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Special Report

YEAR REVEALS NEWLY IDENTIFIED CORNEA LAYER

WITH CLINICAL DIAGNOSIS BEING central to the ophthalmic practice, the past year has proven to be especially noteworthy for the corneal and refractive arenas.

Among the highlights are the identification of a new layer in the cornea referred to as Dua's layer, as well as important considerations regarding posterior corneal astigmatism and toric IOLs, and the use of aberrometry to determine toric IOL corrective power.

(See story on page 18 : New layer)

Focal Points

LIONS EYE INSTITUTE MARKS 40 YEARS OF OCULAR RESEARCH



TAMPA, FL :: **THE LIONS EYE INSTITUTE** for Transplant and Research (LEITR)—the only combined eye bank and ocular research center in the world—marked its 40th anniversary this past year. In the celebration, its leaders reviewed the organization's successes and laid out its vision for the future.

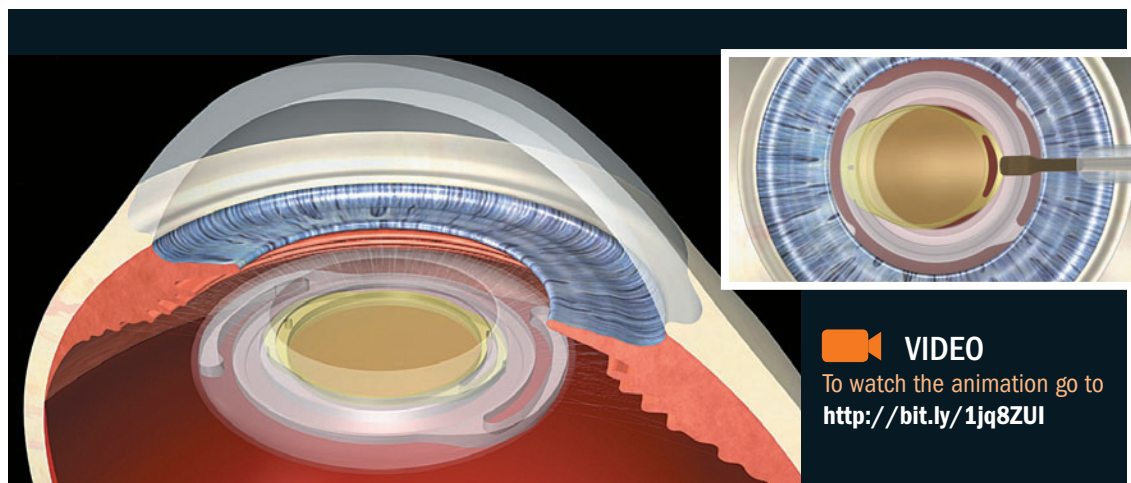
According to the LEITR, it has brought the "gift of sight" to more than 58,000 men, women, and children worldwide since Lions Club International members formed it in 1973.

(See story on page 6 : Milestone)

YEAR IN REVIEW CATARACT: TECHNOLOGY

2013 BRINGS new IOL options

Pseudophakic selection still limited, but surgeons have greater access to toric, presbyopic lenses



VIDEO

To watch the animation go to <http://bit.ly/1jq8ZUI>

IN VIEW: A novel modular IOL (HARMONI, ClarVista Medical) is a two-component system featuring a base component and an optic component. The base component is a positioning device for the optic component and contains an annular groove that captures the optic component. The optic component comes in monofocal, toric, and multifocal configurations. (Images and video courtesy of ClarVista Medical; animation by David Rennke)

By Cheryl Guttman Krader;

*Reviewed by Malik Kahook, MD,
Randall Olson, MD, and Mark Packer, MD*

CATARACT SURGEONS IN the United States still have limited options for pseudophakic correction compared with their colleagues elsewhere in the world. However, 2013 has brought access to a toric IOL able to correct near, intermediate, and distance vision (model AT50T; Trulign Toric, Bausch + Lomb).

In addition, the FDA approved a third toric IOL (model ZCTXXX, Tecnis Toric, Abbott Medical Optics) for the U.S. market.

Ophthalmology Times Editorial Advisory

Board members, Malik Kahook, MD, Randall Olson, MD, and Mark Packer, MD, spoke about these new implants and other developments in IOL technology.

PREMIUM TORIC TECHNOLOGY

The Trulign Toric IOL is a modification of the existing hinged-plate haptic silicone Crystalens AO platform that differs from the parent lens only by having toric correction on the posterior surface of the biconvex optic and two axis orientation marks on the anterior optic surface.

In regard to the Trulign Toric IOL, Dr. Packer noted there is a gamut of opinion about the Crystalens IOL (non-toric) in terms of its performance

(Continues on page 14 : Technology)



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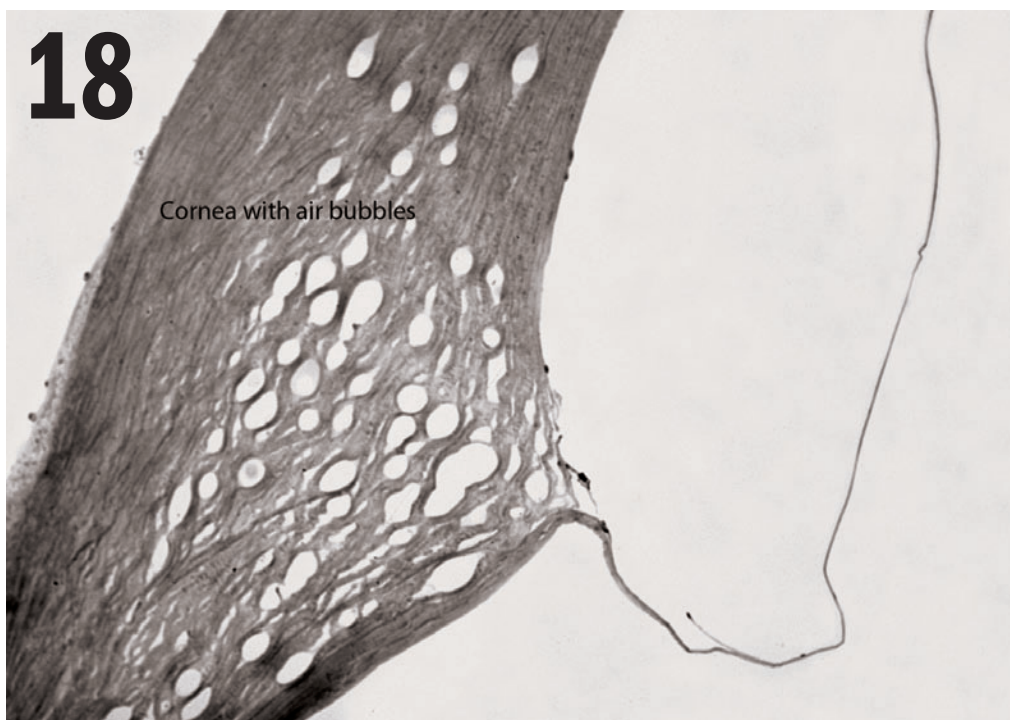
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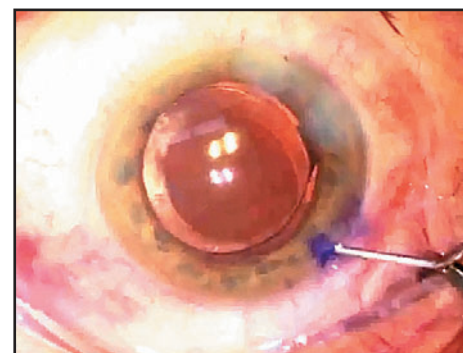


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Video



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The skinny on obesity

A pictorial about eating ourselves to death in America



By Peter J. McDonnell, MD

director of the Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, and chief medical editor of *Ophthalmology Times*.

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AS A SCHOOL project, my son once looked into the work of Dorothea Lange, a famous photographer who documented rural life in the Western United States during the Great Depression. She was employed by the Farm Security Administration of President Franklin Roosevelt's administration, with the intent that her pictures of poor and hungry Americans would galvanize support for an initiative known as the "New Deal."

Essentially, she was hired by the government to provide propaganda in support of government policy.

Many of the photographs appeared in *Life* Magazine, as well as other national media. Propaganda or not, much of her work is fascinating. If you "Google" the photographer's name, you will see these iconic images of poor (and hungry) Americans as they lived some 80 years ago. And, you will be impressed by how remarkably thin are the subjects.

Today, it's a different story. The poor in America, on average, are less likely to be thin and significantly more likely to be obese than are their fellow citizens who live above the poverty level. Hence the epidemic of diabetes and diabetes-related eye disease.

WHY IS THIS THE CASE?

Here's an interesting factoid: The U.S. Supplemental Nutrition Assistance Program (aka food stamps) is the largest means-tested social support program in our country. At a cost of \$6.3 billion per month, 47.6 million people (15% of the population) are given financial support to buy food.

Beyond this, with school lunch programs and other governmental food supplies, a total of some 100 million Americans (about one-third of our population) were given food by Uncle

Sam last year. The poor, as a result, are not thin the way they used to be, but rather are significantly more likely to meet the elevated body mass index levels required to qualify for the diagnosis of obesity.

The upshot is that if Lange were alive today, the subjects of her pictorials would be not thin, but plump. The farm programs initiated by Roosevelt in the 1930s, some might say, have ultimately proven too effective, at least according to the bathroom scales and the obesity-related illnesses that plague our citizens.

WHAT DO WE DO NOW?

Some, like Mayor Bloomberg of New York, believe the answer is restrictions on the size of servings of food and beverages that vendors can sell. Others criticize this as an attempt of a "nanny state" to micromanage our lives. Some believe that financially penalizing those who are not able to maintain their weight in a healthy range, by charging them more for health insurance, will modify behavior. Others argue that such an approach, making the overweight or smokers pay more for health coverage, is unethical or should be made illegal. Some believe that better education about healthy eating habits in our public schools will solve the problem.

My idea is that we only allow the government to supply or fund the purchase of healthy food. This is the kind of food that is nutritious and filling but that virtually defies someone to overindulge enough to become obese.

For example, instead of pasta, potato chips, and soda, we would provide broccoli, tomatoes, apples, and skim milk. And everyone who is not a smoker gets a daily multivitamin with the AREDS formula in hopes of reducing the risk of age-related macular degeneration. ■

Reference

- Food for thought. Morning Market Briefing by ConvergeX. p.M14 Barron's Nov 4, 2013.

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Through its multifaceted content channels, *Ophthalmology Times* will assist physicians with the tools and knowledge necessary to provide advanced quality patient care in the global world of medicine.

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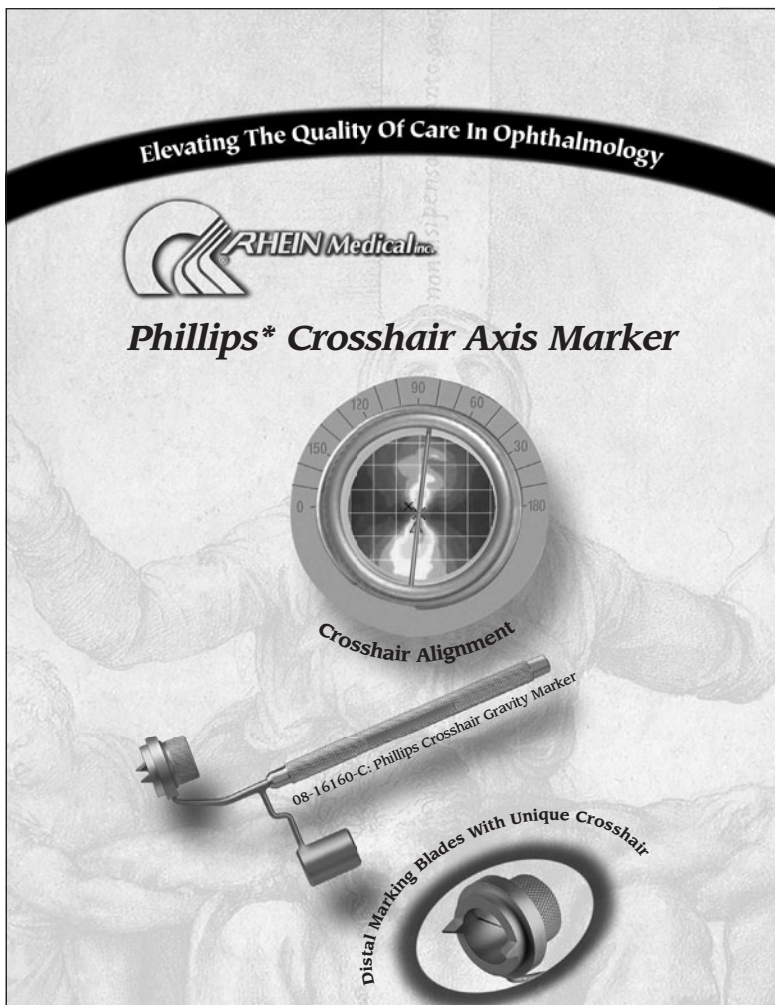
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Lions Eye Institute marks 40 years of ocular research

Leaders and members celebrate accomplishments, map out future plans for institute

By Beth Thomas Hertz

TAKE-HOME

► While marking its 40th anniversary this year, the LEITR recognized its many achievements while also laying out its plans moving forward.

TAMPA, FL ::

The Lions Eye Institute for Transplant and Research (LEITR)—the only combined eye bank and ocular research center in the world—marked its 40th anniversary this past year with a celebration where its leaders reviewed the organization's successes and laid out its vision for the future.

A gala ball was held in November as part of the ongoing celebration.

As of the anniversary observation, the institute has brought the “gift of sight” to more than 58,000 men, women, and children worldwide since it was formed in 1973, according to the LEITR.



Woody

That number is expected to be close to 62,000 by the end of this year, said Jason Woody, president and chief executive officer of LEITR.

HISTORY

The institute was formed by a group of local Lions Club International (LCI) members, an organization that was asked by Helen Keller to be “knights against blindness,” Woody said.

LCI members were already known for their work providing such items as eyeglasses and guide dogs, but the Tampa group decided to expand its mission into creating an eye bank, he explained.

Starting in a small facility at the University of South Florida—with one employee, John Brinser, and help from local ophthalmologist William Edwards, MD, who did the retrievals after-hours—LEITR facilitated 30 transplants

Continues on page 8 : Research



A The Lions Eye Institute for Transplant and Research's (LEITR) recently renovated 45,000-square-foot facility features an eye bank, research center, and the Foundation. The research center currently houses three state-of-the-art laboratories and two sleeping suites that allow visiting researchers access to tissue 24/7.

B For the first time in Florida, DSAEK is performed by William J. Lahners, MD, Center for Sight (right), with preloaded cornea tissue prepared by the LEITR. At left, Patrick Gore, RN, director of business and strategic development, LEITR, developed this innovative methodology, which allows eye banks to prepare and preload the tissue into a sterile delivery device, simplifying surgery while greatly reducing the risk of damage to the donated tissue.

C LEITR's newly appointed scientific director, Mitch McCartney, PhD (center), demonstrates the dissection of human retinal tissue that will be processed for light microscopy to research associates Nicholas Sprehe (left) and Ashley Morganti (right).

D Eye banking in the early years—John Brinser was the first eye bank employee, functioning as both the director and technician (circa 1973).

(Images courtesy of Lions Eye Institute for Transplant and Research)

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CENTURION
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RESEARCH

(Continued from page 6)

its first year. By 1975, Dr. Edwards was serving as the medical director for the growing institute.

The organization moved into increasingly larger space over the years, and today is housed in a 45,000-square-foot renovated facility that formerly housed a cigar factory in the Ybor City area of Tampa.

Along the way, it made a commitment to being a leading research center as well as an eye bank, Woody said.

Today, both functions share the space and the donated tissue.

"Having our eye bank and ocular research center located in the same building has been an invaluable differentiator for

our organization," he said. "This model allows researchers 24/7 access to ocular tissue, which means better results for research and transplantation."

It also lets LEITR work on two fronts—saving sight today and looking for ways to save it in the future, he said.

NEW SCIENTIFIC DIRECTOR

LEITR welcomed its first scientific director, Mitch McCartney, PhD—a 25-year veteran of the ophthalmic pharmaceutical industry—in September. He previously led research initiatives within Alcon Laboratories Inc., where he set up the electron microscopy unit and integrated it into their research process, and the Novartis Institutes for Biomedical Research.



Dr. McCartney

His primary mission, Dr. McCartney said, is to develop further the re-

search initiatives that have been started at LEITR.

"We have worked with local universities for a number of years, but I am charged with taking this work to the next level, operating our own independent program and enhancing our collaborations with many organizations," he said.

Dr. McCartney outlined three long-term initiatives that are under way:

■ **Enhance the tissue's potential by performing initial model steps on the tissue in-house, as part of LEITR's mission in providing tissue samples to other organizations.** For example, he said, the institute might complete steps A, B, and C of a research model before sending the tissue to the collaborators who have the capacity to do more advanced work with the sample due to having made a large capital investment in technology, such as mass spectroscopy. "Our work enables the sample to get into model systems more quickly," Dr. McCartney said.

■ **Create a biorepository in which LEITR would freeze, embed in paraffin, and document certain aspects of healthy and diseased donor tissue by photography as well as genotyping the specimen. A blood sample and donor history will be incorporated into the repository as well. By offering well-characterized tissue samples, the institute will help researchers identify new insights into the disease process.**

■ **Establish its own basic science research program to further both bench science and corneal transplant surgeons' clinical needs.**

"LEITR has made some significant research strides over the past years and I believe that is just the beginning," Dr. McCartney said. "I was very interested in this job, because I enjoy building research

LEITR MILESTONES

1973: Created

1973-1993: Provided 11,205 corneas for transplant

1994-2004: Provided nearly 20,000 corneas for transplant, nearly doubling previous 20-year total, in just 10 years

2004-2012: Provided 27,543 corneas for transplant

programs and because this institute has the potential to help the research community do better science and help improve their model systems by using human ocular tissue."

FUTURE PLANS

Dr. McCartney noted LEITR's recent two large, groundbreaking research developments, which included the completion of pre-loaded EndoGlide cartridges that will make corneal surgeries more efficient.

He also said LEITR's work in helping to show that the pharmacological dilation of pupils is possible after death will be useful in evaluating eyes with limited clinical history and open windows for research of various ocular diseases.

Foundation Director Kelley Sims stressed its success in donating nearly \$1 million annually in needed eye tissue to help blind and visually impaired people throughout the world.

Because of gifts designated specifically for research, the foundation has also set aside more than \$125,000 for future scientific projects, he said.

Woody also announced that in the next year, LEITR would invest more than \$300,000 in staff and equipment to make its laboratory state of the art.

"We intend to be the new pioneers of ocular research," he said. ■

IMPORTANT SAFETY INFORMATION

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The consumables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AEs/COMPLICATIONS: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

ATTENTION: Refer to the Directions for Use and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

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CATARACT: SURGERY

INTEGRATION SHINES IN 2013 SPOTLIGHT OF DEVELOPMENTS

New devices reflect physicians' increased interest in combined surgical systems

By Cheryl Guttman Krader;

Reviewed by Malik Kahook, MD, Randall Olson, MD, and Mark Packer, MD

While discussion about the cost-benefit ratio of femtosecond laser-assisted cataract surgery made headway during 2013, laser manufacturers continued to upgrade their platforms in ways that would improve their performance and make them more user-friendly.

take-home

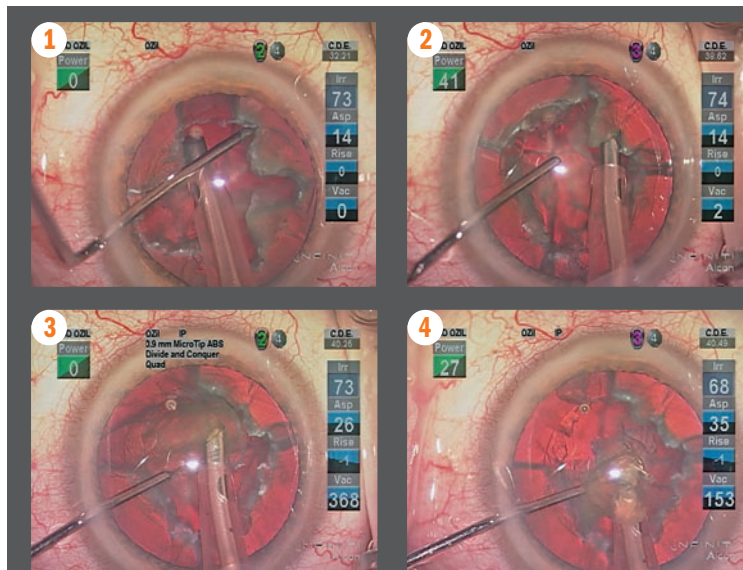
► Much progress was made in 2013 for femtosecond laser technology and integrated surgical platforms, but some obstacles still remain.

However, perhaps the biggest news in the femtosecond laser arena was the acquisition of OptiMedica by Abbott Medical Optics (AMO).

This piece of business news—plus the new phaco-emulsification unit introduced by Alcon Laboratories, the Centurion Vision System—reflect what may be a main theme of the year for cataract surgery: a growing interest in providing users with integrated surgical systems.

“More and more, we are seeing manufacturers aiming to integrate their diagnostic and surgical technologies with the goal of helping cataract surgeons achieve improved refractive outcomes and fewer complications,” said Randall Olson, MD, professor and chairman, Department of Ophthalmology and Visual Sciences and chief executive officer, John A. Moran Eye Center, University of Utah, Salt Lake City.

Dr. Olson—along with Malik Kahook, MD, The Slater Family Endowed Chair in Ophthalmology and professor of ophthalmology, University of Colorado, Denver; and Mark Packer, MD, private practice, Bowie, MD, and clinical associate professor of ophthalmology, Oregon Health and Science University, Portland—spoke to *Ophthalmology Times* about recent developments in cataract surgery.



1 Using the Centurion Vision System (Alcon), the cyclodialysis spatula and phaco tip push against the nuclear corners in cross-handed fashion as they fracture the posterior nuclear plate.

3 Vacuum has built to 368 mm Hg, providing good suction adherence and allowing the first plate to be rolled into the bowl that is now partial as it is comprised of three plates.

2 The obliquely oriented tip is shaving the firm corner off the fourth quadrant in the final step of creating the thin nuclear bowl.

4 In FP 3, vacuum, ultrasonic energy, and flow simultaneously and in concert deform, emulsify, and aspirate the nuclear emulsate.

(Images courtesy of James A. Davison, MD)

INTEGRATING TECHNOLOGIES

Dr. Kahook and Dr. Packer consider integration an attractive feature of the Centurion system. The unit was developed to communicate seamlessly with other Alcon surgical technologies, including the Verion Image Guided System, the LenSx femtosecond laser, and the LuxOR LX3 with Q-VUE ophthalmic microscope.

The various pieces of equipment in operating rooms (ORs) come from a number of manufacturers, and so there is no way for all the technology to communicate with each other, Dr. Packer said.

The introduction of the Centurion system and Verion imaging—combined with the earlier acquisitions by Alcon of LenSx and Endure Medical Systems (manufacturer of the LuxOR surgical microscope)—is exemplary of how the industry is well on its way to providing components for building a fully integrated OR, he noted.

The acquisition of OptiMedica puts AMO in a better position to begin to create its own suite of technologies, Dr. Packer said.



Dr. Packer

Continues on page 10 : **Integration**

Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**INTEGRATION**

(Continued from page 9)

He noted that after acquiring Bausch + Lomb, Valeant is continuing to look for growth opportunities and innovation, and he expects to see more developments coming from this company.

Also weighing in on the integration capability of the Centurion system, Dr. Kahook noted that among its other innovations is a proprietary new fluidics system (Active Fluidics Technology) that allows surgeons to set and maintain a target IOP during the procedure.



Dr. Kahook

"The ability to regulate chamber dynamics by programming in IOP rather than adjusting bottle height should offer a major safety benefit," said Dr. Kahook, who had an opportunity to preview

the system prior to its United States launch.

The pressurized infusion technology that will allow surgeons to "set and forget" IOP will be very helpful for increasing surgical safety by reducing surge, Dr. Packer said. "It is not possible to adjust the bottle height fast enough to account for surge that occurs quickly," he said.

"With all of the advances that have been occurring in cataract surgery technology, it has seemed archaic still to be using gravity infusion with a bottle of BSS hanging over the table," he added, noting that low OR ceiling height was sometimes a limiting factor in obtaining adequate infusion pressure for performing bimanual microincisional cataract surgery.

FURTHER INNOVATION

Another innovation on the Centurion is its Balanced Energy Technology, which enhances phaco efficiency through use of OZil Intelligent Phaco and its new INTREPID Balanced tip. Balanced Energy Technology creates a unique tip motion

that allows for finer control of ultrasound application and a reduction in ultrasound usage.

Another newsworthy development in phacoemulsification technology, Dr. Kahook said, was the unveiling of a new portable phacoemulsification unit from Oertli, CataRhex 3.

This novel machine was introduced at the 2013 European Society of Cataract and Refractive Surgeons (ESCRS) Congress in October.

"CataRhex 3 is a first-of-its kind, compact modern phaco unit that hangs on an IV pole," Dr. Kahook said. "Since it can travel with the surgeon from one OR to another, it may be attractive to anyone who operates out of several centers and wants to have access to the same technology at each."

FEMTOSECOND LASERS

Cost remained a major obstacle to wider adoption of the femtosecond laser in 2013.

"There is no question that traditional phacoemulsification is a great surgery, and so it is hard to justify use of a new, very expensive device that perhaps can provide only incremental benefits," Dr. Kahook said.

However, multimodal capability can be an attractive feature to buyers, he added.

Some units already have additional corneal surgery indications, and surgeons can expect to see devices with expanded functions that may include applications for glaucoma surgery, Dr. Kahook said.

Dr. Packer highlighted a 2013 paper from Australian cataract surgeons on the cost-effectiveness of femtosecond laser-assisted cataract surgery [Abell RG, Vote BJ. *Ophthalmology*. 2013; Oct 10, Epub ahead of print].

The authors compared femtosecond laser-assisted and conventional cataract surgery using published data on outcomes and time trade-off utility values converted from visual acuity results. Not surprisingly, Dr. Packer said, they concluded the laser procedure was not cost-effective.

"The improvements gained from switching

to laser surgery from standard phacoemulsification are incremental, not revolutionary like they were when going from extracapsular cataract extraction to phaco," he said. "However, the laser technology is still young, and its potential probably goes far beyond what is even being talked about today.

"There is reason to be excited, but the enthusiasm has to be tempered with a dose of realism," Dr. Packer said.

Dr. Olson said he has no doubt that use of the femtosecond laser can make a difficult cataract surgery case more straightforward, but whether it offers an advantage in routine surgery is unclear and there is still controversy over whether it improves refractive results.

As the femtosecond laser can create a more



Dr. Olson

perfect capsulotomy than a manual technique, it is theorized that its use should be associated with more predictable IOL position and therefore a better refractive outcome.

However, Dr. Olson noted that in a study presented at the 2013 ESCRS Congress, Oliver Findl, MD, questioned whether the laser-assisted procedure would result in better and more predictable IOL position.

Dr. Findl evaluated the effect of rhexis size and shape on IOL tilt, decentration, and anterior chamber depth (ACD) at 3 months in 254 eyes operated on with a manual technique and implanted with one of several modern IOLs.

He found no difference in ACD or tilt comparing eyes with a suboptimal rhexis versus controls, and only little difference in decentration, which he said was probably clinically irrelevant.

Consistent with Dr. Findl's conclusion, another published study from the Australian cataract surgeons found no differences in visual acuity or refractive outcomes comparing groups of eyes operated on with a laser-assisted versus

Continues on page 13 : Femtosecond

Mobile suite reaches 100 facilities

BLOOMINGTON, MN ::

SIGHTPATH MEDICAL'S MOBILE femtosecond laser suite for cataract surgery (MoFe) is now used by more than 100 facilities in 30 states. This milestone comes less than 1 year after the mobilized service was launched.

The service is helping surgeons across the

country achieve profitability in as few as 10 cases per month. The service is offered on a per-procedure basis, eliminating upfront capital investment and ongoing maintenance expenses that may make the purchase of a femtosecond laser for cataract surgery difficult to justify.

"Of the roughly 400 facilities offering laser-

assisted cataract surgery in the United States, 100 are using [this mobile service]," said Joel Gaslin, vice president of sales and marketing, Sightpath Medical. "This level of adoption confirms that surgeons feel working with Sightpath is a convenient and cost-effective way to offer state-of-the-art care in their communities." ■

For the treatment of elevated IOP

UNLOCK TREATMENT POSSIBILITIES



SIMBRINZA™ Suspension provided additional 1-3 mm Hg IOP lowering compared to the individual components¹

- IOP measured at 8 AM, 10 AM, 3 PM, and 5 PM was reduced by **21-35%** at Month 3²⁻⁴
- Efficacy proven in two pivotal Phase 3 randomized, multicenter, double-masked, parallel-group, 3-month, 3-arm, contribution-of-elements studies^{2,3}
- The most frequently reported adverse reactions (3-7%) in a six month clinical trial were eye irritation, eye allergy, conjunctivitis, blurred vision, dysgeusia (bad taste), conjunctivitis allergic, eye pruritus, and dry mouth⁵
- Only available beta-blocker-free fixed combination^{2,3}



INDICATIONS AND USAGE

SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination indicated in the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Dosage and Administration

The recommended dose is one drop of SIMBRINZA™ Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA™ Suspension may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

IMPORTANT SAFETY INFORMATION

Contraindications

SIMBRINZA™ Suspension is contraindicated in patients who are hypersensitive to any component of this product and neonates and infants under the age of 2 years.

Warnings and Precautions

Sulfonamide Hypersensitivity Reactions—Brinzolamide is a sulfonamide, and although administered topically, is absorbed systemically. Sulfonamide attributable adverse reactions may occur. Fatalities have occurred due to severe reactions to sulfonamides. Sensitization may recur when a sulfonamide is readministered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation.

Corneal Endothelium—There is an increased potential for developing corneal edema in patients with low endothelial cell counts.

Severe Hepatic or Renal Impairment (CrCl <30 mL/min)—SIMBRINZA™ Suspension has not been specifically studied in these patients and is not recommended.

Adverse Reactions

In two clinical trials of 3 months' duration with SIMBRINZA™ Suspension, the most frequent reactions associated with its use occurring in approximately 3-5% of patients in descending order of incidence included: blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Adverse reaction rates with SIMBRINZA™ Suspension were comparable to those of the individual components. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA™ Suspension patients.

Drug Interactions—Consider the following when prescribing SIMBRINZA™ Suspension:

Concomitant administration with oral carbonic anhydrase inhibitors is not recommended due to the potential additive effect. Use with high-dose salicylate may result in acid-base and electrolyte alterations. Use with CNS depressants may result in an additive or potentiating effect. Use with antihypertensives/cardiac glycosides may result in additive or potentiating effect on lowering blood pressure. Use with tricyclic antidepressants may blunt the hypotensive effect of systemic clonidine and it is unknown if use with this class of drugs interferes with IOP lowering. Use with monoamine oxidase inhibitors may result in increased hypotension.

For additional information about SIMBRINZA™ Suspension, please see Brief Summary of full Prescribing Information on adjacent page.

Learn more at myalcon.com/simbrinza

References: 1. SIMBRINZA™ Suspension Package Insert. 2. Katz G, DuBiner H, Samples J, et al. Three-month randomized trial of fixed-combination brinzolamide, 1%, and brimonidine, 0.2% [published online ahead of print April 11, 2013]. *JAMA Ophthalmol*. doi:10.1001/jamaophthalmol.2013.188. 3. Nguyen QH, McMenemy MG, Realini T, et al. Phase 3 randomized 3-month trial with an ongoing 3-month safety extension of fixed-combination brinzolamide 1%/brimonidine 0.2%. *J Ocul Pharmacol Ther*. 2013;29(3):290-297. 4. Data on file, 2013. 5. Whitson JT, Realini T, Nguyen QH, McMenemy MG, Goode SM. Six-month results from a Phase III randomized trial of fixed-combination brinzolamide 1% + brimonidine 0.2% versus brinzolamide or brimonidine monotherapy in glaucoma or ocular hypertension. *Clin Ophthalmol*. 2013;7:1053-1060.

SIMBRINZA™
(brinzolamide/brimonidine
tartrate ophthalmic suspension)
1%/0.2%

ONE BOTTLE. MANY POSSIBILITIES.

BRIEF SUMMARY OF PRESCRIBING INFORMATION INDICATIONS AND USAGE

SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% is a fixed combination of a carbonic anhydrase inhibitor and an alpha 2 adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

DOSE AND ADMINISTRATION

The recommended dose is one drop of SIMBRINZA™ Suspension in the affected eye(s) three times daily. Shake well before use. SIMBRINZA™ Suspension may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes apart.

DOSE FORMS AND STRENGTHS

Suspension containing 10 mg/mL brinzolamide and 2 mg/mL brimonidine tartrate.

CONTRAINDICATIONS

Hypersensitivity - SIMBRINZA™ Suspension is contraindicated in patients who are hypersensitive to any component of this product.

Neonates and Infants (under the age of 2 years) - SIMBRINZA™ Suspension is contraindicated in neonates and infants (under the age of 2 years) *see Use in Specific Populations*

WARNINGS AND PRECAUTIONS

Sulfonamide Hypersensitivity Reactions - SIMBRINZA™

Suspension contains brinzolamide, a sulfonamide, and although administered topically is absorbed systemically. Therefore, the same types of adverse reactions that are attributable to sulfonamides may occur with topical administration of SIMBRINZA™ Suspension. Fatalities have occurred due to severe reactions to sulfonamides including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, and other blood dyscrasias. Sensitization may recur when a sulfonamide is re-administered irrespective of the route of administration. If signs of serious reactions or hypersensitivity occur, discontinue the use of this preparation *[see Patient Counseling Information]*

Corneal Endothelium - Carbonic anhydrase activity has been observed in both the cytoplasm and around the plasma membranes of the corneal endothelium. There is an increased potential for developing corneal edema in patients with low endothelial cell counts. Caution should be used when prescribing SIMBRINZA™ Suspension to this group of patients.

Severe Renal Impairment - SIMBRINZA™ Suspension has not been specifically studied in patients with severe renal impairment (CrCl < 30 mL/min). Since brinzolamide and its metabolite are excreted predominantly by the kidney, SIMBRINZA™ Suspension is not recommended in such patients.

Acute Angle-Closure Glaucoma - The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. SIMBRINZA™ Suspension has not been studied in patients with acute angle-closure glaucoma.

Contact Lens Wear - The preservative in SIMBRINZA™, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA™ Suspension but may be reinserted 15 minutes after instillation *[see Patient Counseling Information]*.

Severe Cardiovascular Disease - Brimonidine tartrate, a component of SIMBRINZA™ Suspension, has a less than 5% mean decrease in blood pressure 2 hours after dosing in clinical studies; caution should be exercised in treating patients with severe cardiovascular disease.

Severe Hepatic Impairment - Because brimonidine tartrate, a component of SIMBRINZA™ Suspension, has not been studied in patients with hepatic impairment, caution should be exercised in such patients.

Potential of Vascular Insufficiency - Brimonidine tartrate, a component of SIMBRINZA™ Suspension, may potentiate syndromes associated with vascular insufficiency. SIMBRINZA™ Suspension should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, or thromboangitis obliterans.

Contamination of Topical Ophthalmic Products After Use - There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers have been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface *[see Patient Counseling Information]*.

ADVERSE REACTIONS

Clinical Studies Experience - Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

SIMBRINZA™ Suspension - In two clinical trials of 3 months duration 435 patients were treated with SIMBRINZA™ Suspension, and 915 were treated with the two individual components. The most frequently reported adverse reactions in patients treated with SIMBRINZA™ Suspension occurring in approximately 3 to 5% of patients in descending order of incidence were blurred vision, eye irritation, dysgeusia (bad taste), dry mouth, and eye allergy. Rates of adverse reactions reported with the individual components were comparable. Treatment discontinuation, mainly due to adverse reactions, was reported in 11% of SIMBRINZA™ Suspension patients.

Other adverse reactions that have been reported with the individual components during clinical trials are listed below.

Brinzolamide 1% - In clinical studies of brinzolamide ophthalmic suspension 1%, the most frequently reported adverse reactions reported in 5 to 10% of patients were blurred vision and bitter, sour or unusual taste. Adverse reactions occurring in 1 to 5% of patients were blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia, ocular discharge, ocular discomfort, ocular keratitis, ocular pain, ocular pruritus and rhinitis.

The following adverse reactions were reported at an incidence below 1%: allergic reactions, alopecia, chest pain, conjunctivitis, diarrhea, diplopia, dizziness, dry mouth, dyspnea, dyspepsia, eye fatigue, hypertonia, keratoconjunctivitis, keratopathy, kidney pain, lid margin crusting or sticky sensation, nausea, pharyngitis, tearing and urticaria.

Brimonidine Tartrate 0.2% - In clinical studies of brimonidine tartrate 0.2%, adverse reactions occurring in approximately 10 to 30% of the subjects, in descending order of incidence, included oral dryness, ocular hyperemia, burning and stinging, headache, blurring, foreign body sensation, fatigue/drowsiness, conjunctival follicles, ocular allergic reactions, and ocular pruritus.

Reactions occurring in approximately 3 to 9% of the subjects, in descending order included corneal staining/erosion, photophobia, eyelid erythema, ocular ache/pain, ocular dryness, tearing, upper respiratory symptoms, eyelid edema, conjunctival edema, dizziness, blepharitis, ocular irritation, gastrointestinal symptoms, asthenia, conjunctival blanching, abnormal vision and muscular pain.

The following adverse reactions were reported in less than 3% of the patients: lid crusting, conjunctival hemorrhage, abnormal taste, insomnia, conjunctival discharge, depression, hypertension, anxiety, palpitations/arrhythmias, nasal dryness and syncope.

Postmarketing Experience - The following reactions have been identified during postmarketing use of brimonidine tartrate ophthalmic solutions in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to brimonidine tartrate ophthalmic solutions, or a combination of these factors, include: bradycardia, hypersensitivity, iritis, keratoconjunctivitis sicca, miosis, nausea, skin reactions (including erythema, eyelid pruritus, rash, and vasodilation), and tachycardia.

Apnea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in infants receiving brimonidine tartrate ophthalmic solutions *[see Contraindications]*.

DRUG INTERACTIONS

Oral Carbonic Anhydrase Inhibitors - There is a potential for an additive effect on the known systemic effects of carbonic anhydrase inhibition in patients receiving an oral carbonic anhydrase inhibitor and brinzolamide ophthalmic suspension 1%, a component of SIMBRINZA™ Suspension. The concomitant administration of SIMBRINZA™ Suspension and oral carbonic anhydrase inhibitors is not recommended.

High-Dose Salicylate Therapy - Carbonic anhydrase inhibitors may produce acid-base and electrolyte alterations. These alterations were not reported in the clinical trials with brinzolamide ophthalmic suspension 1%. However, in patients treated with oral carbonic anhydrase inhibitors, rare instances of acid-base alterations have occurred with high-dose salicylate therapy. Therefore, the potential for such drug interactions should be considered in patients receiving SIMBRINZA™ Suspension.

CNS Depressants - Although specific drug interaction studies have not been conducted with SIMBRINZA™, the possibility of an additive or potentiating effect with CNS depressants (alcohol, opiates, barbiturates, sedatives, or anesthetics) should be considered.

Antihypertensives/Cardiac Glycosides - Because brimonidine tartrate, a component of SIMBRINZA™ Suspension, may reduce blood pressure, caution in using drugs such as antihypertensives and/or cardiac glycosides with SIMBRINZA™ Suspension is advised.

Tricyclic Antidepressants - Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with SIMBRINZA™ Suspension in humans can lead to resulting interference with the IOP lowering effect. Caution is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines.

Monoamine Oxidase Inhibitors - Monoamine oxidase (MAO) inhibitors may theoretically interfere with the metabolism of brimonidine tartrate and potentially result in an increased systemic side-effect such as hypotension. Caution is advised in patients taking MAO inhibitors which can affect the metabolism and uptake of circulating amines.

USE IN SPECIFIC POPULATIONS

Pregnancy - *Pregnancy Category C*: Developmental toxicity studies with brinzolamide in rabbits at oral doses of 1, 3, and 6 mg/kg/day (20, 60, and 120 times the recommended human ophthalmic dose) produced maternal toxicity at 6 mg/kg/day and a significant increase in the number of fetal variations, such as accessory skull bones, which was only slightly higher than the historic value at 1 and 6 mg/kg. In rats, statistically decreased body weights of fetuses from dams receiving oral doses of 18 mg/kg/day (180 times the recommended human ophthalmic dose) during gestation were proportional to the reduced maternal weight gain, with no statistically significant effects on organ or tissue development. Increases in unossified sternebrae, reduced ossification of the skull, and unossified hyoid that occurred at 6 and 18 mg/kg were not statistically significant. No treatment-related malformations were seen. Following oral adminis-

tration of ¹⁴C-brinzolamide to pregnant rats, radioactivity was found to cross the placenta and was present in the fetal tissues and blood.

Developmental toxicity studies performed in rats with oral doses of 0.66 mg brimonidine base/kg revealed no evidence of harm to the fetus. Dosing at this level resulted in a plasma drug concentration approximately 100 times higher than that seen in humans at the recommended human ophthalmic dose. In animal studies, brimonidine crossed the placenta and entered into the fetal circulation to a limited extent.

There are no adequate and well-controlled studies in pregnant women. SIMBRINZA™ Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers - In a study of brinzolamide in lactating rats, decreases in body weight gain in offspring at an oral dose of 15 mg/kg/day (150 times the recommended human ophthalmic dose) were observed during lactation. No other effects were observed. However, following oral administration of ¹⁴C-brinzolamide to lactating rats, radioactivity was found in milk at concentrations below those in the blood and plasma. In animal studies, brimonidine was excreted in breast milk.

It is not known whether brinzolamide and brimonidine tartrate are excreted in human milk following topical ocular administration. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2%, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use - The individual component, brinzolamide, has been studied in pediatric glaucoma patients 4 weeks to 5 years of age. The individual component, brimonidine tartrate, has been studied in pediatric patients 2 to 7 years old. Somnolence (50-83%) and decreased alertness was seen in patients 2 to 6 years old. SIMBRINZA™ Suspension is contraindicated in children under the age of 2 years *[see Contraindications]*.

Geriatric Use - No overall differences in safety or effectiveness have been observed between elderly and adult patients.

OVERDOSAGE

Although no human data are available, electrolyte imbalance, development of an acidotic state, and possible nervous system effects may occur following an oral overdose of brinzolamide. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored.

Very limited information exists on accidental ingestion of brimonidine in adults; the only adverse event reported to date has been hypotension. Symptoms of brimonidine overdose have been reported in neonates, infants, and children receiving brimonidine as part of medical treatment of congenital glaucoma or by accidental oral ingestion. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

PATIENT COUNSELING INFORMATION

Sulfonamide Reactions - Advise patients that if serious or unusual ocular or systemic reactions or signs of hypersensitivity occur, they should discontinue the use of the product and consult their physician.

Temporary Blurred Vision - Vision may be temporarily blurred following dosing with SIMBRINZA™ Suspension. Care should be exercised in operating machinery or driving a motor vehicle.

Effect on Ability to Drive and Use Machinery - As with other drugs in this class, SIMBRINZA™ Suspension may cause fatigue and/or drowsiness in some patients. Caution patients who engage in hazardous activities of the potential for a decrease in mental alertness.

Avoiding Contamination of the Product - Instruct patients that ocular solutions, if handled improperly or if the tip of the dispensing container contacts the eye or surrounding structures, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions *[see Warnings and Precautions]*. Always replace the cap after using. If solution changes color or becomes cloudy, do not use. Do not use the product after the expiration date marked on the bottle.

Intercurrent Ocular Conditions - Advise patients that if they have ocular surgery or develop an intercurrent ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning the continued use of the present multidose container.

Concomitant Topical Ocular Therapy - If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

Contact Lens Wear - The preservative in SIMBRINZA™, benzalkonium chloride, may be absorbed by soft contact lenses. Contact lenses should be removed during instillation of SIMBRINZA™ Suspension, but may be reinserted 15 minutes after instillation.

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Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**FEMTOSECOND**

(Continued from page 10)

conventional technique [Abell RG, et al. *Ophthalmology*. 2013;120:942-948].

However, the results did show that the laser-assisted procedure reduced effective phacoemulsification time by 83%, allowed for a zero ultrasound procedure in 30% of eyes, and reduced endothelial cell loss by 36%.

"This paper provides support for the safety advantages of using the laser to fragment the lens," Dr. Packer said. "However, the lack of any benefit for improving vision or reducing refractive error was interesting because many surgeons think those are advantages of using the laser for capsulotomy. In the economic model in the United States, the justification for charging extra for the laser is that it delivers a better refractive outcome for patients having a premium surgery procedure."

OTHER ARTICLES OF INTEREST

Another publication in the peer review literature on femtosecond lasers that Dr. Packer thought was worth mentioning was an article in the April edition of *Journal of Cataract & Refractive Surgery* [Talamo JH, et al. *J Cataract Refract Surg*. 2013;49:501-510], that compared two different optical patient interfaces on a prototype of the OptiMedica laser.

The two technologies were tested in bench and clinical studies. Results showed multiple advantages for using a liquid optical immersion interface instead of a curved contact lens interface.

"The liquid interface between the laser and the eye minimizes compression and therefore reduces corneal folds," Dr. Packer said. "Since the corneal folds act to scatter laser light, the capsulotomy may contain skip areas that increase the potential for an anterior capsule radial tear."

He noted that only the OptiMedica and LensAR laser systems feature the liquid patient interface.

A third paper from the Australian cataract surgeons that gained Dr. Packer's interest raised a safety concern with laser capsulotomy [Abell RG, et al. *Ophthalmology*. 2013; Epub

ahead of print]. The study compared femtosecond laser-assisted and conventional phaco surgery in groups of about 800 eyes each. Four surgeons who used three different femtosecond lasers performed the procedures.

The analyses found a significantly higher rate of anterior capsule tears in eyes undergoing femtosecond laser-assisted surgery than in a control group, 1.87% versus 0.12%. Of the 15 anterior capsule tears that occurred in the femtosecond laser group, seven extended to the posterior capsule.

"Most of the eyes with a tear did well," Dr. Packer said. "However, a wraparound tear is certainly not a good thing, and some eyes needed a vitrectomy and ended up with a sulcus lens. Cataract surgery with the femtosecond laser is an evolving story. Now, the potential for an increased risk of capsular tears is one issue that laser manufacturers need to look at."

The study authors proposed a few reasons to explain the greater risk of anterior capsule tears with the femtosecond laser, including the fact that the laser creates a capsulotomy with postage-stamp perforations and aberrantly placed pulses as the result of saccadic eye movement.

SIZE MATTERS

Dr. Packer suggested that capsulotomy size might also be an explanation.

Capsulotomies had an average diameter < 5 mm, consistent with what appears to be a trend for surgeons to create smaller capsulotomies when using the laser than when performing a manual technique, he noted. A smaller capsulotomy might predispose to tearing because its rim is less elastic and weaker—because the capsule is thinner—than that of a larger capsulotomy.

Dr. Packer said the reason why surgeons may be creating smaller capsulotomies with the laser is that they are centering the opening on the optical axis in order to optimize visual outcomes with their premium IOLs.

However, in doing so, the capsulotomy is decentered relative to the capsule. In the latter situation, making a smaller capsulotomy helps to ensure that there is 360° overlap of the capsular rim over the optic and that the IOL remains stable in the capsular bag. ■

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Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**TECHNOLOGY**

(Continued from page 1)

for providing an extended range of vision and the underlying mechanism of any benefit.

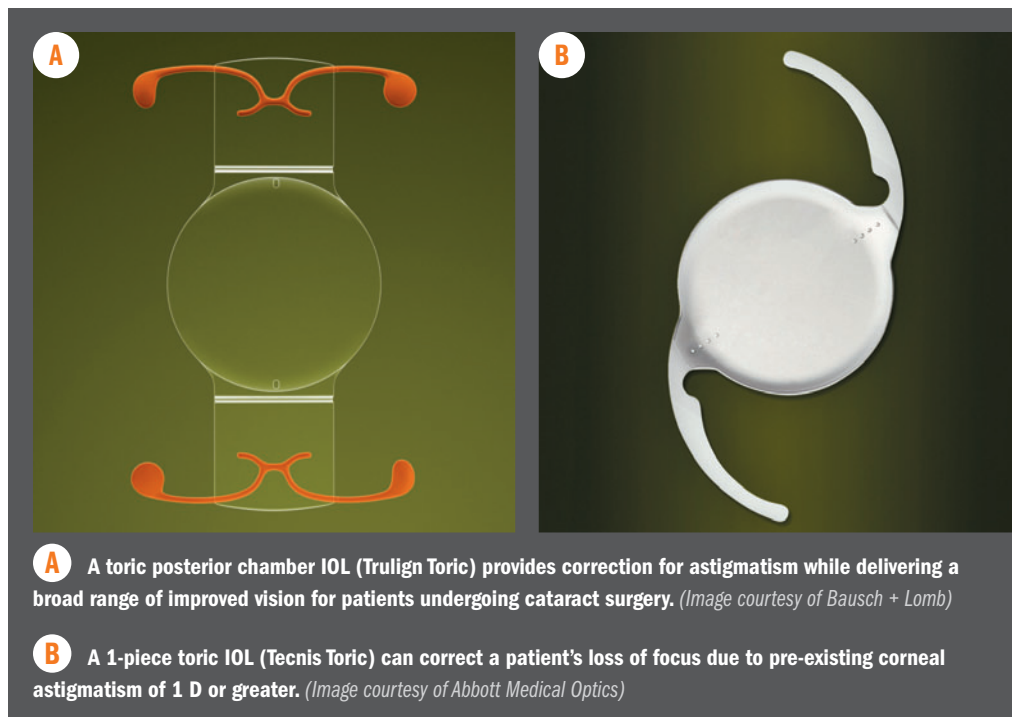
However, based on available evidence, he said he is convinced that it provides better intermediate and near vision than a monofocal IOL and therefore reduced dependence on glasses.

"Whether the reason for the performance of the Crystalens IOL is increased depth of field or true accommodation is a matter of discussion, and it is worth noting that the FDA did not give the Trulign Toric IOL an indication for 'accommodation,'" said Dr. Packer, who is in private practice, Bowie, MD, and clinical associate professor of ophthalmology, Oregon Health and Science University, Portland. "However, with the Trulign we finally have a toric lens that can provide more than just good distance vision, and the FDA study data show that it does a very good job of correcting astigmatism."

Dr. Packer noted that in the FDA study, distance uncorrected visual acuity (UCVA) was 20/40 or better in 98% of eyes with the Trulign Toric IOL implanted, which is a better result than that achieved in the FDA studies for the AcrySof Toric (Alcon) or Tecnis Toric (Abbott Medical Optics) lenses.

He proposed the difference might be explained by the polyimide loops of the Trulign Toric IOL as they might provide better rotational stability.

"Surgeons who use the Crystalens are well familiar with how difficult it is to rotate the lens in the eye," Dr. Packer said. "Whereas a single-piece acrylic IOL is relatively easy to



A A toric posterior chamber IOL (Trulign Toric) provides correction for astigmatism while delivering a broad range of improved vision for patients undergoing cataract surgery. (Image courtesy of Bausch + Lomb)

B A 1-piece toric IOL (Tecnis Toric) can correct a patient's loss of focus due to pre-existing corneal astigmatism of 1 D or greater. (Image courtesy of Abbott Medical Optics)

rotate, moving the Crystalens requires freeing the haptic loops from the capsule equator. I think better rotational stability with a toric IOL translates into better UCVA."

Dr. Packer said he is looking forward to having the toric versions of the AcrySof ReSTOR and Tecnis multifocal IOLs as those implants are doing well outside of the United States.

Dr. Olson agreed that having a premium IOL available that also offers toric correction is an important step forward, although he said he is waiting to see more data on the Trulign before making any comments about it.

The AcrySof platform lends itself well to non-rotation and that the AcrySof Toric IOL has demonstrated good clinical performance, noted Dr. Olson, professor and chairman, Department of Ophthalmology and Visual Sciences and chief executive officer, John A. Moran Eye Center, University of Utah, Salt Lake City.

Additionally, it appears that the new Tecnis

toric IOL seems to deliver reliable astigmatic correction. However, he welcomes evidence to show that any toric IOL is better than another.

"Theoretical reasons for superiority are interesting, but I like to see the proof," Dr. Olson said.

Although available data demonstrate the efficacy of toric IOLs for reducing or eliminating astigmatism and their popularity is growing, he said any cataract surgeon offering astigmatic correction still needs to know how to use incisional techniques.

"A lot of patients are unhappy with any amount of residual astigmatism above 0.5 D, and some are even unhappy at that level," Dr. Olson said.

PRESBYOPIA-CORRECTING IOL DEVELOPMENT ONGOING

The category of presbyopia-correcting IOLs has been pretty static in 2013.

Eye-care job platform receives upgrade

RALEIGH, NC ::

LOCAL EYE SITE, A LEADING JOB SEARCH platform focused entirely on the eye-care industry, unveils its redesigned website, *LocalEyeSite.com*.

The new site has been developed from the ground up to provide better management of increasing traffic, along with greater numbers

of registrations and job listings. With more than 65,000 registered users and nearly 700 job postings, the upgrade will ensure that the website remains the single most comprehensive resource for jobs in the eye-care industry, according to Brad McCorkle, founder of Local Eye Site.

"Our goal with this redesign was to create

an even better experience for our users, while also building an improved infrastructure that will handle greater traffic and future development on all platforms—especially mobile," McCorkle said.

"What hasn't changed is that employers still have access to the Power Network, and everything remains free for job seekers," he added. ■

Special Report) CATARACT & REFRACTIVE YEAR IN REVIEW

In this category as well, Dr. Olson said he believes that no one available platform stands out for “delivering a clear knockout punch.” For that reason, he believes that most surgeons are using the various products in different situations determined on a case-by-case basis while still waiting for a truly accommodating IOL.

Development of the DynaCurve (NuLens)—a sulcus-based accommodating IOL—and the FluidVision accommodating IOL (PowerVision) continued during 2013, and the available research findings indicate each has a large range of accommodation. However, these investigational lenses remain years away from FDA approval, Dr. Olson said.



Dr. Kahook

Dr. Kahook, The Slater Family Endowed chair in ophthalmology and professor of ophthalmology, University of Colorado, Denver, noted that while the DynaCurve and FluidVision IOLs have been in development for some time, there is still not enough clinical data to prove they can provide reliable and long-term accommodation.

In addition, he raised concern that none of the accommodating IOLs in development addresses the problem of PCO development that will limit the function of an accommodating IOL months after implantation.

The need to limit PCO was just one of the issues considered by Dr. Kahook in developing a novel modular IOL system (HARMONI, ClarVista) that entered clinical investigation in October.

The platform consists of a base component and an optic component that fits into an annular groove within the base. It is implantable through a 2.2-mm incision and is also designed to deliver improved refractive outcomes—both by having a more predictable effective lens position and allowing intraoperative customization of lens power.

In addition, its modular design provides for safe and easy postoperative enhancement with minimal to no manipulation of the capsular bag.

“One of the major factors that has hindered the adoption of premium IOLs is the inability to address refractive surprise, glare, and overall patient dissatisfaction postoperatively,” Dr. Kahook said. “Many patients express displea-

sure with the results of a diffractive IOL, and the current options to address dissatisfaction include permanent corneal modifications or IOL exchange.

“The HARMONI Lens system allows surgeons to address the refractive issues directly by elegantly replacing the optic component

through a minimally invasive incision without fear of injuring the capsular bag as is the case with traditional IOL exchanges,” he continued. “The two-component design also enables use of a slightly larger rhexis to limit glare from the anterior capsule edge, and the

Continues on page 16 : Lens design

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► While U.S. cataract surgeons still have limited access to pseudophakic correction technology, there were several premium IOLs made available this year that offer toric correction, an important step forward.

While U.S. cataract surgeons still have limited access to pseudophakic correction technology, there were several premium IOLs made available this year that offer toric correction, an important step forward.



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Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**LENS DESIGN**

(Continued from page 15)

base component provides a superior barrier to inhibit posterior capsule opacification proliferation. The flexibility of the platform also allows for future upgrades from a monofocal lens to a premium lens or to new technology that is not yet on the market."

UPDATES ON EXISTING IOLS

Dr. Olson observed that 2013 was the first full year during which cataract surgeons had access to three different single-piece hydrophobic acrylic IOLs: the original AcrySof, the Tecnis 1-piece, and the enVista (Bausch + Lomb).

He noted that he believes these products are more similar than dissimilar.



Dr. Olson

That impression seems to be reinforced by the absence of any solid evidence from comparative studies to show otherwise, Dr. Olson said.

While the enVista is touted for its glistening-free material, Dr. Olson said that the acrylic material of the Tecnis IOL enjoys a good reputation in terms of glistenings. Though there is much talk about the negative impact of these material defects, there is a need for evidence from well-designed studies to demonstrate that the average level of glistenings that can develop in a hydrophobic acrylic lens truly affects vision, he noted.

Also within the topic of IOL news during 2013, Dr. Packer felt a published paper [Venter JA, et al. *J Cataract Refract Surg.* 2013;39:1477-1484] reporting outcomes of the zonal refractive IOL (Lentis Mplus, Lentis) was worth mentioning.

Although the lens is not available in the United States, he said he felt the paper was noteworthy for two reasons: first, the retrospective case series includes data for follow-up to 6 months in 4,683 patients with bilateral implants (9,366 eyes)—which likely makes it the largest published series on any single IOL.

In addition, Dr. Packer said he was pleasantly surprised by the overall excellent results given the size of the population and his original skepticism based on the lens design.

At 6 months, mean binocular logMAR UNVA was 0.159, 97.5% of patients were satisfied and willing to recommend the procedure, and only 55 eyes (0.6%) had undergone IOL exchange for dysphotopsia.

"When I first saw this optic, I thought the design, which is like the Ben Franklin bifocal, would cause significant dysphotopsias," Dr.

Packer said. "The published results and information shared with me by colleagues who are using the lens clearly shows that first reactions are sometimes wrong.

"Nevertheless, the data from this series are a reminder that explantation for dysphotopsias is a reality with multifocal IOLs," he said. "Despite careful patient selection and thorough counseling about the development of halos and other visual symptoms, not everyone is happy with the outcome."

According to a study conducted by Dr. Olson and colleagues, pseudophakic dysphotopsia is a common and clinically significant problem even in ideal patients with a monofocal IOL implanted [Kinard K, et al. *J Cataract Refract Surg.* 2013;39:590-597].

On reviewing charts from almost 3,000 patients, they identified 70 who had uneventful surgery, logMAR best-corrected visual acuity 0.02 or better after 1 year, and no ocular complaints or pathology.

The patients underwent comprehensive examination and completed questionnaires to evaluate dysphotopsias, visual function, and satisfaction.

The dysphotopsia questionnaire asked patients to rate various symptoms on a scale of 0 (no problem) to 10 (debilitating). The results showed almost 30% of patients gave a score of 5 or greater for multiple symptoms and 17% rated a number of symptoms with a score of 8 or greater.

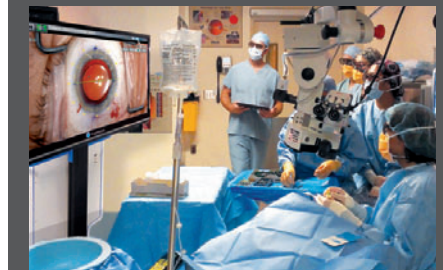
DEGREE OF DYSPHOTOPSIA AS PREDICTOR

Correlation analyses showed the degree of pseudophakic dysphotopsias was a strong predictor of both level of patient dissatisfaction and outcomes on the visual function questionnaire.

"In this study of 'supernormal' cataract surgery patients, we found dysphotopsia was far and away the biggest complaint and that it became a functional problem for patients as they went about their daily tasks," Dr. Olson said. "Pseudophakic dysphotopsia is really the 900-pound gorilla in the room. Patients may not spontaneously report it, but it is a real problem that is more common than surgeons realize and an issue that IOL manufacturers need to address."

Dr. Olson noted that so far, he believes Rayner is the only manufacturer showing interest in the problem. Otherwise, he said Samuel Masket, MD, holds a patent for a lens to address dysphotopsia.

Based on the concept that dysphotopsias are a function of capsular overlap of the IOL optic, the lens features a groove into which the anterior capsular leaf is inserted. ■

OT OphthalmologyTimes.com
Online Exclusive**CATARACT: CLINICAL DIAGNOSIS****BETTER REFRACTIVE OUTCOMES IN SURGERY**

Iqbal "Ike" Ahmed, MD, utilizes the TrueVision onscreen three-dimensional high-definition guidance refractive cataract tool set to position a toric IOL accurately. (Photo courtesy of Mark Packer, MD)

CHANGING CATARACT PRACTICE In 2013, cataract surgeons gained access to new IOLs, a new phaco unit, and a new topical NSAID. Perhaps the most important developments were in diagnostics, including technologies for intraoperative imaging and for bringing preoperative diagnostic information into the operating room. Go to <http://bit.ly/1eZzde7>

CATARACT: DRUG THERAPY**MEDICATION PROTOCOLS FOR CATARACT SURGERY**

INFECTION PROPHYLAXIS Although modern cataract surgery is extremely safe, postoperative endophthalmitis remains the most feared complication, and cystoid macular edema continues to be the most common cause of vision loss after routine cataract procedure. In 2013, discussion continued about the role of intracameral versus topical antibiotics for infection prophylaxis. Go to <http://bit.ly/IG1Kte>

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Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**REFRACTIVE: CLINICAL DIAGNOSIS**

Newly identified Dua's layer may alter approach to corneal biomechanics

Refractive focus also includes posterior corneal astigmatism, aberrometry for toric IOLs

By **Lynda Charters**; Reviewed by Uday Devgan, MD, Peter S. Hersh, MD, and Jonathan Talamo, MD

WITH CLINICAL DIAGNOSIS being central to the ophthalmic practice, the year has proven to be especially noteworthy for the corneal and refractive arenas. Among the highlights are the identification of a new layer in the cornea, important considerations regarding posterior corneal astigmatism and toric IOLs, and the use of aberrometry to determine toric IOL corrective power.

DUA'S LAYER

The discovery of a heretofore-unrecognized layer in the cornea, referred to as Dua's layer, was a noteworthy event, according to Uday Devgan, MD, associate clinical professor, Jules Stein Eye Institute, University of California-Los Angeles' School of Medicine, and chief of ophthalmology, Olive View UCLA Medical Center.

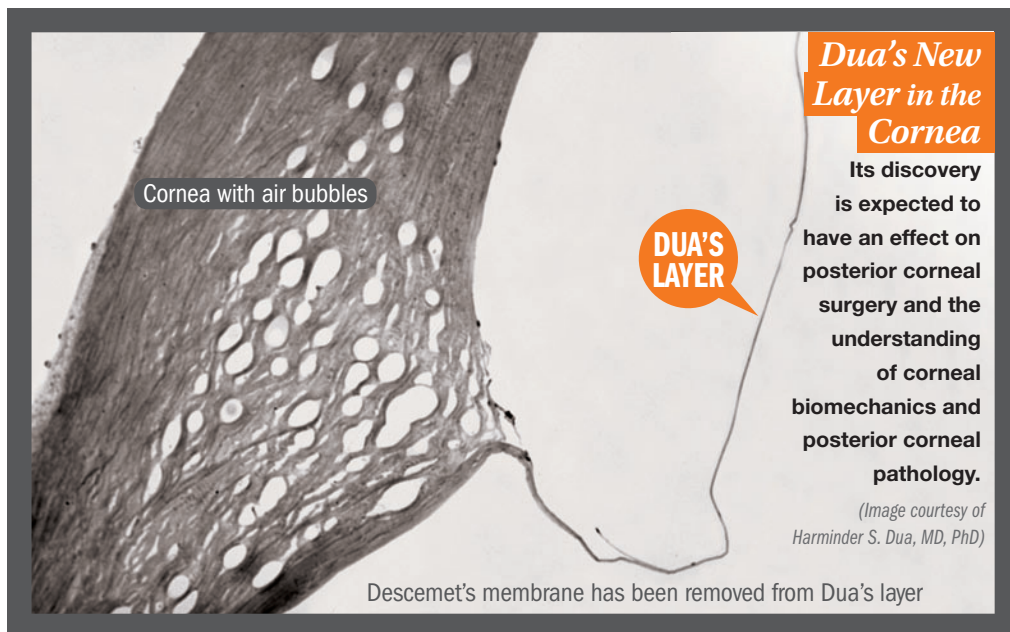
Harminder Singh Dua, MD, PhD, MBBS, chairman of the Division of Ophthalmology and Visual Sciences at the University of Nottingham, United Kingdom, and associates recently reported their discovery in *Ophthalmology* (2013;120:1778-1785).

This new corneal structure—between Descemet's membrane and the corneal stroma—was found to be 15 μ m thick when imaged by electron microscopy. Investigators noted that this layer was very strong and impervious to air.

The presence of Dua's layer is highly relevant in lamellar dissection for corneal transplantation where air could be injected below it using the big bubble technique to help minimize the risk of tearing, Dr. Devgan said.

In diseases, such as keratoconus, a defect in Dua's layer could account for the pathogenesis of corneal hydrops because it would allow passage of water from the aqueous.

Some debate surrounds the identification of Dua's layer as expressed by Jester and colleagues (*Ophthalmology* 2013;120:1715-1717) and whether the new corneal layer is indeed a new layer that deserves the title, noted Peter S. Hersh, MD.



Dr. Hersh is the director, Cornea and Laser Eye Institute, Hersh Vision Group, Teaneck, and clinical professor of ophthalmology, and chief, Cornea and Refractive Surgery, Rutgers-New Jersey Medical School, Newark.

"We will see more arguments among pathologists about Dua's layer and what it actually means—both with regard to the general description of the anatomy of the cornea and also the implications of it for lamellar techniques, such as deep anterior lamellar keratoplasty and Descemet's stripping automated endothelial keratoplasty," he said.

POSTERIOR CORNEAL ASTIGMATISM AND TORIC IOLs

The importance of the effect of the posterior corneal surface on the overall refractive astigmatism of the eye was acknowledged by Doug Koch, MD, and his associates from Baylor University, Waco, TX. Investigators reported their findings in the *Journal of Cataract and Refrac-*

take-home

► **Making the headlines in clinical diagnosis was the identification of a new layer in the cornea, considerations regarding posterior corneal astigmatism and toric IOLs, and the use of aberrometry to determine toric IOL corrective power.**

tive Surgery (Koch DD, Jenkins RB, Weikert MP, Yeu E, Wang L. EPub ahead of print 2013 Oct 26).

"We have all seen the patient who underwent IOL implantation with a perfectly positioned spherical IOL and absolutely no astigmatism apparent in our keratometry or corneal topography measurements, but has a cylindrical component to his refraction," Dr. Devgan said.

This is due to the astigmatic effect of the posterior cornea that is not measured by routine keratometry, topography, or other methods that focus on the anterior corneal surface, he noted.

Dr. Koch and his colleagues noticed this in particular with patients with toric IOLs implanted who still had significant residual astigmatism even with a perfectly positioned IOL, Dr. Devgan explained. They devised the Baylor toric nomogram that takes into account the average posterior corneal astigmatism for patients with against-the-rule (ATR) and with-the-rule (WTR) astigmatism.

"Simply stated, we should aim to leave eyes with a small degree of WTR astigmatism as



Dr. Devgan

measured by our keratometry devices,” Dr. Devgan said. “When using the AcrySof toric IOLs (Alcon Laboratories), which are spaced evenly in half-diopter steps at the corneal plane, I remember that I should add-up to the next toric T step for against-the-rule, while I should wimp down one toric T step for with-the-rule. By linking the add-up for ATR and wimp-down for WTR, it makes it easy to remember.”

Another option is to measure the posterior corneal surface accurately before surgery using corneal tomography devices, such as the Galilei Dual Scheimpflug Analyzer (Ziemer) or Pentacam (Oculus), and then use the total corneal power via ray tracing to determine the amount of astigmatism that needs to be addressed by the toric IOL, according to Dr. Devgan.

Finally, intraoperative aberrometry may be beneficial when taking aphakic refractions during surgery since the entire cornea, anterior and posterior, will be taken into account during the biometric analysis, Dr. Devgan said.



Dr. Hersh

Dr. Hersh also noted that there is a debate about when to use toric IOLs, when to treat corneal astigmatism, and when the astigmatism is lenticular in nature.

“As we gain more knowledge about anterior and posterior corneal curvatures from Scheimpflug analysis, the increasing use of optical coherence tomography, and from intraoperative wavefront analysis,” he said, “these techniques are enhancing our ability to implant the appropriate lenses—whether they be toric or not—and also improving our ability to place the appropriate lenses in patients who have undergone previous LASIK or PRK procedures.

“It is making the problem of postoperative refractive errors after cataract surgery performed after LASIK far more manageable,” Dr. Hersh said.

INTRAOPERATIVE ABERROMETRY AND TORIC IOLS

Jonathan Talamo, MD, considers the use of intraoperative aberrometry to be an essential component in implantation of toric IOLs.

“Without aberrometry, the surgeon relies completely on the measurement of anterior corneal astigmatism and manual reference markings on the eye to calculate the corrective power of a toric IOL and align the IOL in the eye,” said Dr. Talamo, associate clinical professor of ophthalmology, Harvard Medical School, Boston. “With intraocular aberrometry, after the cataract is removed, the aphakic refraction is determined.”



System upgrade

WaveTec Vision released a hardware upgrade (VerifEye) for its ORA System, used by ophthalmic surgeons to improve the accuracy of cataract surgery.

(Photo courtesy of WaveTec Vision)

The results obtained with toric IOLs probably have a great deal to do with the posterior corneal astigmatism, Dr. Talamo noted.

“Even though we can image the back of the cornea with tomography and optical coherence tomography, there is no good way to translate those measurements into anything meaningful about refractive astigmatism,” he said.

When measuring an aphakic refraction using the newest-generation aberrometer (VerifEye, WaveTec Vision), the measurement incorporates the posterior astigmatism into the equation, he said.

Practically speaking, in a patient with WTR astigmatism, the aberrometer shows that the astigmatism is lower than might be anticipated by looking at the anterior corneal measurements using topography or tomography alone, Dr. Talamo said. In patients with ATR astigmatism, the astigmatism tends to be greater when relying on topography or tomography alone.



Dr. Talamo

Dr. Talamo and his colleagues conducted a study in which they compared the refractive results after toric

IOL placement with and without the use of intraoperative aberrometry.

In the prospective non-randomized study, the results of which were presented at the 2013 meeting of the American Academy of Ophthalmology, they studied consecutive eyes with ($n = 37$) and without ($n = 30$) use of the ORA System (WaveTec Vision) intraoperatively. The preoperative characteristics of both patient populations were well matched.

The authors found that the absolute reduction in astigmatism after surgery was significantly lower in the eyes in which aberrometry was performed intraoperatively compared with the eyes in which it was not performed.

In addition, the likelihood that the patient would have an absolute astigmatism that was

sufficiently low to facilitate an excellent visual result was also significantly greater in the eyes in which aberrometry was performed. The patients had a high chance of being within 0.25 or 0.5 D of the targeted correction with aberrometry, he noted.

“There was a highly statistically significant difference in clinically relevant outcomes,” Dr. Talamo said.

In addition to seeing a higher mean reduction in postoperative astigmatism in the aberrometry group (75% versus 57%), the use of aberrometry made it more than twice as likely (78% versus 37%) that the postoperative refractive astigmatism would be within 0.5 D of target.

In the aberrometry group, the VerifEye axis was used along with conventional preoperative marking technique to guide initial rotational placement of the IOL, and additional rotations in 32% of eyes were needed to refine IOL position.

Astigmatic IOL power was changed during surgery in 25% of the aberrometry group based on aphakic refraction, while spherical power was changed about one-third of the time.

“This technology allows surgeons to have more confidence to be less aggressive in patients with WTR astigmatism and more aggressive in patients with ATR astigmatism when choosing toric IOL powers,” Dr. Talamo said. ■

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Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**REFRACTIVE: SURGERY**

CXL at center of surgical highlights

FDA approval of topography-guided PRK brings additional benefits to small subset of patients

By **Lynda Charters**; Reviewed by Peter S. Hersh, MD, and Jonathan Talamo, MD

THIS YEAR HAS seen exceptional activity surrounding collagen crosslinking (CXL)—both by itself and as an adjunctive technique for treating keratoconus and potentially for treating refractive errors.

The results of the original U.S. multicenter CXL trial are working their way through the FDA approval process.

Peter S. Hersh, MD, is hopeful that the approval decision will be forthcoming in the near future.

“The outcomes looked very encouraging, and I hope that we might know more in the new year,” said Dr. Hersh, director, Cornea and Laser Eye Institute, Hersh Vision Group, Teaneck, and clinical professor of ophthalmology, and chief, Cornea and Refractive Surgery, Rutgers-New Jersey Medical School, Newark.

ABOUT THE STUDY

That study assessed the standard CXL technique with a 3-mW ultraviolet light source and a 30-minute riboflavin “soak” for the treatment of keratoconus and corneal ectasia.

The study included 293 eyes with keratoconus and 219 eyes with corneal ectasia that underwent the CXL procedure to evaluate the ability of the technology to stabilize the progressive diseases.



Dr. Hersh

“Other potential benefits of the technique also became apparent,” Dr. Hersh said.

Researchers found a significant difference in 1-year outcomes between the treated eyes and the sham-treated control eyes.

In the keratoconus eyes treated with CXL, investigators found a significant improvement and flattening of the corneal topography by 1.6 D compared with continued disease progression in the untreated group.

Considering this and the low-risk profile—as well as long-term results internationally—the procedure seems to be safe and effective for treating keratoconus and ectasia, Dr. Hersh noted.

An evaluation of his cohort of about 100

patients that is part of the U.S. multicenter trial found:

■ **Improvements in corneal topography indices and in corneal and total ocular higher-order aberrations (HOAs).**

■ **Increases in vision from 20/137 uncorrected to 20/117 uncorrected and from 20/45 best-corrected vision to 20/34 best-corrected vision in the treated eyes.**

Subjective improvements were also reported on patient-completed questionnaires, he said.

Based on the results in this patient cohort, Dr. Hersh and associates reported outcomes that might be predictive of improvement.

“We observed that patients with keratometry readings of 55 D or more before treatment and patients with correctable vision of 20/40 or worse were more likely to have improvements in topography and visual acuity outcomes,” he said.

Their findings can be found in the *Journal of Cataract and Refractive Surgery* (2013;39:1133-1140).

WAYS IN WHICH CXL IS EXPANDING

Aside from the original U.S. multicenter study, there are three other Avedro U.S. multicenter protocols. Dr. Hersh discussed these three protocols first, as well as the various avenues into which CXL is evolving:

POWER INCREASED. One study of accelerated CXL in which the power was increased to 30 mW was completed.

“The initial 6-month results of that randomized study are encouraging with improvement in the treatment group compared with the control group,” Dr. Hersh said.

PULSING TECHNIQUE. Another study was started recently in which accelerated CXL with a pulsing technique is being assessed—i.e., rather than using continuous wavelight, the light is pulsed (on for 1 second and off for 1 second).

“The presence of oxygen is important for one pathway of the CXL process, and ox-

Topo-guided PRK tops list of 2013 advances

“THE BIG NEWS of 2013 has been the approval by the FDA of topography-guided PRK (Wavelight Allegretto Laser, Alcon Laboratories) in the United States. I am very excited by this,” said Jonathan Talamo, MD, associate clinical professor of ophthalmology, Harvard Medical School, Boston.

Though wavefront-guided treatment is very effective for the vast majority of cases, Dr. Talamo explained, there is a small subset of patients who will benefit greatly from topography-guided PRK—such as patients who have corneal irregularities after previous surgeries or those with corneal topographic asymmetries that will leave the patients with higher-order aberrations.

Wavefront-guided treatments are based on the wavefront profile of the entire eye, which, Dr. Talamo noted, may be harder to measure reproducibly and may not reflect abnormalities in the cornea alone but may reflect lenticular aberrations, which can change over time.

He soon hopes to be involved in a clinical trial of topography-guided PRK and CXL to treat keratoconus.

“Topography-guided technology is going to be very helpful to surgeons in the United States,” Dr. Talamo said. ■

xygen is rapidly depleted during ultraviolet exposure,” Dr. Hersh said. “With the pulse technique, additional oxygen is able to diffuse into the stroma during the dark phase.”

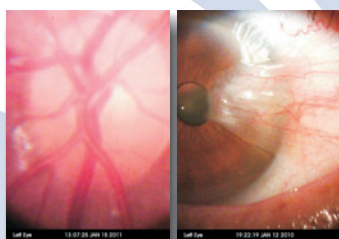
The hope is that with more oxygen availability, the CXL strengthening effect will become more robust, he noted.

ADJUNCT TO LASIK. Another study is currently evaluating the potential for CXL as an adjunct to LASIK, specifically in patients who have more than 2 D of hyperopia.

Continues on page 24 : **Crosslinking**

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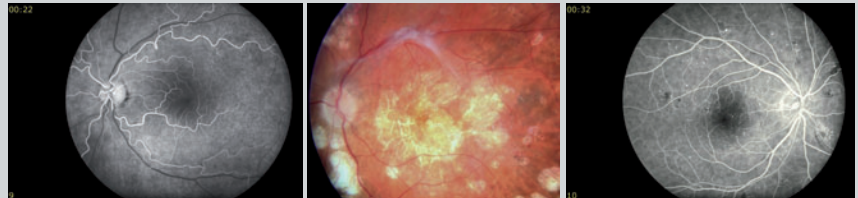
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Special Report) **CATARACT & REFRACTIVE** YEAR IN REVIEW**CROSSLINKING**

(Continued from page 20)

"The goal is enhanced stability of the hyperopic corrections over time, with improvement of our LASIK outcomes," Dr. Hersh said.

TOPOGRAPHY-GUIDED CXL. Surgeons in Europe are beginning to use topography-guided CXL. The dosage of the ultraviolet light is patterned by corneal topography.

Dr. Hersh explained that a new system has an eye-tracking modality (KXL II System for Accelerated CXL, Avedro Inc.). This allows the surgeon to apply the light at graded powers over specific locations on the cornea, as guided by corneal topography.

"The early results are encouraging with substantial improvements in topography achieved in patients with keratoconus," Dr. Hersh said. "Also of great interest is the use of CXL for treatment of simple refractive errors."

Early results in patients with simple myopia and astigmatism show that different treatment patterns and ultraviolet energies possibly can correct low degrees of myopia and astigmatism.

"This is very exciting from the refractive surgery standpoint," Dr. Hersh said.

FURTHER APPLICATIONS. Also, in Europe and elsewhere, CXL has been used as an adjunct to corneal implants (Intacs, Addition Technology) and as an adjunct to topography-guided PRK in patients with ectasia and keratoconus.

Dr. Hersh also is involved in a study with his clinic in which he and his colleagues are using microwave treatments with CXL.

"Some patients treated in this study have had [more than] 15 D of flattening, with one very happy patient improving from counts fingers to 20/25 uncorrected over the first year after treatment," Dr. Hersh said.

HOT ISSUES IN CXL

Although the FDA in the United States has not yet approved CXL, the procedure is almost universally accepted around the world as the first-line treatment for keratoconus, particularly in patients with progressive disease and in younger patients.

"The current issues in refractive surgery are the indications for CXL and the various clinical approaches of the technology and their efficacies," said Jonathan Talamo, MD, associate clinical professor of ophthalmology, Harvard Medical School, Boston.

OT OphthalmologyTimes.com **ONLINE EXCLUSIVE****REFRACTIVE: DRUG THERAPY****BESIFLOXACIN IN PRK AS A PUBLIC HEALTH ISSUE**

OFF-LABEL USE An important drug therapy finding in 2013 was evidence that topical besifloxacin 0.6% (Besivance, Bausch + Lomb) used off-label as prophylaxis before PRK causes significant problems with healing of the corneal epithelium and delayed recovery of vision following the refractive procedure.

"We found that when we applied besifloxacin under a bandage contact lens at the time of surgery in the presence of an epithelial defect there were significant problems with impaired healing, prolonged re-epithelization, corneal haze, pain, and inflammation that ultimately led to scarring and some loss of vision in certain cases," said Jonathan Talamo, MD, associate clinical professor of ophthalmology, Harvard Medical School, Boston. Dr. Talamo and colleagues reported their evidence in *Cornea* (2013;32:1365-1368). Go to <http://bit.ly/1ePJ4m4>.

EPITHELIUM-ON OR EPITHELIUM-OFF?

Recently, there has been increasing interest in "epithelium-on" CXL, in which the corneal epithelium is left on when the riboflavin is applied in contrast to the standard CXL in which the epithelium is removed ("epithelium-off").

In the epithelium-on procedure, the riboflavin requires more time to penetrate into the cornea.

Although now, loading times are becoming shorter as newer and more concentrated solutions with proprietary additives are being developed that facilitate penetration deeper into the corneal stroma without scraping the epithelium, Dr. Talamo said.



Dr. Talamo

"This more rapid penetration is important because the patient comfort is increased, the visual recovery is faster, and the incidence of complications is reduced dramatically without the need for epithelial healing," he said.

Much of the controversy surrounding epithelium-on and epithelium-off procedures is about efficacy.

Some histologic, microscopy, and optical coherence tomography studies have reported evidence regarding cell death in the cornea associated with the application of ultraviolet light. With the epithelium-on procedure, cell death is not evident, less evident, or evident to a more shallow corneal depth, Dr. Talamo noted.

"The argument by proponents of epithelium-off CXL is that the desired effect is not reaching the deep layers of the cornea or the effect might not be as complete or long-lasting," Dr. Talamo said.

He also noted that the literature on this topic is contradictory.

In a multicenter study, CXL-USA, in which Dr. Talamo is participating, there is a large body of epithelium-on data suggesting that the procedure is effective and in many cases equally effective to that of the epithelium-off procedure.

About one-half of studies in the peer-reviewed literature show that the procedure is effective, and the other half that it is not.

"The variable results probably have more to do with a lack of consistency with making sure that the cornea is loaded with riboflavin and a lack of understanding about the appropriate parameters for establishing the dose of the ultraviolet light, that is, continuous delivery or fractionated delivery," Dr. Talamo explained.

The answers to these questions are still forthcoming. However, there seems to be a groundswell of opinion in the direction of the epithelium-on procedure, especially when doing CXL in conjunction with other procedures—which is the approach that will truly deliver refractive changes to patients with keratoconus—as healing problems may increase if the epithelium is scraped off, he commented. ■

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Dr. Talamo is co-chairman of the medical advisory board for and a consultant to CXL Ophthalmics.

REFRACTIVE: TECHNOLOGY

OCT: It's all about better imaging

Refractive technologies also advance with laser-assisted cataract surgery

By Lynda Charters; Reviewed by Peter S. Hersh, MD, and Jonathan Talamo, MD

ADVANCES IN TECHNOLOGIES

enabling the imaging of the cornea using optical coherence tomography (OCT) and laser-assisted cataract surgery have captured the attention of many ophthalmologists during the past year.

INNOVATIONS IN IMAGING TECHNOLOGY

Use of corneal OCT is generally on the upswing, with newer-generation technology providing better imaging and a better ability to analyze the corneal epithelial thickness.

However, the newer systems cannot provide a limbus-to-limbus picture of the cornea as the older systems could do, according to Peter S. Hersh, MD, director, Cornea and Laser Eye Institute, Hersh Vision Group, Teaneck, and clinical professor of ophthalmology, and chief, Cornea and Refractive Surgery, Rutgers-New Jersey Medical School, Newark.

The technology is being used to measure corneal power more accurately by assessing both anterior and posterior corneal curvature measurements, Dr. Hersh noted.

This is of particular importance before cataract surgery in patients who underwent a previous LASIK procedure.

OCT is being used more to measure the corneal epithelial thickness, which guides surgeons' selections of treatments for a number of corneal problems, he added.

"We can see, for example, if corneal irregularities are secondary to the epithelium or secondary to the stroma," Dr. Hersh said. "This can guide us in selection of either superficial keratectomy or excimer laser phototherapeutic keratectomy." He noted that the technology will tell the depth at which surgeons either want to:



Dr. Hersh

- Perform superficial keratectomy (in the case of a relatively smooth stromal surface).
- Convert to excimer laser to reach the right level (in the case where the epithelium is masking underlying stromal irregularity).
- Perform a deeper lamellar procedure.

The ability to image the depth of stromal



Capabilities

Ophthalmic surgeons note that expanding capabilities—including use of the Catalys Precision Laser System, for instance—are advancing refractive laser-assisted cataract surgery.

(Photo courtesy of Abbott Medical Optics/OptiMedica)

scars has been very helpful for anterior lamellar procedures in order to determine the depth of lamellar dissection, he added.

It is also helpful for diagnosing and following patients with keratoconus and refractive regression after LASIK.

"If we can see that there has been a change in the epithelial thickness in association with refractive regression after LASIK, this might suggest an epithelial treatment—such as debridement—and if there is no change that might suggest changes in the stroma that are leading to refractive changes," Dr. Hersh explained.

REFRACTIVE LASER-ASSISTED CATARACT SURGERY

Jonathan Talamo, MD, commented on the rapid advancement of refractive laser-assisted cataract surgery (ReLACS as he refers to the procedure) over the past year.

"While these systems have been available for the past few years, a full suite of capabilities has only been approved by the FDA for multiple devices during the last year," said Dr. Talamo, associate clinical professor of ophthalmology, Harvard Medical School, Boston. These systems include:

- LenSx Laser (Alcon Laboratories)
- Catalys Precision Laser System (Abbott Medical Optics/OptiMedica)

take-home

► Innovations in imaging and refractive laser-assisted cataract surgery are among the technologic advancements noted by surgeons in 2013.

■ Victus femtosecond laser platform (Bausch + Lomb)

■ LensAR Laser System (LensAR Inc.)

With these units, surgeons can perform peripheral and astigmatic corneal incisions, arcuate capsulotomies, and lens softening and fragmentation.

"The ability to leverage the various capabilities is improving as we understand what they do to

the cornea and the lens during surgery and IOL placement after surgery," Dr. Talamo said.

During development of the Catalys Precision Laser System, of which Dr. Talamo was involved, it became clear that when the distance is reduced between the posterior capsule and the point at which the laser begins lens softening and fragmentation—as well as when the space between the laser spots is reduced

during lens softening—the amount of ultrasound energy applied during phacoemulsification can be radically reduced.



Dr. Talamo

Dr. Talamo cited recent studies by Abell et al. (*Ophthalmology*. 2013;120:942-948. doi: 10.1016/j.ophtha.2012.11.045. Epub 2013 Mar 7) and Mayer et al. (*Am J Ophthalmol*. 2013;Nov 7. doi:pii: S0002-9394(13)00639-9. 10.1016/j.ajo.2013.09.017

Continues on page 26 : Technology

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DOSAGE AND ADMINISTRATION: The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

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TECHNOLOGY

(Continued from page 25)

Epub ahead of print)—both of which reported up to a dramatic reduction, especially in dense cataracts.

“The implications are faster visual recovery, because of less corneal edema, cellular loss, and inflammation,” Dr. Talamo said.

GREATER UNDERSTANDING OF ARCULATE INCISIONS

Another important advance of the past year is in the understanding of how to use femtosecond laser for cataract surgery to correct astigmatism with arcuate incisions.

A number of investigators are trying to develop nomograms, and online calculators are available.

Dr. Talamo said that he uses the AMO LRI Calculator with the Donnenfeld nomogram, which is available online, with the Catalys laser to correct corneal astigmatism with arcuate incisions.

Using this nomogram, he multiplies by 85% after having determined that multiplying by 68% was insufficient.

“I am seeing an improvement in my results

without an overcorrection,” he said. “This area is rapidly evolving.”

Much work continues with intrastromal incisions using the femtosecond laser, with which the anterior cornea is not cut.

Dr. Talamo said he believes that incisions created with a femtosecond laser are more accurate than the incisions that are created manually.

He also has observed that imaging for femtosecond laser is continuing to improve rapidly with high-resolution OCT, making it possible to do very precise adjustments “on the fly” after the laser is docked on the eye.

The patient interfaces are also improving.

“There seems to be a trend away from using an interface that presses firmly on the corneal toward one with a fluid-filled interface such as that on the AMO/OptiMedica Catalys Precision Laser System and LensAR Laser System or a soft contact lens attachment as employed by the Alcon/LenSx SoftFit,” he said. ■

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Dr. Hersh has no proprietary interest in the subject matter.

JONATHAN TALAMO, MD

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Dr. Talamo is a consultant to Abbott Medical Optics and OptiMedica.

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¹Bullimore MA, The IOLMaster and Determining Toric IOL Power, 2013

²Bullimore MA, Buehren T, Bissman W, Agreement between a partial coherence interferometer and 2 manual keratometers.

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