US Ophthalmologists' Wish Lists

Products surgeons wanted to bring home from the ESCRS meeting.

BY CONNI BERGMANN KOURY, EXECUTIVE EDITOR

We at Cataract & Refractive Surgery Today *asked four surgeons to identify five devices and/or technologies that are in use overseas but currently unavailable stateside that they wished they could have brought home from Milan 2012, the European Society of Cataract & Refractive Surgeons annual meeting.*

"When I began my career as an ophthalmologist," Doyle Stulting, MD, director of the Stulting Research Center at the Woolfson Eye Institute in Atlanta told *CRST*, "I believed that the United States was well ahead of the rest of the world with respect to scientific innovation and the quality medical care. Now, I am sure that is not the case. I must attend meetings outside of the country to learn about new products, and a walk around the exhibit floor in other countries leads me past many products that I would like to take home to my patients. Selecting only a handful of them is a difficult task."

Dr. Stulting's sentiments were echoed by Scott M. MacRae, MD, a professor of ophthalmology and a professor of visual science at the University of Rochester Medical Center in New York. "In the past, US ophthalmologists delighted their patients with a stunning array of sight-enhancing devices," he said. "Inefficiencies and overregulation by well meaning officials have severely stagnated this process, delaying much needed solutions by years—and sometimes a decade—as is the sad case of corneal collagen cross-linking (CXL). In 2012, the US ophthalmic market reached a new low in innovation. Innovative device companies now see the US market as the last market they attempt to enter worldwide, whereas in 2000, it was the premier market companies raced to enter. US Congressional leaders on both sides of the aisle are recognizing this counterproductive trend and are working to remedy it. This article highlights some of the exciting devices available to our international colleagues that US doctors can look forward to when our lawmakers break the regulatory gridlock."

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LASER TECHNOLOGY

Those surveyed are eagerly anticipating US availability of advanced laser technology. Dr. Stulting said that many of the lasers available in the United States have features that can be used internationally but are "locked out" here, including topography-guided LASIK and Q-adjusted treatments that allow the physician to customize the asphericity of the patient's cornea on the WaveLight Allegretto Wave Eye-Q Laser (Alcon Laboratories, Inc.). "Other advanced lasers are not available, and the companies that manufacture them do not plan to apply for FDA approval because of cost," he added.

Douglas D. Koch, MD, professor and the Allen, Mosbacher, and Law chair in ophthalmology at the Cullen Eye Institute of the Baylor College of Medicine in Houston agreed regarding the desire to see software

unlocked on many laser platforms. Specifically, he would like to be able to use the iDesign wavefront-imaging device for the Star S4 excimer laser (Abbott Medical Optics Inc.). "Unlocking the software would enable the use of wavefront-guided technology for smaller pupils, refractive treatments outside current FDA-restricted limits, and variable-spot scanning for conventional treatments." He added that the iDesign has five times greater resolution than its preceding devices and offers the possibility of superior outcomes for normal eyes and great potential to dramatically improve treatments of highly aberrated eyes.[1]

Dr. MacRae said that patients postcorneal transplantation, those who have undergone CXL for keratoconus, and those who have had trauma/pterygium can be visually rehabilitated by reducing or eliminating higher-order aberrations. He added that these approaches will not be studied "for decades" in the United States by the limited number of US laser manufacturers This is because "each cornea treated is idiosyncratic, making it very difficult to provide evidence of a consistent therapeutic effect and the prohibitive costs of such studies in this small atypical population."

Dr. MacRae also wishes that phototherapeutic keratectomy could be performed using all US-approved laser platforms. For the same reason noted previously, however, he does not believe this will happen. "The current FDA policy on [phototherapeutic keratectomy] is archaic and has created a monopoly on [the procedure] by one company, thereby making this well proven technology inaccessible to many US patients."

Both Drs. MacRae and Stulting are disappointed that Schwind's Amaris laser is not available in the US market. "The Schwind laser has been dubbed 'the best laser we'll never see,'" said Dr. Stulting. "The most commonly used lasers in the United States are rarely used outside of [this country]—not because we are so far ahead of the rest of the world, but because we are so far behind it." Dr. MacRae added that the laser uses a 750-Hz pulse frequency, a 1,050-Hz eye tracker, and online optical coherence tomography during the ablation, but Schwind has decided not to bring the technology to the US market because of the need for a costly FDA trial.

Dr. Koch would like to have access to the ReLEx smile procedure (Carl Zeiss Meditec AG), a minimally invasive, all-in-one laser vision correction procedure performed with the VisuMax femtosecond laser (Carl Zeiss Meditec, Inc.) "This is a fascinating and promising alternative to LASIK that involves refractive correction by using the femtosecond laser to create a lenticle that is extracted through a 4-mm incision," he said.

CORNEAL COLLAGEN CROSS-LINKING

Dr. Stulting and Stephen F. Brint, MD, associate clinical professor of ophthalmology at Tulane University School of Medicine in New Orleans, identified a riboflavin-ultraviolet-A light combination product for CXL as a must have for US surgeons. Dr. Stulting added that the technology should include iontophoretic riboflavin and the ability to deliver light at a high fluence. "Almost 10 years after the first print publications demonstrating [the] safety and efficacy of this procedure, multiple confirmatory international reports, and a well-designed controlled, prospective clinical trial, this remarkable treatment is still not approved for use in the United States," Dr. Stulting said. "It is sad that we still do not have FDA approval of a product that could prevent or delay almost 50% of the corneal transplants performed in the US today, and that many US ophthalmologists provide it to their patients outside of FDA clinical trials or send them across our borders for treatment. The indications for CXL continue to widen and now include microbial corneal ulcers, corneal melts, and corneal edema."

ADVANCED IOLS

Multifocal

Multifocal IOL technology available overseas attracted the panel's attention. Dr. Stulting wants a toric multifocal lens. "Currently, only spherical multifocal lenses are available in the United States, forcing us to correct astigmatism with relaxing incisions or a second corneal procedure like PRK or LASIK," he said. "It is difficult to understand why a toric multifocal lens manufactured on the same physical platform as a currently approved astigmatic and multifocal lens could not be approved after laboratory verification of optical performance only."

Dr. Koch concurred, saying he would like access to new multifocal IOL options, including toric, low-add power, and new optic designs. He said that the increased range of options would offer more patients the kind of tailored visual outcome that would make multifocality an option. Specifically, he cited the Mplus (Oculentis GmbH). Dr. MacRae is also a fan of the Mplus, saying that it is a rotationally asymmetric multifocal lens where the upper half is a monofocal design for distance and the 3.00-D power added to the lower half allows for near vision similar to a traditional bifocal spectacle design. In his optics lab, Dr. MacRae has

THE WISH LIST

A brief look at where some of the ophthalmologists' picks for their wish lists are in the US pipeline. For more information, use your smartphone to photograph the accompanying QR codes.

LASER TECHNOLOGY

Wavelight Allegretto Wave Eye-Q Laser (Alcon Laboratories, Inc.)

A representative from Alcon Laboratories, Inc., said that he could not provide a comment on the US status of topography-guided LASIK and Q-adjusted treatments via the Wavelight Allegretto Wave Eye-Q Laser.

iDesign Wavefront Imaging Device for the Star S4 (Abbott Medical Optics Inc.)

"We are planning to release [the] iDesign diagnostic system in the United States this year," Steve Chesterman, director, public affairs/communications, for Abbott Medical Optics Inc., told *Cataract & Refractive Surgery Today* in an email.

Amaris Laser System (Schwind eyetech-solutions)

Sources indicate that the company has no plans to bring the device to the US market.

ReLEx smile procedure with the VisuMax (Carl Zeiss Meditec, Inc.)

In April 2012, Carl Zeiss Meditec announced its intention to initiate a US clinical trial of the ReLEx smile procedure for the correction of myopia, having received conditional approval for the trial from the FDA. According a company news release, the VisuMax Laser Keratome is currently cleared in the United States for creating corneal flaps as well as for lamellar and penetrating keratoplasty for corneal transplantations. VisuMax ReLEx smile, which is the first small-incision, single-step, and all-femtosecond laser vision correction method, was launched internationally in September 2011.

CORNEAL COLLAGEN CROSS-LINKING

There are several CXL clinical trials underway in the United States. These include investigations sponsored by Avedro, Inc., CXL-USA, the Cornea and Laser Eye Institute, and Rush Eye Associates. Please visit www.clinicaltrials.gov.

ADVANCED IOLS

Mplus (Oculentis GmbH)

No additional information was provided.

FineVision MicroF (PhysIOL s.a.)

A representative from PhysIOL told *CRST* that the company will begin the FDA approval process for its premium IOLs (the FineVision trifocal and the Ankrois toric) this year.

Visian ICL Toric (STAAR Surgical)

According to a company statement, "On November 16, 2012, STAAR submitted additional information to the FDA on the Toric ICL, and we are in active discussions with the FDA. It continues to be a goal of the company to bring this product to the US market."

Artisan iris-clip IOL (Ophtec USA, Inc.)

"Ophtec USA currently has two pre-market approval devices approved in the United States, the Artisan/Verisyse Myopia Lens and the Capsular Tension Ring, as well as several ancillary 510(k) devices," wrote Rick McCarley, president and CEO of the company. "We have several [investigational device exemption] clinical studies that are active, including the Artiflex/Veriflex Myopia Lens, the Artificial Iris (Model 311), the Artisan Aphakia Lens for Adults, and the Artisan Aphakia Lens for Pediatrics. The Artiflex/Veriflex Lens and Artificial Iris Lens have been in studies for several years, however the Artisan Aphakia Lens studies were only initiated in the fourth quarter of 2012."

Light Adjustable Lens (Calhoun Vision, Inc.)

D. Verne Sharma chairman and CEO of Calhoun Vision, wrote, "We have successfully completed phases 1 and 2 of the required PMA clinical studies. We have been approved to commence phase 3 and are planning to begin patient enrollment and treatments shortly. After completing treatments and follow-up, we would be hopeful of FDA approval in approximately 3 years' time and are looking forward to making the [Light Adjustable Lens] available to US surgeons."

THE WISH LIST (CONTINUED)

Sulcoflex (Rayner)

No additional information was provided.

ARTIFICIAL IRIS

HumanOptics is planning to begin a clinical trial of its CustomFlex Artificial Iris in the United States later this year, according to the company.

CORNEAL INLAYS

Kamra (AcuFocus, Inc.)

A spokesperson for AcuFocus told *CRST* that the inlay is in the FDA process, but the company is not able to elaborate. The spokesperson did share the company's milestones. More than 18,000 inlays have been implanted worldwide, including 12 ophthalmologists who have the Kamra, and it is approved in 47 countries, most recently Korea and Canada.

Raindrop Near Vision Inlay (ReVision Optics)

Stephen Slade, MD, one of the clinical trial investigators for ReVision Optics and chief medical editor of *CRST* said that the inlay is in FDA trials and is showing excellent results. He added that it is hard to predict timing in terms of approval, but the company is "well into the process." For more visit www.clinicaltrials.gov/ct2/show/NCT01373580.

bench tested the Mplus and the FineVision MicroF (PhysIOL), an apodized and diffractive trifocal with a 1.75-D and 3.50-D add power, which he said provides excellent intermediate and near vision.

Toric

Toric phakic lenses would be extremely useful in patients with significant myopia and astigmatism, Dr. MacRae said. The lens would obviate the risk associated with and the need for a second surgery such as PRK or LASIK after waiting a "debilitating 3 months for the IOL wound to heal." Dr. Brint agreed, stating that he would like to have the toric Visian ICL (STAAR Surgical Company). "The great majority of phakic IOL candidates have cylinder, which currently must be addressed [via] a separate laser procedure. Even though clinical trials have been complete for years, this is still not available in the United States." Likewise, he added that the toric Artiflex IOL (Ophtec) would be useful in his practice.

Iris Clip

Drs. Stulting and Brint want access to the Artisan iris-clip IOL (Ophtec). Dr. Stulting explained: "As a corneal surgeon with a referral practice, I occasionally see aphakic patients needing corneal transplantation and IOL implantation. For 30 years, the rest of the world has had access to the aphakic Artisan iris-clip lenses that can be used in patients with adequate iris support, but inadequate capsular support. It is the lens of choice for many international surgeons in this situation. The lack of an iris-clip lens forces me to choose between an anterior chamber lens and a scleral-fixated posterior chamber lens in these eyes."

Other Technology

The Light Adjustable Lens (CalhounVision), moving through the FDA approval process, is CE marked and available in Europe. "This [lens] has great potential, some of which is not realized yet, but will help in fine-tuning the final refractive result," Dr. Brint said. "Most cataract practices have, by patients' demands, become increasingly refractive-cataract practices. This IOL system helps to nail the refractive target, inducing or eliminating monovision as desired, and other IOL parameters yet to be fully explored, such as addressing presbyopia and higher-order aberrations."

The Sulcoflex (Rayner) is a hydrophilic acrylic IOL designed to be used as a piggyback lens. Dr. Koch would like to have this in his armamentarium because "it allows treatment of pseudophakic spherical and astigmatic refractive errors and has a multifocal option, which can be removed or exchanged over time as the patient's eyes and/or visual needs change."

ARTIFICIAL IRIS

Dr. Stulting believes that US surgeons should have access to the artificial iris from HumanOptics. "This spectacular product is being held up because the FDA wants rabbit biocompatibility trials (among other things)," he said. "In spite of the fact that over 150 compassionate use implants have been performed in this country and many more outside of the United

States—the FDA is essentially demanding rabbit studies to confirm human studies."

COMBINATION DRUGS

Dr. Stulting said that much of the world has access to combination pharmaceuticals that are not available in this country. "Fourth-generation fluoroquinolones combined with steroids would simplify postoperative medication regimens and probably improve compliance," he said. "Combination glaucoma products would certainly improve compliance and reduce preservative toxicity in glaucoma patients. It is too bad that the clinical trials for those products create such a barrier that [their] approval in this country will be rare."

CORNEAL INLAYS

Dr. Koch put corneal inlays on his wish list. "The Kamra (AcuFocus Inc.) and Raindrop Near Vision Inlay (ReVision Optics) are excellent, removable options for providing useful near vision in our presbyopic patients."

CONCLUSION

"In its zeal to accomplish its primary task of protecting US citizens, the FDA has made the pathway to drug and device approval long, arduous, and expensive," said Dr. Stulting. "The approval process does not take into account the available alternatives and international experience. As a result, we are years behind the rest of the world in providing new technologies to our patients. We need a regulatory system that actively facilitates the approval of new products when the balance of scientific evidence from all sources supports that action—especially when the alternative treatments are clearly inferior."

Dr. MacRae acknowledged that US surgeons and patients have benefited greatly from clinical trials that have proven safety and efficacy for many ophthalmic devices, "but a new approach by the FDA is clearly needed if our patients are to benefit from the tremendous technologies available to our colleagues internationally. We will need an innovative and cooperative approach by Congress, regulatory officials, clinicians, and industry to serve our US patients better." ■

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1. Cummings AB. The Best of 2012: Trends and breakthroughs in cataract and refractive surgery. *Cataract & Refractive Surgery Today Europe.* November/December 2012;7(10)47-62.