Accommodation restoration: Is clinical availability near?

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

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.
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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 in 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 “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 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 average 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 the highest, yet the average being nearly twice the industry average.

Turnover Statistics

<table>
<thead>
<tr>
<th>SILICON VALLEY AVERAGE</th>
<th>NETFLIX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average annual total employee turnover</td>
<td>18% to 20%</td>
</tr>
<tr>
<td>Average annual voluntary employee turnover</td>
<td>10% to 13%</td>
</tr>
<tr>
<td>Average annual involuntary employee turnover</td>
<td>6% to 10%</td>
</tr>
</tbody>
</table>

(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 technologists who can perform patient workouts 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 self-driven to do the right thing that they require much less direct supervision.

Continues on page 6 : Editorial
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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 exchange, 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. 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% 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”?■

References

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• The treatment of endogenous anterior uveitis.

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• For the treatment of inflammation and pain associated with 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.
• For the treatment of 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.

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The results you want. The relief they need.

DUREZOL® Emulsion has head-to-head data vs prednisolone acetate in patients with endogenous anterior uveitis.¹
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 ophthalmic 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 technological advancements from one manufacturer against prior generations of devices alone from that same instrument maker,” said Dr. Hida, medical director and chief of cataract surgery for Brasilia Ophthalmology Hospital in Brasilia, Brazil. “When it comes to torsional and translational 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 a new 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.

### Take-Home

- Several new refractive surgical platforms have been introduced recently.
- Many ophthalmologists are discovering the new technologies to be more efficient and produce better results.
- Wilson Takashi Hida, MD, PhD, said that comparing two different new platforms can be more difficult.
- Most studies in the field compare new technological advancements from one manufacturer against prior generations of devices alone from that same instrument maker.
- When it comes to torsional and translational 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 a new 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.
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 results 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-µm 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-µm 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

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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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’sEye Center, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore.

“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 or randomized clinical trials performed to demonstrate that adjustable 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 the Journal of AAPOS, 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.

(Figure courtesy of David L. Guyton, MD)

Success rates (Percent within 8° of straight)

![Success rates bar chart](image-url)

(FIGURE 1) According to Dr. Guyton and colleagues’ published results of their adjustable suture technique in children in the Journal of AAPOS, 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.

(Figure courtesy of David L. Guyton, MD)
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**SUTURE MATERIALS**

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The results of the study also showed that the percentage of patients who had a reduction in visual acuity was significantly lower in the treatment group compared to the control group. This result suggests that the treatment was effective in improving visual acuity in patients with mixed astigmatism.

The results of the study also showed that the percentage of patients who had a reduction in the number of lines of vision loss was significantly lower in the treatment group compared to the control group. This result suggests that the treatment was effective in reducing the number of lines of vision loss in patients with mixed astigmatism.

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**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*

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**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.”

**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 antigen-1 antagonist; mecamylamine, a nonspecific nicotinic acetylcholine receptor blocker; and multi-targeted kinase (src) inhibitors. Subcutaneous delivery strategies include:

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

Oral delivery methods being tested include:

1. PKC-beta inhibitors
2. Oral minocycline (microglial activation inhibitor)
3. Atorvastatin, a statin lipid-lowering agent
4. Vascular adhesion protein-1 inhibitor
5. 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 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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**LLOYD PAUL AIELLO, MD, PhD**

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Dr. Aiello is a consultant for Genentech, Genzyme, Akcea, Kedara, Merck & Co., and ThromboGenics. He also received grant support from Opentech.
Ocular oncology embraces EDI-OCT as valuable tool for clinical imaging

Capabilities enable specialists to identify, diagnose variety of intraocular tumors

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

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.

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 appearance 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.

Small choroidal melanomas (≤3mm 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 containing:

- **EDOCT**

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

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**Seeing the differences**

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ILEVRO™ Suspension

Designed to put potency precisely where you need it¹,²

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 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 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.

EDI-OCT
(nepafenac ophthalmic suspension) 0.3%

(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.

IDENTIFYING HEMANGIOMAS

Hemagiomas, which can be difficult to see clinically and on ultrasound, could be readily identified in most cases with EDI-OCT. The contour of hemangiomas 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 hyper- trophy 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.
A s 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) (Kera ring, Mediphacos). We also use the implant to treat patients who present with keratoconus.

**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...
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 instruments 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 implantation2,3—at a high-volume center like ours small percentages still translate into large numbers of patients.

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 both before and during laser ablation; a feature that further minimizes the risk of endothelial perforation.

**POSTLASIK ECTASIA**

*(Continued from page 19)*

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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)*
Experience the superior visualization of the LuxOR™ LX3 with Q-VUE™ Ophthalmic Microscope. It delivers superior red reflex stability and greater depth of focus, revealing every facet of your procedures in crisp, brilliant detail.¹

¹. Data on file, Alcon Laboratories, Inc.
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.

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 calculate 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 (VerifEye, 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.
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 (SiS 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 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 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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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.

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 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 µm of stroma via ablation (LASIK or PRK) or as a lenticule (SMILE) from a 550-µm thick cornea.

Using the mathematical model, the calculated postoperative PTTS was 75% after SMILE performed with a 130-µm cap, 68% for PRK, and 54% for a thin-flap (100 µm) 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 µm). Mean values for SEQ, cylinder, and pachymetry in both groups were approximately –4.83 D, 0.56 D, and 540 µm, respectively.

The mean ±SD thickness of the cap in the SMILE group was 130 ± 6 µm and the LASIK group had a mean flap thickness of 96 ± 12 µm. Mean OZ diameter
was 6.7 ± 0.39 mm for SMILE and 6.08 ± 0.22 mm for LASIK. Mean (range) lenticule thickness was 107 µm (72 to 149) for SMILE, while the LASIK group had a mean ablation depth of 81 µm (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.

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 – 0.16 µm in the SMILE eyes and 0.31 – 0.12 µm after LASIK.

Dr. Reinstein is a consultant for Carl Zeiss Meditec AG.

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)

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.

“The 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.

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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 femtosecond laser lens treatment,” Dr. Krueger said.

“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 µJ/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 1 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 µJ/pulse and 0.45 to 1.45 M pulses per lens). All subjects had ≤ Grade 2 cataract and had already elected to have lens replacement 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 6.2 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 crystalline 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 equivalence 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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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

SEUL, 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.

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

The Amaris PTK ablation target is 55 µm centrally and 65 µm 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.

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.

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.

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 0.5% (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 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.”

Dr. Kim reported no conflicts of interest.

For more information, go to http://bit.ly/1ddStRs.

(Video courtesy of Jung Sub Kim, MD.)
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 Miller School of Medicine, 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.

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.

**Pros and Cons 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 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.

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 visual acuity was 20/25 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 fiduciary 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.”

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 3.6º.

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.

**Take-home**

- Corneal astigmatism may be reduced or nearly eliminated after intrastromal femtosecond laser astigmatic keratotomy, explains one ophthalmologist.

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.
Topography-guided custom ablation expands patient pool for surgery

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

By Cheryl Guttmann 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 vision correction of keratoconus 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 into preoperative topographic 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 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.

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 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 wear 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
E: fprice@pricevisiongroup.net
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 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.

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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‘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.*

His 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 quiriness.

(Continues on page 36: *The ‘Like’ Beast*)

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**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 already begun testing their ICD-10, a survey shows that physicians and health care providers at hospitals and group practices. As October 1 inches closer, health-care organizations are in for a rude awakening when they finally realize what the new coding 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 managers need to prepare for ICD-10. The survey found that 42% of respondents have 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 unlike 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 patient workups, because she felt she was really good at expeditiously troubleshooting the old会见. When I asked her what was up, she stated she loved completing patient workups, because she felt she was really good at expeditiously troubleshooting the 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.

The “Like” Beast is cagey and wily. It will continue to morph and grow, then regenerate and morph into a sneaker 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 stay in your clinic. Trust me. The beasts will be sleeping sound and waiting for you.

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 expeditiously 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 sneaker 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.

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• 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 application 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 pages 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 decenteration
• Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
• Capsular tear
• Corneal abrasion or defect
• Pain
• Infection
• Bleeding
• Damage to intracocular 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.
What ophthalmologists need to know about changing landscape of diagnosis, treatment coding

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CPT codes evolving for glaucoma services

CPT 66183 has 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.

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 has 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 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 respectively—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 an 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 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.


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What’s New in 2014

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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.

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BETTER
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FASTER
- Laser procedure efficiency with reduced programming and suction time
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