

Accommodating IOLs

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This first installment of a three-part series on premium IOL technology highlights the latest peer-reviewed articles available regarding accommodating lenses. Many of the technologies discussed are not yet available on the US market, but we have done our best to present relevant international literature for our readers' benefit.

My personal experience with accommodating IOLs is limited to 6 years of implanting the various models of the Crystalens (AT45, AT45-SE, AT50/52-SE, HD500/520; Bausch & Lomb, Rochester, NY). As the literature demonstrates, this pioneering technology is based on the hypothesis that an artificial lens can be displaced anteriorly through the restoration of ciliary body function. Surgeons' experience has shown that this technology is not a one-size-fits-all fix for presbyopia. The capsular bag's dimensions, axial length, and capsular fibrosis can still negatively affect the predictability and function of every accommodating lens available on the US and international markets. Improvement will occur only when surgeons can accurately determine the appropriate optic/haptic diameter required (ie, wider availability of anterior segment analysis [eg, anterior segment optical coherence tomography, ultraviolet microscopy, and Scheimpflug photography]), eradicate capsular fibrosis (ie, arrest the proliferation of lens epithelial cells after surgery), and conquer the range of accommodative amplitudes as they relate to axial length.

An article addressing accommodating IOLs would not be complete without an acknowledgment of the time and dedication of the team at Eyeonics, including its cofounders, J. Andy Corley and J. Stuart Cumming, MD. Always a forward thinker, Andy fought hard to ensure that premium IOL technologies would not be held captive by any government policy or commercial medical insurance industry fee structure. Eyeonics paved the way for industry and physicians to place a premium on technological advancement, hard work, and surgical skill. As efforts toward health care reform continue, I believe it is important for ophthalmologists and members of industry to work together to ensure that the United States continues to foster technological advances and maintains a competitive marketplace. Although I believe in the provision of health care to the uninsured, I would also argue that not every medical technology needs to be public (ie, available to all without regard to cost or expertise). In my view, a multipayer system is integral to the growth of the ophthalmic industry and the highest quality of medical practitioners and care.

—Mitchell C. Shultz, MD, Section Editor

Accommodating IOLs are designed to reverse the effects of presbyopia by mimicking the natural focusing ability of the crystalline lens. To date, investigators have taken several different approaches to replicating accommodation. Single-optic lenses such as the 1CU (Human Optics AG, Erlangen, Germany), the Crystalens (Bausch & Lomb, Rochester, NY), the Tetraflex (Lenstec KH-3500; Lenstec, Inc., St. Petersburg, FL), and the BioComFold (Morcher GmbH, Stuttgart, Germany) are based on the focus shift principle.¹⁻³ Also called passive- or optic-shift lenses, these IOLs are designed to "transmit ciliary muscle contraction into a change of dioptric power of the eye."¹ Theoretical calculations suggest that moving the lens forward by 1 mm increases its effective power by 0.80 to 2.30 D, depending on the axial length of the eye and the IOL's power.⁴ At present, the Crystalens is the only single-lens accommodating IOL cleared for clinical use in the United States.

Currently under review by the FDA is the Synchrony Dual-Optic IOL (Visiogen, Inc., Irvine, CA). This lens' high-powered anterior optic is connected to a minus-powered posterior lens by a spring-like haptic. Because the lens completely fills the capsular bag, its haptics "allow anterior and posterior axial displacement of the front optic in response to changes in the ciliary body tone and capsular tension."³ Other investigational technologies such as the NuLens accommodating IOL (NuLens Ltd., Herzliya Pituah, Israel) and lens refilling with intracapsular polymers have shown promising results in animal models,¹ but they are not expected to be approved for use in humans in the near future.

In 2007, Menapace et al declared that passive-shift IOLs were failures as accommodating and capsular bag implants.¹ Nevertheless, this design remains dominant among accommodating IOLs. This article summarizes the most recent peer-reviewed research currently published on these presbyopia-correcting IOLs.

1CU

Investigators typically evaluate the function of accommodating lenses by measuring various permutations of visual acuity (ie, UCVA and BSCVA at distance and near) as well as the objective and subjective amplitude of accommodation. One of the challenges of evaluating accommodating IOLs is differentiating between true accommodation and pseudoaccommodation,³ as demonstrated by a clinical study of the 1CU IOL conducted by Wolffsohn et al.⁵ Four months after receiving the accommodating lens, the treated eyes (n = 20) had an average subjective amplitude of accommodation of 2.24 ± 0.42 D and an average static/dynamic objective amplitude of 0.72 ± 0.38 D/ 0.71 ± 0.47 D. By 2 years postoperatively, the average subjective and objective amplitudes of accommodation had decreased by -0.25 ± 0.59 D and 0.19 ± 0.44 D, respectively. Based on these results, the investigators concluded that “the greater subjective than objective amplitude of accommodation most likely results from the interaction between the depth of focus of the eye [a factor contributing to pseudoaccommodation] and the aspheric nature of the 1CU IOL.” They added that “the objective accommodating effects of the 1CU lens appear to be limited.”⁵

A prospective study in which 20 patients were randomized to receive a 1CU lens in one eye and a monofocal AcrySof MA30 IOL (Alcon Laboratories, Inc., Fort Worth, TX) in their other eye did not detect a significant difference in near vision between the IOLs. Partial coherence interferometry showed that the 1CU lenses shifted anteriorly by a mean of 0.009 ± 0.025 mm at a 1.50 D target and 0.010 ± 0.01 mm at a 2.50 D target during accommodation. Under the same conditions, the monofocal lens moved posteriorly (mean, 0.005 ± 0.011 mm at 1.50 D and 0.01 ± 0.01 mm at 2.50 D). The investigators did not note a correlation between distance-corrected near visual acuity and the movement of either IOL. Although the small anterior movement observed with the 1CU IOL was not clinically significant, it “suggested that the engineering concept behind the [IOL] was valid.” The investigators concluded, however, that “patients with a 1CU IOL who demonstrate good near vision are likely to be using pseudoaccommodative factors rather than the focus shift of the lens.”⁶

Uthoff et al also had difficulty discriminating between true and false pseudophakic accommodation in their analysis of 553 eyes implanted with the 1CU IOL. By 12 months postoperatively, the eyes in the 1CU group had a slightly better Niden distance-corrected near visual acuity (5.77) than those implanted with a monofocal IOL (n = 219; 6.41). This difference translated into a half-step improvement in near reading acuity with the 1CU lens. The investigators

also observed a statistically significantly greater accommodative response of 11 cm in the 1CU versus the control group. Because the range varied widely among patients, however, “no homogeneous group demonstrated improvement in uncorrected near vision with [distance-corrected near visual acuity].”⁷ Furthermore, the investigators could not attribute the Canvas of J2 to J4 achieved by 2.7% of the patients who received the 1CU to the lens’ movement alone, and thus they could not conclusively state “whether accommodative optic shift or pseudoaccommodative effects are responsible for our clinical results.”⁷

Laser interferometric measurements obtained from 15 eyes implanted with the 1CU lens showed that the average anterior movement of the IOL’s optic (5 ± 14 μ m; approximately 0.50 D) could not produce the 0.10 D of myopization required to achieve a clinical improvement in near vision.⁸

A study comparing the refractive outcomes with the Crystalens AT-45 (n = 69 eyes) and the 1CU (n = 39 eyes) found that a higher percentage of eyes implanted with the latter lens achieved better UCVA’s at all time periods. By 1 year postoperatively, 92.3% of the eyes in the 1CU group had a binocular distance-corrected near visual acuity of J3 or better versus 84.2% in the AT-45 group. According to the investigators, their use of distance-corrected near visual acuity as an outcome measurement demonstrated “the accommodating function of both lens types without the contribution of pseudoaccommodative factors of myopia and cylinder.”⁹

CRYSTALENS AT-45

The Crystalens AT-45 IOL was approved for clinical use in the United States in 2003. Since then, its original design has been supplanted by the Crystalens Five-O and the Crystalens HD. A PubMed search on the keyword *Crystalens*, however, only returned peer-reviewed data about the Crystalens AT-45.

In a prospective, multicenter, phase 3 clinical trial, 51.5% of patients (64 of 124) implanted binocularly with the AT-45 achieved a distance-corrected near visual acuity of J1 (20/25). An even higher percentage (83.9% [104 of 124]) had distance-corrected near visual acuities of J2 (20/32) or better, and 100% (124) saw J3 (20/40) or better. The Crystalens also satisfied the FDA’s requirement that at least 92.5% of the eyes implanted with the lens achieve a best-corrected distance visual acuity of 20/40 or better. At 1 year postoperatively, 99.2% of the Crystalens eyes (235 of 243) had a best-corrected distance visual acuity of 20/40 or better. A sub-study of patients who received the Crystalens found that “significantly more eyes with [the accommodating IOL] achieved 20/20 (J1+) or better visual acuity than those implanted with a standard IOL (75.2% vs 20.3%, $P = 0.49$).”¹⁰

MacSai et al observed significantly better uncorrected

near (J1) and distance (20/17) binocular visual acuities in eyes with the Crystalens AT-45 (n = 56) than in eyes with a monofocal IOL (near, J6; distance 20/20; n = 56). The subjective and objective measurements of accommodation were also statistically significantly better with the Crystalens (2.42, 2.4 ± 0.39 D) than with the monofocal IOL (0.91 ± 0.24 D), but the “perceived accommodation (5.79 D) was much greater than measured accommodation (1.96 to 2.42 D) in Crystalens patients.”¹¹

TETRAFLEX

A comparative study by Wolffsohn et al found that the Tetraflex IOL (n = 28 eyes) provided significantly greater objective (0.39 vs 0.17 D) and subjective (3.10 vs 2.00 D) accommodation than a standard monofocal lens (n = 10 eyes). The subjective measurements suggest a near point of 16 to 100 cm and 31 to 200 cm for the Tetraflex and monofocal IOLs, respectively. By 6 months postoperatively, the investigators observed that the ability of patients in the Tetraflex group to read the smallest print had decreased compared with earlier evaluations, and this change was accompanied by a nearly statistically significant reduction in the subjective amplitude of accommodation.¹²

Sanders and Sanders reported that 63% of 95 eyes implanted with the Tetraflex IOL achieved a distance-corrected near visual acuity of 20/40 or better by 6 months postoperatively. In addition, “100% of the 74 [eyes available for evaluation] at 6 months or more had an accommodative amplitude of more than 1.00 D, 75.7% could accommodate more than 2.00 D, 71.6% could accommodate 2.50 D or more, and 18.9% could accommodate more than 3.00 D.”¹³

SYNCHRONY DUAL-OPTIC IOL

A pilot study suggested that the Synchrony Dual-Optic IOL improved the near visual acuity of presbyopic eyes more effectively than a single-optic monofocal IOL. Of the 24 eyes available for follow-up at 6 months, 23 (96%) had a distance-corrected near visual acuity of J3 (20/40) or better, and 17 (70.8%) required 1.00 D or less of add to reach J1+. A comparison of defocus curves showed that the Synchrony had a significantly larger mean accommodative range than the monofocal IOL (3.22 ± 0.88 D vs 1.65 ± 0.58 D). Because the Synchrony’s amplitude of accommodation was consistent with the observed improvement in distance-corrected near visual acuity, the investigators suggested that the study provided a “proof of principle for the function of a dual-optic accommodating IOL as well as rudimentary indicators of [the lens’] clinical efficiency.”¹⁴

LENS REFILLING

In 2007, Menapace et al wrote that, of all the lens-based presbyopia-correcting technologies, “lens refilling carries

the potential of fully restoring accommodation.” To date, attempts to replace the crystalline lens with a synthetic polymer have been complicated by the material’s leaking into the anterior chamber and a high rate of secondary cataracts.¹

Nishi et al tested a refilling technique in the eyes of rabbits and pigs that appeared to resist leakage and reduce posterior capsular opacification (PCO). In one variation, the investigators plugged the anterior capsulorhexis with an accommodating IOL. An alternate approach designed to reduce the risk of PCO involved injecting the silicone polymer between an anterior and a posterior accommodating IOL. The investigators tested the latter procedure with and without the creation of a posterior capsulorhexis.

When the investigators applied continuous and eccentric pressure (to simulate rubbing of the eye) to the anterior optic, only a small amount of the polymer leaked from the capsule. The material was easily removed from the anterior chamber with aspiration or irrigation. The investigators observed mild-to-moderate PCO in all but two of the refilled eyes, but the opacification appeared to be limited to the periphery of the visual axis. These results suggest that the technique developed by Nishi et al “may provide a future breakthrough for possible clinical applications of lens capsule refilling.”¹⁵ ■

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1. Menapace R, Findl O, Kriechbaum K, Leydolt-Hoepf C. Accommodating intraocular lenses: a critical review of present and future concepts. *Graefes Arch Clin Exp Ophthalmol*. 2007;245:473-489.
2. Findl O, Leydolt C. Meta-analysis of accommodating intraocular lenses. *J Cataract Refract Surg*. 2007;33:522-527.
3. Buznego C, Trattler WB. Presbyopia-correcting intraocular lenses. *Curr Opin Ophthalmol*. 2009;20:13-18.
4. Nawa Y, Ueda T, Nakatsuka M, et al. Accommodation obtained per 1.0 mm forward movement of a posterior chamber intraocular lens. *J Cataract Refract Surg*. 2003;29:2069-2072.
5. Wolffsohn JS, Hunt OA, Naroo S, et al. Objective accommodative amplitude and dynamics with the 1CU accommodative intraocular lens. *Invest Ophthalmol Vis Sci*. 2006;47(3):1230-1235.
6. Hancock J, Spalton D, Heatley C, et al. Objective measurement of intraocular lens movement and dioptric change with a focus shift accommodating intraocular lens. *J Cataract Refract Surg*. 2006;32:1098-1103.
7. Uthoff D, Gulati A, Hepper D, Holland D. Potentially accommodating 1CU intraocular lens: 1-year results in 553 eyes and literature review. *J Refract Surg*. 2007;23:159-171.
8. Uthoff D, Holland D, Hepper D, et al. Laserinterferometric measurements of accommodative changes in the position of an optic-shift intraocular lens. *J Refract Surg*. 2009;25:416-420.
9. Buratto L, Di Meglio G. Accommodative intraocular lenses: short-term visual results of two different lens types. *Eur J Ophthalmol*. 2006;16(1):33-39.
10. Cumming JS, Colvard DM, Dell SJ, et al. Clinical evaluation of the Crystalens AT-45 accommodating intraocular lens. *J Cataract Refract Surg*. 2006;32:812-825.
11. Macsai MS, Padnick-Silver L, Fonges, BM. Visual outcomes after accommodating intraocular lens implantation. *J Cataract Refract Surg*. 2006;32:628-633.
12. Wolffsohn JS, Naroo SA, Motwani NK, et al. Subjective and objective performance of the Lenstec KH-3500 “accommodative” intraocular lens. *Br J Ophthalmol*. 2006;90:693-696.
13. Sanders DR, Sanders ML. Visual performance results after Tetraflex accommodating intraocular lens implantation. *Ophthalmology*. 2007;114:1679-1684.
14. Ossma IL, Galvis A, Vargas LG, et al. Synchrony dual-optic accommodating intraocular lens. Part 2: pilot clinical evaluation. *J Cataract Refract Surg*. 2007;33:47-52.
15. Nishi O, Nishi K, Nishi Y, Chang S. Capsular bag refilling using a new accommodating intraocular lens. *J Cataract Refract Surg*. 2008;34:302-309.