

Surgical Treatment of High Myopia

BY ALLON BARSAM, MD, MA, FRCOPHTH



Although several excellent modalities are available for correcting high myopia, the surgical treatment of this condition remains one of the biggest challenges for refractive surgeons. Selecting the safest and most appropriate technique for each patient is critical. Today's refractive surgeons can treat higher levels of myopia more safely and predictably thanks to a better understanding of iatrogenic ectasia as well as the availability of screening modalities, improved platforms for LASIK, and better techniques for advanced surface ablation. More advanced IOLs and technology for sizing and delivering these devices have allowed ophthalmologists to use intraocular solutions to maximize visual quality in highly myopic eyes when laser treatment is not appropriate.

Treatment can provide patients with considerable benefits. The World Health Organization has listed myopia and uncorrected refractive error among the leading causes of blindness and visual impairment in the world. The prevalence of myopia in Western populations is estimated to be approximately 25%.¹ Myopia can be broadly classified into two groups: (1) low to moderate myopia, which is 7.00 D or less of myopic spherical equivalent with or without astigmatism and (2) high myopia, which is more than 7.00 D of myopic spherical equivalent with or without astigmatism.

Patients with high myopia who have poor vision with spectacles and are intolerant of contact lenses now have several choices for surgical correction. In recent years, ophthalmologists have favored LASIK and advanced surface ablation for the surgical correction of refractive error in most patients who wish to be independent of spectacles. These procedures provide rapid visual recovery, excellent visual outcomes, and a relatively painless postoperative recovery. For patients with high degrees of myopia, refractive surgery with an excimer laser may be less predictable than treatments for lower levels of myopia. Haze has been reported to be a significant long-term problem in eyes with high myopia treated with PRK.² Refractive lens exchange (RLE) may increase the risk of retinal detachment and generally is not considered in prepresbyopic patients with myopia who can still accommodate.

Phakic IOLs represent an alternative surgical treatment for moderate to high myopia. Although many lenses with different designs have been implanted worldwide, currently, only two of these IOLs are approved for use in the United States. In 2004, the FDA approved the Verisyse phakic IOL, marketed internationally as the Artisan lens by Ophtec BV and distributed in the United States by Abbott Medical Optics Inc. The Verisyse/Artisan phakic IOL is an iris claw-fixed ACIOL. The FDA approved the Visian ICL, manufactured by STAAR Surgical Company, in December 2005. The Visian Toric ICL (STAAR Surgical Company; not available in the United States) has a toric anterior surface and is designed to vault anteriorly to the crystalline lens in the ciliary sulcus. Phakic IOLs have the benefit of being a reversible procedure. Their insertion requires intraocular surgery, and the associated risks include endophthalmitis, surgically induced astigmatism, the loss of corneal endothelial cells, chronic uveitis, pupillary block glaucoma, pigment dispersion syndrome, and cataract formation. In addition, the lens power calculation and surgical implantation of phakic IOLs require special techniques, and the long-term outcomes of several types of phakic IOLs are unknown.

New studies are reported regularly on the rapidly advancing frontier of surgical treatment for high myopia, and ophthalmologists' knowledge and understanding of the available surgical options are constantly evolving. This month's "Peer Review" column highlights current studies on this fascinating topic. I have recently published research on this topic and am excited to share the results with you. I hope you enjoy this installment of "Peer Review," and I encourage you to seek out and review the articles in their entirety at your convenience.

ANTERIOR CHAMBER PHAKIC IOLS

Акay et al evaluated two foldable ACIOLs for high myopia in a prospective, interventional case series. The investigators implanted the Artiflex IOL (Ophtec BV), an iris-claw lens, in 62 eyes and the ICare phakic IOL

(Cornéal), an angle-supported lens, in 42 eyes. The range of myopia treated was -7.75 to -26.00 D spherical equivalent. At the 18-month follow-up, UCVA improved from 1.60 ± 0.10 logMAR to 0.37 ± 0.23 logMAR in the Artiflex group and from 0.70 ± 0.20 logMAR to 0.47 ± 0.14 logMAR

in the ICare group. The mean decrease in endothelial cell density was 241 cells/mm² (8.61%) in the Artiflex group and 223 cells/mm² (8.42%) in the ICare group, which was significant compared with the preoperative values for both groups ($P < .001$).³

In a nonrandomized, multicenter clinical trial, Lane and Waycaster assessed the impact of bilaterally implanting the AcrySof Cachet phakic IOL (Alcon Laboratories, Inc.) on vision and quality of life in 138 patients with high myopia. Mean uncorrected distance visual acuity at 6 months, 1 year, and 2 years postoperatively was statistically better than corrected distance visual acuity at baseline (0.12 logMAR, 0.11 logMAR, and 0.12 logMAR, respectively, vs 0.06 logMAR; $P < .005$). The increase in patients' satisfaction with their UCVA postoperatively compared with preoperatively was significant ($P < .0001$), and patients' distance vision without spectacles improved from 0% preoperatively to 94% postoperatively ($P < .0001$). The rate of endothelial cell loss was consistent with normal age-related changes in the cornea. Also, most patients reported improved satisfaction with their UCVA and quality of life.⁴

POSTERIOR CHAMBER PHAKIC IOLS

In a large cohort study, Alfonso et al evaluated the long-term safety and efficacy of the Visian ICL for the treatment of high myopia in 188 eyes. The mean spherical equivalent decreased from -11.17 ± 3.40 D (standard deviation) preoperatively to -0.88 ± 0.72 D 5 years postoperatively. The mean uncorrected and corrected distance visual acuities (Snellen decimal) were 0.69 ± 0.26 (20/30 Snellen equivalent) and 0.83 ± 0.15 (20/25 Snellen equivalent), respectively. None of the eyes lost more than 2 lines of visual acuity, and 70% of eyes achieved 0.80 or better distance BCVA. Three eyes (1.6%) developed a late anterior subcapsular cataract, which was clinically significant in one case and required explantation of the phakic IOL and phacoemulsification. Three eyes (1.6%) had a mild, transient increase in IOP (up to 27 mm Hg), but a second surgical procedure or prolonged use of topical medication was not required. The total amount of endothelial cell loss, which was considered cumulatively at consecutive intervals throughout 5 years, was 7.7%. There was a tendency toward decreased phakic IOL anterior vault over time. No vision-threatening complications occurred.⁵

Shimizu et al assessed the early clinical outcomes of implanting a posterior chamber phakic IOL with a central hole (Visian V4 ICL; STAAR Surgical Company) for the correction of moderate to high myopia. The study included 20 eyes of 20 patients with spherical equivalents of -7.36 ± 2.13 D (mean \pm standard deviation). Before implantation of the IOL and at 1 week and 1, 3, and 6 months postoperatively, the investigators assessed the

safety, efficacy, predictability, stability, and adverse events of the surgery. At 6 months, 95% and 100% of eyes were within ± 0.50 and ± 1.00 D of the targeted correction, respectively. The change in manifest refraction from week 1 to month 6 was 0.06 ± 0.28 D. A significant rise in IOP (including pupillary block) or a secondary cataract did not occur in any of the eyes during the period of observation.⁶

LASIK AND SURFACE ABLATION

Alió et al evaluated the clinical outcomes of LASIK in eyes with high myopia using optimized aspherical profiles and the 500-Hz Amaris excimer laser (Schwind eye-tech-solutions; not available in the United States). The investigators used the 60-kHz IntraLase femtosecond laser (Abbott Medical Optics Inc.) to create the flap. The retrospective study included 51 eyes of 32 patients with high levels of myopia or myopic astigmatism (spherical equivalent ≥ 8.50 D). Alió and colleagues recorded postoperative changes in visual acuity and refraction for 6 months. At 3 months postoperatively, a significant improvement (15 logMAR lines) was observed in distance UCVA ($P < .01$), but no significant changes were observed in the last 3 months of follow-up ($P = .61$). This improvement was consistent with a significant reduction of manifest refraction ($P < .01$). Distance BCVA remained unchanged or improved in 98% of eyes at 3 months postoperatively, with only one eye's losing 1 logMAR line of distance BCVA. Six months postoperatively, 84.3% of eyes had a spherical equivalent within ± 0.50 D of emmetropia. A limited but significant induction of primary spherical aberration and coma was also found ($P < .01$), and a surgical enhancement was required in four eyes (7.8%).⁷

COMPARATIVE STUDIES

Hassaballa and Macky retrospectively compared the outcomes of the Artisan IOL and the Visian ICL in 68 highly myopic eyes of 34 patients. The investigators found that both lenses demonstrated comparable safety, predictability, and efficacy 1 year postoperatively. The mean preoperative spherical equivalent was -12.89 ± 3.78 D for the Artisan group ($n = 42$) and -12.44 ± 4.15 D for ICL group ($n = 26$; $P = .078$). The mean postoperative distance UCVA was 0.39 ± 0.13 logMAR and 0.41 ± 0.15 logMAR (20/50 Snellen equivalent) for the Artisan and ICL groups, respectively ($P = .268$). The mean postoperative spherical equivalent was -0.86 ± 0.50 D for the Artisan group and -0.63 ± 0.38 D for the ICL group ($P = .67$). The mean postoperative distance BCVA was 0.36 ± 0.12 logMAR (20/40-3 Snellen equivalent) and 0.31 ± 0.12 logMAR (20/40 Snellen equivalent) for the Artisan and ICL groups, respectively ($P = .128$). The change

in IOP at 1 year was 0.64 ± 2.7 mm Hg for the Artisan group and 1.88 ± 0.6 mm Hg for the ICL group ($P = .77$).⁸

Nanavaty and Daya compared RLE with phakic IOLs and concluded that phakic IOLs provide better visual outcomes for distance. They found that, when laser ablative surgery is not possible, phakic IOLs and additive procedures are a safe option in myopic eyes with a deep anterior chamber, whereas in hyperopic eyes, RLE may be a better option. According to the authors, factors surgeons should consider when choosing between RLE and a phakic IOL include age, axial length, type and magnitude of refractive error, anterior segment configuration, endothelial cell count, and the patient's desire for presbyopic correction. The investigators noted that, in practice, phakic IOLs demonstrate better postoperative visual outcomes compared with RLE. They recommended that surgeons not consider RLE for patients under the age of 50, except high hyperopes (≥ 4.00 D) and patients in whom the anterior chamber depth is shallow and thus unsuitable for a phakic IOL. For these eyes, the authors recommend an age threshold of 45 years.⁹

According to Nanavaty and Daya, the primary advantages of phakic lenses are rapid visual recovery, reversibility, a broader range of treatable ametropia than with RLE, high rates of predictability, and stability with the preservation of accommodation. With RLE, the risks of retinal detachment, cystoid macular edema, glare, halos, and posterior capsular opacification remain. Risks with phakic IOLs include pigment dispersion, cataract formation, glaucoma, and inflammation.⁹

Shin et al compared changes in higher-order aberrations (HOAs) in 30 eyes (18 patients) implanted with the Visian ICL and 33 eyes (18 patients) that underwent wavefront-guided LASEK. All eyes were highly myopic and had a spherical equivalent of -6.00 to -9.00 D. Three months postoperatively, ICL implantation induced fewer ocular and corneal HOAs and resulted in better contrast sensitivity at mesopic levels compared with wavefront-guided LASEK. In the ICL group, HOAs changed for the entire ocular trefoil-y, spherical aberration, internal optical spherical aberration, and corneal trefoil-y. In the LASEK group, increased HOAs were observed for total HOAs, entire ocular and corneal spherical aberration, secondary astigmatism, and tetrafoil. The ICL group had lower induced aberration values of entire ocular and corneal HOAs compared with the LASEK group. No significant differences in contrast sensitivity between groups at the photopic level were noted, but contrast sensitivity values were significantly lower for 3 ($P = .01$) and 6 cycles per degree ($P < .001$) in the LASEK group at the mesopic level. At the mesopic level, total HOAs, trefoil-y, spherical aberration, and secondary astigmatism were higher in the LASEK group. A limitation of this study, however, was the relatively short follow-up period of 3 months.¹⁰

Barsam and Allan conducted a meta-analysis of randomized controlled trials (RCTs) comparing refractive surgery with the excimer laser and phakic IOLs for the correction of between 6.00 and 20.00 D of myopia. The investigators performed a comprehensive literature search using the Cochrane Collaboration methodology to identify RCTs and analyzed data for efficacy outcomes, accuracy outcomes, safety outcomes, adverse effects, and quality-of-life measures. The review included three RCTs and 228 eyes. Eyes in the the phakic IOL group were less likely to lose 2 or more lines of BCVA at 12 months (odds ratio, 0.35; 95% CI, 0.19-0.66; $P = .001$). Phakic IOL surgery scored more highly among patients on satisfaction and preference questionnaires.^{11,12}

The results of the meta-analysis showed that phakic IOLs are safer than the excimer laser for the correction of high myopia 1 year postoperatively. Barsam and Allan noted, however, that some potential long-term risks that are unique to patients with phakic IOLs, such as continued endothelial cell loss and cataract formation, are not apparent with 1 year of follow-up. Longer follow-up is required for a balanced evaluation of safety and to establish the ideal myopic range for excimer laser and phakic IOL treatments.^{11,12} ■

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