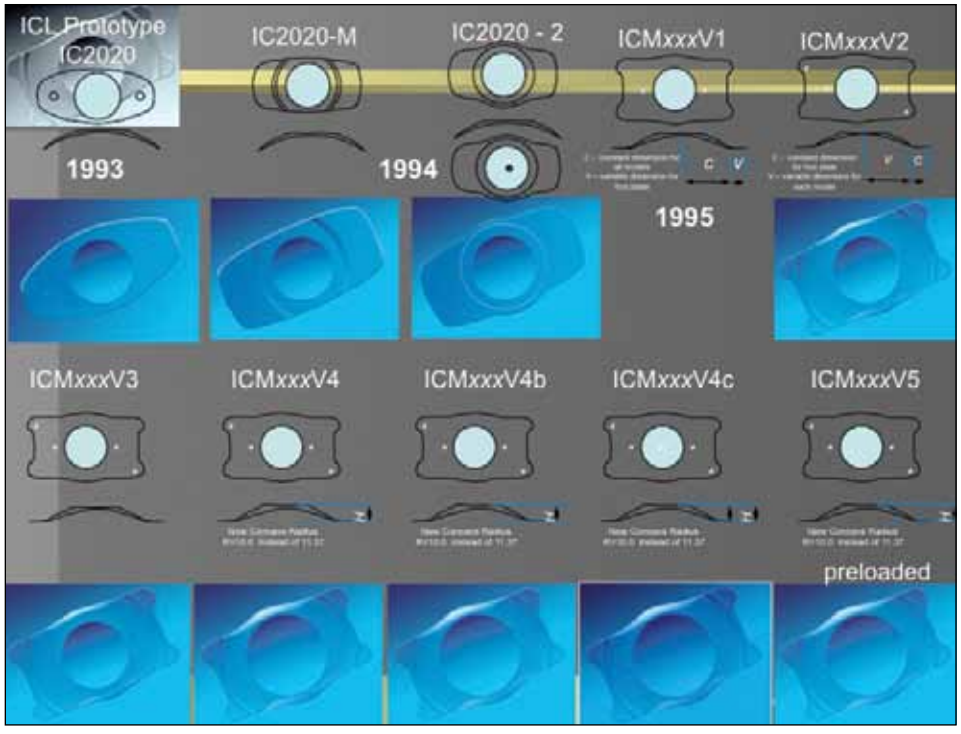


Figure 1. Evolution of the Visian ICL lens design, from its inception in 1993 to present.

CATARACT AND PUPILLARY BLOCK

Of the many factors that influenced changes to the ICL design, one of the largest driving forces was cataract and pupillary block. After gaining initial experience with the lens, we noticed that rotation was common after implantation. Therefore, haptics were added to the ICL profile to enhance stability and enforce lens position in the sulcus. Unfortunately, because the ICL sat closer to the crystalline lens, many patients developed cataract after implantation.

By the end of the 1990s, we started discussing the benefits of

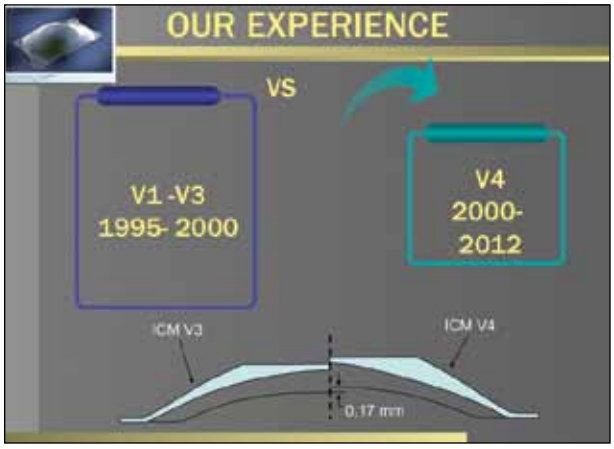


Figure 2. One change in the design of the Visian ICL increased the posterior-base curve.

leaving space between the ICL and the crystalline lens to alleviate the problem with cataract formation. One solution was the introduction of different levels of vault, which was a way to introduce more space between these two structures (Figure 2). Other reasons for cataract formation included surgical trauma and use of high viscosity ophthalmic viscosurgical devices. Since this evolution, the risk for cataract formation after ICL implantation is relatively low. Of the eyes I have implanted with the V4 model since 1999, only three have experienced cataract after surgery, representing a mere 0.036% of my cases. In each case, the eye was myopic, the cataract formed because there was no vault between the ICL and the crystalline lens, and formation occurred between 1 and 3 years after surgery.

CONCLUSION

History teaches us many marvelous things. Over the past 20 years, I have watched the evolution of the Visian ICL. From implanting the first design back in 1993 to implanting the Visian ICL with the KS-Aquaport in 2012, I have always been proud of the results I achieve with this lens. If I could remind surgeons of the two greatest innovations in the design of the Visian ICL, it would be the introduction of haptics in 1994 and the KS-Aquaport in 2011. ■

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

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2. Alfonso JF, Ferrer-Blasco T, González-Méijome JM, et al. Pupil size, white-to-white corneal diameter, and anterior chamber depth in patients with myopia. J Refract Surg. 2010;26(11):891-898.

Comparison of the Visian ICL With and Without CentraFLOW Technology

The major advantage of the Visian ICL with CentraFLOW technology is that an iridectomy is no longer needed.

BY JOSÉ F. ALFONSO, MD, PHD

Over the past 10 years, we have implanted more than 3,000 Visian ICLs (STAAR Surgical) of varying models. Beginning in 2008, we gained experience with the V4b (lens model with no KS-Aquaport), which required an intraoperative iridectomy to improve aqueous flow. The lens itself was so beneficial to patients that the additive procedure was worthwhile. However, the need to perform intraoperative iridectomy has now disappeared, thanks to the latest model, the Visian ICL with CentraFLOW technology, using the KS-Aquaport. Below we present a comparison between these two lenses.

SIMILARITIES

The Visian ICL with and without the KS-Aquaport are similar lenses in Europe. Both are packaged in the same preservation media, balanced saline solution, and the myopic versions are available in the same four standard sizes (12.1, 12.6, 13.2, and 13.7 mm). Because the lens is already fully hydrated, the final in-vivo dimensions are unchanged. Additionally, both lenses have a wide diopter range, thereby treating myopia up to 18.00 D and myopic astigmatism up to 6.00 D, including mixed astigmatism.

With both lenses, obtaining preoperative anterior segment measurements are crucial. We use optical coherence tomography (OCT) to measure the horizontal angle-to-angle anterior chamber diameter and use this measurement to calculate the size of the phakic lens. In my opinion, horizontal and vertical angle-to-angle values (0° to 180° and 90° to 270°) are more consistent and reproducible than white-to-white values obtained with either the Orbscan (Bausch + Lomb) or Pentacam (Oculus Optikgeräte GmbH). With OCT, our general approach to selecting the size of the Visian ICL is to add 1.1 mm to the angle-to-angle value.

DIFFERENCE

The difference between the two models is the addition of a 0.36-mm port located in the center of the optic, which allows a more natural aqueous flow within the eye and also eases the process of removing ophthalmic viscosurgical device (OVD) from the eye. The advantage of the central port, the KS-Aquaport, is that it eradicates the need for an iridectomy after the Visian ICL is implanted.

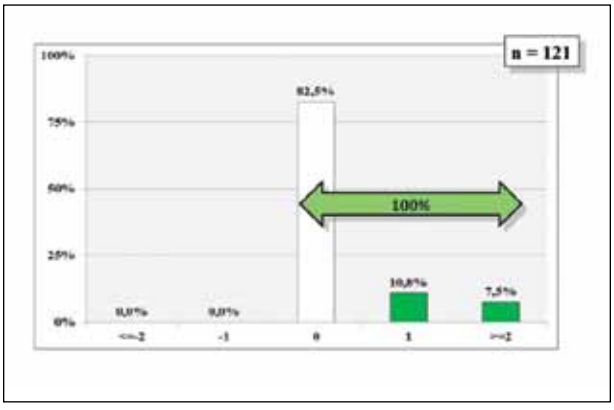

Figure 1. Postoperative distance BCVA in eyes implanted with the Visian ICL without the KS-Aquaport.

The surgical procedure with the Visian ICL with the KS-Aquaport is so easy that it is the first surgery our fellows learn to perform after cataract surgery. First, the incision is created at the steepest meridian and, after OVD is injected, a paracentesis is made as a safety maneuver. During surgery, it is possible to see the flow of aqueous humor and OVD through the KS-Aquaport.

TWO STUDIES

We conducted two studies, one on 121 myopic eyes (69 patients; mean age, 30.3 ±4.6 years) that received the Visian ICL without KS-Aquaport and one on 138 myopic eyes (70 patients; mean age, 30.5 ±4.8 years) that received the Visian ICL with KS-Aquaport. In the eyes implanted with the non–KS-Aquaport lens, surgery was completed between September 2010 and June 2011, and there was a minimum of 6 months of follow-up. At each visit, we checked visual acuity, refraction, and vault (in microns). In the KS-Aquaport group, surgery was completed between January 2012 and June 2012. Again, there was a minimum of 6 months of follow-up, and visual acuity, refraction, vault (in microns), and intraocular pressure (IOP) were

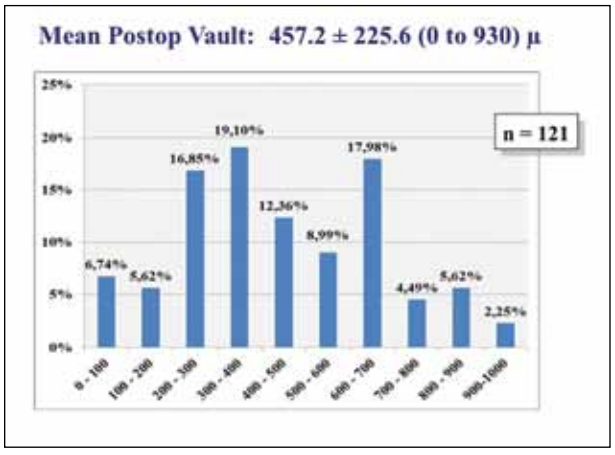

Figure 2. The mean postoperative vault in eyes implanted with the non–KS-Aquaport model.

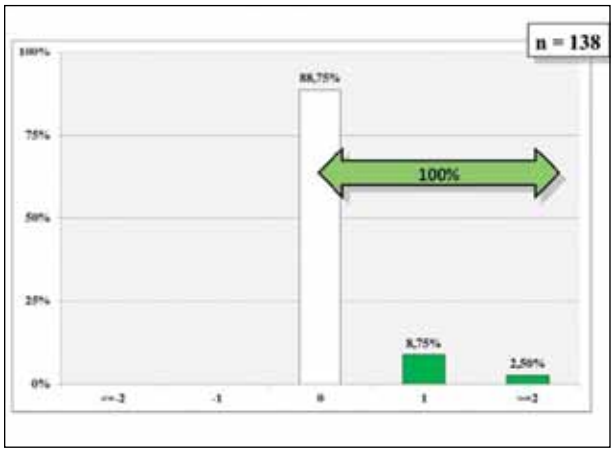

Figure 3. Distance BCVA achieved with the KS-Aquaport lens was the same or better than before surgery.

checked at each visit.

In the eyes that received the non–KS-Aquaport lens, the mean myopic correction was -8.17 ±3.35 D (range: -2.00 to -18.00 D), and the mean refractive astigmatism correction was -0.87 ±0.66 D (range: 0.00 to 2.50 D). Postoperatively, emmetropia was achieved in most cases (myopia: -0.09 ±0.28 D, range: -1.50 to 0.50 D; astigmatism: -0.26 ±0.39 D, range: -1.50 to 0.00 D), with visual acuity at the highest values (distance UCVA: 0.9 ±0.2, range: 0.4 to 1.0; distance BCVA: 1.0 ±0.1, range: 0.5 to 1.0).

Postoperatively, all eyes achieved the same or better distance BCVA than before surgery (Figure 1), and approximately 93% of eyes were within ±0.50 D of the intended refraction. The mean postoperative vault was 457.2 ±225.6 µm (range: 0 to 930 µm), with 90% of eyes being within a safe range (Figure 2). In 6.74% of eyes, there was less than 100 µm of vault; in these cases, we always consider exchanging the ICL when there is central or peripheral contact with the crystalline lens. Additionally, in 5.62% of eyes, the vault was between 100 and 200 µm, and in these cases we suggest exchanging the ICL if there is peripheral touch with the crystalline lens. Lastly, 2.25% of eyes had 900 to 1,000 µm of vault, and in these cases we monitor IOP. At the first sign of IOP rise or pupil abnormalities, we suggest exchanging the ICL.

Results with the Visian ICL with KS-Aquaport were similar. The mean myopic correction was -8.16 ±2.54 D (range: -3.00 to -17.50 D), and the mean refractive astigmatism correction was -1.16 ±0.64 D (range: -0.25 to 3.00 D). Again, emmetropia was achieved in the majority of cases after surgery (myopia: -0.01 ±0.10 D, range: -0.50 to 0.00 D; astigmatism: -0.20 ±0.40 D, range: -1.75 to 0.00 D) and both distance UCVA and BCVA was excellent (0.90 ±0.10, range: 0.7 to 1.0; 0.99 ±0.05, range: 0.8 to 1.0, respectively).

Predictability with the Visian ICL with KS-Aquaport was better than with the previous model, with almost 99% of eyes achieving ±0.50 D of the intended refraction. All eyes were within ±1.00 D of intended refraction and also achieved the same or better distance BCVA than before surgery (Figure 3). Additionally, the IOP remained stable after surgery, and the mean vault was greater than it was with the non–KS-Aquaport model (488.90 ±211.47 µm; range: 0.00 to 980.00 µm). The percentage of eyes with low and high vault were similar in both groups; however, the KS-Aquaport group has the added advantage of avoiding angle closure due to the continuous flow of aqueous humor through the central port. Therefore, we can conclude that high vaults are well tolerated. Additionally, because there is no need for an iridectomy, we can better protect the crystalline lens.

CONCLUSION

Although we enjoyed much success with the Visian ICL without the KS-Aquaport, the latest model, which incorporates the central port, simplifies surgery even further because there is no longer a need to perform an intraoperative iridectomy. This lens is an effective, safe, and predictable alternative for the correction of myopia. ■

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The Benefits of an Iridotomy-Free ICL

This surgeon overviews his first 130 cases with the Visian ICL with the KS-Aquaport.

BY ERIK L. MERTENS, MD, FEBOPHTH

In June 2011, I transitioned from implanting the Visian ICL to the Visian ICL model that incorporates the KS-Aquaport (STAAR Surgical). Physically, not much is different between these two lenses; procedurally, however, one small change has made all the difference in my surgical technique. In short, the only variation between these lenses is one small hole located in the center of the optic.

This centralized hole, the KS-Aquaport, is designed to eliminate the need for an iridotomy after implantation by restoring a more natural aqueous flow within the eye. Two other holes, located on either side of the optic, are part of both designs, which facilitate easier removal of ophthalmic viscosurgical device (OVD) after surgery. These two holes may also allow aqueous to flow over a wider surface area of the crystalline lens.

After reviewing my first 130 cases with the Visian ICL with KS-Aquaport, I can easily say that, collectively, these three holes ensure that I perform safer and quicker surgery and provide patients with better surgical results. Most notably, this design eliminates the need for and issues associated with subsequent iridotomy and can potentially reduce endothelial cell loss. Therefore, Visian ICL implantation is now more like a LASIK procedure.

A REVIEW OF THE RESULTS

Since June 2011, I have implanted 98 spheric and 32 toric Visian ICL lenses with the KS-Aquaport. In every case, there was no change in the refractive outcome and no intraocular pressure rises postoperatively. The mean preoperative spherical equivalent was -6.15 ±2.72 D (range: -1.25 to -15.75 D), the mean preoperative sphere was -5.60 ±2.83 D (range: 0.00 to -14.75 D), the mean preoperative cylinder was -1.10 ±1.24 D (range: -6.00 to 0.00 D), and the mean scotopic pupil size was 6.46 ±2.83 mm (range: 4.5 to 9.0 mm).

A total of 128 eyes were available for 3-month follow-up. The mean improvement in sphere, cylinder, and spherical equivalent was 0.03 ±0.16 D (range: -0.25 to 1.25 D), -0.04 ±0.16 D (range: -1.25 to 0.00 D), and 0.01 ±0.133 D (range: -0.25 to 1.25 D), respectively. At 6 months, 80 eyes were available for follow-up. At this time, the mean improvement was 0.01 ±0.07 D (range: -0.25 to 0.50 D), -0.04 ±0.15 D (range: -1.00 to 0.00 D), and -0.01 ±0.06 D (range: -0.25 to 0.25 D), respectively. From these results, it is easy to see that the Visian ICL with the KS-Aquaport is doing a great job at correcting refractive error (Figure 1).

Parameter	Mean±SD (range), № eyes
Age (Years)	31.66±7.4 (18 to 47), 130
ACD (mm)	3.25±0.24 (2.8 to 3.95), 130
WTW (mm)	11.90±0.37 (11 to 12.7), 130
Scotopic Pupil (mm)	6.46±0.80 (4.5 to 9), 130
Sphere preop (Diopters)	-5.60±2.83 (-14.75 to 0.00), 130
Cylinder preop (Diopters)	-1.11±1.24 (-6.00 to 0.00), 130
SEQ preop(Diopters)	-6.15±2.72 (-15.75 to -1.25), 130
Sphere 3 months	0.03±0.16 (-0.25 to 1.25), 128
Cylinder 3 months	-0.04±0.16 (-1.25 to 0.00), 128
SEQ postop 3 months (Diopters)	0.01±0.133 (-0.25 to 1.25),128
Sphere 6 months	0.01±0.07 (-0.25 to 0.50), 80
Cylinder 6 months	-0.04±0.15 (-1.00 to 0.00), 80
SEQ postop 6 months (Diopters)	-0.01±0.06 (-0.25 to 0.25), 80

Figure 1. Dr. Merten's study parameters and outcomes.

We also looked at efficacy. At 6 months, the postoperative UCVA and BCVA were almost identical to the preoperative BCVA, with an efficacy index of 1.05 (Figure 2). Additionally, 5.00% of eyes gained 1 line and 28.75% gained 2 lines of BCVA, whereas 66.25% of patients remained unchanged 6 months after implantation. Lastly, with regard to predictability, there is a nice tight line over the whole range of correction (Figure 3), as 94.5% of patients achieved a spherical equivalent within ±0.50 D and 98.4% achieved a spherical equivalent within ±1.00 D at 3 months. At 6 months, 96.2% and 100% of patients achieved these same spherical equivalent ranges (Figure 4).

A REVIEW OF THE PROCEDURE

Implantation of the Visian ICL with the KS-Aquaport is extremely straightforward and a video demonstration can be viewed at eyetube.net/?v=nebod. After the patient is draped, both myself and my nurse check the lens to ensure it is the

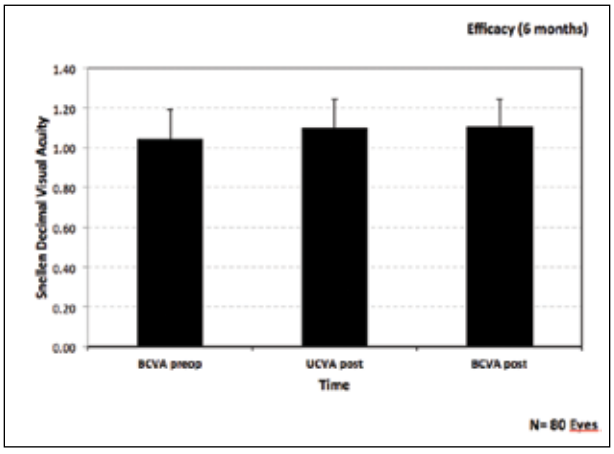

Figure 2. Efficacy at 6 months for eyes implanted with the Visian ICL with the KS-Aquaport.

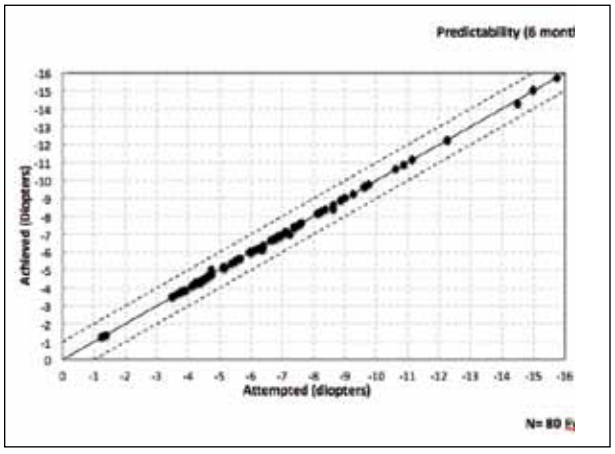

Figure 3. Predictability at 3 months for eyes implanted with the Visian ICL with the KS-Aquaport.

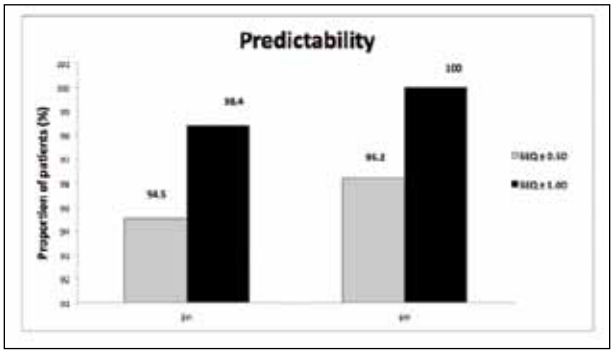

Figure 4. Predictability at 6 months for eyes implanted with the Visian ICL with the KS-Aquaport.

correct lens. Then, under the microscope, it is loaded into an injector and the cartridge is filled with methylcellulose. I like to use a forceps to pull the ICL into the top of the cartridge until all three holes are visible.

The next step is to make a 600 µ groove as a three-step incision. This provides a watertight incision at the end of surgery. During injection of the ICL, I recommend inserting the lens slowly near the end of implantation, and I also recommend tucking the ICL haptics underneath the iris. Once the lens is in place, the OVD is irrigated from the anterior chamber while directing the irrigation port toward the KS-Aquaport.

CONCLUSION

After assessing my results in 130 eyes implanted with the Visian ICL that incorporates the KS-Aquaport, I have concluded that this lens has good efficacy, predictability, and safety up to 6 months postoperative. This lens can be implanted to successfully correct myopia and astigmatism, and patients are happy with their visual outcomes. From my point of view, this procedure is quicker and easier than ever before, thanks to the addition of the KS-Aquaport in the central optic and the two additional holes on either side of the optic. This lens is my first choice in patients who opt for a phakic IOL to correct their refractive errors.

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Success With Introducing Visian ICL CentraFLOW Technology

Following these three pointers may make your transition easier.

BY BOON SIONG LIM

At Vista Eye Specialist, we offer patients the opportunity for spectacle independence through a variety of surgical methods including bladeless LASIK, bladeless cataract surgery with the option for premium IOLs, the Kamra corneal inlay (AcuFocus, Inc.), and the Visian ICL (STAAR Surgical). Our experience with this phakic IOL began in 2005, and we have implanted more than 600 lenses, including in six of our staff members, and enjoy more than 90% of the market share in Malaysia. In 2011, our surgeons implanted 180 ICLs. Below I overview three keys to success for implementing the Visian ICL with KS-Aquaport successfully into a refractive practice.

THREE KEYS TO SUCCESS

No. 1: Committing 100% to new technology. When implementing a new technology into practice, it is crucial that everyone—the entire staff and the surgeon(s)—believes in its success and how it benefits patients. We believe that no longer needing to perform Nd:YAG peripheral iridectomy prior to surgery is a significant benefit not only for the patient but for the practice as well. In a recent survey, the majority of our patients indicated that peripheral iridectomy was one of the possible barriers to proceed with surgery and, if they did proceed with surgery, one of the most unpleasant and painful parts of the ICL journey. Since we introduced the KS-Aquaport technology in January 2012, we have achieved a 100% conversion rate from the previous V4 models, including one of our staff receiving the new model lens.

No. 2: Executing proactively and effectively. One method is to set up a project team made up of staff from key departments including counselors, optometrists, and marketing. This team works with each department to facilitate execution of this new technology, ensuring more thorough dissemination of information and uniform understanding of the technology's nuances, including finding out if patients are willing to pay more for the procedure. This is key to developing the right marketing and pricing strategies. By truly understanding the technology and translating it into actual benefits that relate to patients, it accelerates acceptance of and conversion to the Visian ICL with KS-Aquaport. Other tasks of the project team include designing and implementing a marketing strategy to recruit new patients, facilitating operational and administrative changes, and soliciting feedback for the continuous fine-tuning of the strategy. We have found that marketing this lens as *HD Vision* has worked well to gain patient interest, and we have been able to refine the pricing strategy, improving our profit margin by 15%. Between January and August 2012, our LASIK volume went down by 13%, in line with the slowdown of global LASIK volumes, and, with our combined marketing effort and staff commitment, our ICL volume went up by 16%.

No. 3: Working with the provider. Aligning strategies and beliefs with a company enhances the working relationship and minimizes misunderstandings and mismatched priorities and messaging. STAAR Surgical helped smooth the learning curve by sharing best practices, facilitating training for staff, and meeting with the marketing team.

MORE EFFICIENT PATIENT FLOW

We began implanting the Visian ICL with KS-Aquaport in January 2012, completing 17 cases on the first day. Because there is no longer a need to perform a peripheral iridectomy, patient flow is more efficient and chair times have decreased, freeing surgeon time for other patients and matters. Our experience also shows that patients have a similar *wow* effect that has become known with LASIK, which has increased our word-of-mouth referral rate for the new model lens. This may partly be due to patient desire for the newest technology, but the biggest reason is that the results speak for themselves—this procedure provides patients with exceptional visual quality and refractive correction after surgery.

Gaining any advantage over your competitors is important. One way to ensure that you can have the upper hand is by introducing and successfully implementing new products such as the Visian ICL with KS-Aquaport. In addition to the three key points listed above, which should help a practice to start using the KS-Aquaport model effectively, remember to put your patients' needs and wants first. Sending informational brochures, having a succinct and informative website, and scheduling follow-up calls are ways to ensure the patient knows that you care about his or her needs and have his or her best interest at heart. ■

Boon Siong Lim is the CEO of VISTA Eye Specialist in Malaysia. He states that he has no financial interest in the products or companies mentioned. He may be reached at tel: +60 12 283 7927; e-mail: boonsiong@vista.com.my.