TAKE THE FAST TRACK TO SURGICAL EXCELLENCE

MAKE THE MOVE TO LASER CATARACT SURGERY

SEE PAGE 7
By Beth Thomas Hertz

FOR THE SECOND year since Ophthalmology Times resumed its Best Programs Survey in 2017 after a brief hiatus, the Bascom Palmer Eye Institute at the University of Miami is at the top of the 2018 Best Overall Programs category, followed again by the Wilmer Eye Institute at Johns Hopkins University. Massachusetts Eye & Ear Infirmary at Harvard University is third, moving up from seventh place last year.

Rounding out the Best Overall category are Wills Eye Hospital at Thomas Jefferson University in fourth, Duke University Eye Center in fifth, University of Iowa in sixth, W.K. Kellogg Eye Center at the University of Michigan in seventh, Stein & Doheny Eye Institute at the University of California, Los Angeles in eighth, Casey Eye Institute at University of Oregon in ninth, and the Moran Eye Center at University of Utah in tenth. There is a tie for 11th: Storm Eye Institute at Medical University of South Carolina and Dean McGee Eye Institute/University of Oklahoma.

The Storm Eye Institute is the only new name on that list this year, narrowly edging Cleveland Clinic’s Cole Eye Institute out of the top dozen.

WILMER LEADS IN BEST RESEARCH CATEGORY

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The Storm Eye Institute is the only new name on that list this year, narrowly edging Cleveland Clinic’s Cole Eye Institute out of the top dozen.
INDICATION FOR USE. The iStent inject® Trabecular Micro-Bypass System Model G2-M-IS is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma.

CONTRAINDICATIONS. The iStent inject is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. BEWARE: Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. MRI INFORMATION. The iStent inject is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. PRECAUTIONS. The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent inject have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with...prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents.

ADVERSE EVENTS. Common postoperative adverse events reported in the randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent inject vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%). CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

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Clinical Diagnosis

18 IDENTIFYING RETINAL VASCULAR DISEASE WITH UWF IMAGING
How improved visualization of periphery benefits diagnosis and management.

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Drug Therapy

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Formulation brings best of both worlds: fast onset of action, high efficacy with twice-daily dosing.

What’s Trending

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1 Orbital pathologies and trauma
OphthalmologyTimes.com/OrbitalTrauma

2 Hey, chocolate chip cookie fans!
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3 SCUT trial delves into corticosteroid use for bacterial corneal ulcers
OphthalmologyTimes.com/SCUTtrial

4 Fungal keratitis diagnosis: Beyond the slit lamp
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eReport

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ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information. INDICATIONS: The TECNIS® 1-Piece Lens is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag. WARNINGS: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS® 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The TECNIS® 1-Piece IOL should not be placed in the ciliary sulcus. PRECAUTIONS: Do not reuse, resterilize, or autoclave.

ADVERSE EVENTS: In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

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Project Diabetes 2000

Spoiler alert—sadly, preventable blindness remains with us

The Decade of the 1980s was an exciting time. The space shuttle was launched, and Dr. Sally Ride became the first woman in space. The first permanent artificial heart was implanted. The personal computer and the internet appeared. The Berlin Wall collapsed.

Sadly, the Iran-Iraq war raged for 8 years, leaving more than 1 million dead.

The world had its problems to be sure, but progress was palpable in so many fields, including medicine and ophthalmology.

So, in this optimistic time of demonstrable scientific achievement, it was logical for the American Academy of Ophthalmology (AAO) to launch, in 1989, the ambitious project known as “Diabetes 2000.” In its role of championing the vision of Americans and echoing the call of President Kennedy to land a man on the moon, this great professional organization decided that the time was right to eliminate preventable blindness from diabetic retinopathy.

Over the decade of the 1990s, this program encouraged collaboration among all stakeholders (the public, primary-care physicians, allied health professionals, and ophthalmologists) to promote education, early detection, and prompt treatment according to protocols, such as laser retinal photocoagulation, that had proven efficacious in rigorously conducted National Eye Institute-sponsored clinical trials.

Continues on page 8: Guest Editorial

By David W. Parke II, MD, FACS
Chief Executive Officer of the American Academy of Ophthalmology

He can be reached at P.O. Box 7424, San Francisco, CA 94120 E-mail: board@aaao.org

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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ALZHEIMER’S DISEASE BIOMARKERS IN THE VITREOUS, STUDY SAYS

ALZHEIMER’S disease leads to severe cognitive dysfunction and eventual death. By 2050, it is expected to affect more than 115 million people worldwide. From time of diagnosis until death, the average survival time is just under 5 years.

Go to ModernRetina.com/Vitreous

ANTI-VEGFs CAN IMPROVE DRSS IN MAJORITY OF PATIENTS

Using a specific anti-vascular endothelial growth factor (VEGF) drug in patients with moderately severe to severe nonproliferative diabetic retinopathy (NPDR) can result in a ≥2-step improvement in diabetic retinopathy severity scores (DRSS) in almost 60% of those treated, according to results of the PANORAMA study.

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FOUR WAYS TO DISCUSS DIABETIC TREATMENT WITH PATIENTS

Take the time at the outset of treatment to explain to patients that their therapy will also need to be similarly long-term and multifaceted. Setting expectations will ensure that patients stay committed and engaged over the full course of their long-term treatment regimen. Here are four pearls ophthalmologists can follow.

Go to ModernRetina.com/FourWays

CUTTERS OR SCISSORS FOR PDR?

Retina surgeons should learn a variety of techniques to treat proliferative diabetic retinopathy (PDR) so they can select which one to use on a case-by-case basis.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE CATALYS PRECISION LASER SYSTEM

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INDICATIONS: The CATALYS Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. WARNINGS: Prior to INTEGRAL GUIDANCE System imaging and laser treatment, the suction ring must be completely filled with sterile buffered saline solution.
Two of our favorite ophthalmologists helped lead this inspiring call to action. Arnall Patz, MD, past president of the AAO, served as the Diabetes 2000 National Chairperson. Ronald Smith, MD, the academy’s Secretary for Education, served as the National Project Director.

Armed with a trove of scientific knowledge about diabetic retinopathy and its treatment, strong leadership, and the excitement of tackling such an important problem, it seemed to many that the success of Diabetes 2000 was assured.

In the fullness of time, we were able to watch this effort play out. Spoiler alert—sadly, preventable blindness from diabetes remains with us today.

As Hillary Clinton would say: “What happened?!” Looking back, few in the 1980s were predicting that the prevalences of diabetes and obesity in the United States would shortly begin to mimic the space shuttle and skyrocket. The more than tripling of the diabetic population in the United States and the not only persistent but dramatic increase in unhealthy eating habits in our population conspired to frustrate efforts to control the disease.

While regular eye exams allow for early detection and maximize the chance of preventing blindness through early intervention, the majority of diabetic patients in the United States do not bother to present for annual dilated eye exams. Public service announcements sponsored by the AAO and featuring celebrities failed to motivate our diabetic population to make sure their eyes are regularly scrutinized for the tell-tale lesions of retinopathy.

Even today, patients may not make their initial presentation to an eye clinic until they have very advanced pathology, including neovascular glaucoma, and irreversible vision loss. Certain racial groups in the United States are particularly affected, as they both have a higher incidence of diabetes and are less likely to have access to the healthcare system.

Can we do better than to shake our heads and say it is a shame that preventable blindness from diabetes remains a scourge? Might we today have the scientific know-how (remote imaging, teledicine, artificial intelligence, anti-VEGF agents, etc.) and the ability to influence behavior and diet that might make this problem solvable? Should we be thinking about committing our profession and our nation to addressing this issue once and for all? ■

References

Flying Eye Hospital celebrates 20 years of eye care in Ethiopia during training project

THE ORBIS Flying Eye Hospital—the world’s only U.S.-accredited teaching hospital on board an MD-10 aircraft—returned to Addis Ababa to conduct a three-week training project earlier this month, invited by the Federal Ministry of Health and in partnership with the Ophthalmological Society of Ethiopia (OSE).

The project focuses on training local eye care teams in adult and pediatric surgery techniques needed to meet the remaining needs of the over 1.6 million Ethiopians living with blindness, and another 3.8 million living with low vision (according to the first national blindness, low vision and trachoma survey in 2006). The Global Trachoma Mapping Project (2013) estimated that Ethiopia is home to 37.5% of the world’s trachoma cases.

Over the course of the three-week project, Orbis said it would aim to train 335 eye care professionals, screen and examine 250 patients, and perform surgery on 122 people. ■
Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.
Mutagenesis: Lifitegrast was not mutagenic in the in vitro Ames assay. Lifitegrast was not clastogenic in the in vivo mouse micronucleus assay. In an in vitro chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.

Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD] of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.
The Best Clinical Care category included Wills in second, Wilmer in third, Massachusetts Eye & Ear in fourth, and Duke in fifth. Best Residency Programs, after Bascom Palmer, were Wills in second, Wilmer in third, University of Iowa in fourth, and Duke in fifth.

The Best Research Programs included Bascom Palmer in second, Massachusetts Eye & Ear in third, Duke in fourth, and W.K. Kellogg Eye Center in fifth.

*Ophthalmology Times* conducted the survey through Survey Gizmo. Of 232 chairmen and residency program directors invited to participate nationally, 58 did, for a 25% response rate.

In interviews with *Ophthalmology Times*, the chairmen at the Bascom Palmer Eye Institute and the Wilmer Eye Institute expressed their appreciation for the commendation and shared some of their thoughts about what makes for a successful program today.

**TEAM PRaised AT BASCOM PALMER**

At Bascom Palmer, Chairman Eduardo C. Alfonso, MD, attributed his institute’s first place ranking in clinical care to the outstanding team that is there, including physicians, scientists, nurses, technicians, and more. About 1,200 people work at Bascom Palmer, he noted, making it one of the biggest eye care teams in the United States, caring for one of the largest patient populations.

“We continue to try to excel in patient care, vision research, and education, working to be at the cutting edge of innovation in all those areas,” he said.

Bascom Palmer was one of the first institutions in the United States to offer the Nightstar gene therapy eye clinical trial for X-linked retinitis pigmentosa, he noted.

“A 23-year-old man from Puerto Rico was the first patient, and he gave a very heart-wrenching interview as to how he was already beginning to feel the difference in terms of his eyesight and, more importantly, the promise that he will not continue to lose eyesight. It is quite remarkable,” Dr. Alfonso said.

He noted that Bascom Palmer has been at the forefront of the use of voretigene neparvovec-rzyl (Luxturna, Spark Therapeutics) to treat RPE65 mutation-associated retinal dystrophy, with The Wall Street Journal writing about their efforts in September (https://on.wsj.com/2DsPRLx).

“We treated a 9-year-old boy from Florida. This was thanks to the wonderful basic research and clinical team headed by Dr. Byron Lam. He and the whole group have been instrumental in advancing gene therapy,” Dr. Alfonso said.

He also praised the work of Dr. John Dye, a Bascom Palmer basic science researcher who developed the early form of mitochondrial gene therapy. “We are looking at gene therapy very carefully because we believe that in the very near future it will be one of the treatments available,” he said.

Continues on page 12: Community
“I am really looking forward to that day when we can stop giving them the monthly injections of anti-VEGF factors and be able to do very specific gene therapy for them. Hopefully, that day will come soon,” he added.

Continuing from page 11:

COMMUNITY

“We think we will be able to move a lot of care to patients’ own space, using devices they have with them, at home or at work.”

— Eduardo C. Alfonso, MD

Bascom Palmer continues to grow, and will be adding more than 100,000 square feet of clinical space over the next five years or so, Dr. Alfonso said. This includes expanding throughout South Florida, as well as adding a facility in Abu Dhabi that is set to open in fall 2019.

The institute is also working on growing in the virtual eye care space. It is currently upgrading communications capabilities across all sites to have the bandwidth to facilitate image transfer and remote visits. For example, the Abu Dhabi facility will not have a full complement of eye specialists on site, but rather will augment the ophthalmologists who will be there with “super specialists” consulting from Miami.

“We want to make it easier for patients to not have to travel a long way when they need a procedure. In our new physical space areas, we are really not concentrating so much on patient exam rooms because I think (some examinations) will happen at the patient’s home. We will focus instead on spaces where patients will be physically treated, which requires a sterile room or equipment that cannot be deployed to homes,” he said.

How all of that develops will ultimately depend on if payment models can be shifted toward population health rather than treating diseases, he noted.

“We think we will be able to move a lot of care to patients’ own space, using devices they have with them, at home or at work,” he said.

“We hope that will change how we provide care because keeping people healthy is a different paradigm.”

COMMUNITY SERVICE

Dr. Alfonso noted that Bascom Palmer continues to build on its strong commitment to community service, internationally as well as locally. For example, the institute holds eye care health fairs almost every weekend in underserved areas around Miami.

The institute was also on standby to help after Hurricane Florence this summer, staying in communication with colleagues in the Mid-Atlantic Region in case they were needed.

“Fortunately, we weren’t needed, but we were ready to go if we were. And we keep in touch with our Caribbean and South American colleagues, because that is where needs tend to arise and the infrastructure is not available for medical responses to crises,” Dr. Alfonso said. “We are available.”

He also said that Bascom Palmer’s Philip J. Rosenfeld, MD, PhD, did a great service to the United States by going to Congress to discuss the cost of optical coherence tomography testing recently.

“We want to make it easier for patients to not have to travel a long way when they need a procedure. In our new physical space areas, we are really not concentrating so much on patient exam rooms because I think (some examinations) will happen at the patient’s home. We will focus instead on spaces where patients will be physically treated, which requires a sterile room or equipment that cannot be deployed to homes,” he said.

Although enacting change in health care today is complex, he said Bascom Palmer is committed to pushing forward, especially in the area of caring for retinal degeneration. Thanks to a $12 million gift from philanthropist Lois Pope, and support from others, Bascom Palmer is creating a one-of-a-kind building at its Palm Beach campus that is dedicated just to scientists and clinicians working on retinal and macular degeneration.

EDUCATION

Education, another area of the Ophthalmology Times survey in which Bascom Palmer ranked number one, continues to be a growing area for the institute as well.

It launched a Global Education Center this year to coordinate all of its educational efforts, including students, residents, and fellows, as well as patients who attend courses.

“We also provide our courses online so our colleagues everywhere can benefit in their continuing medical education,” he said.

Bascom Palmer also now offers a unique master’s degree in Vision Science and Ophthalmology. Students come from all over the world to take this two-year program, he said. Many have finished medical school abroad, and want to get a better background in ophthalmology so they can embark on a research career, in industry or academia, or apply for
The trail is clear.
Weaving along Hawaii’s Na Pali Coast is the breathtaking Kalalau Trail. The trail is demanding...but in the end, its beauty is worth every step. Kalalau was early inspiration for us, today representing our innovative spirit and deep commitment to advancing the treatment of eye diseases. This is the journey we’re all on at Kala and the one we can take together.

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clinical positions such as residencies and fellowships.

“It gives them the didactic basis that they may have not gotten in the country where they obtained their degree,” Dr. Alfonso said. “We really found a need for this because we have such an international presence of observers and residents and fellows who rotate at Bascom Palmer and we clearly saw that they were in need of a core curriculum so they could expand their careers.”

That was the first time such a thing had been done, he noted, and the vision behind it continues today. All faculty members at the Wilmer Eye Institute are tenure-track and are expected to do research, write papers, and advance the field, he said.

“We do our best to stay true to Dr. Wilmer’s vision of asking ourselves: Is the way we are doing things the best way, or is there a better way? That is the recipe for essentially taking better care of our patients and being better teachers to our residents and advancing the field of ophthalmology.”

Peter J. McDonnell, MD, chairman at the Wilmer Eye Institute, said his program’s top ranking in research has deep historical origins.

“When Dr. Wilmer started the Wilmer Eye Institute in 1925, he felt that a focus on science was so important that having science throughout the institute would make us better doctors and better teachers,” Dr. McDonnell said. “He created what was unique at the time—all-in-one-building, all-under-one-roof, laboratories and scientists next to doctors, and patients next to students. Everyone mixed together.”

That was the first time such a thing had been done, he noted, and the vision behind it continues today. All faculty members at the Wilmer Eye Institute are tenure-track and are expected to do research, write papers, and advance the field, he said.

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“Research is not a separate thing here. It’s the basis for our strong focus on research and why we spent over $40 million last year on research,” he said. “Research is not a separate thing here. It’s throughout the institute,” he added.

Wilmer has just over 200 full-time faculty members, with 50 of those being PhD-level scientists who do not do patient care. It also has many clinician-scientists who see patients two or three days a week and spend the rest of their time in the laboratory or doing clinical research.

All residents are expected to do research as well, and they are motivated at least in part by a generous prize given each year to the one who does what the faculty judges as the most exciting work. Along those lines, Wilmer’s residency program is intentionally kept small—five per year—to enable the faculty to really focus on their complete development.

“Our goal is not to produce the largest number of residents, or to provide all the ophthalmologists for the state of Maryland. Our goal is to produce people who will be the leaders in the field,” Dr. McDonnell said. “We have a map of the world in which we have highlighted all the places that people who trained at Wilmer have gone on to be department chairs. It’s now at 110.”

Dr. McDonnell also said that in the past two years, Wilmer faculty members have started six biotech companies to work on translating laboratory discoveries into new drugs and devices.

“We think that partnering with an existing large company or creating a new company is the best way to do that,” he said, noting that the institute has a large partnership with German pharmaceutical company Bayer to develop several of its laboratory discoveries into therapies for retinal disease.

These ventures also include nanotechnology to replace glaucoma drops and cell engineering for optic nerve regeneration, he said.

Dr. McDonnell said that the Wilmer Eye Institute has expanded around Maryland in recent years to try to meet the ever-growing demand for its services.

“We are dealing with a demographic tidal wave in America of age-related eye problems,” he said.

He proudly noted that every patient who has called for an appointment in the past three years was asked if they want to be seen that same day. About 50,000 people have said, “yes.”

Patients are not just coming from the area around Baltimore, he noted. The staff saw patients from all 50 states and 84 countries last year, he added.

RESEARCH

That was the first time such a thing had been done, he noted, and the vision behind it continues today. All faculty members at the Wilmer Eye Institute are tenure-track and are expected to do research, write papers, and advance the field, he said.

‘Is the way we are doing things the best way, or is there a better way? That is the recipe for essentially taking better care of our patients and being better teachers to our residents and advancing the field of ophthalmology.’

— Peter J. McDonnell, MD

Dr. McDonnell also said that in the past two years, Wilmer faculty members have started six biotech companies to work on translating laboratory discoveries into new drugs and devices.

“We think that partnering with an existing large company or creating a new company is the best way to do that,” he said, noting that the institute has a large partnership with German pharmaceutical company Bayer to develop several of its laboratory discoveries into therapies for retinal disease.

“These ventures also include nanotechnology to replace glaucoma drops and cell engineering for optic nerve regeneration, he said.

RESEARCH IS BACKBONE OF WILMER

Peter J. McDonnell, MD, chairman at the Wilmer Eye Institute, said his program’s top ranking in research has deep historical origins.

“When Dr. Wilmer started the Wilmer Eye Institute in 1925, he felt that a focus on science was so important that having science throughout the institute would make us better doctors and better teachers,” Dr. McDonnell said. “He created what was unique at the time—all-in-one-building, all-under-one-roof, laboratories and scientists next to doctors, and patients next to students. Everyone mixed together.”

That was the first time such a thing had been done, he noted, and the vision behind it continues today. All faculty members at the Wilmer Eye Institute are tenure-track and are expected to do research, write papers, and advance the field, he said.

“We do our best to stay true to Dr. Wilmer’s vision of asking ourselves: Is the way we are doing things the best way, or is there a better way? That is the recipe for essentially taking better care of our patients and being better teachers to our residents and advancing the field of ophthalmology.”

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P reparations are well under way for the Glau-
coma Research Foundation (GRF)’s signature annual event, Glaucoma 360, to be held Jan. 31 to Feb. 2, 2019, at the Palace Hotel in San Francisco. The three-day event features a gala on Thursday night, a day dedicated to innovation on Friday, and continuing medical education programming on Saturday.

The GRF is also commemorating its 40th anniversary this year. As part of the milestone, the GRF announced it will begin the next phase of its breakthrough research program, Catalyst for a Cure. This third phase of this collaborative endeavor builds on 16 years of seminal research on glaucoma, early biological indicators, and measurement of glaucoma, and will focus on restoring vision in glaucoma patients, not just halting disease progression, said Thomas M. Brunner, president and chief executive officer of the foundation.

“This initiative brings together scientists from different backgrounds to work collaboratively to understand glaucoma and find ways to improve treatment and, ultimately, cure this blinding disease,” he said.

The foundation launched “The Cure is in Sight”—a $15 million capital campaign designed to re- enforce its mission, strengthen education and awareness efforts, and facilitate strides in scientific discovery—in 2014.

It has been such a success that the foundation has announced it will extend the campaign in an effort to raise $25 million by 2020. These new funds will be used to help implement the new strategic plan and boost collaborative research, including the Catalyst for a Cure Vision Restoration Initiative.

Brunner said it is gratifying that with all of the developments in glaucoma today, experts are finally willing to start talking about a cure.

“It really seems like the potential is there between stem cells and genetic engineering, gene therapy, CRISPR technology and just the understanding of the genetics of glaucoma,” he said. “We’ve been at this 40 years and have invested some $60 million in research and really have seen tremendous strides. We see Glaucoma 360 as being an important piece of it because it brings people together to really focus on the unmet needs in glaucoma today.”

He said the GRF believes there is a real potential to find ways to regenerate, restore, or replace damaged neurons to restore vision.

“It’s an ambitious goal, but we are very excited that the scientific and medical communities see this as being within the realm of possibility,” he said.

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

**The Annual Gala**
The Annual Gala will kick off the three days on Thursday night. This event will include a dinner, live auction, presentation of The Catalyst Award, the President’s Reception, and a special musical performance from Mads Tolling & The Mads Men, featuring popular Bay Area singer Fred Ross. It will also feature a research update on the biomarker initiative, which is now in human testing at Stanford University, Brunner said.

Launched in 2007, this annual benefit showcases the visionaries and catalysts who share GRF’s mission to cure glaucoma and restore vision through innovative research. It has raised more than $5 million over the years.

At the event, Robert L. Stamper, MD, will receive the Visionary Award and Mona and Ed Zander will receive the Catalyst Award.

**NEW HORIZONS FORUM**
The New Horizons Forum, a full day dedicated to speeding the development of new therapies and diagnostics for glaucoma patients, will be held Friday. It unites key clinical, industry, financial, and FDA leaders in a unique exchange on research innovation and advances in glaucoma treatment to help speed the translation of new ideas into clinical practice.

Founders and co-chairs are Adrienne Graves, PhD, who is an independent director at Akorn Inc., Nicox S.A., Surface Pharmaceuticals, and TearLab Corp., and Andrew G. Iwach, MD, executive director of Glaucoma Center of San Francisco and chair of the Board of Directors for GRF.
Dr. Graves added, “We will highlight early-stage companies with innovations in drug therapies/targets, glaucoma devices, and drug delivery technologies. An exciting topic for researchers and patients alike will be vision restoration.”

The keynote speaker this year will be Janey L. Wiggs, MD, PhD, who is the Paul Austin Chandler Professor of Ophthalmology at Harvard Medical School at Massachusetts Eye and Ear Infirmary. Her topic is “Glaucoma Genetics: Working Toward A Cure.”

“We are very excited to have Dr. Wiggs as keynote speaker,” Dr. Iwach said.

“She is one of the top specialists in glaucoma and genetics in the nation and we expect that her lecture on the changing role of genetics in glaucoma will be a real highlight of the meeting,” he added.

**CME SYMPOSIA**

Saturday is the dedicated educational programming day, with presentations planned for ophthalmologists in the morning and for optometrists in the afternoon.

Dr. Iwach described the faculties as being a “stellar lineup of key opinion leaders.”

In the morning, the Shaffer-Hetherington-Hoskins Lecture Keynote speaker will be L. Jay Katz, MD, chief of the Wills Eye Glaucoma Service and professor of ophthalmology at the Sidney Kimmel Medical College in Philadelphia. His topic will be “Screening for Glaucoma: New Strategies.”

A few other highlights:

- **Shan C. Lin, MD:** Refractive Considerations in Cataract Surgery in Glaucoma Patients
- **Yvonne Ou, MD:** Virtual Reality and Visual Fields
- **Tom Samuelson, MD:** Stents, Trabs, and Tubes: Decision Making in Surgical Glaucoma
- **Robert Stamper, MD:** OCT Angiography – Where We Are, What Do We Need to Learn
- **Ruth D. Williams, MD:** Private Equity and Ophthalmology: Will I Be Left Behind?

Dr. Iwach said he attends many medical meetings each year and finds some of them lack cutting-edge new material. He added he’s proud that the presenters at this meeting take it very seriously. They typically prepare new materials and new slides, for example, and are committed to providing an excellent educational experience.

“When we started this meeting, we wondered if we’d have enough new things to talk about each year, and boy, do we!” Dr. Iwach said. “I always learn something, and I believe our attendees do, too.”

For more information or to register for Glaucoma 360, go to [www.glaucoma360.org](http://www.glaucoma360.org)

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**Duke Eye Center**

The Duke Eye Center booth presentations are not affiliated with the official program of AAO 2018.
Identifying retinal vascular disease with UWF imaging
How improved visualization of the periphery benefits diagnosis and management

By Prof Armin Wolf; Special to Ophthalmology Times

Fundus photography and fluorescein angiography are well-established tools in the diagnosis and management of retinal vascular disease. In particular, the seven-standard fields (7SF) developed in the Early Treatment Diabetic Retinopathy Study (ETDRS) have been widely employed; many treatment algorithms derived from multicenter studies are based on this 75°-imaging technique.

The development of ultra-widefield (UWF) imaging provides more information for clinicians and researchers. The widest available field of view currently from a single image is that provided by the Optos devices, which combine a scanning laser ophthalmoscope and an ellipsoidal mirror. These UWF devices produce a 200° field of view (roughly 82.5% of the total retinal surface area) in a single image capture.

The use of UWF imaging is becoming standard practice in diabetic retinopathy (DR) and retinal vein occlusion (RVO), as well as providing important new insights into the management of retinopathy of prematurity and rare hereditary retinal vascular conditions.

Patients with DR typically have ischemic changes in the central field that are visible with conventional imaging. However, recent studies suggest UWF imaging may lead to more accurate classification of the disease because it can reveal more retinal vascular pathology than 7SF imaging, including 3.9 times more nonperfusion and 1.9 times more neovascularization. (Figures 1 and 2a,b).

Diabetic Retinopathy
In about 10% of patients, UWF angiography leads to a diagnosis of DR that would have been missed entirely by 7SF.

The improved retinal visualization of UWF imaging may also influence follow-up and treatment. For example, while we know that panretinal photocoagulation (PRP) reduces ischemia in the retina and is widely accepted as appropriate treatment for proliferative DR, it also has significant morbidity (in the form of macular edema, loss of peripheral vision, and decreased night vision) that we would rather avoid. Through better visualization of the periphery with UWF, it is possible to identify areas of non-ischemic retina that could be avoided during PRP to preserve the areas of healthier retinal tissue.

Close evaluation of UWF angiography in high-risk diabetic patients who do not yet have neovascularization and capillary dropout may help to identify predictors of proliferative DR. Identification of the extent of retinal nonperfusion area and calculation of the nonperfusion index using UWF fluorescein angiography has been shown to be highly correlated with severity of DR and the presence of predominantly peripheral lesions, themselves a risk factor for progression of DR. Recent evidence suggests that late angiographic posterior and peripheral vascular leakage (LAPPEL) or PVL (peripheral vessel leakage) may be a marker of inflammation and a precursor of capillary dropout. Perivascular leakage, as demonstrated by UWF imaging, is associated with neovascularization and possibly with macular edema. The use of UWF to detect LAPPEL or PVL could allow us to treat at-risk patients with intravitreal anti-VEGF before these complications

Continues on page 22: Retinal vascular disease
GETTING TO THE TOP TAKES FOCUS.

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2018 Image of the Year
American Society of Retina Specialists

Photographer: Brenda Fallas
Bascom Palmer Eye Institute

Co-author: J. William Harbour, MD

Description: 2-year-old boy with stage D+ retinoblastoma of the right eye
Corneal melting: Negotiating a sight-threatening disease
Managing these patients requires looking below the surface to determine culprits

By Lynda Charters; Reviewed by Esen K. Akpek, MD

STERILE MELTING of the cornea/keratolysis is a catastrophic inflammatory scenario that can develop in association with systemic diseases that can cause tear film abnormalities particularly in patients with Sjögren’s syndrome, and rheumatoid arthritis, as well as toxicity caused by instillation of various eyedrops such as nonsteroidal anti-inflammatory eye drops after surgery or abuse of topical anesthetics to name a few.

Recognizing the active corneal melt versus non-healing epithelial defect is just the beginning for ophthalmologists caring for affected patients, Esen Akpek, MD, said.

The patient evaluation should include a number of considerations on the part of the ophthalmologist that include the shape and location of the corneal involvement, and determination of the presence of an epithelial defect, necrotic tissue or thinning and stromal melting, infiltrates, anterior chamber inflammation, and limbal or scleral involvement, as well as the status of the fellow eye.

The ocular external examination should include evaluation of the conjunctiva for any scarring, follicles, and papillae and of the tear film and ocular surface epithelium using corneal fluorescein staining and conjunctival lissamine green staining, she advised. Dr. Akpek is the Bendann Family Professor of Ophthalmology, Wilmer Eye Institute, Johns Hopkins University School of Medicine, and Director, Ocular Surface Disease and Dry Eye Clinic, Baltimore.


“This syndrome is known to be widely overlooked, especially in the male population and when ocular findings are the initial symptoms,” she commented.

LOCATION IS EVERYTHING

Corneal melts can develop in the peripheral or central cornea, mid-peripheral areas or combinations. The location can be important in determining the underlying etiology.

However, peripheral ulcerative keratitis (with scleritis or limbal vasculitis) can accompany systemic vasculitides, such as Wegener’s granulomatosis, polyarteritis nodosa, microscopic polyangiitis, or Churg-Strauss syndrome, she said.

The first rule is ordering of cultures to rule out infection, Dr. Akpek emphasized.

Suspicion of autoimmune disorders call for specific tests to measure serum rheumatologic factors, including antinuclear antibody, anti-ro and la, rheumatoid factor, and anti-double-stranded DNA, and C-reactive protein, among others.

Dermatologic diseases or sarcoidosis also should be considered in the differential diagnosis. Suspicions of infectious processes call for tests to rule out tuberculosis, syphilis, hepatitis C, human immunodeficiency virus, herpes simplex virus, varicella zoster virus, and immunodeficiency syndromes, for example, common variable immunodeficiency, with chronic colonization of the ocular surface.

TAKE-HOME

» Corneal melts can develop in the peripheral or central cornea, mid-peripheral areas or combinations. The location can be important in determining the underlying etiology.

innate and adaptive immunity. Complement activation triggers a sequence of biologic reactions in which each component is activated by the upstream component. Complement interacts with the Fc portion of IgG and IgM, resulting in C3a and C5a, which cause the mast cells to activate and the resultant cascade to edema in the tissue. In addition, adaptive immune system elements such as lymphocytes and antigen presenting cells are also densely populated in the peripheral cornea.

Paracentral sterile keratitis is likely associated with autoimmune connective tissue diseases, immune dermatologic disorders, and autoimmune diseases of the lacrimal system as opposed to central corneal involvement, which is more likely to be infectious.

Dr. Akpek has no financial interest in any aspect of this report.

ESEN K. AKPEK, MD
c: esaakpek@jhmi.edu

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RETINAL VASCULAR DISEASE

(Continued from page 18)

occur, thereby postponing or avoiding PRP and its associated damage.

We are also using UWF to increase the efficiency of laser surgery in patients with DR. When patients undergo surgery to treat a non-clearing vitreous hemorrhage or tractional retinal detachment, we treat the far periphery initially but it is difficult to know how centrally to draw the borders. My current approach is to use UWF imaging to guide my secondary laser treatment of the remaining ischemic areas several weeks postoperatively.

Future protocols for DR will continue to change dramatically thanks to insights gained from UWF angiography.

RETINAL VEIN OCCLUSION

Vein occlusions have been classified as ischemic or nonischemic based on the amount of retinal nonperfusion. UWF imaging now provides the opportunity to visualize greater areas of peripheral nonperfusion, which should lead to more accurate classification of RVO. Some researchers are already using UWF angiography to develop an ischemic index that better represents the amount of nonperfused to total visualized retina to aid in this classification.

UWF imaging could help to explain the considerable variability we see in nonperfusion among patients with RVO. A better understanding of this variability and its relationship to the extent and location of vein occlusion may prompt more robust analysis of risk factors for ischemic progression.

There has been debate over whether PRP of the ischemic areas in RVO can reduce the burden of intravitreal injections; to date, the available literature is inconclusive. It is unclear whether previous studies have failed to show a reduction in injections because the laser treatment was ineffective generally or because the laser treatment was not appropriately targeted as would now be possible with UWF imaging to guide treatment. We are recruiting patients for the PEARL study, which will evaluate whether laser treatment of peripheral ischemic areas specifically identified by UWF angiography affects intravitreal injection outcomes.

HEREDITARY VITREORETINAL PATHOLOGY

In many patients with genetic vitreoretinal pathologies such as familial exudative vitreoretinopathy (FEVR) or Norrie disease, the condition is related to defects in the development of retinal vessels and, in particular, to immature development of the peripheral vasculature, similar to what we see in retinopathy of prematurity (ROP).

These conditions range from mild (with no clinical symptoms or visual deterioration) to quite severe cases in which there may be a full retinal detachment. Imaging of the peripheral vasculature is required for diagnosis (Fig 3a,b). Early detection is critical because laser treatment in the earlier stages of the disease can improve outcomes. We are finding that in children with severe vitreoretinal pathology, imaging of their parents or other family members often aids in diagnosis.

We examined a young child with severe FEVR. The child’s mother had no symptoms and completely normal central angiography, but UWF angiography revealed peripheral pathology in the mother’s eyes, and further testing showed she had the same genetic variant or single nucleotide polymorphism (SNP) as the child.

We know that four SNPs [FZD4 (frizzled-4), NDP (Norrie disease pseudoglioma), LRPS (low-density lipoprotein receptor-like protein 5), and TSPAN12 (tetraspanin 12)] are responsible for nearly 50% of FEVR cases. However, there can be significant variation in the clinical presentation of patients with the same genetic variation, as in the case described above.

In another case, a child was diagnosed with severe ROP. Although he had been born preterm, at 26 weeks, he needed minimal oxygen after birth and had no other risk factors for ROP, so the severity of the condition was surprising. We performed UWF angiography of the whole family and found both parents also had abnormal peripheral vasculature not associated with any known disease. We believe they may have a new variant of hereditary silent protein disease that contributed to what appeared to be ROP.

It is possible that this genetic mutation may have been a risk factor not just for retinopathy but for the child’s prematurity in the first place. Previously published work has shown that in patients with severe ROP there is a higher rate of Norrie disease mutations and that FZD4 gene mutation may be a risk factor for retinopathy and pre-term birth.

There are probably quite complex interrelationships among FEVR, Norrie disease, retinopathy of prematurity, and other conditions, such as Coats’ disease. We have a lot to learn about how to use this genetic information in combination with imaging. We are looking at phenotype/genotype correlations and hoping that UWF imaging can help to identify patients at risk.

In other rare genetic retinal vascular pathologies UWF imaging is already leading to new treatment protocols. In a recent study involving subjects with Eales disease, UWF angiography led to immediate changes in the treatment plans of one-third of the patients because of peripheral changes picked up in the UWF imaging that had not previously been visible.

UWF imaging gives us a chance of detecting pathology before complications occur and potentially guiding more effective treatments.
NEW SOLUTIONS

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A multicenter clinical trial reported excellent visual outcomes and high patient satisfaction with bilateral implantation of this IOL after cataract surgery, said Dr. Dick, professor of ophthalmology and chairman, Ruhr University Eye Hospital, Bochum, Germany.

This IOL boasts a number of characteristics, i.e., negative spherical aberrations providing its smooth hyperbolic curve, an infinite number of focal points that extend the depth of focus, refractive power that is maximal in the center that continuously decreases without steps to the periphery, and a large optic that ensures maximal light in the eye, Dr. Dick said.

The IOL powers range from +15 to +30 D in 0.5-D steps; the overall and optic diameters are 8.6 and 8.9 mm; the lens thicknesses range from 0.8 to 1.7 mm, the refractive index is 1.428 ± 0.003, and the water content is 42 ± 2%, Dr. Dick noted.

The IOL after bilateral implantation during femtosecond laser-assisted cataract surgery. Patients were followed for 6 months postoperatively. The primary endpoint was the binocular uncorrected visual acuity. The targeted treatment was 0.0 ± 0.25 D in the dominant eye and -0.50 ± 0.25 D in the non-dominant eye.

Dr. Dick noted that the uncorrected distance visual acuity and the uncorrected intermediate visual acuity were excellent and the uncorrected near visual acuity was very good.

Investigators reported that implantation of the IOL after laser cataract surgery was safe and effective. Patients were highly satisfied with their levels of spectacle independence, he noted.

When patients were questioned about use of spectacle correction postoperatively, 95.6% reported never or rarely experiencing halos and 87% reported never or rarely experiencing glare. The fact that there still were few photic phenomena at all is under investigation, Dr. Dick noted.

“This large trial confirmed the previous results of investigations with smaller numbers of patients,” he said.

“Bilateral implantation of the EDOF WIOL-CF provided excellent distance and intermediate vision and good near vision while maintaining excellent contrast sensitivity, high patient satisfaction, and high levels of spectacle independence,” Dr. Dick concluded. “The WIOL-CF is a novel, effective, and reliable surgical solution for the correction of presbyopia.”

**CLINICAL TRIAL**

This 11-center, prospective, clinical trial—conducted in Belgium, the Czech Republic, Germany, Italy, and Spain—included 230 eyes of 115 patients (44 men, 71 women). The mean patient age was 65.0 ± 6.7 years (range, 50 to 75 years). The average IOL power was 25.0 ± 2.37 D (range, 17.0 to 30.0 D).

The investigators conducted the trial with the goal of evaluating the clinical outcomes of the WIOL-CF after bilateral implantation during femtosecond laser-assisted cataract surgery. Patients were followed for 6 months postoperatively. The primary endpoint was the binocular uncorrected visual acuity.

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**TAKE-HOME**

> Investigators share highlights from the multicenter clinical trial results of a novel one-piece, extended-depth-of-focus IOL in cataract patients after bilateral implantation.
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Flap motility sign: Endpoint of safe phacoemulsification?

Inverted non-fluttering flaps are signs of posterior capsular rupture

By Lynda Charters; Reviewed by Rohit Om Parkash, MBBS, MS

PHACOEMULSIFICATION is one of the most common surgeries performed worldwide, but it is not without problems, i.e., radial tears in the margin of the capsulorhexis can occur often. However, the good news is that there is now a recognized sign, namely, the flap motility sign, that can alert clinicians to the optimal course for the remainder of the surgery.

Most tears do not extend to the equator. However, when a tear does reach the equator and beyond, according to Rohit Om Parkash, MBBS, MS, it is due to the irrigating fluid and the intercapsular pressure created by lens material. If the tear reaches the posterior capsule and the posterior capsule ruptures, the surgery is complicated by vitreous loss or nuclear drop.

At that point, the surgeon reaches a crossroad and must choose between an extracapsular cataract surgery/manual small incision cataract surgery or phacoemulsification.

STUDY RESULTS

The investigators looked at the following parameters: anterior chamber depth, cataract type and density, tear shape, and the extension of the tear in relation to the equator.

Dr. Parkash explained, “We also examined the nature and motility of the flaps of the capsular tears in relation to the extension of the tear up to or beyond the equator. The nature of the flap was described as everted or inverted flat. The motility of the flap was described as fluttering or non-fluttering.”

The investigators hypothesized that the everted and fluttering flaps did not extend past the equator, while the inverted flat and non-fluttering flaps did extend past the equator.

STUDY DESIGN

Dr. Parkash and colleagues recognized the need to simplify this process for surgeons and undertook a study in which they described various types of anterior capsular tears in an effort to identify an early diagnostic flap motility sign that points to the potential for posterior capsular rupture after posterior extension of radial tears.

They conducted a prospective study at the Dr. Om Parkash Eye Institute, Amritsar, India, that included 4,331 eyes undergoing phacoemulsification from April 2015 to February 2016. Among those cases were 25 consecutive cases of anterior capsular tears. The goals were three-fold: classify the types of anterior capsular tears, study the motility and nature of the flaps in anterior capsular radial tears, and study the relation of motility and nature of flaps in relation to posterior capsule rupture.

Taking-home

Recognition of the flap motility eliminates dilemmas in the presence of anterior capsular tears and reveals the extent of the anterior capsule tears, explains Rohit Om Parkash, MBBS, MS.

‘Surgeons with all levels of surgical expertise can be confident in their decision making and prevent surgical catastrophes.’ — Rohit Om Parkash, MBBS, MS

Continues on page 27: Flap motility
and fluttering nature of the flap, phacoemulsification can be performed using safe phacoemulsification techniques.

The endpoint of safe phacoemulsification is when the flap stops fluttering and lies flat. This indicates that the tear is no longer pre equatorial and has just extended beyond equator.

At this defining moment, much before the onset of signs of posterior capsule rupture, the surgeon should convert to extra capsular cataract surgery or manual small incision cataract surgery. The timely conversion helps to prevent the dreaded complications associated with posterior capsule rupture.

“Recognition of the flap motility eliminates dilemmas faced by surgeons in the presence of anterior capsular tears and reveals the extent of the anterior capsular tear,” Dr. Parkash concluded. “Surgeons with all levels of surgical expertise can be confident in their decision making and prevent surgical catastrophes. Recognition of this sign makes the decision to implant an intraocular lens in the bag conclusive.”

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Dr. Parkash has no financial interest in the subject matter.

Eyevance buys rights to corneal epithelial defect candidate

EYEVANCE Pharmaceuticals announced a worldwide licensing agreement with OcuNexus Therapeutics for a 30-base antisense oligomer (NEXAGON) being developed for the orphan indication of persistent corneal epithelial defect (PED) nonresponsive to standard of care.

The first-in-class unmodified antisense oligodeoxynucleotide inhibits a cell membrane hemi-channel forming protein, connexin43 (Cx43). Cx43 is overexpressed after acute injury or in chronic disease states leading to pathological prematurely open hemichannels, allowing ATP to enter the extracellular space.

Extracellular ATP triggers and perpetuates the immune system’s inflammasome pathway releasing multiple proinflammatory cytokines resulting in microvascular breakdown, vessel leak and limbal tissue ischemia.

NEXAGON inhibits Cx43 overexpression and the inflammatory cascade, re-establishing limbal microvasculature and promoting regeneration of the corneal epithelium, according to the company in a prepared statement.

“Eyevance is committed to developing and commercializing innovative eye care products. Accordingly, our acquisition of NEXAGON from OcuNexus represents a landmark deal for our growing organization,” according to Jerry St. Peter, chief executive officer and director, Eyevance.
Study: Cataract complication rates of residents lower than expected

Improvement was seen with experience gained, show data from comparative study

By Lynda Charters; Reviewed by Rosa Braga-Mele, MD

CATARACT surgeries performed by resident surgical trainees do not appear to be associated with more complications than surgeries performed by staff surgeons. That is the conclusion reached by a large study that evaluated almost 9,000 procedures of phacoemulsification cataract surgery. This was the first large comparative study performed in North America.

Considering the estimated 3 million cataract surgeries performed annually in the US, that study was certainly warranted. However, before the study was undertaken, no large comparative studies had been performed to establish definitely the intraoperative complication rates of novice surgeons compared with staff surgeons in North America. Only smaller, retrospective non-comparative surveys had been performed, according to Rosa Braga-Mele, MD, emphasizing the importance of such a study.

Phacoemulsification cataract surgery is by far the most commonly performed surgery in the developed world and it is an important part of ophthalmology surgical training, she pointed out. “The complication rates, have decreased with new technology and refined techniques.” The published posterior chamber rates of rupture and vitreous loss rates for residents range from 2.0% to 14.7% and for staff surgeons from 0.19% to 2.7%.

COMPARATIVE STUDY

Dr. Braga-Mele and colleagues performed a prospective, observational study that compared the intraoperative complication rates in phacoemulsification cataract surgery performed by resident trainees and staff ophthalmologists at a Canadian academic center.

The investigators included consecutive cases of primary phacoemulsification cataract surgery and intraocular lens (IOL) implantation with residents present in the operating room.

The data collected included case tracking forms and intraoperative complication tracking forms completed by residents following each case. The variables included the levels of resident training, case complexity, resident participation, and intraoperative complications.

The last included the following categories: no complication, wound burns, anterior chamber tears, posterior chamber tears, vitreous loss, dropped lens/fragment, iris prolapse, other iris complication, central Descemet’s membrane damage, hyphema, dislocated IOL, zonular loss, and choroidal hemorrhage, she explained. She is professor of ophthalmology, University of Toronto, and director of the Cataract Surgery at Kensington Eye Institute, Toronto.

The study covered the period from January 2016 to December 2016; 8,738 procedures were included. Of the 3,775 cases in which residents were involved, 83% were performed by residents and the remaining 17% were performed by staff.

In most cases (83%) when residents were involved, they were completing the entire case.

Two-thirds of the cases were considered simple. The one-third of cases that were complex involved patients with small pupils/intraoperative floppy iris syndrome, 8.4%; corneal issues, 5.3%; hypermature cataracts, 4.2%; and zonular issues/pseudoexfoliation syndrome, 3.3%. Some cases had a combination of challenges, most often the presence of a hypermature cataract with mature pupilary and zonular issues.

She noted that complications developed in 233 (2.7%) cases. When broken down by residents and staff surgeons, the rate of any complication was 2.7% in each group. The analysis identified a significant difference in vitreous loss occurrence between staff and residents; interestingly the chances of vitreous loss occurring were lower when a resident was involved in the case.
This was likely the effect of the complexity and higher degree of complexity of the case. It is not surprising that complex cases have higher odds of having a complication develop, and this is statistically significant. The staff surgeons perform more complex cases and are likely doing cases of higher complexity," she said.

When the investigators evaluated only simple cases, there were no significant differences in the complication rates between the staff surgeons and residents.

When they evaluated only cases in which residents were involved, there was an increase in the complication rates during a 5- to 8-week training period and then a subsequent trend was seen toward decreasing complication rates as the residents gained experience.

**HOW THE RESULTS STACKED UP**

When Dr. Braga-Mele and colleagues compared their results to previously published studies, no startling differences were found.

In an Australian study by Fong et al. (Clin Exp Ophthalmol 2012;40: 597-603) that included 1,851 patients, surgical audit data were available for fewer than a third of cases and excluded the challenging cases. The study found no significant difference in the overall complication rates tracked, or in the rates of posterior chamber rupture, i.e., staff surgeons, 2.7% and residents 3.9%, P=0.7.

Randleman et al. (Arch Ophthalmol 2007; 125: 1215-1219) evaluated the resident surgeon phacoemulsification learning curve based on a retrospective review of 680 cases and found a significant reduction in the rates of vitreous loss after the residents had completed their first 80 cases (51% to 1.9% P=0.03), a result that was similar to the current trend identified toward decreased complication rates after 8 weeks.

A third study by Hashemi et al. (Cataract Refract Surg 2013; 39: 1377-1382) found when residents were unsupervised in the operating room, the odds of vitreous loss increased markedly compared with residents who were supervised.

The current study findings were that the intraoperative complication rates in cataract surgery are low, resident involvement in cataract surgery does not increase the complication rates, the complexity of the case is associated with higher complication rates, and the resident surgical experience is associated with lower complication rates, she said.

"The current results are based on findings at an institutional level. Individually, there likely are surgeons who have higher rates of posterior capsular rupture and those who have lower rates. There is a good chance that among those surgeons with the lowest rupture rates, having residents increases their rupture rates, but all is well below what we consider acceptable. In addition, some surgeons might perform more complex cases and have a higher complication rate as a result," she said.

Dr. Braga-Mele has no financial interest in any aspect of this report.

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LASIK procedure provides full vision range for presbyopic ametropes

Approach combining micro-monovision with spherical aberration modulation deemed safe

By Cheryl Guttman Krader; Reviewed by Alfredo Castillo, MD, PhD

A PROPRIETARY LASIK procedure that combines micro-monovision with modulation of spherical aberration (Presbyond Laser Blended Vision, Carl Zeiss Meditec) is a safe and effective procedure for improving visual function in ametropic presbyopes, according to findings from a prospective, longitudinal study conducted by Alfredo Castillo, MD, PhD.

Dr. Castillo, Head, Department of Ophthalmology, Hospital Quironsalud, and Professor of Ophthalmology, Universidad Europea de Madrid, Madrid, Spain, analyzed outcomes from follow-up to 6 months for a series of 50 patients, including 19 hyperopes (SE +0.5 to +2.5 D), 14 low myopes (SE -0.75 to -3.0 D), and 17 patients with moderate myopia (SE > -3 to -5.5 D). Patients were eligible for the procedure if they were medically suitable for LASIK, had corrected distance visual acuity (CDVA) > 20/25 in each eye, and demonstrated tolerance to >-0.75 D anisometropia.

The procedure involves correcting the dominant eye to plano and targets low myopia (-0.5 to -1.5 D) in the non-dominant eye.

Results were good across all three ametropic groups. For the population overall, near uncorrected visual acuity (UCNVA) was significantly better than the preoperative distance-corrected near visual acuity (DCNVA), and uncorrected dis-

Ablation profiles

PREOP \hspace{1cm} 1M \hspace{1cm} 3M \hspace{1cm} 6M

GROUP I 0.74 0.72 0.86 0.84
GROUP II 0.49 0.82 0.85 0.92
GROUP III 0.29 0.75 0.86 0.86

PREOP \hspace{1cm} 1M \hspace{1cm} 3M \hspace{1cm} 6M

GROUP I 0.67 0.93 0.96 0.96
GROUP II 0.95 0.83 0.97 0.98
GROUP III 0.91 0.83 0.89 0.99

PREOP \hspace{1cm} 1M \hspace{1cm} 2M \hspace{1cm} 6M

GROUP I 0.58 0.92 0.93 0.92
GROUP II 0.94 0.78 0.89 0.93
GROUP III 0.85 0.78 0.93 0.99

UDVA UNVA UIVA
Group I Hyperopia (+0.5 +2.5 D)
Group II Myopia < 3 D (-0.75 -3 D)
Group III Myopia > 3 D (-3 -5.5 D)

Comparison Preop and Postop Near Visual Acuity (NVA)

FIGURE 2) Comparison between preoperative Bilateral Corrected Distance Near Visual Acuity (BCDNVA) and the Bilateral Uncorrected Distance Visual Acuity (BUDNVA). It shows an statically significant difference (p<0.05).

TAKE-HOME

A study evaluating visual acuity, quality of vision, and patient-reported outcomes in patients with hyperopia (SE +0.5 to +2.5 D) or myopia (SE -0.75 to -5.5 D) support the use of a proprietary LASIK procedure (Presbyond Laser Blended Vision, Carl Zeiss Meditec) for correcting ametropic presbyopia.
Experience confirmation you can see. With the enhanced real-time visual guidance of VerifEye® Lynk Technology, the ORA SYSTEM® is the one and only intraoperative aberrometer that’s clinically proven to improve refractive outcomes at the time of cataract surgery.
tance visual acuity (UCDVA) in the non-dominant eye was better than expected. Importantly, patients reported excellent outcomes, Dr. Castillo said.

“There are several cornea-based surgical methods for correcting presbyopia, including corneal inlays, multifocal corneal ablation profiles, and monovision approaches. Laser blended vision is a safe, effective, and predictable method that may have a benefit for better contrast sensitivity function compared with multifocal IOLs and intracorneal inlays,” he commented.

“It is suitable for emmetropes and for patients with a specific range of refractive errors. The procedure, however, should be avoided in patients with amblyopia or strabismus and in anyone who demonstrates strong ocular dominance.”

**ABLATION PROFILES**

**Continued from page 32**

**The ablation profile is determined using proprietary planning software for the CRS-Master workstation (Carl Zeiss Meditec) and takes into account spherical aberrations, pupil size, final intended refraction, and the functional age of the eye. The ablation can be performed with the MEL-80 or MEL-90 laser (Carl Zeiss Meditec) and has a non-linear aspheric profile that induces modulates spherical aberration to increase depth of field.**

**SERIES OUTCOMES**

Dr. Castillo reported that there were no intraoperative complications. Four patients (8%; three hyperopes, 1 myope) underwent a second procedure for refractive enhancement. Overall, analysis of SE outcomes showed the procedure had good predictability.

Results from visual acuity testing showed that patients achieved a full range of good uncorrected vision. Across the three groups at the 6-month visit, mean binocular UCDVA (decimal) ranged from 0.84 to 0.92, mean intermediate uncorrected visual acuity ranged from 0.96 to 0.99, and mean UCNVA was between 0.92 and 0.99. Preoperatively, mean binocular DCNVA was between 0.41 and 0.59, reported Dr. Castillo.

“The dominant eye is treated for distance vision and the non-dominant eye for near, but each eye achieves some intermediate vision because the treatment increases depth of field. The procedure is called ‘laser blended vision’ because of the overlap between the two eyes in the intermediate vision range.”

**FDA okays insert for noninfectious posterior segment uveitis**

**EYEPOINT Pharmaceuticals Inc. announced that the FDA has approved fluocinolone acetonide intravitreal implant (YUTIQ) for the treatment of chronic noninfectious uveitis affecting the posterior segment of the eye. YUTIQ utilizes the company’s Duraset drug delivery technology and is a non-bioerodible intravitreal micro-insert in a drug delivery system containing 0.18 mg fluocinolone acetonide, designed to release consistently over 36 months. The product is supplied in a sterile single-dose preloaded applicator that can be administered in the physician’s office. In clinical trials, YUTIQ significantly reduced the rate of recurrent uveitis flares versus sham, and the most common adverse reactions reported were cataract development and increase in IOP.**
The crossover between ophthalmology aesthetics

The market for ocular aesthetics is vast, yet very much underserved in 2018

By Melissa Toyos, MD

Ocular Aesthetics has long been considered not serious, scientific or important, compared to “real” ophthalmology. LASIK, contact lenses and presbyopic intraocular lenses serve both functional and aesthetic purposes, but services that are aesthetic alone can be dismissed.

The truth is, there is no more important feature in facial aesthetics than the eyes, and any aesthetic enhancements need to support the eyes’ healthy function. Who but ophthalmologists have unique knowledge of the eyes, coupled with the fine motor skills to treat this delicate area that is so important to aesthetic outcomes?

Ophthalmologists have been on the forefront of advancing aesthetic technologies for decades. A husband-and-wife team of ophthalmologists first brought onabotulinumtoxinA (BOTOX Cosmetic, Allergan) to the public. The radiofrequency craze that is currently sweeping the aesthetics field was utilized in our experiments with conductive keratoplasty decades ago.

Ophthalmologists are also seeing the value of continuous wave lasers in retina and glaucoma—lasers that are only just beginning to penetrate the aesthetics field. We have a great deal to offer facial aesthetics, and the addition of those services can be very rewarding for both patients and physicians.

A Natural Marriage
I first noticed this natural marriage between ophthalmology 20 years ago, when patients asked me if their cataract surgery had caused wrinkles around their eyes. Of course, they just couldn’t see the wrinkles before! As a physician who these patients already viewed with trust and respect, it made sense for me to treat wrinkles in the eye area, and eventually to offer other facial aesthetic services.

The patients overlap, and so do many techniques and technologies. For example, the same laser we use to rejuvenate the trabecular meshwork in selective laser trabeculoplasty (SLT) is used to rejuvenate the skin and cheeks (Selecta II, Lumenis; MicroPulse, Iridex).

Today my practice offers many aesthetic services, including intense pulsed light (IPL) therapy (Optima IPL, Lumenis), treatment with a fractionated CO2 laser for facial resurfacing and tightening (Slim Evolution II with MiXto Pro, Lasering), invasive and noninvasive upper and lower lid blepharoplasty, hyaluronic acid fillers (Juvederm, Allergan; Restylane, Galderma), onabotulinumtoxinA, and deoxycholic acid (KYBELLA, Allergan) for fat under the chin. We also offer custom skin care products, and I prescribe products like bimatoprost (Latisse, Allergan) for aesthetic purposes.

Recently, I treated a patient simultaneously for clinical problems and an aesthetic complaint. Here in Nashville, we treat many of the Tennessee Titans cheerleaders. One of them came to me with dry eye complaints, as well as forehead pigmentation from sun exposure. After her exam, I used IPL to treat her dry eye and the forehead pigmentation, as well as facial rosacea on the cheeks and chin. IPL improved her dry eye symptoms, and it rejuvenated her skin, reduced redness, and improved her comfort.

Take-home

Ophthalmologists have a great deal to offer facial aesthetics, and the addition of those patients can be very rewarding for both patients and physicians, says Melissa Toyos, MD.

OPHTHALMOLOGISTS STILL LEADING

Colleagues in the aesthetics sphere recently pointed out to me that in our selfie culture, everyone is now in the public eye. Everyone is very aware of their appearance and wants to look their best. Combine that observation with the fact that our population is aging, and you see that the market for aesthetics is vast. It’s also woefully underserved.

Although many healthcare providers are getting into the aesthetic market, some of them unfortunately do not have our knowledge or experience. Patients are eager to learn more about their health and aesthetics from knowledgeable and reputable sources, but they don’t always find them.

Whom do you trust to perform blepharoplasty on your patients or inject fillers around their eyes—an ophthalmologist or someone in another specialty? For those cataract patients of mine with the “new” wrinkles around their eyes, I trusted myself to do it, and 20 years later, I still do.

Melissa Toyos, MD

MELISSA TOYOS, MD
P: 901/683-7255
Dr. Toyos is a consultant for Iridex; speaker and consultant for Valeant and Serr; researcher for Kuly, Lumenis, Magnifeye, Novalign, Optomeva, and Serr; speaker, consultant and researcher for Shin, Mollicisust, and MiXto Learning; and consultant and researcher for Digisight.
Wavefront-guided LASIK: bigger increases in corrected/uncorrected VA

WFG LASIK achieved better 25% contrast acuity gains in corrected/uncorrected distance VA

By Lynda Charters; Reviewed by Edward E. Manche, MD

ADVANCES continue in the visual improvements and the quality of vision achieved after LASIK. A comparison of wavefront-optimized (WFO) and wavefront-guided (WFG) LASIK using a high-resolution aberrometer found excellent clinical outcomes and predictability values with both technologies. WFG LASIK fared better than WFO LASIK with better improvements in three parameters: 25% contrast acuity, gains in corrected distance VA (CDVA), and uncorrected distance VA (UDVA).

Edward Manche, MD, and co-investigator Joshua Roe, MD, undertook a prospective study in which each participant was randomized to treatment with WFG LASIK in one eye and WFO LASIK in the fellow eye. The instruments used to perform WFG LASIK were the CustomVue S4 IR excimer laser and the iDesign aberrometer (Johnson & Johnson Vision) and for WFO LASIK the Alcon Allegretto Eye-Q 400 Hz excimer laser (Alcon). The Intralase iFS 150 femtosecond laser (Johnson & Johnson Vision) was used to create all flaps. Patients were asked to complete a validated questionnaire preoperatively and postoperatively 1, 3, 6, and 12 months to survey the quality of vision, Dr. Manche recounted. He is Director of Cornea and Refractive Surgery and Director of Research, Cornea and Refractive Surgery, Byers Eye Institute, and Professor of Ophthalmology, Stanford University School of Medicine, Stanford, CA.

One hundred patients (200 eyes) were included in the study. The mean patient age was 33.57 ± 7.82 (range 21-55); 52% of patients were women. The baseline characteristics of both groups of eyes were well matched.

STUDY RESULTS

The investigators reported that on postoperative day one all 100 eyes in the WFG and WFO groups had 20/32 or better UDVA, 97% and 98%, respectively, had 20/25, and 91% and 85%, respectively, had 20/20. At the 20/12.5 level, WFG LASIK showed better results with 36% achieving that level compared with 29% in the WFO group.

At 12 months postoperatively, similar results were seen in both groups in 97 eyes that completed the examination. The respective percentages of eyes in the WFG and WFO groups were as follows: 99% and 97% had 20/32, 97% and 96% had 20/25, 91% and 85% had 20/20, and 99% and 97% had 20/12.5.

‘The WFG group had more gains in 25% contrast acuity in the WFG group, CDVA, and UDVA at the 20/12.5 level.’ — Edward E. Manche, MD

(Continues on page 38: WFG LASIK)
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97% had 20/25, and 91% and 92% had 20/20 and 71% and 76% had 20/16, and 36% and 29% had 20/12.5, and 2% and 0% had 20/10.

At 12 months, measurement of the low-contrast CDVA showed that 47% and 54% of patients in the WFG and WFO groups, respectively, had 20/50 vision.

There was no statistically significant difference in predictability, with 94.0% achieving ±0.5 diopter (D) of the targeted refraction in the Allegretto WFO group compared with 92.0% with the iDesign WFG group. The respective percentages for ±1.0 D were 97% and 99%.

The results of the quality-of-vision questionnaire indicated that there were no significant differences at any time point and in any parameters (frequency, severity, and bothersomeness of symptoms) analyzed between the two technologies.

The WFG group had a significantly (P=0.04) better mean change in the CDVA compared with the WFO group. Sixty-five percent of eyes gained one or more lines in the WFG group compared to 53% in the WFO group. The WFG group gained 0.8 line compared with 0.6 line in the latter.

The study showed excellent clinical outcomes and predictability in both groups, identical self-reported quality of vision in the two groups, and no difference in the induction of higher order aberrations between the two groups. However, the WFG group had more gains in 25% contrast acuity in the WFG group, CDVA, and UDVA at the 20/12.5 level.
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A new topical corticosteroid, loteprednol etabonate ophthalmic suspension 1% (KPI-121 1%) (INVELTYS, Kala Pharmaceuticals), is the first to receive FDA approval for twice-daily dosing to treat ocular pain and inflammation following ocular surgery. The drug was approved in August 2018.

The big plus for the treatment is that the twice-daily instillation provides significant efficacy while effectively cutting in half the postoperative daily instillation requirement of this steroid, a major boon for the elderly population. All other such drugs generally require instillation four times daily, which is associated with patient non-compliance.

In addition to the less-frequent dosing schedule, the drug’s delivery platform also offers a notable advantage. The mucous-penetrating capability of the Kala AMPLIFY Mucus-Penetrating Particle technology prevents drug washout by the tear film, with resultant increased delivery to the target ocular tissues. Preclinical studies have shown increased penetration of loteprednol by threefold or greater into the cornea and aqueous humor compared with other steroids.

“INVELTYS is a nanoparticle suspension of loteprednol etabonate with superior pharmacokinetics that will reach the target tissues much more efficiently because of its mucus-penetrating properties and thus will enhance its ability to relieve inflammation and pain postoperatively. This mucus-penetrating particle product is innovative and exciting because we finally have a commercially approved nanoparticle drug with improved delivery over existing products. Physicians have been focusing on improved drug delivery of ophthalmic medications for reaching the target tissues for quite some time, and INVELTYS represents a significant advance in drug delivery that will be an important entry into the surgical space,” Terry Kim, MD, said.

Similar Effect on IOP for KPI-121 1% vs Placebo

<table>
<thead>
<tr>
<th>MEAN IOP (SAFETY POPULATION)</th>
<th>KPI-121 1% – BID</th>
<th>VEHICLE</th>
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<tbody>
<tr>
<td>Day 1</td>
<td>15.7 (3.37)</td>
<td>15.6 (2.96)</td>
</tr>
<tr>
<td>Day 8</td>
<td>14.3 (3.02)</td>
<td>13.5 (3.10)</td>
</tr>
<tr>
<td>Day 15</td>
<td>14.5 (2.77)</td>
<td>14.2 (2.96)</td>
</tr>
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NUMBER OF PATIENTS WITH IOP INCREASE > 5 mmHG LEADING TO IOP ≥ 21 mmHG (SAFETY POPULATION)

<table>
<thead>
<tr>
<th></th>
<th>KPI-121 1% – BID</th>
<th>VEHICLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 8</td>
<td>0 (0.0%) n=240</td>
<td>1 (0.5%), n=204</td>
</tr>
<tr>
<td>Day 15</td>
<td>0 (0.0%) n=212</td>
<td>0 (0.0%), n=159</td>
</tr>
</tbody>
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(FIGURE 1) Statistically significant improvements in primary sign endpoint (conjunctival hyperemia) in three clinical trials. Statistical significance achieved (p=0.0405) for Phase 2 primary sign endpoint (conjunctival hyperemia at Day 29). (Figures courtesy of Terry Kim, MD)

C L I N I C A L T R I A L R E S U L T S

In its two multicenter phase III randomized clinical trials in a total of 711 patients, loteprednol etabonate achieved statistical significance for both primary endpoints—the proportion of patients with complete resolution of anterior chamber cells and the proportion with complete resolution of pain on postoperative day 8 maintained through the end of the study with-
out the need for rescue medications. The patients instilled loteprednol etabonate or vehicle twice daily beginning on day 1 postoperatively and over the course of 2 weeks, Dr. Kim explained. He is professor of ophthalmology, Duke University School of Medicine, and chief of the Cornea and External Disease Division, Duke University Eye Center, Durham, NC.

The combined phase III efficacy results showed that loteprednol etabonate was significantly better than the vehicle for resolving inflammation at days 8 and 15 and for relieving pain at those same time points postoperatively (P<0.001 for both comparisons). In addition, at day 4 postoperatively INVELTYS had a rapid onset of effect in completely relieving pain in significantly more patients (P<0.001) compared with the vehicle.

“These improvements were seen with twice-daily dosing after only 3 days of use,” Dr. Kim emphasized.

Adverse events occurred more often with the vehicle than with INVELTYS. The IOP profile was comparable between INVELTYS and the vehicle. The most frequently reported adverse events were eye pain, posterior capsule opacification, and cystoid macular edema, each reported with about a 1.0% incidence with KPI-121 1% treatment vs. about 2.3%, 1.5%, and 1.5%, respectively, with the vehicle.

A SAFER STEROID FORMULATION

Dr. Kim believes that the therapy is a safer steroid because the chemistry is different from the typical steroids that are commercially available.

“Yes, this drug is the steroid loteprednol etabonate, but it is a totally different formulation. Hence, it is not weaker or “softer,” as evidenced by the inflammation and pain endpoints that were efficiently met and the early response data. This is a potent steroid, and its molecular design differentiates it from other steroids,” he said.

The difference results from a change on the molecule in the position of C20, which is replaced by an ester group, which resulted in faster metabolism and absent or less intraocular pressure spiking and cataract formation that occurs with conventional steroids. This change may lead to the erroneous belief that the drug was a softer steroid, Dr. Kim pointed out.

“It is noteworthy that we are finally going to have a nanoparticle formulation of a corticosteroid that has a trusted safety profile. With this formulation using mucus-penetrating technology, I am excited that we will have an efficacious corticosteroid to address inflammation and pain in our cataract patients that allows half the dosing with faster positive results,” Dr. Kim concluded.

The product is scheduled to be launched during the first quarter of 2019. An ongoing phase III trial is enrolling patients to test the efficacy of another concentration of KPI-121 0.25% for treating dry eye disease.
Real-world study of fluocinolone acetonide implant shows DME benefit

Study indicates improvement in treatment burden and retinal thickness fluctuation

By Cheryl Guttman Krader; Reviewed by Alexander M. Eaton, MD

REAL-WORLD OUTCOMES in the United States are very favorable using the fluocinolone acetonide (FaC) 0.19 mg implant (Iluvien, Alimera Sciences) to treat diabetic macular edema (DME), said Alexander M. Eaton, MD.

He reported results from the (US Retrospective Chart Review in Patients Receiving Iluvien (USER) study, a multicenter, retrospective chart review study that is collecting data from patients who are being treated with the implant per the US FDA-approved indication. According to the labeling, the implant is indicated for patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in IOP.

Data were analyzed from 160 eyes of 130 patients who had at least 1 year of follow-up after injection of the FaC implant. Mean duration of DME for the cohort was 4.4 years. All patients were receiving therapy for edema that persisted or recurred and therefore had persistent DME, said Dr. Eaton, Founder and Director, Retina Health Center, Fort Myers and Naples, FL.

The results showed a significant reduction in treatment burden compared with the period before patients received the FaC implant. Safety data showed a marked reduction in the IOP signal within this cohort compared to that observed in the pivotal Fluocinolone Acetonide in Macular Edema (FAME) study.

‘Based on the positive results from the USER study, it seems reasonable to ask whether we are approaching treatment for DME backward.’ — Alexander M. Eaton, MD

‘Based on the positive results from the USER study, it seems reasonable to ask whether we are approaching treatment for DME backward and if it is time for a paradigm shift where the FaC implant would be first-line therapy and supplemented with anti-VEGF injections as needed,” he said.

“I think we need to stay tuned for additional data, but the mitigation of an IOP response and the significant reduction in treatment burden seen in the USER study certainly makes the implant a lot more appealing than it was before the results were available.”

The USER study entered patients at four US centers who received the FaC implant before January 1, 2016 in at least one eye. The patients included in the outcomes analysis had a mean age of approximately 70 years and a mean duration of diabetes of 24 years. Mean HbA1c was 7.07%, nearly 90% of patients were white and had type 2 diabetes, and approximately 70% of the patients were pseudophakic. Mean duration of follow-up was 899 days before the FaC implant and 403 days after it was placed.

Mean visual acuity (VA) analyzed for visits at 3-month intervals from 36 months prior to receipt of the FaC implant through 24 months after showed that VA remained stable, but visual function was maintained in the cohort with a significantly reduced treatment burden (once every 2.9 months before the FAc implant to once every 14.3 months after; P<.001).

Approximately two-thirds of patients required no additional treatment after getting the FaC implant; 17.4% of patients received anti-VEGF injections, 7.5% received additional corticosteroid, and 6.0% were treated with laser.

An analysis with patients divided into four groups according to baseline VA (<20/200, 20/200 to <20/100, 20/100 to <20/40, and ≥20/40) showed a significant reduction in need for treatment across all groups. Before getting the FaC implants, patients in all four groups were being treated approximately every 2 to every 3 months. After getting the FaC implant, treatment frequency across the four groups ranged from a maximum of about once every 7 months to a low of once every 22 months.

“Patients with better VA at baseline needed less frequent treatment after getting the FaC implant. They also had had little room for improvement in VA, but patients who had the worst VA at baseline benefited with improvement after getting the FaC implant,” he said.

Mean retinal thickness trended downward from the beginning of the study, but the improvement was greater after patients received the FaC implant. Fluctuation in retinal thickness, evaluated by analyzing the maximum range of the retinal thickness fluctuations as derived from the difference of minimum and maximum central subfield thickness, decreased by more than 50% after patients received the FaC implant, from approximately 225 microns to less than 100 microns (P<.001). Subgroup analyses showed the statistically significant benefit for reduced retinal thickness fluctuation after FaC implant injection was present regardless of baseline VA.

“Consistent with other evidence, we found a poor correlation between retinal thickness and VA in our patients with DME. There was a stronger correlation between the amplitude of fluctuation and VA. This finding suggests that mitigating the amplitude of the fluctuation of retinal thickness might translate into
beneficial effects on vision, and that certainly makes sense theoretically,” he said.

**PROPER PATIENT SELECTION**

Mean IOP was stable throughout the follow-up period prior to FAc implantation and elevated slightly after patients received the FAc implant. Mean IOP was 14.6 mmHg at the time of injection and reached a maximum of 16.2 mmHg at 15 months, but declined thereafter, which was explained by initiation of treatment for IOP-lowering.

He reported that most IOP elevations were controlled with topical medications. Twenty-eight (17.5%) eyes were receiving IOP-lowering medication on the day of the FAc implant injection and 24.4% were receiving IOP-lowering medication after its administration during the follow-up. Two eyes underwent incisional IOP-lowering surgery after FAc administration, which was the same number that had incisional IOP-lowering surgery in the period before receiving the implant, he said.

He reported no significant difference in the percentage of patients who were on an IOP-lowering medication on the day of the FAc implant injection compared with after.

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**MacuHealth announces Canadian medical advisory board**

**MACUHEALTH** introduced its new Medical Advisory Board to the eye care professionals of Canada in line with the company’s focus to continue to uphold its tradition of excellence in science and products. The board is comprised of premier retina specialists, experts, and key opinion leaders in ophthalmology across Canada. The newly appointed advisory board will provide MacuHealth with valuable insight to help shape the company’s overall nutraceutical direction in supporting patients with a lifetime of superior eye health and exceptional vision.

From its original three senior members, Dr. Alan Berger, BSc, MDCM, FRSCS, Dip. ABO, Dr. Robert Devenyi, MD, MBA, FRSCS, FAC, and Dr. Jeffrey Machat, MD, FRSCS, DABO, the board will soon expand to provide representation at the Provincial level in order to provide all eye-care professionals with the state-of-the-art science and information on MacuHealth.

“We are extremely honoured to present our Canadian Medical Advisory Board,” said MacuHealth President and CEO Frédéric Jouhet.

“MacuHealth has a strong position in Canada and is committed in supporting all eye-care professionals in delivering the utmost science-based care to their patients. Having a prestigious group of doctors on our Board helps us provide the best product for macular degeneration patients and overall visual performance, this is a tremendous opportunity to reach all doctors and patients.”

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**OCTOBER 15, 2018 :: Ophthalmology Times**

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Visit cornea360.org to register, book your hotel accommodations, and stay current with important meeting information.
Cryopreserved amniotic membrane (AM) tissue is an ocular surface disease (OSD)-modifying therapy that aids corneal epithelialization, reduces inflammation and fibrosis, prevents structural damage, and has antimicrobial properties. Most conventional therapies for OSD are palliative in nature, whereas AM is a regenerative intervention. In fact, one of the most interesting aspects of cryopreserved AM tissue is its ability to regenerate corneal nerves when used in the treatment of OSD.

AM technology has evolved and improved and been perfected to the point where it now serves a huge previously unmet need in my practice for OSDs such as dry eye disease (DED) as well as a host of common and recalcitrant ocular surface corneal stromal conditions such as keratitis, recurrent corneal erosions, filamentary keratitis, persistent epithelial defects, neurotrophic corneas, and herpetic ulcers, among others.

Any time we treat infectious keratitis, the goal is first to kill the organism and second to preserve the structural and optical integrity of the cornea. AM can significantly reduce the inflammatory and degradatory responses while at the same time providing its own nonspecific but intrinsic antimicrobial activity. The antimicrobial activity of AM is by no means a substitute for high-potency, specifically tailored antibiotic, antifungal, antiviral, or antiprotozoan therapy. It does, however, provide a great means of additional antimicrobial control, in contrast to the standard bandage contact lens—which, while affording optical clarity, can in some cases prevent the access of antibiotics to the eye and decrease oxygen availability to the ocular surface. AM provides a bandage effect while also allowing access of oxygen and antimicrobials; and instead of trapping degradatory enzymes, AM absorbs and neutralizes them.

Two types of AM tissue are available for ophthalmic applications: cryopreserved AM tissue, and dehydrated extracellular membrane derived from human amniotic tissue. Cryopreserved AM (Prokera, Bio-Tissue) must be kept frozen and brought to room temperature before placement. Dehydrated AM (AmbioDisk, IOP Ophthalmics/Katena; BioDOptix, Derma Sciences) is stored at room temperature but must be rehydrated for clinical use. Cryopreservation supports retention of biologic properties that promote anti-inflammatory effects and healing. Cryopreserved amniotic membrane tissue contains the novel matrix heavy chain (HC)-hyaluronic acid (HA)/pentraxin 3 (PTX3), which research has associated with AM’s anti-inflammatory, antiscarring, and regenerative properties. HC-HA/PTX3 is not present in dehydrated amniotic tissue.

A recent retrospective study demonstrated that a single application of Prokera self-retained cryopreserved amniotic membrane (cAM) can accelerate the recovery of the corneal surface and help reduce signs and symptoms of DED for at least 3 months. These results are consistent with another prospective study that showed that this lasting effect is correlated with corneal nerve regeneration as evidenced by an increase in corneal nerve density and improved corneal sensitivity. While dehydrated AM may work for selected patients, the proteins in the cryopreserved preparations are more plentiful and active.

The beauty of currently available forms of AM tissue is their versatility. We have at our disposal several types of sutureless CAM in the form of Prokera, Prokera Slim, Prokera Clear, and a double thickness Prokera Plus. They all act as a biological bandage, with the stromal side in contact with the cornea. The double thickness product (Prokera Plus) can be used for aggressively active inflammatory conditions; and the most common—Prokera Slim—has a redesigned annulus for increased comfort. I use Prokera Slim for a wide variety of conditions almost every day in my practice. For the occasional monocular patient who still needs to see with the semi-translucent membrane in place, Prokera Clear, with a small central opening, is available.

Dehydrated AM requires the placement of a bandage contact lens on top of the membrane to ensure centration and maintain proper orientation of the membrane. I find these to be particularly useful for patients who have an unusual lid configuration, glaucoma tube shunts, or a contracted conjunctival cul de sac.

The third type of AM available today is an off-label, non-reimbursed eye drop formulation that is provided through a small number of carefully managed compounding pharmacies. These formulations come in vials that must be kept frozen by the patient and thawed and instilled several times a day. AM extract is also in development by true biologic companies. For example, Noveome Biotherapeutics has a proprietary preparation of amniotic cell super-

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Any time we treat infectious keratitis, the goal is first to kill the organism and second to preserve the structural and optical integrity of the cornea.

— John Sheppard, MD

Continues on page 45: Cryopreserved AM

OCTOBER 15, 2018 :: Ophthalmology Times

BY JOHN SHEPPARD, MD; SPECIAL TO OPHTHALMOLOGY TIMES
Vascular stress a contributor to age-associated vision loss

VASCULAR stress exacerbates age-associated vision loss, according to a recently published article in *Experimental Biology and Medicine* (http://journals.sagepub.com/doi/full/10.1177/1535370218794915). The study, led by Dr. Rajashekhar Gangaraju, in the Department of Ophthalmology and the Department of Anatomy and Neurobiology at the University of Tennessee Health Science Center in Memphis, TN, demonstrates that chronic activation of endothelial cells that line the surface of blood vessels promotes age-dependent losses in visual acuity in an animal model.

During aging, some cells stop growing and functioning. These “senescent” cells can also have bystander effects on other cells and prevent them from performing their functions. Activation of the endothelial cells results in a severe inflammatory response that includes release of the pro-inflammatory cytokine TNF-alpha. Dr. Gangaraju’s group has previously shown that TNF-alpha results in premature senescence in endothelial cells.

Performing LIV tests allows you to objectively evaluate retinal health now and over time, for tailored treatment and more precise disease management.

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**References**

Combination therapy for DME results in longer, better BCVA/CMT outcomes

Pairing of ROCK inhibitor and anti-VEGF drug may work better compared to monotherapy

By Lynda Charters; Reviewed by Hamid Ahmadieh, MD

A COMBINATION therapy of a Rho kinase inhibitor and an anti-vascular endothelial growth factor (VEGF) drug may be highly beneficial for patients with diabetic macular edema (DME). The results of a pilot study of fasudil (Asahi Kasei Pharma, Tokyo, Japan) and bevacizumab (Avastin, made for F. Hoffmann-La Roche, Basel, Switzerland, by Genentech, San Francisco) showed that adjunctive intravitreal injection of fasudil might prolong and enhance the effects of bevacizumab for DME compared with bevacizumab monotherapy.

To now, anti-VEGF drugs have been the primary treatment for patients with impaired vision from DME, and while they have been efficacious, anti-VEGF drugs cannot positively impact the local inflammation and the resultant endothelial damage induced by leukocytes that are associated with the disease and cause retinal vessel permeability, according to Hamid Ahmadieh, MD, the lead author of this study, and deputy director of research, Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

And this is where there may be a role for fasudil.

Previous in vivo and in vitro studies have shown that the drug inhibited the leukocytic activity and thereby the damage.

CLINICAL TRIAL
This prospective clinical study included 44 eyes of 44 patients (mean age, 57.9 ± 8.4 years; range, 44-75 years) with center-involving DME who were randomized to either the combined treatment group or the bevacizumab monotherapy group. Dr. Ahmadieh recounted that the combined treatment group received three consecutive intravitreal injections of the two drugs per month (1.25 mg of bevacizumab and 50 μM/L of fasudil), while the monotherapy group (1.25 mg of bevacizumab) received one injection monthly for 3 months. The investigators evaluated the changes in the best-corrected visual acuity (BCVA) and central macular thickness (CMT) between the two groups.

The parameters were measured at 3 and 6 months after the start of treatment; the BCVA at the 6-month evaluation was the primary outcome. Data were available from 42 eyes, because two patients were lost to follow-up.

BCVA IMPROVEMENTS
Dr. Ahmadieh reported that the mean BCVA improved significantly in both groups by the 3-month time point, and was greater in the combination group at both 3 and 6 months (P=0.008 and P<0.001, respectively).

“In the combination therapy and monotherapy groups, respectively, 54.5% and 10% of the eyes gained 15 or more ETDRS letters by the final evaluation, a difference that reached significance (P = 0.026),” he said.

However, the improvement in the BCVA persisted significantly (P < 0.001) to the 6-month time point only in the combination therapy group. In the monotherapy group, the BCVA decreased significantly by 5 ± 7 letters between the evaluations at 3 and 6 months. The changes in the BCVA were reflected in the changes in the CMT, which decreased significantly in both treatment groups at month 3; however, this reduction was significantly more pronounced in the combination group than in the monotherapy group. More importantly, the CMT reduction was sustained up to 6 months only in the combination group.


CONCLUSION
The authors concluded that when the fasudil was administered intravitreally along with bevacizumab, the combination “is likely to promote the efficacy and increase the durability of anti-VEGF drugs in the treatment of severe DME.” However, they also pointed out that these results must be confirmed in larger and longer studies and the pharmacokinetics of intravitreal fasudil need to be assessed.

The central macular thickness reduction was sustained up to 6 months only in the combination group.

While they are efficacious, anti-VEGF drugs cannot positively impact the endothelial damage induced by leukocytes.

ADD A ROCK kinase (ROCK) inhibitor to an anti-VEGF drug may enhance and prolong the effects of the anti-VEGF therapy for treating patients with diabetic macular edema.

Hamid Ahmadieh, MD
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Dr. Ahmadieh has no financial interest in any aspect of this report.
Embracing and managing AI to produce eye care solutions
‘Narrow AI’ can perform specific tasks with excellent— or even super-human—ability

By Sameer Trikha, MBA FRCOphth

AI solutions company Visulytix has developed an eye care analysis tool that is being rolled out to selected institutions around the world—both for clinical use and to support investigational studies. The decision support tool, Pegasus, facilitates specialist level decision-making support, at scale, to eye care providers: a first for the industry.

The benefits of AI will be a game changer for the screening and care of conditions like glaucoma, age-related macular degeneration, and diabetic retinopathy, but how can AI systems be successfully managed?

EVALUATION

While such systems are likely to attract much fanfare, they must be evaluated quantitatively, as well as for their ability to work ‘out of the box’ and in diverse clinical environments.

Eye care professionals will be required to embrace the technology and understand, at least at a general level, some of the technical and statistical terms that may be used in product documentation and performance. These include such terminology as sensitivity, specificity, and accuracy.

It will be important to evaluate the context in which the AI system should be deployed, as well as any contraindications for its use.

There are misconceptions regarding the abilities of the first generation of AI decision support systems. It is anticipated that they may grow and are assumed to perform a variety of tasks healthcare professionals currently undertake; but this is not the case. Instead, they should be thought of as ‘narrow AI’ that is, technology that can perform a very specific ‘narrow’ task with excellent (and in some cases super-human) ability.

Eye care professionals will still need to obtain the same qualifications and learn the anatomy and pathophysiology around the eye.

As AI systems become diffused into clinical practice, the technology will need to be incorporated into staff induction, training and continuous professional development.

In many organizations, key performance indicators (KPIs) are in place to evaluate staff effectiveness. These may include the number of glasses sold by the sales team and the total resultant value. Such KPIs are often used to focus the staff member on how he or she may add value to an organization.

An AI system will have model and performance metrics that should also be measured. Routine audits and post-market surveillance will become commonplace. In the same way staff undergo regular appraisal—with poorer performers being informed of the gap between what they are and should be delivering—a parallel AI system performance should also be appraised.

TAKE-HOME

• As AI systems become diffused into the clinic, technology and continuous professional development will need to be incorporated into staff training to drive practice gains.

SAMIR TRIKHA, MBA FRCOphth
Ph: 44/08081-974030
Dr. Trikha is a consultant ophthalmic surgeon at King’s College NHS Foundation Trust, and founder/chief medical officer at Visulytix, London, UK.

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Buy Early • Save Money
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THE PROPELLER TURBO TIP for cataract surgery is an important advance that represents the next generation in tips for torsional phacoemulsification, said Tadahiko Kozawa, MD, who is the inventor of the tip. He noted that the tip, which is manufactured by Charmant Inc., is only available in Japan, and it is still being refined.

“The propeller turbo tip has a round, straight shaft instead of a bent design and it operates without side-to-side movement,” said Dr. Kozawa, Department of Ophthalmology, Kozawa Eye Hospital and Diabetes Center, Mito, Japan. “Therefore, the propeller turbo tip has the configuration that most surgeons prefer and minimizes the risk of causing damage to ocular tissues.”

These advantages of the propeller turbo tip come with the same crushing performance as a traditional torsional tip, he said.

“During other words, the propeller turbo tip is a more surgeon- and patient-friendly instrument that maintains the benefit of a torsional tip while solving its problems,” Dr. Kozawa said.

TAKE-HOME
» The propeller turbo tip for torsional phacoemulsification has a straight design and operates without side-to-side movement. It has the same crushing performance as a traditional torsional tip but minimizes the risk of ocular tissue damage.

PROOF OF PERFORMANCE
The crushing ability of the propeller turbo tip was demonstrated in a bench study where its action was recorded with high-speed video. Not only did the new tip work well to break apart the nucleus, but compared with use of a traditional torsional tip, the propeller turbo tip aspirated the pieces much more smoothly, causing minimal scattering of nuclear fragments.

‘The propeller turbo tip is a more surgeon- and patient-friendly instrument that maintains the benefit of a torsional tip while solving its problems.’ — Tadahiko Kozawa, MD
Technology innovations that will improve your revenue cycle

Small adjustments, such as paperless billing and eligibility software, can drive big gains

By Avery Hurt

WORK SMARTER, not harder. It’s the 21st century, after all.

If you’re looking for innovations to boost your billing and collections efforts, you might want to consider embracing technology. These innovations may cost you some time and effort up front but may save you a bundle in the long run. Here are three ways to make technology work for you.

GO PAPERLESS

According to a recent survey conducted by HIMSS Analytics, nearly all medical providers still invoice patients via paper. However, more than half of surveyed patients said they would prefer to be billed electronically and pay their bills online, too. Paying bills by credit card via online patient portals can be second nature for patients who are used to adding to cart and going straight to electronic check out.

“These days, people want to be able to pay their bills on their smartphones while waiting in line to pick up the kids,” says Barbie Hays, coding and compliance strategist for the American Academy of Family Physicians (AAFP). If you’re still sending paper invoices, consider moving into the Digital Age. Sending electronic invoices and accepting payments online can make a significant difference in your collections rate.

ACCEPT PAYMENT ON THE SPOT

Even better than billing and accepting payment online is collecting money at the time of visit. Your chance of collecting a payment decreases by almost 20% the minute the patient walks out of your office, Nancy White said in a widely cited American Physical Therapy Association podcast. Accepting credit cards is one of the best ways to boost your in-office payment rate. Because fewer people carry cash these days, the ability to accept credit and debit cards at the front desk is essential in today’s practice. Just be sure you’re compliant with the Payment Card Industry Data Security Standards (PCI DSS) regulations. Hays notes that keeping patients’ credit card information on file is no longer recommended because of the increasing security risks involved, especially if you are the victim of a ransomware attack. If you explain to patients that the minor inconvenience of having to enter their credit card information for every transaction is actually a security precaution, that should resolve any complaints as well bolster their confidence about your stewardship of their data, both financial and medical.

CHECK ELIGIBILITY WHILE YOU SLEEP

Eligibility verification software is a tool that can help with your collections. This innovative technology is generally an add-on to your EHR that allows you to check a patient’s eligibility, copay, and coinsurance. It runs in the background to send requests in batch.

“It saves time because you don’t have to call to check verification for each patient individually,” says Brennan Cantrell, commercial health insurance strategist for the AAFP. The software doesn’t work for all plans, but it should work for many of your patients with big national payers. Because the program is generally a third-party add-on, it will likely cost extra.

“For most practices, it well may be worth the cost.”

Editor’s note:
This article originally appeared in sister publication, Physician’s Practice.
Your staff’s lasting legacy
How a news broadcast reshaped a preconceived notion about the millennial generation

Putting It in View By Dianna E. Graves, COMT, BS ED

While I was waiting for the water to boil for the last of the season’s corn on the cob, I was loosely watching the national news. The anchor was doing a story about millennials, and commented that they are known as the “entitled generation.”

A friend chimed in and stated that they believed this to be a true statement because the only thing that “drove” them was money. For argument’s sake, I stated that I didn’t believe that was all true because I had a large number of my staff that are millennials and I have found them to be very driven about their roles in the clinic. They want to learn everything, want to do, and touch everything, and then move on to the next thing. And yes, there was the money issue as well—but I really felt that their position and role was most important to them.

Since I didn’t really care to argue anymore about that point, I remained silent until the anchor stated that the boomer generation (mine) was known as the “Me” generation.

This got my attention fast!

As a manager and an educator—I don’t think it has been about me for the last 30 years! My whole life has revolved around the needs of the staff, the doctors and the family—and if there is any sanity left at the end of the day, and “those” and “them” and all the other labels people get tagged with to put them in a little pigeon hole.

This was the mindset I had as I was thinking about my technicians’ meeting that evening and what message I was going to send to the staff. I was indignant about the label on my generation—and even more on their label. I was trying to figure out how to work that in to the final message.

Like any group, we have generational clashes: cell phone usage is always an issue, and arrival and departure times are blurry (even though they have clocks on their phones and wrists). I’ve also noticed their feelings get hurt from the other technicians’ sense of humor, but it seems to me they have no sensor when they say things behind “closed doors.”

GENERATIONAL CLASHES

I was spinning my wheels trying to decide what message to send them, until an ad came on the radio that afternoon. In the background of the announcer, John F. Kennedy was delivering his “Ask not what your country...” speech. And then it hit me. I knew what needed to be said, and how to do it.

I raced through the meeting. We discussed cell phone usage, clinic start/stop times, lunch times and EMR concerns on documentation. Just like any other technician meeting in the country. And then I told them to put their agendas down.

I pulled a chair up in the middle of the crowd and I started.

“The other night I was watching TV and the

news anchor said that most of you folks were from the ‘entitled generation.’ That all you are worried about was money.” Yes, it got their attention.

“And I figured well, I don’t think that’s totally true. I thought that, while everyone was aware of money, the millennials were more concerned about LEGACY.”

“But, you know, I didn’t really care what someone thought about your group—until they said that my group was the “Me” generation, and then I really got irritated because it intimated that all my generation thought about was ourselves.”

I then began to discuss how we had a number of technicians in the past year and a half that had retired. These people had been hardworking boomers that had spent the latter parts of their years here training the next generation (them). They had worked hard to ensure that the next group coming in would do it the “right way,” which is the way they wanted it done so that their legacy wouldn’t be tarnished.

I asked them to take a moment and think about some of the folks that had left, and think about what they had done for them. Not because they got paid more for their training, because they did not get paid to share their knowledge; but because they wanted it done right.

I asked them to stop and think of the gift they had given the people that they left behind. I asked them to remember that while they did this teaching, they were kind, and fair, collegial and caring. And yes, they were also demanding, exasperating, and grumpy and on some days, even down right snarky when the trainee didn’t do it right for the 30th time. But, they still coached to try to make it better.

I told them, “John Kennedy said to a generation who was ‘looking for something’ to ‘ask not what your country could do for you—but what you could do for your country.’ To stop thinking about what we were owed, but what we owed back to our country.

“When he started the Peace Corps and peo-
ple flocked to give and be part of it. And when he stated that we would go to the ‘moon not because it was easy, but because it was hard’ a nation believed that we could. And then we did.”

I reminded them that, when given an impossible task, everyday people will step up and do what is asked.

It was pretty quiet. Everyone was nodding and listening. And thinking.

decide to go to someone else and not even try to ask you for help because they knew they would get minimal to little help when they asked?”

LEAVE A LASTING LEGACY
Throughout the past few months, I have had some of the millennials come in and sit and tell me that they have

And then I asked the question they knew that was coming.

“So, when you leave here for whatever reason, retirement, new job or moving—what will your legacy be? What will people say about you and what you did in your time here? “Better yet, or how did you do it? Did you teach and leave out a few strategic parts so you would always be the best, or did you teach fairly? Were you kind, or only kind to their faces? Could they count on you to help or did they

decide to go to someone else and not even try to ask you for help because they knew they would get minimal to little help when they asked?”

LEAVE A LASTING LEGACY
Throughout the past few months, I have had some of the millennials come in and sit and tell me that they have

I reminded them that, when given an impossible task, everyday people will step up and do what is asked.

— Dianna E. Graves, COMT, BS ED

And then I asked the question they knew that was coming.

“So, when you leave here for whatever reason, retirement, new job or moving—what will your legacy be? What will people say about you and what you did in your time here? “Better yet, or how did you do it? Did you teach and leave out a few strategic parts so you would always be the best, or did you teach fairly? Were you kind, or only kind to their faces? Could they count on you to help or did they

thought long and hard about what they “want” for themselves in the future, and how they want to be remembered.

I listened patiently, nodded appropriately and then said, “So what are you going to do about it? Because why are we all waiting!!”

The last person I talked to smiled at me, was quiet for a bit, and then said, “I’ll get back to you, John.”

And that was good enough for me.

DIANNA E. GRAVES, COMT, BS ED
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Graves is a clinical services manager at St. Paul Eye Clinic PA in Woodbury, MN. Graves is a graduate of the School of Ophthalmic Medical Technology, St. Paul, MN, and has been a member of its teaching faculty since 1983.

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The [inlay] itself has no refractive power,” said Ralph Chu, MD, Chu Vision Institute, Bloomington, MN, and clinical investigator, ReVision Optics. “It is refractively neutral and improves near vision by altering the prolate shape of the cornea and increasing the central power of the cornea. The change in shape is very gradual and very smooth, which gives the marked improvement in near vision with very little change to distance vision.” He evaluated visual outcomes and topographic changes in a cohort of 23 patients who were part of a multicenter trial with 373 patients that led to the approval of the device.

To read more, go to OphthalmologyTimes.com/Inlay

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ANY MEDICAL PRACTICE with multiple owners must have a funded buy-sell agreement in place to protect the partners and their families from the death or exit of a partner. We look at what should be covered in this essential legal document and what happens when it isn’t complete.

A “buy-sell agreement” is most simply defined as an agreement between all the owners of a practice as to how (or if) the business will continue after the death or exit of a partner and how or if they or their family will be compensated when such an event occurs.

The death of a partner is the most obvious and commonly addressed issue, but it is neither the only issue partners face nor is it the most likely.

The disability of a partner is nine times more likely than death before the age of 65. In addition, the disqualification of a partner due to arrest or incarceration, loss of license or certification, or commission of non-criminal act that makes them an unacceptable partner is a problem.

Examples of acts by a single partner that can destroy a business overnight include recent high-profile #metoo claims and acts of overt racism that have been shared on social media with instant mob response. Negative national exposure that goes viral can make continuing with that response. Negative national exposure that can destroy a business overnight include recent high-profile #metoo claims and acts of overt racism that have been shared on social media with instant mob response. Negative national exposure that goes viral can make continuing with that response.

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■ Make sure your practice is covered in case of death, disability, divorce, departure, and disqualification, says Ike Devji, JD. If you haven’t done so already, review your buy-sell with counsel.

TAKE-HOME

DON’T BE LEFT IN THE DUST

In one real-life case study, a physician practice owner brought two younger doctors as minority owner partners. The senior physician assumed that he’d practice most of his life and eventually sell the practice to the other doctors in the future, so they rightly entered a basic buy-sell agreement that was funded with enough life insurance to pay off a partner’s family in case of the death of any one partner.

Unfortunately, what actually happened was not covered.

The senior doctor became disabled and was unable to perform his specialty. The younger doctors lacked the cash to buy him out, so he was going to sell the majority of the practice to a third-party doctor in order to exit with enough cash.

So as not to lose ownership of the practice, the younger doctors pulled all their cash together, re-mortgaged the office building they owned to pull out the equity, agreed to a five-year stream of high payments to the senior doctor, and convinced him to take less than the agreed upon value of the practice to get the deal closed.

Fortunately, he did agree and was also covered by high limit “own occupation” personal disability insurance.

The buy-sell should also have included provisions for both the temporary disability of partner and a disability buy-out, which was needed here.

Had they been better advised and done so, all parties would have been better off. The senior doctor would have received slightly more cash right away and the younger doctors would have been able to keep their savings and the equity in their building while avoiding the stream of burdensome payments required to keep their business.

MUST-KNOW BASICS ABOUT YOUR MEDICAL PRACTICE BUY-SELL AGREEMENT:

1. The biggest mistake most doctors make is not having any buy-sell agreement at all.

2. A failure to have a buy-sell routinely results in threats to your income and practice including:
   - Being put into business with your partner’s spouse
   - Lawsuits and liquidation of otherwise sound practices
   - Having to liquidate other personal assets for an emergency buy-out
   - Significant expense, delay, and interference with patient care and doctor profit

3. The second-biggest mistake is not having a buy-sell wide enough in coverage to include all the “Five Ds”: Death, Disability, Divorce, Departure, and Disqualification.

4. If you do have an agreement make sure it is actually adequately funded with life, disability, disability buy-out, and any other insurance required and that the insurance limits are reviewed every year or two and kept adequate to meet the valuation your buy-sell specifies. 75 percent of the agreements we see are outdated, underfunded, or unfunded.

5. Review (or establish) your buy-sell with counsel now, before it is a problem. Most doctors don’t know what would happen and how well they are covered against the Five Ds. The first time most doctors find out what they have is in a crisis, when an old document is finally located and found to be lacking.

Editor’s Note:
This article originally appeared in sister publication Physician’s Practice.
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Legal considerations of practice expansions: Common approaches

Think carefully about your long-term goals before choosing a specific pathway

By Erika L. Adler

Physicians often reach out to me when looking to expand their medical practices. Many have no idea what type of expansion they are looking for or what their options might be. Since expansion can mean so many different things depending on who you ask, it is important for a practice to think carefully about its long-term goals and choose the expansion approach that works best.

Many expansion ideas can even be combined. Here are some common expansion approaches for medical practices:

1. Expansion through acquisition of additional space and equipment.
   A practice might consider expansion if it has outgrown space for its providers, and/or has inadequate equipment or other facilities in which to serve its patients. This might mean opening a second office or acquiring additional equipment to meet demand. Sometimes, expansion goals can be achieved through short-term space and equipment leases, which can help a practice get a feel for expansion without a long-term capital commitment. Even renting space through a space and/or equipment extender can offer. Finally, many states require written documentation for practice extenders. Physicians need to do their homework when hiring practice extenders and should not consider this approach as a quick way to increase revenue. Practices must confirm proper billing and coding of all professional services, provide the appropriate level of supervision (if any), and meet any prescription authorization requirements. It’s also important to be familiar with the scope of a mid-level’s license so that the practice is not expecting more than what the extender can offer. Finally, many states require written documentation for practice extenders. A review of legal requirements is therefore important.

2. Expansion through additional providers.
   Many practices seek ways to expand their revenue without taking on additional debt. This can be a challenge even when patient volume is available since the hours in the day for patient care are limited. Financial expansion of a medical practice can be achieved through the addition and effective use of practice extenders. If you’re thinking about adding mid-levels to your practice, it’s important to consider some important questions:

   - Is the patient volume really there?
   - Is the reimbursement going to cover the expense of the provider?
   - Do you have adequate physicians to provide supervision?
   - Is your patient base willing to see a mid-level?
   - Do you have the space and equipment to add new providers to your practice?

   Taking-home: Whether you want to expand through space and equipment, additional providers, or acquisitions and mergers, research how each expansion will impact the long-term goals you’ve set for your practice.

3. Expansion through merger or acquisition.
   Another popular practice expansion approach is merging or integrating with a different practice of the same or different specialty.

   There are many supergroups in which certain specialties have been rolled together into a larger practice with multiple locations, sometimes expanding beyond state lines. Such an expansion can benefit physicians who are looking for managerial support, additional clinicians, marketing, and patient volume.

   On the other hand, the larger such groups become, the more physicians may lose a sense of the personalized practice they once enjoyed. Nonetheless, supergroups appear to be a growing trend throughout the marketplace.

   It’s important to obtain complete legal and financial advice before entering into any such transaction as there are many legal, compliance, tax, and other issues to consider. Smaller expansion efforts through strategic mergers with complementary specialties is also a great way for practices to expand.

   By merging into a single entity, groups can often share overhead, staffing, ancillary services, and space.

   The result can be a larger footprint in the region, increased revenue, and locked-in patient referrals. Again, there are many legal and related issues to discuss with a lawyer when considering such an expansion.

   The above concepts are only some ideas of how practices can expand. Practices might also expand by offering new services to their patients or even updated technology, e.g., telemedicine. Other practices might choose to expand by bringing in specialists to capture their ongoing referrals. For every practice, the best expansion route depends entirely on the practice’s goals and expectations.

Editor’s Note:
This article originally appeared in sister publication Physician’s Practice.
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You’re better off with the 20-20-20 rule

“You can’t cure your eye strain by switching to a smartphone.”

Artwork by Jon Carter

in case you missed it

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Artwork by Jon Carter

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Fungal keratitis: beyond the slit lamp

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Technician plays key role in ophthalmic exam

Some components of the ophthalmic exam are performed by technicians, requiring adequate knowledge of eye to diagnose appropriately.

By Michael W. Stewart, MD

The ocular surface and adnexa, and the clear view of the retina and choroid obtained through transparent ocular media in most patients, are conducive to making ophthalmologic diagnoses based solely on the visual examination. A thorough ocular and systemic history, however, will suggest the correct diagnosis in most cases.

When parts of the complete examination—uncorrected and corrected visual acuity, pupillary examination, confrontation visual fields, ocular motility, and intraocular pressure—are added to the history, most diagnoses can be correctly made without the use of a slit lamp, ophthalmoscope, or ancillary testing.

The unofficial rule of thumb that "80 percent of diagnoses are made based on the history, 10 percent on the physical examination, and 10 percent by ancillary testing" holds true not only for internal medicine but also for ophthalmology.

TECH ROLE CONTINUED ON PAGE 3
Dry eye is one of the most frequent causes of patient visits to eye care practitioners, affecting an estimated 30 million people in the US. Dry eye symptoms may adversely affect visual function, potentially resulting in reduced quality of life and productivity. 

Determining the major etiology behind the dry eye is essential to optimal management. In aqueous deficient dry eye, hyperosmolarity results when lacrimal secretion is reduced. In evaporative dry eye, tear hyperosmolarity is caused by excessive evaporation from the exposed tear film due to insufficient production of protective lipids.

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References
13. Lane S, Paugh JR, Webb JS, Christiansen M. An evaluation of the in vivo retention time of a novel artificial tear as compared to a placebo control. Poster presented at: The Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO); May 5-7, 2009; Fort Lauderdale, FL. 
Tech role

Continued from page 1

A word of caution should be made though, because some patients relate an unreliable history or one filled with extraneous facts, which can lead to the inability to arrive at a proper diagnosis.

When dealing with challenging patients, experience and expertise are required to “weed through” histories to identify relevant facts.

This article will discuss important components of the ophthalmic examination that are usually performed by technicians.

Adequate knowledge of the eye, ocular adnexa, sensory inputs, and visual pathways are critical to arriving at some of the important diagnoses discussed as follows.

Cases were extracted from the author’s practice to illustrate principles and to emphasize the importance of thoughtful, complete adherence to the correct examination sequence.

Anatomy

The eye is situated within the bony orbit and is covered and protected by the eyelids. Fibers that transmit visual signals leave the eyes within the optic nerves (cranial nerve II), pass through the optic foramen in the posterior orbital wall and the cavernous sinuses, before converging at the optic chiasm.

Nasal fibers of the optic nerves—those that perceive the temporal visual fields—cross through the chiasm to the contralateral side where they converge with temporal fibers from the other nerve to form the optic tracts.

These terminate in cell bodies within the lateral geniculate bodies of the thalamus. Optic radiations connect these cells to the visual cortex in the occipital lobe—the area of the brain that perceives vision.

Other cranial nerves integral to the visual system include III (oculomotor), IV (trochlear), V (trigeminal), VI (abducens), and VII (facial). These nerves provide motor input to the muscles in the orbit, face, ciliary body, iris, and eyelids, as well as sensation to the eyelids, eyes, and orbital tissue.

Examination

The complete ophthalmic examination consists of assessments and measurements of the following:

1. Visual acuity
2. Motility
3. Visual fields
4. Pupils
5. Eyelids and adnexa
6. Anterior segment
7. Intraocular pressure
8. Fundus

The technician should approach each patient systematically with careful attention to data gathering according to the aforementioned list. This approach is particularly significant when faced with complex patients for which a diagnosis is not readily apparent; in these patients, careful performance of each step is vital.

The balance of this article will use case presentations to illustrate the importance of several components of the ophthalmic exam.

Visual acuity measurements

Visual acuity is usually measured by having patients read Snellen eye charts. Some acuity numbers have particular significance.

1. A visual acuity of 20/40 is generally needed to read standard newsprint. Having 20/40 in one eye usually qualifies one to obtain a driver’s license in any state.

2. A visual acuity of 20/200 defines blindness in most cases. Legal blindness is defined as a patient who has one of the following deficits:
   a. Best corrected visual acuity of 20/200 or worse in the better eye, or
   b. A visual field of 10 degrees or less regardless of the visual acuity.

Note that patients frequently express the following misconceptions:

- “I’m legally blind in my right eye.” Remember that legal blindness is a patient definition, not an eye definition.

- “I’m legally blind without my glasses.” Remember that legal blindness is based on the best corrected visual acuity.

Never assume that patients are capable of reading the letters on the eye chart. Illiterate patients may identify the big “E” but may not recognize any other letters, and such a patient is unlikely to admit to not being able to read.

If one suspects that a patient with 20/400 visual acuity should be able to see better, the examiner should test visual acuity with the “tumbling E” chart or children’s charts that contain drawings.

FIGURE 2.
This MRI scan of the brain shows a small right occipital lobe infarction (see white arrow).

FIGURE 3.
This cerebral angiography frame shows a posterior communicating artery aneurysm (red arrow) that is pushing acutely on the third nerve.
**Tech role**

Continued from page 3

**CASE 1**
A 75-year-old woman who had previously undergone successful bilateral cataract surgery awoke with painless, significant vision loss in her left eye. She saw her cataract surgeon who could not make a diagnosis; he sent her to a retina specialist who also was unable to determine the cause.

A neuro-ophthalmology consult was requested, but the patient ended up on my schedule instead.

My technician began to methodically collect data and emerged from her room in 5 minutes with the correct diagnosis.

Here is what she had found:

**Visual acuity:**
- OD: 20/20
- OS: counting fingers

**Automated refraction:**
- OD: -0.25 + 0.50 x 90
- OS: +12.50 D

**Visual acuity OS with AR and pinhole:** 20/40

**Pupils:** No afferent pupillary defect

**Certain data in this case contribute to making the correct diagnosis:**
- The AR (+12.50 D) is more suggestive of aphakia than pseudophakia.
- The visual acuity when measured with the AR and pinhole establishes the fact that this eye still can see well.
- The absence of an afferent pupillary defect rules out optic nerve and widespread retinal disease.

With these data my technician diagnosed a dislocated intraocular lens (IOL). The slit lamp photographs taken after pupillary dilation are shown in Figures 1A and 1B.

**Fibrotic capsular remnants can obscure the edges of implants and confuse examiners regarding the presence or absence of a lens.** The silicone plate/haptic IOL in this eye had dislocated through a previously opened (by YAG laser capsulotomy) posterior capsule and settled against the inferior ciliary body in a difficult-to-visualize position.

Following vitrectomy surgery with IOL exchange and the implantation of an anterior chamber IOL, the patient achieved a visual acuity of 20/20.

**CASE 2**
A 75-year-old man complained of a spot in the left side of his vision for four days. This was unaccompanied by other symptoms, was unchanging, and was present in both eyes.

On examination his best corrected visual acuity measured 20/20 OU, but on confrontation visual field testing he had a left-sided defect approximately 45 degrees from fixation in both eyes. A Humphrey 24-2 visual field was normal in each eye.

Because of the concern that his history and confrontation field defects suggested the presence of a lesion that may not have been detected on Humphrey field testing, magnetic resonance imaging (MRI) of the brain was obtained.

It showed damage in the visual cortex of the right occipital lobe due to a cerebrovascular accident (stroke) (Figure 2).

The patient was referred to his primary care physician for further evaluation and initiation of antplatelet or anticoagulant therapy.

**CASE 3**
A 44-year-old man complained of the worst headaches of his life and double vision for one day. His visual acuities were 20/20 OU, but he had a left exotropia and left ptosis. The left eye could not adduct, and there were severe deficiencies in supraduction and infraduction.

The pupillary diameters measured 3 mm OD and 5 mm OS, the left pupil reacted sluggishly to light, but there was no afferent pupillary defect.

This constellation of symptoms (exotropia with gaze restrictions, ptosis, and mydriasis) is characteristic of a pupil-involving third nerve palsy.

Though pupil-sparing third nerve palsies are usually vascular (due to diabetes or systemic arterial hypertension), a pupil-involving third nerve palsy is due to compression of the third nerve by a posterior communicating artery within the brain (Figure 3).

This constitutes a neurosurgical emergency that requires immediate referral of the patient to the emergency room (ER).

The patient needs emergent neuro-vascular imaging with magnetic resonance angiography or cerebral angiography, followed by clipping or coiling of the aneurysm, because rupture of the aneurysm produces a 50 percent mortality rate.

Critical to making this diagnosis is the identification of the mydriasis. If the pupil is normal, the patient is diagnosed with a vascular third nerve palsy, does not require referral to the ER, and can be followed as an outpatient. Pupillary involvement (mydriasis), however, necessitates an emergent referral to the ER.

**Conclusion**
These three cases illustrate the relevance of key steps in the patient workup that are usually conducted by the technician. Performing these accurately means making the correct diagnosis, even when other technicians and physicians failed to do so. In some cases this may even mean saving the patient’s life.

Remember that examinations need to be performed methodically and completely to not overlook important findings. Therefore, the technician must learn proper technique for each step of the examination to recognize significant abnormalities, because some of these will not be recognizable later in the examination.
Tapping technician’s expertise in averting claim denials

Knowledge is power: know the top reasons why claims get denied and be proactive in prevention

By Matt Baugh

Exceptional patient care and valuable protected revenue can be achieved when we, as ophthalmic technicians, assist ophthalmologists by performing at our best. Taking patient histories, performing delegated ancillary testing, and scribing with the physician all proved opportunities to ensure that patients have a rewarding experience while we are with them in the office.

In addition to quality medical care, how can you help avoid claim denials, which are costly to the practice and confusing for the patient?

Claim denials are costly for any ophthalmology practice. It takes a team of committed individuals to help prevent these mistakes through a process of education, application, and communication. Technicians are critical members of the team who help bridge the gaps between the front and back office and between physicians and patients. This article addresses three pertinent questions about claim denials and the technicians’ role in how to avoid them.

1. WHY DO CLAIM DENIALS MATTER?

Ophthalmic practices are always seeking ways to increase efficiency. Every practice has processes in place to deal with claim denials, but how about a process that helps avoid the majority of these denials? Claim denials create inefficiencies by causing unnecessary work or rework.

By avoiding and preventing claim denials, technicians can dramatically increase the overall efficiency of the practice by decreasing the amount of work done on the back end with correcting and resubmitting claims.

Why should the technician want to be involved? Learning how to avoid claim denials supports ophthalmic technicians’ ultimate goal of caring for patients.

When a claim is denied, patients are often notified by their insurance, which creates unnecessary stress and worry for the patient, in addition to more work for them. Techs can help by recognizing common claim denial reasons and working to prevent them.

2. WHAT ARE SOME TYPICAL DENIALS?

There are many reasons why claims are denied. Some of the top reasons include insufficient documentation, inappropriate CPT or ICD-10 codes, missing or wrong modifiers, correct coding initiative (CCI) edits, prior authorization not obtained, and medical vs. vision. Following is an overview of common claim denials and how technicians can help patients steer clear of them.

Insufficient documentation

Sufficient and appropriate documentation is needed to help establish medical necessity for all billable services: exams, testing, minor and major surgeries, etc. As technicians, we can help ensure that all documentation is complete and appropriate by knowing the requirements.

How many elements of the exam are needed for a new patient level 4 E/M code? How many elements of the history of present illness are present? What are the different requirements for intermediate and comprehensive eye visit codes? Does this test require an interpretation or report?

Knowing the answers to these questions allows the tech to appropriately assist in fulfilling the necessary document requirements and prevent these types of claim denials.

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Inappropriate codes
“As gas is to a car and electricity is to a light bulb, so are diagnosis codes (ICD-10) to procedure (CPT) codes.” You need to have the correct CPT code for the procedure, test, or surgery associated with the correct diagnosis for the claim to be accepted by insurance.

Once we know the medical necessity requirements for specific services, we can actively look over the chart documentation to make sure the test and diagnosis are correctly linked. A necessary step is appropriately identifying laterality, coding to the highest level of specificity (avoid using unspecified codes), using the correct CPT code and modifier. “Scrubbing” documentation in this way by reviewing the documentation before the claims are sent to insurance can significantly decrease the amount of denials.

Missing or wrong modifiers
Did you know that certain tests and surgeries are always bundled together? Sometimes a modifier allows these tests to be billed out, and sometimes they don’t. Modifiers tell the whole story to the payer and indicate that the test, surgery, or exam has been changed in some way.

The incorrect use or absence of a required modifier is one of the top five reasons claims are denied. Knowing how to use modifiers appropriately will help technicians understand some billing nuances and limitations.

Modifiers can be appended to office visits (-24, -25, -57), diagnostic testing services (-RT, –LT, –TC, -26, -50, -59), and surgeries (-50, -54, -55, -58, -59, -78, -79, -RT, -LT).

Following is a helpful summary of how and when to use the most common office and surgery modifiers.

CCI edits
CCI edits are a list of services that are “bundled” or not individually payable when performed the same day. CCI edits affect the following in various combinations:
- Exams can be bundled with other exams.
- Exams can be bundled with tests.
- Tests are often bundled with other tests.
- Tests can be included with surgery bundles.
- Surgery can be combined with other same day/same session surgery.

The next chart is a grid of which
testing services are bundled together. The description “mutually exclusive” is used to describe a combination of tests that should never be unbundled (by using a modifier) unless a payer has a written policy that states it is OK to do so. Billing for a combination of tests that are bundled can be unbundled in specific situations (using a modifier).

Billable same-day combinations do not require the use of a modifier to be billed out. For example, when fluorescein angiography and indocyanine green choroidangiography are performed by two separate machines on the same patient, is only one of the tests billable? Which test? The answer: The one that gives the physician the information needed for diagnosis and or treatment.

**Prior authorization not obtained**

Prior authorizations are becoming a more common requirement for commercial insurance and Medicare Advantage plans. Although a prior authorization does not guarantee payment, no prior authorization guarantees no payment.

Technicians play a critical role in making sure prior authorizations are in place for tests and minor procedures that are performed in the clinic and minor rooms. Make a list of these common tests and procedures that require a prior authorization.

**Medical vs. vision**

Patients can have vision insurance coverage, which covers routine eye exams usually once per year and requires a “vision” diagnosis as the primary diagnosis, or medical insurance coverage, which covers medical eye problems and requires a medical diagnosis as a primary diagnosis.

What are vision diagnoses? Refractive diagnoses such as myopia, hyperopia, and presbyopia are typically billed for vision exams.

Some vision insurance plans also require the use of a Z code:
- Z01.00—encounter for examination of eyes and vision without abnormal findings
- or
- Z01.0—encounter for examination of eyes and vision without abnormal findings

Medical diagnoses are anything pathologically occurring with the eyes: glaucoma, cataracts, macular degeneration, to name a select few. How many times do you hear this from a patient in response to your question of, “How can we help you,” or “What brings you in today?” “I am here for my yearly checkup” or “my annual eye exam” (or maybe even “I don’t know!”)?

These are not appropriate chief complaints and phrases that indicate that the patient would like to use his vision insurance. Technicians can communicate with physicians when patients want their vision insurance billed for this particular visit and if a medical concern is revealed during the exam, explain to the patient what the next step may be (consider billing medical insurance, returning for another visit to address the medical concern, potential out-of-pocket expenses if the patient has only vision coverage).

If the claim is sent to the wrong insurance or the correct primary diagnosis is not listed, this can be difficult and time-consuming to fix on the back end.

**CLAIM DENIALS CONTINUED ON PAGE 10**
Neurostimulation in the treatment of dry eye disease

Inducing a basal tear response has potential to counteract the progressive nature of dry eye

By Marc Bloomenstein, OD, FAAO

In addition to symptoms that may compromise vision, dry eye disease (DED) discomfort can be potentially detrimental to patients’ quality of life. Interventions designed to treat signs and symptoms of DED can be burdensome, especially if a multitiered approach is used.

Regimens involving any combinations of pharmacotherapy, warm compresses, supplemental tears, and omega-3 supplementation require diligence for what may seem like modest improvement. Yet, current treatment approaches can be highly effective when employed correctly. At the same time, patients and providers welcome approaches to simplify treatment.

A recent innovation in DED is said to be an effective treatment with potential to reduce reliance on pharmacotherapy. The TrueTear device (Allergan) uses neurostimulation to induce the production of basal tears, or more simply, a “real tear.”

The patient-administered device is inserted into the nose so that two prongs at the distal end approach the ophthalmic branch of the trigeminal nerve. A short electrical pulse—its strength can be attenuated by the power settings—stimulates activity within the trigeminal nerve (5V1), with additional activity to cranial nerve VII, thus innervating the lacrimal glands.

How it works
Although it might seem that using TrueTear would induce reflex tears, the resulting response is the induction of a basal tear response. The mechanism by which patients begin to produce natural tears is not yet understood. Two theories regarding the mechanism of action have surfaced:

- Stimulation of the trigeminal afferent nerve fibers in the nasal cavity via the anterior ethmoidal nerve may initiate the nasolacrimal reflex, thereby leading to “an increase in activity in the superior salivatory nucleus region of the brain, which is responsible for control of natural lacrimation.”

- The electrical stimulus to the trigeminal afferent nerve fibers may cross over to the pterygopalatine ganglion, in turn shifting to the parasympathetic pathway to stimulate facial nerve VII that connects to goblet cells and meibomian glands.

These two theories are not mutually exclusive, and it may be that each mechanism is partly accurate.

In the prospective, single-arm, multicenter, open-label OCUN-010 study, patients exhibited improvement on Schirmer’s testing on days 0, 7, 30, 90, and 180 compared with baseline.3

Anecdotally, I can confirm these results in patients in my clinic, with some saying they experience longer-lasting relief from symptoms related to the use of artificial tears.

Neurostimulation history
Many may recognize the concept of neurostimulation in medicine. For example, studies have described the use of neurostimulation in the management of chronic migraine pain,4 in rehabilitative settings, and for the treatment of post-traumatic stress disorder5 and cognitive neurologic conditions, such as Alzheimer’s disease.6 Neurostimulation has been used successfully for over 30 years.7

The U.S. Food & Drug Administration has approved neurostimulation devices, including pacemakers, defibrillators, cochlear implants, and implantable devices intended to treat pain, essential tremors, refractory epilepsy, Parkinson’s disease, obsessive-compulsive disorder, obesity, and even retinitis pigmentosa.8-17

Why this approach?
The science behind TrueTear provides strong rationale for its use and supports its clinical applicability. However, there may be more reasons to consider adding this device to one’s dry eye practice—especially for patients using supplemental tears.

The plethora of supplemental tear

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options means that each patient can likely be matched with a formulation that will provide some benefit. At the same time, artificial tears are inherently palliative. In this regard, using the TrueTear device has potential to replace artificial tears with real ones.

TrueTear can potentially be complementary to other treatments. The device is disruptive in the sense that it offers a fundamentally different mechanism of action (or perhaps multiple mechanisms), but it does not change the overall approach.

There will still be patients with underlying inflammation who will benefit from pharmacotherapy. Anything we can do to liberate patients from multiple forms of therapy is beneficial. We need only evaluate experience in treating glaucoma to note that as the regimen’s complexity increases, adherence tends to decline. Plus, patients may realize cost benefit from avoiding drops.

Many patients may be candidates for this device. The potential to reduce...

**NEUROSTIMULATION CONTINUED ON PAGE 10**

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**New device | DRY EYE**

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**INTRODUCING TRUETEAR TO THE PRACTICE**

By Patti Barkey, COE

Introducing any new product or service to one’s practice should be thoughtful and purposeful. The TrueTear device is no exception.

Given that this device is relatively new to market and based on its distinctive mechanism for relieving dry eye, it is understandable that there is no rulebook, per se, on how to roll it out. Each provider and clinic operation will need to determine on their own whether TrueTear is something to which they want to dedicate time and resources and then how to introduce it to patients.

For our practice, TrueTear has been very successful. Patients have been receptive, and our clinicians have reported encouraging early results using the device. At the same time, we think that our careful process of rollout and introduction contributed to our success.

Following is a summary of our perspective on how we introduced TrueTear to the practice and lessons we learned along the way.

**INITIAL ROLLOUT:** When we first decided to introduce TrueTear, we chose to offer it to any patient taking supplemental tears as part of her regular dry eye therapy regimen. (This is a huge group of people in our practice.) By specifically targeting this group, we allowed our staff to hone in on early education to these patients. New patients who might be considered for supplemental drops were added to the list—by doing so we think we are hitting the lion’s share of candidates.

**30-DAY FOLLOW-UP VISIT:** We require patients to schedule a follow-up appointment 30 days later. At first, this was in the interest of due diligence—the device was new and we wanted to see how patients were doing. As we learned, the re-check is a good opportunity to support the education provided during the initial visit. We found that while most patients used the device properly, some hadn’t mastered their technique. Some had dialed up the power and reached a level of success and confidence with use. The re-check appointment qualifies as a billable office appointment because it is a valuable touch point in ensuring the patient is using the device properly, deriving benefit, and is satisfied with the treatment plan.

**STAFF TRAINING:** Before offering TrueTear, all clinicians who would be using the device received training. Most staff participated in training, including using the device themselves (if appropriate). We understood that everyone would be more effective at training patients if they had experience themselves. This relates to my belief that anyone who would encounter a patient who is a potential candidate or already using the device should be able to answer questions from the patient.

**CONSENT AND DOCUMENTATION:** Another reason training staff about TrueTear is crucial is to ensure proper documentation protocols. In our case, we prepared a consent form with contraindications and instructions for use so that patients were fully aware. We also created a purchasing agreement that relayed conditions for returning the device if it was unsuccessful.

**PATIENT EDUCATION:** Every practice will have its own style for educating patients. However, fundamental aspects to training might be helpful. For example, it helps to train patients in a quiet place away from distractions. While that is implicitly logical, there is a less appreciated reason for performing training in this manner: using the TrueTear device may cause the patient to sneeze. Keeping tissues on hand in the training area and training away from other patients might avoid concerns about spreading germs. We also position patients in front of a mirror while they are trialing the device so they can see for themselves what a properly inserted device will look like. In a similar vein, we instruct our counselors to be careful with their word choice. Action words like “buzz,” “shock,” “zoom,” “vibrate,” “flutter,” “zap,” or “stimulate” might imply movement and induce undue anxiety. Instead, we prefer to describe the sensation as a “gentle pulse.” This may seem like a minor point, but anything we can do to make patients comfortable with using TrueTear will help them have a good experience with the device.

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Patti Barkey is practice administrator, chief executive officer, and certified ophthalmic executive in Jacksonville, FL. She is also creator and executive director of Dry Eye University and executive director for Dry Eye Access. She speaks on behalf of Allergan, Johnson & Johnson Vision, and ScienceBased Health.
Claim denials
Continued from page 7

The ideal process to handle the question of, “Is this exam medical or vision?” begins when the patient first makes the appointment, reinforced at registration and during the exam, communicated to the physician, and then verified by scrubbing the documentation.

How does this knowledge boost my career?
The more you know, the more you can help. Just like learning about the anatomy of the eye, various diagnoses or procedures can help you help the patient and physician; learning about reasons claims are denied and how to prevent them can give you more tools to help patients, physicians, and your practice.

What type of technician do you want to be?
Tech 1 has limited skills and tools to help the practice, like a pocketknife. Tech 2 has many skills and tools to help the practice, such as a Swiss army knife. Secondly, which technician is more valuable to the patient, physician, and practice: Tech 1 or Tech 2?

By increasing your skills and learning how to avoid claim denials you increase your value to your practice and enhance your ability to be of service to patients. With increased ability comes greater job satisfaction, stability, responsibilities, and possible growth opportunities.

Neurostimulation
Continued from page 9

dependence on other forms of therapy suggests that TrueTear may be useful for a range of patients across nearly the spectrum of DED severity. I am educating my patients with signs of DED that TrueTear may reduce or eliminate the need for supplemental tears by inducing a physiologic, natural tear.

Introducing to patients
It is worth the time to educate patients about and demonstrate its proper use. DED patients are motivated to learn about modalities that might offer symptomatic relief.

It’s important to have a device in the office to show patients its basic principles and to assuage anxieties or apprehension. Using TrueTear is similar to using a nasal spray.

Convey to patients before they start using TrueTear:
- TrueTear has been proven safe and effective in clinical trials.
- The intensity of the electrical stimulation can be modulated.
- Stimulation can be sustained for as long as the patient feels comfortable.
- TrueTear is Bluetooth-enabled; the accompanying smartphone app provides information about how often the device is used—but more importantly, it tracks the battery life (Note: the app is currently supported only on Apple devices; Allergan plans to release an Android version soon.)

It may be that using neurostimulation with patients experiencing mild DED can provide long-term benefit in slowing or stopping progression. Equally as promising, stimulating the basal tear response might affect long-term remodeling, delivering on the promise of restoring homeostasis to the ocular surface.

References

HOW DO I LEARN MORE?

We learn by doing, so try it out.

Start by auditing and scrubbing your own charts. Then contact your billing office/staff and identify top reasons why claims are being denied.

Next, discuss what you and the clinical team can do to help prevent these denials. Always use a trusted source.

Remember, learning about the coding and billing process can be overwhelming at times, but as you educate yourself using trusted sources, apply what you learn through practice, and communicate and implement the needed changes, you will become a valuable and indispensable part of the patient care team by helping fulfill the technician’s role in avoiding claim denials.
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