ASCRS AND AAO RELEASE UPDATED JOINT SHARED CARE GUIDELINES

The American Society of Cataract and Refractive Surgery (ASCRS) and the American Academy of Ophthalmology (AAO) released updated guidelines about when shared care is appropriate in certain patients, according to a joint statement from the ophthalmic organizations. The revised statement[1] reportedly is the result of a 2-year discussion between the ASCRS and AAO to modify the original guidance first issued in 2000. The updated document reflects the standards-driven approach in which patients are managed in the current health care environment, and it emphasizes the role of the patient as the ultimate decision maker, with appropriate consideration for quality of care and patients' safety.

In the revised guidance, the ASCRS and AAO focus less on legal and ethical perils, while encouraging ophthalmologists to use professional judgment consistent with applicable ethics and law in interpreting and applying the guidelines to the particular circumstances of their individual practices.

The updated position paper

- Acknowledges that sharing management can serve patients' legitimate interests and can be done appropriately
- Is more appropriate for integrated care systems
- Improves and updates key definitions of terms such as *comanagement* and *transfer* and distinguishes between them
- Removes most references to legal and ethical perils
- Removes a prohibition against routine arrangements and instead emphasizes standards mutually agreed upon
- Adds three categories of circumstances that justify integrated care: barriers to patients' travel, the unavailability of an operating ophthalmologist, and patients' prerogatives
- Adds nine criteria for acceptable arrangements
- Strikes an explicit requirement for written consent and allows verbal consent with documentation

For more information, contact Nancey McCann, ASCRS director of government relations, at (703) 591-2220.

1. Ophthalmic Postoperative Care: a Joint Position Paper of the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery. September 9, 2015. http://bit.ly/1UHNhLL. Accessed September 9, 2015.

Allergan to Acquire AqueSys

Allergan has entered into an agreement under which it will acquire AqueSys for $300 million, plus regulatory and commercialization milestone payments related to AqueSys' lead development programs, including the Xen 45, according to a company news release.

"The acquisition of AqueSys is part of our larger commitment to being a best-in-class company within eye care, and more specifically with respect to glaucoma," Brent Saunders, president and CEO of Allergan, said in an interview with *CRST*. "We have a broad portfolio of pharmacological solutions in glaucoma, and we have some really interesting projects in R&D, most notably bimatoprost (Lumigan) SR, but as we look at the treatment of this disease, it's important to look at more dropless therapies, and by adding a [microinvasive glaucoma surgery] implant to our portfolio, it allows us to have a full range of solutions for physicians and patients with glaucoma."

The acquisition of AqueSys provides Allergan with the Xen 45, a soft shunt that is implanted in the subconjunctival space in the eye through a minimally invasive procedure with a single-use, preloaded proprietary injector. The proprietary Xen 45 technology facilitates aqueous fluid flow to lower IOP while protecting against the potential for hypotony that is associated with current subconjunctival procedures, according to Allergan.

"We currently have a few drugs on the market for glaucoma, most notably drugs like Alphagan (brimonidine tartrate), Lumigan (bimatoprost), and Combigan (brimonidine tartrate/timolol maleate)," Mr. Saunders said. "When we look at some of the more significant issues that patients with glaucoma face, it has to do with compliance with therapy, or meeting the goal of IOP reduction. Many patients are not meeting their goal, or they are failing to comply. The combination of our own bimatoprost SR as well as now adding the AqueSys Xen 45 into our portfolio gives us the additional complementary products that are dropless and that will solve for both compliance as well as the potential for reducing pharmacological intervention for those patients not meeting goal."

The Xen 45 has received CE Mark approval in the European Union, where it is indicated for the reduction of IOP in patients with primary open-angle glaucoma when previous medical treatments have failed. The CE Mark allows treatment in conjunction with a cataract procedure or as a standalone procedure. The implant is also approved for use in Turkey, Canada, and Switzerland. AqueSys is pursuing reimbursement in these countries. In the United States, the Xen 45 is in late-stage development, with the final US investigational device exemption clinical trial fully enrolled in the second quarter of 2015. Final approval by the FDA is expected by late 2016 or early 2017, according to Allergan.

Pending regulatory approvals, Allergan anticipates closing the transaction in the fourth quarter of 2015.

To see Mr. Saunders talk about the acquisition of AqueSys, go to eyewiretoday.com/tv/eyewiretv-mdash-breaking-industry-news-from-the-escrs-meeting-in-barcelona.

Heidelberg Unveils Cataract and Refractive Imaging Platform

Heidelberg Engineering previewed its cataract and refractive imaging platform at the annual meeting of the European Society of Cataract and Refractive Surgeons in Barcelona. According to the company, the platform is based on an upgradable, modular design, which allows configuration of each product to the specific diagnostic workflow in a practice or clinic. The main options with the new platform include IOL biometry, corneal topography/tomography, anterior segment biometry, and anterior segment imaging.

The new platform is reportedly based on swept-source optical coherence tomography technology, and all measurements and analysis are based on high-resolution diagnostic images. According to the company, this feature mitigates the effects of confounding factors such as coexisting abnormalities, which often cannot be unambiguously identified without diagnostic imaging. The new approach increases ophthalmologists' confidence in the measurements.

The cataract and refractive imaging platform fully integrates with the company's Heyex Pacs, the next-generation Heidelberg Eye Explorer platform, which provides centralized management of diagnostic images in ophthalmology.

The cataract and refractive imaging platform is under development and not yet for sale.

Oculus Surgical Premieres the Pentacam AXL

Oculus Surgical premiered its new Pentacam AXL at the annual meeting of the European Society of Cataract and Refractive Surgeons. The device measures the anterior eye segment as well as axial length, and it is equipped with comprehensive Pentacam HR basic software modules such as the unique fast screening report and the valuable cataract Pre-OP Display, according to a news release.

All data (axial length, keratometry values, anterior chamber depth, corneal diameter) are automatically transferred to the IOL calculation software, which rules out manual transcription errors. The IOL power calculator includes formulas for normal eyes (Haigis, SRK/T, Holladay1, Hoffer Q) as well as eyes that have undergone refractive surgery (PotvinShammasHill for postmyopic LASIK and PotvinHill for postradial keratotomy). The IOL power calculator for toric IOLs is based on meridional analysis using total corneal refractive power, in which posterior corneal power is already considered. The built-in IOL database includes IOLs from many manufacturers.

Because the axial length and the three-dimensional scan are performed during the same measurement routine and on the same measurement axis, there is no need to relocate the patient. According to the company, measurements are performed in seconds, making the examination a breeze for both the patient and examiner.

Alcon Unveils Innovations for Cataract Surgery Patients

Alcon introduced cataract surgery innovations at the European Society of Cataract and Refractive Surgeons Congress in Barcelona, according to a news release.

To be launched in several European countries, the innovations include the AcrySof IQ PanOptix presbyopia-correcting IOL, the UltraSert Delivery System preloaded with the AcrySof IQ Aspheric IOL, and the ORA System with VerifEye+ Technology.

The AcrySof IQ PanOptix presbyopia-correcting IOL is a trifocal lens that addresses near, intermediate, and distance vision for patients suffering from cataracts and presbyopia. With an intermediate focal point at 60 cm and 88% light transmission, this lens is designed to provide a crisp quality of vision and comfortable intermediate vision, reducing dependency on reading glasses.

The AcrySof IQ Aspheric IOL with UltraSert Preloaded Delivery System is a single-use injector designed to facilitate smooth, consistent delivery of the AcrySof IQ Aspheric IOL, while maintaining the integrity of the incision to limit stretching of the wound.

The ORA System with VerifEye+ Technology allows surgeons to evaluate refractive findings, refine IOL and cylindrical power, and optimize IOL alignment in real time so as to improve refractive outcomes in cataract surgery.

Topcon's SP-1P Fully Automated Specular Microscope Receives FDA Clearance

Topcon Medical Systems announced that its SP-1P Fully Automated Specular Microscope has received 510(k) clearance from the FDA, according to a company news release.

The SP-1P is a fully automated instrument that offers innovative features for the documentation and analysis of the condition of the corneal endothelium. A 10.4-inch rotatable touch panel monitor eliminates the need for a control lever and can be turned to various angles so that the instrument can be used from virtually any position. When the operator taps on the center of the patient's pupil displayed on the monitor, the SP-1P automatically centers, focuses, and acquires the endothelial cell image, which takes a few seconds and requires minimum training, according to Topcon.

Other features of the SP-1P include a wide-angle "panorama" photography mode that substantially increases the size of the analyzed area and an automatic measurement and analysis of the endothelium with instant results and intuitive operation. The SP-IP also has an easy-to-read screen, comprehensive analysis software, and a color histogram displayed on the screen after the analysis.

Topcon said the SP-1P will be sold through authorized US distributors and in a direct way to corporate accounts.

Valeant Pharmaceuticals to Acquire Synergetics USA

Valeant Pharmaceuticals International announced that its affiliate has entered into a definitive agreement under which Valeant will acquire Synergetics USA for $6.50 per share in cash, according to a company news release. In addition to the upfront cash payment, Synergetics stockholders will receive additional cash payments of up to $1 per share if specified sales milestones are achieved following the closing. The transaction is expected to close in the fourth quarter of 2015 and is subject to customary closing conditions and regulatory approvals. At $6.50 per share, the offer is worth about $166 million based on Synergetics' diluted outstanding shares as of April 30.

Under the terms of the agreement, Valeant will commence a tender offer to acquire all outstanding shares of Synergetics' common stock for $6.50 per share in cash plus one contingent value right entitling the stockholder to receive up to $1 per share if specified sales thresholds for Synergetics are achieved following the closing. The details of the contingent cash consideration payments are as follows:

- $0.50 per share in cash payable upon sales of the company's ophthalmology products achieving $55 million on a trailing four calendar quarter basis prior to June 30, 2018
- $0.50 per share in cash payable upon sales of the company's ophthalmology products achieving $65 million on a trailing four calendar quarter basis prior to June 30, 2018, with a pro-rata portion payable for net sales above $55 million but less than $65 million

Following the successful completion of the tender offer, Valeant will acquire all remaining shares not tendered in the tender offer through a second-step merger at the same price and with the obligation to make the same contingent cash consideration payments as are made to stockholders tendering their shares in the tender offer. The tender offer and withdrawal rights are expected to expire at 12 AM Eastern Standard Time on the 20th business day after the launch of the tender offer, unless extended in accordance with the merger agreement and the applicable rules and regulations of the US Securities and Exchange Commission.

The consummation of the tender offer is subject to various conditions, including a minimum tender of a majority of outstanding Synergetics' shares on a fully diluted basis, the expiration or termination of any applicable waiting periods under applicable competition laws, and other customary conditions. The Board of Directors of Synergetics unanimously approved the transaction.

William Blair & Company acted as the financial advisor to Synergetics, and Armstrong Teasdale acted as legal advisor to Synergetics. Skadden, Arps, Slate, Meagher & Flom acted as legal advisor to Valeant.

Fewer Keratoplasties for Keratoconus Performed Since the Introduction of CXL

The frequency of keratoplasty for keratoconus has decreased by more than half at a hospital in Norway since the introduction of corneal collagen cross-linking (CXL), according to a study in *Cornea*.[1]

The investigators compared data from a cohort of patients from the Oslo Hospital University corneal

transplant registry from 2005 to 2006 (period 1) and 2013 to 2014 (period 2). Patients during period 1 had surgery before the introduction of CXL treatment, and patients in period 2 had surgery after this treatment was well established at the hospital. Patients' age and gender were registered, and the investigators used the Amsler-Krumeich classification system to grade the degree of keratoconus.

According to the study, the total number of keratoplasties performed during period 1 was 137, and keratoconus was the cause of surgery in 55 eyes (55 patients). For period 2, the total number of keratoplasties was 231, and keratoconus was the cause of surgery in 26 eyes (26 patients). The difference in the number of keratoplasties for keratoconus in both periods was statistically significant (P = .003). There were no significant differences in the distributions of age and gender between both periods. In period 1, 63.6% of the eyes were graded as stage 4 versus 96.2% in period 2 (P = .001).

"We have compared the number of patients with keratoconus who underwent keratoplasty immediately before and after CXL treatment was well established in our department," the investigators said. "Although we performed more keratoplasty procedures in the last period compared with the first period (231 vs 137), the frequency of keratoplasties in patients with keratoconus was more than halved (reduced from 55 to 26 cases). ...There is reason to believe that this reduction is in great part a result of the introduction of CXL. This study is the first to report such a decrease. However, large longitudinal studies in patients with keratoconus are warranted to make definite conclusions about this matter." ■

1. Sandvik GF, Thorsrud A, Råen M, et al. Does corneal collagen cross-linking reduce the need for keratoplasties in patients with keratoconus? *Cornea*. 2015;34(9):991-995.

LETTERS

EARLY R&D

The article "History of a Corneal Inlay" by Stephen Daily appeared in our June edition. It provided an overview of the development of the newly FDA-approved Kamra inlay (AcuFocus) from the time the patent for the technology was acquired in 2002 to the present. Before the patent was acquired, Dr. Miller and colleagues performed much of the early scientific discovery and testing of the inlay technology.

The story starts in 1977, when a colleague and I did the original work in humans on the quantification of the small-aperture effect. I highlight humans because the optical physicists had predicted that diffraction would theoretically degrade the retinal image created by a small-aperture system. Our early results taught us that the human brain plays a major role in enhancing the retinal image created by the small aperture. This study also taught us how opaque (dark) the ring must be to yield a clinically acceptable depth of focus effect.[1,2]

Once I realized that, in our modern world of bright artificial lighting, a small-aperture device would let in enough light to create a clinically useful retinal image, we started clinical investigations with contact lenses imprinted with small-aperture rings.[3-6]

The contact lens research proved that the small-aperture principle successfully treated presbyopia without significantly lowering the perceived brightness of the retinal image. However, we also learned that, if the center of the ring was not coaxial with the patient's pupil, then the depth of focus effect was reduced. That is when we decided to surgically implant a black-ring device (porous to nutrients) into the cornea so it would stay centered. Note the dates on the patents do not represent all the years of research preceding the patent approval.[7-9]

In about the year 2000, Ramgopal Rao, an engineer/businessman, and I formed a company (Boston Innovative Optics), which made and tested the intracorneal black ring inlay. The results were very promising. Thus, in 2002, I presented our work on the corneal inlay at the Innovator Session of the American Society of Cataract and Refractive Surgery annual meeting.

In 2002, we also licensed the product to The Innovation Factory, which then spun off AcuFocus. In the last decade, I am pleased to note that the AcuFocus team has improved the product to a level that garnered FDA approval. ■

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1. Miller D, Johnson R. Quantification of the pinhole effect. *Surv Ophthalmol*. 1977;21:347-350.
2. Green DG, Powers MK, Banks MS. Depth of focus, eye size, and visual acuity. *Surv Ophthalmol*. 1981;26:52.
3. Atebara N, Miller D. Masked contact lens. US patent 4,955,904. September 11, 1990.
4. Miller D, Meshel L. Annular contact lens. US patent 5,245,367. September 14, 1993.
5. Miller D, Meshel L. Annular masked contact lens. US patent 5,757,458. May 26, 1998.
6. Miller D, Meshel L. Annular mask contact lens. US patent 5,786,883. July 28, 1998.
7. Miller D, Blanco E. A system and method for increasing the depth of focus of the human eye. US patent 6,554,424. April 29, 2003.
8. Miller D, Blanco E. A system and method for increasing the depth of focus of the human eye. US patent 6,874,886. April 5, 2005.
9. Miller D, Blanco E. System and method for increasing depth of focus of the human eye. US patent 8,343,215. January 1, 2013.