Progressions in Presbyopia-Correcting Corneal Surgery

Various new methods of presbyopic correction show promise.

BY ERIC T. BROOKER, OD

Presbyopia is a visual disability that continues to affect more than one-third of the US population or about 100 million individuals, and this number is estimated to grow to 125 million by 2020. In countries in Asia, presbyopia is even more prevalent, affecting nearly 50% of the population.[1]

As the number of presbyopes increases, so does their demand for a permanent, minimally invasive surgical solution to reduce their dependence on reading glasses. Recently, there has been significant progress in procedural options for the cornea-based surgical correction of presbyopia, but many of them are only available outside the United States. The new procedures can be divided into two categories: laser refractive correction and corneal inlays.

LASER REFRACTIVE CORRECTION

The Intracor procedure, developed by Technolas Perfect Vision GmbH (Munich, Germany; not available in the United States), uses a femtosecond laser to create intrastromal concentric rings within the cornea. These rings weaken the peripheral cornea, which steepens the central zone. The procedure produces a multifocal cornea, designed to maintain the patient's distance vision while improving his or her near and intermediate visual acuity. In a study reported at the past annual meeting of the ASCRS in San Diego, Luis A. Ruiz, MD, shared 2-year follow-up results for 94 eyes. At the 2-year mark, 92.6% of the presbyopic eyes treated with Intracor had a bilateral uncorrected distance visual acuity of at least 20/25 and uncorrected near visual acuity of J3 or better. Additionally, 75% of the eyes achieved an uncorrected near visual acuity of J1, 97% saw at least J2, and all saw at least J3.[2]

The initial experience with Intracor has been promising, but the procedure has a few downsides. First, because the alterations to the cornea are not reversible, there is no straightforward solution for patients who are unhappy or experiencing continuous visual problems postoperatively. Second, progressive presbyopia may diminish Intracor's effectiveness. Third, if the treatment is decentered, significant visual problems could result, and the additional avenues for treatment are limited. Finally, treated patients often complain of night halos, although the problem tends to resolve over time.[3]

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Another corneal surgical treatment for presbyopia, known as *presby-LASIK*, is being performed using several laser platforms. A recent addition, Supracor (which is CE Marked but not available in the United States), is performed with the Technolas Excimer Workstation 217P. The procedure uses a new aberration-optimized presbyopic algorithm to reshape the cornea. In a multicenter European clinical evaluation, Supracor was found to provide 87% of patients with 20/25 uncorrected distance visual acuity and J2 uncorrected near visual acuity when evaluated binocularly.[4]

CORNEAL INLAYS

Corneal inlays are small artificial implants that are inserted into the cornea via either a femtosecond laser-created pocket or corneal flap to alter the optics of the

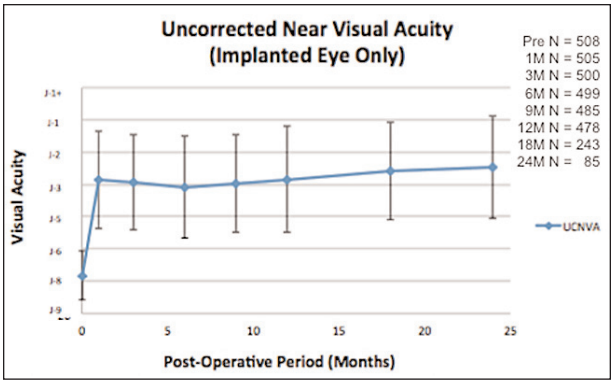

Figure 1. Patients who received the Kamra inlay in the US investigational device exemption (IDE) trial achieved an uncorrected near visual acuity of J2 to J3, on average, postoperatively.

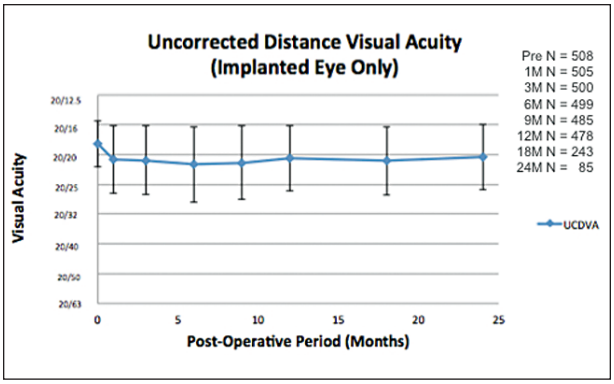

Figure 2. In the US IDE trial of the Kamra inlay, patients maintained 20/20 uncorrected distance visual acuity in their implanted eye.

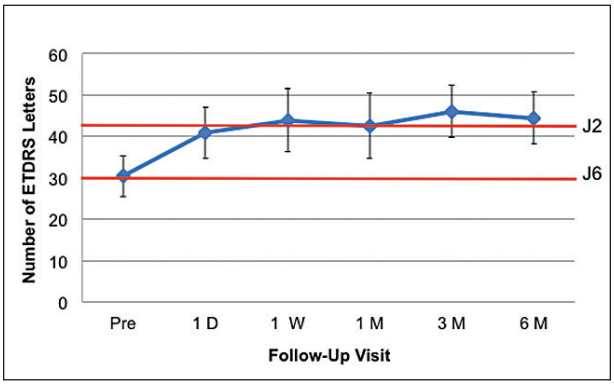

Figure 3. Near acuity improved from J6 to J2, on average, in patients implanted with the Kamra inlay after prior LASIK treatment.

eye and improve near vision. Several inlays are in development or in use globally but are unavailable in the United States, including the Vue+ (formerly PresbyLens; ReVision Optics, Inc. Lake Forest, CA), Flexivue Microlens (Presbia Coöperatief UA, Amsterdam, Netherlands), and Kamra (AcuFocus, Inc., Irvine, CA).

The Vue+ intracorneal inlay is a 2-mm hydrogel corneal implant indicated for the correction of presbyopia. Its functionality is based on the principle of multifocality. The Vue+, which is 30 µm thick, is designed to change the curvature of the central cornea of one eye to add near and intermediate focusing power. The implant is removable. The Vue+ is in US clinical trials, has CE Mark approval, and is available for sale in Europe. Six-month data on 34 patients who received the implant were presented at the 2010 ASCRS meeting by Enrique Barragan, MD, of Monterrey, Mexico.[5] The mean uncorrected near visual acuity in the implanted eyes was J1 (ie, a 4-line improvement). Intermediate visual acuity improved by a mean of 2 lines, and distance visual acuity decreased by a mean of 1.5 lines. Binocularly, no patient saw worse than 20/25.

The Flexivue MicroLens is a refractive corneal inlay based on the multifocal (bifocal) principle. This removable inlay is 3 mm wide, is approximately 15 µm thick, and is made of a hydrophilic polymer. Recent studies of the Flexivue Microlens lens performed by Ioannis Pallikaris, MD, of the University of Crete, Greece, were conducted on 20 patients.[5] The flap was created with a femtosecond laser. Postoperative uncorrected near visual acuity was 20/25 or better in 77% of the patients. Ninety-two percent of the patients did not use reading glasses, and 8% used reading glasses for less than half of their near activities after surgery. Of the patients with 15 months' follow-up, 77% saw 20/16 at near, and their operative eye showed a slight decrease in distance vision.

The Kamra inlay has CE Mark approval and is in US IDE clinical trials for the treatment of presbyopia. Unlike the other implants described herein, the Kamra inlay utilizes small-aperture optics to increase the depth of focus by allowing only focused light rays to enter the eye. As a result, the inlay continues to provide near vision as the crystalline lens loses its accommodative function. The inlay is commercially available in Europe, Asia, Latin America, and the Middle East. It is placed in a stromal pocket or under a lamellar flap. The pocket procedure was used for the 507 emmetropic patients in the manufacturer's current US study, conducted under an IDE.[6] If necessary, patients who receive the Kamra inlay can have it removed, and their vision will reportedly revert to baseline. In the clinical trial, on average, patients achieved J2 to J3 for near and maintained good distance vision at 20/20 out to 18 months (Figures 1-2).

Outside the United States, the simultaneous treatment

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of ametropia and presbyopia using LASIK and a Kamra inlay is gaining popularity. In this procedure, called *sim-LASIK*, the inlay is placed under a LASIK flap immediately following an excimer laser ablation. The 1-year results for a series of 1,535 consecutive eyes (1,535 presbyopic patients) in Japan showed that the mean uncorrected near visual acuity at 30 cm improved by 4 lines from J9 preoperatively to J2.[7] The patients' mean uncorrected distance visual acuity improved 8 lines from 20/125 preoperatively to 20/20. Ninety percent of the patients were satisfied with their results.[7]

The most recent and exciting application for the Kamra inlay is the correction of presbyopia in patients who have undergone LASIK. The surgeon creates a pocket under the LASIK flap and inserts the corneal inlay. A recent study found that a femtosecond laser-created corneal pocket can be created beneath a previous LASIK flap and a small-aperture corneal inlay can be safely inserted to correct presbyopia.[8] Initial results show improvement in near visual acuity with a minimal reduction in distance visual acuity. At 3 months postoperatively, the mean uncorrected near visual acuity improved by 4 lines from J6 preoperatively to J2 (Figure 3).[8]

THE FUTURE

The future of presbyopic correction is very promising. A variety of procedures now in development will soon offer patients a wide range of choices. It is up to eye care practitioners to help patients choose the option that best meets their individual needs. The ideal procedure will maintain patients' distance vision and improve their near and intermediate vision, but it will also be reversible, noninvasive, stable, and immune to the progressive nature of presbyopia. ■

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1. CIA World Factbook. https://www.cia.gov/library/publications/the-world-factbook/geos/ch.html. Accessed September 20, 2011.
2. Ruiz LA. Is intrastromal surgery just for presbyopia? Paper presented at: 2010 ASCRS Annual Meeting; April 9-14, 2010; Boston, MA.
3. Mertens E. Flapless intrastromal correction for presbyopia with femtosecond laser. Paper presented at: 2011 ASCRS Annual Meeting; March 25-30, 2011; San Diego, CA.
4. Chaubard J, Castanera J, Pietrini D, Roure A. Technolas Perfect Vision GmbH. Six month European study results of excimer-based treatment of presbyopia using the Technolas excimer workstation. March 2011. http://www.better-reading-vision.net/dasat/images/7/100917-tpv-supracor-white-paper-march-2011.pdf. Accessed September 20, 2011.
5. Dalton M. Intracorneal inlays showing positive outcomes. *EyeWorld*. June 2011. http://www.eyeworld.org/article-intracorneal-inlays-showing-positive-outcomes. Accessed September 20, 2011.
6. Waltz K. Multicenter prospective clinical trial of corneal inlay to improve near vision in emmetropic presbyopic patients. Presented at: 2011 ASCRS Annual Meeting; March 25-30, 2011; San Diego, CA.
7. Tomita M. Simultaneous intracorneal inlay implantation and LASIK for the treatment of presbyopia: one year results. Presented at: 2011 ASCRS Annual Meeting; March 25-30, 2011; San Diego, CA.
8. Sanchez L. Creating a femtosecond pocket under previous LASIK flap for correction of presbyopia with a corneal inlay. Presented at: 2011 ARVO Meeting; May 1-5, 2011; Fort Lauderdale, FL.