Compared against AcrySof® IQ (SN60WF), HOYA AF-1™ FY-60AD and enVista® IOLs (MX60).

Directions for Use that could increase complications or impact patient outcomes. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus.

Important Safety Information.

ADVERSE EVENTS:

- In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL. Johnson & Johnson
- Ony IOL. Johnson & Johnson
- Ophthalmology, Dallas, TX.

PRECAUTIONS:

- Do not reuse, resterilize, or autoclave.

INDICATIONS:

- Indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

ATTENTION:

- Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

LEADING INNOVATION | HIGH-QUALITY VISION | EXCEPTIONAL SATISFACTION

Not actual patients.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS: The TECNIS® 1-Piece Lens is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag. WARNINGS: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS® 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus. PRECAUTIONS: Do not reuse, resterilize, or autoclave. ADVERSE EVENTS: In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic). ATTENTION: Reference the Directions for Use for a complete listing of indications and important safety information.

*Not affiliated with the official program of ASCRS 2019.

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Dr. Jack T. Holladay, MD, MSEE, FACS

American Society of Cataract and Refractive Surgeons (ASCRS)

The process is prone to three pitfalls following keratometry or corneal refractive surgery: inaccuracies related to keratometry, prediction of effective lens position, and optical biometry.

The process is prone to three pitfalls following keratometry or corneal refractive surgery: inaccuracies related to keratometry, prediction of effective lens position, and optical biometry.
Valuing power of the lenticle

Pearls for overcoming pitfalls related to keratometry, prediction of effective lens position, optical biometry

IN VIEW
Keratoconus cap with bifocal power: After keratometry or corneal refractive surgery, the only relevant part of the cornea is the 4.5-mm lenticle, according to Jack T. Holladay, MD, MSEE, FACS.

Formulas for the calculation of IOL power have been around since S.N. Fedorov’s original publication of “Estimation of Optical Power of the Intraocular Lens” in 1967.

The process is prone to three pitfalls following corneal refractive surgery or keratoconus: inaccuracies related to keratometry, prediction of effective lens position, and optical biometry.

After keratometry or corneal refractive surgery, the only relevant part of the cornea is the 4.5-mm lenticle, explained Dr. Holladay, clinical professor of ophthalmology, Baylor College of Medicine, Houston.

Keratometry measures the front-surface ring of the lenticle—ranging from 2 mm to 3.2 mm depending on the keratometer—using a back radius of 4, 6, or 28 points and presuming a back radius of 82.2% of the front radius.

4.5 mm lenticle

By Nancy Groves;
Reviewed by Jack T. Holladay, MD, MSEE, FACS

EVEN AFTER decades of making periodic adjustments and updates to formulas for the calculation of IOL power to improve accuracy, choosing the correct power can still be challenging, said Jack T. Holladay, MD, MSEE, FACS.
THE STARS HAVE ALIGNED. DISTANCE AND STABILITY.

ACTIVE FOCUS™ Optical Design:

Only one presbyopia-correcting IOL design delivers a full range of vision with uncompromised distance and unrivaled stability. Please see next page for Important Product Information and supporting references.
OPHTHALMOLOGIST’S EXPERIENCE LEADS TO CREATION OF ‘FLOATER REMINDER SHEET’

THE PREVALENCE of floaters is reported to be 24% in those aged 50 to 59 years, but increases to 87% among those aged 80 to 89 years.1

Floaters can be extremely bothersome and interfere with daily activities, but most importantly, they can be a sign of a retinal tear or detachment especially if acute in onset and accompanied by photopsia.

Twenty years ago, I was pitching Wiffle balls to my younger son, Ryan, and unfortunately, did not follow the advice I give my patients regarding protective eyewear. I did not realize how hard a three-year-old could hit a Wiffle ball with an oversized bat, and I was struck at close range just below the left eye by the batted ball.

The next day, I developed floaters unaccompanied by photopsia in my left eye, but they were subtle, and like a typical physician I ignored them for a few days. I finally saw a dear friend of mine, a retina specialist, and was diagnosed with an inferior horseshoe tear.

I was treated with laser photoagulation and subsequently developed two more retinal tears which were also treated. My retina specialist and friend told me to call him immediately if I noted any increase in floaters or if I developed photopsia and offered to charter a private plane and fly into see me immediately as he was leaving on a golf trip!

The problem was even though I give these same retinal detachment warnings to all of my patients who present with floaters, I realized it is extremely difficult to know as these black bugs are constantly whizzing by while you are driving or even examining patients if they are new.

I must admit I was nervous for several months after the incident regarding missing new symptoms and developing a retinal detachment. I found myself making drawings and written descriptions of my floaters and constantly checking my left eye by looking into the blue sky (with my right eye closed) where my floaters were most apparent and compared these findings with my drawings and notes.

I found these drawings to be extremely helpful and gave me great peace of mind.

Fast forward 20 years, and I still see intermittent floaters. My older son, Tyler, now a third-year medical student at Rosalind Franklin University of Medicine and Science (Chicago Medical School), plans on becoming an ophthalmologist and is familiar with the Amstler grid and its usefulness in self-monitoring for macular degeneration.

He has noticed me checking my self for new floaters and returning to my drawings and descriptions and has helped me develop what we call the “Floater Reminder Sheet.”

I have found it extremely helpful and I wanted to share my story and our floater reminder sheet with other ophthalmologists so that they can use it with their patients. I am glad to report my retina remains attached and I am relatively asymptomatic and have learned to live with floaters.

—Bruce H. Kaplan, MD
Chairman, Department of Ophthalmology
Rosalind Franklin University of Medicine and Science
North Chicago, IL

References

For readers interested in receiving the Floater Reminder Sheet for their office, please send an e-mail to Tyler.Kaplan@my.rums.org

Letters to the Editor may be submitted to Sheryl.Stevenson@ubm.com
Letters may be edited for clarity and length.

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AcrySof® IQ ReSTOR® Family of Multifocal IOLs Important Product Information
CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.
INDICATIONS: The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Multifocal IOLs include AcrySof® IQ ReSTOR® and AcrySof® ReSTOR® Toric. They are intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. In addition, the AcrySof® IQ ReSTOR® Toric IOL is intended to correct pre-existing astigmatism. The lenses are intended to be placed in the capsular bag. WARNINGS PRECAUTIONS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling for each IOL. Physicians should inform patients that, in the absence of the pre-existing astigmatism, patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. A reduction in contrast sensitivity may occur in low light conditions. Visual symptoms may be significant enough that the patient will request explant of the multifocal CIO. Spectacle independence rates vary; some patients may need glasses when reading small print or looking at small objects. Posterior capsule opacification (PCO), when present, may develop faster into clinically significant PCO with multifocal IOLs. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs. Do not rectify or do not store over 40°C; use only sterile irrigating solutions such as BSS® or BSS PLUS®, Sterile Intracocular Irrigating Solutions. ATTENTION: Reference the Directions for Use labeling for each IOL for a complete listing of indications, warnings and precautions.
INDICATIONS AND IMPORTANT SAFETY INFORMATION
Rx Only

INDICATIONS: The TECNIS® 1-Piece Lens is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag. WARNINGS: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS® 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus. PRECAUTIONS: Do not reuse, resterilize, or autoclave. ADVERSE EVENTS: In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic). ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

*Compared against AcrySof® IQ (SN60WF), HOYA AF-1™ FY-60AD and enVista® IOLs (MX60).


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Optical sector must embrace the telemedicine wave

Keep refractive surgery in forefront when it comes to technology

By Stephen Hannan
Clinical Services Director, Optical Express

E: StephenHannan@OpticalExpress.co.uk

TECHNOLOGY has revolutionized our behavior. It’s changed the way we stay in contact with friends, do our shopping, read the news, and access our bank accounts. Whatever we’re doing, it’s likely that it’s facilitated by technology in some way.

The best technology makes life easier through simplicity, speed and ease of use. The same should be true in healthcare. Increasingly, patients are calling for more convenient ways of accessing health services.

The healthcare system is adapting to the modern world, albeit slowly. The sector typically has lagged behind when it comes to adopting tech.

For example, in the United Kingdom, there is a growing number of services for people who would like to have a consultation with a general practitioner (GP) via video call, but the National Health Service (NHS) is only beginning to embrace these options.

The NHS’ long-term plan, launched by Prime Minister Theresa May, will soon see patients routinely speaking to their GP via Skype or a smartphone, and refractive surgery should not be left behind when it comes to tech.

In December, the GMC published research into regulatory approaches to telemedicine around the world, looking at examples the UK could learn from. The research highlighted how new approaches can offer streamlined services for both healthcare professionals and patients, as well as increasing access to healthcare, especially in remote areas. When used in the right circumstances, most patients do not see any difference in the quality of care provided via telemedicine, the research found.

At Optical Express, we wanted to see if the same would be true in refractive surgery. We know that many people prefer telemedicine: It’s convenient, effective and fits more easily into the busy lives of patients.

Preoperative consultation with the ophthalmologist is a crucial part of the process. It’s the point when the patients ask any final questions they may have, having already had information in other forms and from their optometrist.

Preoperative consultation also is the point when the patients formally give their consent to go ahead with the procedure. Therefore, we wanted to quantify the difference, if any, that having a consultation using telemedicine could have on the quality of the consent process.

LARGE SERIES

In our research, we looked at the experiences of 11,938 refractive surgery patients. We gave each patient the choice of a preoperative consultation with their surgeon by telemedicine or in person.

Following surgery, patients were asked to provide feedback on their experiences so that we could capture clinical data, including factors associated with consent quality.

Of the patients who chose a preoperative consultation by telemedicine, more than 95% said they believed that they were adequately consented for surgery, a similar proportion to those who had the consultation in person.

Our figures clearly suggest that whether the preoperative consultation was in person or via telemedicine, this did not have any impact on whether patients felt they had been properly consented. In the small number of instances where there was dissatisfaction with the consenting process, this was primarily due to a perceived poor outcome of surgery, rather than the method of consent.

This research fully supports the telemedicine approach to surgeon consultations and preoperative consent.

It doesn’t mean we should stop offering in-person consultations, of course. There are many circumstances in which a face-to-face meeting is required. But, in cases in which a remote consultation is possible, the patient should have the choice.

Refractive surgery is an area that has always brought together the latest technology with medical expertise and insight. We must extend this to the consultation process. If we don’t, we will be letting patients down.
XIIDRA MAY INTERRUPT THE CYCLE OF INFLAMMATION CENTRAL TO DRY EYE DISEASE¹,²

The exact mechanism of action of Xiidra in Dry Eye Disease is not known.¹

Xiidra blocks the interaction of ICAM-1 and LFA-1, which is a key mediator of the inflammation central to Dry Eye Disease. In vitro studies have shown that Xiidra may inhibit the recruitment of previously activated T cells, the activation of newly recruited T cells, and the release of pro-inflammatory cytokines.¹

**Indication**
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

**Important Safety Information**
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration. Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, see accompanying Brief Summary of Safety Information on the adjacent page and Full Prescribing Information on Xiidra-ECP.com.

References:

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BRIEF SUMMARY:
Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSEAGE AND ADMINISTRATION
Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single-use container. Discard the single-use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

CONTRAINDICATIONS
Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients in the formulation.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinustitis.

Postmarketing Experience
The following adverse reactions have been identified during postapproval use of Xiidra. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Rare cases of hypersensitivity, including anaphylactic reaction, bronchospasm, respiratory distress, pharyngeal edema, swollen tongue, and urticaria have been reported. Eye swelling and rash have been reported.

USE IN SPECIFIC POPULATIONS
Pregnancy
There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD]), based on the area under the curve [AUC] level. Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data
Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg / day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg /day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg/kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation
There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use
Safety and efficacy in pediatric patients below the age of 17 years have not been established.

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast. Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation. Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD]) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.

Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421. For more information, go to www.Xiidra.com or call 1-800-828-2088. Marks designated © and ™ are owned by Shire or an affiliated company. ©2018 Shire US Inc. SHIRE and the Shire Logo are trademarks or registered trademarks of Shire Pharmaceutical Holdings Ireland Limited or its affiliates. Patented: please see https://www.shire.com/legal-notice/product-patents. Last Modified: 01/2018 533769
more than 11,000 global thought-leaders are expected to descend upon Vancouver, BC, for the Association for Research in Vision and Ophthalmology’s (ARVO) 2019 annual meeting, April 28 to May 2.

This marks the first time the annual meeting will be held outside of the United States, and for the first time, ARVO received more abstract submissions from non-U.S. scientists than their U.S.-based counterparts.

**IMAGING IN THE EYE**

Being held in the Western Canadian city on April 26–27, the annual ARVO Imaging Conference is bringing together members of the basic science, clinical, engineering, and industrial communities who all share a common interest in new innovations, techniques, and methods for imaging in the eye and their applications to clinical ophthalmology, fundamental vision research, and biomedicine.

There will be some new additions to the agenda this year, including a Friday night speaker and panel discussion, featuring Philip J. Rosenfeld, MD, PhD, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine.

Dr. Rosenfeld will discuss OCT in the diagnosis and management of age-related macular degeneration. He has been a pioneer in the use of drugs to prevent blindness in neovascular (wet) age-related macular degeneration.

The session, which also includes a networking reception, will be held from 6:30 p.m. to 9 p.m. April 26.

**LEARN SKILLS WITH ARVO**

Education also is a priority for ARVO, which, in 2018, debuted its new online learning platform, ARVOLearn.

The platform uses the latest advances in online learning technology, allowing users to view session presentations from recent ARVO meetings, an on-demand course or a series of mini-courses available at their convenience.

ARVO Online Education also will offer a new event later this spring titled “Artificial Intelligence in Ocular Medicine: Seeing into the Future.”

The session will highlight the artificial intelligence (AI) technology that has been approved for clinical use or is currently in the development pipeline and how to integrate these potential technologies into a research or clinical practice.

The AI session also will feature panel discussions that will be live or recorded as well as a technology showcase with video presentations, a series of recorded presentations and discussion forums. Registration for the AI event opened earlier this month.

**MYOPIA SPECIAL ISSUE**

The journal Investigative Ophthalmology and Visual Science (IOVS) has released a special issue on myopia. This special issue has been produced in collaboration with the Australia-based International Myopia Institute.

The special issue was organized by Professors Earl Smith and James Wolffsohn and facilitated by Dr. Monica Jong, executive director of the institute.

The myopia special issue includes a series of white papers summarizing the current knowledge in the field, showing trends for future developments, and facilitating further research, by bridging gaps and connecting people who so far had not intensively exchanged information and ideas.
A small benefit from Brexit to Commonwealth ophthalmologists

By Erica Crompton; Reviewed by Dinesh Verma, MD

Britain has long depended on physicians from India to run NHS; reliance likely to increase

It’s not been widely reported in the United Kingdom (UK) media, more so in the Indian press, but some doctors coming from outside Europe, in particular India, are welcoming Brexit as it may create more jobs for their medical graduates.

According to the Hindustan Times, Britain has long depended on physicians from India to run the National Health Service (NHS). The reliance may increase after the UK leaves the European Union and EU-trained doctors no longer have the right to work here.1

India is the largest-source country of doctors in the NHS after Britain—currently, 25,281 doctors gained their medical qualifications in India.

OPINIONS ARE MIXED

While some younger surgeons and students born in India are welcoming Brexit to improve their chances of a Tier 2 Visa stay in the UK, not everyone agrees Brexit will benefit Commonwealth surgeons, such as Dinesh Verma, MD, a former Consultant Ophthalmologist in the NHS and independent sector for over 25 years, including Cambridge University Hospitals.

Like many ophthalmologists, Dr. Verma qualified in India (MBBS in 1978 at Maulana Azad Medical College) and was awarded his MD in ophthalmology in 1983, again in India, at the All India Institute of Medical sciences. He migrated to the UK in the same year, gaining a diploma in ophthalmology from the Royal College of Surgeons of Edinburgh in 1985. Later in 1988, he achieved a FRCO.

“Personally, I voted to remain but I can see why a small majority from England voted for Brexit,” Dr. Verma said. “I believe it was mainly for the NHS and other private practices. Since the vote, McIndoe and his team have been providing strategic advice and support to businesses concerned about their ability to recruit and retain international employees, both now and in the post-EU commercial environment.

BREXIT’S BENEFICIARIES

“Whilst in general, I believe Brexit to be a huge mistake, there can be no doubt that some people will benefit when the UK leaves the EU,” McIndoe said. “From a corporate immigration perspective, the UK relies heavily upon foreign talent to help support and grow our economy. We need external workers covering all skill levels and across a very wide variety of sectors and industries. One sector hit particularly hard by the Brexit process has been healthcare, with one in 11 NHS posts currently unfilled, rising to one in eight across available nursing positions.2

“Employee shortfalls will continue, and indeed probably worsen once we leave the EU, and what is less clear is how employers will source staff once free movement ceases. For ophthalmologists and other highly qualified medics from beyond the EU, Brexit may indeed level the playing field in terms of access to roles within the UK—one free movement of workers ends, all doctors and nurses wishing to work in the UK will have to apply for a Tier 2 visa, regardless of their country of origin.”

McIndoe also reckons that the passporting of European medical qualifications may also end after Brexit. EU-qualified individuals will also be stripped of that benefit and will have to prove their capability in the same way as any other non-EU applicants.

“These changes may encourage increased applications from Commonwealth countries such as Pakistan and India. The £30,000 minimum salary requirement remains in place for Tier 2 visa applications, ensuring Brexit will only really benefit more highly qualified and senior practitioners,” McIndoe said.

Commonwealth countries have always had a medical training program inspired and founded by Britain.

SOME BREXIT FALLOUT

UK mainstream media haven’t widely reported any benefits to Brexit in terms of physicians, perhaps for unfounded fear of mass Asian immigrants if they hear that it will be easier after Brexit to get a UK visa as a professional.

“Personally, I don’t think that will happen due to deep-seated institutional racism in NHS which will only increase after Brexit,” Dr. Verma said.

Ophthalmology in the UK owes so much to Commonwealth-born eye surgeons who do so much for the NHS and other private practices. While it seems benefits to Brexit are slim-pickings it is refreshing to read in the Indian media, that Brexit is offering hope to a few, he noted.

References

2. https://www.bmj.com/content/364/bmj.k5308
Visual concerns following traumatic brain injury
Potential issues may impact reading speed, reaction time, memory, orientation, glare

By Steve Lenier; Reviewed by Eric L. Singman, MD

The parts of the brain that are concerned with vision span its length and breadth, including the cerebrum, cerebellum, thalamus, mid-brain, and brainstem.

DEFICITS AND DEFECTS

An injury to these areas can cause a number of different defects in vision, as shown in Table 1, and can also lead to higher-order deficits including reading speed, reaction time, memory impairment, orientation, and glare.

Table 1. System Defects

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<th>Afferent System Defects</th>
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<td>Reduced Acuity, Color, Brightness, Contrast Sensitivity</td>
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<td>Pupilary reaction</td>
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PATIENTS also should be asked specifically whether any activities cause headache, nausea, glare, dizziness, fatique, anxiety, or a sense of information overload.

TBI affects more than vision, and the vision expert might be the first provider a patient sees. It behooves them to ask about other TBI-related concerns with the aim of possibly referring the patient to specialists. This can include whether they notice any mental slowness or suffer from tinnitus, neck pain, bruxism, sleep problems, weight changes, and mood swings.

EVALUATION

“When evaluating a patient with a head injury, it is critically important to ask the correct questions,” said Eric L. Singman, MD, PhD, division chief of the general eye service, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore. “It is often helpful to ask the patient’s significant other about their observations. The evaluator should ask not only about the patient’s vision but also how the patient responds in different environments.”

Dr. Singman said at the very least, a patient should be asked whether they have noted a change in ability to perform normal activities of daily living, such as reading, driving, using a computer, riding a bicycle, walking, and performing fine motor tasks such as writing or sewing.

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<td>Convergence deficiency</td>
</tr>
<tr>
<td></td>
<td>Pupilary reaction</td>
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DIAGNOSES

These conditions span a variety of visual diagnoses, some shown here with their ICD-10 codes.

| Strabismus (eso-, exo-, hyper-, hypo-, cycle-tropias) | H50.xx |
| Monofixation syndrome | H50.42 |
| Spasm of conjugate gaze | H51.0 |
| Convergence insufficiency | H51.11 |
| Convergence excess | H51.12 |
| Other specified disorders of binocular movement | H51.8 |
| Paresis of accommodation | H52.52 |
| Spasm of accommodation | H52.53 |
| Diplopia | H53.2 |
| Anomalous retinal correspondence | H53.31 |
| Fusion with defective stereopsis | H53.32 |
| Simulataneous visual perception w/o fusion | H53.33 |
| Suppression of binocular vision | H53.34 |
| Visual field defects | H53.4x |
| Color vision deficiencies | H53.5x |
| Glare sensitivity | H53.71 |
| Heterophoria (unspecified) | H55.50 |
| Nystagmus | H55.50 |
| Saccadic eye movements (deficiency) | H55.81 |
| Other irregular eye movements | H55.89 |
| Neurologic neglect syndrome (incl. visuospatial neglect) | R41.4 |
| Visuospatial deficit | R41.842 |

TREATMENT TEAM

A complete TBI team might include:

- Neurologist
- Neuro-ophthalmologist
- Neuro-optometrist/low vision specialist
- Neuro-otolaryngologist
- Neuro-psychologist
- Neuro-psychiatry
- Neurosurgeon
- Psychiatrist
- Social worker
- Speech therapist

THE FUTURE

Continued developments in technology will allow improved diagnosis and treatment, including:

- The use of eye tracking systems to detect visuomotor defects and track progress. Identify those areas of the brain associated with visual neglect.
- The use of diffusion tensor imaging to demonstrate damage from mild TBI too subtle to detect on standard imaging.
- The use of the fMRI, dark adaptometry and electroretinography (ERG) to check glare complaints.
- The use of the infrared pupillometry and autorefractometry to demonstrate defects in autonomic transmission to the intraocular muscles (iris and ciliary body) and track progress during recovery.
- The use of fMRI to objectively evaluate whether rehabilitative exercises for visuomotor deficits improve neuronal synchronization and recruitment.

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This article was adapted from Dr. Singman’s presentation at the 2018 meeting of the Current Concepts in Ophthalmology meeting in Baltimore. Dr. Singman has no financial interests or relationships to disclose.
**Dextenza®**
(dexamethasone ophthalmic insert) 0.4 mg
for intracanalicular use

**BIG TIME INNOVATION**

**THE FIRST AND ONLY OPHTHALMIC STEROID INSERT**

Dextenza is an advancement in steroid treatment

- Resorbable, so no need for removal
- Insert can be removed via saline irrigation or manual expression, if necessary
- Physicians rated DEXTENZA as easy to insert*
- Designed to deliver a tapered dose
- Contains fluorescein for visualization
- No additional components or assembly required

**INDICATION**

Dextenza is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

Dextenza is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

**WARNINGS AND PRECAUTIONS**

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during treatment.

Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

**ADVERSE REACTIONS**

The most common ocular adverse reactions that occurred in patients treated with Dextenza were:

- Anterior chamber inflammation including iritis and iridocyclitis (9%)
- Intraocular pressure increased (5%)
- Visual acuity reduced (2%)
- Eye pain (1%)
- Cystoid macular edema (1%)
- Corneal edema (1%)
- Conjunctival hyperemia (1%)

The most common non-ocular adverse reaction that occurred in patients treated with Dextenza was headache (1%).

*73.6% of physicians in Study 1 and 76.4% in Study 2 rated DEXTENZA as easy to insert.

**References:**

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Dextenza is a registered trademark of Ocular Therapeutix, Inc. PP-US-DX-0071 02/2019
Dextenza® (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use

BRIEF SUMMARY: Please see the DEXTENZA Package Insert for full prescribing information for DEXTENZA (1).

1 INDICATIONS AND USAGE
DEXTENZA® (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular pain following intracanalicular surgery (1).

4 CONTRAINDICATIONS
DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

5 WARNINGS AND PRECAUTIONS

5.1 Intraocular Pressure Increase
Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during the course of the treatment.

5.2 Bacterial Infection
Concomitant use of an antibiotic eye ointment may delay healing and increase the incidence of bleb formation.

5.3 Viral Infections
Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex) (see Contraindications (4)).

5.4 Fungal Infections
Fungal invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate (see Contraindications (4)).

5.5 Delayed Healing
The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

6 ADVERSE REACTIONS
The following serious adverse reactions are described elsewhere in the labeling:

• Intraocular Pressure Increase [see Warnings and Precautions (5.1)]
• Bacterial Infection [see Warnings and Precautions (5.2)]
• Viral Infection [see Warnings and Precautions (5.3)]
• Fungal Infection [see Warnings and Precautions (5.4)]
• Delayed Healing [see Warnings and Precautions (5.5)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation; delayed wound healing; secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the corneal sclera (see Warnings and Precautions (5)).

DEXTENZA was studied in three randomized, vehicle-controlled studies (n = 351). The mean age of the population was 68 years (range 43 to 87 years), 62% were female, and 85% were white. Forty-six percent had brown iris color and 31% had blue iris color. The most common ocular adverse reaction that occurred in patients treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (9%); intraocular pressure increased (7%); visual acuity reduced (2%); eye pain (1%); cystoid macular edema (1%); corneal edema (1%); and conjunctival hyperemia (1%).

The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA was headache (16%).

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no adequate or well-controlled studies with DEXTENZA in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. In animal reproduction studies, administration of topical ocular dexamethasone to pregnant mice and rabbits during organogenesis produced embryofetal lethality, and a high incidence of cleft palate in a mouse study. A daily dose of 0.75 mg/day in the mouse is approximately 6 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m² basis. In a rabbit study, topical ocular administration of 1% dexamethasone throughout organogenesis (0.36 mg/day on gestational days 6-18) produced embryofetal malformations (see Animal Data). Data

Animal Data

Topical ocular administration of 0.15% dexamethasone (0.75 mg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in a mouse study. A daily dose of 0.75 mg/day in the mouse is approximately 6 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m² basis. In a rabbit study, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.36 mg/day on gestational days 7-18) produced intestinal anomalies, intestinal atresia, gastroschisis and hypoplastic kidneys. A daily dose of 0.24 mg/day is approximately 6 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m² basis.

8.2 Lactation
Safety and effectiveness in pediatric patients have not been established.

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

17 PATIENT COUNSELING INFORMATION
Advise patients to consult their surgeon if reaction that occurred in patients treated with DEXTENZA was headache (16%).

8.5 Pediatric Use

CLINICAL DIFFERENCES

Dr. Goldstein said that PIC and MFC differ in several clinical features. PIC is a non-inflammatory condition that is not associated with vasculitis, vitritis, anterior chamber cells, or cystoid macular edema (CME). Furthermore, and in spite of its name, PIC lesions, which are located only in the posterior pole, involve primarily outer retina and perhaps choriocapillaris, not the deeper choroid, and the most common cause of decreased vision in patients with PIC is subretinal neovascularization.

MFC represents a group of inflammatory conditions in which anterior uveitis, vitritis, vasculitis, and CME can be present. In addition, there are choroidal lesions that may be located in the posterior pole or peripherally. CME is the most common cause of visual loss in patients with MFC, although affected patients may also have subretinal neovascular membranes causing decreased vision.

The etiology of MFC may be idiopathic, but it can also develop in association with certain systemic diseases, including tuberculosis, sarcoidosis, and Blau syndrome. Whereas PIC is now considered idiopathic, it is not unrealistic to expect that underlying genetic, infectious, or molecular causes may be uncovered in the future through research advances, including the application of genomic sequencing. Likewise, additional disease associations for MFC may exist.

Underlying etiologies for PIC and MFC may be missed if the two phenotypes are considered as one.

Understanding etiology is important for identifying appropriate treatment. Dr. Goldstein highlighted the case of a patient with MFC that was diagnosed as idiopathic and worsened following initiation of immunosuppressive therapy.

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This article was adapted from Dr. Goldstein’s presentation during Uveitis Subspecialty Day at the 2018 American Academy of Ophthalmology. She has no relevant financial interests.
5 ways to integrate ocular surface care into your patients’ regimen

Start ocular surface treatment 6 weeks prior to cataract surgery for best outcomes

By Laura M. Periman, MD; Special to Ophthalmology Times

MANAGING CATARACT SURGERY and ocular surface disease can be tricky, and can vary from patient to patient. However, by properly screening patients first and following the steps below, optimal ocular surface results can be achieved preoperatively and postoperatively.

1. GIVE ALL CATARACT PATIENTS A SPEED QUESTIONNAIRE

We have good evidence of the high prevalence of dry eye and meibomian gland dysfunction (MGD) in older adults. Any cataract surgeon focused on optimizing the accuracy of his or her surgical results has to take this seriously, because dry eye has been correlated with IOL calculation errors and poor refractive outcomes. The answer is better, more consistent screening.

In my practice, every cataract patient is supposed to complete a SPEED questionnaire at check-in. A SPEED score ≥8 automatically triggers my technicians to add a layer of dry eye testing before I see the patient.

In our case, that includes osmolarity, MMP-9, and meibography. A higher SPEED score also prompts me to look carefully for comorbidities and exacerbating medications.

I also pay close attention to lid anatomy, lid closure, and lid mechanics in my exam. None of this adds much to my total time with the patient, but it does help ensure that I catch more dry eye before surgery.

Our surgeries and topical medications can indeed exacerbate ocular surface disease and if dry eye and MGD are not recognized and treated prior to surgery, then patients often blame the surgery, the surgeon, and sometimes the entire eye-care team.

Ocular surface problems represent a brewing storm on the horizon. As tempting as it is to focus only on the refractive or cataract surgery, ocular surgery may steer your patient straight into that storm.

2. HAVE A POSTOPERATIVE PLAN FOR THE PATIENT WITH MGD

For patients with significant MGD, a short, 6-week course of topical and nutritional therapy will likely not be sufficient to truly address all of the six interrelated pathophysiologic processes that are affecting their meibomian gland function and tear film quality.

The topical medications and surgical impact on the corneal nerves may make the MGD worse postoperatively. In many cases, I tell them that rehabilitation of their ocular surface will be a two-step process. Phase 1 is getting them ready for surgery with the kit described earlier. Phase 2, after they have recovered from surgery, involves treating their MGD to get the most out of their new vision.

I like to treat these patients with a foundational therapy of omega-3 fatty acids and an immunomodulator. Then I’ll layer on as appropriate a combination of hypochlorous acid (Avenova) to control the bacterial component.
of MGD, intense pulsed light (IPL) for inflammation, and thermal pulsation therapy (Lipi-Flow) for the gland obstruction.

In my clinical experience, waiting until after cataract surgery and making sure I have cleared up the inflammation first helps to ensure that patients get a longer duration of effect from the thermal pulsation therapy.

Practically, identifying the problems before surgery and separating out dry eye and MGD management from cataract or refractive surgery also separates out the surgical event from the longer-term maintenance of the tear film and ocular surface health.

Education, images, and objective testing help patients to understand that surgery did not cause their lid problems. MGD has to be treated as a separate problem from cataract and refractive surgery—but one that very much affects their quality of vision and satisfaction with the surgery.

3 IMPROVISE WHEN TIME IS CONSTRAINED

Younger patients may not routinely get a dry eye screening, but we need to make sure we have easy ways to evaluate the ocular surface quickly when something during the exam suggests it may be a contributing factor.

I recently worked in a family friend for an eye exam while she was home from college on break. This young computer science major was complaining of blurry, fluctuating vision. It turns out she was wearing orthokeratology lenses at night. Both eyes had significant corneal warping and, in the left eye, subepithelial fibrosis, mild haze, and an off-center optical axis that contributed to her visual complaints and reduced BCVA.

Since we had not done a full dry eye workup on her, I performed a quick retroillumination exam of the lower lids which identified significant gland dropout.

Then, I took a quick infrared image of the meibomian glands using a topographer (ReSee-Vit Antares, Veatch Instruments). While this is not as detailed as meibography (LipiScan, Johnson & Johnson Vision) that is typically performed, it was a rapid test that then demonstrated the significant gland atrophy problem to the young patient.

Once thought to be an age-related condition, MGD is showing up increasingly in children and young adults.2

A recent study also demonstrates that contact lens wear causes significant morphological and functional changes in the meibomian glands.3 We do not yet know whether changing wear habits or reducing digital device use can reverse
damage and lead to improvements. I recommended immediate discontinuation of orthokeratology and instructed her return to glasses and soft contacts along with anticipatory guidance that the vision will fluctuate as the corneal warpage improves.

I started her on omega-3 supplements (to help compensate for her self-reported nutrient-poor college diet) and the topical immunomodulator that her insurance would cover—in this case, lifitegrast (Xiidra, Shire/Takeda Pharmaceuticals).

She also had acne rosacea and was using harsh skin washes that can affect the meibomian glands.

I like to treat inflammatory skin conditions with IPL therapy and educate the patient on ingredients and skin care practices anywhere near the eyelids that negatively impact dry eye and MGD.

I make it easier on them with written instructions, a treatment schedule, and a starter kit. My kit contains a heat mask (Bruder), preservative-free chlorous acid lid cleanser (Avenova), and a starter kit. My kit contains a heat mask (Bruder), preservative-free articular tears, an immune modulator (Restasis, Allergan; or Xiidra) and an omega-3 supplement (HydroEye, ScienceBased Health).

I tell them if they follow this regimen, we can measure biometry at the next visit and typically proceed with the surgery we have scheduled in 6 weeks. If a steroid is necessary, and the insurance covers it, I reach for the surgery planning.

I am confident that I can get most eyes in better shape during the 6-week interval between the initial cataract or refractive surgery consultation and surgery, as long as treatment is started right away and the patient complies throughout that preoperative period.

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Managing irregular cornea with scleral contact lenses

Usage is a good option for successful visual rehabilitation in these patients

*By David P. Piñero Llorens, PhD; Special to Ophthalmology Times*

Two subgroups were distinguished in scleral lenses depending on the presence of corneal bearing or not: corneo-scleral or semi-scleral. Recently, the Scleral Lens Education Society (SLS) has defined a more precise differentiation between different modalities of scleral lenses not only based on the lens diameter, but also on the diameter of visible iris of the eye in which the lens is fitted, as detailed in Table 1.

SLS supports public education that highlights the benefits and availability of scleral contact lenses.

Researchers found that fully scleral lens of a specific diameter can behave as miniscleral or large-scleral, depending upon the eye on which it is fitted.

This type of lens must always be inserted after being completely filled with saline solution, avoiding the formation of bubbles during the insertion that ultimately could lead to discomfort and poor vision in the patient.

Scleral contact lenses have always been considered suitable for the correction of irregular astigmatism (post-corneal refractive surgery, post-keratoplasty, including keratoconus and other ectatic disorders, as they are able to neutralize irregularities with the tear film meniscus that form with the cornea, while maintaining high levels of comfort.

However, there are also other indications feasible for corneo-scleral and fully scleral contact lenses, such as the correction of refractive errors that cannot be corrected satisfactorily with rigid gas-permeable (RGP) corneal or soft contact lenses, the introduction of prismatic corrections, for cosmetic purposes and even in healthy corneas, due to the advantages of this type of lens: less palpebral interaction, great comfort as conjunctival sensitivity is lower than that of the cornea, no possibility of generating corneal distortion if the fitting is adequate and a simplified fitting process.

In addition, the process of insertion and removal of the lens is simplified by the use of a suction cup, avoiding the contact of the fingers with the eye at all times.

**THE SCLERAL CONTACT LENS ICD**

The ICD16.5 contact lens (Irregular Corneal Design, Paragon Vision Sciences, distributed by Lenticon, Madrid, Spain) is a fully scleral contact lens that has four differentiated zones allowing a correct centration with no corneal touch and a stable positioning over the conjunctiva (Figure 1).

These zones are: central clearance zone (CCZ), peripheral central clearance zone (PCCZ), limbal clearance zone (LCZ), and scleral landing zone (SLZ) (Figure 1). The geometry of these zones can be modified to achieve a perfect fitting of the lens independently from the corneo-scleral profile.

Likewise, a peripheral toricity can be added if the conjunctival-scleral profile presents a significant level of astigmatism or to stabilise a scleral lens with toric power to compensate for residual astigmatisms during fitting.

This contact lens is fitted considering the sagittal height instead of keratometry that can be measured using optical coherence tomography (OCT), Scheimpflug.
The OCULUS Pentacam® offers you a higher degree of safety!

- Effective Preoperative Planning
- Time Saving without Compromise
- Easy Measurement Process

Your Direct Route to Reliable Results

The Pentacam® is equipped with intuitive and user-friendly software features that help the physicians select the best refractive surgery option for the patient to ensure patient safety and optimal results. With a post-surgical scan, the precise corneal measurements allow you to detect rare post-op irregularities early. Surgical success is documented completely from start to finish.

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cameras, or more precisely with corneo-scleral topographers, such as the Eye Surface Profiler (ESP) from Eaglet-Eye. A central of vault of around 300 μm is required for obtaining an appropriate fitting, with no corneal bearing during wearing due to a potential conjunctival compression of the lens (Figure 2).

This lens is an RGP contact lens manufactured in material HDS100 from Paragon Vision Sciences. The material used is a thermoset fluorosilicone acrylate copolymer derived primarily from siloxane acrylate, trifluoroethyl methacrylate, and methylmethacrylate with a water content of less than 1% (Paflufocon D), with a Dk (oxygen permeability) of 100 Fatt.9

RESULTS WITH SCLERAL LENS ICD16.5

Our group conducted a study to assess results obtained with the fully scleral contact lens ICD16.5 in corneas with different types of problems. The study was consecutive and prospective, and was carried out in the Contactology Unit of the Department of Ophthalmology (Oftalmar) of the Vithas MediInternational Hospital in Alicante, Spain.

The study included a total of 42 eyes of 27 patients, 15 men (55.6%) and 12 women (44.4%). The average age of patients in the study was 39 ± 12 years (range, 14 to 65 years).

Inclusion criteria for the study were that the participants had no active ocular disease, no severe dry eye, no previous intolerance to soft or corneal gas permeable contact lenses, and they also agreed to and signed informed consent papers.

A prefitting examination also proves to be a valuable step in the process, and our study results bear this out. In all cases, a very complete pre-fitting examination was carried out that included: filiation data, uncorrected and corrected visual acuity, manifest refraction, biomicroscopy, corneal topography with the Sirius system (CSO), ocular aberration measurements with the iTrace system (Tracey Technologies) and previous anterior segment examination by optical coherence tomography with the 3D OCT-1000 system (Topcon).

The patient was evaluated after 1, 3, 6 and 12 months of contact lens wear to check the success of the fitting. In our study, a total of 25 eyes with keratoconus (59.5%) were fitted, four of them with previous implantation of intracorneal ring segments and 10 with previous corneal collagen crosslinking, six eyes with irregular cornea after previous LASIK surgery (14.3%), two eyes with irregular cornea after radial keratotomy surgery (4.8%), three eyes after keratoplasty (7.1%), one eye with endothelial corneal decompensation (2.4%), two cases of dry eye (4.8%), and two eyes with myopia magna (4.8%).

The mean sagital height required for the fitting was 4294.12 ± 292.56 μm (4,000 to 4,900 μm) and the mean optical power was −6.96 ± 6.95 D (−21 to +4 D). After 1 hour of wearing the lenses, the mean apical vault measured by optical coherence tomography was 299.4 ± 85.56 μm (201 to 420 μm).

Concerning the visual outcomes, a significant improvement in decimal visual acuity was achieved with the contact lens after 1 month of wearing compared to that obtained with glasses before fitting (p < 0.001), without significant
changes occurring during the rest of the follow-up (Figure 3).
This is consistent with the results of previous studies using the same model or other models of scleral contact lenses.\textsuperscript{2-15}

There was a tendency to an increasing positive over-refraction during the follow-up, although it did not reach statistical significance ($p = 0.17$).

This change was consistent with a slight anterior ($p = 0.91$) and posterior corneal flattening ($p = 0.37$), which did not reach either statistical significance.

Moreover, the noted change is in agreement with current studies reporting the level of corneal molding induced by fully scleral contact lenses.\textsuperscript{16,17}

In our study, we detail that a small but statistically significant pachymetric increase was also observed at 3 months of wearing (minimum thickness $p = 0.001$, central thickness $p = 0.08$), without significant changes afterward (minimum thickness $p = 0.86$, central thickness $p = 0.88$).

This minimal pachymetric increase has been reported by other authors\textsuperscript{18} and does not seem to be related to problems of clinically relevant hypoxia as high Dk material has been used.

Vincent et al. concluded in a prospective study that, although a small amount of corneal swelling was induced following 8 hours of miniscleral lens wear (on average <2%), modern high Dk miniscleral contact lenses that vault the cornea do not induce clinically significant corneal edema or hypoxia-related posterior corneal curvature changes during short-term wear.

Regarding ocular high-order aberrations, there was a significant reduction, especially of the primary coma, as indicated in Figure 4. This also has shown to be consistent with the significant gain in corrected distance visual acuity that has been achieved with the contact lens.

The tolerance of the contact lens was good in all cases, with the following complications or difficulties reported:

\begin{itemize}
\item Abandonment of fitting: 3 cases (6.8\%) due to poor tolerance as a consequence of an ex-cessive lens indentation throughout the day
\item Lens power adjustments required during the first month (8 cases, 18.2\%)
\item Adjustments of the scleral landing zone due to lens fogging (5 cases, 11.4\%) or excessive scleral indentation (2 cases, 4.5\%)
\item Episodes of occasional conjunctival hyperemia (tobradex, thealoz, recugel) (5 cases, 11.4\%)
\end{itemize}

\textbf{CONCLUSIONS}

In conclusion, the fully scleral contact lens ICD16.5 is a good option for achieving a successful visual rehabilitation in irregular corneas, especially if previous fittings with other types of contact lenses have failed.

This type of lens is able to provide a significant increase in visual acuity combined with a significant improvement in visual quality, maintaining high levels of comfortability.

The fitting process of these lenses is relatively simple and can be highly optimized by introducing the appropriate changes in the different zones of the lens.

\textbf{References}

2. Piñero DP. Full scleral lens fitting in an eye with high corneal astigmatism after radial keratotomy and several retreatments. \textit{I-Site Newsletter} 2017, February.
Anterior capsular contraction syndrome (ACCS) is a complication of cataract surgery characterized by capsular contraction and excessive fibrosis and constriction of the anterior capsulorhexis margin, ACCS is believed to result from metaplasia and fibrosis of residual lens epithelial cells (LECs). It has the potential to affect refractive and functional outcomes by causing obstruction of the visual axis and shifts in the position of the anterior capsule, possibly leading to ACO and ACCS through cultured rabbit lens epithelial cells. 

Factors associated with an increased risk of these events include a small diameter capsulorhexis, zonular weakness, uveitis, pseudoxfoliation syndrome, retinitis pigmentosa, and diabetes mellitus, among others. IOL material also appears to play a role, as capsule contraction is therefore important for maintaining a successful outcome with refractive cataract surgery.

Two IOL platforms that are commonly used in the United States—TECNIS® (Johnson & Johnson Surgical Vision, Inc.) and AcrySof® (Alcon Laboratories)—are 1-piece hydrophobic acrylic implants. According to research discussed here, the development and degree of ACO and capsulorhexis phimosis are greater with the AcrySof® platform than with a TECNIS® IOL and the findings may be explained by differences in the fabrication of the two IOL designs (TECNIS® ZCB00V, AcrySof® SN60WF, and a hydrophobic IOL from Hoya). They analyzed a serial of postoperative slit-lamp photographs with these lenses to compare ACCS results, then explored the relationship between IOL design, aqueous humor, and ACCS through culturing rabbit lens epithelial cells.

Searching the literature for related studies uncovered a paper from Austrian investigators reporting outcomes from 1, 3, and 5 years of follow-up in a randomized, controlled, prospective, double-blind study of patients (50 at 1 and 3 years; 25 at 5 years) undergoing bilateral cataract with implantation of an AcrySof® SA60AT in one eye and the TECNIS® ZCB00 in the fellow eye. At all 3 follow-up intervals, ACCS was present in a significantly greater percentage of eyes implanted with an AcrySof® IOL compared with the TECNIS® IOL group: 18.0% vs 2.7%, respectively at 1 year (P < .01); 92.0% vs 24.0% at 3 years (P < .01); and 100% vs 52% at 5 years (P < .01)

The AcrySof® IOL was also associated with more severe ACO. Using a grading scale of 0 (none) to 4 (constriction of the capsulorhexis opening), mean scores in the AcrySof® and TECNIS® IOL groups were 0.30 and 0.04, respectively, at 1 year, 1.44 and 0.26, respectively, at 3 years, and 1.8 and 0.6, respectively, at 5 years (P < .02 for all comparisons). In addition, grade 2 (moderate diffuse opacification with folds) or greater ACO was present in 80% of eyes with an AcrySof® IOL versus 8% of eyes implant-
ed with a TECNIS® IOL. Capsular phimosis was also observed in a significantly higher percentage of eyes with an AcrySof® IOL compared with the TECNIS® IOL at 1 year (18% vs 0%), 3 years (30% vs 0%), and 5 years (48% vs 4%; P < .01 for all comparisons) (Figure).

In a prospective, randomized, contralateral-eye controlled study, 50 patients undergoing bilateral cataract surgery received the AcrySof® IQ SN60WF IOL and the TECNIS® ZCB00 IOL in fellow eyes. Evaluations of slit-lamp photographs obtained at 2 and 3 years postoperatively showed that significantly more eyes developed ACO after implantation of the AcrySof® IQ SN60WF IOL compared with the TECNIS® ZCB00 IOL at both timepoints (P < .02 and P < .003, respectively). In the United States, another recent publication retrospectively compared the incidence of ACCS in eyes implanted with the SN60WF (n = 571) and the TECNIS® ZCB00 (n = 476) IOLs; 6.5% of AcrySof® IOL eyes and 16% of eyes implanted with the TECNIS® lens had at least 1 risk factor for ACCS (P < .0001). Mean postoperative follow-up for these groups was 4.2 months and 5.7 months, respectively. The incidence of ACCS, defined as a capsular opening area less than 10 mm², was significantly greater in the SN60WF group (8 eyes, 1.40%) than in the TECNIS® group (1 eye, 0.21%; P < .045).

Underlying mechanisms
Various mechanisms have been proposed to explain the lower propensity for ACO and capsulorrhesis phimosis with a TECNIS® IOL compared with the AcrySof® lens. One idea is that the 360° square edge of the TECNIS® IOL serves as a barrier to LEC migration between the anterior capsule and IOL than the interrupted square edge on the AcrySof® lens. A difference in IOL optic surface configuration has also been suggested to be a factor by influencing LEC migration or reducing contact between the optic and the anterior capsule. Compositional differences in the hydrophobic acrylic materials of both lenses may also be involved.

Personal experience
Six years ago at Mercy Eye Center, a decision was made to switch from using AcrySof® lenses to TECNIS® IOLs. The change was driven by surgeons’ frustrations with glistenings in the AcrySof® acrylic material, disappointing outcomes with the early generation of the AcrySof® multifocal IOL, and a cost difference favoring the TECNIS® portfolio. Reduced development of ACO and capsulorrhesis phimosis may be another benefit of the switch to TECNIS® IOLs. Although the studies on this topic have only evaluated the aspheric monofocal TECNIS® IOL, all members of the TECNIS® portfolio share the same material and design features that have been suggested as potential factors in limiting these complications.

Over the past 6 years, I and my colleagues have been very satisfied with the performance and clinical outcomes we are achieving with the entire family of TECNIS® IOLs. We are considering further studies to identify significant clinical differences in ACCS, such as a retrospective study comparing rates of laser anterior capsulotomy before and after the change in IOL technologies, or ideally a prospective study to document ACC.

Conclusion
ACCS can have visually significant consequences and compromise outcomes of refractive cataract surgery. Surgical strategies for limiting this complication have been described and include use of an appropriately sized capsulorrhesis and thorough cleanup of LECs. Evidence showing a decreased occurrence of ACO and ACC with the TECNIS® IOL compared with an AcrySof® IOL might be something else for cataract surgeons to consider.

REFERENCES

TECNIS® Monofocal 1-Piece IOL
Rx Only
PRECAUTIONS: Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects. Do not soak or rinse the intraocular lens with any solution other than sterile saline for appropriate support of the IOL is not possible; circumstances that would result in damage to the endothelium during implantation; suspected microbial infection; or patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL. Children under the age of 2 years are not suitable candidates for intraocular lenses. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus. ADVERSE EVENTS: In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic). TECNIS is the trademark of Johnson & Johnson Surgical Vision, Inc. All other trademarks are the intellectual property of their respective owners.

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Listen to patients’ needs, motivations, and expectations to understand why they have come to refractive surgery, and what they expect from it,” said Dr. Ambrósio, adjunct professor of ophthalmology, Federal University of the State of Rio de Janeiro (UNIRIO), and director of refractive surgery, VisareRIO, Rio de Janeiro, Brazil.

“In addition, imaging has revolutionized our ability to screen, plan, and evaluate the results of refractive procedures, gaining fundamental relevance in the preoperative workup,” he said.

DIVING DEEPER

The list of diagnostic technologies is long and growing, starting from classic slit lamp biomicroscopy with digital documentation, central corneal thickness, and Placido’s disk-based topography.

Scheimpflug tomography provides a three-dimensional picture of the cornea, an imaging technique distinct from front-surface topography as well as from segmental tomography by OCT. Very high-frequency ultrasound provides epithelial thickness mapping. Proper nomenclature is essential to distinguish technologies.

In addition, ocular wavefront, ocular scattering evaluation, novel ocular surface imaging with meibomimetry, IOP, corneal biomechanical assessment, confocal, and specular microscopy are available.

Molecular biology and genetics are moving toward practical applications for patient evaluation.

Every refractive surgeon must understand

MAKING THE MOST OF DIAGNOSTIC TECHNOLOGY TOOLKIT

Advancements in preoperative assessment, techniques help to enhance refractive surgical outcomes

By Fred Gebhart; Reviewed by Renato Ambrósio Jr., MD, PhD

C areful preoperative evaluation can help ophthalmologists boost patient satisfaction by improving surgical outcomes and avoiding many of the potential complications of refractive surgery. Preoperative assessment must include understanding and proper counseling of patients as well as provide a comprehensive evaluation for planning the procedure and screening for potential complications, said Renato Ambrósio Jr., MD, PhD.
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Special Report ) NEW INITIATIVES IN REFRACTIVE SURGERY

DIAGNOSTIC

(Continued from page 24)

this arsenal as well as how and when to use it for patients, he noted.

“We have to understand if the candidate presents for elective refractive surgery, or if the case requires a therapeutic approach,” Dr. Ambrósio said. “If the treatment is done on the cornea, should it be a phakic IOL or crystalline lens surgery? If the patient is a candidate for corneal laser-vision correction, is it best to do LASIK, SMILE, or PRK?”

It is important to recognize the complications to be avoided and how to identify the cases at higher risk, Dr. Ambrósio added.

“We have to know our ourselves and our tests and the conditions we have to identify,” he said.

Ectasia, or keratectasia, is a rare but very serious complication of laser-vision correction. Ectasia has three primary roots:

1. the innate structure and biomechanical properties of the cornea,
2. the impact from the surgery on the cornea, and
3. postoperative trauma, most often due to eye rubbing.

Key to prevention is understanding the pathophysiology of ectasia to assess the individual risk of biomechanical decompensation, he said.

“The literature recognizes forme fruste keratoconus as the major risk factor for ectasia, but the reality is that any cornea can develop ectasia,” Dr. Ambrósio said. “All it takes is the unfortunate combination of corneal structure, surgical impact, and mechanical trauma, such as eye rubbing.”

Eye rubbing alone may trigger ectasia progression, and patients should be educated about it. While there is some divergence in the literature on what is fruste, or subclinical keratoconus, we have evolved from the ability to diagnose very mild disease with normal slit lamp and good visual acuity toward the characterization of the susceptibility for ectasia development.

Dr. Ambrósio’s group recently published a novel tomographic assessment of ectasia risk using artificial intelligence based on Pentacam data. The resulting Pentacam Random Forest Index (PRFI) yielded ectasia diagnosis with 94.3% sensitivity and 98.8% specificity.

Integrating Scheimpflug tomography and biomechanics yielded a Tomographic and Biomechanical Index (TBI) that significantly augments sensitivity for ectasia diagnosis.

The original study found the TBI has 90.4% sensitivity with 96% specificity, compared with 79% sensitivity of the BAD-D, he noted.

Dr. Ambrósio added that further improvements are possible along with the inclusion of extra data such as epithelial thickness from segmental or layered tomography to further enhance accuracy.

Artificial intelligence could also integrate corneal data with the impact from the procedure.

“The Enhanced Ectasia Susceptibility Score (EESS) conjugates the data from the cornea—such as tomography and biomechanics along with age and the impact from the refractive surgery—to estimate a risk,” Dr. Ambrósio said. “The risk is never zero, but should be acceptable and we have to understand it.”

Some patients may better qualify for a procedure according to the corneal impact, he noted.

“SMILE has a corneal-weakening factor which is between LASIK and PRK,” he said. “That is not to say that SMILE or any other procedure is better than the others, but we can find the best procedure for each case. This is truly customization to optimize surgical outcomes.”

DRY EYE, OCULAR SURFACE

Dry eye is another contribution to patient dissatisfaction. Patients asking for refractive surgery correction typically opt for surgery because they are, or have become, intolerant of contact lenses, which is commonly associated with some degree of tear dysfunction.

Ocular surface evaluation has evolved including non-invasive break-up time, meibomian gland imaging, and tear osmolarity. Patient education and ocular surface optimization should enhance chance of success for these cases.

The goal is to optimize the chance of success, which, intimately, is related to patient satisfaction and safety, he said.

Refractive surgeons must be conscious of the opportunities and rationale for a proper preoperative assessment in order to minimize complications and maximize outcomes.

References


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This article was adapted from Dr. Ambrósio’s presentation during Refractive Surgery Subspecialty Day at the 2018 meeting of the American Academy of Ophthalmology. He is a consultant to Alcon Laboratories, Carl Zeiss Meditec, and Ocuoks.
PEARLS FOR BUILDING THE CORNEAL INLAY PATIENT BASE IN YOUR PRACTICE

By Lynda Charters; Reviewed by William F. Wiley, MD

Numerous advances have been made in refractive surgery technology that provide patients with numerous options from which to choose.

“Among the options, corneal inlays are one of the newest advances that we have seen,” according to William F. Wiley, MD, medical director, Cleveland Eye Clinic, Brecksville, OH.

The most recent developments in this market include the approval of the Kamra corneal inlay technology (AcuFocus) in mid-2015; the Raindrop Near Vision Inlay (ReVision Optics), which was approved in 2016 and recently pulled from the market; and the Flexivue MicroLens (Presbia), for which approval is pending.

Developing a Market Base

One of the biggest problems with corneal inlays in a refractive practice is developing the patient base for the technology. In a typical refractive surgery practice, Dr. Wiley pointed out, most patients who seek out a refractive procedure are those with myopia and hyperopia who represent the smaller part of the bell-shaped curve of possible refractive clients.

“The traditional market audience for corneal inlays lies in the meat of that bell-shaped curve and represents over 100 million patients with presbyopia,” he said. “The reality is that it is hard to get those patients into the office.”

The target market for corneal inlays includes patients between 45 and 60 years old with a prescription ranging from +0.5 to –0.75 D who have had an eye examination within the previous year, he said.

“The issue with the presbyopic patient base is that the bulk of the target audience is not coming into our offices,” Dr. Wiley said. “They are solving their presbyopic problem with over-the-counter readers.”

Re-Thinking Demand

The patients who are seeking refractive surgery can now be offered a combination approach to meet their visual needs. The typical patient considering a refractive procedure is a 50-year-old with a bilateral refractive error of –4 D.

“This is the group that is motivated to become spectacle independent for distance and near vision,” he commented.

Dr. Wiley can now satisfy that patient’s goal for distance and near vision by combining inlays with a refractive surgery. Typically, he explained, the distance eye is targeted for plano and the non-dominant eye is left with about –0.75 D of myopia. During the same surgery for LASIK, the corneal inlay is implanted into a pocket that is under the LASIK flap.

“The excimer laser is the perfect tool to prepare the eye for the ultimate refraction,” he said.

Following surgery patients have 20/20 distance vision and functional near vision that continues to improve over time.

“These results let us increase the ‘wow’ effect on the first postoperative day,” Dr. Wiley said.

The key to building the corneal inlay patient base is the recognition that almost every presbyopic patient is a candidate for corneal inlays. LASIK is the perfect tool to bring those patients to the refractive sweet spot, he pointed out.

When implanting the aperture inlay, that refractive sweet spot is –0.75 to –1 D. Dr. Wiley explained that functionally the intermediate vision intersects with the aperture optic to extend the focus to both distance and near vision.

Making the adjustment to that proper target is important. Dr. Wiley offered the analogy that implanting a corneal inlay without adjusting to the appropriate target is comparable to implanting a premium cataract surgery without addressing the astigmatism.

Inlay Myths

The first is that implanting inlays is not the same as monovision. Dr. Wiley demonstrated that monovision has a very narrow depth of focus, while the Kamra inlay provides a wide depth of focus and sharper vision.

Another consideration is that monovision is a static solution for a dynamic problem, he noted, in that presbyopia continues to progress over time. In contrast, inlays are a dynamic solution to presbyopia progression.

Another fallacy is that inlays are intended to serve a niche market. However, analysis of his practice showed that the corneal inlay is the choice of patients seeking to correct their presbyopia.

Another myth is that all inlays cause haze. This concern arose because of problems that developed specifically with the Raindrop Near Vision Inlay; by 5 years postoperatively about 75% of patients developed haze at some point with about 20% of patients having the inlay removed. The FDA issued a warning letter recommending close follow-up of patients who received this implant as well as close follow-up after the device is removed. Even though the risks are low with aperture inlays, because of the potential risks, it is important to have proper informed consent with all corneal inlays and care should be taken to use the most up to date techniques and technologies.

Location is everything. Dr. Wiley explained that haze may develop because of shallow implantation of shape changing inlays. In contrast, the aperture inlay is implanted deeper, which results in a much lower incidence of haze. In his hands, less than 1% of 353 Kamra implants were removed because of haze, compared with 40% of 15 Raindrop inlays.

The Keys to Success

Besides the target of –0.75 D of myopia in the inlay eye, preoperatively, the ocular surface should be optimized preoperatively.

The depth of the inlay is clearly the paramount factor. The pocket for the inlay should be at a depth of 250 to 300 microns, with 4 x 4 or less spot/line separation settings on the femtosecond laser. Dr. Wiley advised using balanced saline solution when dissecting the pocket.

Continues on page 28: Corneal Inlays
IN A STUDY comparing monovision LASIK with refractive lens exchange (RLE) in patients age 45 to 60, similar outcomes were achieved, according to John Vukich, MD.

The study included 608 patients (1,216 eyes) in the monovision LASIK group and 590 patients (1,180 eyes) in the RLE group. Patients were –10 to +3 D and comparable in terms of preoperative cylinder, dry eye, glare, halos, and difficulty with night driving, said Dr. Vukich, adjunct associate clinical professor, University of Wisconsin-Madison School of Medicine.

Patients in the RLE group received an extended depth-of-focus (EDOF) IOL in at least one eye.

Among the patients, those in the 45 to 50 range were more likely to have monofocal LASIK, while those age 55 to 60 were more likely to have RLE. In those between ages 49 to 54, there was an equal distribution between the two approaches.

Overall, both groups had solid and very comparable results, Dr. Vukich said. In the laser-vision correction (LVC) group, the postoperative sphere in the near eye had a distribution around –1.5 D.

For 3-month binocular uncorrected distance visual acuity results, the only difference found was in hyperopic RLE patients, who had a better result: 84.8% were 20/20 or better compared to 77% of those who received LVC.

For binocular near vision acuity, there was no difference in outcomes among the hyperopes, plano presbyopes, and low myopes in both groups. In the LVC group, 98.7% of high myopes had J5 or better uncorrected near visual acuity.

“The take-home point we’re starting to glean is there are some trends, but RLE is a viable and very reasonable option to offer patients across the various ranges,” Dr. Vukich said.

When analyzing patient satisfaction, it was 98% or better in the moderate to high myopes who had LVC, which was a higher percentage than other groups.

“But when you look at the hyperopes, plano presbyopes, and low myopes, there was no difference in the number of patients who were satisfied or very satisfied,” Dr. Vukich said. “Again, you’re starting to see a trend that RLE with an extended depth-of-focus lens is very comparable.”

When asked if they would recommend their procedure to friends and relatives, the moderate to high myopes in the LVC group had the highest percentage of positive responses, although all patient groups were in the high 80s to 90s.

The moderate to high myopes in the LVC group were not as satisfied with their close-up vision as those in the RLE group.

“There’s going to be some setting of expectations with those patients,” Dr. Vukich pointed out.

However, there was no difference between LVC and RLE for distance activities. For dry eye, there were no major statistical differences, although there was a trend for more dry eye among the RLE patients.

“That’s something that we might not have predicted,” Dr. Vukich said.

Overall, the percentages of patients with dry eye were low in both groups.

There was no major difference in the percentage of patients with difficulty night driving between the two groups.

When analyzing monovision, the patients who were satisfied or very satisfied were mostly –1 D or greater than –1 D. However, there was a drop in satisfaction at –2 and –2.75 D, which gives surgeons some feedback for future targeting, Dr. Vukich said.

Age did not appear to be a factor in the difference in satisfaction with the monovision a patient had, he added.

Surgeons looking to use LASIK monovision should aim for –1.25 to –1.75 D and provide thorough counseling to plano presbyopia patients, Dr. Vukich advised.

Data provided by ClearSight LASIK indicated that patients achieve three lines of uncorrected near vision with the Kamra implant with no effect on the uncorrected distance vision.

“Inlays have a place in the surgical correction of presbyopia and in refractive surgery practices,” Dr. Wiley said. “Significant improvements have been made in the surgical techniques, patient selection and perioperative patient management that have resulted into successful integration of inlays into our practice, which can be translated to other refractive surgery practices.”

Dr. Wiley is a consultant to CorneaGen and an investigator for Presbia.
Intraocular inflammation of lashes. Eyelash changes are usually reversible upon discontinuation of treatment. Hair in the treated eye. These changes include increased length, thickness, and number during treatment with travoprost ophthalmic solution. TRAVATAN Z® Solution should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema—Macular edema, including cystoid macular edema, has been reported during treatment with travoprost ophthalmic solution. TRAVATAN Z® Solution should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Angiogenesis—Inflammatory, or Neovascular Glaucoma—TRAVATAN Z® Solution has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.

Bacterial Keratitis—There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Use with Contact Lenses—Contact lenses should be removed prior to instillation of TRAVATAN Z® Solution and may be reinserted 15 minutes following its administration.

Adverse Reactions
The most common adverse reaction observed in controlled clinical trials with TRAVATAN® (travoprost ophthalmic solution) 0.004% and TRAVATAN Z® Solution was ocular hyperemia, which was reported in 30% to 50% of patients. Up to 3% of patients discontinued therapy due to conjunctival hyperemia. Ocular adverse reactions reported at an incidence of 5% to 10% in these clinical trials included decreased visual acuity, eye discomfort, foreign body sensation, pain, and pruritus.

Additional adverse reactions have been identified during post approval use of TRAVATAN® or TRAVATAN Z®, or a combination of these factors, include: arrhythmia, vomiting, epistaxis, tachycardia, and insomnia. In postmarketing use with prostaglandin analogs, periorbital and lid changes including deepening of the eyelid sulcus have been observed.

Use in Specific Populations
Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

For additional information on TRAVATAN Z® Solution, please refer to the Brief Summary of Prescribing Information on the following page.

*Study Design: Double-masked, randomized, parallel-group, multicenter noninferiority comparison of the efficacy and safety of travoprost 0.004% preserved with benzalkonium chloride (BAK) and TRAVATAN Z® Solution after 3 months of treatment in patients with open-angle glaucoma or ocular hypertension. Mean baseline IOPs were 27.8 mm Hg (n=322), 25.5 mm Hg (n=322), and 24.8 mm Hg (n=322) at 8 AM, 10 AM, and 4 PM for TRAVATAN Z® Solution. At the end of month 3, the TRAVATAN Z® Solution group had mean IOPs (-0.2, 0.8) and 18.7 mm Hg (-0.4, 0.5), 17.7 mm Hg (-0.4, 0.6), and 17.4 mm Hg (-0.2, 0.8) at 8 AM, 10 AM, and 4 PM, respectively. Statistically equivalent reductions in IOP (95% CI about the treatment differences were entirely within ±1.5 mm Hg) were demonstrated between the treatments at all study visits during the 3 months of treatment.

TRAVATAN Z® (travoprost ophthalmic solution) 0.004%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE
TRAVATAN Z® (travoprost ophthalmic solution) 0.004% is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSEAGE AND ADMINISTRATION
The recommended dosage is one drop in the affected eye(s) once daily in the evening.

TRAVATAN Z®- (travoprost ophthalmic solution) should not be administered more than once daily since it has been shown that more frequent administration of prostaglandin analogs may decrease the intraocular pressure lowering effect.

Reduction of the intraocular pressure starts approximately 2 hours after the first administration with maximum effect reached after 12 hours.

TRAVATAN Z®- Solution 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.

CONTRAINdicATIONS
None

WARNINGS AND PRECAUTIONS

Pigmentation
TRAVATAN Z® ophthalmic solution has been reported to cause changes to pigmented tissues. The most frequently reported changes have been increased pigmentation of the iris, perilobal tissue (eyelid) and eyelashes. Pigmentation is expected to increase as long as travoprost is administered. The pigmentation change is due to increased melanin content in the melanocytes rather than an increase in the number of melanocytes. After discontinuation of travoprost, pigmentation of the iris is likely to be permanent, while pigmentation of the perilobal tissue and eyelash changes have been reported to be reversible in some patients. Patients who receive treatment should be informed of the possibility of increased pigmentation.

The long-term effects of increased pigmentation are not known.

Iris color change may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither new nor thickened tissue is apparent to be affected by treatment. While treatment with TRAVATAN Z®- (travoprost ophthalmic solution) 0.004% can be continued in patients who develop noticeably increased iris pigmentation, these patients should be examined regularly.

Eyelash Changes
TRAVATAN Z®- Solution may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and number of lashes. Eyelash changes are usually reversible upon discontinuation of treatment.

Intraocular Inflammation
TRAVATAN Z®- Solution should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema
Macular edema, including cystoid macular edema, has been reported during treatment with travoprost ophthalmic solution. TRAVATAN Z®- Solution: Should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Angle-closure, Inflammatory or Neovascular Glaucoma
TRAVATAN Z®- Solution has not been evaluated for the treatment of angle-closure, inflammatory or neovascular glaucoma.

Bacterial Keratitis
There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface.

Use with Contact Lenses
Contact lenses should be removed prior to instillation of TRAVATAN Z®- Solution and may be reinserted 15 minutes following its administration.

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 rates in the clinical studies of another drug and may not reflect the rates observed in practice. The most common adverse reaction observed in controlled clinical studies with TRAVATAN® (travoprost ophthalmic solution) 0.004% and TRAVATAN Z®- (travoprost ophthalmic solution) 0.004% was ocular hyperemia which was reported in 30 to 40% of patients.

The most common adverse reactions in clinical trials with TRAVATAN® (travoprost), TRAVATAN Z®- (travoprost), triflusal, and TRAVATAN Z® Solution included abnormal vision, blepharitis, blurred vision, cataract, conjunctivitis, corneal staining, dry eye, iris discoloration, keratitis, lid margin crusting, ocular inflammation, photosensitivity, subconjunctival hemorrhage and tearing.

Nonocular adverse reactions reported at an incidence of 1 to 5% in these clinical studies were allergy, angina pectoris, anxiety, arthritis, back pain, bradycardia, bronchitis, chest pain, cold/flu syndrome, depression, dyspepsia, gastrointestinal disorder, headache, hypercholesterolemia, hypertension, hypotension, infection, pain, postural disorder, sinusitis, urinary incontinence and urinary tract infections.

In postmarketing use with prostaglandin analogs, periorbital lid changes including deepening of the eyelid sulcus have been observed.

USE IN SPECIFIC POPULATIONS

Pregnancy
Pregnancy Category C

Teratogenic effects: Travoprost was teratogenic in rats, at an intravenous (i.v.) dose up to 10 mcg/kg/day (250 times the maximal recommended human ocular dose (MRHOD), evidenced by an increase in the incidence of skeletal malformations as well as external and visceral malformations, such as fused sternebrae, domed head and hydrocephaly. Travoprost was not teratogenic in rats at i.v. doses up to 3 mcg/kg/day (75 times the MRHOD), or in mice at subcutaneous doses up to 1 mcg/kg/day (25 times the MRHOD). Travoprost produced an increase in post-implantation losses and a decrease in fetal viability in rats at i.v. doses > 3 mcg/kg/day (75 times the MRHOD).

In the offspring of female rats that received travoprost subcutaneously from Day 7 of pregnancy to lactation Day 21 at doses of > 0.12 mcg/kg/day (3 times the MRHOD), the incidence of postnatal mortality was increased, and neonatal body weight gain was decreased. Neonatal development was also affected, evidenced by delayed eye opening, pinna detachment and preputial separation, and by decreased motor activity.

There are no adequate and well-controlled studies of TRAVATAN Z®- (travoprost ophthalmic solution) 0.004% administration in pregnant women. Because animal reproductive studies are not always predictive of human response, TRAVATAN Z®- Solution should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

A study in lactating rats demonstrated that radiolabeled travoprost and/or its metabolites were excreted in milk. It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRAVATAN Z®- Solution is administered to a nursing woman.

Pediatric Use

Use in pediatric patients below the age of 16 years is not recommended because of potential safety concerns related to increased pigmentation following long-term chronic use.

Geriatric Use

No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

Hepatic and Renal Impairment

Travoprost ophthalmic solution 0.004% has been studied in patients with hepatic impairment and also in patients with renal impairment. No clinically relevant changes in hematology, blood chemistry, or urinalysis laboratory data were observed in these patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility
Two-year carcinogenicity studies in mice and rats at subcutaneous doses of 10, 30, or 160 mcg/kg/day did not show any evidence of carcinogenic potential. However, at 100 mcg/kg/day, male rats were only treated for 62 weeks, and the maximum tolerated dose (MTD) was not reached in the mouse study. The high dose (100 mcg/kg) corresponds to exposure levels over 400 times the human exposure at the maximum recommended human ocular dose (MRHOD) of 0.04 mcg/kg, based on plasma active drug levels. Travoprost was not mutagenic in the Ames test, mouse micronucleus test or rat chromosome aberration assay. A slight increase in the mutant frequency was observed in one of two mouse lymphoma assays in the presence of rat S-9 activation enzymes.

Travoprost did not affect mating or fertility indices in male or female rats at subcutaneous doses up to 10 mcg/kg/day (250 times the maximum recommended human ocular dose of 0.04 mcg/kg/day on a mcg/kg basis (MRHOD)). At 10 mcg/kg/day, the mean number of corpora lutea was reduced, and the post-implantation losses were increased. These effects were not observed at 0.3 mcg/kg/day (75 times the MRHOD).

PATIENT COUNSELING INFORMATION

Potential for Pigmentation

Patients should be advised about the potential for increased brown pigmentation of the iris, which may be permanent. Patients should also be informed about the possibility of eyelid skin darkening, which may be reversible after discontinuance of TRAVATAN Z®- (travoprost ophthalmic solution) 0.004%.

Potential for Eyelash Changes

Patients should also be informed of the possibility of eyelash and vellus hair changes in the treated eye during treatment with TRAVATAN Z®- Solution. These changes may result in a disparity between eyes in length, thickness, pigmentation, number of eyelashes or vellus hairs, and/or direction of eyelash growth. Eyelash changes are usually reversible upon discontinuation of treatment.

Handling the Container

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

When to Seek Physician Advice

Patients should also be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician’s advice concerning the continued use of TRAVATAN Z®- Solution.

Use with Contact Lenses

Contact lenses should be removed prior to instillation of TRAVATAN Z®- Solution and may be reinserted 15 minutes following its administration.

Use with Other Ophthalmic Drugs

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

Rx Only

U.S. Patent Nos. 5,631,287; 5,889,052; 6,011,062; 6,235,781; 6,503,497; and 6,849,253

ALCON LABORATORIES, INC.
Fort Worth, Texas 76134 USA

(Continued from page 1)

**Inaccuracies Related to Keratometry**

However, for irregular corneas (e.g., post-refractive keratoconus, post-penetrating keratoplasty, and scars), keratometry is inaccurate due to sample size and should be replaced with zonal topography or tomography.

Topography measures the entire front surface of the lenticle, with about 14,000 points, whereas tomography measures the front/back surfaces, using about 40,000 points, Dr. Holladay said.

“What we want is the power of that lenticle, and since the sample size is much better, in both of these conditions (keratoconus and refractive surgery) you should always get topography or tomography,” Dr. Holladay said.

After keratoconus, the cornea becomes a simultaneous bifocal. A bifocal “cap” is formed with 2 to 5 D more power than the paracentral power within the pupil.

“What you want is the paracentral power that’s in the pupil,” he said. “The cap gives you reading power, just like a bifocal intraocular lens. Patients don’t look through the average, and that’s what the keratometer is going to give you. You have to move that mouse around in the paracentral area to get an average value and avoid the cone, because that’s for reading; it’s not for distance vision.”

However, in post-refractive surgery, the cornea is not a bifocal. It is flattest in the center of the cornea following myopic surgery and steepest in the center after hyperopic surgery. If it was centered on the pupil it will be de-centered relative to the visual axis. The pupil size is critical, and the key is to find the power within the zone. If the pupil is smaller than average, the power has to be customized.

**Effective Lens Position**

Another pitfall is that the prediction of effective lens position is inaccurate if using keratometry; neither the cap power nor the flattened cornea after myopic refractive surgery will size the eye correctly, Dr. Holladay said.

Rather, the “double K method” is more reliable. Use keratometry before refractive surgery or the paracentral power in keratoconus to estimate the size of the anterior segment, then use the refractive vergence power measured with zonal power.

**Optical Biometry**

A third source of errors is optical biometry. It can yield imprecise results in long eyes (>25 mm), which are common in refractive surgery and keratoconus, thus the axial length must be shortened with all formulas. The error resulted more than a decade ago from calibrations made for OCT that included eyes up to 26 mm long; calibrations were then extrapolated from 26 to 36 mm.

“If you extrapolate you overestimate the length of the eye, and the eyes are progressively shorter,” he said. “In fact, for a 36-mm eye, it’s really 34.”

A linear regression model to compensate for long eyes was published in 2011 by Wang and Koch, and further axial length adjustment formulas were published in the *Journal of Cataract and Refractive Surgery* in October 2018.

**Take-home**

- Despite ongoing fine-tuning of the formulas for the optical power of IOLs, errors are still possible, often related to keratometry, prediction of effective lens position, and optical biometry.

**Zeiss Receives FDA Clearance for Epithelial Thickness Mapping for HD-OCT**

**The Zeiss** Medical Technology Segment of Carl Zeiss Meditec announced it has received 510(k) clearance from the FDA for the CIRRUS HD-OCT platform, expanding the capabilities of its anterior segment premier module to include epithelial thickness mapping (ETM).

“The addition of this new software is another testament of our continued commitment to providing our customers innovative platforms so they can provide their patients the highest level of care,” said Jim Mazzo, global president of ophthalmic devices, Carl Zeiss Meditec.

ETM with CIRRUS provides a detailed 9-mm map of epithelial thickness that enables more thorough assessment of patients before refractive surgery, allows monitoring of the cornea’s response to treatment, and aids in managing patients with ocular surface disorders, such as dry eye, and progressive corneal diseases, such as keratoconus. With ETM, patients can expect a quick, comfortable non-contact exam that takes less than 1-second.

“Zeiss has been at the forefront of industry-defining advancements that have made the CIRRUS HD-OCT the industry’s standard of care for identifying retinal and glaucoma disease,” said Ludwin Monz, PhD, president and CEO, Carl Zeiss Meditec. “This milestone is yet another example of the strength and breadth of our portfolio, expanding CIRRUS’ anterior segment capabilities to serve the needs of all eye-care professionals.”
MODERN laser refractive surgery performed as LASIK, PRK, or a lenticule extraction procedure (SMILE, Carl Zeiss Meditec) can improve vision, nonvisual function, and quality of life for patients with myopia. Because of advances, each method delivers safe and effective outcomes, said Jodhbir S. Mehta, MD, PhD.

Each procedure has advantages and disadvantages that may be considered in relation to patient-specific factors to guide customized treatment decisions.

“We now have three great laser-based procedures to treat myopia, and that raises the question of which to choose,” said Dr. Mehta. "We usually consult the patient first, taking into account their occupation, sports activity, and risk of eye contact. The decision of which to choose,” said Dr. Mehta.

He considers several “bespoke features” when deciding which laser refractive surgery is best for a patient seeking myopia correction. Because of the long time needed to create the lenticule, he excludes SMILE if a patient seems nervous or is likely to be uncooperative.

SMILE, PRK OVER LASIK

As flapless procedures, both SMILE and PRK are preferred over LASIK in patients whose occupation exposes them to risk of eye contact. SMILE patients with moderate to high myopia find the wound healing response is less intense after the femtosecond laser procedure than after an excimer laser ablation. Other bespoke features he considers include:

- **Presence of Dry Eye**—patients at risk of dry eye preoperatively may be more suited to PRK and SMILE than LASIK
- **Desire for Rapid Visual Recovery**—LASIK gives the fastest visual recovery followed by SMILE and then PRK
- **Level of Preoperative HOA**—high levels of HOA can be treated with a topography-guided ablation that is currently only available with LASIK and PRK.

‘Bespoke’ laser refractive surgery

<table>
<thead>
<tr>
<th>BESPOKE FEATURE</th>
<th>PROCEDURE</th>
<th>PRK/ASA</th>
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Procedure of choice. 5+ Least 2+  (Figure courtesy of Jodhbir S. Mehta, MD, PhD)
2019: State of corneal crosslinking for patients with keratoconus

Stabilization, improvement in corneal curvature measurements seen in many treated cases

By Steve Lenier; Reviewed by Uri S. Soiberman, MD

KERATOCONUS—a common, gradually progressive corneal ectasia in which a loss of structural integrity leads to a bulging, cone-shaped cornea—is not uncommon, with incidence rates reported up to 265 per 100,000.

Based on the results of the U.S. Multicenter Clinical Trial of Corneal Collagen Crosslinking for Keratoconus Treatment, the original Dresden protocol entailing epithelial removal followed by application of riboflavin and use of full-fluence UV-A irradiation received FDA approval in 2016 for use in progressive keratoconus and in post-refractive ectasia as well. It’s also used off-label for infectious keratitis.

Unfortunately, disease onset tends to be in early adolescence, and these younger patients are at risk for rapid progression and a lifelong visual disability, noted Uri S. Soiberman, MD, assistant professor of ophthalmology, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore.

At the institute, eligible patients have been treated with CXL protocol with great success. Eligibility criteria included 1 D or more of progression in corneal curvature per year, minimal corneal thickness of 400 μm, and best spectacle-corrected visual acuity of 20/25 or worse.

“Our results at Wilmer are consistent with those of the larger randomized, controlled U.S. trial,” he said. “We see either stabilization or improvement in corneal curvature measurements in most of our treated patients. Treating very rapidly progressive disease remains a challenge, as well as very advanced disease. Early detection is of utmost importance in keratoconus.”

Unfortunately, epi-off CXL is not appropriate for all keratoconus patients. Patients with very advanced disease and thin corneas will not benefit from the treatment. New approaches are being developed, such as customized treatments, and novel epi-on (trans-epithelial) procedures.

URSI. SOIBERMAN, MD

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This article was adapted from Dr. Soiberman’s presentation at the 2018 Johns Hopkins Wilmer Eye Institute’s Current Concepts in Ophthalmology meeting in Baltimore. Dr. Soiberman has no financial interests to disclose.

(FIGURE) Corneal flattening 15 months after crosslinking in a patient with keratoconus. (Figure courtesy of Uri S. Soiberman, MD)
Hydrophilicity RIS setting stage as new paradigm for refractive surgery

Laser technology has potential to modify IOL refractive index without change to lens shape

By Fred Gebhart; Reviewed by George O. Waring IV, MD, FACS

DEVELOPING femtosecond laser technology can change the refractive qualities of an IOL after it has been implanted.

The same technology, hydrophilicity refractive index shaping (RIS), has the potential to alter the refractive qualities of the cornea without changing its physical shape.

“This is a new paradigm and is potentially huge in refractive surgery,” said George O. Waring IV, MD, FACS, founder of Waring Vision Institute, Mount Pleasant, SC, and adjunct assistant professor of bioengineering, Clemson University. “It could change the ways we approach refractive surgery, either at the IOL plane or at the corneal plane.”

Dr. Waring described the current state of refractive index shaping as applied to acrylic IOLs. He is a consultant to Perfect Lens LLC, one of several companies developing RIS platforms and applications.

“What is being done is utilizing a femtosecond laser to selectively change the refractive index of the target material, which changes the optical properties of how a refractive material performs,” Dr. Waring said.

“You can essentially create a shape with a material plane, create a three-dimensional structure within an existing physical space without changing or disrupting the surface of the material or the tissue where the effect is aimed,” he said. “You can create a lens within a lens without disrupting the surface of the material, in this case an IOL.”

The femtosecond laser very precisely affects the hydrophilicity of the target material to alter its refractive characteristics in a limited area, Dr. Waring continued. The technology also exploits Fresnel optics to produce an effect called phase wrapping.

“Phase wrapping allows you to effect a large optical change efficiently in a small physical space,” he said. “This allows for larger treatments within an IOL. This could potentially offer numerous benefits in a clinical setting, in the laser suite, because the entire process is minimally invasive.”

Benchtop testing promises a wide variety of clinical applications. The technology allows the ophthalmologist to take control of most optical properties and qualities that affect both additive and subtractive measures, including spherical aberration, asphericity, toricity and multifocality.

The femtosecond laser that alters the optical qualities of the IOL is a proprietary application using a dedicated device, Dr. Waring said, but the laser form factor and liquid optic interface are intuitive and familiar to anyone who is used to docking or utilizing the femtosecond laser instruments now in clinical use.

The entire process is image guided and has been tested across multiple brands of acrylic IOLs with a high degree of precision across brands.

RESULTS ‘DRAMATIC’

While the technology still needs further testing and clinical trials, benchtop test results are dramatic. The power of an IOL can be reduced, or increased, up to six diopters. And once changed, the power can be changed and adjusted at least multiple times without significantly affecting the modulation transfer function of the lens.

Spherical aberration can be adjusted to customize an off-the-shelf IOL to the patient’s own optics.

Starting with a non-toric monofocal lens, RIS makes it possible to create a spherical and/or astigmatic pattern a treatment unique to each patient.

For patients implanted with a monofocal lens who later wish they had opted for a multifocal implant, RIS may offer a solution.

Benchtop tests show a monofocal lens can be converted into a multifocal lens, and vice versa.

The most important optical change when converting from monofocal to multifocal functionality is a reduction in modulation transfer function because light is now being redistributed across multiple foci.

“It appears that we may also be able to reverse multifocality for people who have struggled with this technology,” Dr. Waring said.

“And when going from multi- to monofocal, we see increased modulation transfer function because we are reassigning light to the same focal point.”

Changes in modulation transfer function also make it possible to adjust the amount of light allocated to different focal points within a multifocal lens.

That opens the door to customized light levels for near, intermediate, and far vision, depending on patient preference and visual need, he noted.

It could also be possible to change the light allocation to the different focal points sequentially to allow for neuroadaptation over several weeks or months to improve the patient’s perception of visual quality.

LOOK TO FUTURE

“The most common opportunities for the refractive types of enhancements that are currently done, small enhancements with laser vision correction, piggyback IOLs or IOL exchange, these can all be done in minimally invasive fashion using laser light in the clinic with this technology,” Dr. Waring said.

“Sequential treatments appear to be possible, so power and other qualities could be changed over one’s lifetime or until the patient is happy with the result,” he added. “And because acrylics can be optimized for this technology, it is entirely conceivable that we could be customizing lenses even before they go into patients’ eyes and then tweaking each lens as needed after implantation.”

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This article was adapted from Dr. Waring’s presentation during Refractive Surgery Day at the 2018 meeting of the American Academy of Ophthalmology. He did not indicate financial interest in the subject matter.

Special Report NEW INITIATIVES IN REFRACTIVE SURGERY
I didn’t realize STARS were little dots that twinkled

—Misty L, RPE65 gene therapy recipient

WE’RE SEEING AMAZING RESULTS. AND SO ARE THEY.

Foundation Fighting Blindness is shining a light in the darkness of Inherited Retinal Degenerations. We are the world’s leading organization searching for treatments and cures, and with many treatments already found, today’s innovations are illuminating a future of possibilities.

Patients with Inherited Retinal Degenerations are urged to partner with us to accelerate the discovery of treatment and cures.

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Visit ECPs4Cures.org to make a donation to help find more cures.

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Long-term data establish SMILE role in myopic treatment armamentarium

Follow-up at 7 years shows procedure safe, effective, provides stable correction

By Cheryl Guttmann Krader; Reviewed by Osama Ibrahim, MD, PhD

RESULTS from long-term follow-up show that small-incision lenticule extraction (SMILE, Carl Zeiss Meditec) provides safe, effective, and stable correction of low to high myopia with astigmatism, said Osama Ibrahim, MD, PhD.

“We have been doing SMILE for more than 10 years, and there are still some challenges that need to be addressed, but SMILE is here to stay,” said Dr. Ibrahim, professor of ophthalmology, Alexandria University, Alexandria, Egypt.

His comments were based on data from 5,263 eyes, of which 264 were seen after 7 years. Because of access to research software, the amounts of sphere and cylinder corrections exceeded those available commercially.

Preoperatively, manifest refraction spherical equivalent (MRSE) for the entire cohort averaged –5.92 D ± 2.13 D and ranged from –1.25 to –14.00 D; MR cylinder averaged –1.26 D ± 1.04 D and ranged up to –6 D. and we get very good results.

At 1 week after surgery, mean MRSE was –0.15 D ± 0.51 D (range, +2.00 to –3.50 D) and mean MR cylinder was –0.12 ± 0.38 D (range, 0.00 to –2.75 D).

“So some cases were initially undercorrected intentionally, and we had some overcorrections that occurred because there was no software adjustment at the time of the procedure,” Dr. Ibrahim said.

Data from follow-up at 1 year was available for 3,876 eyes, 587 eyes were seen at 2 years, and 264 eyes were seen at 7 years. Results from manifest refraction were generally stable over time except for a slight increase MRSE in later years.

At 7 years, 264 eyes were just 19 or 20 years old, and the late change in MRSE is explained by an increase in axial length over time,” Dr. Ibrahim said. “The MR cylinder, however, was unchanged.”

Refractive predictability was excellent for the overall cohort and across all subgroups when eyes were divided by degree of myopia into mild-moderate (MRSE –6.0 D), high (MRSE –6.0 to –10.0 D) and very high (MRSE >–10.0 D). At different follow-up intervals, achieved MRSE was ±0.25 D of target in about 80% of eyes.

“SMILE is not a procedure for treating a specific level of myopia,” Dr. Ibrahim said. “Rather, it can treat a broad range."

Analyses of changes from baseline BSCVA provided assurance about the safety of the procedure. The percentage of eyes losing 2 or more lines from preoperative BSCVA was ≤1% at any follow-up; BSCVA was unchanged or improved in 89% to 95% of eyes across the different follow-up intervals, and the percentage of eyes that gained 1 or more lines of BSCVA increased over time.

“Safety was our main concern when we started with SMILE because we were still refining the techniques and technology,” Dr. Ibrahim said. “Luckily, we found in our follow-up that some early losses of BSCVA were transient.”

He pointed out that gains in BSCVA after SMILE may be explained not just by loss of minification but by the flattening response that occurs after SMILE. Topographic maps show a 6.0- or 6.5-mm diameter area of flattening following removal of a 6.0-mm lenticule whereas after LASIK, the area of flattening is smaller in diameter than the ablation zone.

“The cornea responds differently to tissue removal than it does to ablation,” Dr. Ibrahim said. “The peripheral cornea relaxes after SMILE, and we believe that is why we can use SMILE to correct higher amounts of myopia and obtain better quality of vision compared with LASIK.”

REMAINING ISSUES

Correction of residual refractive error after SMILE has been done with LASIK and PRK, but ongoing research is investigating enhancement by performing SMILE in the cap or in the residual bed. So far, the latter techniques have been associated with encouraging results.

Other techniques under development include customization (wavefront guidance), cyclotorsion adjustment, and treatment of hyperopia. In addition, more study is needed to prove that SMILE has an advantage over LASIK when it comes to preserving corneal biomechanical integrity and to corroborate its long-term stability.

“Some people still need to be convinced that we are not getting regression after SMILE,” Dr. Ibrahim said. “Looking at eyes in our series that had residual error later during the follow-up we found that they had the same error from the beginning.”

Postoperative Results

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<tr>
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<tr>
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<tr>
<td>MR Sphere</td>
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<tr>
<td>MR Cylinder</td>
<td>–0.47 D ± 0.86 D</td>
<td>up to –3.25 D</td>
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Follow-up that includes data from 264 eyes seen at 7 years after surgery show that small-incision lenticule extraction (SMILE, Carl Zeiss Meditec) is safe, effective, and provides stable correction for eyes with up to –14.0 D of myopia and up to –6.0 D of astigmatism.

take-home

Follow-up that includes data from 264 eyes seen at 7 years after surgery show that small-incision lenticule extraction (SMILE, Carl Zeiss Meditec) is safe, effective, and provides stable correction for eyes with up to –14.0 D of myopia and up to –6.0 D of astigmatism.

OSAMA IBRAHIM, MD, PhD
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This article was adapted from Dr. Ibrahim’s presentation during Refractive Surgery Subspecialty Day at the 2018 meeting of the American Academy of Ophthalmology. He is a consultant to Carl Zeiss Meditec.
A NOVEL TECHNIQUE to treat keratoconus that uses corneal allogenic intrastromal ring segments (CAIRS) was simple, safe, and effective in a small pilot study, said Soosan Jacob, MS, FRCS, DNB, director and chief, Dr. Agarwal’s Refractive and Cornea Foundation, and senior consultant, Cataract and Glaucoma Services, Dr. Agarwal’s Group of Eye Hospitals, Chennai, India.

Dr. Jacob developed the technique because the use of synthetic ring segments often has led to complications such as extrusion, migration, melt, corneal necrosis, and even infections necessitating corneal transplantation, she said. She wanted to find a way to decrease the incidence of these complications.

In the study, which was published in the Journal of Refractive Surgery,1 CAIRS trephined from donor cornea were then implanted into femtosecond laser-dissected channels in the cornea in 24 eyes (20 patients) with keratoconus. The CAIRS were used in the 6.5-mm optic zone.

Dr. Jacob initially used ring segments (Intacs, Addition Technology) not as an implant but as an instrument to help get the CAIRS in, but later she found that the CAIRS pushed right in.

Afterward, accelerated corneal crosslinking (CXL) or contact lens-assisted CXL (another approach developed by Dr. Jacob, for crosslinking thin corneas) was performed.

MAKING CHOICE

The choice was made depending on each patient’s minimum corneal thickness. With contact lens-assisted CXL, a riboflavin-soaked bandage contact lens is placed on the eye to help increase the corneal thickness. The contact lens used is ultraviolet barrier-free.

The results in patients having accelerated CXL or contact lens-assisted CXL were similar in the study, Dr. Jacob said. Significant improvement occurred both for uncorrected distance visual acuity (mean, 2.79 ± 2.65 lines; range: 0 to 8 lines) and corrected visual acuity (mean, 1.29 ± 1.33 lines; range: 0 to 5 lines). There also were significant improvements in spheric equivalent, simulated maximum keratometry, steepest keratometry, topographic astigmatism, anterior and posterior best fit spheres, mean power in the 3- and 5-mm zones, as well as other areas. No eye had any progression during the follow-up, which ranged from 6 to 18 months. All segments remained in position, and no segment-induced complications occurred.

“There is basically no disadvantage [with CAIRS],” Dr. Jacob said. “It’s biocompatible, easily available, effective, stable, safe, reversible, and adjustable.”

She looks forward to the creation of nomograms for CAIRS, femtosecond-cut CAIRS, eye bank-prepared segments, modified segments, and increased storage abilities.

Reference


CAIRS may eliminate complications from synthetic ring segments

Novel technique could help surgeons treating keratoconus, ectasia

By Vanessa Caceres; Reviewed by Soosan Jacob, MS, FRCS, DNB

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VIDEO Watch videos of CAIRS on Dr. Jacob’s YouTube channel:
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CAIRS may eliminate complications from synthetic ring segments

Novel technique could help surgeons treating keratoconus, ectasia

By Vanessa Caceres; Reviewed by Soosan Jacob, MS, FRCS, DNB

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**Ophthalmology Times**
NO-donating drugs yield significant IOP lowering

Therapy causes trabecular meshwork to relax, regulates permeability of Schlemm's canal

By Lynda Charters; Reviewed by Gail F. Schwartz, MD

In the quest to provide more options to glaucoma patients, nitric oxide (NO)-donating drugs can provide significant reductions in IOP associated with open-angle glaucoma (OAG) and ocular hypertension (OHT) in clinical and experimental settings when compared with timolol.

NO offers a few advantages, in that, it can diffuse across cellular membranes and is a potent vasodilator, said Gail F. Schwartz, MD.

In addition, it is synthesized endogenously by L-arginine via NO synthase (NOS), which then generates NO, and it activates soluble guanylyl cyclase, which results in up-regulation of cyclic guanosine monophosphate that serves as a second messenger, said Dr. Schwartz, who is in a private glaucoma practice and assistant professor, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore.

In the eye, NO causes the trabecular meshwork to relax, regulates the permeability of Schlemm’s canal, and causes vasodilation of the ocular blood vessels. In addition, research has shown that dysfunction of the NO-guanylyl cyclase pathway is associated with an increased incidence of glaucoma, which provides insight into the drug’s mechanism of action.

HOW NO WORKS

In normal eyes, she explained, NO is involved with IOP homeostasis. The conventional pathway in the eye, i.e., the trabecular meshwork and Schlemm’s canal, is IOP sensitive, in contrast to the uveoscleral pathway. With increases in IOP, the cells in Schlemm’s canal are affected by pressure and ultimately collapse; this is the same stress to which vasoconstricted blood vessels are subjected.

When the IOP increases, endothelial NOS (eNOS) is produced and increases the supply of NO that, in turn, relaxes the trabecular meshwork and Schlemm’s canal and increases the permeability of the trabecular meshwork and improves aqueous outflow.

In contrast to the fine-outflow process in normal eyes, in glaucomatous eyes, the IOP homeostasis that depends on NO is disrupted in a few ways.

“eNOS expression is decreased in the ciliary muscle, trabecular meshwork, and Schlemm’s canal,” Dr. Schwartz said. “The levels of NO in the aqueous humor are decreased. Genetic variations in eNOS have been associated with primary open-angle glaucoma [POAG].”

When treating glaucoma, systemically administered nitroglycerin reduces the IOP in OAG, but not in closed-angle glaucoma because the NO cannot reach the trabecular meshwork, which eliminates the incremental benefit of latanoprost (Xalatan, Pfizer) when it is administered alone.

When administered topically, nitroglycerin has been shown to reduce IOP in primates; increased dietary intake of nitrate contained in green leafy vegetables can lower IOP in OAG and OHT. The study showed maximal IOP lowering with LBN 0.024% and 0.040%.

“LBN significantly reduced IOP by 2 mm Hg or more in 45% of patients compared with latanoprost 0.005% alone,” she said. “A greater proportion of patients taking LBN had IOP <18 mm Hg at all visits compared with latanoprost.”

The phase II, sleep lab crossover Constellation Study included patients with OAG and OHT with a baseline IOP over 22 mm Hg. The researchers reported that LBN improved ocular perfusion pressure compared with timolol (nocturnal) and baseline (p = 0.01 and p < 0.006, respectively). LBN also significantly (p = 0.004) reduced the nocturnal IOP by -2.25 mm Hg compared with the -0.1 mm Hg-reduction seen with timolol.

The Jupiter Study, an open-label, single-arm, 1-year safety study, included patients with OAG and OHT, three-quarters of whom had an IOP below 21 mm Hg. LBN achieved a significant (p = 0.001) 26% reduction in IOP that was sustained over the course of the study.

The phase III, 1-year Apollo and Lunar studies compared LBN 0.024% with timolol 0.5%. The results showed that at 17 of 18 time points, the IOP in patients taking LBN was lower than in those taking timolol; the average IOP reduction was 32% compared with baseline. The IOP decrease was sustained to week 52 of the study.

LBN has received approval for clinical use to treat OAG and OHT. A boon for patients is its once-daily dosing. The adverse effects seen with LBN are similar to those with latanoprost (hyperemia, ocular irritation, eye pain, and pain at the installation site).

TAKE-HOME

Nitric oxide-donating drugs can provide significant reductions in IOP associated with open-angle glaucoma and ocular hypertension.

CLINICAL TRIALS

The phase II VOYAGER 28-day dosing study compared LBN 0.024% with latanoprost 0.005% in OAG and OHT. The study showed maximal IOP lowering with LBN 0.024% and 0.040%.

“LBN significantly reduced IOP by 2 mm Hg or more in 45% of patients compared with latanoprost 0.005% alone,” she said. “A greater proportion of patients taking LBN had IOP <18 mm Hg at all visits compared with latanoprost.”

Dr. Schwartz explained that LBN relaxes trabecular meshwork cells in vitro, which latanoprost does not. LBN lowers the IOP in both FP receptor knockout mice and prostaglandin-non-receptor rabbits, which latanoprost also does not.

“Higher concentrations of latanoprost over 0.005% do not lower IOP better than lower concentrations possibly because of saturation of the FP receptors,” she noted.
4 ways to build a better work environment

Supportive leadership creates a culture that benefits your whole team

By Donna Suter

want to have more good days.” This line from an episode of “The Good Doctor” holds the key to your success as a practice owner. I suggest the following rules are as true for you as they were for the characters in the episode, titled “Aftermath.”

If the show writers of this series can resolve the weight of your emotions in 50 minutes, then this writer can offer corresponding rules and guidance in 1,200 words or less. Here we go:

RULE #1 IF IT WASN’T DOCUMENTED, IT WASN’T PERFORMED
Be careful of “cloning” previous visits, “pulling forward,” or defaulting all fields to “normal” whencharting patient care.

Proper charting documentation is crucial. There is a difference between wellness coverage versus medical visits, and the way these are charted may be reviewed, as the Office of Inspector General (OIG) has identified this as a target area for audits. Establish triage guidelines and how to communicate your intentions to either diabetic or glaucoma candidates using wellness eye benefits or diabetic or glaucoma patients returning for medical exams as part of their follow-up care.

RULE #2 LUNCH WITH THE BOSS IS NEVER JUST ‘LUNCH’
There is a lot that goes into running a practice, a great deal of which is the help you get from others. While leadership as a discipline is very, very important, the personal and interpersonal sides of leadership are every bit as important as the great leadership themes of vision and/or execution, strategy, and the like. And that is where lunch comes in. Be friends with employees without employees taking advantage of you.

Build a culture that allows employees to feel appreciated—it has more to do with success than your business acumen. People’s hearts and minds are constructed to perform best under certain conditions. No pressure, but they all depend on your style and behavior. For your team, it might be lunch that brings “the secret sauce” to practice dynamics.

RULE #3 BOUNDARIES ARE FOR LEADERS
I’m not really sure your bestie should be someone who works for you. Henry Cloud, PhD, writes in his self-help books about boundaries. According to Dr. Cloud, a boundary is a structure that determines what will exist and what will not—so keep this thought in mind.

RULE #4 YOU ALWAYS GET WHAT YOU CREATE AND WHAT YOU ALLOW
I heard this quote from psychologist, Nancy Martin, PhD. Dr. Martin showed me that how I carried myself taught others how to treat me in about 15 minutes. Most importantly, she taught me the same communication basics that (ones that Dr. Cloud also uses)—on how to pick up the pieces when things fall apart. Part of gaining all this communications expertise is learning how to say you are sorry and forgive yourself.

Part of gaining all this communications expertise is learning how to say you are sorry and forgive yourself. There is a tremendous personal power in knowing you control your attitude. It rings a balance that creates a harmony which allows you to handle the practices ups and downs.

IT’S ALL ABOUT SUPPORT
Support is important. Having a supportive friend not in the practice is a valuable connection. Later, you will be one radiating success. A pleasurable career grows from your meaningful achievements. Small steps achieved through becoming a leader that creates a culture that supports your team. When people exclaiy that they just don’t know how you do it all, tell them it all started with wanting to have more “good days.”

DONNA SUTER
s.suter4pr@gmail.com
Suter is a business coach/trainer specializing in the eye care field, and she speaks at trade shows and conferences.

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CAUTION Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS Federal (USA) law restricts this device to sale by, or on the order of, a physician.

INTENDED USE The ORA SYSTEM® technology utilizes wavefront aberrometry data to measure and analyze the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

WARNING AND PRECAUTIONs: The following conditions may make it difficult to obtain accurate readings using the ORA SYSTEM® technology:

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• Patients having corneal pathology such as Fuchs’, ERMD, keratoconus, advanced pterygium, impairing the cornea, or any other pathology that the physician deems would interfere with the measurement process;

• Patients for which the preoperative regimen includes residual viscous substances left on the corneal surface such as lidocaine gel or viscoelastics;

• Visually significant media opacity, such as prominent floats or asteroid hyalosis, will either limit or prohibit the measurement process;

• Patients having received retro or peribulbar block or any other treatment that impair their ability to visualize the fixation light.

• Use of iris hooks during a ORA SYSTEM® technology image capture will yield inaccurate measurements.

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ATTENTION Refer to the ORA SYSTEM® Operator’s Manual for a complete description of proper use and maintenance, as well as complete list of contraindications, warnings and precautions.
Don't underestimate the importance of yearly vision exams

“He made me come in for an eye exam because I’ve been having too many near death experiences.”

Artwork by Jon Carter

in case you missed it

Guest editorial: ‘The ophthalmic sector must embrace telemedicine’ PAGE 7

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» Evolving cataract surgical strategies
» Weighing surgical outcomes of femtosecond laser-assisted cataract surgery versus phacoemulsification

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