

Top Products of 2009

The surgeon who received the 2009 Innovator's Award from the ASCRS and the AAO's Kelman Award shares his picks from last year.

BY ROBERT H. OSHER, MD

The year 2009 may be remembered by some as the year of the great health care reform debate and by others as the year when the New York Yankees regained their swagger. For ophthalmologists, 2009 was a fertile year for innovation that has raised the bar of excellence in cataract surgery. This article reviews some of the year's highlights.

HIGH DEFINITION IN THE OR

Sony Electronics Inc. (Park Ridge, NJ) introduced a high-definition camera system, the PMW-10MD, which became commercially available in the third quarter of 2009. The remarkable resolution is 1080p, and images can be viewed on either a stand-alone or a wall-mounted monitor. The easy-to-use high-definition recorder with an optional printer is certain to set a new standard in video recording. In my experience, families who view surgery on this system are "blown away" by the experience, and the quality of the image is unprecedented for educational presentations.

MICROSCOPES

The OPMI Lumera (Carl Zeiss Meditec, Inc., Dublin, CA) validated the concept of stereo coaxial illumination for achieving the most spectacular red reflex ever recorded. In October, Zeiss unveiled its new OPMI Lumera 700, which will be the first microscope specifically designed for both cataract and retinal surgeons. It features an integrated keratoscope, an electronic inverter tube, and a wide-angle fundus viewing system.

BLADES

BD (Franklin Lakes, NJ) has continued to champion safety with its shielded blades. At the AAO Annual Meeting, the company introduced the new 2.2- and 2.4-mm Osher guarded safety knife with a shortened blade configuration for greater protection of the natural lens. With this design, the novel internal-flare incisional architecture was devel-

oped to allow greater maneuverability of the instrument within microincisions.

ADHESIVES

Two tissue adhesives, I-Zip (Ocular Therapeutix, Inc., Waltham, MA) and OcuSeal (BD) were in clinical trials aimed at achieving the perfectly sealed incision at the end of the operation. Much of the enthusiasm for tissue glue was created by Amar Agarwal, FRCS, FRCOphth, of Chennai, India. His technique of fixating a PCIOL without sutures has been improved by tucking the haptics into intrascleral tunnels, as published by Gabor Scharioth, MD, of Germany.¹

OPHTHALMIC VISCOSURGICAL DEVICES

Abbot Medical Optics Inc. (AMO, Santa Ana, CA) introduced a new combination pack containing Healon5 and Healon. This pairing will allow surgeons to take advantage of the viscomydriasis and chamber-deepening properties of Healon5 while permitting faster removal of the OVD at the end of the case through the use of Healon for the lens' implantation.

PHACO TECHNOLOGY

Bausch + Lomb (Rochester, NY) introduced a micro-coaxial system capable of removing the lens through sub-2-mm incisions on the company's Stellaris Vision Enhancement System. Coupled with its sub-2-mm Akreos AO Microincision Lens, Bausch + Lomb has become the frontrunner in sub-2-mm cataract surgery. AMO introduced dual-pump technology, which gives the surgeon the option of either a peristaltic or a venturi pump. At the AAO Annual Meeting, Alcon Laboratories, Inc. (Fort Worth, TX), debuted Ozil Intelligent Phaco, which allows the surgeon to set a vacuum threshold lower than the vacuum limit, at which point a burst of longitudinal energy will clear an occlusion. By preventing the pump from stopping, the benefits of this feature include improved

followability of nuclear material and a more stable chamber, because occlusion does not break at maximum vacuum. Ozil Intelligent Phaco enhances the efficiency of torsional ultrasound, because the nuclear material is continuously repositioned at an optimal shearing plane, with longitudinal energy only occurring on demand.

Also at the Academy meeting, Alcon introduced the Ozil 12° surgical tip in either a traditional Kelman or a reverse-bevel configuration. I designed this tip to blend the cutting efficiency of torsional ultrasound with enhanced phacoaspiration. The company also released its polymer I/A tip in three configurations: straight, bent, and curved. These single-use disposable tips are designed to enhance capsular protection and reduce the chance of contamination. Alcon also unveiled a new vitrector that features a redesigned 23-gauge tip, which fits through a 1-mm side-port incision and can execute up to 2,500 cuts per minute.

FEMTOSECOND LASERS

In 2009, LensAR Inc. (Winter Park, FL), LenSx Lasers Inc. (Aliso Viejo, CA), and OptiMedica Corp. (Santa Ana, CA) astonished audiences by performing with femtosecond lasers a perfect laser capsulorhexis, nuclear splitting and softening, and precise primary and relaxing astigmatic incisions. Preliminary enthusiasm from offshore investigators indicates that more accurate and efficient cataract surgery may be just around the corner. Some economic and regulatory challenges, however, must be overcome before legions of ophthalmologists jump on the femtosecond bandwagon. After 4 decades of rumors about laser cataract surgery, it actually appears to be imminent.

PRELOADED IOL INJECTORS

Perhaps the single most conspicuous difference between the 2009 meetings of the ASCRS and ESCRS was the prevalence of preloaded injectors at the latter. The FDA recently approved and granted New Technology IOL status to the iSert Preloaded IOL Injection System (Hoya Surgical Optics, Inc., Chino Hills, CA) for the insertion of the lens through a 2.4-mm incision. I hope this development signals a coming flurry of competitive activity that will lead to the availability in this country of a variety of preloaded injectors that permit the IOL's implantation through a small incision while eliminating time-consuming loading, iatrogenic optical marks, and the potential for contamination.

IOLs

Last year showcased many innovations in IOL technology. Bausch + Lomb cracked the 2-mm barrier when it received FDA approval for the Akreos AO Microincision Lens. Bausch + Lomb also became the first company to provide lenses in 0.25 D increments with its Crystalens, a

development emphasizing the importance of precise IOL selection. Explosive growth in the toric IOL market was evident with the release of and NTIOL status granted to the AcrySof IQ Toric lens (Alcon). At the ESCRS meeting in Barcelona, Spain, the company introduced the T6 through T9 models of this IOL (not available in the United States) for high cylindrical correction. The FDA approved AMO's three-piece Tecnis Multifocal lens, and the single-piece design became available in some countries. The US launch of the AcrySof IQ Restor IOL +3.0 D has been greeted with enthusiasm by ophthalmologists. This lens improves vision at an intermediate distance compared with the AcrySof IQ Restor IOL +4.0 D (both lenses from Alcon).

In Europe, Oculentis GmbH (Berlin, Germany) introduced the hydrophilic multifocal Lentis Mplus IOL, which has a unique appearance similar to the executive bifocal. Although the United States still lacks a multifocal toric lens, both the M-flex Multifocal IOL (Rayner Intraocular Lenses Ltd., Hove, East Sussex, United Kingdom) and the Acri.Lisa toric lens (Carl Zeiss Meditec AG, Jena, Germany) attracted large audiences at the ESCRS meeting.

Perhaps the most exciting news in accommodating lenses occurred when AMO added the dual-optic Synchrony lens to its portfolio by purchasing Visiogen. STAAR Surgical Company's (Monrovia, CA) Collamer Accommodating Study Team (CAST) announced that the company's Collamer NanoFlex lens was demonstrating accommodative activity. Innovator Ioannis Pallikaris, MD, from Crete, Greece, endorsed the full-sized, accommodating hydrophilic WIOL-CF lens from A.M.I. Care SRO (Prague, Czech Republic). The NuLens (NuLens Ltd., Herzliya Pituah, Israel) exhibited excellent accommodative amplitudes in the first published human series,² accompanied by a supportive editorial from Emanuel Rosen, MD. STAAR Surgical Company introduced in the United States the Visian TICL (Toric Implantable Collamer Lens), which delivered impressive uncorrected visual outcomes. The Light Adjustable Lens (not available in the United States; Calhoun Vision, Inc., Pasadena, CA) received positive reviews from its European user group at the ESCRS meeting in Barcelona.

It would be fair to conclude that strong market trends favor increasing use of toric lenses, expanding accommodating lens technology, and implanting premium IOLs through smaller incisions in order to reduce or eliminate surgically induced cylinder.

INSTRUMENTS

As cataract incisions become smaller, it becomes more difficult to obtain a microscissors and a microforceps that are capable of reaching different meridians in both the horizontal and vertical planes. Getting "oar-locked" can be frustrating, especially in cases of iris reconstruction or

complex maneuvering of an IOL. Crestpoint Management Ltd. (St. Louis, MO) and Bausch + Lomb in association with Geuder AG (Heidelberg, Germany) have introduced a unique set of microscissors and microforceps that I designed. These instruments feature multiple tips with differently angled configurations on an interchangeable handle to allow the surgeon access to different meridians inside the eye. The same companies introduced the Osher semilunar markers for accurately identifying and marking the intended axis for aligning a toric IOL, performing astigmatic keratotomy, or placing limbal relaxing incisions. Unlike circular markers, the open design of the semilunar markers allows the degree indicator to snuggle up to the limbus to promote highly accurate marking of the target meridian.

A real milestone was reached with the introduction of the first automated IOL injector by Australian John Smiles, MD.³ A new regulatory battle in some parts of Europe has led to the mandated use of disposable instruments due to rising concern about HIV, hepatitis, and Creutzfeldt-Jakob disease. Last year, BD introduced the first line of disposable instruments for cataract surgery in the United States. America is not immune to this controversy, given Centers for Medicare & Medicaid Services' recent decision that all products labeled *single use* must either be discarded after one case or sent to one of the agency's approved reprocessing centers. I myself would hate to see the extraordinary quality and unprecedented craftsmanship of my favorite instruments replaced by less exquisite, inexpensive, disposable instruments.

DEVICES

Drs. Keiki Mehta and Cyrus Mehta from India have developed a HEMA "lifeboat" that looks like a soft contact lens and can be injected into the eye to separate nuclear fragments from an open posterior capsule, thus preventing posterior subluxation of lenticular material into the vitreous. After completing phacoemulsification, the surgeon can remove the device through the original small incision.⁴

Several devices have been developed for stabilizing a loose capsular bag in the presence of weak zonules. The Yaguchi capsular expander is a clever modification of the T-shaped capsular hooks introduced by Dr. Kozawa of Japan. The FDA approved the Ahmed Capsular Tension Segments and the Henderson Capsular Tension Ring with eight curvilinear segments for easier cortical removal (both products from Morcher GmbH, Stuttgart, Germany; distributed in the United States by FCI Ophthalmics, Inc., Marshfield Hills, MA). Hanita Lenses (Kibbutz Hanita, Israel) initiated sales of its AssiAnchor (not available in the United States), which secures the capsular bag to the scleral wall.⁵ MicroSurgical Technology (Redmond, WA) introduced the larger 7-mm Malyugin Ring, which has proven highly effective for manag-

ing a small pupil during cataract surgery. Despite the lack of FDA approval, prosthetic iris devices continue to evolve, with more than 50 color options available in the Morcher IrisMatch System (Morcher GmbH). Outside the United States, HumanOptics AG (Erlangen, Germany) has introduced a full-sized, soft device that has limited color options but can be trephinated for an ideal fit.

DIAGNOSTICS

Haag-Streit AG (Köniz, Switzerland) introduced the Lenstar LS 900—the first innovation in optical biometry in 10 years—and it received FDA approval. The unit collects nine important measurements at once, including axial length, keratometry, anterior chamber depth, and lens thickness.

Clarity Medical Systems, Inc. (Pleasanton, CA), introduced Holos (not available in the United States), a high-definition intraoperative wavefront prototype capable of confirming emmetropia and toricity in real time while the patient is on the operating table. By allowing continuous measurements, the Holos technology creates a movie rather than the snapshots of traditional Talbot-Moiré technology (WaveTec Vision Systems, Inc., Aliso Viejo, CA).

Another promising technology still in its infancy is iris "fingerprinting," which I introduced during the 2009 Innovator's Lecture at the ASCRS meeting in San Francisco. Imaging the unique landmarks of the iris (crypts, nevi, stromal pattern, Brushfield spots, etc.) promotes greater accuracy when determining the axis of the toric lens' alignment. Developed initially by Micron Imaging (Pegram, TN), the software allows the placement of the major meridians onto a captured image. The software overlays the major meridians and indicates the degrees at which any landmark is located. The user can add the goal line to map the intended axis for optimal alignment. Second-generation software has been developed by Carl Zeiss Meditec AG, Haag-Streit AG, and TrueVision Systems, Inc. (Santa Barbara, CA).

SensoMotoric Instruments GmbH (Teltow, Germany) introduced proprietary technology (not available in the United States) for toric lens orientation at the 2009 AAO Annual Meeting.

PHARMACEUTICALS

Blepharitis took center stage in 2009, as many cataract surgeons added AzaSite (Inspire Pharmaceuticals, Inc., Durham, NC) to their preoperative regimen. The newest fluoroquinolone, besifloxacin (Besivance; Bausch + Lomb), debuted. Durezol (Sirion Therapeutics, Tampa, FL) grew in popularity not only with cataract surgeons but also among corneal and glaucoma subspecialists in search of the maximal anti-inflammatory effect from a topical steroid. Allergan, Inc. (Irvine, CA), introduced preservative-free

Acuvail labeled for b.i.d. dosing. Ista Pharmaceuticals, Inc. (Irvine, CA), completed several phase 3 studies confirming the efficacy of Xibrom as a once-daily drop. Several published reports from retinal surgeons supported that non-steroidal anti-inflammatory drugs effectively treat cystoid macular edema.^{6,7}

EDUCATION

Eyemaginations, Inc. (Towson, MD), has introduced state-of-the-art products for educating cataract patients. A module designed by David Chang, MD, and the company was released last year. It describes for patients the latest options in refractive IOLs.

Surgical simulators are proving to be highly beneficial for educating ophthalmology residents at teaching institutions. One of the pioneering companies, VRmagic GmbH (Mannheim, Germany), has had its EYESI dry laboratory installed at more than a dozen US residency programs and received favorable reviews. Jansuke Akura, MD, from Japan developed the KITARO simulator, a demonstration of which won the overall prize in the ESCRS Video Competition in Barcelona.

The *Video Journal of Cataract and Refractive Surgery* celebrated its 25th anniversary with the launch of a high-definition Web site. In 2009, the journal featured phaco techniques, complications management, refractive laser and lens surgery, and innovative highlights from around the world.

CONCLUSION

The flurry of innovations touched upon in this article is enough to make today's cataract surgeon giddy. Although the economy remains in a state of flux, my crystal ball predicts that 2010 will be another great year for this subspecialty. ■

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