KAMRA INLAY RECEIVES FDA APPROVAL

The FDA has approved the Kamra inlay (AcuFocus), which is indicated to improve near vision by extending depth of focus in presbyopic patients who have emmetropic refractions (+0.50 D to -0.75 D). The approval, announced on April 17, 2015, represents the first major advancement in the surgical correction of presbyopia in over a decade.

"Today is a momentous occasion, not only for AcuFocus but for the whole industry, because this is a first-of-its-kind therapy in the United States and really is trailblazing for other entities to attack presbyopia," Jim Mazzo, chairman and CEO of AcuFocus, said in an interview with Eyewiretoday.com. "Presbyopia affects a lot of people and what the Kamra inlay is going to be able to do is take care of near all the way through to distance [vision]. We are thrilled with this approval."

The Kamra inlay approval was based on the results of 508 patients treated at 24 investigational sites worldwide. Patients in the clinical study experienced an average improvement in uncorrected near visual acuity of 3 lines between their preoperative exam and the 12-month follow-up visit. This improvement was maintained over the 5-year duration of the study. Mean preoperative uncorrected distance visual acuity in the inlay-implanted eye was maintained across all follow-up examinations, according to an AcuFocus news release.

"Near-vision loss from presbyopia can be a significant challenge in the everyday lives of patients, especially those who are emmetropic, which means they previously enjoyed normal vision without the need for glasses, contacts, or other correction," Daniel S. Durrie, MD, founder of Durrie Vision, Overland Park, Kansas, said in the news release. "With the approval of the Kamra inlay, we now have a reliable solution for presbyopes who want to enjoy many daily activities without reading glasses."

The Kamra inlay is an ultra-thin opaque ring that is implanted monocularly into the patient's nondominant eye. The device utilizes the principle of small-aperture optics, or pinhole effect, to extend depth of focus for patients suffering from age-related near-vision loss. The inlay measures 3.8 mm in total diameter and has a 1.6-mm central aperture. As a result of this design, central focused light is allowed to reach the retina uninterrupted, resulting in functional vision from near to far without reading glasses, according to AcuFocus.

Dr. Durrie is a consultant to AcuFocus.

Abbott Medical Optics Introduces the Compact Intuitiv Phacoemulsification System

Abbott Medical Optics announced the launch of the Compact Intuitiv Phacoemulsification System at the American Society of Cataract and Refractive Surgery meeting in San Diego.

The Compact Intuitiv system features fluidics and multi-directional ultrasound, and it is designed to deliver chamber stability, minimal clogging, and dependability, according to a company news release.

"The Compact Intuitiv provides the peristaltic fluidics from the (Whitestar) Signature. It provides the phaco parameters of the Signature. And it does this with a touchscreen interface," Daniel Chang, MD, a partner at Empire Eye and Laser Center in Bakersfield, California, said in an interview with Eyewiretoday.com.

The Intuitiv has real-time chamber stability technology designed to maintain IOP and provide excellent control, according to AMO. Other features include small-bore, flexible tubing for control and chamber stability; predictability of gravity-fed infusion; and automatic occlusion sensing and exceptional chamber stability.

Dr. Chang is a consultant to AMO.

FDA Approves AcrySof IQ Restor +2.5 D Multifocal IOL

Alcon received approval from the FDA for its AcrySof IQ Restor +2.5 Diopter IOL for the correction of near, intermediate, and distance vision. The Centers for Medicare and Medicaid Services added the AcrySof IQ Restor +2.5 D IOL to the list of its recognized presbyopia-correcting IOLs, confirming that AcrySof IQ Restor +2.5 D IOLs will be eligible for reimbursement as both a Medicare-covered service (treat-

ment of cataract) and as a noncovered service (presbyopia correction). Alcon will commercialize the AcrySof IQ Restor +2.5 D IOL in the United States in the near future.

"We are pleased by the FDA's decision to approve our AcrySof IQ Restor +2.5 D IOL," Sabri Markabi, senior vice president, research and development for Alcon, said in a company news release. "This technology complements our existing AcrySof IQ Restor +3.0 D IOL in the marketplace, providing more presbyopia-correcting options for ophthalmic surgeons and the patients they serve."

The AcrySof IQ Restor +2.5 D IOL is commercially available in the European Union, Australia, Canada, Japan, and countries in Central and South America. Close to 27,000 AcrySof IQ Restor +2.5 D IOLs have already been implanted in patients in the countries where they are commercially available.

"With the addition of AcrySof IQ Restor +2.5 D IOL, surgeons now have a broader range of treatment options to meet the vision needs of cataract patients seeking presbyopia correction, based on various lifestyle requirements," Lisa Cibik, MD, director of cataract services at Associates in Ophthalmology of Pittsburgh, said in the news release. "The Restor +2.5 D IOL helps surgeons meet the needs of cataract patients with active lifestyles."

Dr. Cinik is a consultant to and speaker for Alcon.

Rhopressa Phase 3 Trial (Rocket 1) Misses Primary Endpoint

Aerie Pharmaceuticals reported that their phase 3 registration trial (Rocket 1) did not meet its primary efficacy endpoint of demonstrating noninferiority of IOP lowering for once-daily Rhopressa compared to twice-daily timolol, the most widely used comparator in registration trials for glaucoma, according to a company news release.

Rhopressa, a novel once-daily, triple-action eye drop is being tested for its ability to lower IOP in patients with glaucoma or ocular hypertension.

Rhopressa did demonstrate noninferiority compared to timolol for patients in the study with IOP below 26 mm Hg at all nine measured time points, and numerical superiority over timolol at the majority of measured time points, according to Aerie. Approximately 80% of glaucoma patients have an IOP of 26 mm Hg or less at the time of diagnosis.

Rhopressa did not meet its primary efficacy endpoint of demonstrating noninferiority of IOP lowering for Rhopressa compared to twice-daily timolol, based upon IOP measurements at the end of week 2, week 6, and day 90. The Rocket 1 study included 182 patients in the Rhopressa once-daily arm and 188 patients in the timolol twice-daily arm. The baseline IOPs tested in the study ranged from above 20 mm Hg to below 27 mm Hg. In addition, the results showed a slight loss of efficacy in the week-6 and day-90 measurements. Across the Rhopressa study of 182 patients, 36 patients or approximately 20% showed signs of loss of efficacy during the study. The primary adverse event was hyperemia, which was experienced by approximately 35% of the Rhopressa patients, of which 80% was reported as mild.

"We are obviously disappointed that we missed the primary endpoint for Rocket 1," Vicente Anido, Jr, PhD, chairman and CEO of Aerie, said in the news release. "We expected Rhopressa to demonstrate better performance based on the results we saw in the previous phase 2b studies. However, if we had set the high end of the baseline range just 1 mm Hg less, we would have demonstrated noninferiority compared to timolol at all nine measured time points and numerical superiority at the majority of time points. We believe Rhopressa shows great promise at IOPs where the majority of patients are represented. Also, we believe the meaningful decrease in the number of patients that experienced efficacy loss at the lower baseline IOPs supports the potential benefit of the Rhopressa on episcleral venous pressure."

Nidek Receives FDA OK for Final Fit Software

Nidek announced that the FDA has approved the use of Final Fit software for the OPD-Scan III aberrometer. The updated Final Fit software will facilitate compatibility with the new aberrometer to perform topography-assisted LASIK, according to a company news release.

The Final Fit software generates laser shot data of the excimer laser system with OPD-Scan III measurement data. Nidek says the OPD-Scan III is a five-in-one true refractive workstation combining a wavefront aberrometer, topographer, auto refractometer, auto keratometer, and pupillometer/pupillographer.

"We are pleased to have this approval, and confident the results reflect the quality of our products," Motoki Ozawa, president of Nidek, said in the news release.

Nidek's NAVEX Quest; EC-5000 Excimer Laser System pairs with the company's product portfolio in diagnostic, surgical instrumentation, optical finishing, and dispensing products for vision care, according to the news release.

Use of Two OVDs During Intumescent Cataract Surgery Reduced Complications

Using both medium- and high-viscosity ophthalmic viscosurgical devices (OVDs) led to safe indentation of the anterior lens capsule and reduced the risk for enlargement of the continuous curvilinear capsulorhexis (CCC) and capsular tear during cataract surgery, according to study in the *Journal of Cataract & Refractive Surgery*.[1]

After staining the capsule with trypan blue, the surgeons

created a central indentation of the anterior lens capsule using a medium-viscosity OVD (Healon 1%; Abbott Medical Optics) in group 1 (n = 21 eyes) and both medium- and high-viscosity (Healon 2.3%; Abbott Medical Optics) OVDs in group 2 (n = 20 eyes). They placed the high-viscosity OVD centrally. Next, they created the CCC and measured the horizontal and vertical diameters of the CCC, the deviation from the target diameter, and recorded intraoperative complications.

According to the study, deviation from the target CCC diameter occurred in 12 eyes (10 oversized, two undersized) in group 1, and in six eyes (4 oversized, two undersized) in group 2. Capsular tears occurred in two eyes in group 1 and none in group 2. The procedure was converted to extracapsular cataract extraction with anterior vitrectomy for one eye in group 1.

1. Hengerer FH, Dick HB, Kohnen T, Conrad-Hengerer I. Assessment of intraoperative complications in intumescent cataract surgery using 2 ophthalmic viscosurgical devices and trypan blue staining. *J Cataract Refract Surg.* 2015;41(4):714-718.

AREDS Scale Predictive of Long-Term Outcomes

Two-year changes in the severity of lens opacities on the Age-Related Eye Disease Study (AREDS) lens grading scale are predictive of long-term clinically relevant outcomes, according to a study in *Ophthalmology*.[1]

The study included AREDS participants whose eyes were phakic at baseline and free of late age-related macular degeneration throughout the study. The investigators graded baseline and annual lens photographs of AREDS participants (n = 3,466/4,757; 73%) for severity of cataracts using the AREDS system for classifying cataracts from photographs. They conducted clinical examinations semiannually to collect data on cataract surgery and visual acuity and analyzed the association of the change in lens opacities at 2 years with these outcomes at 5 years (adjusted Cox proportional hazard models).

The investigators reported the adjusted hazard ratios (HRs) for association of progression to cataract surgery at 5 years. For eyes with a nuclear cataract, there was an increase of 1 unit or more compared with less than a 1-unit change at 2 years (HR, 2.77; 95% CI, 2.07-3.70; $P < .001$). For eyes with a cortical cataract, there was an increase of 5% or more in lens opacity in the central 5 mm of the lens compared with less than a 5% increase at 2 years (HR, 1.91; 95% CI, 1.27-2.87; $P = .002$). For eyes with a posterior subcapsular cataract, there was an increase of 5% or more versus less than 5% in the central 5 mm of the lens (HR, 8.25; 95% CI, 5.55-12.29; $P < .001$).

"Relatively short-term, modest changes in the severity of all three types of lens opacities on the AREDS scale were predictive of long-term clinically relevant outcomes," the investigators said. ■

1. Indaram M, Agrón E, Clemons TE, et al. Changes in lens opacities on the Age-Related Eye Disease Study grading scale predict progression to cataract surgery and vision Loss: Age-Related Eye Disease Study Report No. 34. *Ophthalmology*. 5:122(5):888-896.