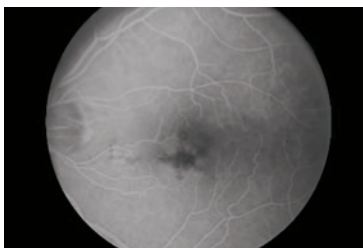


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Special Report

EXPLORING NEW THERAPIES FOR NEOVASCULAR AMD



CLEVELAND :: **THE TREATMENT OF WET** age-related macular degeneration has evolved through three eras: the thermal laser era, the photodynamic laser era, and now the pharmacologic era, noted Lawrence J. Singerman, MD, clinical professor of ophthalmology, Case Western Reserve University School of Medicine, Cleveland.

(See story on page 12 : *Neovascular*)

Practice Management

FUTURE UNCERTAIN FOR OPHTHALMIC RESEARCH FUNDING

SALT LAKE CITY :: **THOUGH THE AFFORDABLE CARE ACT (ACA)**—commonly known as “Obamacare”—was the answer for which many physicians hoped would remedy the issue of research funding, it is too early to determine the impact of the health-care system overhaul, said Randall J. Olson, MD.

(See story on page 30 : *Funding*)

LPK technique gives boost to advanced keratoconus

Results show improvements in cylinder, SE, visual acuity with low rate of endothelial cell loss

NOVEL SURGICAL TECHNIQUE



Lamellar-perforating keratoplasty (LPK) was developed by Cesar Carriazo, MD, as a modification to pachymetry-assisted lamellar keratoplasty (PALK).

To watch a surgical case, go to <http://bit.ly/1fwkPa9>

For more surgical videos, go to

- <http://bit.ly/1hqoYp>
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(Videos courtesy of Cesar Carriazo, MD)

By Cheryl Guttman Krader;

Reviewed by Cesar Carriazo, MD

BOGOTA, COLOMBIA :: **OUTCOMES OF EYES** undergoing lamellar-perforating keratoplasty (LPK) show this new partial-thickness corneal transplantation technique is a suitable alternative to penetrating keratoplasty for eyes with advanced keratoconus, said Cesar Carriazo, MD.

“Patients with advanced keratoconus have had no options for visual rehabilitation other than penetrating keratoplasty,” said Dr. Carriazo, founder

and scientific director, Carriazo Centro Oftalmológico, Barranquilla, Colombia and refractive and anterior segment ophthalmologist, Instituto Barraquer de America, Bogota, Colombia. “With LPK we can offer them the advantages of a minimally invasive procedure.”

Dr. Carriazo developed LPK as a modification to pachymetry-assisted lamellar keratoplasty (PALK).

HOW IT'S DONE

In LPK, as in PALK, an excimer laser (Amaris 1050RS, Schwind eye-tech-solutions) is used to perform a pachymetry-guided, 8-mm ablation of the recipient eye, leaving 100 μ m of posterior stroma, Dr. Carriazo explained.

Then, in LPK, the laser is used to create multiple microperforations around the periphery of the stromal bed. Due to the fast speed of the laser (1,050 Hz), the laser treatment of the recipient eye takes just about 90 seconds.

After placing air in the anterior chamber, an 8-mm

(Continues on page 10 : *Keratoconus*)

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- No labeled drug-drug interactions^{1,4}

Indication

RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Important Safety Information

RESCULA is contraindicated in patients with hypersensitivity to unoprostone isopropyl or any other ingredient in this product.

RESCULA has been reported to increase pigmentation of the iris, periorbital tissues, and eyelashes. Patients should be advised about the potential for increased brown iris pigmentation which is likely to be permanent.

RESCULA should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular edema, including cystoid macular edema, has been reported. RESCULA should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

*In pooled safety analyses of pivotal trials comparing RESCULA with timolol maleate 0.5%.⁴

Please see Brief Summary on reverse and full Prescribing Information, available from your Sucampo representative.

Brief Summary of Prescribing Information for RESCULA.

INDICATIONS AND USAGE

Rescula (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

DOSAGE AND ADMINISTRATION

The recommended dosage is one drop in the affected eye(s) twice daily.

Rescula may be used concomitantly with other topical ophthalmic drug products to lower intraocular pressure. If two drugs are used, they should be administered at least five (5) minutes apart.

CONTRAINDICATIONS

Rescula is contraindicated in patients with hypersensitivity to unoprostone isopropyl or any other ingredient in this product.

WARNINGS AND PRECAUTIONS

Iris Pigmentation

Unoprostone isopropyl ophthalmic solution may gradually increase the pigmentation of the iris. The pigmentation change is believed to be due to increased melanin content in the melanocytes rather than to an increase in the number of melanocytes. The long term effects of increased pigmentation are not known. Iris color changes seen with administration of unoprostone isopropyl ophthalmic solution may not be noticeable for several months to years. Typically, the brown pigmentation around the pupil spreads concentrically towards the periphery of the iris and the entire iris or parts of the iris become more brownish. Neither nevi nor freckles of the iris appear to be affected by treatment. Treatment with Rescula solution can be continued in patients who develop noticeably increased iris pigmentation. Patients who receive treatment with Rescula should be informed of the possibility of increased pigmentation.

Lid Pigmentation

Unoprostone isopropyl has been reported to cause pigment changes (darkening) to periorbital pigmented tissues and eyelashes. The pigmentation is expected to increase as long as unoprostone isopropyl is administered, but has been reported to be reversible upon discontinuation of unoprostone isopropyl ophthalmic solution in most patients.

Intraocular Inflammation

Rescula should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.

Macular Edema

Macular edema, including cystoid macular edema, has been reported. Rescula should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

Contamination of Tip and Solution

To minimize contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use. There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.

Use with Contact Lenses

Rescula contains benzalkonium chloride, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of solution and may be reinserted 15 minutes following its administration.

ADVERSE REACTIONS

Clinical Studies Experience

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

In clinical studies, the most common ocular adverse reactions with use of Rescula were burning/stinging, burning/stinging upon drug instillation, dry eyes, itching, increased length of eyelashes, and injection. These were reported in approximately 10–25% of patients. Approximately 10–14% of patients were observed to have an increase in the length of eyelashes (≥ 1 mm) at 12 months, while 7% of patients were observed to have a decrease in the length of eyelashes.

Ocular adverse reactions occurring in approximately 5–10% of patients were abnormal vision, eyelid disorder, foreign body sensation, and lacrimation disorder.

Ocular adverse reactions occurring in approximately 1–5% of patients were blepharitis, cataract, conjunctivitis, corneal lesion, discharge from the eye, eye hemorrhage, eye pain, keratitis, irritation, photophobia, and vitreous disorder.

The most frequently reported nonocular adverse reaction associated with the use of Rescula in the clinical trials was flu-like syndrome that was observed in approximately 6% of patients. Nonocular adverse reactions reported in the 1–5% of patients were accidental injury, allergic reaction, back pain, bronchitis, increased cough, diabetes mellitus, dizziness, headache, hypertension, insomnia, pharyngitis, pain, rhinitis, and sinusitis.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Rescula. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish causal relationship to drug exposure.

Voluntary reports of adverse reactions occurring with the use of Rescula include corneal erosion.

There have been rare spontaneous reports with a different formulation of unoprostone isopropyl (0.12%) of chemosis, dry mouth, nausea, vomiting and palpitations.

USE IN SPECIFIC POPULATIONS

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

Pediatric Use - the safety and efficacy of RESCULA in pediatric patients have not been established.

It is not known whether RESCULA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RESCULA is administered to a nursing woman.

No overall differences in safety or effectiveness of RESCULA have been observed between elderly and other adult populations.

CLINICAL PHARMACOLOGY

Mechanism of Action

Rescula is believed to reduce elevated intraocular pressure (IOP) by increasing the outflow of aqueous humor through the trabecular meshwork. Unoprostone isopropyl (UI) may have a local effect on BK (Big Potassium) channels and CIC-2 chloride channels, but the exact mechanism is unknown at this time.

STORAGE AND HANDLING

Store between 2°–25°C (36°–77°F).

For more detailed information please read the Prescribing Information.

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Revised 01/2013

References: 1. RESCULA [package insert]. Bethesda, MD: Sucampo Pharmaceuticals, Inc; 2012. 2. Data on file. CSR C97-UIOS-004. Sucampo Pharmaceuticals, Inc. 3. Data on file. CSR C97-UIOS-005. Sucampo Pharmaceuticals, Inc. 4. Data on file. Integrated summary of clinical safety. Sucampo Pharmaceuticals, Inc. 5. McCarey BE, Kapik BM, Kane FE; Unoprostone Monotherapy Study Group. Low incidence of iris pigmentation and eyelash changes in 2 randomized clinical trials with unoprostone isopropyl 0.15%. *Ophthalmology*. 2004;111(8):1480-1488.

A cloudy view of the future

Species 'evolution' unsettling to restoring vision, faith in humanity



By **Peter J. McDonnell, MD**

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

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SOME DAYS I JUST can't help feeling great about the future, especially the future of medicine. Some scientist—in my department or someplace else—will show me how stem cells made from adult skin fibroblasts can be coached to become a retina, a sheet of retinal pigment epithelial cells, a layer of ganglion cells with axons that look like they're trying to regrow an optic nerve, or some other feat of magic that makes me believe we will soon be restoring vision to those who have become "permanently" blind.

Ophthalmology residents today know so much more about medical science and the diagnosis and treatment of eye disease, and can do so much more than residents did in my day that the difference is almost ridiculous. And people whose vision was routinely wiped out by choroidal neovascularization when I was a young ophthalmologist are now routinely having their vision saved.

It makes me think that there has never been a better time to be alive or to be a physician, and that hard work and scientific discovery are dramatically improving the human condition.

MOVING FORWARD?

And then on other days, like today, I watch videos and read stories on the Internet of people being gunned down in the streets of giant "world-class" cities like Kiev, Caracas, Bangkok, and Aleppo by their fellow citizens. Whatever the facts about who is protesting over what and the political details—of which my knowledge in some of these instances is minimal—I find it so discouraging to see barbaric responses to apparently unarmed protestors.

That this type of thing happens in the year 2014 makes me question whether, in fact, our human species is really advancing.

I know, or have met, ophthalmologists from all of these cities and wonder what it must be like to have to run a practice and take great care of patients amid such turmoil.

▣ From what I read, the economy of Venezuela is in chaos, with rampant inflation, widespread shortages, and escalating crime rates.

▣ In Kiev and Bangkok, there certainly is considerable turmoil and uncertainty about the government.

▣ In Aleppo, an ophthalmologist would literally be operating his or her practice in a war zone.

It must border on heroic, it seems to me, for an ophthalmologist to be able to obtain everything he or she needs and provide the best care for patients in such environments.

Sadly, in such situations, it is probably the poor patients who suffer the most, as their well-educated physicians and other professionals leave their strife-torn lands for more stable and safe environments in which to raise their families.

Far be it for me to blame an ophthalmologist who decides to leave a practice in one of these cities and relocate, but clearly this type of "brain drain" can quickly reverse many years of progress in a country's medical system and society.

So I find myself questioning whether there is an inevitable "march of progress," in which societies progressively improve, people get more access to education, economies strengthen, and the lives we humans lead gradually, but irreversibly, become better.

Is it only a matter of time when we live in a future world in which the work of stem cell biologists will give sight to the blind?

Or can any of our societies and great cities fall back into the kind of chaos we've been seeing lately? ■

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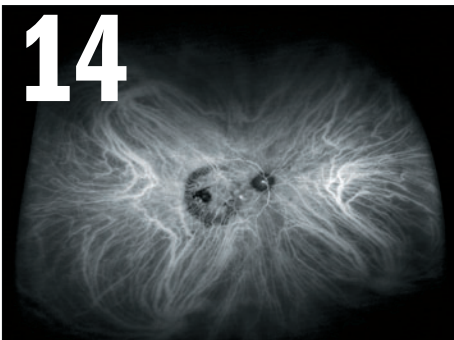
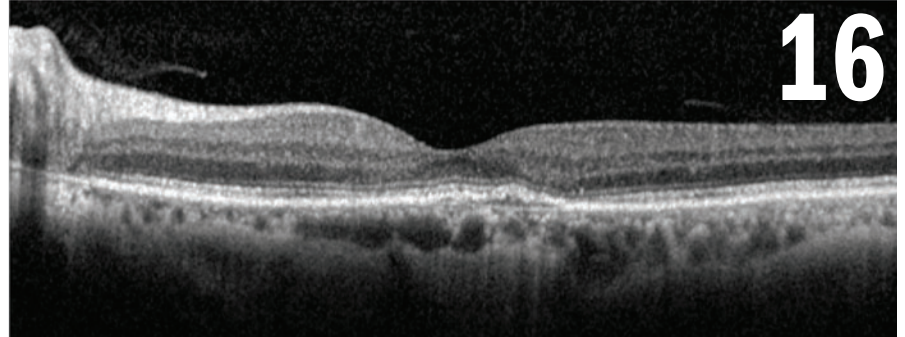
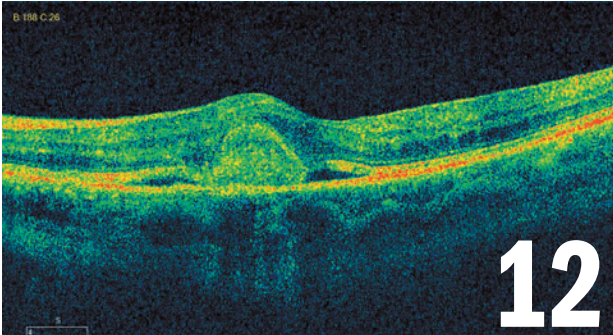
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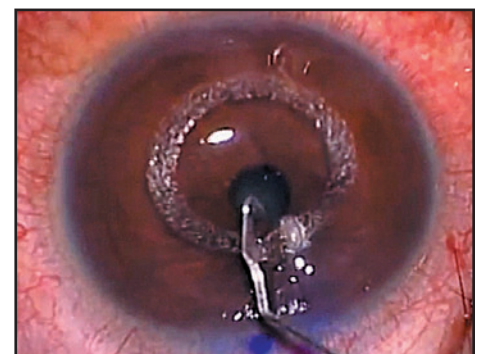


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Video



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**Available in 1.6-mL
and 3-mL bottle sizes**

IMPORTANT RISK INFORMATION ABOUT PROLENSA®

Indications and Usage

PROLENSA® (bromfenac ophthalmic solution) 0.07% is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Dosage and Administration

Instill one drop into the affected eye once daily beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days post surgery.

Please see brief summary of full Prescribing Information on adjacent page.

References: 1. PROLENSA® Prescribing Information, April 2013. 2. Data on file, Bausch & Lomb Incorporated. 3. Baklayan GA, Patterson HM, Song CK, Gow JA, McNamara TR. 24-hour evaluation of the ocular distribution of ¹⁴C-labeled bromfenac following topical instillation into the eyes of New Zealand White rabbits. *J Ocul Pharmacol Ther.* 2008;24(4):392-398. 4. BROMDAY® Prescribing Information, October 2012.

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BAUSCH + LOMB

Warnings and Precautions

- Sulfite allergic reactions
- Slow or delayed healing
- Potential for cross-sensitivity
- Increased bleeding of ocular tissues
- Corneal effects, including keratitis
- Contact lens wear

Adverse Reactions

The most commonly reported adverse reactions in 3%-8% of patients were anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and blurred vision.

PROLENSA®
**(bromfenac ophthalmic
solution) 0.07%**

INDICATIONS AND USAGE

PROLENSA (bromfenac ophthalmic solution) 0.07% is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

DOSAGE AND ADMINISTRATION**Recommended Dosing**

One drop of PROLENSA ophthalmic solution should be applied to the affected eye once daily beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period.

Use with Other Topical Ophthalmic Medications

PROLENSA ophthalmic solution may be administered in conjunction with other topical ophthalmic medications such as alpha-agonists, beta-blockers, carbonic anhydrase inhibitors, cycloplegics, and mydriatics. Drops should be administered at least 5 minutes apart.

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS**Sulfite Allergic Reactions**

Contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Slow or Delayed Healing

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

Potential for Cross-Sensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other NSAIDs, including bromfenac. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

Increased Bleeding Time

With some NSAIDs, including bromfenac, there exists the potential for increased bleeding time due to interference with platelet aggregation. There have been reports that ocularly applied NSAIDs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

It is recommended that PROLENSA ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Keratitis and Corneal Reactions

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs, including bromfenac, and should be closely monitored for corneal health.

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

Post-marketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patient risk for the occurrence and severity of corneal adverse events.

Contact Lens Wear

PROLENSA should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

ADVERSE REACTIONS**Clinical Trial 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 clinical practice.

The most commonly reported adverse reactions following use of PROLENSA following cataract surgery include: anterior chamber inflammation, foreign body sensation, eye pain, photophobia and vision blurred. These reactions were reported in 3 to 8% of patients.

USE IN SPECIFIC POPULATIONS**Pregnancy**

Treatment of rats at oral doses up to 0.9 mg/kg/day (systemic exposure 90 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD]) assuming the human systemic concentration is at

the limit of quantification) and rabbits at oral doses up to 7.5 mg/kg/day (150 times the predicted human systemic exposure) produced no treatment-related malformations in reproduction studies. However, embryo-fetal lethality and maternal toxicity were produced in rats and rabbits at 0.9 mg/kg/day and 7.5 mg/kg/day, respectively. In rats, bromfenac treatment caused delayed parturition at 0.3 mg/kg/day (30 times the predicted human exposure), and caused dystocia, increased neonatal mortality and reduced postnatal growth at 0.9 mg/kg/day.

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

Because of the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal cardiovascular system (closure of ductus arteriosus), the use of PROLENSA ophthalmic solution during late pregnancy should be avoided.

Nursing Mothers

Caution should be exercised when PROLENSA is administered to a nursing woman.

Pediatric Use

Safety and efficacy in pediatric patients below the age of 18 have not been established.

Geriatric Use

There is no evidence that the efficacy or safety profiles for PROLENSA differ in patients 70 years of age and older compared to younger adult patients.

NONCLINICAL TOXICOLOGY**Carcinogenesis, Mutagenesis and Impairment of Fertility**

Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (systemic exposure 30 times the systemic exposure predicted from the recommended human ophthalmic dose [RHOD]) assuming the human systemic concentration is at the limit of quantification) and 5 mg/kg/day (340 times the predicted human systemic exposure), respectively, revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various mutagenicity studies, including the reverse mutation, chromosomal aberration, and micronucleus tests.

Bromfenac did not impair fertility when administered orally to male and female rats at doses up to 0.9 mg/kg/day and 0.3 mg/kg/day, respectively (systemic exposure 90 and 30 times the predicted human exposure, respectively).

PATIENT COUNSELING INFORMATION**Slowed or Delayed Healing**

Advise patients of the possibility that slow or delayed healing may occur while using NSAIDs.

Sterility of Dropper Tip

Advise patients to replace bottle cap after using and to not touch dropper tip to any surface, as this may contaminate the contents. Advise patients that a single bottle of PROLENSA, be used to treat only one eye.

Concomitant Use of Contact Lenses

Advise patients to remove contact lenses prior to instillation of PROLENSA. The preservative in PROLENSA, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of PROLENSA.

Concomitant Topical Ocular Therapy

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

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New surgical options help individualize glaucoma care

Trends may help mitigate risks, provide new therapies for treatment of mild-to-moderate disease

By **Liz Meszaros**; Reviewed by **Thomas W. Samuelson, MD**

TAKE-HOME

► **Recent advances in surgical therapeutic modalities are enabling ophthalmologists to provide individualized care for their patients with glaucoma.**

MINNEAPOLIS ::

Advances in surgical therapeutic modalities for glaucoma are providing surgeons with more options for more individualized treatment, said Thomas W. Samuelson, MD.

Traditionally, glaucoma treatment has included medicine, laser, trabeculectomy, and transscleral procedures, according to Dr. Samuelson, founding partner and attending surgeon of Minnesota Eye Consultants, Minneapolis.



Dr. Samuelson

Yet, this wide spectrum of treatments also involves a wide spectrum of risks, he noted.

“We know well what to do surgically for patients with severe disease,” Dr. Samuelson said. “However, what do [we do] surgically with uncontrolled mild-to-moderate disease?”

“We can watch [patients’ glaucoma] get worse as we add a third and fourth medication,” he said. “We can offer them surgery. But if we do so, we have to take good care to make sure that our surgical risk doesn’t outweigh our disease risk.”

With time and research, newer options are becoming available.

“Finally, we’re seeing investment in surgical glaucoma,” Dr. Samuelson said. “If we’re under-invested in glaucoma, it is not in drug therapy [nor is it] in diagnostics—it is in the surgical therapeutic modalities or neurodegenerative/neuroprotective treatments.”

WEIGHING THE RISKS

Over the years, highly efficacious procedures

for the treatment of glaucoma have been available, according to Dr. Samuelson.

Yet, he said, they may entail significant risk—which leads to a very large safety gap for patients.

That is, there is a huge gap in safety between medicines and lasers on one hand, and trabeculectomy and tubes on the other hand, Dr. Samuelson explained.

“Many would argue that the safety of tubes and ‘trabs’ is far less than desired, but no one would argue their efficacy for the most part,” he said. “What we haven’t had are procedures that err on the side of safety. Tubes and ‘trabs’ are highly efficacious, but they are considerably less than safe.”

For decades, ophthalmology has applied these procedures across this spectrum of glaucoma severity, he continued.

If a patient’s response to medical and laser therapy failed then we tended to advance toward trabeculectomy.

“But the risk of functional impairment among individuals is highly variable,” Dr. Samuelson continued. “There is somewhat of a mismatch. There’s a wide spectrum of risk, but until now we have not had a wide spectrum of procedures.”

With the advent of microinvasive glaucoma surgery (MIGS), these risks are perhaps being mitigated, he noted.

MEGATRENDS IN GLAUCOMA SURGERY

“We’re seeing a lot of discussion about MIGS filling the safety gap between trabeculectomy and medical therapy,” Dr. Samuelson said. “We’re also standardizing filtration surgery even more, and we are trying to individualize care.”

MIGS currently includes a variety of new instruments and techniques that are rapidly evolving in the hands of ophthalmic surgeons.

MIGS devices include:

- **Ex-Press Glaucoma Filtration Device** (Alcon Laboratories)
- **AqueSys Implant (AqueSys)**—not yet

Ophthalmology Times Podcast



Listen to **Thomas W. Samuelson, MD**, present *The David Worthen Memorial Lecture during the Current Concepts in Ophthalmology meeting at The Wilmer Eye Institute/Johns Hopkins University*. Dr. Samuelson’s presentation is entitled “*Individualizing Glaucoma Surgery*.” Go to OphthalmologyTimes.com/individualized

approved in the United States

■ **iStent Trabecular Micro-Bypass Stent** (Glaukos Corp.)

■ **Trabectome** (NeoMedix Corp.).

■ **CyPass Micro-Stent** (Transcend Medical)—not yet approved in the United States

“In glaucoma surgery 2013, we had far more options to offer patients—all with varying degrees of efficacy and risk,” Dr. Samuelson said. “Our goal is to match surgical risks with the risk of the disease. MIGS helps fill that safety gap; it’s not for everyone, but it is for some patients for sure.”

Dr. Samuelson led a prospective randomized clinical trial—the first and most comprehensive PMA, IDE trial for a glaucoma therapeutic device, he noted—in which he and his colleagues compared cataract surgery results alone with results achieved with cataract surgery plus the trabecular micro-bypass stent, a small device placed in Schlemm’s canal.¹

In all, 240 eyes with mild-to-moderate open-angle glaucoma with IOP of ≤ 24 mm Hg controlled on one to three medications were randomly assigned to undergo cataract surgery with implantation of the trabecular micro-bypass stent (treatment group) or cataract surgery only (control group), according to Dr. Samuelson.

Seventy-two percent of treatment eyes versus 50% of control eyes achieved the primary outcome of unmedicated IOP ≤ 21 mm Hg at 1 year ($p < 0.001$).

The secondary outcome measure was un-

Continues on page 10 : **Individualized**

KERATOCONUS

(Continued from page 1)

graft—created by removing the endothelium from the donor cornea—is placed onto the dried recipient bed and fixated with 16 nylon 10-0 interrupted sutures.

The rationale for perforating the periphery of the host stromal bed in LPK is to enable better coaptation of the donor and host edges, he noted.

TAKE-HOME

► **Lamellar-perforating keratoplasty (LPK) is a new excimer laser-assisted transplantation technique developed for eyes with advanced keratoconus.**

The microperforations cause the recipient bed to sink inward toward the anterior chamber and thereby the technique allows the donor tissue to lie deeper in the recipient base.



Dr. Carriazo

“Since the recipient eye has 100 μm of residual stroma, the upper surface of the graft lies slightly above the level

of the host cornea after pachymetry-assisted lamellar keratoplasty,” Dr. Carriazo said. “In eyes with advanced keratoconus, the cornea is thinner in the periphery as well as centrally, so the difference in height between the graft and host is even greater. That discrepancy can lead to high astigmatism.”

The microperforation technique addresses this problem, he said.

LPK OUTCOMES

To demonstrate the outcomes of LPK, Dr. Carriazo reviewed data from a series of 11 eyes. Mean (range) pachymetry was 452.6 (379 to 600) μm preoperatively and 670 (500 to 712) μm at 6 months. Mean cylinder was about -4 D preoperatively and was improved after removal of the stitches to -2 D at 2 years after surgery. Mean spherical equivalent improved from about -5 D preoperatively to about -1 D at 2 years after the surgery.

All eyes achieved improved uncorrected visual acuity and best-corrected visual acuity (BCVA), although haze developing after subsequent refractive surgery limited BCVA gain in 3 eyes. Endothelial cell loss averaged just 11%, Dr. Carriazo noted. ■

CESAR CARRIAZO, MD

E: ccarriazo@carriazo.com

Dr. Carriazo receives royalty fees from Schwind.

Bausch + Lomb unveils reusable injector system

By Rose Schneider

BRIDGEWATER, NJ ::

BAUSCH + LOMB ANNOUNCED the U.S. introduction of a new injector system (Bausch + Lomb Injector System) designed exclusively for use with the glistening-free, hydrophobic acrylic IOL (enVista).

The injector—complete with a reusable hand piece and single-use cartridge—allows surgeons safe, controlled delivery of the IOL through unenlarged phaco incisions as small as 2.2 mm.

“With the addition of (the injector), Bausch + Lomb is proud to provide surgeons with a full system intended specifically for enVista implantation,” said Cal Roberts, MD, chief medical officer, Bausch + Lomb. “This new injec-

tor will help surgeons and their staff provide exceptional IOL technology to their cataract patients, helping them see better to live better.

The injector was developed with the input from surgeons around the world with the ultimate goal of securely and accurately implanting the IOL while minimizing mishandling, loading errors, and damage to the lens.

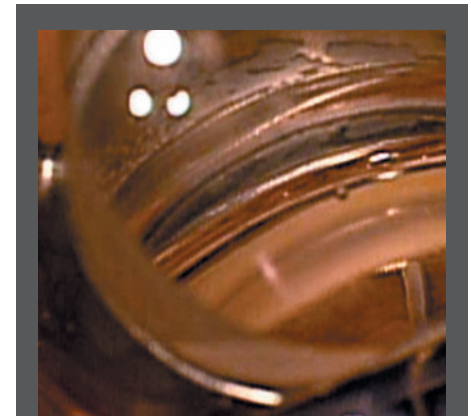
The reusable hand piece is made of high-quality titanium material designed for both reliability and comfort for the surgeon and staff. In addition, the proprietary disposable cartridge is designed for easy lens loading, easy wound entry, and smooth delivery of the IOL. ■

INDIVIDUALIZED

(Continued from page 9)

medicated IOP reduction $\geq 20\%$ at 1 year, and 66% of treatment eyes met this, compared with 48% of control eyes ($p = 0.003$), according to Dr. Samuelson.

However, he stressed, a full 50% of patients who underwent phacoemulsification alone achieved the first outcome measure,



The trabecular micro-bypass stent (iStent, Glaukos) is the first FDA-approved glaucoma device to be placed permanently within the canal via an ab-interno approach. (Image courtesy of Thomas W. Samuelson, MD)

and 48% with phacoemulsification alone achieved the second outcome measure.

“Phacoemulsification significantly lowered pressure in early-to-moderate glaucoma,” he said.

Even so—MIGS, in general, and trabecular micro-bypass stent, in particular—builds on this phacoemulsification platform allowing greater reduction in the need for pressure-lowering medications, he concluded. ■

Reference

- Samuelson TW, Katz LJ, Wells JM, et al. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology*. 2001;118:459-467. Doi:10.1016/j.ophtha.2010.07.007. Epub 2010 Sep 15.

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Dr. Samuelson delivered the David Worthen Memorial Lecture at the annual Current Concepts in Ophthalmology meeting at the Wilmer Eye Institute/Johns Hopkins University. Dr. Samuelson has served as both a consultant and adviser for Advantix, Glaukos Corp., and Optos Surgical.

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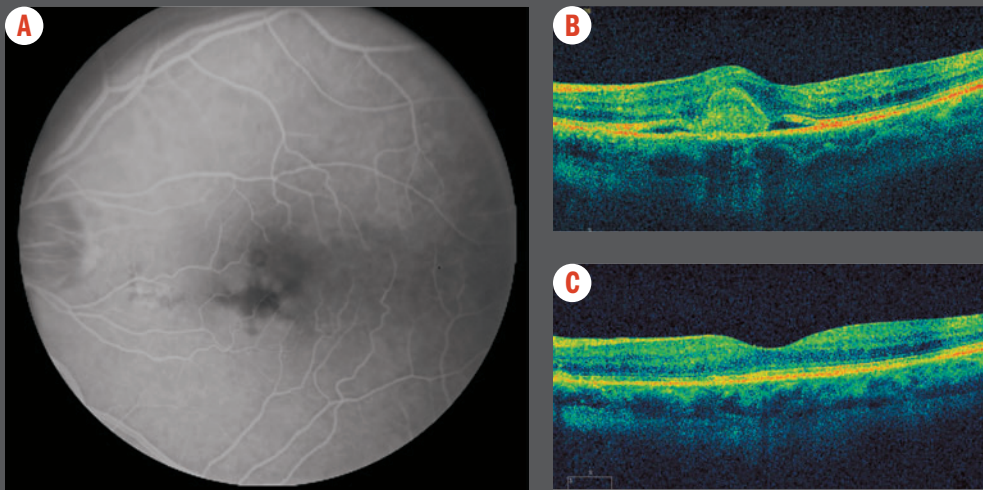
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Study Patient With CNV



These images are from a patient in a clinical trial in which investigators are masked as to whether the patient receives study drug or placebo in combination with ranibizumab (Lucentis, Genentech). Figures **A** and **B**, showing choroidal neovascularization, are pre-treatment. Figure **C** shows regression, with no need for a second ranibizumab injection, 1 month later.

(Images courtesy of Lawrence J. Singerman, MD)

EXPLORING NEW THERAPIES FOR NEOVASCULAR AMD

Researchers look to combination treatment to enhance anti-vascular endothelial growth factor and beyond

By **Liz Meszaros**; Reviewed by Lawrence J. Singerman, MD, FACS

take-home

► Combination treatment for neovascular age-related macular degeneration is more likely to provide more favorable results by eliminating vascular endothelial growth factor and possibly causing true regression of choroidal neovascularization, reducing the risk of visual loss.

CLEVELAND ::

Though anti-vascular endothelial growth factor (VEGF) therapy—currently the primary treatment modality for neovascular age-related macular degeneration (AMD)—has changed the game, ophthalmologists and researchers press on for other possible and even better options.

The treatment of neovascular AMD has evolved through three eras: the thermal laser era, the photodynamic laser era (which was shorter), and now the pharmacologic era, noted Lawrence J. Singerman, MD, FACS, clinical professor of ophthalmology, Case Western Reserve University School of Medicine, Cleveland.

Ophthalmology Times Podcast

Listen to Lawrence J. Singerman, MD, present *The Ronald G. Michels Memorial Lecture* during the Current Concepts in Ophthalmology meeting at the Wilmer Eye Institute/Johns Hopkins University. Dr. Singerman's presentation is entitled "Perspectives in the Management of Macular Degeneration." Go to OphthalmologyTimes.com/neovascular

"But don't throw away your thermal laser," added Dr. Singerman, also professor of clinical ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine.

"I have many patients [whom] I treated with one thermal laser treatment very close to the fovea even decades ago, and they still have decent vision and don't need monthly anti-VEGF injections," he said. "Many patients will go many years without the need for further treatment after well-applied thermal laser for extrafoveal choroidal neovascularization (CNV)."

A combination of thermal laser with anti-VEGF therapy can work if there is a broad area of CNV, he continued.

"If you are treating with anti-VEGF therapy, you could treat the extrafoveal area with thermal laser and cut down on the number of injections you will have to give the patient over the next year or two," Dr. Singerman said.

"You will need fluorescein angiography to follow these cases, so don't throw that away either," he added. "It's not all OCT."



Dr. Singerman

WHY COMBINATION THERAPY?

Combination treatment is more likely to provide more favorable results by eliminating VEGF and possibly causing true regression of CNV, reducing risk of visual loss. The approach may also reduce the number of injections needed, thereby reducing the rate of complications.

"Finally, combined treatment may reduce the overall cost of treatment due to a reduction in the number of injections necessary for successful outcomes," he said.

Currently, monotherapy anti-VEGF therapy is the mainstay in the treatment of neovascular macular degeneration and has changed the game for ophthalmologists, Dr. Singerman said.

This therapy has its limitations, however, he noted. The majority of patients do not achieve significant visual gain or final visual acuity of 20/40 or better. Up to 25% to 30% of patients actually lose vision.

Along with anti-VEGF agents, numerous other agents are being studied, including:

Special Report) CONTEMPORARY CLINICAL & THERAPEUTIC ANALYSIS OF **RETINAL DISEASES**

■ **E10030** (Fovista, Ophthotech) is an anti-PDGF drug, which—according to a recent phase IIb study, when given with ranibizumab (Lucentis, Genentech)—confers a 62% comparative benefit over ranibizumab alone. A phase III study is currently under way.

■ **SQUALAMINE** (Ohr Pharmaceutical) is an eye drop that inhibits VEGF, platelet-derived growth factor, and basic fibroblast growth factor using a novel anti-angiogenic mechanism and may reduce the number of intravitreal anti-VEGF injections needed. Squalamine was awarded FDA fast-track designation for wet AMD in May 2012. A phase II study is now under way, comparing placebo with squalamine drops.

■ **ACU-4429** (Acucela) is a visual cycle modulator taken orally and is being evaluated for treatment of geographic atrophy (GA). This agent is designed to be selective for rod photoreceptors and has demonstrated efficacy in multiple pre-

OT OphthalmologyTimes.com *ONLINE EXCLUSIVE*

EXPERTS WEIGH IN ON WET AMD TREATMENT OPTIONS

AT PRESENT, three anti-vascular endothelial growth factor agents are commercially available with an indication for treatment of neovascular age-related macular degeneration, and a fourth option is widely used off-label. Four ophthalmologists share clinical perspectives for why they each consider a particular agent to be the best. Go to <http://bit.ly/1gFo06X>

clinical models. A phase IIa study has demonstrated its safety and tolerability and confirmed its biological activity, and a phase IIb/III study is under way.

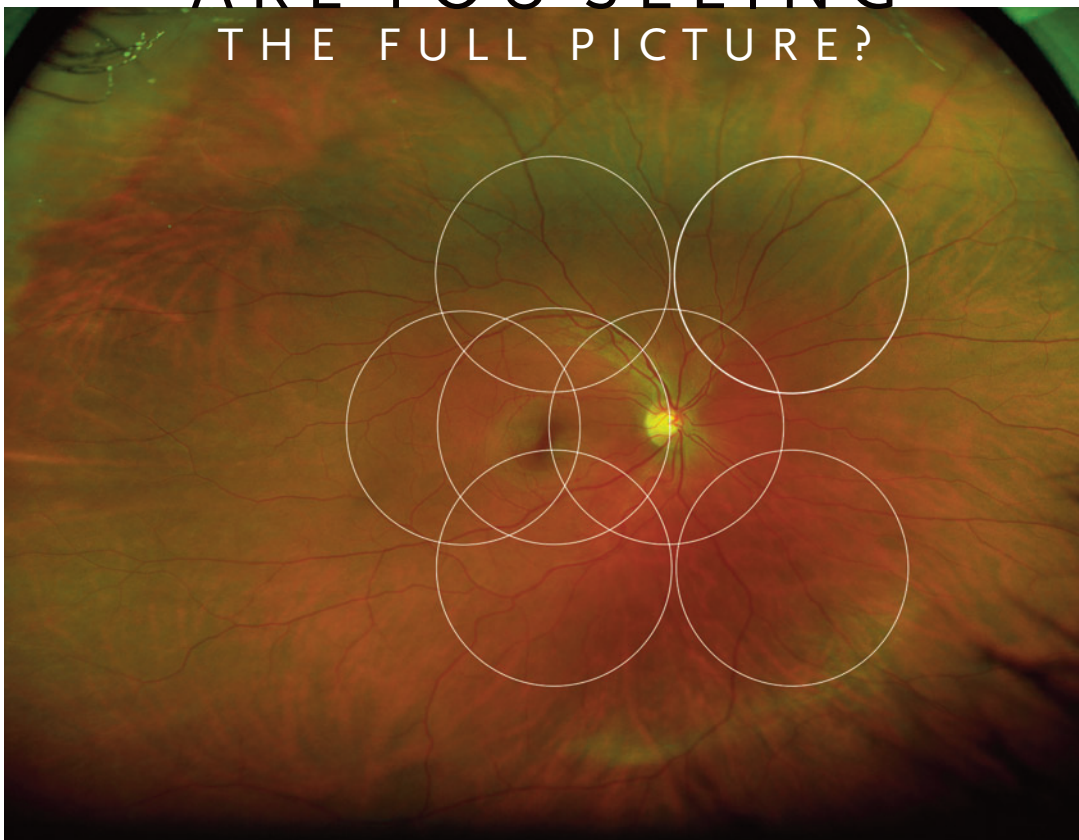
■ **LFG316** (Novartis) is a complement inhibitor against C5, administered intravitreally. A phase II study is currently under way for treatment of GA.

■ **ANTI-FACTOR D** (Genentech) is a promising treatment for GA and is the first study to show a beneficial treatment effect with a com-

plement inhibitor. The phase II study showed that the drug reduced the rate of disease progression, with a greater reduction in progression rate in subjects with a specific biomarker. ■

LAWRENCE J. SINGERMAN, MD
 P: 216/831-5700 E: retina@retina-assoc.com
 Dr. Singerman delivered the Ronald G. Michels Memorial Lecture at the annual Current Concepts in Ophthalmology meeting at the Wilmer Eye Institute/Johns Hopkins University. He discloses research support and/or serves on the advisory boards with Acucela, Alcon Laboratories, ArcticDx, Genentech, National Eye Institute, Ophthotech, Novartis, Ohr Pharmaceutical, and Valeant Pharmaceuticals.

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1 Kiss et al. Comparison of ultra-widefield fluorescein angiography with the Heidelberg Spectralis® noncontact ultra-widefield module versus the Optos® optomap. Clin Ophthalmol. 2013; 389-94. 2, 3 Data on file

Future of retinal imaging advancing on multiple fronts in ophthalmology

Swept-source OCT, OCT angiography, wide-field angiography currently or soon to be in use

By Cheryl Guttman Krader; Reviewed by Srinivas R. Sadda, MD

LOS ANGELES ::

RETINAL IMAGING HAS entered a golden era in which a number of new techniques and technologies have recently become commercially available or are around the corner, said Srinivas R. Sadda, MD.



Dr. Sadda

“We have seen rapid advances in retinal imaging over the past decade that have dramatically transformed our practices, and we can expect the pace of these advances to accelerate over the next decade,” said Dr. Sadda, professor of ophthalmology,

University of Southern California, and director, Doheny Image Reading Center, Doheny Eye Institute, Los Angeles.

“I feel it is an exciting time to be an ophthalmologist, and I hope others share this excitement,” he said.

Noting that the number of developments makes it impossible to discuss them all, Dr. Sadda chose to focus on swept-source optical coherence tomography (OCT), OCT angiography, and wide-field angiography as techniques that are currently, or soon to be, in use.

PHOTOACOUSTIC IMAGING

Dr. Sadda began by highlighting photoacoustic imaging as an example of very novel technology.

Unlike other imaging technologies that identify differences in light reflection by ocular tissues, photoacoustic imaging is based on differences in light absorption. Light absorption leads to tissue heating, resulting in tissue expansion and the creation of pressure waves that are detected with a transducer to allow imaging.

“Photoacoustic imaging is great for studying tissues containing chromophores that absorb light, like the retinal blood vessels and the retinal pigment epithelium (RPE),” Dr. Sadda said. “It allows the blood vessels to be seen in brilliant detail and the RPE mosaic to be visualized as well when coupled with adaptive

optics. It is hoped that in the future it will be very useful for evaluating RPE function.”

SWEPT-SOURCE OCT

The latest generation of commercially available Fourier-domain OCT technology includes swept-source OCT platforms. Advantages of swept-source OCT include faster speed and better sensitivity, particularly in the evenness of the sensitivity as one moves away from the zero-delay line (typically at the top of the image).

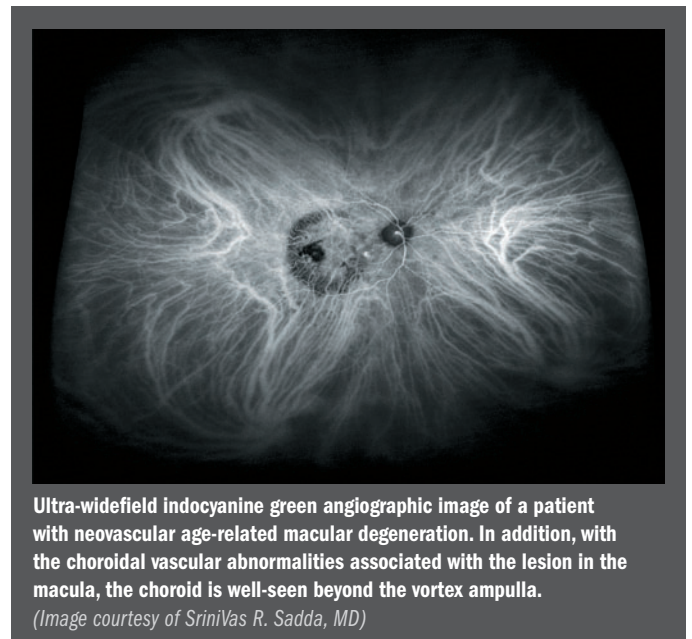
The high speed of swept-source OCT minimizes concerns with fixation and more importantly enables wider-angle imaging and averaging of these larger areas with high resolution.

“Some research instruments are capable of megahertz scanning, which offers the possibility to generate images with 4-megapixel resolution and at whatever depth or plane that we want,” Dr. Sadda said. “With swept-source OCT, we can get very dense volume scans that yield images resembling those of fundus photographs, but with the advantage of being depth resolved.”

The reduced sensitivity loss with greater depth is allowing imaging of the outer retina in greater detail. Some research instruments allow visualization of the photoreceptor outer segment mosaic even without adaptive optics, Dr. Sadda noted.

Since the swept-source OCT devices operate at a longer wavelength than earlier-generation OCT systems,

they also have the ability to penetrate into deeper ocular structures, which may obviate the need for other enhanced depth imaging strategies.



Ultra-widefield indocyanine green angiographic image of a patient with neovascular age-related macular degeneration. In addition, with the choroidal vascular abnormalities associated with the lesion in the macula, the choroid is well-seen beyond the vortex ampulla. (Image courtesy of Srinivas R. Sadda, MD)

“I can foresee many advantages for using this type of an approach for studies of the choroid,” Dr. Sadda said. “The great thing is that with swept-source OCT, we are able to image the vitreous and the choroid simultaneously with the same level of detail.”

He added that glaucoma specialists are excited about using this technology for optic nerve head imaging where it can be used to see details of the lamina cribrosa.

OCT angiography is already available for studying the retinal and choroidal microvasculature and is being developed using different strategies, including a phase-contrast approach and a split-spectrum amplitude decorrelation technique.

Wide-field imaging strategies are expanding to indocyanine green angiography and OCT. The latter provides a high-resolution, large view of the retina with a non-contact exam. ■

take-home

► Retinal imaging is rapidly advancing with the introduction of novel technologies and new imaging techniques.

SRINIVAS R. SADDA, MD

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Dr. Sadda is a consultant to and receives research support from Carl Zeiss Meditec and Optos.

How cost utility justifies surgery for repair of retinal detachment

Parameter serves as measure of cost effectiveness, options for surgically based treatment

By **Liz Meszaros**; Reviewed by **William E. Smiddy, MD**

MIAMI ::

REPAIR OF RETINAL detachment is valuable and cost effective, particularly when compared with other ophthalmologic (especially injection-based) and non-ophthalmologic treatments, according to William E. Smiddy, MD.

“Health-care costs have been increasingly scrutinized—especially by the non-providers and the non-receivers of health care,” said Dr. Smiddy, professor of ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami.

“All too often, the newer treatments are quick to be incorporated into the mainstream without any really good standardization for what this really is costing,” Dr. Smiddy said.

Though pharmacologic-based treatments have revolutionized the ability to help patients with a wider array of disease processes, they are expensive compared with surgical costs, he noted.

“I have a real fear that the expense of these newer treatments may not be as valuable and may run the risk of crowding out some of the things we have that are very effective,” Dr. Smiddy said.

“We can be confident, and probably should be better at articulating the cost effectiveness of surgically based treatments, especially in the repair of retinal detachments,” he said. “We need to make this point by speaking the language of the health-care-policy makers.”

COST UTILITY

Cost utility is perhaps the most crucial parameter, Dr. Smiddy continued.

The most useful measurement tool is the time trade-off (TTO) method, for which patients must answer how much of their remaining life expectancy would they be willing to trade for the correction of a medical illness. TTO measurements allows for comparisons across a range of medical conditions.

For example, a person with a low CD4 count

with AIDS might be willing to give up about 21% of his or her expected life to be cured, he noted. Someone with severe angina might be willing to give up 17% or almost half of his or her life so as not to be afflicted with angina.¹

“We can apply this to ophthalmology, and find that for every given line of visual loss, we can calculate a certain utility,” Dr. Smiddy said. “This comes out to a 0.03 or 3% of [a patient’s] life for each additional line of vision [that one] may be able to obtain.”

take-home

► **Repair of retinal detachment is cost effective, especially when compared with injection-based treatments.**

MEASURING COSTS

Treatment options for retinal detachment include pneumatic retinopexy, scleral buckling, vitrectomy, and a combined pars plana vitrectomy/scleral buckle procedure. These are all relatively highly successful treatments for this potentially blinding condition, Dr. Smiddy noted.

He, along with Jonathan Chang, MD, developed a Markov model of primary retinal detachment repair that included surgical fees, ambulatory surgery center/hospital costs, the cost of cataract extraction, anesthesia costs, and outpatient exam fees for 1 year of care.

“Retinal detachment surgery compares very favorably with other surgical treatments, and is almost as cost effective as panretinal photo-

Ophthalmology Times Podcast

Listen to William E. Smiddy, MD, present *The Joseph Smiddy Memorial Lecture during the Current Concepts in Ophthalmology meeting at the Wilmer Eye Institute/Johns Hopkins University*. Peter J. McDonnell, MD, chairman of the Wilmer Eye Institute, introduced Dr. Smiddy, whose talk was entitled, “Cost Utility of Retinal Detachment Repair.” Go to OphthalmologyTimes.com/retinalrepair

coagulation for preventing visual loss due to proliferative diabetic retinopathy,” he said. “Similarly, these numbers are very much less than injection-based numbers for certain agents.

“When we have similar costs for the same result, we can feel completely justified in trying to tailor the treatment to the patient and the situation,” Dr. Smiddy concluded. “Either way, although treatment of choice is not a slam dunk, all options are very cost effective.” ■

Reference

1. Brown MM, Brown GC, Sharma S, Landy J. Health care economic analyses and value-based medicine. *Survey of Ophthalmol.* 2003;48:204-223.

WILLIAM E. SMIDDY, MD

P: 305/243-4000

Dr. Smiddy delivered the Joseph Smiddy Memorial Lecture at the annual Current Concepts in Ophthalmology meeting at the Wilmer Eye Institute/Johns Hopkins University.

Dr. Smiddy is an attendee of the Alimera Sciences steering committee.

Voyant and Allergan sign R&D agreement

SALT LAKE CITY ::

THE JOHN A. MORAN EYE CENTER at the University of Utah announced that Voyant Biotherapeutics—a company formed out of its Center for Translational Medicine—has signed an exclusive research and development

collaboration agreement with Allergan. The two companies will work together to identify disease-associated pathways and targets for the development of new therapeutic agents to treat ocular disease, primarily for age-related macular degeneration. ■

Laser therapy a novel approach to treating patients with DME, CSR

Technique uses photothermal stimulation along with algorithm for management of endpoint

By **Daniel Lavinsky, MD**, Special to Ophthalmology Times

PORTO ALEGRE, BRAZIL ::

A NOVEL APPROACH to laser therapy of the macula allows for precise control of low-level laser dosages at short durations. The technique works by first titrating to a barely visible level, and then by allowing clinicians to select the percentage of energy delivered to the eye below that level—enabling less-damaging laser treatments.

Use of such photothermal stimulation with an algorithm (PASCAL Streamline Laser System with Endpoint Management, Topcon Medical Laser Systems) has proven to be extremely effective in treating patients with diabetic macular edema (DME) and central serous chorioretinopathy (CSR). The endpoint software uses a computational algorithm to determine laser parameters for retinal heating and maximize the margins between visible and subvisible endpoints, while providing linear control over a non-linear process.

PATIENT POPULATION

My colleagues and I have treated about 58 patients with DME and CSR using the laser therapy and algorithm.

In our practice in Porto Alegre, Brazil, there is a high population of patients with DME.

However, our insurance companies do not cover the expense of ranibizumab (Lucentis, Genentech), and many patients cannot afford anti-vascular endothelial growth factor (VEGF) treatments. Therefore, we tend to treat with laser often.

We also believe in combining either photothermal stimulation or photocoagulation with anti-VEGF therapy.

In patients with DME, preliminary data show a decrease in central macular thickness, and most importantly, an increase in letters in vision in patients who have undergone photothermal stimulation.

CSR is a disease that can be very difficult

to treat. Usually, acute CSR will resolve itself. If it does not resolve in 4 to 6 months, however, it is considered to be chronic with limited treatment options.

Some clinicians use photodynamic therapy with verteporfin (Visudyne, Valeant Ophthalmics), which—along with being expensive—has many side effects.

Photothermal stimulation with algorithm has proven to be an effective treatment for patients with CSR.

TREATMENT PROTOCOL

When treating patients with CSR, first differentiate between acute and chronic CSR.

I treat with laser therapy 3 to 4 months after symptoms appear and use optical coherence tomography (OCT) to confirm the presence of fluid. If symptoms have existed for more than 4 months, I move directly to photothermal stimulation.

Areas of leakage or areas of retinal fluid are treated with an almost confluent grid of 200 μ m burns per spot and endpoint setting of 30% energy from titration burn.

The titration burn at 100% energy is extremely important if it is necessary for surgeons to titrate outside the central area; it is enough to create the first barely visible burn at 3 seconds

and then it will be used to reduce the energy.

From there, I change the energy to my desired level.

When treating patients with DME, the process is more complicated, because the disease is more chronic. I prefer to use combination therapy with anti-VEGF treatment.

If a patient has very light DME to very light edema, I use only a laser with algorithm at 30%.

If a patient has a denser edema and thicker retina, I use anti-VEGF and then combine

take-home

► An ophthalmologist with a practice in Brazil explains how using photothermal stimulation with an algorithm is an effective treatment for his patients with diabetic macular edema and central serous chorioretinopathy.

PATIENTS WITH DME, CSR

Endpoint management
 •200 μ m spot size
 •Area Centroid lens
 •1200mW for 100%
 •30%
 •0.25 spot distance
 •Landmarks on
 •200 burns

VIDEO To view more on using photothermal stimulation for patients with diabetic macular edema and central serous chorioretinopathy, go to <http://bit.ly/MYfh2f> and <http://bit.ly/Nud7XV>.
 (Videos courtesy of Daniel Lavinsky, MD)

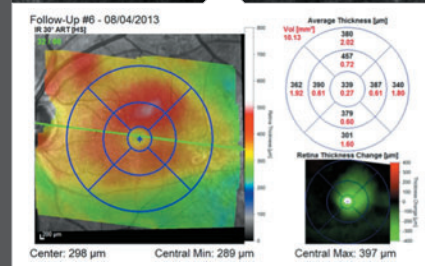
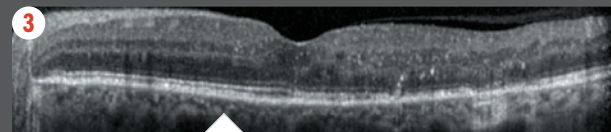
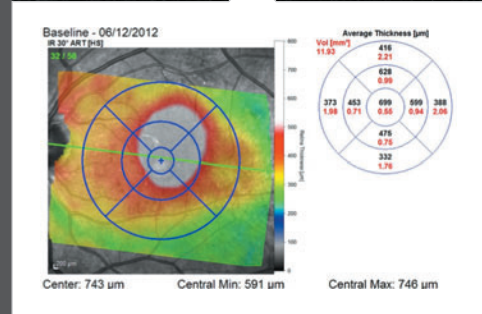
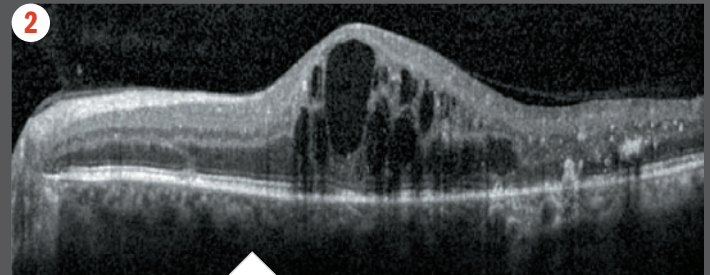
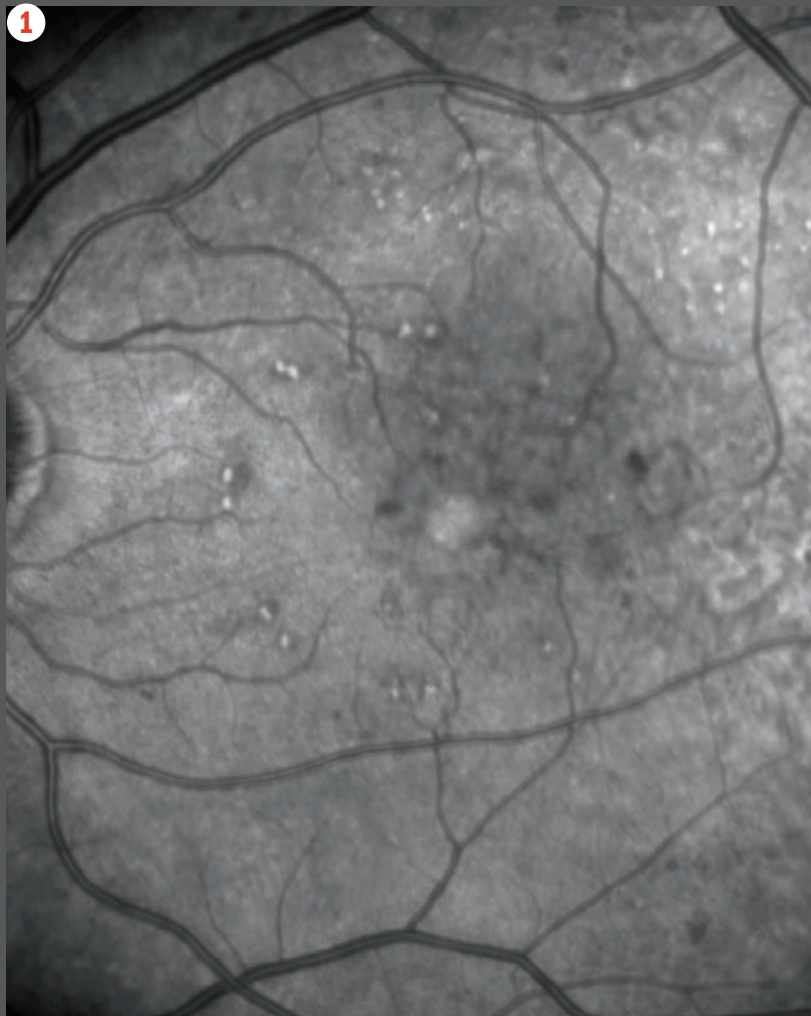
the endpoint software with 30% photothermal stimulation. This way, I can decrease the number of treatments and the number of injections.

If a patient has moderate or mild DME, I start with laser and do not use injections.

If the patient has severe edema, I start with injections, followed by photothermal stimulation.

My goal is to decrease the number of injections.

Special Report) CONTEMPORARY CLINICAL & THERAPEUTIC ANALYSIS OF **RETINAL DISEASES**



1 Infrared autofluorescence imaging for a 54-year-old white male patient with bilateral, severe diabetic macular edema. The landmark provides physicians with reference markers set by visible titration on the outer edges of the patterns used for treatment.

2 Preoperative images in the same patient, where his vision was 20/80.

3 The patient's vision continued to improve through his 6-month postoperative visit, where it was 20/25. (Images courtesy of Daniel Lavinsky, MD)

DME PATIENT CASE

A 54-year-old white male had been suffering from bilateral, severe DME for 15 years. He could not afford anti-VEGF treatments, because his insurance did not cover the cost.

He was treated first with conventional photocoagulation with no success. We then treated using photothermal stimulation and the algorithm with landmarks turned “on”—landmarks provide reference markers set by visible titration on the outer edges of the patterns used for treatment—and 760 burn spots.

The landmarks caused damage to the retinal pigment epithelium (RPE), and after 1

to 2 months we were able to see in vivo that the laser burn restored, so there was a healing process for photocoagulation.

Even with the landmarks—which are photocoagulation burns—they will heal.

We will only see the spots in infrared autofluorescence imaging, because of the RPE proliferation of the damage that we caused. (Figure 1)

The patient's vision continued to improve preoperatively through his 6-month postoperative visit to 20/25. (Figures 2 and 3)

The landmarks are important for physicians who want to determine if a patient was

treated with laser, and the burns do not affect results.

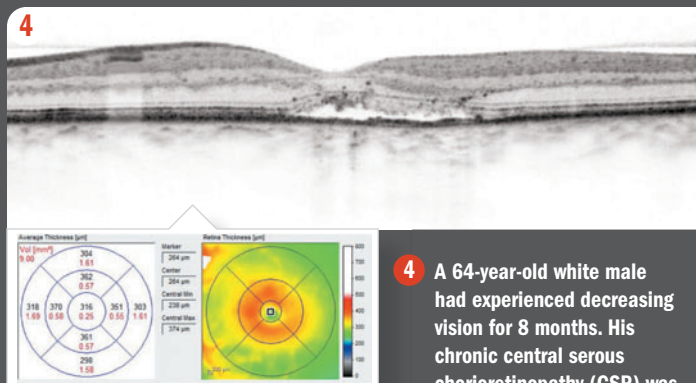
CSR CASE STUDIES

In one case, a 64-year-old white male had experienced decreasing vision for 8 months. His chronic CSR was diagnosed with 20/60 visual acuity and a point of leakage very close to fovea revealing a retinal detachment. (Figure 4)

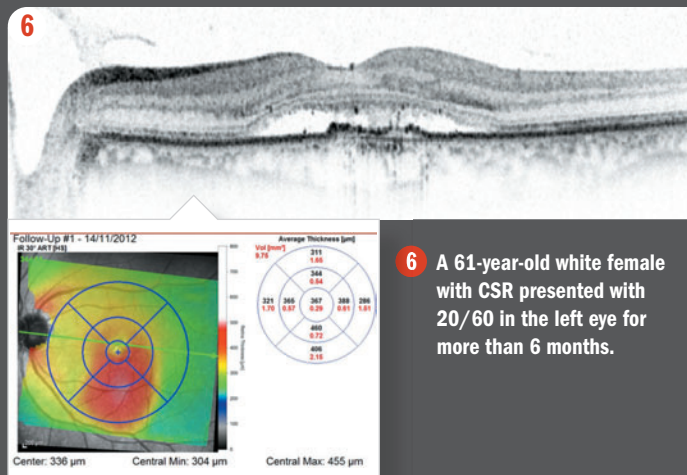
The patient was treated using photothermal stimulation with algorithm. We used a 200-µm spot size and 110 mW of power for

Continues on page 18 : Photothermal

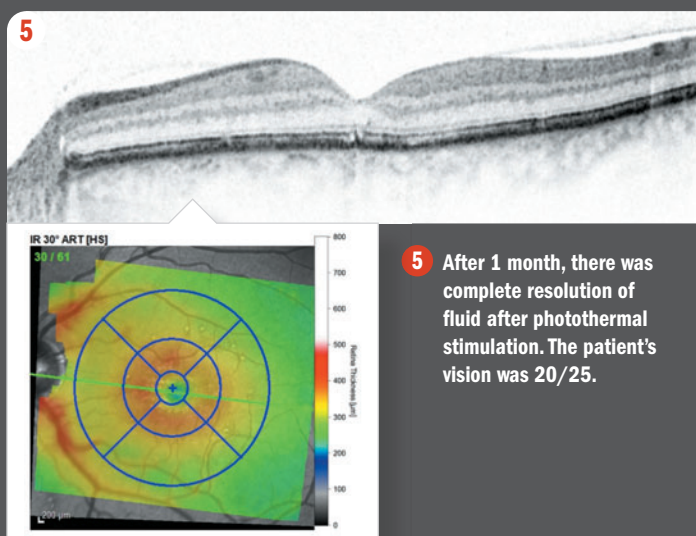
Special Report) CONTEMPORARY CLINICAL & THERAPEUTIC ANALYSIS OF **RETINAL DISEASES**



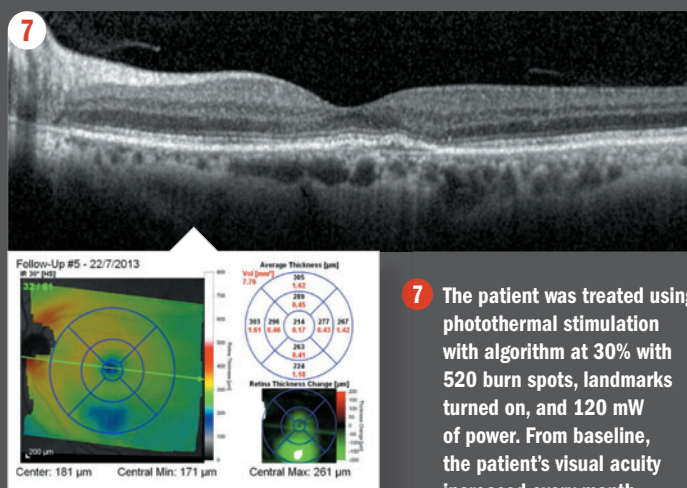
4 A 64-year-old white male had experienced decreasing vision for 8 months. His chronic central serous chorioretinopathy (CSR) was diagnosed with 20/60 visual acuity and a point of leakage very close to fovea revealing a retinal detachment.



6 A 61-year-old white female with CSR presented with 20/60 in the left eye for more than 6 months.



5 After 1 month, there was complete resolution of fluid after photothermal stimulation. The patient's vision was 20/25.



7 The patient was treated using photothermal stimulation with algorithm at 30% with 520 burn spots, landmarks turned on, and 120 mW of power. From baseline, the patient's visual acuity increased every month postoperatively for 4 months.

(Images courtesy of Daniel Lavinsky, MD)

PHOTOTHERMAL

(Continued from page 17)

a 100% (titration) burn, which served as a landmark. Using the landmarks in the patient's retinas, we knew that we treated from the landmark to the fovea almost confluent using 0.25 spacing.

We then treated with photothermal stimulation with algorithm at a 30% setting, and landmarks set "on" with 538 burns because of the patient's chronic case. We used autofluorescence as a method of imaging to show lipofuscin of the RPE, so if we damaged the RPE cell, the barely visible burns will let us see hyper-autofluorescence burns.

We could not see any hypo- or hyperautofluorescent burns when using 30% photothermal stimulation with algorithm.

After 1 month, there was complete resolution of fluid after photothermal stimulation. (Figure 5)

In another case, a 61-year-old white female presented with 20/60 in the left eye for more than 6 months. (Figure 6)

She reported a very strange symptom of seeing "butterflies," caused by fluid in her eye. She had chronic CSR.

The patient was treated using photothermal stimulation with algorithm at 30% with 520 burn spots, landmarks turned on, and 120 mW of power. From baseline, the patient's visual acuity increased every month postoperatively for 4 months. (Figure 7)

The patient's CSR completely resolved. She ended up with 20/20 and reported never seeing the butterflies again.

CONCLUSION

In the clinic, photothermal stimulation with

an algorithm is a fast, accurate therapy for patients with CSR and DME.

The key tangible benefit of utilizing software for advanced algorithms during laser treatment is the ability to titrate for visible burn and decrease the energy endpoint to a subvisible level.

Eye-care specialists can now treat based on the endpoint of a treatment and create a burn pattern that is visible on angiography, OCT, or completely subvisible by any clinical imaging modality with photothermal stimulation capability. ■



DANIEL LAVINSKY, MD, is professor of ophthalmology, Federal University of Rio Grande do Sul, Porto Alegre, Brazil. Dr. Lavinsky is a consultant to Topcon Medical Laser Systems. Readers may contact him at daniellavinsky@gmail.com.

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Appropriate case selection maximizes success with ocriplasmin treatment

Clinical care guided by knowing who responds best and that not all patients respond

By Cheryl Guttman Krader; Reviewed by Peter Stalmans, MD, PhD

LEUVEN, BELGIUM ::

FINDINGS FROM THE phase III clinical trials investigating ocriplasmin (Jetrea, ThromboGenics) for the treatment of symptomatic vitreomacular adhesion—vitreomacular traction (VMT) with or without macular hole—together with understanding of the natural history of the condition provides guidance for optimizing patient outcomes in clinical practice, according to Peter Stalmans, MD, PhD.



Dr. Stalmans

“My recommendation is to treat immediately after the diagnosis is made, especially in VMT patients with a macular hole,” said Dr. Stalmans, of the Department of Ophthalmology, University Hospitals Leuven, Belgium.

CHOOSING CASES FOR SUCCESS

Results of the pivotal Microplasmin for IntraVitreous Injection-Traction Release without Surgical Treatment (MIVI-TRUST) trials showed that size of the vitreomacular traction insertion, macular hole aperture, and presence of an epiretinal membrane (ERM) were factors for predicting outcome. Since patients in Belgium currently must pay out-of-pocket for ocriplasmin treatment, Dr. Stalmans said he uses this information as a guide to identifying cases that are most likely to achieve success.

His criteria are contact area between the posterior hyaloid and retina $<1,500 \mu\text{m}$, macular hole aperture $\leq 250 \mu\text{m}$, and absence of a concomitant ERM.

“My commercial experience with ocriplasmin injection between the end of June 2013 and January 2014 includes 35 eyes,” Dr. Stalmans said.

Using these parameters for case selection, VMT release was achieved in 75% eyes with VMT only and in 80% of VMT with macular hole, with subsequent macular hole closure in 55%. In MIVI-TRUST, where about 37% of eyes had a concomitant epiretinal membrane, the VMT release rate was just 26%, he noted.

SCHEDULING SECONDARY SURGERY

In the MIVI-TRUST trials, the first follow-up optical coherence tomography (OCT) was performed at 1 week post-injection and was done using time-domain technology.

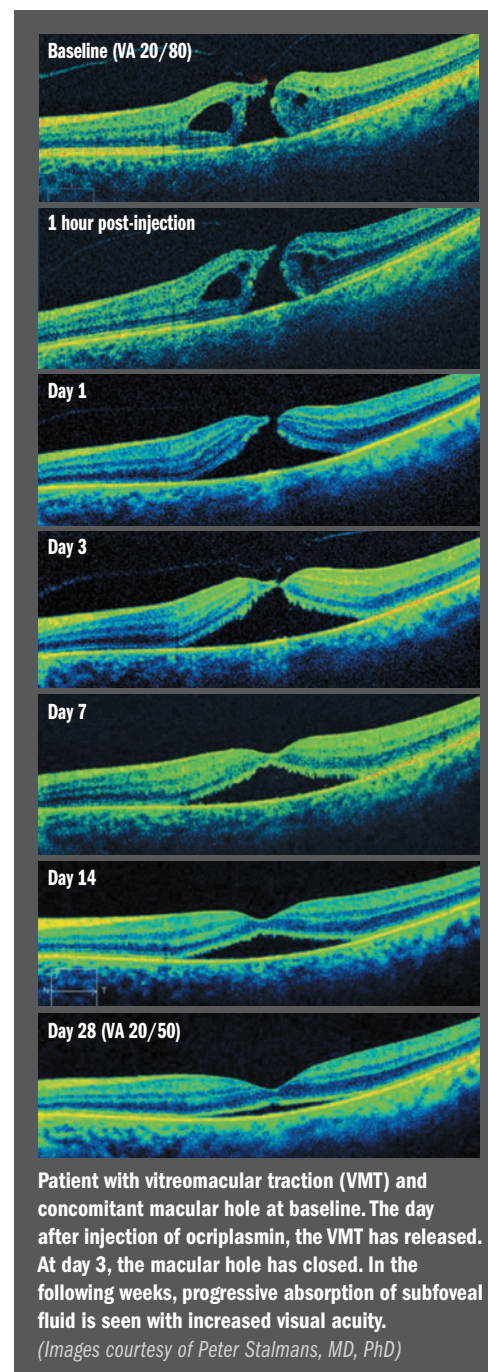
In clinical practice, Dr. Stalmans has been obtaining spectral-domain OCT images and at earlier intervals. With the additional information from the more intensive follow-up and higher resolution images, he has determined that 80% of eyes show a treatment benefit within 24 to 48 hours after injection. In most others, the effect may not be seen for 1 to 2 weeks.

However, based on MIVI-TRUST, it is clear that if ocriplasmin is effective, the benefit will be seen within 4 weeks.

Knowing this time course of response and that time is of the essence for optimizing visual recovery in patients with a macular hole, Dr. Stalmans said that he simultaneously offers these patients ocriplasmin and recommends scheduling a date for surgery in 6 to 8 weeks.

“We explain to the patient that we will wait up to 1 month to determine if there is benefit from the ocriplasmin,” he said. “If the ocriplasmin does not work, there is not a significant delay before proceeding with surgery.

“And when it does, being able to cancel the surgery is a real psychological victory for the patient,” he added.



Patient with vitreomacular traction (VMT) and concomitant macular hole at baseline. The day after injection of ocriplasmin, the VMT has released. At day 3, the macular hole has closed. In the following weeks, progressive absorption of subfoveal fluid is seen with increased visual acuity. (Images courtesy of Peter Stalmans, MD, PhD)

OT OphthalmologyTimes.com
Online Exclusive

A LOOK AT OCRIPLASMIN IN EXUDATIVE AMD

OCRIPLASMIN ACHIEVED complete resolution of vitreomacular adhesion (VMA) in more study patients with VMA and exudative age-related macular degeneration compared with patients in a sham group. For more about the study, go to <http://bit.ly/1fxfQAn>

Though there is less concern about the timeliness of surgery in eyes with VMT and no macular hole, Dr. Stalmans noted he might
Continues on page 22 : **VMT patients**

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Aflibercept acuity gains rival laser for BRVO

Monthly injections yielded superior vision increases, marked retinal thickness decreases

By **Lynda Charters**; Reviewed by *W. Lloyd Clark, MD*

COLUMBIA, SC ::

MONTHLY INTRAVITREAL INJECTIONS of aflibercept (Eylea, Regeneron Pharmaceuticals) achieved superior gains in visual acuity and significant decreases in macular edema in patients with branch retinal vein occlusion (BRVO). The drug was also well tolerated.

Primary results of the VIBRANT Study—a phase III, multicenter, double-masked clinical trial of aflibercept for BRVO—were highlighted by W. Lloyd Clark, MD. The study included 183 patients who were randomly assigned to monthly aflibercept (n = 91) or laser at baseline (n = 92).

The primary endpoint was the percentage of patients who gained 3 lines (15 letters or more) of visual acuity.

Secondary endpoints were the mean changes in best-corrected visual acuity (BCVA) and central retinal thickness (CRT) measured on optical coherence tomography (OCT) images and the mean change in the National Eye Institute Visual Function Questionnaire-25 (VFQ-25) total score—all of which were assessed at week 24 of the study.

Patients continued in the study until week 52. However, the trial is ongoing, according to Dr. Clark, assistant clinical professor of ophthalmology, University of South Carolina School of Medicine, Columbia, SC, and in private practice, West Columbia, SC.

All patients were treatment-naïve and had center-involved macular edema and visual acuity levels between 20/40 and 20/320. The treatment groups were well balanced at the start of the study.

More than 90% of patients completed the week 24 evaluation.

The mean number of injections in the aflibercept group was 5.7 of a possible 6 injections. In the laser group, all patients were treated with laser at baseline and could receive additional laser at month 3 if needed. Most patients received the maximal laser treatment.

At week 24, 53% of eyes in the aflibercept group gained 15 or more letters of vision compared with 27% of eyes in the laser group ($p < 0.001$), Dr. Clark noted. Eyes treated with aflibercept gained 17 letters of BCVA at week 24 compared with 6.9 letters in the laser group ($p < 0.0001$). There was a “rapid and persistent” decrease ($-280.5 \mu\text{m}$) in the CRT seen on OCT images, while the decrease in the laser group was more moderate ($-128.8 \mu\text{m}$) ($p < 0.0001$), he said.

QUALITY-OF-LIFE SCORES

Both treatment groups also had an improvement in the quality of life measured on the VFQ-25. The mean total score in the aflibercept group was 7.7 and that in the laser group 6.3—a difference that did not reach significance.

The implications of the quality-of-life results are unclear, because 98% of patients had a better eye upon study enrollment, according to Dr. Clark.

The aflibercept group had more ocular adverse events compared with the laser group, which were associated with the injection process. Conjunctival hemorrhages were by far the most common adverse event followed by ocular pain, foreign-body sensation, and tearing. Retinal neovascularization developed in 3 eyes in the laser group.

Development of a traumatic cataract in one patient was the only serious adverse event in the aflibercept group.

One death and one nonfatal stroke occurred in the laser group.

Systemic adverse events also occurred, but there was no difference between the two groups. No safety signals emerged between the treatment groups, he added.

“Monthly intravitreal aflibercept injections resulted in superior gains in visual acuity and significant reductions in macular edema compared with laser treatment,” he said. ■

W. LLOYD CLARK, MD

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Dr. Clark is a consultant to Regeneron Pharmaceuticals and has received research funding from the company.

VMT PATIENTS

(Continued from page 20)

also set up a tentative future date at the time of diagnosis for patients with severe metamorphopsia.

COUNSELING AND FOLLOW-UP

Informing patients about possible adverse events is important when treating with ocriplasmin. About 50% of patients develop floaters and flashers in the first 24 to 48 hours post-injec-

tion—a phenomenon that is often described as the type of snow seen on a television screen when there is no cable reception.

In addition, about 5% to 10% of patients experience an early, temporary decrease in visual acuity. The latter event is nearly always associated with the presence of subretinal fluid and is a positive prognostic sign, Dr. Stalmans said.

“In patients [treated with ocriplasmin], there is about a 90% correlation between the occurrence of subretinal fluid and hyaloid detachment,” he said. “Frequently, first the fluid appears and the treatment benefit occurs days to weeks later.”

Since the visual side effects are most likely to

occur early after treatment and aiming to facilitate patient access for follow-up care, Dr. Stalmans said he always schedules his ocriplasmin injection cases in the beginning of the week.

“If anyone is particularly worried and would like to be seen, it is much easier for them to be seen by a retinal specialist on a weekday than on the weekend,” he said. ■

PETER STALMANS, MD, PHD

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Dr. Stalmans' university institution receives lecture fees and grant support from ThromboGenics.

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Dexamethasone for DME therapy delivers long-term visual benefits

Improvement achieved rapidly after treatment compared with sham group, with average of 4.1 injections

By **Lynda Charters**; Reviewed by **David S. Boyer, MD**

LOS ANGELES ::

USE OF A dexamethasone intravitreal implant (Ozurdex, Allergan) provided long-term visual improvements in patients with diabetic macular edema (DME) treated with two doses of the drug, according to study investigators.

“[The dexamethasone implant] fulfills an unmet need in the treatment of inflammation in DME,” explained David S. Boyer, MD, clinical professor of ophthalmology, University of Southern California Keck School of Medicine, Los Angeles.

“It is a potent steroid in a novel, long-acting delivery system [Novadur, Allergan] that provides sustained, localized release of dexamethasone—which inhibits a variety of inflammatory mediators involved in macular edema,” he said.

TWO DRUG GROUPS VERSUS SHAM

Dr. Boyer—on behalf of the Macular Edema Assessment of Implantable Dexamethasone in Diabetes Study Group—presented the results of phase III multicenter, masked, randomized, sham-controlled trials to assess the safety and efficacy of the dexamethasone implant for treating DME with 700 or 350 µg of the drug in a posterior segment drug-delivery system.

The phase III studies—010 and 011—were parallel studies in which 1 eye of each patient was treated.

A total of 347 patients were randomly assigned to the 700-µg dose, 343 patients to the 350-µg dose, and 350 patients to sham treatment. Patients—all of whom had diabetes and a central retinal thickness of 300 µm or more—were assessed for re-treatment every 3 months after the month 6 evaluation; re-treatments could not be performed earlier than every 6 months.

The primary end point was 3 years and a gain in best-corrected visual acuity (BCVA) of 15 or more ETDRS letters. Secondary end points were the percentage of patients with a

gain of 20 or more letters, mean BCVA change from baseline, mean BCVA change in a subset of pseudophakic patients (25% of study population), and changes in retinal anatomy seen on optical coherence tomography.

The three groups were well matched demographically at baseline:

- Most patients (90%) had type 2 diabetes.
- The mean diabetes duration was more than 16 years.
- The mean duration of DME was about 15 months.

Patients could receive up to 7 treatments. Over the 3-year study period, in the 700-µg group, the mean number of treatments was 4.1; in the 350-µg group, 4.4 treatments; and in the sham group, 3.3 treatments.

“Use of the dexamethasone implant led to a clinically meaningful improvement in vision, that is, 3 lines or more (15 letters or more), in the high-dose group in 22.2% of patients, and in the low-dose group in 18.4% of patients compared with 12% in the sham group,” Dr. Boyer said. “The results were significant ($p < 0.05$).”

Some patients achieved 4 or more lines of vision (20 or more letters): 8.5% in the high-dose group, 11% in the low-dose group, and 4.6% in the sham group.

These results were also significant ($p < 0.05$) compared with the sham group.

PATIENT SUBSET

In the subset of pseudophakic patients, “the early increase in vision following treatment was maintained throughout the course of the study” compared with phakic patients who lost some of the gain in vision as the result of cataract development, Dr. Boyer noted.

The lens status at baseline was irrelevant, because “in all groups the patients’ vision improved,” he said.

The mean average decreases in central retinal thickness compared with baseline were significantly greater in the two drug groups compared with the sham group. In the high-dose group, the average decrease was 111.6 µm, and in the low-dose group 107.9 µm compared with 41.9 µm in the sham group—differences that also reached significance ($p < 0.05$).

Development of cataract and increase in IOP were the two main adverse events. Cataracts developed in about 70% of patients. IOP increased following each treatment and then decreased without an added effect.

“Only 0.3% of patients required a trabeculectomy in the two drug groups—1 patient in each group—to control IOP,” Dr. Boyer noted.

REVIEW OF STUDY RESULTS

“Long-acting dexamethasone provided long-term visual improvement in patients with DME,” Dr. Boyer concluded.

The percentage of patients with 3 lines or more gains in visual acuity was significantly higher in the treated groups compared with the sham group, he noted.

Despite development of cataracts in most patients, the visual benefit of the drug treatment was restored after cataract surgery and the vision did not worsen.

DME improved rapidly after treatment, with an average treatment of 4.1 injections.

The drug’s safety profile was good as or better than that of steroids used routinely in clinical practice. IOP elevations rarely required treatment.

There was no evidence of arterial thrombotic events, Dr. Boyer summarized. ■

take-home

► A dexamethasone implant provides long-term visual improvements in patients with diabetic macular edema treated with two doses of the drug.



Join the discussion about the use of dexamethasone for DME at [Facebook.com/OphthalmologyTimes](https://www.facebook.com/OphthalmologyTimes).

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Dr. Boyer is a consultant to Allergan.

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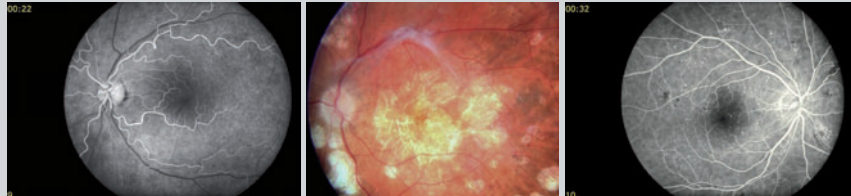
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Varying ranibizumab treatment may improve vision results in DME cases

Increasing dose, frequency of medication may be option if patient has partial/no response, study shows

By **Nancy Groves**; Reviewed by **Dilsher S. Dhoot, MD**

SANTA BARBARA, CA ::

PATIENTS WITH PERSISTENT diabetic macula edema (DME) who have partial or no response to treatment with bevacizumab (Avastin, Genentech) may achieve improved vision after a medication change to ranibizumab (Lucentis, Genentech), show results of a small investigator-sponsored study.

Further, if patients continue to have an incomplete response to treatment with 0.5-mg ranibizumab, injections of 2 mg may achieve results, according to investigators.



Dr. Dhoot

“On average, we found that patients in this study [REEF: Open Label, Phase 1/II, Residual Edema Evaluation with 0.5 mg and 2.0 mg Ranibizumab Formulations]—regardless of whether they had few or many previous bevacizumab injections—had

an improvement in vision of approximately 8.7 letters,” said Dilsher S. Dhoot, MD, of California Retina Consultants and Research Foundation, Santa Barbara, CA.

ABOUT THE REEF STUDY

The 12-month, prospective, multicenter, open-label pilot clinical trial of intravitreal ranibizumab 0.5 and 2 mg in patients with DME enrolled 43 patients who had at least 2 consecutive bevacizumab injections (mean 4.7 injections) administered less than 7 weeks apart within 1 year of the baseline study visit and showed partial or no response.

During the study, all patients received 3 mandatory 0.5-mg injections of ranibizumab at baseline, month 1, and month 2. Patients who had a complete response received additional 0.5-mg injections as needed through month 12. Those with partial or no response received 3 mandatory doses of 2 mg of ranibizumab at months 3, 4, and 5 and as-needed dosing through month 12.

The primary outcome measure was mean change in visual acuity at 6 and 12 months. The secondary outcome measures were mean change in retinal central subfield thickness (CST)

and rates of partial and complete response to either ranibizumab dose.

The mean age of the subjects was 64 years (42 to 85 years); there were 23 males and 20 females. The mean ETDRS vision was 59 letters (33 to 73), and the mean CST was 501 μm (301 to 828 μm). Mean retinal volume was 9.89 mm^3 (6.72 to 14.41 mm^3). The mean number of previous lasers of the macula was 2.5 (0 to 7), and the mean number of intravitreal triamcinolone injections was 0.26 (0 to 4). Twenty patients had proliferative diabetic retinopathy and 23 had nonproliferative diabetic retinopathy.

Among the non-responders, the mean CST before the two consecutive intravitreal bevacizumab injections was 459 μm ; afterward, the mean was 461 μm .

VISUAL ACUITY OUTCOMES

Results of the REEF study showed a mean gain of +8.8 letters in visual acuity from baseline through 6 months. The mean change in CST was a decrease of -165 μm . About 60% of patients achieved a reduction of greater than 25% in CST to less than 300 μm on optical coherence tomography.

“When we stratified visual acuity based on pre-trial bevacizumab, we found that there was no difference between patients who had 4 or less injections of pre-trial bevacizumab (gain of +9.1 letters) and those who had 5 or more (gain of +8.3 letters) ($p = 0.538$),” Dr. Dhoot said.

“There was also no difference in mean retinal thickness stratified by pre-trial bevacizumab; patients with 4 or less injections had mean decrease of -189 μm , and those with 5 or more injections had mean decrease of -122 μm ($p = 0.404$),” he said.

Among the 43 subjects in the study, 30 were non-responders and 13 were partial responders to bevacizumab. After receiving the 3 mandatory 0.5-mg ranibizumab injections, 22 of 29

take-home

► A switch from bevacizumab to ranibizumab and—in some patients—a subsequent higher dose of ranibizumab resulted in further improvement for patients with diabetic macular edema in a recent study.

were partial responders (75.9%), 6 were non-responders (20.7%), and 1 was a complete responder (3.4%).

The partial and non-responders then received 3 monthly injections of 2-mg ranibizumab; 15 of 28 (53.6%) had an additional CST reduction of greater than 10%, and 13 (46.4%) had less than 10% reduction. At month 6, 10 of 28 patients (35.7%) required no further treatment.

Looking more closely at the patients who had not responded to the 3 ranibizumab 0.5-mg doses and then received 3 injections of

the higher dose, 3 of the 6 patients achieved a reduction of more than 10% in CST through month 6.

The safety data from the study showed no Anti-Platelet Trialists Collaboration events during follow-up through 6 months. One patient died of pneumonia 9 weeks after the last ranibizumab 0.5-mg injection. No cases of endophthalmitis were reported.

The study is now complete, and the investigators are analyzing 12-month data. Results have not yet been reported.

The small number of patients and lack of a control group limited the study, Dr. Dhoot said. However, the results support further investigation comparing the safety and efficacy of ranibizumab versus bevacizumab in the treatment of DME. ■



Weigh in on the discussion about varying the treatment for DME by increasing the dose or frequency of medication at [Facebook.com/OphthalmologyTimes](https://www.facebook.com/OphthalmologyTimes).

DILSHER S. DHOOT, MD

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Dr. Dhoot has served as a consultant for Regeneron and ThromboGenics. The investigator-sponsored study was partially funded through a grant from Genentech.

Visual acuity, visual symptoms are driver for corneal inlay satisfaction

Device scores are high among patients with presbyopia for near vision, lack of glare/halos

By Lynda Charters; Reviewed by Roger F. Steinert, MD

IRVINE, CA ::

Corneal inlays for presbyopia are a treatment modality worthy of consideration, according to Roger F. Steinert, MD.

One such investigational hydrogel inlay (Raindrop Near Vision Inlay, ReVision Optics)—which has the same refractive index as the cornea—works by reshaping Bowman's layer and the anterior cornea to create smooth transition zones for near, intermediate, and distance vision.

The device—which currently is implanted monocularly in the United States—is positioned in the cornea at about a depth of 200 μ m.

The inlay provides plus power with a profocal shape in the corneal center, explained Dr. Steinert, the Irving H. Leopold Professor and Chair, professor of biomedical engineering, and director, Gavin Herbert Eye Institute, University of California, Irvine.

STUDY OF THE INLAY

Dr. Steinert and colleagues conducted a multicenter, prospective, non-randomized case series that included 45 patients who underwent implantation of the inlay in the non-dominant eye.

Patients were evaluated preoperatively and at 1, 3, 6, 9, and 12 months postoperatively. Among the factors measured were uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), patients' self-reported symptoms, and patients' satisfaction with near and distance visual acuity and overall.

Univariate and multivariate analyses showed visual acuity and visual symptoms are the main drivers of patient satisfaction. For example, glare and halos are associated with multifocal IOL implantation, and visual dysphotopsias cause the greatest dissatisfaction. Presence of glare and halos seems to have a greater impact on patients' perceptions of visual outcomes than the visual acuity at any distance.

Patients who expressed satisfaction with the corneal inlay were found to have a mean UNVA

at all postoperative evaluations that was almost 20/20. Patients who expressed dissatisfaction had a postoperative UNVA of about 20/25 to about 20/30. The data showed a smaller difference in UDVA (about 20/32) between patients who were satisfied and those who were not.

"Better near acuity in the eye with the inlay was associated with higher near and overall patient satisfaction," Dr. Steinert said. "Better distance acuity in the eye with the inlay was not associated with greater distance vision or overall patient satisfaction."

Patients graded their symptoms—which included glare, halos, visual fluctuations, and diplopia—on a scale of 0 to 4, with 0 indicating no symptoms and 4 indicating severe symptoms. The maximal possible score was 16.

When the cumulative intensity score was evaluated regarding distance vision, most patients who were satisfied with near vision had a cumulative intensity symptom score that was near the preoperative score.

The cumulative intensity score of the unsatisfied patients peaked at 1 month postoperatively at about 5 and by month 12 was 2, according to Dr. Steinert.

Stronger visual symptoms were associated with lower odds of near, distance, and overall patient satisfaction, he added. ■



Dr. Steinert

ROGER F. STEINERT, MD

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Dr. Steinert is a consultant and medical monitor for ReVision Optics.

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Ophthalmic research faces uncertain future in funding

How the Affordable Care Act will affect ongoing and future research dollars

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

TAKE-HOME

► **With a decline in research funding over the years, it is hoped by many that the Affordable Care Act will be the relief needed to keep the field growing and desirable to future ophthalmologists.**

SALT LAKE CITY ::

Funding for ophthalmic research continues to be in a state of flux. Though the Affordable Care Act (ACA)—commonly known as “Obamacare”—was the answer for which many physicians hoped would alleviate the issue, Randall J. Olson, MD, said it is too early to determine the impact of the health-care system overhaul.

“We can guess and throw out a bunch of different possibilities and say which of these is going to take traction or not, (but) that’s just guessing,” said Dr. Olson, professor and chairman, Department of Ophthalmology and Visual Sciences, and chief executive officer, John A. Moran Eye Center, University of Utah School of Medicine, Salt Lake City.

Dr. Olson blamed the ACA’s “stormy” roll-out last fall for the confusion surrounding its future impact.

However, politics also played a role in the ACA’s troubled start, which is not good for ophthalmic researchers, he added.

“Politically—because, indeed sadly, the ACA has become a very big political hot potato—it’s not a red or blue issue,” Dr. Olson said. “This funding of our core basic research—which is our feedstock for the future—is not being invested in and not taken seriously.”

Instead, focus should be taken much more intensely on ophthalmic research, as fund-

ing for the field has been in rapid decline for more than 30 years, according to Dr. Olson.

RESEARCH FUNDING CRISIS

Even if a grant is approved in time, “there are always a few months [during which] the National Institutes of Health (NIH) says: ‘We’re not ready to fund it yet,’ and you’ve got to be in place to cover that,” Dr. Olson explained.

For instance, where researchers could often cover themselves well if they had a couple of grants, Dr. Olson said in his experience, 80% of the cost could be covered at best.

When considering what won’t be funded—plus the necessary pilot studies—for every new \$1 million of NIH funding, researchers would have to come up with about \$300,000 to keep their project together.

“This is a tragic situation,” he said. “It’s discouraging many of the best and brightest who wanted to pursue research. They’re looking at this and saying: ‘You know, to be an independently funded person is a pretty difficult thing when I see senior members who have been successful for years and years, who are well regarded in the field, and they’re not getting funding.’”

Because of these issues, Dr. Olson said he fears the ophthalmic research community is facing a crisis.

“We are at a point where only the strongest are going to be able to pay,” he said.

In addition, Dr. Olson said the field could also be in danger due to “dramatic” cutbacks of ophthalmology research from several of the major groups involved in providing new ophthalmic products.

“I’m concerned about the United States losing its competitive edge,” Dr. Olson added.

ACA AND RESEARCH CAN UNITE

All hope is not lost, however. Though no one can foretell how the ACA will impact ophthalmic research funding, there definitely will be some form of benefit, Dr. Olson stressed.

“The general rule of thumb is we’re having

a hard time figuring out how to have enough money to pay for a lot of the different needs that are there,” he said.

That is where the ACA comes into play, Dr. Olson added.

Outcomes research is the area that will likely reap the most benefit from the health-care overhaul, he said.

“(The ACA) could increase our research funding, although it may crowd out traditional types of research and be more of outcomes research . . . re-engineering . . . looking at better ways and processes moving forward,” Dr. Olson said.

It is important to remember, however, that the increase of funding will not be going toward any kind of historic new treatments, Dr. Olson said, as outcomes research will never be that way.

Instead, he explained, it will be an engineering process that will slowly improve.

“It doesn’t take much of the general overall cost of the bill,” Dr. Olson said, “if you can show that these kinds of projects that work in place actually result in overall savings.”

Additionally, if Congress is willing to reinvest part of those savings into additional such research, “this could be a dramatic increase and very important,” he said.

Nevertheless, the future does remain uncertain.

“Stay tuned and watch this very carefully, because one way or another we’re going to see major change going forward,” Dr. Olson concluded. ■



Dr. Olson



What effect is the Affordable Care Act having on research funding for ophthalmology? Join the discussion at [Facebook.com/OphthalmologyTimes](https://www.facebook.com/OphthalmologyTimes).

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Dr. Olson has no relevant financial interests to disclose.

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