WHY YOU SHOULD CONSIDER ADOPTING PHAKIC IOLS

QUALITY OF LIFE AND QUALITY OF VISION ARE TWO PRIME FACTORS IN WEIGHING THIS REFRACTIVE SURGICAL CHOICE.

BY MARK PACKER, MD, FACS

In my experience, no patients are happier, nor are any more grateful for your services, than those who have received phakic IOL implants. There are many reasons to consider implanting phakic IOLs in your patients seeking refractive surgery. This article lays out some of those reasons and includes a nonexhaustive review of the literature demonstrating the efficacy and safety of one particular phakic IOL model.

In the United States, at present, there are two FDA-approved phakic IOL platforms: the Visian ICL (STAAR Surgical) and the Verisyse Phakic IOL (Johnson & Johnson Vision). My experience with phakic IOLs is mainly limited to the former, and therefore so is the scope of this article. Some of the statements that follow can be applied more broadly to both types of FDA-approved phakic IOLs, and perhaps to others available outside the United States as well. In my remarks, however, I will refer only to the Visian ICL.

REASONS TO CONSIDER

In my opinion, you should consider adopting the Visian ICL as part of your refractive surgical armamentarium, and here are some of the reasons why:

Reason No. 1: Because the ICL does not require tissue alteration for refractive correction, the quality of postoperative UCVA does not vary with preoperative refractive error. In a commentary in *JAMA Ophthalmology* on long-term outcomes after posterior phakic IOL implantation for myopia, Stephen D. McLeod, MD, noted, "Phakic intraocular lenses can provide optically superb correction of relatively high degrees of ametropia that lie well beyond the recommended range for keratorefractive procedures, such as laser in situ keratomileusis and photorefractive keratectomy."[1]

Reason No. 2: ICL implantation outperforms excimer laser procedures in moderate to high myopia. Schallhorn et al recently reported that, "in a prospective, randomized, study comparing ICL implantation and photorefractive keratectomy, the ICL performed better than photorefractive keratectomy in all measures of safety, efficacy, predictability, and stability, supporting the ICL as a viable alternative to this popular refractive surgical procedure."[2] Further, a review by Barsam et al found that phakic IOLs were more accurate and safer than excimer laser surgical correction for moderate to high myopia in the range of -6.00 to -20.00 D.[3] The reviewers noted that phakic IOL implantation is often reserved for treatment of higher levels of myopia (> -7.00 D), but it may be considered over laser refractive surgery for eyes with lower levels of myopia (≤ 7.00 D) with or without astigmatism as well.[3]

Reason No. 3: Patients report significant gains in quality of life following

ICL implantation. In a study of quality of life before and after implantation of the Visian ICL, Ieong et al found that "implantation provided significant gains across a broad range of life activities and is clearly a life-changing intervention for many patients with high myopia."[4]

DATA REVIEW

The following brief review of data on the effectiveness, quality of life results, and safety of the Visian ICL can help to provide surgeons with a foundation for considering adoption of this mode of refractive surgical correction.

Effectiveness. In 2016, I examined the peer-reviewed literature from the decade since FDA approval of the Visian ICL.[5] The resulting meta-analysis indicated that refractive correction with the ICL is predictable and stable over a wide range of refractive errors.

In a multicenter clinical trial that supported FDA approval of the Toric Visian ICL, 210 eyes with a mean spherical equivalent of -9.00 D and mean cylinder of approximately 2.00 D were enrolled. Postoperatively, 77% of treated eyes had a UCVA equal to or better than the preoperative BCVA. At 1 year postoperative, UCVA was 20/20 in 83% of treated eyes and 20/40 in 96%.[6] These results rival those of LASIK for lower refractive errors,[7,8] for which the efficacy index remains below 1.0. They also rival the results of small-incision lenticule extraction in eyes with less than -8.00 D of myopia without astigmatism, where about 88% achieve 20/20 UCVA.[9]

In the study of the Visian ICL by Schallhorn et al, 86% of eyes achieved 20/20 UCVA at 1 week postoperative.[2] Alfonso and colleagues, who reported 5-year follow-up in 188 eyes of 111 patients, noted that mean manifest refraction spherical equivalent (MRSE) decreased from -11.17 ±3.40 D preoperatively to -0.23 ±0.50 D at 1 month postoperative.[10] Furthermore, they found that a high level of predictability was achieved early after surgery: 86.7% of eyes were within ±0.50 D and 96.8% within ±1.00 D of attempted correction at 1 month. This improvement was maintained over the 5-year period of follow-up.

These results are representative of those identified in my meta-analysis of the literature,[5] and they underscore the outstanding efficacy of ICL implantation.

Quality of life. Kobashi and coauthors compared quality of life following Visian ICL implantation in patients with mean preoperative MRSE of -9.97 ±2.51 D (range, -3.00 to -14.50 D) to that following LASIK in patients with mean preoperative MRSE of -6.31 ±2.20 D (range, -3.00 to -12.88 D). They reported that scores for activity limitations, symptoms, appearance, and satisfaction with correction were significantly higher in the phakic IOL group than in the LASIK group.[11] These authors concluded that ICL implantation "may offer significant vision-related quality-of-life advantages (eg, fewer activity limitations and symptoms and better appearance and satisfaction with correction) over wavefront-guided LASIK for myopia in the long term."

The possibility of providing substantial gains in quality of life for our patients creates a strong incentive for surgeons to consider phakic IOL implantation.

Safety. Specific safety concerns related to phakic IOL implantation include cataract, increased IOP, and effects on corneal endothelial health. Because of the position of the Visian ICL in the posterior chamber, close to the crystalline lens, the long-term incidence of anterior subcapsular cataract raises concern. Fortunately, a postmarketing study of the ICL provides reassuring data.[12] In that trial, the incidence of anterior subcapsular cataract was studied in 526 eyes of 294 patients, followed for up to 7.5 years, including 334 eyes available for analysis at 5 or more years. Over that period, a total of 31 eyes developed anterior subcapsular opacities; however, only five of these eyes developed visually significant anterior subcapsular cataracts. Per eye, the risk of developing any anterior subcapsular cataract opacity was 6.1% at 5 years, and the risk of developing a visually significant anterior subcapsular cataract was 1.2%. With regard to the incidence of cataract, evidence shows that older age and higher levels of myopia represent risk factors; thus, patient selection can reduce this risk.[5]

The incidence of elevated IOP requiring treatment, especially in the immediate postoperative period when pupillary block may occur, is another important safety concern. In the same Visian ICL postmarketing clinical trial,[12] there were 17 cases of pupillary block out of 526 eyes implanted (3.2%). All were treated successfully with Nd:YAG laser iridotomy. There were also three eyes with elevated IOP due to retained OVD, all of which resolved after irrigation and aspiration. The risk of elevated IOP in the early postoperative period can be mitigated by use of proper surgical technique; it depends on construction of iridotomies of adequate size and thorough removal of OVD.

Corneal endothelial health was also addressed in the same postmarketing study. Based on clinical data collected through 5 to 7 years postoperatively, the calculated chronic rate of loss of endothelial cell density (ECD) was approximately 1.8% per year.[12] Moya and coauthors published a cumulative 12-year retrospective study including data from 144 eyes implanted with Visian ICLs between 1998 and 2001.[13] These authors reported a 6.46% surgically induced decrease in ECD in the first year, followed by an average yearly rate of decrease of 1.20%.[13] These rates should be viewed in the context of the expected age-related loss of ECD, which is about 0.6% per year.[14] Of note, no cases of corneal decompensation in the absence of trauma have been reported following implantation.[15]

The reported rates of these specific complications have generally remained low.[5] Given the significant

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improvements in vision and quality of life made possible by the ICL, and the high degree of patient satisfaction associated with its use, the benefits of ICL implantation appear to outweigh the risks.

MAKE PATIENTS SAY 'WOW!'

In my experience, no surgical procedure engenders a more profoundly positive emotional response than bilateral same-day sequential ICL implantation. Rose et al, investigating the quality of life of individuals with myopia, observed that, "in many, [myopia] led to a lack of self-confidence because of teasing and feelings of inadequacy; this, in turn, could lead to social isolation and difficulties forming relationships."[16] After ICL implantation, by contrast, patients immediately see the world without the handicap that has caused many of them loneliness and suffering, and they often shed the burden of those years with a joyful flood of tears. ■

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