Focusing on a better view

Novel transparent, head-wearable camera display aims to make ophthalmic surgery more precise

By Vanessa Caceres
Reviewed by Anat Loewenstein, MD

A NEW head-mounted camera display customized for ophthalmic surgery could help eye surgeons with surgical resolution and precision, said Anat Loewenstein, MD, Department of Ophthalmology, Tel Aviv Medical Center, Tel Aviv, Israel.

The head-mounted display—also called a transparent, head-wearable display—and three-dimensional (3-D), ultra-resolution camera with a remote digital arm have several features, including 10× HD resolution, natural 3-D vision, and intuitive head gesture control that is essentially an extension of the body. “There is the potential for unlimited virtual information that is personalized and overlaid,” Dr. Loewenstein said.

Dr. Loewenstein shared information about the Clarity surgeon-centered visualization and information platform, designed by the company Beyeonics. The company is a spinoff of Elbit, which developed
Our most innovative drop works to restore the tear film. It provides optimal relief by addressing every major type of dry eye:

- Evaporative Dry Eye
- Aqueous-deficient Dry Eye
- Mixed Dry Eye

With advanced, lipid nano-droplet technology, the lubricant is rapidly delivered across the ocular surface—resulting in better coverage* to provide fast hydration and locking in moisture for long-lasting relief.

1-2,5,6,8

TALK TO A REPRESENTATIVE TO LEARN MORE

© 2018 Novartis

1. Ketelson H, Rangarajan R. Pre-clinical evaluation of a novel phospholipid nanoemulsion based lubricant eye drops. Poster presented at: The Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO); May 7–11, 2017; Baltimore, Maryland, USA.
6. Lane S, Paugh J, Webb JR, Christensen MT. 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 3-7, 2009; Fort Lauderdale, FL.

*Compared to SYSTANE® BALANCE.
Surgery

8 PEARLS FOR PKP IN PEDIATRIC PATIENTS
Surgeons can achieve good visual results in children with corneal diseases by following these pearls.

Special Report

16 IMPROVING DETECTION OF MISSED RETINAL BREAKS
Obtain good history; take advantage of core vitrectomy, technology to optimize visualization.

Clinical Diagnosis

23 DEBATING HYPEROPIA TREATMENT OPTIONS
Questions about glasses versus observation for moderate hyperopia unanswered in study.

Also In This Issue

5 EDITORIAL

Digital App

Introducing the Ophthalmology Times app for iPad and iPhone. Download it for free today at OphthalmologyTimes.com/OTapp

What’s Trending

See what the ophthalmic community is reading on OphthalmologyTimes.com

1 3 pearls for uveitis diagnosis
http://bit.ly/2RX2oXy

2 DME: What it is and how to treat it

3 Zeroing in on the presence of dry eye

4 IPL + thermal pulsation: A thorough dry eye approach
http://bit.ly/2PLwTX

Video

See how iStent implantation affects cataract surgery, go to https://bit.ly/2FgjOx3
(Video courtesy of Doug Katsev, MD)

eReport


Facebook

Like Ophthalmology Times at Facebook.com/OphthalmologyTimes
Age is but a number

How does an ophthalmologist know when he or she is old?

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.

He can be reached at 727 Maumenee Building 600 N. Wolfe St. Baltimore, MD 21287-9278 Phone: 443/287-1511 Fax: 443/287-1514 E-mail: pmdonn1@jhmi.edu

FOR US OPHTHALMOLOGISTS, these twelve months of 2018 represent the antepenultimate year before the all-so-significant (to eye doctors) 2020. As 2018 comes to an end, the wise ophthalmologist will no doubt take a minute to reflect on this year’s accomplishments and what triumphs and challenges may be ahead.

For this medical editor, 2018 was a mixed blessing because it included one of those birthdays that people refer to as a “milestone.” Please don’t feel badly if you were too busy to send me a card. Truth be told, I don’t celebrate birthdays anymore because I don’t want to attach significance to arbitrary numbers. Though inside I still feel like one of those youthful, wild-and-crazy 18 year olds who will one day be appointed to the Supreme Court, the birthdate on my driver’s license makes it clear that I am officially old enough to know better.

Which begs the question: How does an ophthalmologist know when he or she has become old?

COUNTING THE WAYS

There are ten reasons why I know I am an old ophthalmologist:

10 I remember a time when doctors were called “doctors” instead of “providers.”

9 I remember when smoking cigarettes was allowed and smoking marijuana was considered naughty.

8 To maintain my medical licensure, I have been required to take state legislature-mandated courses on prescribing powerful opioids for pain control because of a belief that doctors were not adequately treating the pain of their patients. A decade or so later, I now have my state legislature mandating that I, in order to maintain my licensure, take courses on how to avoid prescribing opioids for pain. (The fact that I am an ophthalmologist and have not needed to prescribe anything stronger than Tylenol in the past three decades, of course, means nothing to the regulators.)

7 I sometimes buy broccoli rabe to sauté with garlic as a side dish for dinner and get excited because of the eye-healthy nutrients.

6 I have stopped complaining about my presbyopia and find myself admiring how my reading glasses make me look like one of the protagonists in the “Revenge of the Nerds” films.

5 Getting lucky means I find my car in the hospital parking structure at the end of a long day.

4 I enjoy hearing about other people’s operations.

3 I now know all the answers, but my kids never call to ask me any questions.

2 I remember a time before every eye disease was curable with an injection of bevacizumab.

And the number one reason I know I am getting old?

1 In 2019, my youngest child will become a card-carrying ophthalmologist.

The ophthalmologists in my family wish you and your families a happy, healthy, and prosperous 2019!

Check out XIIDRA-ECP.COM
XIIDRA® (lifitegrast ophthalmic solution) 5%  

**SIGN & SYMPTOMS HAVE MET THEIR MATCH**

**XIIDRA IS THE ONLY TREATMENT FDA-APPROVED TO TREAT BOTH SIGNS AND SYMPTOMS OF DRY EYE**

- Proven to treat signs of inferior corneal staining **AT 12 WEEKS** in 3 of 4 trials
- Proven to treat symptoms of eye dryness **AT 6 AND 12 WEEKS** in all 4 trials

**XIIDRA IS CONTRAINDICATED IN PATIENTS WITH KNOWN HYPERSENSITIVITY TO LIFITEGRAST OR TO ANY OF THE OTHER INGREDIENTS.**

**INDICATION**

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

**IMPORTANT SAFETY INFORMATION**

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

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

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

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

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

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

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

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and 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.
Corneal diseases are thought to be responsible for 10% of worldwide blindness in young patients, and are frequent causes of blindness in developed and underdeveloped countries. However, unlike in adults, these diseases are more challenging in children, said Gerald W. Zaidman, MD. “The patients are different,” said Dr. Zaidman, professor of ophthalmology, New York Medical College, and vice chairman of ophthalmology, Westchester Medical Center, both in Valhalla, NY. “The eyes are different,” he said. “The diseases are different. The surgery and the anesthesia are different.”

Dr. Zaidman shared pearls for achieving successful outcomes before and after penetrating keratoplasty (PKP) in these patients.

EXAMINATION UNDER ANESTHESIA

The youngest patients undergo examination under anesthesia (EUA), because it is crucial to diagnose and manage children with a cloudy cornea accurately. The standard examination includes measurement of the refraction (if possible), IOP, corneal diameter, slit lamp evaluation, A/B-scan ultrasonography, and ultrasound biomicroscopy (UBM).

Pediatric transplant cases are especially challenging because of the severity of ocular pathologies, technical difficulties of operating on small eyes with elastic sclera, shallow anterior chambers, and anterior displacement of the iris and lens. The youngest patients are unable to cooperate and hard to examine. In addition, sudden rapid graft rejection can occur in these patients.

The indications for corneal transplantation in children include congenital disorders, which accounts for 65% such as Peters anomaly, sclerocornea, congenital hereditary, endothelial dystrophy, and congenital glaucoma; followed by acquired non-traumatic diseases in 20% of patients, such as keratoconus, herpes simplex virus (HSV), corneal ulcers, rosacea, and regrafts, and finally, trauma in 10%. This is in contrast to adults in whom endothelial disease accounts for 45% of cases, keratoconus 35%, failed grafts 15%, and finally, scars/opacities, according to Dr. Zaidman.

PARENTAL INVOLVEMENT

Importantly, when evaluating and treating pediatric patients, surgeons have to be concerned with more than just the surgery itself.

This means evaluating the patients’ social situations and educating the parents about their participation in what he referred to as the “marathon” of office visits, EUAs, and drop instillation postoperatively.

Surgical Challenges in Pediatric versus Adult PKP

- The patients are different
- The eyes are different
- The diseases are different
- The surgery and the anesthesia* are different

*Dedicated pediatric anesthesiology

(Photos courtesy of Gerald W. Zaidman, FAAO, FACS)

Challenges of Pediatric Corneal Transplants

- Severe ocular pathology
- Technically difficult
- Smaller eye; elastic sclera
- Shallow AC; anterior displacement iris/lens
- Young age, poor cooperation, hard to examine
- Sudden rapid rejection

“Surgeons must discuss with parents the realistic success rates in pediatric transplantation cases, and that a clear graft does not equal good vision,” he said.

EARLY SURGERY

The timetable itself for infants with a congenital disorder can be daunting. The office visits begin before 3 weeks of age, and EUAs are performed from 4 to 6 weeks of age. Surgery

By Lynda Charters; Reviewed by Gerald W. Zaidman, FAAO, FACS
FROM THE EXPERTS IN LOTEPREDNOL ETABONATE FOR OVER 20 YEARS

COMING SOON

BAUSCH + LOMB’S NEWEST ARRIVAL

A NEW LOTEPREDNOL ETABONATE FORMULATION

© 2018 Bausch & Lomb Incorporated. All rights reserved. LED.0058.USA.18
in the first eye is performed between 8 to 12 weeks of age and in the second eye from 4 to 6 weeks after the first surgery.

General anesthesia is administered (mannitol, hyperventilation). Donor tissue is used from donors 4 to 19 years old; the donor tissue is oversized by 0.5 mm.

A scleral support ring is put in place and the anterior chamber is entered carefully and a viscoelastic injected. Synechialysis then is performed.

'**SANDWICH TECHNIQUE**'
AND SUTURE REMOVAL
A special technique is used to excise the host cornea in children. This technique is designed to minimize the severe amount of positive pressure that pediatric corneal surgeons encounter during the surgery. It is called the “sandwich technique,” in which the donor cornea is placed onto the host cornea and sutured into position into the recipient’s sclera.

The recipient’s cornea then is slid out from under the donor cornea, avoiding vitreous/lens prolapse. Interrupted sutures then are used to adhere the graft in place, Dr. Zaidman explained.

During the first 2 months postoperatively, the patient is examined two to three times weekly. EUAs are performed frequently during the early postoperative period, and the sutures are removed early during that period.

Over the long term, topical steroids are tapered slowly over the course of 1 year. Sedation is administered as needed.

**‘NO’ TO VACCINATIONS, ‘YES’ TO ORAL MEDICATIONS**

“The children receive no vaccinations during the first year postoperatively,” Dr. Zaidman said. He also pointed out the importance of both co-management with a pediatric ophthalmologist and optical correction as soon as possible after the sutures are removed.

The long-term visual outcomes of PKP in children with Peters anomaly type I are often quite good.

Dr. Zaidman reported that at 3 years postoperatively, 90% of the eyes with Peters type I have clear grafts (2 regrafts), 29% have 20/50 or better, 25% of eyes have 20/60 to 20/100, and 54% of eyes have 20/100 or better vision. In his hands, no eyes were lost, and none had no light perception vision. Most eyes withvisual acuity of 20/200 or worse had glaucoma.

Similar results also were reflected in the Australian Corneal Graft Registry, 1985-2009. A total of 765 patients younger than 20 years was identified.

In children younger than 5 years, 65% had Peters anomaly or a congenital defect and of these more than half (56%) had clear grafts. Seventy-six percent of the children ranging in age from 5 to 12 years had keratoconus or an opacity or scar due to trauma or HSV; in 80% the grafts were clear. In children who were 13 to 19 years of age, 86% had keratoconus, and 90% had a clear graft.

Endothelial rejection was the most common cause of graft failure, and glaucoma was the most common cause of poor vision.

**Indications for Corneal Transplant Surgery**

**Children > 400 cases**
- Congenital—65%
  - Peters anomaly, sclerocornea—65%
  - CHED—15%
  - Congenital glaucoma—15%
- Traumatic—10%
- Acquired non-traumatic—25%
  - Keratoconus, HSV, corneal ulcers, rosacea, regrafts

**Adults > 3,500 cases**
- Endothelial disease—45%
- Keratoconus—35%
- Failed grafts—15%
- Scars/opaclities

**Postoperative Care**

- First 2 months
  - 2–3×/week
  - Frequent postoperative EUAs
  - Early suture removal
- Long term—slow taper of topical steroids over one year
- Sedation p.r.n.
- No vaccinations for one year
- Co-management with pediatric ophthalmologist necessary
- Optical correction ASAP after suture removal

**Seven Tips for Best Results in this Pediatric Population**

- Examination under anesthesia using ultrasound biomicroscopy
- Parental education and involvement
- Surgery children are 8 to 12 weeks old
- Performance of the sandwich technique, preferably using optical coherence tomography
- Early suture removal
- Avoidance of vaccinations for 1 year
- Prescription of oral medications for HSV

**Corneal**

(Continued from page 8)

GERALD W. ZAIDMAN, FAAO, FACS
E: pedkera@aol.com
Dr. Zaidman did not indicate any proprietary interest in the subject matter.
ILUVIEN® is a CONTINUOUS MICRODOSING™ Delivery System specifically engineered for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

In pivotal studies, ILUVIEN demonstrated efficacy in visual acuity through 24 months (primary endpoint), which was sustained for up to 36 months.1,2,3

Adverse reactions in the ILUVIEN Phase 3 clinical trials were consistent with other corticosteroid treatments.1

INDICATION
ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

IMPORTANT SAFETY INFORMATION

Contraindications
- ILUVIEN is contraindicated in patients with active or suspected ocular or periorcular infections including most viral diseases of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- ILUVIEN is contraindicated in patients with glaucoma who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

Warnings and Precautions
- Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the intravitreal injection.
- Use of corticosteroids including ILUVIEN may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.
- Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

Adverse Reactions
- In controlled studies, the most common adverse reactions reported were cataract development (ILUVIEN 82%; sham 50%) and intraocular pressure elevation of ≥10 mm Hg (ILUVIEN 34%; sham 10%).

Please see Brief Summary of Full Prescribing Information on the following page.

**Table 1: Ocular Adverse Reactions Reported by ≥1% of Patients and 12 months after study entry.**

Over the three-year follow up period, approximately 1% of the last subject completed the last 36-month follow up visit for the two primary trials in which patients with diabetic macular edema were treated with either ILUVIEN®. The safety and tolerability profile of ILUVIEN® cannot be directly compared to rates in the clinical trials of another drug and may be influenced by differences in patient demographics, disease severity, treatment regimen, other concurrent medications, and concomitant medical conditions.

**WARNINGS AND PRECAUTIONS**

**Intravitreal Injection-related Effects:** Intravitreal injections, including those with ILUVIEN®, may be associated with eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the intravitreal injection.

**Steroid-related Effects:** Use of corticosteroids including ILUVIEN® may produce posterior subcapsular cataracts, increased intraocular pressure and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

**Risk of Implant Migration:** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

**ADVERSE REACTIONS**

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

Adverse reactions associated with ophthalmic steroids including ILUVIEN® may include anterior chamber cell, conjunctival hyperemia, and intraocular pressure. Adverse events associated with corticosteroid use include posterior subcapsular cataract, increased intraocular pressure, and retinal detachments. Patients should be monitored following the intravitreal injection.

**Postmarketing Experience:** The following reactions have been identified during postmarketing use of ILUVIEN® in clinical practice. Because they are reported voluntarily, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ILUVIEN®, or a combination of these factors, include reports of drug administration error and reports of the drug being ineffective.

**Table 2: Summary of Elevated IOP-Related Adverse Reactions**

<table>
<thead>
<tr>
<th>Event</th>
<th>ILUVIEN (N=375)</th>
<th>Sham (N=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOP elevation ≥ 10 mm Hg from baseline</td>
<td>127 (34%)</td>
<td>18 (10%)</td>
</tr>
<tr>
<td>IOP elevation ≥ 30 mm Hg</td>
<td>75 (20%)</td>
<td>8 (4%)</td>
</tr>
<tr>
<td>Any IOP-lowering medication</td>
<td>144 (38%)</td>
<td>26 (14%)</td>
</tr>
<tr>
<td>Any surgical intervention for elevated intraocular pressure</td>
<td>18 (5%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

**Figure 1: Mean IOP during the study**

**Cataracts and Cataract Surgery**

At baseline, 235 of the 375 ILUVIEN® subjects were phakic; 121 of 185 sham-controlled subjects were phakic. The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN® group (82%) compared with sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN® group and 19 months in the sham group. Among these patients, 80% of ILUVIEN® subjects vs. 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 months (Median Month 15 for both ILUVIEN® group and for sham) of the studies.

**Postmarketing Experience:** The following reactions have been identified during postmarketing use of ILUVIEN® in clinical practice. Because they are reported voluntarily, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ILUVIEN®, or a combination of these factors, include reports of drug administration error and reports of the drug being ineffective.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** Pregnancy Category C.

There are no adequate and well-controlled studies of ILUVIEN® in pregnant women. Animal reproduction studies have not been conducted with fluocinolone acetonide. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. ILUVIEN® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Systemically administered corticosteroids are present in human milk and could suppress growth and interfere with endogenous corticosteroid production. The systemic concentration of fluocinolone acetonide following intravitreal treatment with ILUVIEN® is low. It is not known whether intravitreal treatment with ILUVIEN® could result in sufficient systemic absorption to produce detectable quantities in human milk. Exercise caution when ILUVIEN® is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness of ILUVIEN® in pediatric patients have not been established.

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

**Table 1 (continued)**

<table>
<thead>
<tr>
<th>Ocular Adverse Reactions</th>
<th>ILUVIEN (N=375)</th>
<th>Sham (N=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract1</td>
<td>192/235 (82%)</td>
<td>61/121 (50%)</td>
</tr>
<tr>
<td>Myopiasis</td>
<td>80 (21%)</td>
<td>17 (9%)</td>
</tr>
<tr>
<td>Eye pain</td>
<td>57 (15%)</td>
<td>25 (14%)</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>50 (13%)</td>
<td>21 (11%)</td>
</tr>
<tr>
<td>Posterior capsule opacification</td>
<td>35 (9%)</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>30 (8%)</td>
<td>11 (6%)</td>
</tr>
<tr>
<td>Vitreous detachment</td>
<td>26 (7%)</td>
<td>12 (7%)</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>14 (4%)</td>
<td>5 (3%)</td>
</tr>
<tr>
<td>Corneal oedema</td>
<td>13 (4%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Foreign body sensation in eyes</td>
<td>12 (3%)</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Eye pruritis</td>
<td>10 (3%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Ocular hyperaemia</td>
<td>10 (3%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Optic atrophy</td>
<td>9 (2%)</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Ocular discomfort</td>
<td>8 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Photophobia</td>
<td>7 (2%)</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Retinal edeases</td>
<td>7 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Anterior chamber cell</td>
<td>6 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Eye discharge</td>
<td>6 (2%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

1 Includes cataract, cataract nuclear, cataract subcapsular, cataract cortical and cataract diabetic in patients who were phakic at baseline. Among these patients, 80% of ILUVIEN® subjects vs. 27% of sham-controlled subjects underwent cataract surgery.

2 235 of the 375 ILUVIEN® subjects were phakic at baseline; 121 of 185 sham-controlled subjects were phakic at baseline.

**Increased Intraocular Pressure**

At baseline, 235 of the 375 ILUVIEN® subjects were phakic; 121 of 185 sham-controlled subjects were phakic. The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN® group (82%) compared with sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN® group and 19 months in the sham group. Among these patients, 80% of ILUVIEN® subjects vs. 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 months (Median Month 15 for both ILUVIEN® group and for sham) of the studies.

**Postmarketing Experience:** The following reactions have been identified during postmarketing use of ILUVIEN® in clinical practice. Because they are reported voluntarily, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ILUVIEN®, or a combination of these factors, include reports of drug administration error and reports of the drug being ineffective.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** Pregnancy Category C.

There are no adequate and well-controlled studies of ILUVIEN® in pregnant women. Animal reproduction studies have not been conducted with fluocinolone acetonide. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. ILUVIEN® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** Systemically administered corticosteroids are present in human milk and could suppress growth and interfere with endogenous corticosteroid production. The systemic concentration of fluocinolone acetonide following intravitreal treatment with ILUVIEN® is low. It is not known whether intravitreal treatment with ILUVIEN® could result in sufficient systemic absorption to produce detectable quantities in human milk. Exercise caution when ILUVIEN® is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness of ILUVIEN® in pediatric patients have not been established.

**Geriatric Use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients.
LASER CATARACT surgery (LCS) remains controversial. However, surgeons who remain skeptical about whether the femtosecond laser has benefit now, and if it holds any promise for the future, should consider that evolution takes place in bursts.

It takes time to critically evaluate new techniques and technologies after they are introduced, said H. Burkhard Dick, MD, PhD.

Dr. Dick noted that ultrasound cataract surgery has a greater than 50-year history. In contrast, femtosecond lasers for cataract surgery have been available for less than 10 years. During this relatively short time, there have been—and continue to be—refinements leading to better outcomes and developments leading to new techniques.

“When new developments, devices, and techniques are critically evaluated in controlled clinical trials, they may be found to provide no improvement, be an incremental advance, or something that is truly better,” said Dr. Dick, professor and chairman, Department of Ophthalmology, Ruhr University Eye Hospital, Bochum, Germany.

“Based on such evidence, other surgeons will decide whether or not to offer the laser,” he said. “I, however, am definitely convinced that it will lead to improved stratified patient care.”

He reviewed one study showing that modifying the laser settings by increasing the vertical spot spacing from 10 to 15 μm was successful for improving the quality of the laser-cut capsulotomy and reducing the number of tags, which are associated with risk of radial tears.

A randomized study evaluating capsulotomy centration methods for LCS showed a benefit for optical coherence tomography (OCT)-based scanned capsule centration versus pupil centration.

OTHER ADVANTAGES

In addition, it provided evidence for guiding capsulotomy sizing to guarantee 360° capsule overlap of a 6-mm optic. The study’s results showed that the optimal size depended on the type of IOL: it was 4.7 mm for a 3-piece IOL, 4.9 mm for a single-piece IOL, and 5.1 mm for a plate haptic IOL, Dr. Dick noted.

Findings from another randomized study conducted by Dr. Dick and colleagues showed that LCS can improve the predictability of refractive outcomes compared with manual surgery.

In the trial that included 100 patients who had LCS in one eye and conventional surgery in the fellow eye, achieved refraction at 6 months was within 0.5 D of target in 92% of LCS eyes versus 71% of eyes in the conventional surgery group.

“It appears that the advantage of the laser is subtle, but that is because standard cataract surgery is already that good,” Dr. Dick said.

He added that an additional benefit of using the laser for capsulotomy creation may be identified when it is used for surgeries involving the new and emerging capsulotomy-fixated IOLs.

Since it was first introduced, the applications of the femtosecond laser have expanded and now include marking of the target axis to guide toric IOL alignment. Initially developed for making corneal marks, the femtosecond laser is now being used to mark the capsule.

“Capsule marking is a unique technique that allows precise identification of the steep axis both intraoperatively and postoperatively if realignment is necessary,” Dr. Dick said. “The capsule marks are stable and precise and provide a landmark for realigning the IOL without any need for remarking.”

Dr. Dick said he has also been using the femtosecond laser for primary posterior capsulotomy (PPC) in pediatric cataract surgery cases for many years.

More recently, he began performing laser PPC in adult eyes as an off-label procedure. Performed as the last step in the surgery and guided by the device’s three-dimensional OCT imaging system, the laser PPC keeps the anterior hyaloid intact and does not damage the IOL, Dr. Dick said.

A randomized study in adult eyes compared the laser PPC with routine manual cataract surgery without PPC. Published results showed laser PPC was a safe and feasible technique for preventing posterior capsule opacification over a 6-month follow-up period.

Recently presented results from follow-up to 2 years showed Nd:YAG capsulotomy had been done in 12% of control eyes but in none of the eyes with a laser PPC.■

‘It appears that the advantage of the laser is subtle, but that is because standard cataract surgery is already that good.’

— H. Burkhard Dick, MD, PhD

Dr. Dick reviewed some of the most recent developments in LCS with a focus on randomized controlled trials conducted by his group.

TAKE-HOME

◗ Since it was first introduced, the applications of the femtosecond laser have expanded.

H. Burkhard Dick, MD, PhD, reviewed developments in laser cataract surgery with a focus on randomized trials conducted by his group.

H. BURKHARD DICK, MD, PHD
dickburkhard@aol.com

This article was adapted from Dr. Dick’s presentation at the 2018 meeting of the American Academy of Ophthalmology. He has received grant/research support from Bausch + Lomb, Johnson & Johnson, and LENSAR, is on the speakers’ bureau for and is a consultant to Bausch + Lomb and Johnson & Johnson, and has intellectual property rights with Johnson & Johnson.
Sutureless intrascleral fixation of IOLs is a modification of the popular Yamane procedure adopted by anterior segment surgeons. The procedure leverages the skills and tool kit of vitreoretinal surgeons to allow performance of the modification that makes it more reliable and efficient, according to Jonathan L. Prenner, MD.

“In our practice, these advances have led us to develop novel approaches to replace the use of anterior chamber IOLs,” said Dr. Prenner, chairman, Department of Ophthalmology, and clinical professor, Rutgers-Robert Wood Johnson Medical School, New Brunswick, NJ. “While these IOLs are good, there may be simpler ways of achieving the same results.”

To that end, Dr. Prenner and his colleagues have hit on a novel technique for sutureless IOL fixation. Sutureless intrascleral fixation of IOLs—replaces use of anterior chamber IOLs in certain scenarios, such as in cases of aphakia and IOL exchange. The 1-year results indicate that the procedure is safe and well tolerated.

The technique is a modification of the popular Yamane procedure adopted by anterior segment surgeons. “The procedure leverages the skills and tool kit of vitreoretinal surgeons to allow performance of the modification that makes it more reliable and efficient in our hands,” said Dr. Prenner during a symposium highlighting the “Best of Retina Society Meetings 2018” at the American Academy of Ophthalmology meeting.

He described a case of a subluxed IOL in the bag that lacked adequate capsular support to facilitate suture fixation of the lens/bag complex. Dr. Prenner used a 25-gauge vitrectomy handpiece to free the lens and remove the capsular material. He said a thorough vitrectomy with scleral depression is important in such cases to control any posterior manipulations.

He used a microkeratome to make a clear corneal incision, a soft-tipped cannula to elevate the lens off of the retinal surface and into the iris plane, removed the leading haptic, and finally divided the lens and removed it.

During this procedure, Dr. Prenner uses a TSK 30-gauge needle to create a 2-mm-long intrascleral tunnel. This needle has a thinner wall that provides a larger effective lumen to dock the haptic. The tunnel is started 2 mm from the limbus at the horizontal meridian.

He implants an IOL (CT Lucia, Carl Zeiss Meditec) during what he considers the most critical part of the procedure. The lens haptics are made of a nearly indestructible material (polyvinylidene fluoride monofilament) that can withstand severe manipulations. A para-
centesis was used to place a forceps into the anterior chamber; the first haptic was docked into the os of the 30-gauge needle, similar to the Yamane procedure.

When the Yamane procedure is performed, according to Dr. Prenner, a potential complication can develop when the first haptic is left in the needle, which is left unattended. “I prefer to remove the first needle and haptic together,” he said.

In the next step, the tip of the haptic is deformed thermally using low-temperature cautery. Another challenging step in the Yamane procedure is the placement of the second haptic in the anterior chamber.

Dr. Prenner and colleagues modified this part of the procedure by putting the lens and haptic into the posterior segment and creating a second intrascleral tunnel. This allows them to work in the posterior segment rather than the anterior segment, which does not allow a great deal of movement. For visualization, a chandelier light is introduced through a pre-placed trocar.

“We are very comfortable manipulating the haptic in the posterior segment,” Dr. Prenner said. “We have 360° of mobility. We can find an easy hand position to match the haptic to the os of the 30-gauge needle and then dock the haptic.”

The next step is removal of the second haptic. A pearl offered by Dr. Prenner is that the low-temperature cautery does not touch the haptic tip, but is placed sufficiently close for the tip to form a bulb that prevents retraction of the haptic through the tunnel.

“This procedure allows creation of an efficient exchange in a transconjunctival sutureless manner,” he said.

Dr. Prenner also advised surgeons to place a peripheral iridotomy at the end of these cases to decrease the risk of reverse pupillary block and uveitis-glaucoma-hyphema (UGH) syndrome.

**STUDY RESULTS**

Nine eyes of eight patients were treated with this sutureless intrascleral fixation procedure.

“The results were reasonable after 1 year,” Dr. Prenner said. “The visual acuity improved in all patients as expected with curing of the aphakia and malposition of the lens.”

Importantly, no significant intraoperative or postoperative complications developed and there was no evidence of haptic erosion.

Dr. Prenner reported one case of iris capture and one case of corneal edema both occurring on postoperative day 1. Both resolved with appropriate treatment.

The results indicated that this novel procedure was well tolerated 1 year postoperatively. Dr. Prenner emphasized that the follow-up was short and he looks forward to longer-term results.
Strategies for improving detection of missed retinal breaks, holes, tears

Obtain good history; take advantage of core vitrectomy, technology to optimize visualization

By Cheryl Guttman Krader; Reviewed by Steve Charles, MD

A HOST OF avoidable problems can limit the success of retinal detachment (RD) surgery. Steve Charles, MD, discussed various failure modes and how and why to circumvent them. Noting that missed retinal breaks/holes/tears are a leading cause of failed RD surgery, he outlined strategies for improving detection.

He emphasized the importance of obtaining a good history, taking advantage of core vitrectomy as a diagnostic tool, and using the right technology to optimize visualization.

As explained by Dr. Charles, a more thorough description of the patient’s evolving symptom history can provide a clue to the site of a retinal break.

“Knowing that the first symptom a patient noticed was a shadow in the upper left-hand corner of his vision will direct you to look for the initial detachment and breaks in the lower right-hand corner when you do your examination,” said Dr. Charles, founder, Charles Retina Institute, Germantown, TN.

He also encouraged surgeons not to overlook the potential to find clues to the site of a retinal break while performing core vitrectomy.

Dr. Charles explained that during peripheral vitreous removal, surgeons should watch carefully for subretinal fluid that may stream out from the break and become visible because of the Schlieren optical effect.

Streaming of vitreous collagen fibers toward the tear is another phenomenon for which to watch.

“Instead of thinking about core vitrectomy as a therapeutic step in the repair procedure, consider that it can be a tremendous asset for your diagnostic effort,” Dr. Charles said.

The ability to identify these clues and to otherwise find retinal breaks depends on having good visualization.

Dr. Charles recommended using conventional endoilluminators that are better than chande-

lier because they provide focal, specular, and retro-illumination; three-dimensional viewing systems that increase depth of field and enable better visualization of transparent vitreous because of software adjustable color parameters; and wide-angle visualization and/or scleral depression to ensure visualization of the peripheral retina.

WHAT NOT TO DO

Better success with RD surgery also involves avoiding certain measures that are not helpful, but may even introduce harm.

Practices that are not the answer for improving outcomes of RD surgery include using rows of 360° laser spots or scleral buckles as safeguard procedures.

Dr. Charles noted that some surgeons place row upon row of laser spots for fear they might have missed the tear.

However, this technique does not eliminate missed breaks and new breaks may develop between or posterior to the laser spots as well.

Furthermore, excessive laser treatment increases inflammation and subsequently proliferative vitreoretinopathy that is a risk factor for RD surgery failure.

Discussing scleral buckling, Dr. Charles noted that some surgeons consider it a good idea to routinely place a scleral band as a precautionary measure.

However, there is no acceptable randomized clinical trial evidence that combining a buckle with vitrectomy increases success rates versus vitrectomy alone.

“New breaks and proliferative vitreoretinopathy often occur posterior to encircling elements, even broad buckles,” Dr. Charles said.

‘New breaks and proliferative vitreoretinopathy often occur posterior to encircling elements, even broad buckles.’ — Steve Charles, MD

Furthermore, buckling makes future glaucoma surgery more difficult and is associated with many complications, including induced axial myopia, diplopia, pain, ocular surface disorders, ptosis, buckle extrusion, or intrusion.

“Some surgeons say that in case a tear was missed, using a scleral buckle in a belt and suspenders approach lets them sleep better at night,” he said. “With all of its downsides, however, it certainly doesn’t let patients sleep better.”

Dr. Charles also commented that there is overemphasis on doing phacoemulsification as a combined procedure.

“Phacoemulsification causes the pupil to come down, makes the case go longer, and leads to suboptimal refractive outcomes,” he explained.

STEVE CHARLES, MD

Reviewed by Steve Charles, MD

This article was adapted from Dr. Charles’ presentation during Retina Subspecialty Day at the 2018 meeting of the American Academy of Ophthalmology. Dr. Charles is a consultant to Alcon Laboratories and receives royalties on the Constellation Vision System.
IN IT FOR THE LONG RUN?
EXPERIENCE THE GYC-500 GREEN PATTERN SCAN LASER PHOTOCOAGULATOR

“I enjoy the compact size and scan pattern delivery system of the GYC-500 Vixi Laser, It has reduced my PRP treatment time from 20 minutes to 5 minutes. After looking at all the other vendors, I went with NIDEK for reliability and the best priced laser out there.”

– Dr. Casimiro Gonzalez, MD
Buena Vista Medical Center
Cudahy, CA

GYC-500 Vixi/GYC-500 Green Laser
Increase your practice efficiency for treatment of retinal pathologies

• Offers a smaller footprint, reliable and easy to use laser for your practice.
• With the option of GYC-500 Vixi pattern scan, physicians can perform faster PRP treatments leading to reduced chair time for the patients.
Hypersonic vitrectomy (Vitesse, Bausch + Lomb) is new technology that removes vitreous through a new concept called vitreous liquefaction. Although it has a number of perceived advantages, hypersonic vitrectomy should only be considered an additional tool for use in selected cases rather than as a replacement for a guillotine cutter in all eyes, said Paulo E. Stanga, MD.

“We have come a long way in vitrectomy surgery, but we have to remember that the guillotine vitrector has been in evolution since 1972 while hypersonic vitrectomy has only been evolving since 2012,” said Dr. Stanga, professor of ophthalmology and retinal regeneration, Manchester Royal Eye Hospital and University of Manchester, Manchester, England.

The hypersonic vitrector is a single lumen device with a needle at its tip that is driven by ultrasound and moves up and down at a frequency >1.7 million times per minute. The rapid movement fragments the vitreous in front of the port into ultra-small pieces, reducing the viscosity of the vitreous and modifying its rheology. The “liquefied” material is readily aspirated into the tip of the small-gauge probe, which remains constantly open, with conventional vacuum and aspiration.

“The with the hypersonic vitrector, we are out of the race for increasing cuts per minute. Instead we talk about stroke, which is the forward movement of the tip of the needle,” Dr. Stanga said. “The hypersonic vitrector is the only device with a 100% duty cycle. With its single lumen, it has a larger opening through which vitreous can be removed from the eye. For that reason and because there is no cutter, fluidics and efficiency are improved.”

Experimental work evaluating hypersonic vitrectomy in cadaver eyes provided evidence that it cuts the collagen fibrils in the vitreous into significantly smaller pieces compared with a guillotine cutter [Pastor-Idoate S, et al. PLoS One. 2017;12(4):e0173883]. Safety studies in living animal models showed that the probe could be used safely when held almost in contact to the retina [Ch’ng SW, et al. PLoS One. 2018;13(6):e0197038].

Published findings from the first clinical trial of hypersonic vitrectomy showed it was effective for removing the vitreous in patients with a variety of vitreoretinal conditions and met safety criteria for core vitrectomy, inducing posterior vitreous detachment (PVD), and peripheral vitrectomy [Stanga PE, et al. Retina. 2018 Oct 23 epub ahead of print].

“The fact that the port is very close to the tip on this device is very helpful when trying to induce PVD,” Dr. Stanga said. Device-related complications included retinal break and detachment in one eye and a postoperative retinal detachment.

“These events were due to excessive traction exerted by the surgeon,” Dr. Stanga said.

Aside from vitreous, it can be used to remove dense hemorrhage, soft lens material, and silicone oil.

In addition, it can be used to perform retinotomy and retinectomy and to inject dyes and triamcinolone without having to be removed from the eye. It also seems to enable complete fluid-air exchange and engagement of some membranes because the port is close to the tip.

Dr. Stanga acknowledged that it is difficult to measure traction objectively, but it is believed that because hypersonic vitrectomy liquefies the vitreous, it causes less traction than conventional vitrectomy.

It is also thought that turbulence is lower with hypersonic vitrectomy because it has a smaller port opening and is used with lower infusion pressures.

Looking ahead, Dr. Stanga said that the technology has potential for fabrication of smaller-gauge instruments and instruments that are more rigid.

‘With hypersonic vitrectomy, I can create the capsulotomy without any traction on the posterior capsule.’ — Paulo E. Stanga, MD

**Accumulating Evidence**

Experimental work evaluating hypersonic vitrectomy in cadaver eyes provided evidence that it cuts the collagen fibrils in the vitreous into significantly smaller pieces compared with a guillotine cutter [Pastor-Idoate S, et al. PLoS One. 2017;12(4):e0173883]. Safety studies in living animal models showed that the probe could be used safely when held almost in contact to the retina [Ch’ng SW, et al. PLoS One. 2018;13(6):e0197038].

Published findings from the first clinical trial of hypersonic vitrectomy showed it was effective for removing the vitreous in patients with a variety of vitreoretinal conditions and met safety criteria for core vitrectomy, inducing posterior vitreous detachment (PVD), and peripheral vitrectomy [Stanga PE, et al. Retina. 2018 Oct 23 epub ahead of print].

“The fact that the port is very close to the tip on this device is very helpful when trying to induce PVD,” Dr. Stanga said. Device-related complications included retinal break and detachment in one eye and a postoperative retinal detachment.

“These events were due to excessive traction exerted by the surgeon,” Dr. Stanga said.

**Further Investigation**

Dr. Stanga has also used the hypersonic vitrector for performing posterior capsulotomy and said he believes it has a benefit for this task compared with a guillotine vitrector.

“It can be very difficult to do a capsulotomy using a guillotine vitrector because the capsule needs to be aspirated into the port that creates traction on the zonules,” he explained. “With hypersonic vitrectomy, I can create the capsulotomy without any traction on the posterior capsule.”

Currently, he is performing animal experiments evaluating hypersonic vitrectomy for proliferative vitreoretinopathy. So far, he has found that the membrane can be removed without damaging the underlying retina. It is also being assessed for epiretinal membrane surgery. In addition to some of the benefits mentioned above, Dr. Stanga noted that the hypersonic vitrector is a multifunction tool.

**Take-home**

> Hypersonic vitrectomy is promising new technology that has been shown effective for removing the vitreous in patients with a variety of vitreoretinal conditions and is being looked at for additional applications.

**Paulo E. Stanga, MD**

E: p.stanga@retina specialist.co.uk

This article was adapted from Dr. Stanga’s presentation at the 2018 meeting of the American Academy of Ophthalmology. Dr. Stanga is a consultant to and receives grant support and fees for speaking from Bausch + Lomb.
a pilot head mount display used by air fighter craft pilots to display flight data, videos, and symbology critical for flight, Dr. Loewenstein explained.

She described how the system has personalized screens that can have various inputs, sizes, and positions. One example she gave was optical coherence tomography imaging that could be potentially overlaid onto the surgeon’s view.

“Basically, it can be personalized to the person’s needs and preferences,” she said.

Users of the system can move their head to change the focus of the camera, and control image enhancement and lighting.

“Using head gestures, the surgeon can shift between different virtual screens, and control functions such as focus and transparency transitions,” according to the Beyeonics website.

At her center, she and fellow surgeons used the Beyeonics system for 25 cases. An additional 15 cases have been performed by Pravin Dugel, MD, Retina Consultants of Arizona, Phoenix.

Surgeries performed so far include vitrectomy, endolaser treatment, removal of lens fragments after cataract surgery, membrane peeling, internal limiting membrane (ILM) peel, retina detachment, and cataract.

Dr. Loewenstein described the transparent head-wearable display worn during surgery as lightweight. She also never experienced any imaging lag time during the surgeries she performed.

Other advantages of the system include good visualization and clarity, good field of view, and the ability to not be attached to the surgical microscope, according to Dr. Loewenstein.

Although Dr. Loewenstein was not aware of the cost of the technology, she said it may rival the price of a surgical microscope.

When asked about the system’s learning curve, Dr. Loewenstein said she believes it is an easy system to learn, once the basics are established.

‘There is the potential for unlimited virtual information that is personalized and overlaid.’

– Anat Loewenstein, MD

Other potential surgical applications described by Dr. Loewenstein included fluorescein imaging to aid with preplanning and reduced illumination that could help when treating epiretinal membrane, so there is less light toxicity.

As a retinal specialist, you need effective patient management options. The IQ 577™ Laser System with MicroPulse® mode enables you to address foveal leakage in a safer and more effective manner—not only around the fovea, but when treating refractory edema over the fovea.¹ The TxCell™ Scanning Laser Delivery System allows single and multi-spot pattern scanning delivery using standard continuous wave laser or MicroPulse laser modes.


© 2018 IRIDEX. All rights reserved. IRIDEX, the IRIDEX logo, IQ 577, TxCell, and MicroPulse are trademarks or registered trademarks of IRIDEX.
Data promising in uveitic macular edema pivotal trial

By Cheryl Guttman Krader

PEACHTREE—a phase III study of suprachoroidal injection with a proprietary formulation of triamcinolone acetonide (CLS-TA, Clearside Biomedical) for the treatment of macular edema due to noninfectious uveitis—met its primary efficacy endpoint and found a favorable safety profile for the investigational agent, said Rahul Khurana, MD.

The study is the first uveitis trial to assess improvement in visual acuity rather than vitreous haze as its primary endpoint, said Dr. Khurana, partner, Northern California Retina Vitreous Associates, Mountain View, CA, and clinical associate professor of ophthalmology, UCSF Medical Center, San Francisco.

The results at the end of the 6-month study showed that compared with sham injection, the percentage of patients gaining ≥15 ETDRS letters from baseline was significantly greater in the group receiving suprachoroidal CLS-TA than in the sham injection control arm (46.9% versus 15.6%).

Analyses of mean change from baseline best-corrected visual acuity (BCVA), mean change in central subfield thickness (CST), resolution of macular edema, and improvement of uveitic inflammation also favored the CLS-TA arm. The safety review showed no significant adverse events were associated with this new type of injection, and there were low rates of IOP and cataract in the CLS-TA arm.

“Macular edema is a leading cause of vision loss in uveitis, and its most challenging aspect is that it often persists despite adequate control of uveitis itself,” Dr. Khurana explained. “The positive efficacy signals and the favorable safety profile of CLS-TA suggest it has benefit for patients with uveitic macular edema associated, which is a complex and often challenging condition.”

The suprachoroidal injection was developed in a collaboration among researchers at Emory University, Georgia Tech, and Clearside Biomedical. It utilizes a 30-gauge needle of <1,000 μm in length to access the suprachoroidal space.

“Animal data show that suprachoroidal injection of triamcinolone leads to higher amount of the drug in the choroid, retinal pigment epithelium, and retina with much lower exposure in the anterior segment compared with intravitreal injections,” he said. “Thus, the suprachoroidal injection has great potential for increased efficacy and better safety than intravitreal treatment.”

STUDY DESIGN

PEACHTREE enrolled patients with macular edema secondary to uveitis in any anatomic location who had a central subfield thickness (CST) ≥300 μm and BCVA ranging from 20/800 to 20/40. Patients with IOP >22 mm Hg or uncontrolled glaucoma were excluded, but patients with IOP <22 mm Hg were eligible, even if they were on up to two IOP-lowering medications.

In this multicenter double-masked study, a total of 160 patients were randomly assigned 3:2 to receive suprachoroidal CLS-TA 4.0 mg or sham injection at baseline and week 12. Rescue therapy was received by 72% of control patients at a median of 36 days versus 13% of patients treated with CLS-TA at a median of 89 days.

Elevated IOP adverse events were more common in the control arm than the CLS-TA arm (15.6% versus 11.5%), which Dr. Khurana said was explained by the higher rate of rescue treatment in the control arm. Rates of IOP elevation ≥10 mm Hg, IOP ≥30 mm Hg, and treatment with IOP-lowering medication were also lower in the CLS-TA arm compared with controls.

No patients required surgery for IOP control. The rate of cataract adverse events was 7.3% in the CLS-TA arm and 6.3% in the control arm. There were no cataract-related surgeries. “It is important to remember that this was a 6-month study and cataract takes longer to develop,” Dr. Khurana said.

At week 4, patients were eligible for rescue therapy.

The two groups were balanced at baseline with respect to demographic characteristics, mean BCVA (Snellen equivalent ~20/80), mean CST (~500 μm), and uveitic anatomic subtypes.

MORE EFFICACY DATA

Mean visual acuity improvement from baseline to month 6 was 13.8 letters in the CLS-TA arm versus 3.0 letters in the control group. The treatment benefit was seen as early as week 4 in the CLS-TA arm, persisted throughout the study, and was consistent across all uveitic anatomic location subgroups.

Dr. Khurana noted that CST decreased by a mean of 153 μm in the CLS-TA arm versus 18 μm in the control arm.

The anatomic response also was seen by week 4 and consistent across all uveitic subtype groups. More than 50% of CLS-TA patients achieved resolution of macular edema defined as CST <300 μm, compared with only 14% of control patients, and more than two-thirds of patients treated with CLS-TA had improvement in uveitic inflammation.

Rescue therapy was received by 72% of control patients at a median of 36 days versus 13% of patients treated with CLS-TA at a median of 89 days.
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.

The technology in sight.
Our proprietary and barrier-breaking AMPPLIFY™ Drug Delivery Technology is designed to help us keep improving what’s possible for eye care.

The vista awaits us.
Visit kalarx.com and let’s get our journey underway.
Refillable implant releasing ranibizumab in phase III study

Therapeutic option could help to reduce treatment burden for many patients with nAMD

By Cheryl Guttman Krader; Reviewed by Dante J. Pieramici, MD

ARCHWAY—a phase III study evaluating the efficacy and safety of ranibizumab 100 mg/mL delivered via the port delivery system (PDS) for the treatment of neovascular age-related macular degeneration (nAMD)—was launched in September 2018.

Dante J. Pieramici, MD, described the study protocol and how it was shaped by findings from the phase II LADDER trial.

He explained that as the Archway trial is getting under way, investigators are being trained in the procedures for implanting and refilling the PDS.

“The training is time- and labor-intensive,” said Dr. Pieramici, director, California Retina Research Foundation, and Partner, California Retina Consultants, Santa Barbara, CA. “It is important, however, for optimizing safety outcomes in this trial that will hopefully lead to approval of a therapeutic option that can reduce the treatment burden for many of our patients with nAMD.”

80% of patients who were in the PDS 100 mg/mL group went 6 months or longer without getting an implant refill

ABOUT THE STUDY

Archway is a multicenter registration trial with a planned enrollment of 360 patients. It is comparing treatment with the PDS implant refilled on a 6-month basis with a special formulation of ranibizumab versus monthly intravitreal injection of ranibizumab 0.5 mg (Lumenis, Genentech).

The population being recruited for the study is represented by patients who have responded to anti-vascular endothelial growth factor (VEGF) therapy and are expected to need ongoing frequent injections. To be eligible for participation in Archway, patients must be at least 50 years of age and have best-corrected visual acuity (BCVA) of 34 ETDRS letters or better.

Other inclusion criteria require a diagnosis of nAMD within the previous 9 months, demonstrating of response to prior intravitreal anti-VEGF treatment, and receiving at least 3 injections in the 6 months prior to screening.

In Archway, the PDS implant will be mandatorily refilled every 24 weeks while the intravitreal ranibizumab arm will receive treatment on a monthly basis. The dose of the implant and the refill schedule were chosen based on results of LADDER that compared PDS filled with three different dosages—10, 40, and 100 mg/mL—against monthly intravitreal ranibizumab 0.5 mg.

The primary objective of the LADDER study was to determine the time until a patient first required implant refill, and the data analysis showed a clear dose-response relationship. Median time to refill was 15 months in the 100 mg/mL group, 13 months for the 40 mg/mL group, and 9 months for patients who received PDS 10 mg/mL.

“Looking at the refill data another way, 80% of patients who were in the PDS 100 mg/mL group went 6 months or longer without getting an implant refill,” Dr. Pieramici said. “Therefore, when designing Archway, we were comfortable choosing 6 months as the standardized refill interval.

“The Archway protocol, however, also includes anatomical and visual acuity criteria for allowing patients in the PDS group to receive a supplemental intravitreal injection of ranibizumab at 8 or 4 weeks prior to mandatory refill,” he said.

Dr. Pieramici said added that Archway has a non-inferiority/equivalence design.

“Although data from LADDER showed that some patients can go longer than 6 months without needing their device refilled, the 6-month interval seemed to be a reasonable approach for establishing non-inferior visual results and anatomic results compared to monthly ranibizumab,” he said. “Should the product become available, we can begin to experiment with extending the treatment interval longer.”

The primary endpoint in Archway is looking at change in ETDRS BCVA from baseline to the average of weeks 36 and 40. The protocol includes numerous secondary functional and anatomical endpoints and comprehensive safety evaluations.

Dr. Pieramici explained that the clinical viability of PDS depends on establishing a good safety profile.

“If the complication rates are too high, the PDS would not be a favorable treatment strategy compared with intravitreal ranibizumab,” he said.

The implant is placed in the superotemporal quadrant of the pars plana about 4 mm posterior to the limbus in a one-time outpatient surgical procedure. Refilling of the implant is performed in the office using a customized needle inserted through the conjunctiva and through the diaphragm of the device.

“Compared with intravitreal injections, the refill procedure is more comfortable for patients but more technically difficult for surgeons,” Dr. Pieramici said.

He also mentioned that although the PDS is currently only being studied as a reservoir for continuous sustained delivery of ranibizumab for treatment of nAMD, it represents an exciting platform for future pharmacologic dosing.

“By changing the implant’s filter parameters, it can likely be used to release other medications and for the management of other diseases,” he said.
Results from the 36-month Hyperopia Treatment Study 1 (HTS1), comparing immediate versus delayed spectacle treatment for moderate hyperopia in children 1 to <3 years of age, are consistent with showing a small to moderate benefit or no benefit of immediate glasses compared with careful observation and glasses if deterioration occurs.

The study randomly assigned patients 1:1 to either observation with glasses not prescribed unless the child met deterioration criteria or immediate prescription of glasses to be worn for the study duration. Its primary outcome, analyzed at study conclusion, compared rates of failure at study conclusion, with failure defined as “doing harm” to visual acuity, stereoacuity, or alignment.

Results showed a 13% lower failure rate in the group randomly assigned to immediate glasses compared with the observation group (21% versus 34%), but the difference between groups was not statistically significant ($p = 0.14$).

**PEDIG STUDY**

Donny W. Suh, MD, highlighted the findings from the National Eye Institute-supported study conducted by the Pediatric Eye Disease Investigator Group (PEDIG).

“Our estimates of failure after 3 years with follow-up every 6 months did not allow us to make any definitive recommendations about management for these children,” said Dr. Suh, chief of pediatric ophthalmology and strabismus, Children’s Hospital and Medical Center, and associate professor, Department of Ophthalmology and Visual Sciences, University of Nebraska Medical Center, Omaha, NE.

Noting that the study has definite limitations, he concluded, “We all agree that further studies are needed to answer this question effectively.”

The study was undertaken because it remains controversial whether young children with moderate to high hyperopia in the absence of strabismus or amblyopia should be prescribed glasses immediately or observed until some sign of decompensation develops.

“You can find literature to support both practices,” Dr. Suh said. “The main question our study asked was: If you delay treatment until the child decompensates or deteriorates, will it cause any permanent damage or harm?”

Children were eligible for HTS1 if on cycloplegic refraction they had $+3.00$ D to $+6.00$ D spherical equivalent refractive error in either eye, astigmatism $\leq 1.5$ D in both eyes, and spherical equivalent anisometropia $\leq +1.50$ D.

In addition, they could not have received prior treatment for refractive error with glasses unless the duration was $\leq 1$ week and the treatment occurred $>2$ months prior to enrollment. They also could not have prior treatment for amblyopia or strabismus or measurable heterotropia at distance or at near by cover/uncover testing.

**STUDY CRITERIA**

Dr. Suh reviewed the protocol definitions and criteria for failure and deterioration. He explained that failure, which was defined at the end of the study, was declared if any of the following criteria were met with and without trial frames and with confirmation by masked test and retest: measurable heterotropia; visual acuity below age norms; stereopsis below age-normal values; or strabismus surgery prior to the 36-month exam.

Deterioration was declared if any of the following criteria were met on unmasked testing in randomized correction and confirmed by retest: mea-
Understanding pros, cons of SS-OCT
Technology yields clinical advantages over previous generation but higher cost a factor

By Cheryl Guttman Krader

THE COMMERCIALIZATION of ophthalmic optical coherence tomography (OCT) is a fascinating story considering its evolution and how the technology moved so rapidly from the laboratory into the clinic, according to Jay S. Duker, MD.

Dr. Duker brought attendees up to date on swept-source (SS-OCT), the latest generation of OCT devices. SS-OCT first became commercially available in 2013, and he noted that it has significant theoretical advantages and promise for having clinical advantages over the previous-generation spectral-domain (SD) systems.

However, he also noted that SS-OCT has some disadvantages, of which higher cost relative to SD-OCT is an issue hampering its uptake.

“The big caveat right now is that SS-OCT devices are not widely available because of their increased cost,” said Dr. Duker, professor and chairman, Department of Ophthalmology, Tufts University School of Medicine, Boston.

Compared with SD-OCT, SS-OCT generally has faster image acquisition, which leads to less tradeoff between image size and resolution, and also allows wider scanning ranges (12 to 16 mm scan lengths are commercially available; longer ranges can be gotten with specific lenses and mosaic programs).

In addition, there is no sensitivity roll-off with SS-OCT. Therefore, vitreous and choroid can be imaged well simultaneously. Because SS-OCT uses a longer wavelength of light than SD-OCT, SS-OCT also provides deeper penetration.

“SS-OCT can penetrate better through lens opacity, choroid, pigment, blood, and intraocular gas than SD-OCT, and based on two published papers, it appears that SS-OCT will allow better imaging of choroidal neovascularization,” he said.

Outlining its disadvantages, he noted that the higher cost of SS-OCT comes from the light source that is used. “SS-OCT requires narrow line width, high-speed, frequency-swept lasers that are very pricey,” he said.

Other disadvantages of SS-OCT compared with SD-OCT include lower axial resolution, worse signal-to-noise ratio, worse motion artifact, and absence of normative databases, which is important for use in glaucoma imaging.

“Worse axial resolution with SS-OCT can be overcome with some image averaging, but in general, the SS-OCT images may not be quite as sharp as what we are used to seeing with SD-OCT,” he said.

CURRENT STATUS
Two SS-OCT systems for posterior segment imaging are available in the United States and elsewhere, the Triton DRI (Topcon Medical Systems) and PLEX Elite 9000 (Carl Zeiss Meditec). In addition, a new optical biometer (IOLMaster 700, Carl Zeiss Meditec) features SS-OCT.

“The company chose to use SS-OCT because of its ability to penetrate denser cataracts more easily and its faster speed of image acquisition,” he said.

He said the Triton DRI is a second-generation machine from Topcon. It has a scanning rate of 100,000 A scans/sec and has built-in cameras for color fundus photography and fundus autofluorescence. It can also be used for fluorescein angiography and OCT angiography, although the latter application is not FDA approved.

The PLEX Elite 9000 also does 100,000 A scans/sec. An upgrade that doubles the scan rate is expected to be forthcoming pending FDA approval. Showing images from a normal eye taken with the currently available and faster scan rates, he pointed out how the upgrade will clearly provide better detail.

The PLEX Elite 9000 features OCT angiography and has FDA approval for that application. It does not have the other capabilities found on the Triton DRI, and access to the PLEX Elite 9000 requires joining the company’s research network.

Both systems feature tracking and have a 12 mm scan length. Although not FDA approved, the PLEX Elite 9000 can do up to a 23 mm cube scan with a lens.

He reviewed images acquired using the two SS-OCT devices that illustrated the wide scanning length, detailed choroidal images, and better OCT angiography image quality compared with SD-OCT angiography. He also noted that the readout on the Triton DRI can show multiple images, which he said is a “handy feature” for clinicians.

JAY S. DUKER, MD
p: 617/636-4677
This article was adapted from Dr. Duker’s presentation at the 2018 meeting of the American Academy of Ophthalmology. Dr. Duker receives research support from Carl Zeiss Meditec and Topcon Medical Systems.

DETERIORATION
(Continued from page 23)
surable heterotropia; if age ≥3 years, visual acuity below age-normal values, significant interocular difference, or stereoacuity below age-normal values; or parental concern.

Rates of deterioration during the 3-year study were 33% for the group prescribed immediate glasses and 58% for the observation group. Dr. Suh noted that the rates of deterioration matched pre-study expectations.

“About one-half of patients were followed without glasses for 3 years,” he said.

Emmetropization over the study period was also evaluated using data from the more hyperopic eye. On average, hyperopia changed little in either group, and there was a between-group difference in the amount of change of just 0.16 D that was not statistically significant.

Discussing the study’s limitations, Dr. Suh said the study had a planned enrollment of 286 patients, but enrollment was slow and only 130 patients completed the trial. In addition, the study did not address the effect of correction on asthenopia, near visual acuity or reading performance.
TRAVEL TO TRANSFORM WITH PASSION TO HEAL™

PROVIDE OPHTHALMOLOGY CARE TO COMMUNITIES IN KENYA

Leverage your professional expertise and skills by making a difference in the world. Travel on a fully funded ME to WE Trip to rural Kenya to help transform eye care for thousands of adults and children in our charity partner’s communities. In collaboration with ME to WE Trips, the Passion to Heal™ initiative funds the cost of these medical volunteer trips, supported by Valeant Pharmaceuticals NA LLC (VPNA).

KENYA  September 15 - 24, 2018

APPLY NOW FOR YOUR FULLY FUNDED TRIP!

PASSIONTOHEAL.COM
DIGITAL IMAGING

TOPCON 50-EX/DX cameras and Imagenet/OIS systems
CALL US TODAY
888.393.4624
 Imaging Specialists For Over 25 Years
www.imacam.com

PRACTICE FOR SALE

OPHTHALMOLOGY PRACTICE FOR SALE
Located in Western Pennsylvania.
Half hour from downtown Pittsburgh. Conveniently located near area hospital.
Doctor is retiring.
Practice is patient ready.
Contact practice manager:
Christine Smith
Phone: (724) 728-2848
Email: pmkuzmanrd@yahoo.com

ADVERTISE TODAY!

Recruitment Advertising Can Work For You!
Reach highly-targeted, market-specific business professionals, industry experts and prospects by placing your ad here!
Narrow your candidate search to the best.

Place a recruitment ad in Ophthalmology Times—in print or online.

Joanna Shippoli
Account Manager | 440-891-2615
joanna.shippoli@ubm.com

Ophthalmology Times
5 ways using KPIs may help increase clinic revenue

Find useful data that might be hiding in practice management, revenue cycle, EHR systems

By Richard Wooten and Patti Peets

Medical practices have a vested interest in protecting—and growing—their revenue, especially as patient payment responsibility increase.

The seemingly straightforward task of collecting patient payments can, in reality, be an arduous and complicated ordeal if the right front- and back-end systems are not in place.

Observing and analyzing key performance indicators (KPIs) can help your practice measure performance from every angle, so you can identify where there are issues in your processes. Then, you can take targeted action to correct them—and boost your revenue.

Here are five ways KPIs can help identify revenue opportunities across every workflow inside your practice as well as tips for finding useful data that might be hiding in your practice management (PM), revenue cycle management (RCM), and electronic health record (EHR) systems.

We’ll also share our favorite metrics for monitoring key growth indicators and moving the needle across all areas of the practice.

1. Verify Eligibility and Prior Authorizations

To increase the revenue you collect from patients, your front desk staff needs to verify the eligibility of every single patient for every appointment.

In addition, staff should confirm how much of a patient’s deductible has been met, so they know how much to collect.

Technology makes it much easier to collect prior balances and take prepayments, set up payment plans, and identify patient eligibility information upfront. As an example, in the urology space, Advanced Urology Institute has implemented kiosks and iPads for patient self-service, freeing up staff to spend time verifying eligibility and securing prior authorizations.

If the payer requires authorization and the authorization is not obtained, the claim will be denied. Consequently, your practice won’t be able to collect that money. To ensure this KPI is being met, look at your denial codes to see what percentage of your denials are due to a lack of authorization. Find them, fix them and, more importantly, change the behavior causing them.

Eventually, you will have zero denials because of authorization absences.

2. Analyze Cancellation Rate

Another KPI you can use to increase your practice revenue from the front end is to review your cancellation rate.

A high cancellation rate leads to decreased productivity, so it’s a good idea to get familiar with what percentage of your appointments are canceled and, more importantly, why they’re being canceled.

Was it because the patient isn’t satisfied? Was the appointment not needed after all? Did the provider cancel the appointment because of last-minute changes?

Make sure you assign the appropriate cancellation reason for every visit, so you can identify trends that are causing decreased productivity and lost revenue.

Once identified, you can analyze what the reasons for cancellations and hoon in on what behavior modification can decrease them.

If you have a high cancellation rate, make sure your practice is utilizing a wait-list functionality.

Make sure to give patients the option to reschedule appointments electronically themselves so they don’t have to worry about calling during standard business hours.

3. Reduce Bill Lag

On the back end, bill lag can indicate unbilled charges and lead to higher accounts receivable (AR). A bill lag is the length of time between when the claim is submitted compared to the date of service. A practice should strive to bill all services within one or two days from the date of service.

To check this, look at your billed date compared to the date of service to determine your bill lag.

Charge lag is also an indication that it is taking your practice longer to enter charges.

If you have unbilled encounters, your charges are not being entered into the system in a timely manner.

To find these, look at any appointments with no charges entered. You can determine your charge lag by running a report after all encounters are fulfilled and compare the charge entered date to the date of service.

Charge lag should ideally be zero, meaning charges entered are billed same day but no more than two days from the date of service.

4. Track Denial Percentages

Ideally, you want your denials to be less than 2% of the claims that go out the door. The higher your denial rate, the more resources it takes to follow up on the denials, which then puts stress on the staff. If your practice cannot follow up on denials, your revenue and profitability will suffer as a result.

Again, as an example, Advanced Urology Institute has found that the first pass resolution rate, in addition to denial percentages, is a valuable KPI for increasing revenue. When the first pass resolution rate is high, fewer resources are needed. That means staff have more time to focus on other tasks such as revenue-generating initiatives.

TAKE-HOME

› Observing and analyzing key performance indicators (KPIs) can help your practice measure performance from every angle, so you can identify where there are issues in your processes.

Continues on page 29:: Indicators
**INDICATORS**

(Continued from page 28)

Your first pass resolution rate can go hand in hand with your denial rate and should be, ideally, 96% or higher. This means that 96% of the claims are getting paid on the first submission.

**At the end of the day, running a practice is a complex and ever-changing challenge, so identifying a handful of high-impact metrics to tackle can be a valuable first step.**

If your first pass resolution rate is lower than that, the first thing you can do is analyze the denial reasons by provider and by payer.

### 5. Reduce Days in Accounts Receivable

Essentially, days in AR indicates how long it takes you to get paid for your services. Ideally, it should be less than 30 days, depending on your payer mix. If it is higher, this could indicate a number of things. It could mean you have a higher than normal denial rate, you have slow to pay payers, or your practice is not collecting patient payment at the time of service. This can happen when you have credentialing issues with a certain payer or a host of other issues indicating less than effective follow up.

Every additional day in AR means a lower likelihood of getting paid. The chances of collecting patient money once it hits 90 days is less than 30%. If more than 15% of your AR is more than 120 days old, then you need to review them at the payer level to determine why different payers are taking so long to pay.

Overall, AR over 120 days is a good indicator of the effectiveness of your front-end and back-end processes.

At the end of the day, running a practice is a complex and ever-changing challenge, so identifying a handful of high-impact metrics to tackle can be a valuable first step.

### RICHARD WOOTEN

Wooten is the chief executive officer of Advanced Urology Institute, where he has grown the Oxford, FL-based specialty group to 102 providers across 40 locations around the state.

### PATTI PEETS

Peets is senior director of revenue cycle management for cloud-based software provider CareCloud.

---

### A legal look at 2019 physician fee schedule

**By Rachel V. Rose, JD, MBA**

**RECENTLY,** the Centers for Medicare and Medicaid Services (CMS) released its annual update for physician service payment rates.

The 2019 Medicare Physician Fee Schedule (PFS) contains changes that physicians should be aware of in order to formulate a fiscally responsible budget.

Two areas of particular note are payments for new Medicare Part B drugs, which should not be surprising in light of other Congressional initiatives related to the 340B Program, and the methodology for paying for evaluation and management (E/M) services. The latter of the two areas received significant backlash from physician groups.

Effective Jan. 1, 2019, CMS reduced the add-on fee for Part B drug payments based on wholesale acquisition cost (WAC) from 6% to 3%.

This payment reduction only affects new drugs. Regarding changes to E/M services, there are two main objectives: reducing administrative burdens and improving payment accuracy. Initially, CMS proposed consolidating the E/M coding levels from five down to two. The final rule compromised and created three levels and phases in the new billing codes, which begin in 2021.

Notably, CMS retained the code for the most complex payments, as physicians voiced concern that removing the codes would mean lower payments for complex cases. One item that received pushback was finalizing the proposed rule’s provision to reduce payments for E/M visits that occur on the same day as the procedure. For now, this provision remains the same.

Another positive for physicians related to the E/M services is that there is no longer a requirement to justify a home visit instead of an office visit. Physicians should stay tuned for the final rule due Nov. 23 and pay special attention to the reduction of payments for same-day E/M services as well as CMS’ comments.

**RACHEL V. ROSE, JD, MBA**

Rachel V. Rose, JD, MBA, advises clients on compliance and transactions in healthcare, cybersecurity, corporate and securities law. She also teaches bioethics at Baylor College of Medicine in Houston. Rachel can be reached through her website, www.rvrose.com.
Upgrading your practice need not be a ‘hair-raising’ experience

Age is but a number
Tips for PKP in pediatric patients
Improving detection of missed retinal breaks
Understanding advantages, limitations of SS-OCT

in case you missed it

Optic Relief: A year in review
Internet shoppers and banana bread

Advertiser Index

<table>
<thead>
<tr>
<th>Advertiser</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCON LABORATORIES INC.</td>
<td>CV2, CV3</td>
</tr>
<tr>
<td><a href="http://www.alcon.com">www.alcon.com</a></td>
<td></td>
</tr>
<tr>
<td>800/862-5266</td>
<td></td>
</tr>
<tr>
<td>ALIMERA SCIENCES</td>
<td>11-12</td>
</tr>
<tr>
<td><a href="http://www.iluvien.com">www.iluvien.com</a></td>
<td></td>
</tr>
<tr>
<td>BAUSCH + LOMB</td>
<td>9, CV4</td>
</tr>
<tr>
<td><a href="http://www.bausch.com">www.bausch.com</a></td>
<td></td>
</tr>
<tr>
<td>800/227-1427</td>
<td></td>
</tr>
<tr>
<td>CORNEA 360</td>
<td>15</td>
</tr>
<tr>
<td><a href="http://www.cornea360.org/">www.cornea360.org/</a></td>
<td></td>
</tr>
<tr>
<td>IRIDEX</td>
<td>19</td>
</tr>
<tr>
<td><a href="http://www.iridex.com/cyclog6">www.iridex.com/cyclog6</a></td>
<td></td>
</tr>
<tr>
<td>888/725-8115</td>
<td></td>
</tr>
<tr>
<td>KALA PHARMACEUTICALS</td>
<td>21</td>
</tr>
<tr>
<td><a href="http://www.kalarx.com">www.kalarx.com</a></td>
<td></td>
</tr>
<tr>
<td>NIDEK INC.</td>
<td>17</td>
</tr>
<tr>
<td>usa.nidek.com</td>
<td>510/226-5700</td>
</tr>
<tr>
<td>SHIRE OPHTHALMIC</td>
<td>5-7</td>
</tr>
<tr>
<td><a href="http://www.shire-eyes.com">www.shire-eyes.com</a></td>
<td>800/828-2088</td>
</tr>
<tr>
<td>TTI MEDICAL</td>
<td>23</td>
</tr>
<tr>
<td><a href="http://www.ttimedical.com">www.ttimedical.com</a></td>
<td>800/322-7373</td>
</tr>
</tbody>
</table>

This index is provided as an additional service. The publisher does not assume any liability for errors or omissions.
GRIESHABER® DSP IMPORTANT PRODUCT INFORMATION

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician. Indications for Use: GRIESHABER® DSP Instruments are a line of single-use vitreoretinal microinstruments which are used in ophthalmic surgery, for cases either in the anterior or the posterior segment. The GRIESHABER® Advanced Backflush Handles DSP are a family of instruments for fluid and gas handling in vitreoretinal surgery. Warnings and Precautions: • Potential risk from reuse or reprocessing GRIESHABER® DSP instruments include: foreign particle introduction to the eye; reduced cutting or grasping performance; path leaks or obstruction resulting in reduced fluidics performance. • Verify correct tip attachment, function and tip actuation before placing it into the eye for surgery. • For light fiber instruments: Minimize light intensity and duration of exposure to the retina to reduce risk of retinal photic injury. The light fiber instruments are designed for use with an ALCON® illumination source. • Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. If stream of fluid is weak or absent, good fluidics response will be jeopardized. • Use appropriate pressure supply to ensure a stable IOP. • If unwanted tissue gets engaged to the aspiration port, it should be released by interrupting aspiration before moving the instrument.

Attention: Please refer to the product labeling for a complete listing of indications, warnings, and precautions.

Non-lipid containing eye drop (Systane Ultra)

Lipid layer thickness (LLT) prior to and 15 minutes following a single drop of emollient or non-emollient eye drop in dry eyes with meibomian gland dysfunction. Data are the mean (±SD) LLT based on stroboscopic video color microscope (SVCM) measurements in study eyes (qualifying eye in subjects with only one qualifying eye, or the eye with the lowest LLT at baseline in subjects with two qualifying eyes).

p<0.001 paired t-test for the change from baseline. p<0.001, n=35, following a single drop.

Baseline | After Leading | After Soothe XP
---|---|---
Lubricant Eye Drop | 50nm | 78nm
|
Soothe XP | 51nm | 78nm | Increase 58%

Improved lipid layer thickness after treatment with Soothe XP

Now Available: Preservative Free!

Soothe® XP helps replenish this layer.

- Up to 86% of patients reporting dry eye symptoms have Meibomian Gland Dysfunction (MGD).1
- MGD can cause the lipid layer to break down, which may lead to a compromised tear film.2
- Soothe XP contains Restoryl® mineral oils that may benefit MGD patients by helping to restore the lipid layer, seal in moisture, and protect against tear loss.

© 2018 Bausch & Lomb Incorporated. PN08785 5X10028.USA.18

Soothe® XP helps replenish this layer.

MGD can cause the lipid layer to break down.

Soothe® XP helps replenish this layer.

MGD can cause the lipid layer to break down.

Soothe® XP helps replenish this layer.

MGD can cause the lipid layer to break down.