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iFS Femtosecond Laser Technology Approved for Arcuate Incisions

The iFS Femtosecond Laser (Abbott Medical Optics Inc.) has received clearance from the FDA to create bow-shaped or curved arcuate incisions in corneal surgery, including cataract surgery.

With this new clearance, which was announced at the ASCRS meeting in Chicago, surgeons can make precise, bladeless arcuate incisions during surgery and customize the incision for each individual patient. Factors such as placement, length, depth, and radius of curvature can influence the surgeon's desired change to the cornea, according to a company news release.

In an interview with *Cataract & Refractive Surgery Today*, Jim Mazzo, senior vice president of Abbott Medical Optics Inc., spoke about the laser's ability to provide customized results for each patient.

"A cornea is like a fingerprint," he said. "Everybody's is completely different, and so a physician now can utilize it for any manipulation of an incision on that cornea, versus being limited to just one kind of nomogram for every patient."

Mr. Mazzo added that practitioners who already own the iFS Femtosecond Laser do not need to change hardware to perform the corneal incisions. A software upgrade is available immediately at no cost.

"I think that's a very important step because as you gain new technology, what you don't want to do is disrupt the very successful practice that the physician already has had," he said.

Carl Zeiss Announces US Clinical Trial of ReLEx Smile Procedure

Carl Zeiss Meditec, Inc., was granted conditional approval from the FDA to initiate a clinical trial in the United States of the ReLEx smile procedure for the correction of myopia.

The ReLEx smile technique for refractive surgery combines femtosecond laser technology and precise lenticular extraction for minimally invasive laser vision correction. It is performed with the VisuMax femtosecond laser (Carl Zeiss Meditec, Inc.).

According to a company news release, the ReLEx smile method generates a refractive lenticule in the intact cornea with the femtosecond laser. The surgeon then removes the lenticule through an incision smaller than 4 mm without needing to move the patient to an excimer laser.

"We are pleased that we can now start this clinical trial, as it represents the first milestone on our path to make this procedure available to surgeons in the United States," Ludwin Monz, MD, president and CEO of Carl Zeiss Meditec, Inc., said in the news release.

VisuMax ReLEx smile was launched internationally in September 2011.

Alcon Debuts the WaveLight EX500 Excimer Laser

Alcon Laboratories, Inc., introduced the WaveLight EX500 excimer laser during the ASCRS meeting in Chicago. The laser received approval from the FDA in December 2011.

With a reportedly faster speed and enhanced laserhead life, the 500-Hz WaveLight EX500 excimer laser features several advances over Alcon's 400-Hz Allegretto Wave Eye-Q laser, according to a company news release. The WaveLight EX500 excimer laser delivers an upgradeable platform, with an advanced multidimensional 1050-Hz tracker synchronized at 500 Hz, noncontact dynamic pachymetry, and a communication-ready small/sleek footprint. It also delivers a 500-Hz pulse-frequency laser capable of a 1.4 sec/D ablation.

Flexivue Microlens Safe and Effective for Presbyopic Correction in Young Patients

In an exclusive interview with *Cataract & Refractive Surgery Today* at the ASCRS meeting, surgeons Kerry K. Assil, MD; Gustavo E. Tamayo, MD; and Ioannis Pallikaris, MD, PhD, said that the Flexivue Microlens (Presbia Coöperatief UA, not available in the United States) is a safe and effective option for presbyopic correction in young patients (40-60 years of age) who are motivated by a desire for spectacle independence. They said the inlay is also a welcome option for pseudophakes as well as post-LASIK patients who have recently become presbyopic.

The three surgeons have considerable experience with various corneal inlays and expressed their preference for

the Flexivue Microlens due to its biocompatibility, reversibility, and invisibility. Biocompatibility of this technology is threefold, Dr. Assil said, and includes permeability, size (being sufficiently thin), and texture. Invisibility is also a key factor, as a future need for cataract surgery is not inhibited by the presence of the inlay in the eye. Prof. Pallikaris said that he has performed cataract surgery and implanted a monofocal IOL without removing the Flexivue Microlens. It is also possible to use intraoperative aberrometry in these cases to optimize results, he said.

Other advantages of the Flexivue Microlens include ease of surgery and simple insertion, Dr. Tamayo said. In his experience, this inlay has provided patients with spectacle independence for near vision. Additionally, the Flexivue Microlens corrects presbyopia from an optical perspective, not by changing corneal biomechanics and shape.

This inlay is a "premium choice for early presbyopes" and is a "natural seller" in this population, Dr. Assil said, as patients tend to prefer technologies that can be updated as their refraction changes with age.

Hoya's Clear Optic IOLs Receive FDA Approval

Two models of clear, foldable, hydrophobic acrylic-optic, aspheric IOLs have received FDA approval: the iSymm (model FC-60AD) and the preloaded iSert (model PC-60AD), both manufactured by Hoya Surgical Optics, Inc.

In an interview with *Cataract & Refractive Surgery Today* at the ASCRS annual meeting, Jake Vander Zanden, president, Hoya Americas, spoke about the unique characteristics of the IOL models.

"What makes our lenses a little different than everyone else's is that we actually have a hybrid one-piece, where we have a PMMA haptic chemically bonded to an acrylic optic," he said. "The thing that makes the optic so special is we have an aspherically balanced curve, which in effect is a bit of a sweet spot in the center of the lens, and that sweet spot in the center of the lens makes it a little bit more forgiving when there's misalignment to the optical axis." Mr. Vander Zanden added that both IOL models are already being shipped to customers in the United States.

Early Results of Epi-on CXL Procedure Encouraging

Early results of a multicenter trial evaluating an epithelium-on corneal collagen cross-linking (CXL) technique indicate that the procedure is a safe and effective treatment for patients with corneal ectatic disease.

After an average of 7 months of follow-up, the patients in the study achieved improvements in UCVA and, to a lesser extent, BSCVA. According to William B. Trattler, MD, who presented the data during a scientific paper session at the ASCRS meeting, there was a general improvement in quality of vision that may be difficult to quantify with study results.

Compared with their preoperative measurements, 43% of the 155 patients in the study showed a reduction in Holladay mean keratometry values, as measured with the Pentacam Comprehensive Eye Scanner (Oculus Optikgeräte GmbH). Based on Magellan mean keratometry, 56% of the patients had a mean reduction and 38% had a reduction in their pachymetric apex of 5 µm or more on Pentacam imaging.

Those numbers, however, may be an imprecise measure of keratometric change, because some patients may experience a "redistribution of their corneal shape into something that is more natural," Dr. Trattler said. As a result, some procedures may yield a steepening in some aspects of the cornea, but that may result in a more spherically shaped corneal surface.

Other outcome metrics may be more generally comparable among studies and with other techniques for performing CXL. During preoperative evaluation, 10% of patients had a UCVA of 20/40 or better and 11% 20/50 or better; after treatment, 16% achieved 20/40 or better vision and 25% 20/50 or better. For BSCVA, 20/30 or better vision was achieved in 44% of patients postoperatively (35% preoperatively) and 20/40 or better postoperatively compared with 61% preoperatively.

Although indications of improved vision are encouraging, the main reason to perform CXL is to treat an underlying weakness in the corneal shape that may continually deteriorate over time, Dr. Trattler said. The most conclusive indication of the treatment's success, therefore, is seen on difference maps comparing individual pre- and postoperative corneal shape, he said.

The ongoing study is being sponsored by CXL-USA, to which Dr. Trattler is a consultant.

Congressman Urges Support for Bill to Reform FDA

Speaking at a recent meeting of cataract and refractive surgeons, Rep. Erik Paulsen, R-Minn., said that the current review process for regulatory approval of medical devices is threatening an industry that provides $21.5 billion in salaries and 2 million jobs to the US economy.

Last year, Mr. Paulsen, who is cochair of the

Congressional Medical Technology Caucus and a member of the House Ways and Means Committee, introduced the FDA Renewing Efficiency From Outside Reviewer Management Act. The act would attempt to streamline the user fee and review process at the FDA. It is hoped that the reforms would result in a faster, more streamlined review process.

Speaking at a government relation symposium during the annual meeting of the ASCRS, Mr. Paulsen stressed that his intent is not to lower standards of safety and efficacy but rather to foster an environment more conducive to innovation.

"The current regulatory environment created by the FDA has forced many American companies to send jobs overseas," he said. "Technology is now being developed in China and Europe with no hope of coming back to the United States."

According to a news release from the ASCRS, Congress is now considering legislation that would reauthorize FDA user fees, and changes to the drug approval and medical device review process will also be considered. Ideally, according to the news release, an omnibus bill covering all of these issues would be signed before the August recess.

Marguerite B. McDonald, MD, Named Winner of Inaugural Visionary Woman Award

Ophthalmic Women Leaders (OWL) announced that Marguerite B. McDonald, MD, of Ophthalmic Consultants of Long Island, received the 2012 Visionary Woman Award at the annual meeting of the ASCRS in Chicago.

This is the first year for the award, which is given to someone who has worked to advance women in eye care. In an e-mail to *Cataract & Refractive Surgery Today*, Dr. McDonald said, "I am incredibly thrilled and grateful to be honored by OWL with the inaugural Visionary Woman Award. OWL has meant a great deal to me from its very inception; talk about an idea whose time had come! Women in our business need and enjoy the opportunity to network with each other; I know many women whose careers have been enhanced and advanced through OWL. Personally speaking, I have met many new friends through OWL, amazing members from whom I have gained knowledge and inspiration."

"Along with being noted for performing the first laser vision correction procedure and elected as the first female president of ASCRS and ISRS, she takes an active role in advancing women's careers through mentoring," OWL President Jan Beiting said of Dr. McDonald in a statement. "She is a trailblazer in every way."

The other finalists for the award were Tamara Bogetti, MBA, publisher at Bryn Mawr Communications LLC, and Suzanne Bruno, MBA, COE, administrator of Horizon Eye Care in Southern New Jersey.

ASCRS Announces New Membership for Optometrists

ASCRS, a 9,000-member international society dedicated to improving the education and skill sets of anterior segment surgeons, announced the establishment of a new membership category that will enable certain optometrists to apply for membership to the organization for the first time.

To be eligible for membership, optometrists must be

Online Survey Results March 2011

What is your current position on laser cataract surgery?
Performing the procedure 21.7%
Interested in beginning to perform the procedure 21.7%
Taking a wait-and-see approach 43.5%
Not planning to adopt the procedure 13%

If you are performing laser cataract surgery, has your use of this technology prompted you to alter other aspects of your surgical technique, as it has authors in the cover series in the March 2012 issue?
Yes 43.5%
No 56.6%

What percentage of patients with ocular allergies do you treat in your practice as opposed to referring them out?
<10% 22.2%
10%-25% 27.8%
25%-50% 11.1%
>50% 38.9%

Would you consider discontinuation of contact lens wear as part of treating a patient with ocular allergies?
Yes 94.4%
No 5.6%

Is it necessary to identify the specific cause of ocular allergy before treating it?
Yes 47.1%
No 52.9%

employed by an ASCRS member who is a board-certified ophthalmologist. The new membership category, which emphasizes a working partnership between ophthalmologists and optometrists, supports an integrated model for the delivery of efficient, high-quality health care to the 77 million American baby boomers rapidly approaching retirement age, according to a news release.

The model, endorsed by the ASCRS Executive Committee and Governing Board, encourages arrangements in which employed optometrists, directed and overseen by ophthalmologists, provide a critical role in the delivery of nonsurgical eye care.

"We are facing an impending crisis in our ability to deliver adequate eye care with our present delivery model," Edward J. Holland, MD, outgoing ASCRS president and director of cornea service at the Cincinnati Eye Institute, said during the general session of the ASCRS Annual Congress and Symposium. "We will simply not have enough ophthalmologists to perform all eye care needs that will be required, both medical and surgical. One solution to this pending crisis is to become more efficient at what we do. An ophthalmologist-led model will allow a gradual transition of nonsurgical eye care to optometry in order to support a more efficient ophthalmic surgeon."

The integrated delivery model and membership category will encourage greater efficiency, as ophthalmologists and optometrists work together to meet the growing demands for service as well as address pending changes in Medicare and general health care delivery.

"At Minnesota Eye Consultants, we have found that an ophthalmologist-led integrated eyecare delivery model that includes ophthalmologists and optometrists working side by side allows us to provide the highest quality care and a good value for our community," said Richard L. Lindstrom, MD, past president of the ASCRS, founder and attending surgeon of Minnesota Eye Consultants, and adjunct professor emeritus at the University of Minnesota, Department of Ophthalmology. "We are pleased that our optometry associates will now be able to access the superior-quality education provided by ASCRS."

"As we watch 10,000 baby boomers turn 65 every day for the next 17 years, it becomes obvious that we as ophthalmologists will not be able to provide all the eye care demands of our patients in the future," said Steven S. Lane, MD, surgeon at Associated Eye Care in Minnesota, ASCRS board member, and chair of the Optometric Task Force. "For this reason I have long been an advocate of an ophthalmologist-led integrated eye care model where optometrists work side by side with ophthalmologists under the same roof to meet the rising demands of our patients. This model will foster not only efficiency but also efficacy where ophthalmologists, optometrists, ophthalmic technicians, opticians, and ophthalmic executive directors work together to deliver patient-centric care. This model is our best opportunity to meet our society's future eye care requirements, and I congratulate ASCRS for embracing it and initiating an optometric membership category. Although controversial, I believe this is a historic step, one that we will all look back upon in the future and applaud."

Halma Acquires Accutome

Halma PLC, a safety, health, and sensor technology group based in the United Kingdom, announced that it has acquired Accutome, Inc., for an initial cash consideration of $20 million and contingent consideration of up to $5 million based on earnings growth.

Accutome, a privately owned company in Malvern, Pennsylvania, designs, manufactures, and sells surgical instruments, including diamond-bladed surgical knives, along with diagnostic instruments and a variety of pharmaceuticals for use in ophthalmology. The existing management at Accutome will remain in place and will continue to operate the business, according to a news release from Halma.

The acquisition is being funded from Halma's existing cash and debt. Accutome will join Halma's Health and Analysis sector within the Health Optics subsector, which already includes ophthalmic diagnostic and surgical instrumentation companies Keeler Instruments, Inc., Volk Optical, Inc., Riester, and Medicel AG.

Effort Seeks to Increase Organ Donation

Abbott Medical Optics Inc. has joined forces with SightLife to increase eye, organ, and tissue donor registration among physicians and to honor those who have already registered, according to a news release from the company. The "Are You A Donor" Campaign was launched at the 2012 ASCRS meeting in Chicago. The objective of the campaign is to encourage ophthalmologists to model good behavior by registering as eye, organ, and tissue donors. Abbott Medical Optics Inc. encourages the ophthalmology community to join in this extremely beneficial program. To learn more, please visit www.areyouadonor.org.

Abbott Medical Optics Inc. joins the Allergan Foundation, ASCRS, Bausch + Lomb, the Eye Bank Association of America, and SightLife in supporting this endeavor. SightLife (www.sightlife.org) is one of the leading eye banks in the world. According to its website, in 2010, the organization provided nearly 5,000 corneas for transplantation. ■