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Intraocular Lens Makers See Unmet Need For Fully "Accommodating" Product

Integrating the merits of various intraocular lens (IOL) implants into a single "accommodating" IOL remains the Holy Grail of eye care companies.

"The goal of an effective, accommodating IOL is that you'll basically be able to have all of the gain in picking up distance vision, intermediate vision and near vision without the compromises" intrinsic to current options, Advanced Medical Optics' Ron Bache, VP-worldwide marketing for refractive products, said in an Oct. 3 interview.

Such a "full service" IOL, with focusing capabilities similar to those of the natural lens, will be "a massive paradigm-shifting event within ophthalmology," he predicted.

Alcon spokesperson Doug MacHatton agrees. "There's no question that we and others would like to find an optimal accommodating lens," he told *"The Gray Sheet."* However, "that is not easy to do."

IOLs give patients the possibility of being glasses-free, or at least less dependent on glasses, following the removal of a clouded lens in cataract surgery. Increasingly, the artificial lenses are also being implanted in severely near-sighted or far-sighted individuals unsuited for refractive LASIK surgery, though this is an off-label application.

Traditional monofocal IOLs "are a fantastic technology," according to Kevin Waltz, OD, MD, Eye Surgeons of Indiana. However, they "cannot treat the same eye for distance and near at the same time."

CrystaLens Is A Good First Step, Industry Reps Say

Premium IOLs, including multifocal lenses and accommodating lenses, attempt to overcome this problem. Both are designed to correct for the effects of presbyopia, or age-associated deterioration of the eye's focusing power.

The multifocal type compensates for this degradation by manipulating or dividing light to achieve two or more points of focus.

While well received by patients, multifocal lenses have limitations. They "split light and bend light and ... certain portions of the light get focused in certain areas, so [ultimately] you're giving a compromise," MacHatton explained.

On the other hand, an accommodating IOL, in concept, allows the patient to focus through a continuous range of vision because it moves within the eye in a manner similar to that of a natural lens.

It is this seamless transition between the distant, intermediate and near vision that represents the attraction of accommodating IOLs.

Today's multifocal lenses include AMO's ***ReZoom*** and Alcon's ***AcrySof Restor***, available in the U.S., and AMO's ***Tecnis***, which is on the market internationally and undergoing trials in the U.S.

The only FDA-approved accommodating IOL is ***CrystaLens***, made by Eyeonics. Internationally, CrystaLens faces competition from HumanOptics' ***1CU*** and Visiogen's ***Synchrony*** accommodating lenses. Synchrony is currently in clinical trials in the U.S.

While CrystaLens offers accommodation, industry players agree the technology has considerable room for improvement.

Waltz, who has consulted for both AMO and Eyeonics, suggested that compared with multifocal options, CrystaLens is associated with superior intermediate and distance vision, but markedly less predictable near vision.

For that reason, a patient's decision to go with a multifocal lens instead of CrystaLens often hinges on how badly he or she wants to be rid of glasses, Waltz said.

In his experience, about two-thirds of patients opt for the perks that come with CrystaLens, with the understanding that reading glasses may be necessary. The rest jump at a multifocal lens because they strongly want to be independent of glasses.

"There is no perfect lens on the market," Bache said.

According to Eyeonics, about 91% of CrystaLens recipients demonstrate near visual acuity of J3 or better, as indicated by their performance on the Jaeger eye chart for near reading, where J1 indicates the highest performance and J6 the worst.

People in the J3 category can read print about the size that appears in a hard cover novel or magazine from about 12-14 inches away, according to Eyeonics' VP-Clinical Outcomes Michael Breen.

Nevertheless, he acknowledged that a company priority is to improve its technology's ability to deliver near visual acuity.

In July, Eyeonics announced CrystaLens sales of $8.4 mil. for the first half of fiscal year 2006, up 21% from the first half of 2005. Over 50,000 patients have been implanted with the technology worldwide, it says.

Life In The Intermediate Zone

Eyeonics highlights two advantages in particular that CrystaLens, despite its shortcomings, enjoys over competing lenses.

First, CrystaLens is not associated with visual disturbances such as glare and haloes - a common complaint of multifocal lens patients, Breen said.

Second, the accommodating lens, by design, ensures superior intermediate vision "because of the fact that it changes power in response to what the accommodative demand is ... rather than having a set amount of focal points built into the lens, based on a multifocal design," he maintained.

He defined the "intermediate" range of vision as 28 inches to 4 feet from a person's eyes.

The seamless transitioning of an accommodating lens means that patients do not have to move their heads or move an object in order to view it clearly; focus is achieved more naturally, according to Breen.

"Looking at a computer screen, ... working on an assembly line with objects that are going by, ... shopping in a grocery store and looking at labels and prices on the shelf, looking at your cell phone as the number's coming across - all those aren't done strictly at near [but] more like arm's length."

"It's amazing the amount of life that occurs these days at that specific distance," Breen observed.

AMO's Bache agreed that CrystaLens provides reliable intermediate and distance vision. "But these patients are paying a significant amount of money to get all three" - distance, intermediate and near.

Eyeonics is attempting to have its reengineered version of CrystaLens with improved near version capabilities reach the market before the commercialization of any competitor's accommodating IOL.

AMO and Alcon declined to give timetables for their accommodating lens programs.

Multifocal IOLs Live On

In the meantime, multifocal lenses will continue to evolve.

Alcon aims to incorporate an aspheric element into its Restor lens by early 2007. This increased complexity in the curvature of the lens will enhance the device's contrast sensitivity and "result in better vision across all focal distances," MacHatton said. In a year or two, Alcon aspires to change the "add power" of its lens to improve its performance in the intermediate zone of vision.

In two to three years, the company wants to reach currently underserved patients with astigmatism by building a multifocal lens with a toric component, which includes a specialized shape at the back of lenses enabling better fit and orientation on the eye's surface. Such technology is now available only in monofocal lenses.

Interestingly, the astigmatic population may ensure that a demand for multifocal lenses remains even as accommodating technologies come to the fore.

MacHatton noted that in order to correct for astigmatism, "you have to have that optic stationary, because if you move it, now the light hits it at a different area and it changes the astigmatic correction. So if you have a lens that moves, you're not going to be able to correct for astigmatism."

AMO says it is developing IOL technology based on patents acquired through its 2005 purchase of Quest Vision.

In addition, the firm has launched a presbyopia laser vision solution in Europe - currently in clinical trials in the U.S. - that it believes could capture those patients and physicians averse to IOL implantation.

- *Ryan Nelson*