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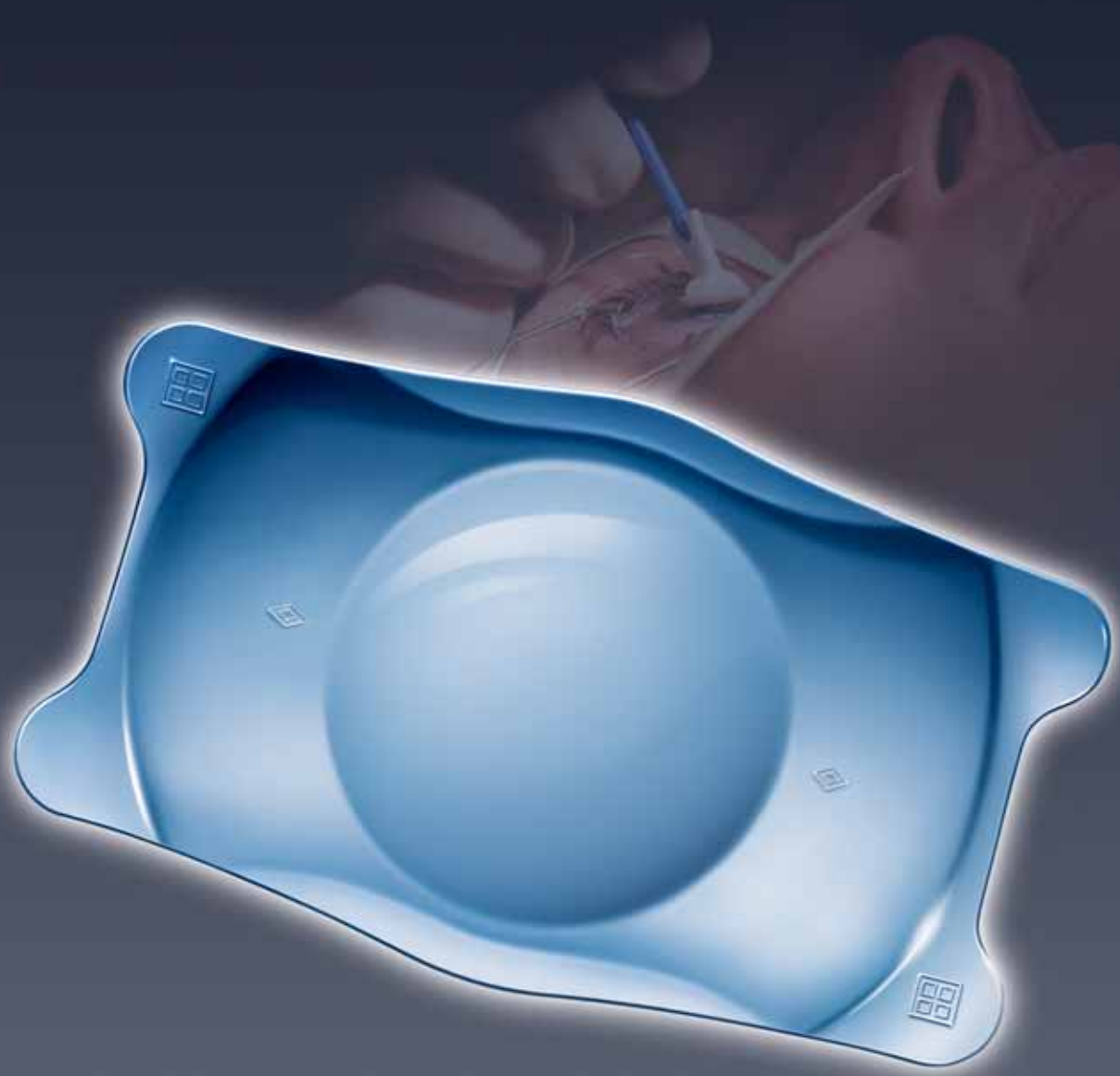

The Visian ICL

Spotlight on the 2009 ICL / Toric ICL Experts Symposium

Sponsored by an unrestricted educational grant from STAAR Surgical

Spotlight on the Visian ICL

Recently, STAAR Surgical (Monrovia, California) hosted an experts symposium on the Visian ICL and Toric ICL. This 2-day spotlight session featured business practice models, clinical data, and new concepts behind the use of phakic IOLs. This supplement highlights information from six presentations made during the symposium, beginning with an overview of Mark Rosenberg's successful business model at the Barnet Dulaney Perkins Eye Center in Phoenix.

Although many refractive procedures sucessfully improve visual acuity, quality of vision may vary significantly. The Visian ICL provides vision correction that goes beyond LASIK, with sharper, immediate quality of vision.

The Visian ICL is the obvious choice for patients who need and expect high-quality results, such as those who lead an active lifestyle. This lens is also available in a toric model for astigmatism correction.

Refractive Business Models in Today's Economic Environment

As phakic IOL volume increases, so will your profitability margin.

BY MARK ROSENBERG

Any time you consider adding a new technology to your practice, you must acknowledge the realistic potential for profitability. From a business prospective and when incorporated correctly, phakic IOLs such as the Visian ICL (STAAR Surgical, Monrovia, California) have the potential to increase the profitability of your practice. If you are not yet vested with phakic IOLs in your business model, you will certainly be left behind, thus jeopardizing the position of your business. This market will undoubtedly change with or without you, and the future of refractive surgery is lens-based—more specifically, phakic IOLs.

ARE PHAKIC IOLs MORE PROFITABLE?

One area that is often overlooked in any profit-and-loss analysis is the cost associated with surgical risks. Implanting a phakic IOL carries a much lower risk, for the surgeon and the patient, compared with LASIK. They have no association with flap-related complications, ectasia, decentration, poor night vision, and dry eye. However, phakic IOLs may cause cataract formation or infection in rare circumstances.

A financial model will help demonstrate the impact of incorporating phakic IOLs, in addition to LASIK, on your bottom line. Consider your fixed overhead including the facility rent and maintenance, counselors, physicians, and advertising/marketing, and procedural costs for LASIK and ICLs. Even at a pretty aggressive price point (we charge $2,995 USD for the ICL and $1,995 USD for LASIK), ICLs are more profitable. Since increasing the number of phakic IOLs and decreasing the number of LASIK procedures we perform, our profit margin has increased.

Using a self-designed refractive surgery profitability model to assess the profitability of phakic IOLs versus LASIK, we discovered that our price point for phakic IOLs must be within $500 to $1,000 of our most expensive LASIK procedure, thus ensuring we are not pricing ourselves out of the market.

The first step to incorporating the phakic IOL into your practice is to learn how to introduce it to patients. Many practices get caught up in offering phakic IOLs as the procedure of exclusion, meaning it is only offered if the patient is not a candidate for LASIK. The better strategy is to present the ICL as a premium solution to vision correction. At the Barnet Dulaney Perkins Eye Center in Phoenix, we advocate the phakic IOL for all ranges of correction, including moderate and high myopia.

Keeping this in mind, it is important to introduce the phakic IOL at the same time you discuss LASIK. Patients in my practice have been extremely interested in the ICL—in part because the procedure is reversible. If removal is necessary, the eye will return to its preoperative state.

In 2010, the number of people in generation Y will equal that of the baby boomer generation. Marketing to this generation is challenging, but it has to be mastered if you expect to stay in business. Don't be afraid to use new social media outlets, including Facebook, Twitter, and YouTube.

The No. 1 piece of advice I can give you is to present the ICL as a premium solution; patients will respond because it creates excitement and enthusiasm and brings impulse back into the purchase. In the end, you will find that the ICL is more profitable than LASIK and has less sensitivity to the current economic status. ■

Mark Rosenberg is the Chief Executive Officer of the Barnet Dulaney Perkins Eye Center, Phoenix. Mr. Rosenberg states that he has no financial interest in the products or companies mentioned. He may be reached at tel: +602 508 4808; e-mail: mrosenberg@bdpec.com.

Toric ICL in Eyes With Stable Keratoconus

Toric ICL induces no changes in corneal topography or corneal HOAs in eyes with stable keratoconus.

BY ALAA EL-DANASOURY, MD, FRCS

Laser vision correction in eyes with keratoconus is a strong contraindication. However, the ICL and Toric ICL (STAAR Surgical, Monrovia, California), being posterior phakic implants, do not act on the cornea. This represents a safe and effective option to treat the refractive error of patients with stable keratoconus.

A total of 37 eyes with stable keratoconus for at least 2 years (confirmed with refraction and/or topography) received the Toric ICL for the purpose of correcting the compound myopic astigmatism associated with stable keratoconus. Twenty-three patients were enrolled in the study; they were at least 21 years of age and intolerant to rigid contact lenses. Additionally, all patients had satisfactory quality of vision. Baseline spherical equivalent ranged from -4.00 to -16.00 D, with a refractive cylinder between 1.00 and 5.00 D. BCVA was at least 20/40 in all eyes. A total of 29 eyes completed the 12-month follow-up; 21 eyes completed 24-month follow-up.

On day 1, early visual recovery was 20/20 UCVA in 33.3% of patients, 20/30 in 81% of patients, and 20/60 or better in 100% of patients (Figure 1). After 12 months, 37.9% of patients gained 1 line of BCVA, with 31% of patients having the same BCVA as they did preoperatively. Additionally, 27.6% gained 2 or more lines of vision.

With respect to changes in simulated keratometry (sim-K) readings, the mean sim-K was 48.60 ±1.44 D at baseline and 48.80 ±1.10 D at 12 months (Figure 2). We also studied the indices of keratoconus and noticed no change in the prediction or severity index of keratoconus. These findings indicate that corneal keratometry does not change after implantation of the Toric ICL.

We also looked at corneal and total higher-order aberrations (HOAs) and compared results in patients with myopia versus keratoconus. What we found is that rates of HOAs did not change significantly in either group of patients. For patients with keratoconus, the root-mean-square (RMS) value for preoperative corneal HOAs was 0.65; it was 0.75, 0.60, 0.63, and 0.73 at months 1, 3, 6, and 12, respectively. Changes in total ocular HOAs in eyes with keratoconus are similar to that of changes in myopic eyes. The RMS value for preoperative total HOAs was 0.69; it was 1.39, 1.38, 1.55, and 1.47 at 1, 3, 6, and 12 months, respectively.

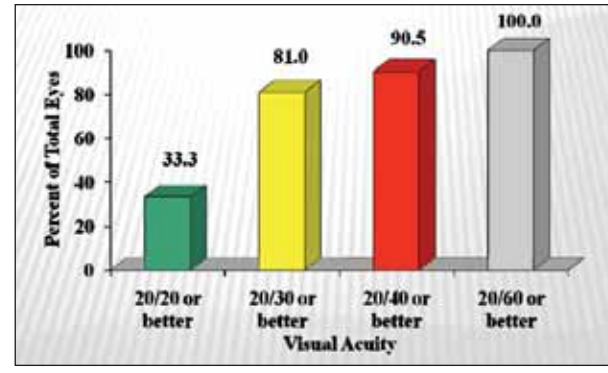

Figure 1. Postoperative UCVA at day 1.

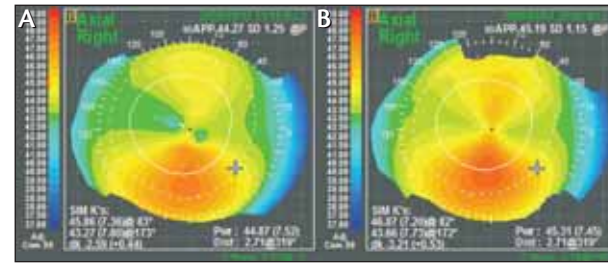

Figure 2. Changes in sim-K at (A) baseline and (B) 12 months were minimal.

CONCLUSION

We have noticed that the positive spherical aberration added into the eye via Toric ICL implantation is likely helpful in patients with keratoconus. Findings indicate that 12 months after implantation of the Toric ICL in eyes with keratoconus there are:

(1) no induced changes in corneal topography,

(2) no induced changes in corneal HOAs, and

(3) changes in total ocular HOAs are similar to those induced in myopic eyes.

The Toric ICL is safe, effective, and predictable. With high patient satisfaction, I believe the Toric ICL is a great option for patients with stable keratoconus. ■

Alaa El-Danasoury, MD, FRCS, is Chief of Refractive Surgery at Maghrabi Eye Hospital, Saudi Arabia. Dr. El-Danasoury states that he is a paid consultant to STAAR Surgical. He may be reached at e-mail: malaa@magrabi.com.sa.

Long-Term Analysis of the Toric ICL

For best results, stay within the company-recommended guidelines for implantation.

BY HOWARD V. GIMBEL, MD, MPH, FRCSC

Over the course of 5 years, I have implanted the Toric ICL (STAAR Surgical, Monrovia, California) in 728 eyes. In addition to being a safe and effective option for pellucid marginal degeneration and keratoconus, results with the Toric ICL are extremely predictable, with a low incidence of complications. This article summarizes our refractive and visual outcomes in eyes with compound myopic astigmatism implanted with the Toric ICL between 2003 and 2008. These cases were completed before we added sulcus-to-sulcus measurements using ultrasonic biomicroscopy (UBM).

The mean preoperative sphere and cylinder were -9.25 D and -1.91 D, respectively. After a minimum of 1-year follow-up, mean sphere and cylinder improved to 0.18 D and -0.40 D, respectively. Additionally, 74.3% of patients maintained their preoperative BCVA, and 19.2% gained 1 or more lines of vision (Figure 1).

Of the 728 eyes, only 12 (1.6%) developed cataract after a mean follow up of 3.1 years. It is important to note that this opacity rate is in line with reported US Food and Drug Administration (FDA) data.[1] In our series, the risk factors for developing an opacity after Toric ICL implantation included: shallow anterior chamber, older age, small corneal white-to-white measurement, low vaulting, and high Toric ICL power. We also experienced a low incidence of removal and replacement; only 17 (2.3%) required removal and replacement due to higher- and lower-than-ideal ICL vaulting. We have observed that higher-than-ideal vaulting occurs more often at a younger age and with eyes having a large white-to-white, deep anterior chamber depth, and high Toric ICL power. Additionally, we have determined that low vaulting is more often associated with eyes having borderline to very small anterior chamber depths, smaller white-to-whites, and ICL length chosen to be 0.5 smaller than the white-to-white.

Ideal vaulting is essential to the success of Toric ICL implantation (Figure 2). After a short learning curve, the rate of cataract and removal and replacement has declined.

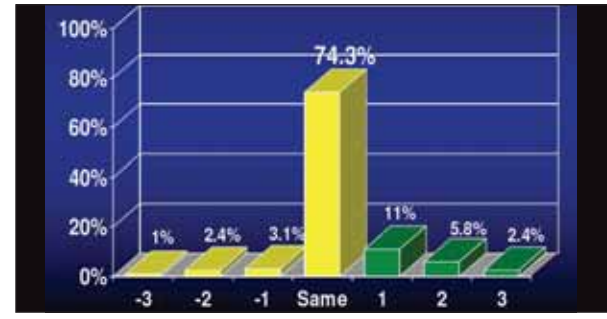

Figure 1. In this series of Toric ICL patients, 74.3% maintained their preoperative BCVA.

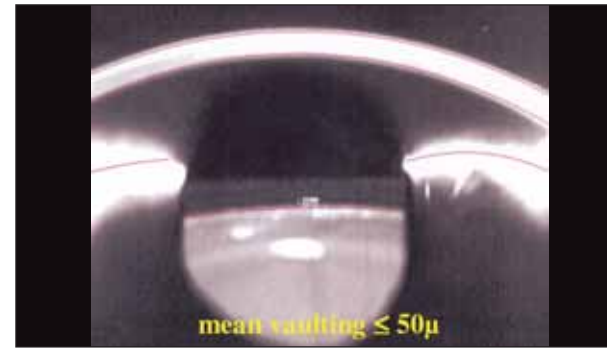

Figure 2. Mean vaulting is 50 µm or less.

CONCLUSION

My total experience with the Toric ICL includes 728 eyes of myopes with astigmatism and more than 20 cases of Toric ICL implantation in eyes with keratoconus, keratectasia, or pellucid marginal degeneration. Our rate of complications with the Toric ICL was low and in line with adverse events reported in the FDA clinical studies. Age and anterior chamber depth seems to play an important role in the outcome. Keeping within the company-recommended range of ICL implantation as well as determining ICL size based on 2 methods (white-to-white and UBM of the sulcus) is what I would recommend to ICL users. By doing so, the rate of complications, removal, and replacements should decrease. ■

Howard V. Gimbel, MD, MPH, FRCSC, is Executive Medical Director of the Gimbel Eye Centre, Calgary, Alberta, Canada. Dr. Gimbel states that he has no financial interest in the products or companies mentioned. He may be reached at e-mail: hvgimbel@gimbel.com.

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New Concepts in Biomechanical and Wound Healing

The wound never truly heals after LASIK.

BY HENRY F. EDELHAUSER, PHD

We recently conducted a study of 233 post-LASIK corneas to examine the histologic, ultrastructural, and immunohistologic findings as well as the physiology and wound strength of these corneas compared with controls. What we found was that even 15 years after LASIK, the loss of wound strength never recovered and the wound itself never healed back to normal.

The corneas, obtained from USA Eye Banks, were from eyes of 122 post-mortem patients who underwent LASIK as early as 1 week and as late as 15 years prior to death. Evaluations were performed with laser capture microscopy, transmission electron microscopy, scanning electron microscopy, or immunofluorescence studies. All corneas had lamellar interface scars between 2 and 8 µm thick, which were most difficult to see after 3 years or later postoperatively. With laser capture microscopy, we were able to locate more hypercellular, thicker scarring at the wound margin (Figure 1); hypocellular, thinner scarring was located at the paracentral and central regions of the scar (Figure 2). In approximately 50% of the cases, variable epithelial ingrowth was determined.

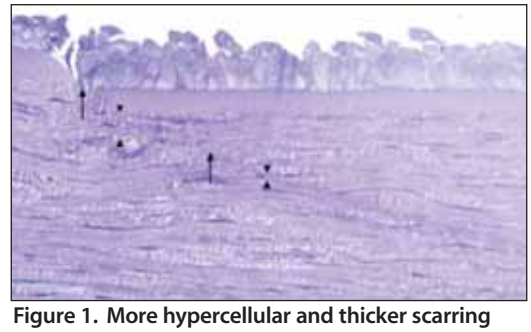

Figure 1. More hypercellular and thicker scarring was located at the wound margin.

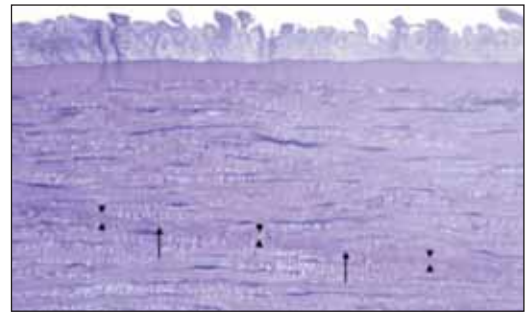

Figure 2. Hypocellular, thinner scarring was located in the paracentral and central regions.

Transmission electron microscopy of the wound margin showed, 3 years postoperatively, that an initial 70-µm wound heals with a 5-µm hypercellular fibrotic stromal scar. At the center of the wound, the hypocellular primitive stromal scar is also 5 µm thick.

LOW BREAKING FORCE

We performed a quantitative wound strength test by fixating the anterior and posterior lamella of the corneal-scleral strip to two 5-mm hooks. The posterior lamellar layer included the residual stromal LASIK bed, and the anterior lamellar layer included the LASIK flap. Compared with controls, cohesive tensile wound strength measurements, also known as the *breaking force*, were lower in post-LASIK versus normal corneas. Additionally, from the literature and our own experimental studies from human LASIK corneas, we found clinical incidence of interface fluid syndrome from high intraocular pressure in 67 eyes of 41 patients and endothelial cell dysfunction in 13 eyes of 12 patients. In such cases, there is a risk for corneal edema.

Interface fluid syndrome ranges from mild to severe. In mild cases, the scar is thicker but there is no inflammation of the cornea. When it progresses to moderate interface fluid syndrome, focal fluid pockets are apparent, with hydropic degeneration of the surrounding keratocytes; focal minimal inflammation may be present. In the most severe cases, the fluid pockets become diffuse and confluent, with hydropic degeneration of surrounding keratocytes and the possible presence of minimal inflammation.

What we found when studying the histopathology of 233 post-mortem, post-LASIK corneas is that the wound is weak and it never heals normally. The findings also suggest that the cornea is at more risk for edema and interface fluid syndrome after LASIK. ■

Henry F. Edelhauser, PhD, practices at the Emory Eye Center, Atlanta. Dr. Edelhauser states that he is a consultant to STAAR Surgical during FDA meetings as well as a consultant to Vision Care and Sanofi-Aventis. He may be reached at e-mail: ophthfe@emory.edu.

Ultrasound and OCT for ICL Size Selection

There is a correlation between ICL length, sulcus size, and vault.

BY ROBERTO ZALDIVAR, MD

Previously, noted complications with posterior chamber lens implantation were associated with the surgical procedure, the need for iridectomy, and sizing selection of the ICL. However, I began to apply this technology to my ICL patients and I found that the complications rate has decreased. Today, I measure both the white-to-white and sulcus and look at the differences to decide the size of the ICL (STAAR Surgical, Monrovia, California). Furthermore, ocular coherence tomography (OCT) helps us to determine if there is enough room and angles to accomodate an ICL. It is also used to postoperatively assess the ICL's vault. The work done with these two units has allowed us to answer some questions we had continually asked ourselves.

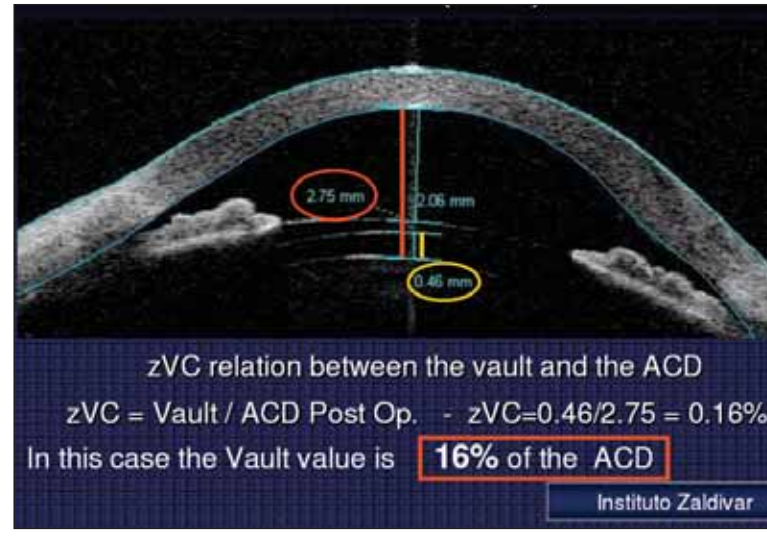

Figure 1. The optimum value of the Zaldivar vault coefficient ranges from 15% to 30%.

QUESTIONS ANSWERED

The questions I had continually asked myself before posterior chamber IOL implantation were:

• **What is the average size of white-to-white and the sulcus?** Depending on the modality used, the average white-to-white is between 11.77 and 11.95 mm. With a manual reading, it was 11.95 mm and with Orbscan (Bausch & Lomb, Rochester, New York), it was 11.77 mm; with ultrasound, sulcus-to-sulcus was 11.56 mm.

• **Is there any correlation between the ICL length, sulcus size, and resulting vault?** The answer is yes—as the difference between the ICL length and sulcus size increases, the vault will also increase. In other words, the longer the length of the ICL, the higher the resulting vault will be. Also, the greater the difference between the ICL length and the sulcus, where the sulcus is smaller, the greater the resulting vault.

ZALDIVAR VAULT COEFFICIENT

I have calculated the relationship between the vault and the internal anterior chamber depth, which I call the *Zaldivar vault coefficient* (Figure 1). This coefficient is the relationship that exists (as a percentage) between the total deepness of the anterior chamber related to the distance between the posterior surface of the ICL and the anterior capsule of the crystalline lens. This measurement is tacked by the postoperative OCT measurement. The optimum value ranges between 15% and 30%. The vault varies as the ICL size increases and as the sulcus size decreases.

CONCLUSION

In addition to calculating the white-to-white and sulcus size, I compare the lengths of each. I also look at the length of the ICL versus the white-to-white and versus the sulcus size. These calculations have allowed me to better assess the proper ICL size for any given patient. My results with the ICL after incorporating the use of ultrasound and OCT have dramatically improved. I would recommend adding these techniques to your practice. ■

Roberto Zaldivar, MD, is the Scientific Director of the Instituto Zaldivar, Mendoza, Argentina. Dr. Zaldivar states that he is a consultant to STAAR Surgical. He may be reached at tel: +54 261 441 9999; e-mail: zaldivar@zaldivar.com.

ICL Versus Laser Vision Correction in the Armed Forces

More soldiers are choosing the ICL and referring it to others.

BY COL. SCOTT D. BARNES, MD

Soldiers in the US Army need an alternative to spectacles and contact lenses, for obvious reasons. For example, due to the high incidence of ocular trauma and poor hygiene sometimes associated with combat, soldiers are restricted from using contact lenses in overseas deployment. Laser vision correction procedures are a viable option, with more than 100,000 procedures performed on soldiers in the US Army; however, the ICL (STAAR Surgical, Monrovia, California) is gaining interest in this population.

Surface procedures such as PRK and LASEK account for more than 90% of all laser vision correction procedures performed on US soldiers; LASIK accounts for less than 10% (Figure 1). Patients who undergo laser vision correction usually say their vision is better than with glasses but may not be as crisp as with their contact lenses. At Warfighter Refractive Eye Surgery Clinic in Fort Bragg, North Carolina, more than 36,000 eyes have undergone some form of laser vision correction, approximately 2,500 of which were LASIK. Why are more soliders not selecting LASIK for correction of refractive errors? The answer is that the technology used for laser vision correction has some unique limitations for the US Army, and the threat of complications—including flap dislocation and LASIK trauma—is real.

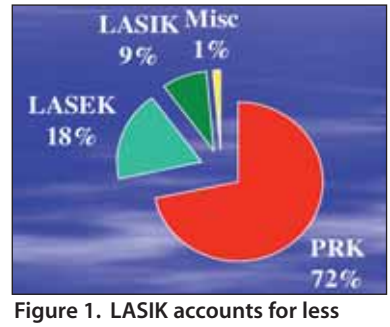

Figure 1. LASIK accounts for less than 10% of laser vision correction procedures performed in the US Army.

Figure 2. Clinically significant corneal haze can occur despite the use of MMC.

Although corneal haze and scarring is not a true element of LASIK, it is present in some cases of surface ablation. Many surgeons elect to use mitomycin C (MMC) prophylactically, but this is not the perfect answer. We have seen clinically significant corneal haze requiring corneal scraping in seven soldiers who underwent surface ablation with MMC elsewhere (Figure 2). Instead, we have opted to use alcohol-assisted LASEK, which brought our haze rate down to 0.7% from 4% when we were doing PRK in those with greater than 4.00 D of myopia or greater than 1.50 D of hyperopia or astigmatism. So while LASEK is a good option, it is not the perfect answer in all cases. I believe that the ICL is a more attractive option for refractive correction in a number of our soldiers.

ADVANTAGES OF ICL

Ten US soldiers received the ICL implant as a test group in early 2006. Results of this test group led to an expanded multicenter trial that began in the summer of 2007. Since this time, more than 500 ICLs have been implanted at Fort Bragg alone. Such cases include soldiers who are required to parachute, dive, and participate in combatives training on a daily basis. We have not seen one instance of a traumatic injury to the ICL or to the eye as a result of the ICL, and patient satisfaction is extremely high. In fact, soldiers who already have ICLs implanted are starting to refer other soldiers. It is not uncommon to hear a soldier say that his vision is much better with the ICL than it was when he wore contact lenses.

CONCLUSION

We have treated US soldiers who require -3.00 to -12.00 D of correction with the ICL. Approximately 30% of the patients we treat have less than or equal to 6.00 D of myopia. We have to remember that not everyone is a candidate for laser vision correction; an irregular, thin, or flat cornea is generally a contraindication. Additionally, the presence of certain corneal scars would generally make someone a poor candidate. In these patients, the ICL may be a perfect solution for refractive correction, and in many cases, it is the best solution for some of our soldiers. ■

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