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Surgery

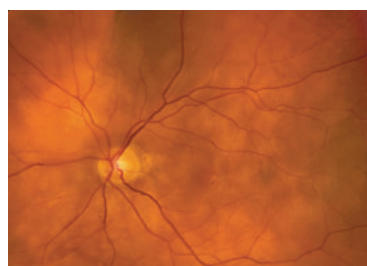
SUTURE TECHNIQUE: SECURING WHAT'S BEST FOR PATIENTS

BALTIMORE :: **MODERN ADJUSTABLE** suture techniques are much improved and applicable to children and adults, as practically all strabismus procedures can be adjusted. However, there are both pros and cons in choosing the adjustable technique over standard strabismus surgery, said David L. Guyton, MD.

(See story on page 12 : Sutures)

Clinical Diagnosis

EDI-OCT IMAGING IMPERATIVE FOR OCULAR ONCOLOGY

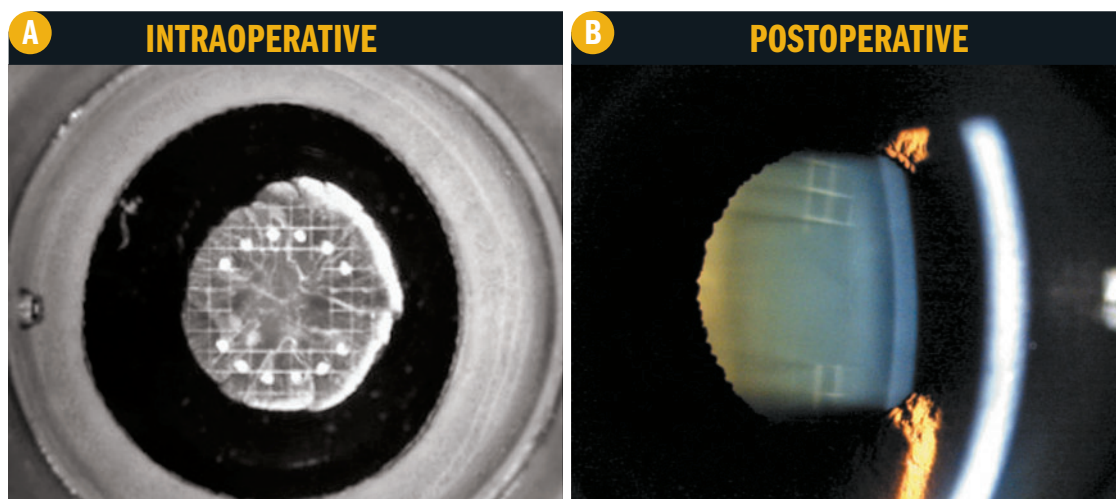


PHILADELPHIA :: **THANKS TO ITS** high resolution and increased depth of visualization into the choroid, enhanced depth imaging-optical coherence tomography (EDI-OCT) is proving itself to be a valuable tool for diagnosing and understanding a variety of intraocular tumors, according to Carol L. Shields, MD.

(See story on page 16 : Oncology)

Accommodation restoration: Is clinical availability near?

Efforts progressing from research, experimentation
to first treatment with commercial system



IN VIEW: **A** Intraoperative photograph of laser lens surgery in a 2+ nuclear sclerotic lens, showing minimal bubble expansion and coalescence along the intersecting squared lines of the laser pattern (anterior "waffle fries"), but extensive posterior lens fracturing (irregular gray circle with randomly radiating lines), due to the density of the lens. The broken circle of white spots is the light reflex from the laser's illumination system.

B The bubbles and evidence of the lens fracturing disappear within the first days after laser lens surgery.

(Images courtesy of Ronald R. Krueger, MD)

By Nancy Groves;

Reviewed by Ronald R. Krueger, MD

CLEVELAND ::

CLINICAL TRIALS OF the first commercial system for restoring accommodation in the crystalline lens with femtosecond lasers began 2 years ago.

However, it is uncertain how soon this technology will be clinically available for correction in presbyopic patients, said Ronald R. Krueger, MD, who has been working on the concept for nearly 20 years.

The technology is a "promising dream," said Dr. Krueger, medical director, Department of Refractive Surgery, Cole Eye Institute, and professor of ophthalmology, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland.

"We need to first continue our clinical studies with the more refined commercial laser, having started 2 years ago with the prototype device," Dr. Krueger said. "Then, we need a better understanding of the internal mechanisms of accommodation so we can develop a safe and effective treatment algorithm. Overall, our technology needs to get better and overcome some of the initial limitations."

Dr. Krueger is a consultant for Alcon Laboratories and also a co-founder and consultant of LensAR. Both companies are involved in femtosecond laser for cataract surgery, but only LensAR is currently developing femtosecond laser technology for presbyopic correction, he noted.

(Continues on page 26 : Accommodation)

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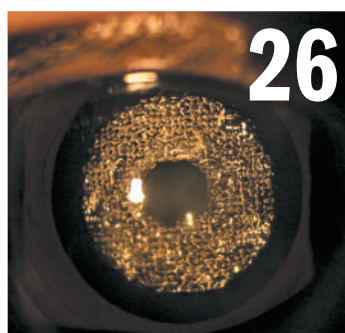
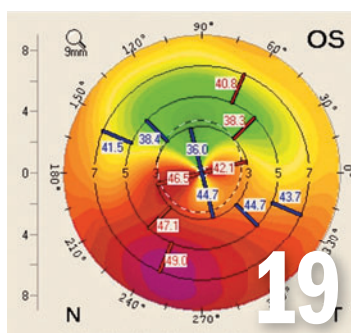
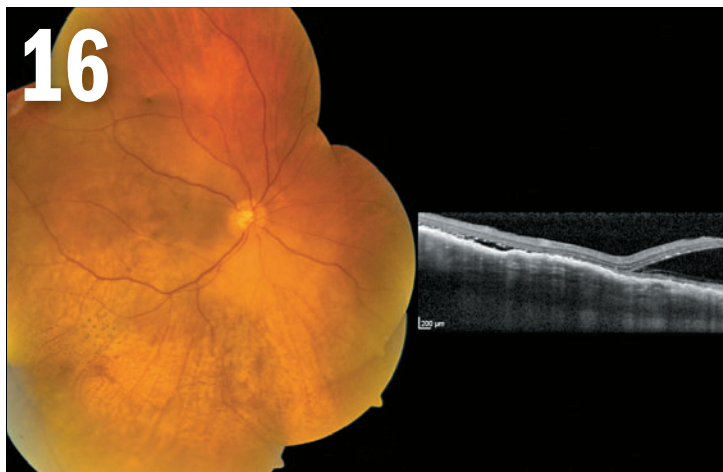
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In Every Issue

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A contrarian view of employee turnover

Is culture of high performance in best interest of best medical practices?



By Peter J. McDonnell, MD

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

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THE IMPORTANCE OF minimizing employee turnover is so ingrained these days as to be considered gospel in management circles. Googling the phrase “avoiding excessive employee turnover” reveals 1.76 million URLs, with titles like “How to Reduce Employee Turnover” (*The Wall Street Journal* Management Guide), “Preventing Employee Turnover” (Deloitte Consulting), and “The True Cost of Employee Turnover” (The Human Resources Social Network).

The hard and soft costs of employee turnover include covering a vacancy with temporary workers or overtime, advertising and recruitment costs, severance pay, training, lost expertise, missed deadlines and disruptions to workflow, and decreased productivity or customer service.

Ophthalmologists who run their practices or oversee academic departments can certainly recognize these issues. Many in management assert that the costs of employee turnover are actually much higher than standard measures appreciate, and so it is almost universally accepted that minimizing such turnover is crucial to success.

Which is why the “high-performance culture” of one company, Netflix, is so interesting.

THE BEST OF THE BEST

According to Chief Executive Officer (CEO) Reed Hastings, “We endeavor to have only outstanding employees. One outstanding employee gets more done and costs less than two adequate employees.”

To get outstanding employees, Netflix:

- Pays more than anyone else.
- Gives employees unlimited vacation time.

■ Gives employees wide latitude in determining how best to meet their expectations for the performance.

■ Let employees choose how they will take their compensation (cash, stock options, or a mixture of the two).

In return, the company is demanding when it comes to performance: “Only the highest-performing employees are retained. All others are let go so that their positions can be made available to more-effective replacements.”

Their CEO says, “At most companies, average performers get an average raise. At Netflix, they get a generous severance package.”

The result is that average annual total and involuntary turnover are high, the latter being nearly twice the industry average.

Turnover Statistics

	SILICON VALLEY AVERAGE	NETFLIX
Average annual total employee turnover	18% to 20%	16% to 28%
Average annual <u>voluntary</u> employee turnover	10% to 13%	3% to 14%
Average annual <u>involuntary</u> employee turnover	6% to 10%	14% to 20%

(Table courtesy of Brian Tayan)

Apparently, most Netflix employees like this system, because annual voluntary turnover is typically lower at Netflix than among its peers. If stock price means anything, the increase over the past 5 years from about \$29 to almost \$400 per share suggests that the company is doing something right.

IS IT PRACTICAL?

In our medical practices, we have all seen technicians who can perform patient workups thoroughly and accurately in half the time as others. And we have all had employees who are able to accomplish twice as much work as their colleagues, or who consistently achieve much higher levels of patient satisfaction than others performing the same role, or who are so self-driven to do the right thing that they require much less direct supervision.

Continues on page 6 : Editorial

Ophthalmology Times

FEBRUARY 1, 2014 ■ VOL. 39, NO. 3

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'Obamacare' confusion blurs ophthalmic focus

Glitches, misunderstandings have created a complicated perspective for the practice

By **Rose Schneider**, Content Specialist, Ophthalmology Times

WASHINGTON, DC ::

The Affordable Care Act (ACA) has clouded the future of ophthalmology, according to William L. Rich, MD. "The whole future is uncertain and we don't have a role in it," said Dr. Rich, medical director of health policy for the American Academy of Ophthalmology and senior partner with Northern Virginia Ophthalmology Associates, Fairfax, VA.

Though Dr. Rich said he supports the ACA, he blamed politics for causing the health-care overhaul to have several major problems, many of which affect ophthalmologists, their practices, and their patients.

He cited the implementation delay, website design flaws, and low penalties for non-participation of young and healthy people as causes for the overhaul's complications and confusion.

Worse yet, Dr. Rich said, these problems have not just caused comprehension confusion—they are going to result in fewer patients seeking medical care.

"When you delay the employment mandate (like the ACA has done), have very low penalties for non-participation by the young, healthy 22-year-olds, and have website design flaws, these will result in fewer patients seeking medical care through the new exchanges," Dr. Rich explained. "So what's going to (occur now) is, in order to make this work with fewer patients and fewer young patients in the ex-

changes, you're going to see insurance companies who are going to protect actuarially their profits," he added, stressing this action will not be helpful for the practice.

Many of the health-care plans set by the ACA will also have high deductibles, which will decrease patient utilization as well, according to Dr. Rich.

This will further result in a greater percentage of patients in Medicaid, he said, and low paying commercial plans with high deductibles in the exchanges (up to \$10,000 for a family of four with an income of \$41,000).

These problems, Dr. Rich said, mean fewer patients will seek care for chronic disease, thus increasing the long-term costs.

"That is a huge problem for the provision of care and that is a huge problem for physicians no matter what their practice opportunities are to get paid," he explained.

The ACA's new payment models—combined with the lack of relief on documentation guidelines and regulations—cause further major problems for ophthalmologists as well, he said.

"How can they really control costs if patients can see anyone?" Dr. Rich asked. "All these create big problems."

LOOKING TO THE FUTURE

The ACA was supposed to increase patient care and utilization in 2014, Dr. Rich said.

wage increase (or whatever the company-wide level).

Is it practical for medical practices to retain only stellar employees and pay them well above other practices, while letting one-fourth to one-fifth of their workforce go every year, to be replaced by new workers who will hopefully prove to be stellar? Would it be consistent with the culture of medical practices to reproduce the Netflix system of "high performance"? ■

IMPACT ON OPHTHALMOLOGY



VIDEO Dr. Rich, of the American Academy of Ophthalmology, discusses what he believes the Affordable Care Act means for ophthalmologists. Go to <http://bit.ly/1hRRT05>.

Instead, he said, "you're going to see more patients, (but) fewer than we anticipated."

Unfortunately, Dr. Rich said, the outlook for 2014 is just not what many had hoped it would be. However, all is not lost, he stressed.

"So how will the ACA affect your practice in 2014? Not as much as planned, not as much as we'd hoped," Dr. Rich said. "There's still some time to get this act together because most of these problems arose from political decisions, not the value of the act or the intent of the act."

"So I think things can still right themselves, but 2014 is going to be pretty rocky with less impact than we hoped," he added. ■

EDITORIAL

(Continued from page 4)

To me, this raises the question of whether many businesses have *too little* turnover.

Such a business would presumably be contented with employees who are average or close to average, and give pretty much every worker the same annual 2%

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- Larcker D, Tayan B. A real look at real world corporate governance. 2013. Pp. 135-138.

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- Bacterial infections — Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Viral infections — Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections — Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.
- Contact lens wear — DUREZOL® Emulsion should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of DUREZOL® Emulsion. The preservative in

DUREZOL® Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL® Emulsion.

Most Common Adverse Reactions

- Post Operative Ocular Inflammation and Pain — Ocular adverse reactions occurring in 5-15% of subjects included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis.
- In the endogenous anterior uveitis studies, the most common adverse reactions occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis.

For additional information about DUREZOL® Emulsion, please refer to the brief summary of prescribing information on adjacent page.



DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

The results you want. The relief they need.

Alcon®
a Novartis company

Reference: 1. DUREZOL® Emulsion package insert.

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Longitudinal versus torsional phaco

New technologies offer better patient recovery outcomes, becoming more preferred option

By Fred Gebhart; Reviewed by Wilson Takashi Hida, MD, PhD



BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Ocular Surgery

DUREZOL[®] (difluprednate ophthalmic emulsion) 0.05%, a topical corticosteroid, is indicated for the treatment of inflammation and pain associated with ocular surgery.

Endogenous Anterior Uveitis

DUREZOL[®] Emulsion is also indicated for the treatment of endogenous anterior uveitis.

DOSAGE AND ADMINISTRATION

Ocular Surgery

Instill one drop into the conjunctival sac of the affected eye 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.

Endogenous Anterior Uveitis

Instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.

DOSAGE FORMS AND STRENGTHS

DUREZOL[®] Emulsion contains 0.05% difluprednate as a sterile preserved emulsion for topical ophthalmic administration.

CONTRAINDICATIONS

The use of DUREZOL[®] Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

WARNINGS AND PRECAUTIONS

IOP 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. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

Bacterial Infections

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

Viral Infections

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. 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.

Topical Ophthalmic Use Only

DUREZOL[®] Emulsion is not indicated for intraocular administration.

Contact Lens Wear

DUREZOL[®] Emulsion should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of DUREZOL[®] Emulsion. The preservative in DUREZOL[®] Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL[®] Emulsion.

ADVERSE REACTIONS

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; secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Ocular Surgery

Ocular adverse reactions occurring in 5-15% of subjects in clinical studies with DUREZOL[®] Emulsion included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis. Other ocular adverse reactions occurring in 1-5% of subjects included reduced visual acuity, punctate keratitis, eye inflammation, and iritis. Ocular adverse reactions occurring in < 1% of subjects included application site discomfort or irritation, corneal pigmentation and striae, episcleritis, eye pruritus, eyelid irritation and crusting, foreign body sensation, increased lacrimation, macular edema, sclera hyperemia, and uveitis. Most of these reactions may have been the consequence of the surgical procedure.

Endogenous Anterior Uveitis

A total of 200 subjects participated in the clinical trials for endogenous anterior uveitis, of which 106 were exposed to DUREZOL[®] Emulsion. The most common adverse reactions of those exposed to DUREZOL[®] Emulsion occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis. Adverse reactions occurring in 2-5% of subjects included anterior chamber flare, corneal edema, dry eye, iridocyclitis, photophobia, and reduced visual acuity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects

Pregnancy Category C. Difluprednate has been shown to be embryotoxic (decrease in embryonic body weight and a delay in embryonic ossification) and teratogenic (cleft palate and skeletal) anomalies when administered subcutaneously to rabbits during organogenesis at a dose of 1-10 mcg/kg/day. The no-observed-effect-level (NOEL) for these effects was 1 mcg/kg/day, and 10 mcg/kg/day was considered to be a teratogenic dose that was concurrently found in the toxic dose range for fetuses and pregnant females. Treatment of rats with 10 mcg/kg/day subcutaneously during organogenesis did not result in any reproductive toxicity, nor was it maternally toxic. At 100 mcg/kg/day after subcutaneous administration in rats, there was a decrease in fetal weights and delay in ossification, and effects on weight gain in the pregnant females. It is difficult to extrapolate these doses of difluprednate to maximum daily human doses of DUREZOL[®] Emulsion, since DUREZOL[®] Emulsion is administered topically with minimal systemic absorption, and difluprednate blood levels were not measured in the reproductive animal studies. However, since use of difluprednate during human pregnancy has not been evaluated and cannot rule out the possibility of harm, DUREZOL[®] Emulsion should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.

Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when DUREZOL[®] Emulsion is administered to a nursing woman.

Pediatric Use

DUREZOL[®] Emulsion was evaluated in a 3-month, multicenter, double-masked, trial in 79 pediatric patients (39 DUREZOL[®] Emulsion; 40 prednisolone acetate) 0 to 3 years of age for the treatment of inflammation following cataract surgery. A similar safety profile was observed in pediatric patients comparing DUREZOL[®] Emulsion to prednisolone acetate ophthalmic suspension, 1%.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Difluprednate was not genotoxic *in vitro* in the Ames test, and in cultured mammalian cells CHL/IU (a fibroblastic cell line derived from the lungs of newborn female Chinese hamsters). An *in vivo* micronucleus test of difluprednate in mice was also negative. Treatment of male and female rats with subcutaneous difluprednate up to 10 mcg/kg/day prior to and during mating did not impair fertility in either gender. Long term studies have not been conducted to evaluate the carcinogenic potential of difluprednate.

Animal Toxicology and/or Pharmacology

In multiple studies performed in rodents and non-rodents, subchronic and chronic toxicity tests of difluprednate showed systemic effects such as suppression of body weight gain; a decrease in lymphocyte count; atrophy of the lymphatic glands and adrenal gland; and for local effects, thinning of the skin; all of which were due to the pharmacologic action of the molecule and are well known glucocorticosteroid effects. Most, if not all of these effects were reversible after drug withdrawal. The NOEL for the subchronic and chronic toxicity tests were consistent between species and ranged from 1-1.25 mcg/kg/day.

PATIENT COUNSELING INFORMATION

Risk of Contamination

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the emulsion. Use of the same bottle for both eyes is not recommended with topical eye drops that are used in association with surgery.

Risk of Secondary Infection

If pain develops, or if redness, itching, or inflammation becomes aggravated, the patient should be advised to consult a physician.

Contact Lens Wear

DUREZOL[®] Emulsion should not be instilled while wearing contact lenses. Patients should be advised to remove contact lenses prior to instillation of DUREZOL[®] Emulsion. The preservative in DUREZOL[®] Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL[®] Emulsion.

Revised: May 2013
U.S. Patent 6,114,319

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TAKE-HOME

► Several new refractive surgical platforms have been introduced recently, and many ophthalmologists are discovering they find the new technologies to be more efficient and produce better results.

BRASILIA, BRAZIL ::

Most ophthalmologic surgeons would likely agree that newer refractive surgical platforms offer improvements over older alternatives. However, comparing two different new platforms can be more difficult, said Wilson Takashi Hida, MD, PhD.

“Most studies in our field compare new technology from one manufacturer against prior generations of technology from that same instrument maker,” said Dr. Hida, medical director and chief of cataract sector of Brasilia Ophthalmology Hospital in Brasilia, Brazil. “When it comes to torsional and transversal technologies, there were a lot of studies that began around 2010 and they all reached the same conclusion: It is a better technology. But they all looked at machines from a single manufacturer. They were all looking at newer technology so of course it should be better than what came before.

“It is more difficult to compare different technologies in a real-world setting,” he continued.



Dr. Hida

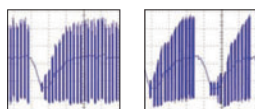
COMPARING, CONTRASTING

Traditional longitudinal phaco used a jackhammer-like in and out motion for phacoemulsification. Bioengineers eventually realized that half the energy used in traditional longitudinal motion is wasted because material is only broken up when the tip moves forward. When the tip moves backward between cuts, it only generates more energy and more heat that can damage the eye.

Stellaris Vision Enhancement System



Hyperpulse 'Waveform' Modulation



50 PPS 40%
Duty Cycle

50 PPS 80%
Duty Cycle

Platform Comparison

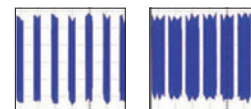
Bausch + Lomb	Alcon Laboratories
U.S. Longitudinal	U.S. Torsional
Venturi Pump Flow-Based Mode	Peristaltic Pump
Burst and Hyperpulse	OZil Continuous
Waveform Modulation	IP
Vacuum Response	Dynamic Rise
Stellaris Premium AFS Phaco Pack	Intrepid Fluidic Management System
Straight Microtip	Kelman Microtip
Stroke 150 μ m	Stroke 100 μ m
1.8 to 2.4 mm	2.2 to 2.4 mm

(Figure courtesy of Wilson Takashi Hida, MD, PhD)

Infiniti Vision System



Hyperpulse 'Square Wave' Modulation



100 PPS 40%
Duty Cycle

100 PPS 80%
Duty Cycle

Bausch + Lomb introduced a more efficient longitudinal platform (Stellaris Vision Enhancement System) which cuts using an elliptical lateral motion. Power modulation and pulse shaping are combined to optimize longitudinal ultrasound energy delivery.

Alcon Laboratories introduced the Infiniti Vision System, which adds torsional technology, called OZil, to cut lens material using circular oscillations similar to turning a doorknob.

But the motion of the phaco tip is just one of several variables that can affect procedural complications and outcomes.

Power output is important, Dr. Hida noted, because lower energy output generally translates into less collateral damage to the corneal endothelium. Balanced fluidics keep the eye inflated, build and maintain currents that bring cataract fragments to the phaco tip, and help keep the tip cool to prevent thermal injury to the eye.

Fluidics are affected by vacuum, which is a function of the type of pump used and tubing size. Micro incisions require micro tubing, but micro tubing requires more vacuum, which creates difficulties in managing fluidics.

Both platforms produced similarly good clinical results, but the Infiniti platform showed lower fluid use and shorter operative times, particularly for patients with hard cataracts.

"I use both machines on a regular basis, so there was no learning curve to affect the re-

sults of this comparison," Dr. Hida said. "Four hundred consecutive and routine cataract patients were prospectively (randomly assigned) to either the Stellaris or the Infiniti platform. Our goal was to compare the clinical and the intraoperative parameters using the same bevel-down technique with both instruments in a real-world population of real patients."

INVESTIGATING FURTHER

The Stellaris system uses longitudinal ultrasound, a venturi pump, pulsed energy modulation energy via a straight microtip with a 150- μ m stroke, and a 1.8- to 2.4-mm incision. The Infiniti system uses torsional ultrasound, a peristaltic pump, pulsed energy modulation via a Kelman microtip with a 100- μ m stroke, and a 2.2- to 2.4- mm incision. The same technique was used for all eyes, including the same ultrasound pulse rate and fluidic settings.

There were no statistically significant differences in patient age or in nuclear density by either LOCS III or Pentacam PNS assessment.

The Stellaris used significantly less total ultrasound time compared with the Infiniti, Dr. Hida found, but the total case time was significantly shorter with the Infiniti system. Infiniti also showed significantly less fluid use per patient.

Despite the differences in intraoperative parameters, there was no statistically significant differences in corrected visual acuity between the two groups at 3 months after surgery. There

was also no difference between the two patient groups in central cornea thickness or endothelial cell loss.

"Both machines are very good," Dr. Hida said. "It is not just this study that shows these platforms are an improvement over older technologies. In terms of clinical results, you can use either machine and produce very good results. For patients, visual recovery after surgery is what is important and both machines did very well."

Dr. Hida added that he is equally comfortable using either the Stellaris or Infiniti platforms.

He explained that some surgeons have preferences for one technology over another based on differences in their own experience and technique, but clinical outcomes are similarly high regardless of which instrument is used.

From a workflow perspective, Infiniti offers improved case time, which can boost patient throughput, and reduced fluid use, which might have an economic impact, Dr. Hida said.

"Some of my colleagues like one machine over another and some don't care," he said. "What we all agree on is that new technology is changing clinical outcomes for the better." ■

WILSON TAKASHI HIDA, MD, PhD

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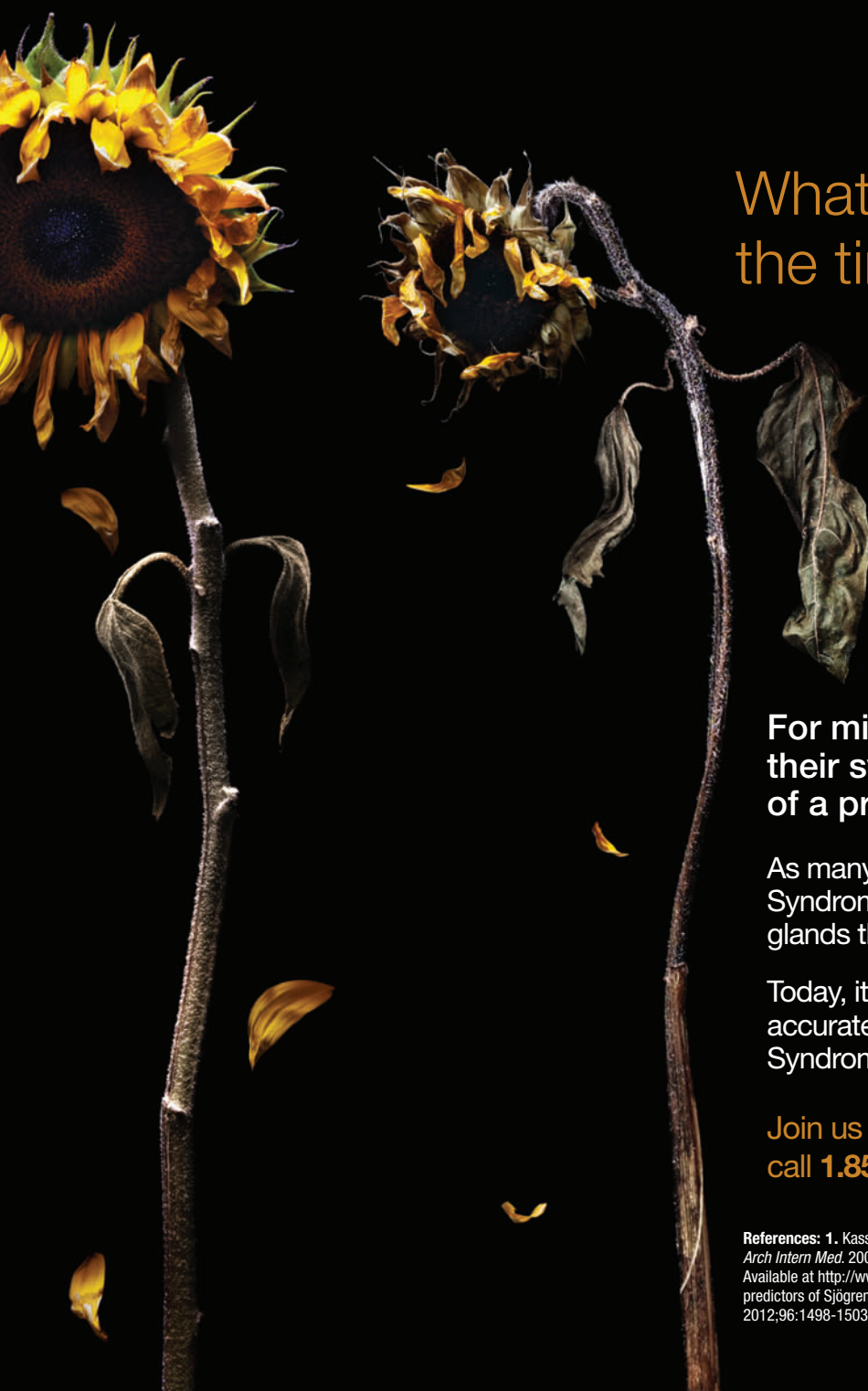
Dr. Hida receives research fees from Abbott Medical Optics, Alcon Laboratories, and Bausch + Lomb, but no fees were received for this study.

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Ophthalmic Diagnostics

Sjögren's
SS syndrome
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Today, it takes an average of 4.7 years to receive an
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References: 1. Kassan SS, Moutsopoulos HM. Clinical manifestations and early diagnosis of Sjögren syndrome. *Arch Intern Med*. 2004;164:1275-1284. 2. Sjögren's Syndrome Foundation. Sjögren's Syndrome Foundation. 2001. Available at <http://www.sjogrens.org>. Accessed September 5, 2013. 3. Liew M, Zhang M, Kim E, et al. Prevalence and predictors of Sjögren's syndrome in a prospective cohort of patients with aqueous-deficient dry eye. *Br J Ophthalmol*. 2012;96:1498-1503. 4. Martin LS, Massafra U, Migliore A. Sjögren's syndrome: an under-diagnosed disorder. *CLJ*. May 2004.

Modern suture techniques perform better in pediatric and adult cases

But choosing adjustable method over standard surgery has advantages and disadvantages

By Nancy Groves; Reviewed by David L. Guyton, MD

TAKE-HOME

► With modern techniques and recent innovations, adjustable suture strabismus surgery can be performed in nearly all pediatric and adult cases, provided that ophthalmologists have had sufficient training.

BALTIMORE ::

MODERN ADJUSTABLE SUTURE techniques are much improved and applicable to children and adults, as practically all strabismus procedures can be adjusted. However, there are both advantages and disadvantages in choosing the adjustable technique over standard strabismus surgery, according to David L. Guyton, MD.

"The concept of fine-tuning the surgery makes sense in preoperative discussions (because) there is less anxiety for the surgeon, and in our hands we really do get better results," said Dr. Guyton, Zanvyl Krieger Professor of Pediatric Ophthalmology at Zanvyl Krieger Children's Eye Center, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore.



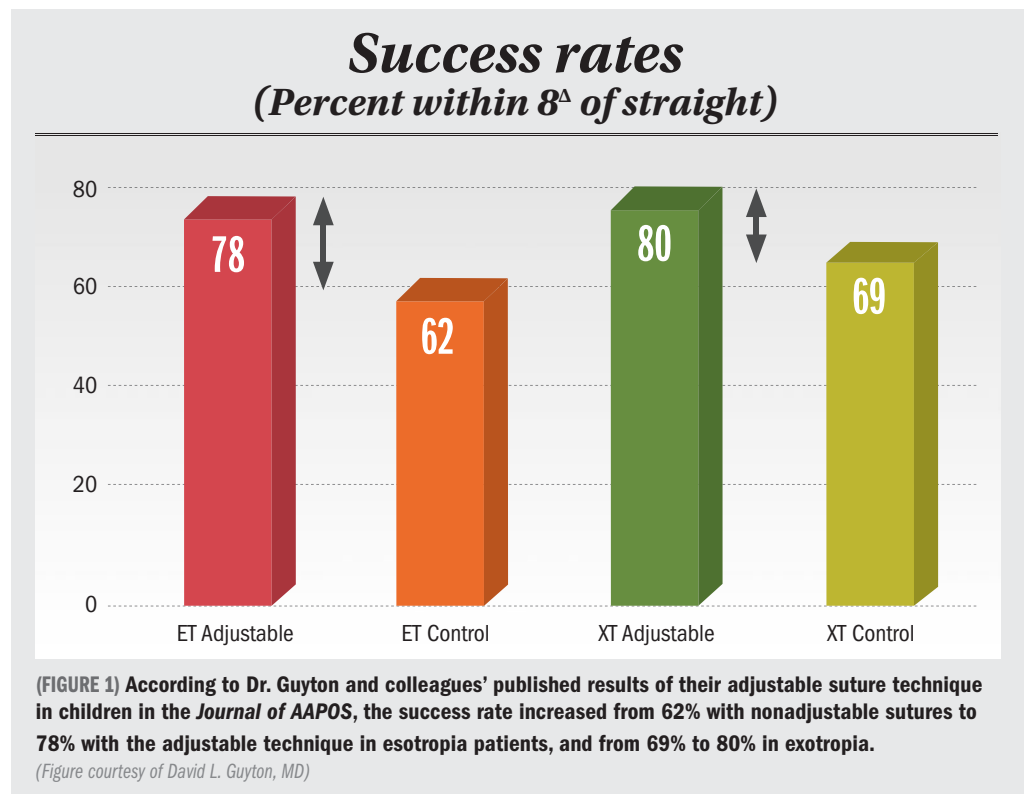
Dr. Guyton

"We don't always know where to leave the muscle, but we definitely know where we don't want it to be, such as causing a large overcorrection or undercorrection," Dr. Guyton said. "That's where adjustable sutures really come to the rescue."

WEIGHING THE BENEFITS

Using adjustable sutures may cost more initially because of more intraoperative and postoperative time involved—plus an additional anesthesia cost in young children—but this may be offset by less morbidity and fewer reoperations, Dr. Guyton said.

To date, however, no cost-benefit studies have been performed nor randomized clinical trials performed to demonstrate that adjust-



able suture strabismus surgery is better than the fixed-suture technique.

Use of the adjustable technique is largely a matter of the ophthalmologist's personal preference, he added.

The roadblocks that prevent some strabismus surgeons from using the technique include a steep learning curve. Dr. Guyton noted that surgeons will need training and experience to achieve high success rates and that success is highly technique-dependent.

Also, more time is required for the adjustable suture technique—about 3 to 5 minutes per muscle intraoperatively and 15 to 20 minutes for adjustment.

Anesthesiologists tend to be initially resistant to this technique, questioning the safety of giving brief IV propofol anesthesia in the recovery room, but with experience this resistance evaporates quickly, Dr. Guyton said.

The techniques for adjustable sutures in children evolved from those used in adults,

he noted. Although such a technique was first described over a century ago, it was rarely used until resurrected and improved by Arthur Jampolsky, MD, in the 1970s.

Adjustable sutures originally were used for less predictable operations, but Dr. Guyton said he uses them for practically any muscle procedure, except when weakening the inferior oblique muscle. Procedures suited to the adjustable suture technique include recessions, resections, tucks, Harada-Ito procedures, transpositions, and lower lid suspensions.

NEW TECHNIQUES

Dr. Guyton and colleagues published results of their adjustable suture technique in children in 2008 in the *Journal of AAPOS*, measuring success within 8 prism D of straight. The success rate increased from 62% with nonadjustable sutures to 78% with the adjustable technique in esotropia patients, and from 69% to 80%

Continues on page 14 : **Sutures**



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*20/16 results delivered with excimer laser, clinical studies sent to FDA via P930016 supplement 021.

Laser assisted *in-situ* keratomileusis (LASIK) can only be performed by a trained ophthalmologist and for specified reduction or elimination of myopia, hyperopia, and astigmatism as indicated within the product labeling. Laser refractive surgery is contraindicated for patients: a) with collagen vascular, autoimmune, or immunodeficiency diseases; b) who are pregnant or nursing women; c) with signs of keratoconus or abnormal corneal topography; d) who are taking one or both of the following medications: Isotretinoin (Accutane) and Amiodarone hydrochloride (Cordarone). Potential side effects to laser refractive surgery may include glare, dry eye, as well as other visual anomalies. LASIK requires the use of a microkeratome that cuts a flap on the surface of the cornea, potential side effects may include flap related complications. Patients are requested to consult with their eye care professional and *Patient Information Booklet* regarding the potential risks and benefits for laser refractive surgery, results may vary for each individual patient.

Restricted Device: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical treatment and management of refractive errors.

Please see brief statement on adjacent page.

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Abbott
Medical Optics

Statements regarding the potential benefits of wavefront-guided LASIK (CustomVue) are based upon the results of clinical trials. These results are indicative of not only the CustomVue Treatment but also the care of the clinical physicians, the control of the surgical environment by those physicians, the clinical trials' treatment parameters and the clinical trials' patient inclusion and exclusion criteria. Although many clinical trial patients after the CustomVue Procedure saw 20/20 or better and/or had or reported having better vision during the day and at night, compared to their vision with glasses or contact lenses before the procedure, individual results may vary. You can find information about the clinical trials below and in the Professional Use Information Manuals for the VIXS STAR S4 Excimer Laser System and WaveScan WaveFront System (CustomVue Treatments).

As with any surgical procedure, there are risks associated with the CustomVue Treatment. Before treating patients with the CustomVue Procedure, you should carefully review the Professional Use Information Manual, complete the Physician CustomVue Certification Course, provide your patients with the Patient Information Booklet for CustomVue LASIK Laser Treatment, and discuss the risks associated with this procedure and questions about the procedure with your patients.

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES:

The VIXS STAR S4 Excimer Laser System and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of low to moderate myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination.

Wavefront-guided LASIK for correction of low to moderate myopic astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the low to moderate myopic astigmatism application is based on a clinical trial of 351 eyes (189 primary and 162 secondary). Of all eyes treated, 318 were evaluated for effectiveness with 98.6% accountability at 3 months, 277 eyes with 96.9% accountability at 6 months, 102 eyes with 95.3% accountability at 9 months, and 86 eyes with 95.6% accountability at 12 months. The studies found that of the 277 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 100% were corrected to 20/40 or better, and 95.8% were corrected to 20/20 or better in 71 spherical myopia eyes; and 99.5% were corrected to 20/40 or better, and 93.2% were corrected to 20/20 or better in 206 astigmatic myopia eyes. The study showed that at the 3 month stability time point: there was a loss of ≥ 2 lines of best corrected vision that can be obtained with spectacles in 1 of 239 astigmatic myopia eyes and there was no loss of ≥ 2 lines of best corrected vision in 79 spherical myopia eyes; there was 1 of 239 astigmatic myopia eyes with best spectacle corrected visual acuity (BSCVA) worse than 20/25 and none in 79 spherical myopia eyes with BSCVA worse than 20/25. During the course of study, no eye lost > 2 lines of BSCVA and no eye had a BSCVA worse than 20/40.

The VIXS STAR S4 IR Excimer Laser System with VSS Technology and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of high myopic astigmatism from -6.00 D to -11.00 D MRSE, with cylinder between 0.00 and -3.00 D in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 1.00 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination.

Wavefront-guided LASIK for correction of high myopic astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the application is based on a clinical trial of 184 eyes. Of all eyes treated, 180 were evaluated for effectiveness with 97.8% accountability at 3 months, 178 eyes with 96.7% accountability at 6 months, 170 eyes with 96.5% accountability at 9 months, and 107 eyes with 93.9% accountability at 12 months. The studies found that of the 178 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 98.3% were corrected to 20/40 or better, 97.2% were corrected to 20/32 or better, and 84.3% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of 83 spherical and 101 astigmatic eyes, no eyes lost 2 or more lines of best corrected vision that can be obtained with spectacles (BSCVA) and none of the eyes had BSCVA worse than 20/40.

The VIXS STAR S4 Excimer Laser System and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 1.00 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination.

Wavefront-guided LASIK for the correction of hyperopic astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the hyperopic astigmatism application is based on a clinical trial of 144 eyes (74 primary and 70 secondary). Of all eyes treated, 134 were evaluated for effectiveness with 98.5% accountability at 3 months, 131 eyes with 97.0% accountability at 6 months, 118 eyes with 90.8% accountability at 9 months, and 27 eyes with 87.1% accountability at 12 months. The studies found that of the 131 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 97.3% were corrected to 20/40 or better, and 66.2% were corrected to 20/20 or better in 74 spherical hyperopia eyes; and 93.0% were corrected to 20/40 or better, and 56.1% were corrected to 20/20 or better in 57 astigmatic hyperopia eyes. The study showed that at the 6 month stability time point: there was no loss of ≥ 2 lines of best corrected vision that can be obtained with spectacles in either 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes; none of the 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/25. During the course of study, one of 63 eyes with astigmatic hyperopia lost > 2 lines of BSCVA at 1 month, no eyes with spherical hyperopia lost > 2 lines of BSCVA, and no eye had a BSCVA worse than 20/40.

The VIXS STAR S4 IR Excimer Laser System with VSS Technology and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of cylinder (from 1.0 to 5.0 D) is greater than the magnitude of sphere and the cylinder and sphere have opposite signs; in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination.

Wavefront-guided LASIK for the correction of mixed astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the mixed astigmatism application is based on a clinical trial of 86 eyes. Of all eyes treated, 86 were evaluated for effectiveness with 100.0% accountability at 3 months, 80 eyes with 95.2% accountability at 6 months, 69 eyes with 86.3% accountability at 9 months, and 63 eyes with 94.0% accountability at 12 months. The studies found that of the 86 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 3 months, 95.3% were corrected to 20/40 or better, 91.9% were corrected to 20/32 or better, and 61.6% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of 86 astigmatic eyes, one eye temporarily lost 2 lines of best corrected vision that can be obtained with spectacles at 1 month and at 6 months and none of the eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/40.

CONTRAINDICATIONS:

Wavefront-guided LASIK is contraindicated in patients with collagen vascular, autoimmune or immunodeficiency disease, signs of keratoconus or abnormal corneal topography, patients taking isotretinoin (Accutane®) or amiodarone hydrochloride (Cordarone®) or are pregnant or nursing.

WARNINGS:

Wavefront-guided LASIK is not recommended in patients who have diabetes, a history of Herpes simplex or Herpes zoster keratitis, significant dry eye that is unresponsive to treatment, or severe allergies. For the treatment of low to moderate myopic astigmatism, lower uncorrected visual acuity may be anticipated in the treatment of higher degrees of myopia with and without astigmatism (± 5.0 D MRSE).

PRECAUTIONS:

The safety and effectiveness of wavefront-guided LASIK surgery has ONLY been established with an optical zone of 6 mm and an ablation zone of 8 mm for myopic astigmatism, and an optical zone of 6 mm and an ablation zone of 9 mm for hyperopic and mixed astigmatism. Long term risks of wavefront-guided LASIK beyond 12 months have not been studied. The safety and effectiveness of the STAR S4 IR Excimer Laser System have NOT been established for wavefront-guided treatment of low to moderate myopic astigmatism in patients whose WaveScan WaveFront diameter is less than 6 mm, for treatments greater than 6 diopters of MRSE or with greater than 3 diopters of astigmatism and for retreatment with CustomVue LASIK. The safety and effectiveness of the STAR S4 IR Excimer Laser System have NOT been established for wavefront-guided treatment of high myopic astigmatism in patients whose WaveScan WaveFront diameter is less than 5 mm, for treatments greater than -11 diopters of MRSE or with greater than 3 diopters of astigmatism. The safety and effectiveness of the STAR S4 IR Excimer Laser System have NOT been established for wavefront-guided treatment of hyperopic astigmatism in patients whose WaveScan WaveFront diameter is less than 5 mm, for treatments greater than 3 diopters of MRSE or with greater than 2 diopters of astigmatism and for retreatment with CustomVue LASIK. The safety and effectiveness of the STAR S4 IR Excimer Laser System have NOT been established for wavefront-guided treatment of mixed astigmatism in patients whose WaveScan WaveFront diameter is less than 5 mm, for treatments greater than 5 diopters or less than 1 diopter of astigmatism and for retreatment with CustomVue LASIK.

Although the WaveScan WaveFront System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher-order aberrations through sixth order, in the clinical studies for low to moderate myopic astigmatism, hyperopic astigmatism and mixed astigmatism, the average higher order aberration did not decrease after CustomVue Treatment. In the clinical studies for high myopic astigmatism, the average higher order aberration increased after CustomVue Treatment.

It is possible, after wavefront-guided LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes or decentered pupils. Pupil size should be evaluated under mesopic illumination conditions.

The use of Percentage Nomogram Adjustment should be based upon careful consideration of patient and surgeon information, in addition to environmental conditions surrounding the surgery. The simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment has not been studied in controlled investigations, and should not be attempted until the accuracy of the Nomogram setting has been verified for the same laser, treatment conditions and type of treatment. Therefore, the combined simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment is not recommended without careful analysis of postoperative refractive results.

ADVERSE EVENTS AND COMPLICATIONS:

The clinical trial for low to moderate myopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 351 eyes at any interval up to 6 months post-treatment: inflammation of the cornea under the flap (1.4%); double or ghost images (1.4%); and scratch on the surface of the eye (1.4%). The following subjective symptoms frequency rated "often or always" were increased in the effectiveness cohort at 6 months post-treatment on 258 eyes compared with pre-treatment on 332 eyes: dryness (9% vs. 6%); fluctuation of vision (3% vs. 2%); glare (4% vs. 2%) and halos (7% vs. 5%).

The clinical trial for high myopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 184 eyes at one or more postoperative examinations up to 6 months post-treatment: epithelium in the interface (1.1%); peripheral corneal epithelial defect at 1 month or later (2.2%); corneal edema between 1 week and 1 month post-operatively (2.7%) and double vision (or "ghost images") in the operative eye (6.0%). The following subjective symptoms were reported as present "often or always" by a higher percentage of subjects 6 months after treatment than before treatment: dryness (10.8% vs. 9.3%); halos (21.6% vs. 15.4%); and ghosting or shadowing of images (2.8% vs. 1.1%).

The clinical trial for hyperopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 144 eyes at any interval up to 6 months post-treatment: cells growing under the flap (2.1%); feeling of something in the eye (1.4%); double or ghost images (11.3%); and scratch on the surface of the eye (2.1%). The following subjective symptoms rated "often or always" were increased in the effectiveness cohort at 6 months post-treatment on 131 eyes compared with pre-treatment on 136 eyes: dryness (17% vs. 6%); blurry vision (10% vs. 7%); fluctuation of vision (14% vs. 6%); halos (10% vs. 5%); double or ghost images (7% vs. 3%).

The clinical trial for mixed astigmatism showed that the following adverse events or complications occurred in at least 1% of the 86 eyes at one or more postoperative examinations up to 3 months post-treatment: miscreated flap (1.2%); cells growing under the flap (4.7%); and double vision (or "ghost images") in the operative eye (8.1%). The following subjective symptoms were reported as present "often or always" by a higher percentage of subjects 3 months after treatment than before treatment: dryness (22% vs. 6%); halos (20% vs. 13%).

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SUTURES

(Continued from page 12)

in exotropia. He has since used the adjustable suture technique in practically all pediatric cases since 1993.

In the October 2013 issue of the *Journal of AAPOS*, Dr. Guyton and colleagues published a report on a new, removable sliding polyglactin

which he said is faster, and because the knot and suture ends are totally buried.

This approach leads to better postoperative comfort and less scarring, however, this technique requires a skilled assistant for best outcomes, he added.

He recommended general anesthesia for children and adults because it is easier to judge the rest position of the eyes and forced ductions are more reliable. It also

The success rate increased from
62% with nonadjustable sutures to **78%**
with the adjustable technique in esotropia
patients, and from
69% to 80%
in exotropia.

910 suture noose—a clove hitch with three slip knots. This minimizes the suture material left to resorb, reducing discomfort, inflammation, and scarring.

“When you finish adjusting and tying the muscle sutures off, you simply pull sideways on the portions of the noose knot and it just comes off,” Dr. Guyton said. “We’ve used that for several years and we’re quite pleased with it.”

‘SHORT-TAG’ NOOSE

Another new technique, developed by David Hunter, MD, PhD, professor of ophthalmology, Boston Children’s Hospital, Harvard Medical School, is the “short-tag” noose. Trimmed pole sutures and the trimmed noose are buried under the conjunctiva. The suture can remain in place if no adjustment is required, but if needed, adjustments can be made up to 7 days after surgery.

When performing surgery, Dr. Guyton said he prefers making a cul-de-sac conjunctival incision,

wears off more quickly than local anesthesia, which may require a wait of 5 or 6 hours before adjustments can be made.

Adjustments in young children are usually performed 1 to 2 hours postoperatively in the recovery room.

Dr. Guyton said his protocol is to instill a drop of topical proparacaine, do a cover test or corneal light reflex test to judge the alignment, and then have the anesthesiologist briefly administer intravenous propofol (2 to 3 mg/kg \pm 1 mg/kg as needed) before making the adjustment.

The actual adjustment procedure itself typically lasts from 5 to 7 minutes. ■

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Dr. Guyton has received grant support from the Hartwell Foundation and the National Eye Institute. He holds patents on fixation detection technology.

Exploring future treatments for diabetic macular edema

Options could improve the effectiveness of therapies, potentially preventing the disease

By Nancy Groves; Reviewed by Lloyd Paul Aiello, MD, PhD

TAKE-HOME

► **The future of treatment for diabetic macular edema is likely to include a wider range of treatment options, improved efficacy, and the possibility of disease prevention.**

BOSTON ::

Advances in the management of diabetic macular edema (DME) are likely to center on additional, more effective treatment options, streamlined delivery mechanisms, individualized therapy—and perhaps most importantly—greater emphasis on prevention, said Lloyd Paul Aiello, MD, PhD.

“It is highly likely that in the future we will have expanded anti-vascular endothelial growth factor (VEGF) and steroid options and better known relative efficacy,” said Dr. Aiello, head of eye research, Joslin Diabetes Center, Harvard Medical School, Boston. “It is likely that less invasive and less burdensome therapeutic delivery mechanisms will become available.

In the mid-term, new therapeutic options for eyes that have an incomplete anti-VEGF response may show efficacy, and at that time usher in a new era of individualized therapy.”



Dr. Aiello

TREATMENTS

Topical, subcutaneous, and oral delivery methods are among the approaches being investigated.

Data may be released within a year or so on phase II evaluation of topical NSAIDs in eyes with noncentral-involved DME being conducted by the Diabetic Retinopathy Clinical Research Network (DRCR.net Protocol R), Dr. Aiello said.

Investigators also have early human data on other agents for topical delivery, such as dexamethasone-cyclodextrin microparticle eye drops; SAR 1118, a lymphocyte function-associated an-

tigen-1 antagonist; mecamylamine, a nonspecific nicotinic acetylcholine receptor blocker; and multi-targeted kinase (src) inhibitors.

Subcutaneous delivery strategies include:

- Exenatide (glucagon-like peptide-1 agonist), which has one case report of complete regression of DME in type 2 diabetes
- Lanreotide autogel, a synthetic somatostatin analogue
- Vascular endothelial-protein tyrosine phosphatase inhibitor

Oral delivery methods being tested include:

- PKC-beta inhibitors
- Oral minocycline (microglial activation inhibitor)
- Atorvastatin, a statin lipid-lowering agent
- Vascular adhesion protein-1 inhibitor
- Alpha V integrin antagonist

Approaches to reducing treatment burden include implants and extended delivery devices.

“Another area that’s very exciting is nanoparticle formulations,” Dr. Aiello said. “These are under way in a variety of approaches and promise potentially better availability and longer duration of action.”

SEEKING MORE DATA

Efficacy data across multiple anti-VEGF agents are also critically needed, Dr. Aiello said.

Ranibizumab is well documented; more data are becoming available on bevacizumab (Avastin, Genentech) and aflibercept (Eylea, Regeneron)—neither of which has FDA approval for DME.

“What is clearly missing is direct, head-to-head comparison studies to help us understand how to use these agents relative to each other,” he said.

That gap is being addressed in DRCR.net Protocol T, a randomized clinical trial to compare the efficacy of intravitreal aflibercept (2 mg), bevacizumab (1.25 mg), and ranibizumab (0.3 mg) when given in eyes with center-involved DME and visual impairment.

Another challenge is improving the drug

response rate. Researchers suspect that VEGF-independent pathways contribute to the incomplete anti-VEGF response in up to half of treated patients. Several of these pathways are known, and many others may exist. Data from human vitreous samples show a broad gradient between high and low levels of VEGF, as well as between levels of other components that may contribute to vascular leakage.

This finding has significant implications, Dr. Aiello said.

A high level of VEGF suggests the eye would respond well to anti-VEGF treatment, whereas a low VEGF level means the eye might be relatively insensitive to a VEGF inhibitor, but potentially could be sensitive to other agents. Patients in the middle of the spectrum might require inhibition of multiple pathways to achieve a complete response.

Prevention as an approach to DME may not be so far in the future as one might think, he continued.

“Since anti-VEGF therapy improves nonproliferative diabetic retinopathy severity in all secondary analyses looked at to date, if we eventually treat in this way we may be preventing the onset of DME along with that treatment,” Dr. Aiello said.

Similarly, if an ongoing DRCR.net protocol shows that anti-VEGF therapy is effective at least transiently for proliferative diabetic retinopathy, this might concurrently treat or prevent onset of DME in these patients.

Improved retinal imaging could also enhance DME treatment. Noninvasive visualization at the cellular level, which is now coming close to reality, might detect DME changes before they become clinically relevant, allowing preventive treatment. ■

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Dr. Aiello is a consultant for Genentech, Genzyme, Kalvista, Vantia, Merck & Co., Thrombogenics. He also received grant support from Optos.

Ocular oncology embraces EDI-OCT as valuable tool for clinical imaging

Capabilities enable specialists to identify, diagnose variety of intraocular tumors

By Cheryl Guttman Krader; Reviewed by Carol L. Shields, MD

TAKE-HOME

► Ocular oncologists are using enhanced depth imaging-optical coherence tomography to identify and learn about choroidal tumors.

PHILADELPHIA ::

THANKS TO ITS high resolution and increased depth of visualization into the choroid, enhanced depth imaging-optical coherence tomography (EDI-OCT) is proving itself to be a valuable tool for diagnosing and understanding a variety of intraocular tumors.

Carol L. Shields, MD, described the EDI-OCT characteristics of six intraocular lesions: choroidal nevus, choroidal melanoma, choroidal metastasis, choroidal lymphoma, congenital hypertrophy of the retinal epithelium (CHRPE), and retinoblastoma.

The information was based on analyses of images obtained using commercially available platforms (Heidelberg Spectralis HRA + OCT, Heidelberg Engineering; iVue, Optovue) in patients seen at the Wills Eye Hospital, Philadelphia. Dr. Shields is co-director of the Ocular Oncology Service, Wills Eye Hospital, and professor of ophthalmology, Thomas Jefferson University, Philadelphia.

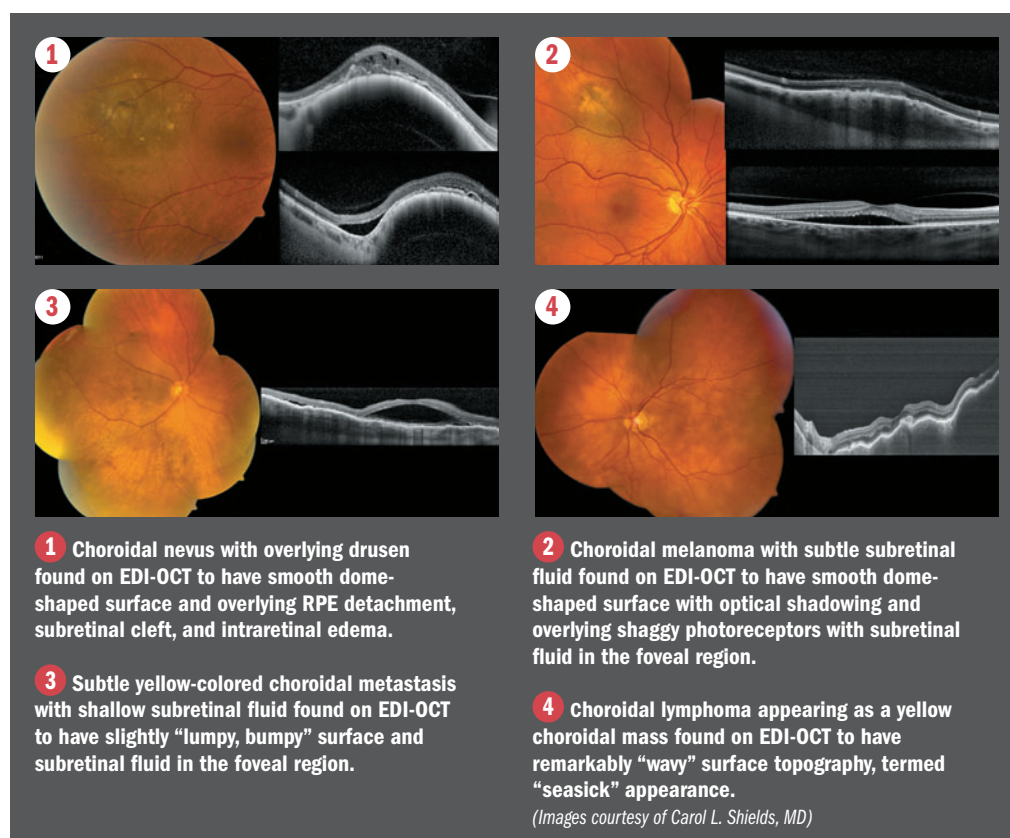
Dr. Shields said that on EDI-OCT, a choroidal nevus appears as a “quiet mound” with a gentle contour and smooth surface, often with an overlying cleft between the retina and retinal pigment epithelium (RPE). (Figure 1)

“This cleft might represent chronic subretinal fluid with retracted photoreceptors,” she said.

OBTAINING SUITABLE IMAGES

However, experience with EDI-OCT shows the technique cannot be used in all patients [Ophthalmology. 2012;119:1066-1072]. In a study including 104 eyes, suitable images were obtained in only about half of patients, Dr. Shields noted.

“Patient cooperation and clear ocular media is important, and so the best patients are younger than 60 years of age with minimal cataract,” she said. “In addition, tumors that are poste-



rior to the equator and <5 mm in diameter seem to be ideal.”

EDI-OCT imaging of choroidal nevi also showed choroidal shadowing in most (94%) as well as choriocapillaris compression (94%), which could be attributed to the tumor’s origin in the outer choroid and inward growth toward the RPE. Detachment of the overlying RPE was seen in 8% of eyes with a choroidal nevus, while photoreceptor loss was observed in 43% of the eyes.

“EDI-OCT gives us the answer as to why some patients with choroidal nevus have poor vision. This could be due to photoreceptor loss,” Dr. Shields said.

EDI-OCT identified overlying shallow subretinal fluid more often than ophthalmoscopic and ultrasonographic exam, but only in a minority of eyes.

Dr. Shields said that the age of the subretinal fluid can be estimated based on the appear-

ance of the photoreceptors. When subretinal fluid is fresh, the photoreceptors appear shaggy from presumed swelling of the tissue or from macrophages on the posterior retinal surface.

As the fluid becomes more longstanding, the photoreceptors take on a stalactite appearance, and when the fluid is very chronic, the photoreceptors completely disappear, leaving a cleft.

SEEING THE DIFFERENCES

Small choroidal melanomas (≤ 3 mm in thickness) share similarities with choroidal nevi in terms of having a mound shape, choroidal shadowing, and choriocapillaris compression.

However, a study comparing the EDI-OCT features of small choroidal melanomas and choroidal nevi showed three significant differences between the two types of lesions with the melanomas being slightly thicker, more often associated with subretinal fluid, and more often

Continues on page 18 : EDI-OCT



ILEVRO™ Suspension

Designed to put potency
precisely where you need it^{1,2}

ONCE-DAILY POST-OP

One drop should be applied once daily beginning 1 day prior to surgery through 14 days post-surgery, with an additional drop administered 30 to 120 minutes prior to surgery³

Use of ILEVRO™ Suspension more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events³

INDICATIONS AND USAGE

ILEVRO™ Suspension is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract surgery.

Dosage and Administration

One drop of ILEVRO™ Suspension should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

IMPORTANT SAFETY INFORMATION

Contraindications

ILEVRO™ Suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

Warnings and Precautions

- Increased Bleeding Time – With some nonsteroidal anti-inflammatory drugs including ILEVRO™ Suspension there exists the potential for increased bleeding time. Ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.
- Delayed Healing – Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including ILEVRO™ Suspension may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- Corneal Effects – Use of topical NSAIDs may result in keratitis. In some patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use.

Patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.

- Contact Lens Wear – ILEVRO™ Suspension should not be administered while using contact lenses.

Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5 to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

For additional information about ILEVRO™ Suspension, please refer to the brief summary of prescribing information on adjacent page.

References: 1. Ke T-L, Graff G, Spellman JM, Yanni JM. Nepafenac, a unique nonsteroidal prodrug with potential utility in the treatment of trauma-induced ocular inflammation. II: In vitro bioactivation and permeation of external ocular barriers. *Inflammation*. 2000;24(4):371-384. 2. Data on file. 3. ILEVRO™ Suspension package insert.

ILEVRO™
(nepafenac ophthalmic
suspension) 0.3%

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EDI-OCT

(Continued from page 16)

exhibiting subretinal fluid with shaggy photoreceptors [*Arch Ophthalmol.* 2012;130:850-856]. (Figure 2 on Page 16)

"We believe the shaggy appearance repre-

sents swollen photoreceptor tips or lipofuscin-laden macrophages clinging to the underside of the photoreceptors," she said.

In contrast to choroidal nevi and choroidal melanomas, choroidal metastases tend to have a subtle "lumpy, bumpy" surface rather than a smooth contour. (Figure 3 on Page 16) In a series of 31 eyes with choroidal metasta-

ses, almost two-thirds had this slightly uneven topography, Dr. Shields noted.

Similar to the nevi and melanomas, the choroidal metastases almost always showed choriocapillaris compression. Photoreceptor loss was also common (64%), as was subretinal fluid (79%), and 7% of eyes with choroidal metastases had debris in the subretinal space.

"With EDI-OCT we can measure the exact thickness of the metastases and [use this] to follow patient response to therapy," she said.

ILEVRO™ (nepafenac ophthalmic suspension) 0.3%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

ILEVRO™ Suspension is indicated for the treatment of pain and inflammation associated with cataract surgery.

DOSAGE AND ADMINISTRATION

Recommended Dosing

One drop of ILEVRO™ Suspension should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

Use with Other Topical Ophthalmic Medications

ILEVRO™ Suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics. If more than one topical ophthalmic medication is being used, the medicines must be administered at least 5 minutes apart.

CONTRAINDICATIONS

ILEVRO™ Suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

WARNINGS AND PRECAUTIONS

Increased Bleeding Time

With some nonsteroidal anti-inflammatory drugs including ILEVRO™ Suspension, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. It is recommended that ILEVRO™ Suspension be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Delayed Healing

Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including ILEVRO™ Suspension, may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Corneal Effects

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including ILEVRO™ Suspension and should be closely monitored for corneal health. Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post surgery may increase patient risk and severity of corneal adverse events.

Contact Lens Wear

ILEVRO™ Suspension should not be administered while using contact lenses.

ADVERSE REACTIONS

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

Ocular Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These events occurred in approximately 5 to 10% of patients.

Other ocular adverse reactions occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment.

Some of these events may be the consequence of the cataract surgical procedure.

Non-Ocular Adverse Reactions

Non-ocular adverse reactions reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects.

Pregnancy Category C: Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 mg/kg/day have revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. At this dose, the animal plasma exposure to nepafenac and amfenac was approximately 70 and 630 times human plasma exposure at the recommended human topical ophthalmic dose for rats and 20 and 180 times human plasma exposure for rabbits, respectively. In rats, maternally toxic doses ≥ 10 mg/kg were associated with dystocia, increased postimplantation loss, reduced fetal weights and growth, and reduced fetal survival.

Nepafenac has been shown to cross the placental barrier in rats.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ILEVRO™ Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic Effects.

Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of ILEVRO™ Suspension during late pregnancy should be avoided.

Nursing Mothers

ILEVRO™ Suspension is excreted in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ILEVRO™ Suspension is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of ILEVRO™ Suspension in pediatric patients below the age of 10 years have not been established.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Nepafenac has not been evaluated in long-term carcinogenicity studies. Increased chromosomal aberrations were observed in Chinese hamster ovary cells exposed *in vitro* to nepafenac suspension. Nepafenac was not mutagenic in the Ames assay or in the mouse lymphoma forward mutation assay. Oral doses up to 5,000 mg/kg did not result in an increase in the formation of micronucleated polychromatic erythrocytes *in vivo* in the mouse micronucleus assay in the bone marrow of mice. Nepafenac did not impair fertility when administered orally to male and female rats at 3 mg/kg.

PATIENT COUNSELING INFORMATION

Slow or Delayed Healing

Patients should be informed of the possibility that slow or delayed healing may occur while using nonsteroidal anti-inflammatory drugs (NSAIDs).

Avoiding Contamination of the Product

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use of the same bottle for both eyes is not recommended with topical eye drops that are used in association with surgery.

Contact Lens Wear

ILEVRO™ Suspension should not be administered while wearing contact lenses.

Intercurrent Ocular Conditions

Patients should be advised that if they develop an intercurrent ocular condition (e.g., trauma, or infection) or have ocular surgery, they should immediately seek their physician's advice concerning the continued use of the multi-dose container.

Concomitant Topical Ocular Therapy

If more than one topical ophthalmic medication is being used, the medicines must be administered at least 5 minutes apart.

Shake Well Before Use

Patients should be instructed to shake well before each use. U.S. Patent Nos. 5,475,034; 6,403,609; and 7,169,767.

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IDENTIFYING HEMANGIOMAS

Hemangiomas, which can be difficult to see clinically and on ultrasound, could be readily identified in most cases with EDI-OCT.

The hemangiomas also had a dome shape and uniformly smooth contour with overlying subretinal fluid.

However, in contrast to the nevi and melanomas, the choriocapillaris and choroidal vessels within the hemangiomas were expanded rather than compressed. Optical shadowing with an indistinct margin and sometimes a small tumor wing into the surrounding tissue was also observed.

Dr. Shields said that choroidal lymphomas showed the most remarkable surface topography on EDI-OCT. The contour of lymphomas varies depending on lesion thickness and can be described using terms relevant to the ocean surface. The thinnest lesions tended to have a flat or "placid" contour, while those measuring about 2 to 3 mm thick were mostly "rippled," and those that were thicker had a more wavy or "seasick" appearance. (Figure 4 on Page 16)

EDI-OCT characteristics of congenital hypertrophy of RPE were described based on imaging performed in a series of 18 eyes. Studies showed all of the lesions were flat, associated with photoreceptor loss, and had a normal choroid. A subretinal cleft was seen in about one-third of eyes. In no case was there subretinal fluid.

Comparing images obtained with time domain and EDI-OCT, Dr. Shields demonstrated how lacunae transmission can be seen much better with the latter technology, and she also showed the 1:1 correlation between the CHRPE margin and area of abnormal photoreceptors.

Images of retinoblastomas were obtained with a portable handheld EDI-OCT instrument. They showed an exophytic mass overlaid with normal retina. ■

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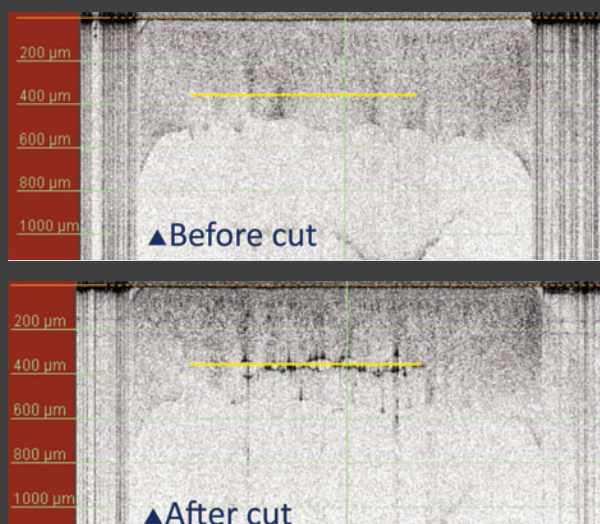
Dr. Shields has no financial interest in the material she presented.

STATE-OF-THE-ART Special Report) REFRACTIVE SURGERY UPDATES

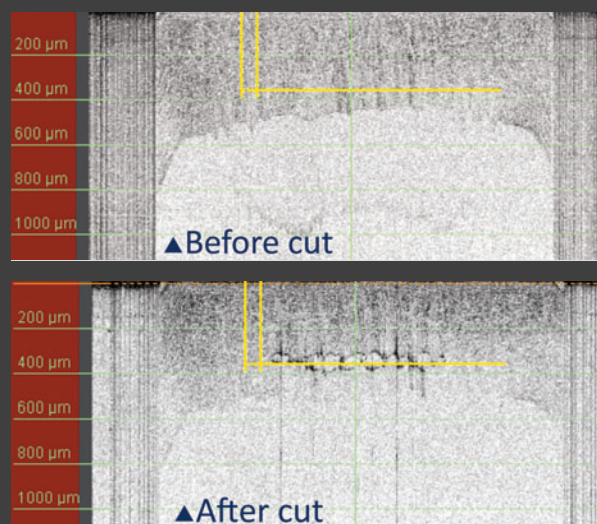
TECHNOLOGIES AND TREATMENTS ADVANCE FOR IMPROVED REFRACTIVE OUTCOMES

OCT Zoom After Laser Ablation

Horizontal Scan



Vertical Scan



Tunnel formation can be confirmed by comparing images of the endothelium before and after ablation (bubbles will be absent before ablation, whereas they will be present after ablation) (Images courtesy of Minoru Tomita, MD, PhD)

MINIMIZING POSTLASIK ECTASIA WITH MAXIMIZED REFRACTIVE TECHNOLOGY

How OCT-guided femtosecond laser intracorneal ring implantation works for high-volume center

By Minoru Tomita, MD, PhD, Special to Ophthalmology Times

take-home

► Intracorneal ring surgery, when combined with an optical coherence tomography-guided femtosecond laser, will be a boon to centers providing high-volume LASIK and keratoconus treatment, relates one surgeon.

As director of a very high-volume LASIK center—where surgeons have operated on more than 1 million patients and continue to perform 5,000 LASIK procedures a month—postLASIK ectasia is a significant concern of mine.

To minimize the occurrence of postLASIK ectasia, the approach in our center has been to focus on patient selection. Patients undergo a variety of thorough tests before surgery to exclude those

with risk factors for postLASIK ectasia, such as high myopia, reduced preoperative corneal thickness, and asymmetrical corneal steepening. As a result, we have been able to reduce the incidence of ectasia after LASIK to about 1 in every 20,000 patients.

However, for those patients who do develop ectasia, our preferred mode of treatment includes use of an intracorneal ring segment (ICRS) (Keraring, Mediphacos). We also use the implant to treat patients who present with keratoconus.



Dr. Tomita

ABOUT THE DEVICE

The polymethyl methacrylate-based ICRS is designed for the treatment of ectatic corneal disorders, such as keratoconus and ectasia. Implanted within the cornea, the device is designed to correct corneal surface irregularities, improve uncorrected and best-corrected visual acuity, and reduce refractive errors by flattening the cornea.

The ICRS is available in a variety of shapes and sizes, allowing surgeons to customize the implant according to patients' corneal parameters. The device comes in two optical zones of

(Continues on page 20 : PostLASIK ectasia)

Special Report) STATE-OF-THE-ART REFRACTIVE SURGERY UPDATES

Just Before Making Tunnels



Surgeons can confirm the endothelium of the applanated cornea. With real-time optical coherence tomography Imaging, tunnels are created at depths that can be visually confirmed in the x/y axis window. (Images courtesy of Minoru Tomita, MD, PhD)

POSTLASIK ECTASIA

(Continued from page 19)

5 and 6 mm (SI5 and SI6, respectively); five arc lengths of 90°, 120°, 160°, 210°, and 355°; and five thicknesses of 150, 200, 250, 300, and 350 µm. This affords physicians several combinations to match more closely with patients' needs.

When the device was first made available, the main mode of implantation was mechanical dissection of the cornea with surgical in-

struments for creating the tunnel into which the ring was subsequently inserted.

Although manual tunnelling is an effective option, care needs to be taken when using this approach. Due to the number of steps involved in this manual technique, there can be a potential for complications, such as epithelial defects, perforation, and infectious keratitis, especially early in the learning curve.¹

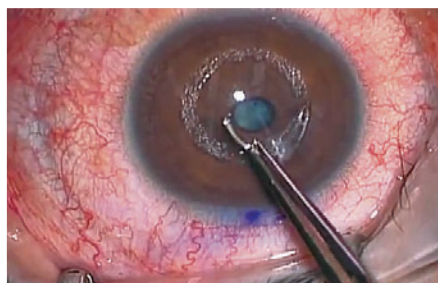
TECHNOLOGY ADVANCES

The advent of femtosecond laser provided surgeons with a faster, less invasive, and more consistent means for tunnel creation.

The laser provides greater flexibility in making tunnels of multiple sizes and depths anywhere in the cornea with superior accuracy and quality.

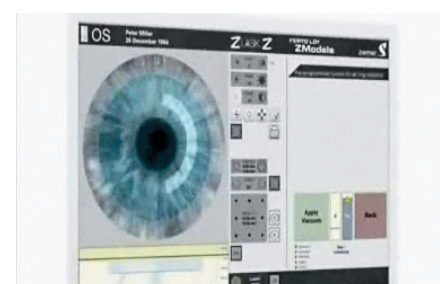
However, through our experience we have learned that certain complications, such as endothelial perforation, still remain a concern. The main reason for the continuing incidence of this complication is surgeons' inability to visualize the depth of the tunnel during its creation. Although this complication occurs at a rather low frequency—for instance, studies have reported frequencies of endothelial perforation of 0.6% to 1.7% during ICRS implantation^{2,3}—at a high-volume center like ours small percentages still translate into large numbers of patients.

ICRS INSERTION



VIDEO To watch a video clip showing insertion of the intracorneal ring segment, go to <http://bit.ly/1mPeV8E>. (Video courtesy of Minoru Tomita, MD, PhD)

TUNNEL CREATION



VIDEO The system provides a visual plan of the intended tunnel. Go to <http://bit.ly/1fijXds>. (Video courtesy of Minoru Tomita, MD, PhD)

We have recently begun using an optical coherence tomography (OCT)-guided femtosecond laser (Z6, Ziemer Ophthalmic Systems) to implant the ICRS. This system allows surgeons to visualize the endothelium both before and during laser ablation, a feature that further minimizes the risk of endothelial perforation.

More specifically, the OCT component of the system lets surgeons confirm the integrity of the endothelium of the applanated cornea before making the tunnel and to view its depth in real time in the x- and y-axis windows.

The system also provides a visual plan of (Continues on page 23 : Cases)



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How technology is making IOL power calculation simpler, more accurate

Intraoperative aberrometry, regression analysis helps eyes with long, short axial lengths

By **Lynda Charters**; Reviewed by **Eric D. Donnenfeld, MD**

NEW YORK ::

CALCULATING IOL powers has become simpler and more accurate in the most difficult cases—eyes with long and short axial lengths—with use of intraoperative aberrometry and an optimized method of regression analysis.

“IOL calculation is paramount for obtaining good refractive results,” said Eric D. Donnenfeld, MD.

Dr. Donnenfeld reviewed the literature on refractive outcomes after IOL implantation. In one recent large study of more than 17,500 eyes conducted by Behndig and colleagues (*J Cat Refract Surg.* 2012;38:1181-1186) it was found that the mean average refractive prediction error was 0.5 D. Only 55% of eyes achieved this refractive target, and that percentage was a global one in a population that included eyes with all axial lengths.

“Calculating the IOL power in long and short eyes is less predictable,” said Dr. Donnenfeld, founding partner of Ophthalmic Consultants of Long Island and Connecticut, clinical professor of ophthalmology, New York University Medical Center, New York, and a trustee of Dartmouth Medical School.

He reported the postoperative refractive results using a new method of calculating IOL powers for eyes with long and short axial lengths using intraoperative aberrometry (ORA System, WaveTec Vision) and a refined method of regression analysis.

Regression coefficients are then applied as part of the calculation process used to calcu-

late the effective lens position. Each lens has a unique set of regression coefficients so that each lens must be studied.

As more cases are added to the study, he noted, the regression analysis can be increasingly refined.

Dr. Donnenfeld and his colleagues have refined the optimized lens models for different axial lengths, specifically in six axial length groups: 21.99 mm or less (short eyes), 22 to 22.99 mm, 23 to 23.99 mm, 24 to 24.99 mm, 25 to 25.99 mm, and 26 mm or more (long eyes).

RETROSPECTIVE STUDY

The investigators conducted a retrospective multicenter analysis of outcomes achieved with a specific IOL (AcrySof IQ SN60WF, Alcon Laboratories). The study included two groups: group 1, in which they evaluated a pre-refined optimization process that was not specific for the six axial length groups; and group 2, in which they evaluated a post-refined optimization process using a formula that was refined for each axial length group.

In both groups, special attention was paid to the long and short eyes. The IOL power calculations were performed using the aberrometer, which Dr. Donnenfeld said he believes is an “indispensable” operating room tool for determining refractive outcomes and honing his refractive results.

He reported that in group 1 (pre-refined optimization) with 3,046 eyes, 80% had 0.5 D or less of ametropia with a mean average refractive prediction error of 0.32 D.

“(However), with those eyes, the prediction value of intraoperative aberrometry and the various formulas used to calculate the IOL powers broke down,” Dr. Donnenfeld said.

When the investigators looked specifically at the short eyes, the results before optimization showed that the outcomes were within

0.5 D of emmetropia in 60% of the 119 short eyes and in about 79% of the 189 long eyes in that group.

In group 2 (post-refined optimization) that included 142 short eyes and 227 long eyes, he pointed out a notable increase in the percentage of short eyes that were within 0.5 D or less of emmetropia (i.e., 73%). Eighty-one percent of the long eyes reached that benchmark.

Globally, in 4,184 eyes that were analyzed post-refined optimization, 82% of eyes were within 0.5 D of emmetropia, he noted.

“This is an extraordinarily good result and much better than that reported in the literature,” Dr. Donnenfeld said.

When the data were optimized further with the newest intraoperative aberrometry with new monitoring hardware (VeriEye, WaveTec Vision), that global figure increases to 86%, he added.

“This technology is valuable for improving refractive outcomes in some of the most difficult cases managed on a daily basis, the high hyperopes and high myopes,” Dr. Donnenfeld said.

WaveTec’s refined optimization process, used with measurements provided by the aberrometer, improved the refractive outcomes in eyes with unusual axial lengths that received the SN60WF IOL, he said. Improvements were also seen globally in eyes that did not have short or long axial lengths.

The aberrometer with its recently introduced hardware—using the same refined optimized process—provided improved outcomes compared with the use of the aberrometer alone.

“The case for the use of intraoperative aberrometry is now indisputable because it allows analysis of posterior corneal astigmatism, the cylinder induced by incisions, and provides results that look at the visual axis rather than the corneal vertex,” Dr. Donnenfeld said. ■



Dr. Donnenfeld

take-home

► **Calculating IOL powers has become simpler and more accurate in eyes with long and short axial lengths with use of intraoperative aberrometry and an optimized method of regression analysis.**

THE IOL POWER FORMULA

The aberrometer measures the aphakic refraction and not the axial length. Dr. Donnenfeld explained that the formula incorporates the aphakic spherical equivalent into a refractive vergence formula.

Regression coefficients are then applied as part of the calculation process used to calcu-

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CASES

(Continued from page 20)

the intended tunnel. Tunnel creation can then be followed in real time through the appearance of bubbles.

Tunnel formation can also be confirmed by comparing images of the endothelium before and after ablation (bubbles will be absent before ablation, whereas they will be present after ablation).

Insertion of the corneal ring into the tunnel created with this system is very simple.

CASE REPORTS

Initial results with the OCT-guided femtosecond laser system have convinced us that ring implantation with this system can ameliorate ectasia while eliminating the occurrence of endothelial perforations.

Two case reports demonstrate the safety and efficacy of using the ring in combination with the OCT-guided system.

■ The first patient is a 33-year-old woman with keratoconus in her left eye. Preoperative exams revealed good visual acuity—uncorrected distance visual acuity (UDVA) of 1.0 decimal and corrected distance visual acuity (CDVA) of 1.5 decimal. She had a Kmax of 46.60 D and a Kmean of 44.40 D.

■ The second patient was a 22-year-old woman with ectasia in her left eye. She had UDVA of 0.15 decimal, CDVA 0.70 decimal, Kmax 49.10 D, and Kmean 42.00 D.

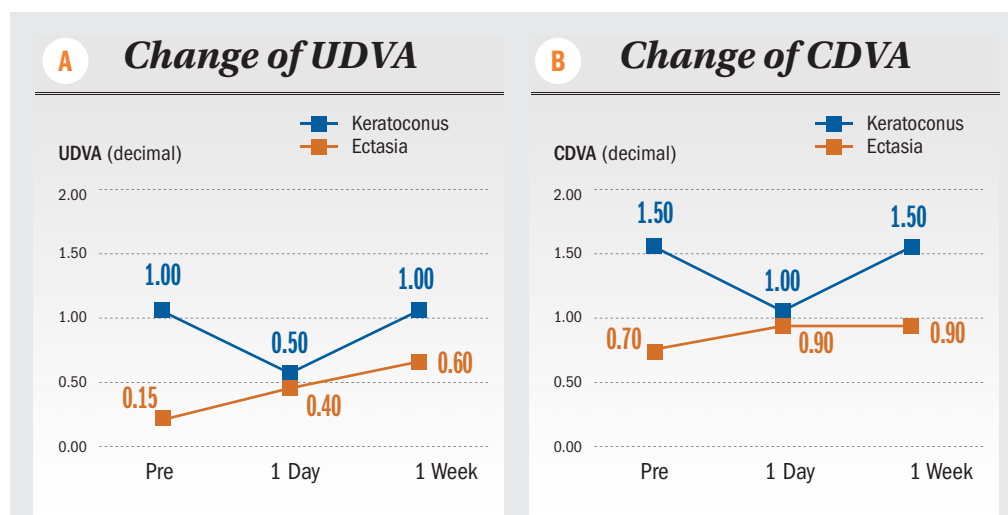
On account of the topographies, we decided to implant the device (SI5 Keraring) with an arc length of 160° and a thickness of 200 μm in both patients.

Although the patient with keratoconus showed a transient drop in UDVA and CDVA 1 day after surgery, she had complete restoration of her distance vision by 1 week postoperatively, achieving the same distance visual acuity as before surgery (Figure 1A and 1B).

The patient with ectasia, having gone into surgery with low visual acuity, showed a gradual improvement of UDVA and CDVA after surgery, with UDVA reaching 0.6 decimal and CDVA reaching 0.9 decimal 1 week after surgery (Figure 1A and 1B).

In terms of topography, the patient with keratoconus who had inferior temporal placement of the ring showed an improvement of 5.3 D a week after surgery (Figure 2A).

In the patient with ectasia, we implanted the



(FIGURE 1) Change of **A** uncorrected distance visual acuity and **B** corrected distance visual acuity in the two patients after intracorneal ring segment implantation. (Tables courtesy of Minoru Tomita, MD, PhD)

ring inferiorly. At 1 week postoperatively she, too, showed a substantial improvement in K value of 6.5 D (Figure 2B).

The implantation procedure was simple and straightforward, and the patients' corneal curvatures were improved.

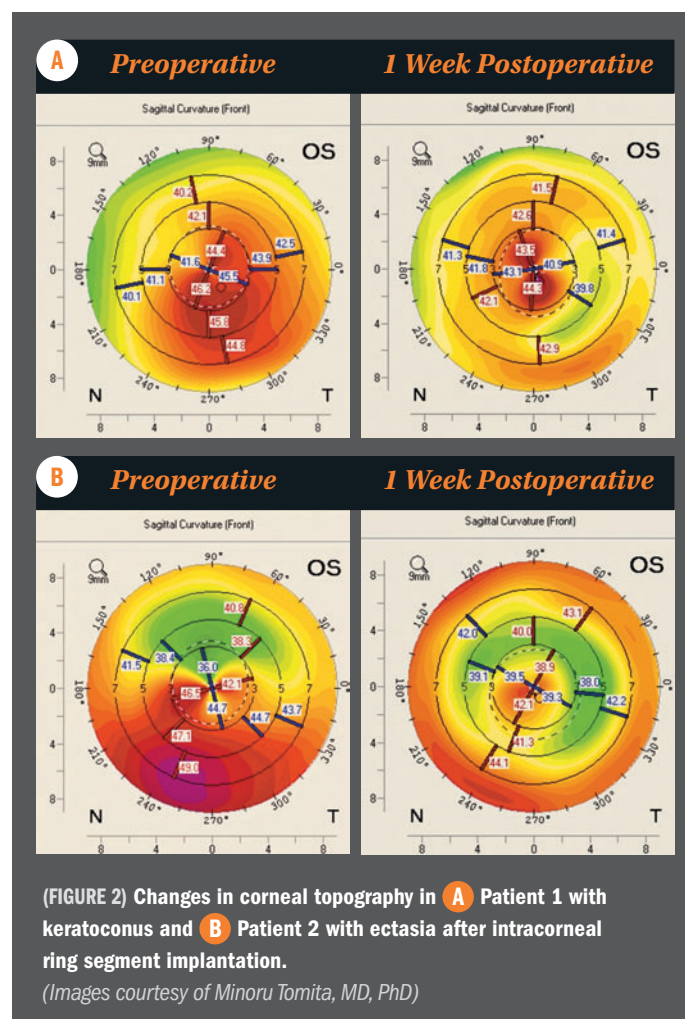
In both cases, the ring was effective in improving visual acuity and keratometric readings. Furthermore, use of the OCT-guided system simplified the implantation of the ring and eliminated the risk of endothelial perforation.

CONCLUSION

The marriage between an established solution for keratoconus/ectasia—an ICRS and an OCT-guided femtosecond laser system for implantation—will simplify corneal ring surgery and make it safer in the future. This combination will be a boon to centers providing high-volume LASIK and keratoconus treatment. ■

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(FIGURE 2) Changes in corneal topography in **A** Patient 1 with keratoconus and **B** Patient 2 with ectasia after intracorneal ring segment implantation.

(Images courtesy of Minoru Tomita, MD, PhD)

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How the flapless SMILE procedure provides improved optical quality

Surgery also retains more postoperative corneal tensile strength after completion

By Cheryl Guttman Krader; Reviewed by Dan Z. Reinstein, MD, MA

THE CORNEAL TENSILE strength after surgery is much greater after small-incision lenticule extraction (SMILE)—a flapless refractive procedure performed using a proprietary femtosecond laser (VisuMax, Carl Zeiss Meditec) to cut an intrastromal lenticule that is removed through a small, 2- to 3-mm incision—than LASIK or PRK for an equivalent tissue removal, said Dan Z. Reinstein, MD, MA.



Dr. Reinstein

The flapless nature of the procedure means that anterior stromal lamellae remain uncut, with the added benefit of the anterior stroma being the strongest part of the stroma.

“With its flap and ablation, LASIK severs the stromal lamellae at its strongest region, whereas SMILE leaves the most anterior stromal lamellae intact,” said Dr. Reinstein, medical director, London Vision Clinic, London, and clinical professor of ophthalmology, Columbia University Medical Center, New York.

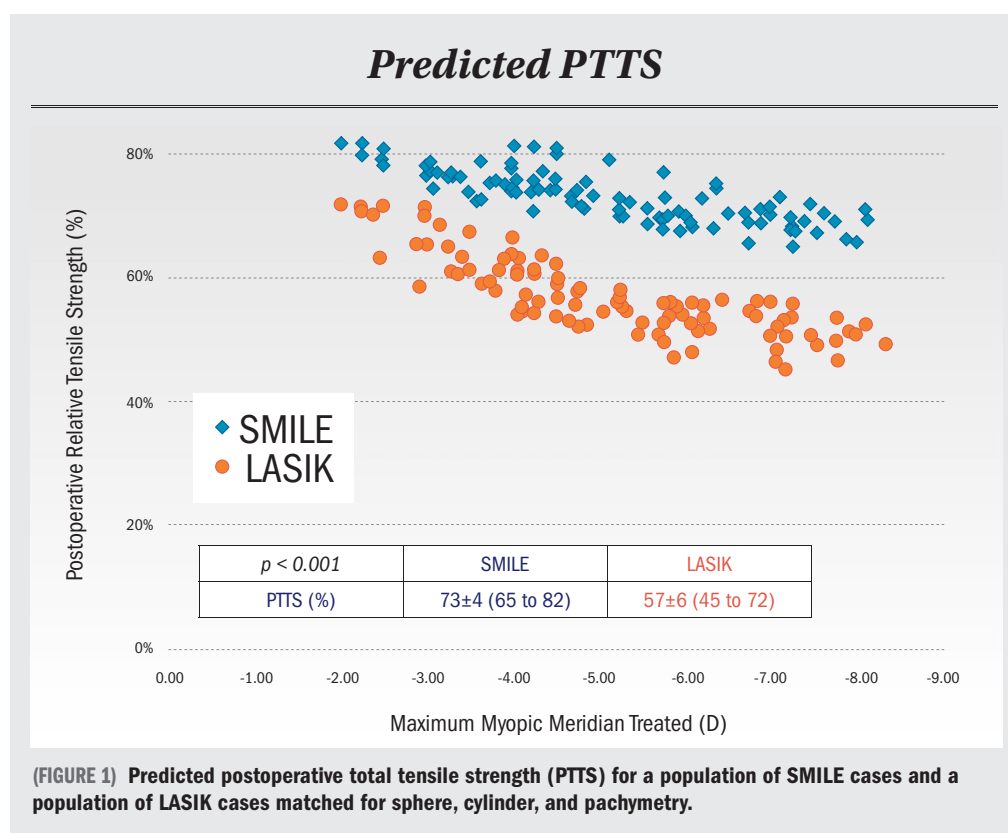
SMILE ADVANTAGES

In fact, he said the difference in tensile strength is enough that the cornea is still significantly stronger after SMILE than LASIK even when a larger optical zone is used in SMILE (i.e., greater tissue removal)—which enables less spherical aberration induction and therefore better optical quality, according to the results of a comparative study reported by Dr. Reinstein.

“With its benefits for maintaining greater corneal strength postoperatively and inducing less spherical aberration, SMILE allows higher levels of myopia to be treated with greater optical and biomechanical safety compared with LASIK,” he said. “Therefore, we believe SMILE should raise the bar for the level of myopia at which phakic IOL implantation becomes the preferred procedure over laser vision correction.”

RESULT EVALUATION

Dr. Reinstein analyzed the relative postoperative total tensile strength (PTTS) after myopic



(FIGURE 1) Predicted postoperative total tensile strength (PTTS) for a population of SMILE cases and a population of LASIK cases matched for sphere, cylinder, and pachymetry.

correction with SMILE and LASIK in matched cohorts of 96 eyes each.

The calculations were based on a mathematical model developed by Dr. Reinstein and colleagues (*J Refract Surg.* 2013;29:454-460) that uses published data on cohesive tensile strength as a function of corneal depth to determine the remaining tensile strength following tissue ablation/removal.

To further illustrate the relative effects of the different procedures on corneal total tensile strength, Dr. Reinstein presented data from his published paper which compared the change in tensile strength as a result of removing 100 μ m of stroma via ablation (LASIK or PRK) or as a lenticule (SMILE) from a 550- μ m thick cornea.

take-home

► Results of a study comparing matched groups of eyes undergoing myopic correction by small-incision lenticule extraction (SMILE) or LASIK show that the optical quality was better and the cornea retained higher tensile strength after the flapless SMILE procedure.

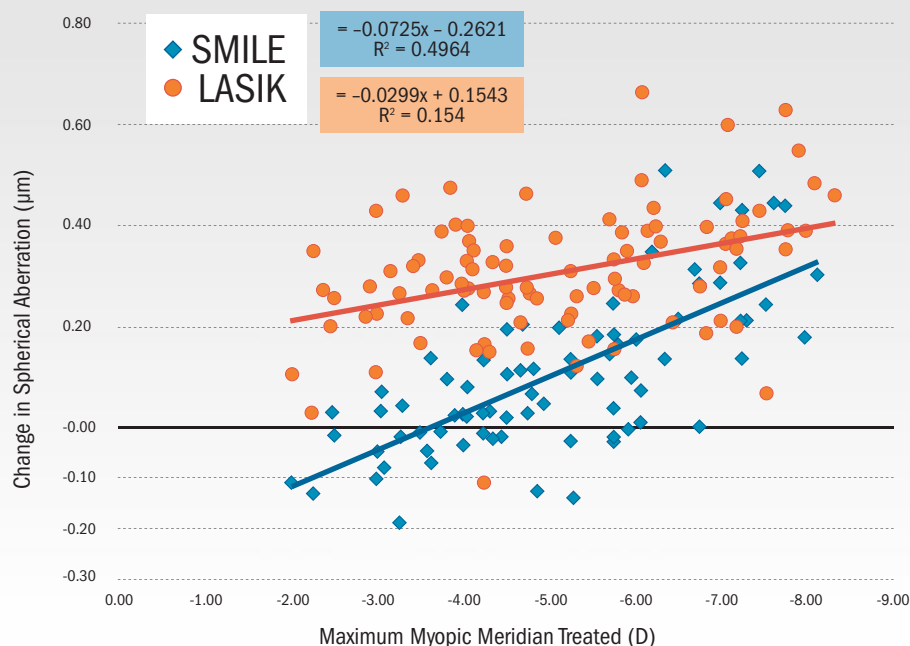
Using the mathematical model, the calculated postoperative PTTS was 75% after SMILE performed with a 130- μ m cap, 68% for PRK, and 54% for a thin-flap (100 μ m) LASIK procedure.

MORE ANALYSIS

In a further analysis, the SMILE and LASIK eyes were matched by sphere (± 0.25 D), cylinder (± 0.25 D), and pachymetry (± 20 μ m). Mean values for SEQ, cylinder, and pachymetry in both groups were approximately -4.83 D, 0.56 D, and 540 μ m, respectively.

The mean \pm SD thickness of the cap in the SMILE group was 130 ± 6 μ m and the LASIK group had a mean flap thickness of 96 ± 12 μ m. Mean OZ diameter

Change in Spherical Aberration



(FIGURE 2) Change in spherical aberration for the matched SMILE and LASIK populations.

(Figures courtesy of Dan Z. Reinstein, MD, MA)

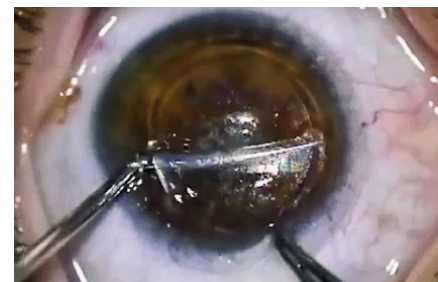
was 6.7 ± 0.39 mm for SMILE and 6.08 ± 0.22 mm for LASIK. Mean (range) lenticule thickness was $107 \mu\text{m}$ (72 to 149) for SMILE, while the LASIK group had a mean ablation depth of $81 \mu\text{m}$ (25 to 134).

Mean PTTS in the SMILE and LASIK groups

was 73% (65% to 82%) and 57% (45% to 72%), respectively.

Across the entire range of myopia treated (up to -8 D), PTTS was about 16% greater on average in the SMILE eyes compared with the LASIK group.

SMILE PROCEDURE



VIDEO To watch a video clip of the small-incision lenticule extraction (SMILE) procedure, go to <http://bit.ly/1jY6EzN>. (Video courtesy of Dan Z. Reinstein, MD, MA)

Analyses of higher-order aberration data confirmed that SMILE induced significantly less spherical aberration than LASIK.

Mean change from baseline spherical aberration was $0.11 \pm 0.16 \mu\text{m}$ in the SMILE eyes and $0.31 \pm 0.12 \mu\text{m}$ after LASIK. ■



Weigh in on the flapless SMILE procedure at [Facebook.com/OphthalmologyTimes](https://www.facebook.com/OphthalmologyTimes).

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Fuchs' endothelial dystrophy: Taking a step back to go forward

By Lynda Charters

ROTTERDAM, NETHERLANDS ::

THE FUTURE OF TREATING Fuchs' endothelial dystrophy may be evolving, said Gerrit R.J. Melles, MD, PhD.

"Perhaps we should take a step back to determine what we are actually treating," said Dr. Melles, director, Netherlands Institute for Innovative Ocular Surgery, Rotterdam. "Does Fuchs' endothelial dystrophy actually exist? Is it an actual dystrophy or is it something else?"

If the disorder is not a dystrophy and can be reversed, this may open the door to a different treatment, he suggested.

Descemet's membrane endothelial keratoplasty (DMEK) and Descemet's membrane endothelial transfer (DMET) are the two most

recent procedures used to treat Fuchs' endothelial dystrophy.

Many surgeons are switching from Descemet's stripping endothelial keratoplasty (DSAEK) because of the high best-corrected visual acuities (BCVAs) achieved with DMEK.

Patients with poor BCVA after DSAEK can achieve high visual acuity after a subsequent DMEK, while the refractive stability is stable after DMEK.

Potential complications of DMEK can be a decreased endothelial cell count, early graft detachment, and secondary glaucoma. The DMET procedure, however, may be the future of treating Fuchs' endothelial dystrophy.

Dr. Melles explained that in these patients, the corneas began clearing 3 months after DMET and the cornea was "fairly normal" after 6 months. However, he said this approach does not work in patients with bullous keratopathy.

"This spontaneous corneal clearing suggests that the host cells must be involved somehow in the corneal clearing or redistribution of the endothelial cells postoperatively," he said.

This then raises the question about what actually is being treated.

"Are we treating a dystrophy or are we treating something else that possibly can be managed another way? Is a topical drop a possible therapy?" Dr. Melles said. ■

Special Report) STATE-OF-THE-ART **REFRACTIVE SURGERY** UPDATES**ACCOMMODATION**

(Continued from page 1)

Based on years of research and experimentation on cadaver eyes and in animal, the first clinical trials were performed by Harvey Uy, MD, in the Philippines in late 2011.

Through this research, Dr. Krueger is convinced that accommodation can be restored without causing significant lens opacities.

"Reliable and significant accommodation restoration is theoretically possible and clinically promising with femto-second laser lens treatment," Dr. Krueger said.



Dr. Krueger

"In the absence of any cataracts and significant symptoms, it certainly warrants further testing with the commercial system being used in laser cataract surgery and with new laser patterns to see if we can get clinical efficacy in restoring accommodation," he added.

PREMISE FOR CONCEPT

The primary concept dates back to an article published in 1998 on the feasibility of using short-pulse lasers to create greater flexibility in the crystalline lens as a prelude to restoring accommodation. This early testing led to a finite element treatment model and additional mechanical testing on human cadaver lenses, in which it was learned that a 2.2 to 8.5 D change in power could be achieved.

Next, a primate study found no progressive cataract formation even when the animals were treated at high-energy levels (energy 25 to 45 μ J/pulse and 2.0 to 11.3 M pulses per lens).

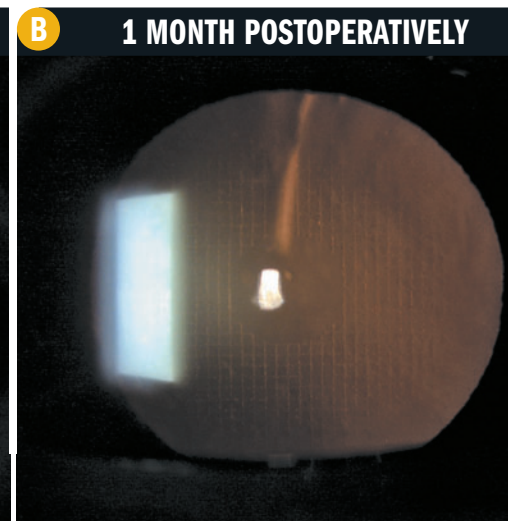
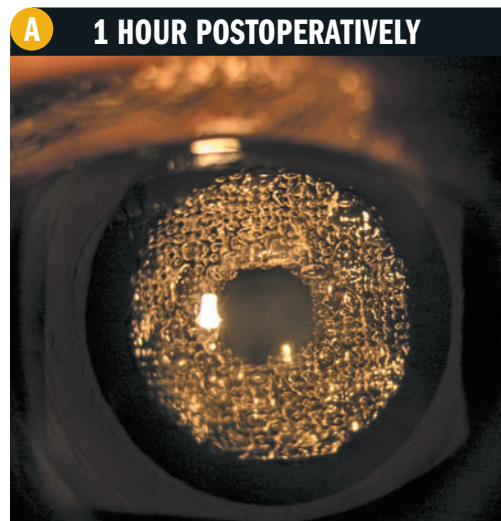
An Nd:vanadate picosecond laser (10 ps) with prototype delivery system was used in this study and a subsequent phase I clinical trial at the Asian Eye Institute in the Philippines in late 2009 and 2010.

In the first series of 5 eyes, one patient had 1.62 D of objective accommodation after treatment; two had about 0.50 to 0.75 D of accommodation, and the remaining two had no change.

In the subsequent phase of the clinical trial, 80 presbyopic patients were treated unilaterally with a range of treatment algorithms (energy 10 μ J/pulse and 0.45 to 1.45 M pulses per lens). All subjects had \leq Grade 2 cataract and had already elected to have lens replacement

take-home

► The goal of restoring accommodation in presbyopic eyes with femtosecond laser treatment seems to be getting closer.



IN VIEW: Anterior "waffle fries" pattern of laser pulses with a 2-mm diameter zone of central sparing seen at **A** 1 hour and **B** 1 month postoperatively. The early pattern of bubbles disappears within the first 24 hours, leaving only a faint, translucent micro-opacity with no progressive cataract. (Images courtesy of Ronald R. Krueger, MD)

surgery after a follow-up of at least 1 month following the laser application.

Dense patterns of bubbles appeared in some eyes after surgery, but later resolved. No progressive opacity was observed among the eyes with only 1 month of follow-up, and even in one patient who postponed the lens replacement surgery for up to 18 months following the laser treatment.

Patients whose eyes experienced laser-induced gas bubbles in the visual axis reported the most severe visual side effects, but these symptoms abated as the bubbles cleared.

The change in objective accommodation in subjects who improved over baseline was a mean of 0.62 D at 1 month in 51% of the subjects, Dr. Krueger noted.

The change in subjective accommodation was similar, 0.70 D in 58% of patients, although one patient improved by 3.62 D.

The mean improvement in best distance-corrected near visual acuity at 1 month was 6 letters in 42% of patients, and the maximum was up to 5 lines.

For his 2012 American Ophthalmological Society thesis, Dr. Krueger described his work to date and concluded that laser disruption could cause pinpoint micro-opacities but not progressive cataract, although it would be preferable to treat eyes that did not have any pre-existing cataract.

He also noted it was unlikely the laser treatment would lead to vision-threatening cataract, but to achieve this, the center of the crystal-

line lens should be avoided to minimize any symptoms generated from the pinpoint opacities that were otherwise reported in this group.

GETTING CLOSER

Though these studies were performed with a prototype laser in the picosecond range, a commercial system has been approved for equivalency within the femtosecond range to refine laser delivery, Dr. Krueger said. The first procedure performed with the LensAR femtosecond laser took place in Birmingham, England, last fall.

Sunil Shah, MD, performed the procedure in a 50-year-old patient with high hyperopia with astigmatism. As a result, there was a small change in refraction, and uncorrected visual acuity improved from 12 letters preoperatively to 27 letters 1 week postoperatively.

Another group of investigators is also working on restoration of accommodation by laser surgery, using a three-dimensional intralenticular cutting system that creates sponge-like compression joints and sliding joints. Omid Kermani, MD, Rudolf F. Guthoff, MD, and Holger Lubatschowski, PhD, conducted a study of 30 eyes at two sites in Germany.

Using wavefront-sensing and optical coherence tomography, the investigators have been able to document some additional power change and change in thickness of the lens during accommodation, Dr. Krueger said. ■

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Dr. Krueger is a consultant for Alcon Laboratories and LensAR, as well as a co-founder and investor in LensAR.

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TransPRK safe, effective at 1 year

Procedure a useful alternative for those wanting faster healing, less postoperative pain

By Fred Gebhart; Reviewed by Jung Sub Kim, MD

SEOUL, SOUTH KOREA ::

TRANSEPITHELIAL PHOTOREFRACTIVE KERATECTOMY (TransPRK) is a safe and effective alternative to other refractive procedures to treat myopia that involve mechanical manipulation of the epithelium, according to 12-month data from a South Korean prospective study.

This all-laser version of PRK showed similar visual and predictive results compared with LASEK and types of PRK that involve mechanical or alcohol-based removal of epithelium. However, it offered faster operative times, faster healing, less haze, and less postoperative pain than the more conventional and more invasive procedures.

Transepithelial PRK with a 750-Hz excimer laser (Amaris, Schwind eye-tech-solutions) is a modified no-touch, continuous single-step technique for combined epithelial and stromal ablation, according to Jung Sub Kim, MD, B&VIIT Eye Center, Seoul, Korea. The platform removes corneal epithelium with a modified PTK mode, which is different from other surface ablation refractive surgical techniques that use a brush, alcohol, and other methods.

UNDERSTANDING TRANSPRK

The excimer laser platform used has been approved for use in Asia and the European Union, but has not been approved for clinical use in the United States.

TransPRK is the next step in the development of surface manipulation, using manual debridement or alcohol-assisted debridement, Dr. Kim said, as laser ablation of the epithelium is faster and more precise than other methods.

The all-laser system combines epithelial ablation and the refractive laser treatment in a single step, which reduces operative time. The no-touch technique is gentler on the eye, which translates into faster healing and faster restoration of visual acuity.



Dr. Kim

take-home

► According to recent study results, transepithelial photorefractive keratectomy is a better alternative procedure than other refractive methods when treating myopia that involves epithelium mechanical manipulation.

The mean corneal epithelial thickness is 53 μ m at the center and 63 μ m at the 8-mm periphery, he continued.

The Amaris PTK ablation target is 55 μ m centrally and 65 μ m at the periphery of the 8-mm ablation zone. The single-step ablation not only reduces operative time, but reduces the risk of dehydration between steps that is part of most other refractive surgical techniques.

EXAMINING THE STUDY

Dr. Kim and his colleagues treated 381 eyes of 159 patients with a mean age of 27.2 years. The cohort included 68 males and 91 females. The mean preoperative spherical refraction was -4.12 D, the mean cylindrical refraction was -0.63 D, and the corrected visual acuity was 20/20 or better for all patients.

Patients with corneal epithelial pathology, keratoconus, ocular inflammation, glaucoma, or posterior segment pathology were excluded.

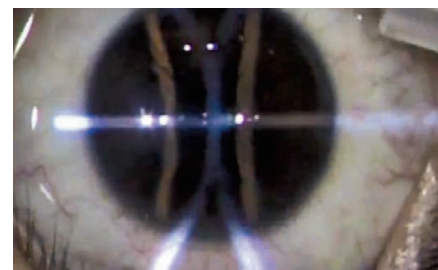
All patients received mitomycin-C (0.01% for 10 to 25 seconds), a soft bandage contact lens for 3 to 4 days as needed, topical levofloxacin 4 times daily for 2 weeks, and fluorometholone (0.1%) 6 times daily after epithelial closure, and tapered over 3 to 4 months.

Postoperative pain was assessed by patient report. Epithelial healing was evaluated by daily slit lamp exam until re-epithelialization was complete. Uncorrected visual acuity, best-corrected visual acuity, remaining refractive error, and corneal haze were evaluated at 3 or 4 days, 3 weeks, and 2, 6, and 12 months following surgery.

RESULTS

Dr. Kim reported that 95.5% of patients had complete epithelial healing at 3 days postoperatively, and all patients showed complete epithelial healing by 4 days. At 12 months, 4 eyes had evidence of grade 1 haze and 1 eye had grade 2 haze. At 12 months, 99.1% of patients had 20/20 or better uncorrected visual acuity. Nearly all patients showed progressively improving visual acuity from 3 weeks through

TRANSPRK PROCEDURE



VIDEO To watch a video clip of the transepithelial photorefractive keratectomy procedure, go to <http://bit.ly/1ddStRs>. (Video courtesy of Jung Sub Kim, MD)

the 2-, 6-, and 12-month exams. Refractive results were excellent and highly predictable. At 12 months, 98.5% of patients were within 0.5 D of the preoperative spherical equivalent target, 96.2% were within 0.5 D of the spherical refraction target and 94.8% were within 0.5 D of the cylindrical refraction target. Results were also extremely stable. Most patients, 97.8%, had a change in spherical equivalent of 0.5 D or less from 2 months postoperatively to 12 months after surgery.

While the outcomes from the excimer laser are highly positive, the instrument is not ideal for all patients, Dr. Kim noted. It is less useful in patients with abnormal or uneven epithelial thickness resulting from scarring due to prior procedures or corneal pathology. The study also did not attempt to evaluate high order aberrations or make direct comparisons with other surface ablation techniques.

"This study, like many others around the world, show that transepithelial PRK using the [laser] platform showed very good effectiveness, safety and predictability, faster epithelial healing, and less postoperative pain than we see in the literature for other types of refractive surgery," Dr. Kim said. "It is a very useful alternative for the patient who wants faster healing and less postoperative pain." ■

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Dr. Kim reported no conflicts of interest.

ISAK safe, predictable for reducing low amounts of corneal astigmatism

Femtosecond laser astigmatic keratotomy can decrease astigmatism to refractively negligible levels

By **Lynda Charters**; Reviewed by **William W. Culbertson, MD**

MIAMI::

CORNEAL ASTIGMATISM CAN be decreased significantly by intrastromal femtosecond laser astigmatic keratotomy (ISAK). The procedure has proven to be safe and predictable for reducing low levels of astigmatism induced after cataract surgery or naturally occurring astigmatism.



Dr. Culbertson

There are both advantages and disadvantages for using femtosecond laser technology to create astigmatic relaxing incisions, said William W. Culbertson, MD, the Lou Higgins Professor of Ophthalmology, Bascom Palmer Eye Institute, University of

Miami Miller School of Medicine, Miami.

POSITIVES, NEGATIVES OF TECHNOLOGY

On the plus side, the technology can provide a precise arc length, axis placement, optic zone, and depth of treatment. Anterior penetrating relaxing incisions are titratable in position and depth; non-orthogonal astigmatism can be treated with the femtosecond laser unlike with the use of a toric IOL; and intrastromal incisions are possible.

On the negative side, the laser is expensive and intrastromal incisions may interfere with LASIK procedures in the future.

One use of the femtosecond laser, ISAK, is associated with a number of advantages. According to Dr. Culbertson, the procedure:

- Is minimally invasive
- Causes no discomfort or epithelial ingrowth
- Has a lower infection risk
- Possible minimal loss of corneal sensation
- Has a high rate of patient satisfaction

The procedure, however, is presently limited to lower amounts of astigmatism (≤ 1.25

D) compared with anterior penetrating relaxing incisions; the nomograms are not yet well established, and enhancement procedures are less straightforward, he noted.

PROSPECTIVE STUDY RESULTS

Dr. Culbertson and his colleagues conducted a prospective study of ISAK that included 15 patients treated with a femtosecond laser platform (IntraLase, Abbott Medical Optics [AMO]) who had undergone a cataract surgery and were pseudophakic with refractive astigmatism (average, 1.12 D) and a later group of 29 cases treated with the another femtosecond laser platform (Catalys Precision Laser System, AMO/OptiMedica) who had naturally occurring topographic astigmatism (average, 1.02 D) treated during cataract surgery.

The IntraLase procedure was much more labor and time intensive than the Catalys procedure, he noted.

The former system's preoperative calculations were made manually using topographic pachymetry to measure the corneal thickness for the depth of the incisions. The intended treatment axes were marked on the cornea preoperatively at the slit lamp to align the intended axis at the laser with the intended axis of the topographic treatment, he explained.

With the latter system, no manual calculations are performed.

With a minimum of 3 months of follow-up, eyes treated with the IntraLase platform had a substantial reduction in the existing cylinder by 72% with slight steepening of the spherical equivalent, Dr. Culbertson said. The mean preoperative uncorrected vision was 20/50 and postoperatively 20/25.

"This result was a considerable improvement," he said.

Results in the 29 patients treated with the Catalys platform indicated that there was a 65% reduction of the preoperative cylinder. Most of the patients had less than 0.5 D of residual cylinder. The average deviation from the intended axis of placement was 3.6°.

The mean postoperative uncorrected distance visual acuity was 20/25.

Twenty-seven of the 29 patients had a best spectacle-corrected visual acuity of 20/20 postoperatively. One patient in this group had an increase in astigmatism from 0.63 to 1.12 D with an axis flip.

ADDITIONAL APPLICATIONS

Other uses for this femtosecond laser technology are pairing of the limbal-relaxing incisions with the main incision and orienting the intended axis to the fiducial mark, he continued.

Dr. Culbertson said he likes to place a small mark intrastromally when implanting a toric lens when he aligns the IOL axis along the preplaced intrastromal marks.

"ISAK is a safe and predictable technique for reducing low amounts of corneal astigmatism," Dr. Culbertson said. "All patients in the IntraLase group, and 28 of the 29 patients in the Catalys group, did very well with reduction of astigmatism to refractively negligible levels." ■



Weigh in on the use of intrastromal femtosecond laser astigmatic keratotomy as a technique to reduce low levels of astigmatism. Join the discussion at [Facebook.com/OphthalmologyTimes](https://www.facebook.com/OphthalmologyTimes).

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Topography-guided custom ablation expands patient pool for surgery

New option enables refractive surgeons to provide excellent outcomes to broader population

By Cheryl Guttman Krader; Reviewed by Karl D. Stonecipher, MD

GREENSBORO, NC ::

THE RECENT FDA approval of topography-guided custom ablation treatment (T-CAT) using an excimer laser (WaveLight Allegretto Wave Eye-Q, Alcon Laboratories) is a valuable step forward.

The treatment option allows refractive surgeons to deliver excellent outcomes to a broader patient population, said Karl D. Stonecipher, MD, an investigator in the pivotal clinical trial.

"We already have great treatments for virgin corneas with wavefront-guided and wavefront-optimized ablations, and so the value of a new option depends on whether it brings something

novel to the table," said Dr. Stonecipher, medical director, TLC Greensboro and TLC Raleigh, North Carolina.

"Used out of the box without any nomogram refinements in the FDA trial, T-CAT LASIK using the [excimer laser] was associated

with unprecedented refractive and visual acuity outcomes," he said. "The results are even more impressive considering that the study population included many eyes that the investigators thought were especially well-suited for T-CAT because of corneal anatomical differences yet within normal limits for laser vision correction."

The topography-guided ablation is determined by proprietary treatment planning software using data acquired with the WaveLight Allegro Topolyzer. Treatment accuracy is assured with the laser's advanced platform for eye-tracking and registration (NeuroTrack).

The FDA clinical trial included 247 eyes that were treated for myopia with or without astigmatism. Analyses of data collected at 3 months showed uncorrected visual acuity was 20/20 or better in 93% of eyes, 20/16 or better in 69%, and 20/12.5 or better in 32%. Best spectacle-corrected visual acuity was 20/40

or better in all eyes and improved by at least 1 line from preoperative in 30% of eyes.

Mean postop MRSE was 0.06 D and stable throughout follow-up to 12 months. Nearly all patients, 98%, said they would undergo the topography-guided ablation again.

SURGICAL DECISION TREE

Based on his own research investigating outcomes after LASIK, Dr. Stonecipher said he has been a firm believer that not all patients need to undergo a wavefront-guided procedure. Results of a randomized study he conducted with Guy Kezirian, MD, showed that eyes without significant higher-order aberrations (HOAs) can achieve equally good results with a wavefront-optimized procedure [*J Refract Surg.* 2008;24:S424-430].

To guide the surgical decision, all patients undergo a full diagnostic evaluation that includes topography, tomography, and wavefront aberrometry. Generally, only patients with preoperative root-mean-square HOAs of 0.35 to 0.4 μm or higher are considered candidates for a wavefront-guided procedure, assuming that it was possible to capture a good wavefront.

Patients with an "odd looking" cornea—i.e., an eye with an asymmetric bowtie pattern that still fits topographic eligibility criteria for LASIK—are considered the ideal example of a patient for T-CAT. However, Dr. Stonecipher noted that in the FDA trial, many patients with completely normal corneas were treated and had an excellent outcome.

"T-CAT ablation profiles create large uniform optical zones, which added to the outstanding results we saw in this FDA trial," he said.

"In treating these patients with a topography-guided ablation, we

have the opportunity to fully replicate the cornea in a way that was not possible before and provide them with better outcomes."

He noted that one downside of the T-CAT treatment is that it removes more tissue than a wavefront-optimized ablation.

Outside the United States, T-CAT is being used to rehabilitate eyes with poor outcomes. In addition, several investigators are using T-CAT in conjunction with cross-linking of the cornea for keratoconus and corneal ectasia.

"It is important to note that this is off-label," Dr. Stonecipher said.

THE WHOLE PACKAGE

Dr. Stonecipher also underscored that regardless of the type of ablation, the outcome of any LASIK procedure depends on the condition of the ocular surface, the flap-making tool used, and the postoperative management received.

"Noise going in leads to noise going out, and so if you are going to do a perfect treatment, you need to have a perfect ocular surface," he said.

"The reality is that most patients seeking LVC have challenges with their vision because of an ocular surface condition. Furthermore, results from the WaveLight T-CAT trial and other studies show that patients who had dry eye before LASIK are likely to have dry eye postoperatively. Capturing accurate diagnostic information for guiding the ablation and minimizing postoperative complaints depends on the patient having good ocular surface health."

Findings from an analysis of data from more than 25,000 eyes provide support for Dr. Stonecipher's belief that use of a femtosecond laser for flap creation will afford superior results. Compared with a mechanical microkeratome, use of the laser minimizes surgically induced HOAs and the chance for a postoperative enhancement.

Regarding postoperative management, Dr. Stonecipher emphasized the importance of patients using good quality products to minimize inflammation and the potential risk of infection in the current refractive patient population. ■



Dr. Stonecipher

take-home

► An algorithmic approach to surgical decisions for laser vision correction takes into account findings from topography, tomography, and aberrometry. Now this decision tree is augmented by a new option for topography-guided custom ablation.

KARL D. STONECIPHER, MD

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Dr. Stonecipher is a consultant to Alcon Laboratories.

Survey weighs LASIK, contact lens wear

Preliminary 1-year data highlight patient satisfaction; dry eye can be problematic for some

By Lynda Charters; Reviewed by Francis W. Price Jr., MD

INDIANAPOLIS ::

PRELIMINARY DATA FROM a 3-year survey comparing satisfaction with LASIK and contact lenses found that patient satisfaction is high with both widely accepted treatments for refractive error.

LASIK results in fewer visual problems with night-time driving for patients who previously wore contact lenses and for those who wore glasses. However, dry eye can be problematic in some patients.



Dr. Price

Francis W. Price Jr., MD, in private practice in Indianapolis, presented the preliminary 1-year results for the Cornea Research Foundation of America. The study, which

was carried out at multiple centers across the United States and three international sites in Spain, Singapore, and Brazil, was an Internet-based, self-reported, prospective trial with two arms: the LASIK arm and the contact lens arm.

In the LASIK group, patients were evaluated preoperatively and 1, 2, and 3 years postoperatively. In the contact lenses group, patients were evaluated at baseline and 1, 2, and 3 years later, Dr. Price said.

Among 1,899 patients enrolled in the study, responses to the 1-year follow-up survey thus far included 356 individuals who wore contact lenses, 448 who wore contact lenses and underwent LASIK, and 154 who wore glasses and underwent LASIK, for a 66% response rate, he noted.

WHAT WAS ASKED IN THE SURVEY

One of the survey questions asked respondents if they would recommend LASIK or contact lenses to a friend or family member. Among the patients who strongly agreed that they would do so, LASIK fared better than contact lenses in that 77% of patients who wore glasses and underwent LASIK and 87% of patients who wore contact lenses and underwent LASIK strongly agreed that they would recommend LASIK compared with 53% of contact lenses wearers who would recommend contact lenses. The difference in the percentages was highly significant ($p < 0.001$).

Another survey question ("At this time, do you believe that LASIK works better for you than contact lens wear?") was aimed at patients who had worn contact lenses and then underwent LASIK. Eighty-three percent strongly agreed and 13% agreed that LASIK was better than contact lens wear.

DRIVING AT NIGHT

A survey question that measured the degree of difficulty patients had with night driving garnered some interesting responses. The percentage of people who wore glasses and underwent LASIK and reported no problems with night-time driving rose from 39% at baseline to 54% 1 year after LASIK.

For subjects who wore contacts initially, the 41% who reported no problems with night-time driving at baseline increased to 62% 1 year after undergoing LASIK. Among the individuals who remained contact lens wearers, the respective percentages were 38% and 41%, essentially unchanged.

The percentages of individuals who reported severe problems with night-time driving were low and comparable among the three groups, Dr. Price pointed out, but he was especially surprised to see the degree of difficulty with night driving experienced by those who initially wore glasses before undergoing LASIK.

"Overall, LASIK significantly improves night driving," he said.

A survey question about the frequency of the sensation of dry eye over the previous week showed that among those who claimed that they never experienced dry eye, there was a big decrease in the percent among those who wore glasses and then underwent LASIK, with the baseline result of 45% compared with 26% 1 year after LASIK.

Among individuals who wore contact lenses before undergoing LASIK, the difference was smaller at 54% and 40%, respectively. Those who continued wearing contact lenses reported the same percentages at baseline and 1 year later (29% and 30%, respectively). The percentages of patients who reported dry eye all the time increased slightly in the three groups.

A question about the daily frequency of artificial tears use showed the percentage of those

"At this time, do you believe that LASIK works better for you than contact lens wear?"

83% strongly agreed

13% agreed

who never use artificial tears dropped substantially in the group that initially wore glasses and underwent LASIK from 76% at baseline to 37% 1 year after LASIK; among those who wore contact lenses and then underwent LASIK the percentages went from 76% to 52%, respectively; and among those who continued contact lens wear the percentages went from 76% at baseline to 66% 1 year later. The differences among groups were significant ($p < 0.0001$).

In patients with severe dry eye who instilled tears more than five times daily, increases were seen mostly in patients who wore glasses and underwent LASIK. "Artificial tear use increased after LASIK," Dr. Price said.

BENCHMARK FOR LASIK

This study, which sampled a large number of patients across the country, sets an appropriate benchmark for LASIK, he added. It compared two widely accepted treatments for refractive error. LASIK and contact lens use both are associated with some risk. Both provide more functional and esthetic correction than glasses.

"Importantly, LASIK improves vision for night driving compared with contact lenses and glasses," Dr. Price concluded. "There is a need for improved dry eye treatments for all forms of visual correction." ■

FRANCIS W. PRICE JR., MD

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Dr. Price has no financial interest in the subject matter. The study was funded by the participating practices.

Drug slows diabetic retinopathy, but delays may limit its effect

Long-term treatment with ranibizumab showed improvement in severity versus sham group

By Lynda Charters; Reviewed by Michael S. Ip, MD

TAKE-HOME

► **The natural history of diabetic retinopathy is modified by long-term treatment with intravitreal ranibizumab, reports one ophthalmologist.**

MADISON, WI ::

The natural history of diabetic retinopathy (DR) changes with long-term intravitreal ranibizumab (Lucentis, Genentech) treatment in some eyes with diabetic macular edema (DME). Severity of the DR regressed more in these eyes compared with sham-treated eyes.

There also was a lower likelihood of progression of the severity of DR, according to the 36-month results of the RISE and RIDE phase III trials.

The clinical unknowns investigators sought to address in these trials that evaluated the severity of diabetic retinopathy with ranibizumab treatment were:

- the long-term effects on the regression of DR.
- the long-term effects of ranibizumab on stopping the progression of DR severity.
- the baseline factors associated with development of proliferative DR in patients with DME.

In these clinical trials, patients were randomly assigned to sham treatment or either 0.3 mg- or 0.5-mg ranibizumab, according to Michael S. Ip, MD, associate professor of ophthalmology, Department of Ophthalmology, University of Wisconsin, Madison.



Dr. Ip

The treated patients received monthly injections to month 24. At that time, the treated patients continued treatment and those in the sham group crossed over to monthly 0.5-mg ranibizumab injections for the next 12 months.

Investigators evaluated severity of DR based on fundus photographs obtained at baseline

and at 3, 6, 12, 18, 24, 30, and 36 months after ranibizumab treatment. Outcomes were two or greater and three or greater step changes (improvements) compared with baseline on the ETDRS severity scale.

Dr. Ip recapped that the severity of DR was significantly more likely to improve in eyes treated with ranibizumab.

"At 24 months, there were more two or more and three or more step improvements in DR severity in the treated groups compared with the sham group," he said.

Specifically, regarding the two or more step changes, 37.2% and 35.9% of patients treated with 0.3 mg and 0.5 mg of ranibizumab had improvements in DR severity. Regarding three or more step changes, the respective values were 13.2% and 14.5%.

PROGRESSION OVER TIME

"These improvements were maintained to month 36," Dr. Ip said. "In the original sham group that received 0.5-mg ranibizumab injections after crossover, there was some improvement in the retinopathy, although it did not reach the level of improvement seen in the patients initially treated with ranibizumab."

At 36 months, regarding the two-step changes in the ranibizumab groups, 38.9% and 39.3%, respectively, of patients in the 0.3- and the 0.5-mg ranibizumab groups had improvements in the DR severity. Regarding the three-step changes, the respective values were 15.0% and 13.2%.

Investigators found that the severity of DR is significantly less likely to worsen in eyes treated with ranibizumab compared with the sham group.

There was also a slight reduction in progression in the sham-treated eyes that crossed over to active treatment. The halting of the progression in DR that was seen at 24 months continued to 36 months.

In the ranibizumab-treated groups, the baseline characteristic that may predict development of proliferative DR was—based on multiple covariate analysis—only capillary loss within the ETDRS grid. In the sham group,

the severity of the DR and the presence or absence of subretinal fluid were associated with proliferative diabetic retinopathy.

"Ranibizumab-treated eyes with DME had greater regression of DR severity compared with the sham-treated eyes at 24 months that continued to 36 months," Dr. Ip said.

"These eyes were less likely to have progression of severity of DR compared with sham-treated eyes at 24 months and the sham-treated eyes that crossed over to ranibizumab treatment at 36 months," he said. "At 36 months, the risk of development of proliferative DR was about three-fold greater in the sham-treated eyes compared with the ranibizumab-treated eyes."

Results suggested that delaying ranibizumab may result in a reduced chance to improve the severity of the DR. However, it is unknown if delaying ranibizumab by less than 2 years would result in a similar loss of benefit, he said.

"We speculated that the longer the delay, the greater the loss of effect of ranibizumab on the severity of DR," Dr. Ip said.

Though results were derived from large, randomized trials, the findings were derived from secondary and exploratory analyses, he cautioned. Investigators do not recommend using ranibizumab specifically or primarily to treat DR severity. Panretinal photocoagulation remains the primary treatment for advanced DR.

Regarding the finding that capillary loss was the factor in the ranibizumab-treated eyes that predicted the risk of progression to proliferative DR, assessing patients for capillary loss may be important to identify susceptible patients.

Identification of other pathophysiologic mechanisms should be addressed in future trials, considering that some eyes still develop proliferative DR despite administration of chronic anti-vascular endothelial growth factor therapies, which suggested that other mechanisms may be involved. ■

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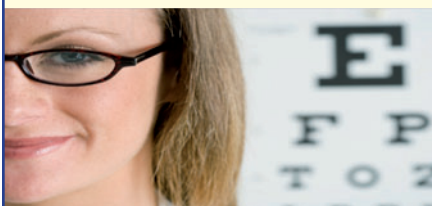
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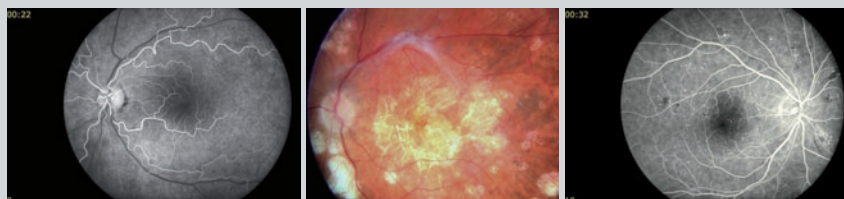
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'Like' it or not, this four-letter word prevails in the clinic

Why managers, technicians need to tame the likability beast before it takes over the practice

Putting It In View By Dianna E. Graves, COMT, BS Ed

TAKE-HOME

► **Nowhere does it state in staff contracts that they have to like everyone, but they will work together professionally and kindly.**

This problem lives in your office in the form of a little "four-letter word."

While the days blend into each other, and the seasons come and go, this little word continues to dwell in the corners—brewing and festering until it develops into that monster that cyclically rears its ugly head, again and again. It disrupts the everyday "ho hum" of clinic life, wreaking havoc with the physicians and the staff, and causing administrators and managers to run for cover.

Slowing growing larger than King Kong himself, we do not know this four-letter word in diabolical descriptors or horrifying adjectives.

No, we have hidden its devastation in something so innocuous that we allow it to

blend into our worlds and reside there in the shadows.

We call this beast, "Like."

Now that I have your attention, let's talk about this devastating word. If you pay attention for a week, you will hear it all over the place and in many different facets.

Remove the benignly thrown out comments: "I really like when I drive into work on Monday and the sun is shining—gives me hope for the rest of the week" or "I tried a pumpkin-and-prune latte this morning on special and did not like that."

Circle the ones you hear regarding work in red. These are the mitotic early cells of the "Like" Beast beginning to develop.

How do I know that you all have this going on in? It's the number one conversation I have when I visit or talk with other managers or go to their clinics to teach.

Surprise, this is coast to coast, even island to island. Yes, it lives here in Minnesota as well—even with our deep, dark, bone-chilling winters. Here are some examples:

■ **PHYSICIANS:** "I don't want you to schedule Suzanne in my clinics anymore. Yes, I know she

is a good technician, but I just don't like her as much as I do Amy. Put her into Dr. Smith's clinic. They are a better fit. Make it happen!"

Recognize that one? Not many managers need a bright flashlight to shine under the stairwell to find this one brewing there.

With job security in mind, your first logical thought is to keep the peace and put Amy with this physician whenever they are in clinic and then switch Suzanne to the other physician.

But is it really that simple?

Let's say this physician is a specialist with a high-patient volume clinic. Amy may be quirky and funny and flits around the clinic all day like a moth to a flame.

Suzanne gets in and gets the job done. She maneuvers her way through chaos and keeps the physician on task and gets everyone out at 5 p.m. But, she's no "fun." What wins? Function or fun?

Instead of having Suzanne and another technician work this physician's clinic, I now have to add a third technician to make up for Amy's quirkiness.

(Continues on page 36: **The 'Like' Beast**)

Physicians unprepared for ICD-10

AS THE OCT. 1, 2014 DEADLINE nears for implementation of the International Classification of Diseases-10th Revision (ICD-10), a survey shows that physicians and health plans may be largely unprepared for the disruption that change will bring to their cash flow.

The survey found that although 76% of respondents had completed an ICD-10 impact assessment, about half of respondents had not determined what effect it will have on their revenue cycles and cash flow.

KPMG LLP, a tax, audit and advisory firm, conducted the survey at the end of a series of

webcasts from Oct. 17 through Dec. 9, 2013. Respondents were from health plans and health-care providers at hospitals and group practices.

"As October 1 inches closer, health-care organizations have their work cut out to properly absorb the impact that the new coding will have on their businesses," said Wayne Cafran, an advisory principal in KPMG's Healthcare & Life Sciences practice, in a prepared statement. "A full 50% stated that they had yet to estimate the new coding system's impact on their cash flow. With estimates by those who did measure the impact tallying anywhere from

\$1 million to more than \$15 million, health-care organizations are in for a rude awakening when they finally realize what the new standards will have on their bottom lines."

About 45% of survey respondents said that denial/variance management would be most affected during the transition.

But many health plans and providers have already begun testing. The survey found that 42% of respondents had already begun testing their coding systems. The Centers for Medicaid and Medicare Services plans to conduct front-end claims testing during the week of March 3. ■

THE 'LIKE' BEAST

(Continued from page 35)

By the way, don't think it hasn't gotten back to Suzanne in very subtle ways that he doesn't like her.

TECHNICIAN A: "I refuse to work with Sarah anymore and don't want to be scheduled in the same clinic with her. She thinks she is better than me because she is a COT and I am a COA and I don't like her."

This one is fun for a lot of the same reasons as above, but we need to delve more here.

If a staff member knows or feels that the physician just doesn't like him or her, there isn't much that can be done because the physician is in a position of power. The presumed unliked employee trundles along and does the best he or she can in a no-win situation—or he or she leaves and joins your most feared competitor.

But when it is a fellow technician, the claws will come out. It is now preservation of the fittest and a catfight will soon ensue.

They will each gather support from the other technicians—we called this choosing sides in elementary school—and will start to drag the other office staff into it as well. Don't be surprised if a physician or two isn't dragged into the whole debacle.

You now have a giant game of dodge ball occurring—with you as the ball!

TECHNICIAN B: "Thanks for choosing me to train for diagnostics, but no thanks. I don't like sitting in a dark room with the patient and listening to a machine beep all day. If I can't do A-scans, then I don't want to do visual fields. I don't like those exams."

This "Like" Beast is cagey and wily. It now has become a war of wits between you and an unforeseen hidden monster.

Is the technician shying away from diagnostics because of insecurity with knowledge and afraid of being in the spotlight? What if he or she makes a mistake? Or, is he or she the clinic social director who does not want to be out of the limelight for fear of missing something that needs "attention," such as a co-worker's wedding pictures or the newest puppy pictures from the mailman.

TAKE THE CHALLENGE

I challenge you to this simple study. Put a piece of paper in your pocket and go live

your life for a week. Every time someone comes to you and tells you they do or don't like something or someone, make a hash mark and then a brief note of the context. At the end of the week you will have quite a list!

Now, here comes the hard part. What do you do with these hash marks?

My staff and I have quarterly technician meetings. It's a time to discuss news, changes, and education and then a chance to give staff a time to vent creatively and discuss things together with the group.

Take your hash marks to the meeting and talk about it. I call it the "Like" conversation.

I remind staff of the following tenets with these caveats:

1. Nowhere in their contract—they don't have one but they understand the meaning—does it state that they have to like everyone, but they will work together professionally and kindly. I have from time to time reminded them that I am aware that not everyone likes me, and that I see this as a flaw in their character! By the way, while I am not fond of every person I meet, I will treat every person with kindness and respect.

2. Stop worrying if the physicians like you. Physicians have enough of their own friends. They want you to do your job and do it well. If you do that for them, they will like you even if they don't remember your name!

3. If you have the skill to perform a diagnostic or special task, I am going to place you there unless you give me a real good reason not to. I once had a young technician who I wanted to place in diagnostics and she was immediately sad, sullen, and withdrawn. When I asked her what was up, she stated she loved completing patient workups, because she felt she was really good at expediently troubleshooting their concerns, doing a great job for the doctors, and ensuring the patient was treated well during the exam. I have to admit she was phenomenal at her job. Why rock the boat? I didn't, and moved someone else into the diagnostic role.

You will never kill the "Like" Beast. It will continue to morph and grow, then regenerate and morph into a sneakier beast. You are only going to be able to keep it at bay.

It will take time and more effort than this wily monster is worth. Left unguarded, it will grow and take over your clinic.

So, go home tonight, grab your lance and trusty steed, and sleep well. Tomorrow, you have Like windmills to slay in your clinic. Trust me. The beasts will be sleeping sound and waiting for you. ■



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OPHTHALMOLOGY TIMES (Print ISSN 0193-032X, Digital ISSN 2150-7333) is published semi-monthly (24 issues yearly) by Advanstar Communications Inc., 131 W First Street, Duluth, MN 55802-2065. Subscription rates: \$200 for one year in the United States & Possessions, Canada and Mexico; all other countries \$263 for one year. Pricing includes air-expedited service. Single copies (prepaid only): \$13 in the United States & Possessions, Canada and Mexico; \$20 all other countries. Back issues, if available are \$25 in the U.S. & Possessions; \$30 in Canada and Mexico; \$35 in all other countries. Include \$6.50 per order plus \$2 per additional copy for U.S. postage and handling. If shipping outside the U.S., include an additional \$10 per order plus \$5 per additional copy. **Periodicals postage paid** at Duluth, MN 55806 and additional mailing offices. **POSTMASTER:** Please send address changes to OPTHALMOLOGY TIMES, P.O. Box 6009, Duluth, MN 55806-6009. Canadian G.S.T. number: R-124213133RT001, Publications Mail Agreement Number 40612608. Return undeliverable Canadian addresses to: Pitney Bowes PO Box 25542 London, ON N6C 6B2 CANADA. Printed in the U.S.A.

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VERION™

IMAGE GUIDED SYSTEM

IMPORTANT SAFETY INFORMATION

CAUTION: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

INDICATION: The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

RESTRICTIONS:

- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindications:

- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocoele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

WARNINGS: The LenSx® Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

PRECAUTIONS:

- Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

AES/COMPLICATIONS:

- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

ATTENTION: Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

IMPORTANT SAFETY INFORMATION FOR THE VERION™ REFERENCE UNIT AND VERION™ DIGITAL MARKER

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

INTENDED USES: The VERION™ Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye in order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION™ Reference Unit provides preoperative surgical planning functions that utilize the reference image and preoperative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION™ Reference Unit also supports the export of the high-resolution reference image, preoperative measurement data, and surgical plans for use with the VERION™ Digital Marker and other compatible devices through the use of a USB memory stick.

The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

CONTRAINDICATIONS: The following conditions may affect the accuracy of surgical plans prepared with the VERION™ Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements.

Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.

The following contraindications may affect the proper functioning of the VERION™ Digital Marker: changes in a patient's eye between preoperative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

WARNINGS: Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker.

Only use the provided medical power supplies and data communication cable. The power supplies for the VERION™ Reference Unit and the VERION™ Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on.

Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system.

The VERION™ Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONS: To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION™ Reference Unit and the VERION™ Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

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CPT codes evolving for glaucoma services

What ophthalmologists need to know about changing landscape of diagnosis, treatment coding

coding.doc By L. Neal Freeman, MD, MBA

TAKE-HOME

► **The 2014 version of Current Procedural Terminology contains two important changes for ophthalmologists who provide glaucoma services.**

OPHTHALMOLOGISTS WHO PROVIDE

glaucoma services should note two important changes—CPT 66183 and CPT 0329T—in the 2014 version of Current Procedural Terminology (CPT).

Examining these changes is especially instructive. There are implications regarding different categories of CPT codes, and the variations between diagnostic and therapeutic services.

ABOUT CPT 66183

CPT 66183 been added to report the insertion of an anterior segment drainage device utilizing an external surgical approach without reservoir. This code replaces Category III code 0192T.

This is not an addition of a previously unrecognized service, but conversion of a Category III CPT code to a Category I CPT code. Alcon Laboratories has instructed practitioners utilizing its glaucoma filtration device (Ex-Press) to report under CPT 66183.

The conversion to CPT Category I implies the service is performed by many physicians or other qualified health-care professionals across the United States. Also, there must be literature support of clinical efficacy.

The elevation to Category I status means that relative value units (RVUs) are now assigned by Medicare. CPT 66183 carries a total of 30.42 RVUs when performed in a facility setting. Although the legislative environment has been somewhat volatile recently regarding payment levels, it is reasonable to estimate a Medicare allowable of \$1,090 for this service based on RVUs. A 90-day global period has been assigned.

Unlike the case for trabeculectomy codes 66170 and 66172—which explicitly distinguish between cases performed in the absence and presence of previous surgery re-

spectively—CPT 66183 is appropriate coding for the service regardless of the previous surgical status of the eye. Modifier -22, Increased Procedural Services, may be added if documentation reflects substantially greater work than typically required. Additional payment may ensue depending on the particular payer.

The American Medical Association's Relative Value Scale Update Committee (RUC) reviews selected codes on an ongoing basis for possible misevaluation. CPT 66183 has been placed on a list due to the novel type of service being offered. The RUC may come back to modify the value of 66183 relative to other codes in the future.

As a Category III code, external placement of an anterior segment drainage device had minimal or no payment rate standardization. In these situations, payers often look to similar services as benchmarks regarding payment rates.

ABOUT CPT 0329T

CPT 0329T—monitoring of IOP for 24 hours or longer, unilateral or bilateral, with interpretation and report—is another addition to the code set for 2014.

It is a Category III code since it is considered as emerging technology. Category III status is often used when tracking of a service is desired. This becomes highly relevant if the code eventually comes up for “promotion” to Category I.

A number of new devices are designed to allow continuous IOP monitoring, similar to the concept of continuous heart rhythm monitoring with a Holter monitor. In contrast, serial tonometry is traditional measurement of IOP at multiple times during the day, typically accomplished with a lengthy office visit by the patient.

CPT 0329T should be used when a monitoring device is fitted to the patient for continuous monitoring over a full day, instead of special ophthalmological service code CPT 92100 (serial tonometry with multiple measurements of IOP over an extended period of time). A new parenthetical has been added after 92100 indicating appropriate use of 0329T.

Most category III codes are not covered

What's New in 2014

CPT 66183 been added to report the insertion of an anterior segment drainage device utilizing an external surgical approach without reservoir. This code replaces Category III code 0192T.

CPT 0329T—monitoring of IOP for 24 hours or longer, unilateral or bilateral, with interpretation and report—is another addition to the code set for 2014.

by many or all payers as they are considered unproven. Frequently, coverage may be considered by the payer on a case-by-case basis. There may be specific guidelines from the payer that indicate if coverage is available. For example, Aetna's Clinical Policy Bulletin, “Glaucoma Testing” (http://www.aetna.com/cpb/medical/data/600_699/0622.html) indicates 0329T is not a covered service.

Ophthalmologists who intend to provide a Category III service to Medicare beneficiaries should strongly consider asking patients to sign an Advance Beneficiary Notice of Noncoverage (ABN). Physicians may collect upfront from patients, but must refund the payment if the carrier reimburses for the service.

Depending on the contract, a form similar to the Medicare ABN may be appropriate for use in patients covered by a private plan.

CPT is an evolving system and annual changes may be frequent. This is yet another reason for ophthalmologists to keep coding information up to date and to educate themselves in this area frequently. ■



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