IN VIEW:

360° of anterior capsule overlap is important to minimize lens tilt with capsular contraction.

(Continues on page 17: Satisfaction)

Listen, counsel before taking action; identify cause

By Cheryl Guttman Krader; Reviewed by John P. Berdahl, MD

with careful selection of candidates based on thorough preoperative evaluation and counseling combined with meticulous intraoperative technique, cataract surgeons have a high likelihood of achieving satisfaction among patients who choose a presbyopia-correcting IOL. However, the rare unhappy patient can ruin the day.

Understanding the patient's complaints and knowing the potential reasons for patient dissatisfaction with a presbyopia-correcting IOL provides a basis for appropriate evaluation and successful management, said John P. Berdahl, MD.

"We really can get these patients to a place where they will be happy," said Dr. Berdahl, assistant clinical professor of ophthalmology, University of South Dakota, and private practice, Vance Thompson Vision, Sioux Falls, SD. "To use a football analogy, we should not give up on them at the 3-yard line when we know that with some extra effort we can get them into the end zone.

"The first thing surgeons need to do is listen to the patient," he said. "Not only will you get information that helps to determine the cause of the problem and therefore an effective solution, but it will make patients feel that you are on their team. To quote the wisdom of my grandmother: People don’t care what you know until they know you care.”

(Continues on page 17: Satisfaction)
Managing unhappy presbyopia patients

IN VIEW: 360° of anterior capsule overlap is important to minimize lens tilt with capsular contraction.
(Image courtesy of Vance Thompson, MD)

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(Continues on page 17: Satisfaction)
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Neuro-ophthalmologists in battle would have altered outcome

Rather than causing me to think of David as a hero, this encounter has always made me think that Goliath was an idiot. Why didn’t Goliath hide behind his shield when he saw David about to shoot the rock at him or at least duck or otherwise protect his head? Why didn’t he run up close to David and just stab him?

There is some controversy about this, but a number of people who ponder this type of question have an explanation for Goliath’s failure, and it is not that he was stupid. Rather, they believe that his pituitary was at fault.¹

Not only do they suspect he had acromegaly, but that he probably had a familial (autosomal dominant) form of the disease.² Familial isolated pituitary adenoma (FIPA) is an autosomal dominant condition with incomplete penetrance caused by germline mutations of the aryl-hydrocarbon receptor-interacting protein gene 4. Goliath’s brother and three sons were giants and one of his sons had six fingers on each hand and six toes on each foot. It must have been quite a treat to receive a year-end postcard of that family! Anyway, the arguments supporting acromegaly in Goliath include:

- His height was “six cubits and a span”—apparently about 6’ 9” (pretty big for those days).
- He presumably had poor vision, as evidenced by his having a shield bearer lead him down to the field of battle to face David, his statement that David was carrying sticks when he had only a single shepherd’s staff, and his failure to duck or hide behind the shield as David prepared to launch his rock and his failure to dodge the missile that beamed him.

My conclusion? If the Philistines had neuro-ophthalmologists in their army, the battle would have turned out very differently.

REFERENCES


THE IDIOM “Don’t bring a knife to a gunfight” is meant to convey the importance of not entering a challenging situation without the proper equipment at hand. The expression has been used in some 20 movies and is also a favorite of some politicians. The concept that one must come properly prepared and equipped to any important task or confrontation is well-appreciated by ophthalmic surgeons, but this particular expression is rarely used by ophthalmologists teaching eye surgery to residents.

Only a philistine would not enjoy a good movie in which the protagonist, like Sean Connery in “The Untouchables,” uses this idiomatic expression to mock his opponent. I mean a philistine in the sense of its common usage of “a person who is hostile or indifferent to culture and the arts.” Of course, this word’s earlier meaning is that of a native or inhabitant of ancient Philistia. The Philistines were a powerful tribe that ranged from Lebanon to Crete to Egypt until they were conquered by the Romans.

DIDN’T GET THE MEMO

The most famous Philistine (actually, the only one whose name I know) was Goliath the Git-tite. Unfortunately for Goliath (the biblical giant whose name has become synonymous with losing in an upset), he did not get the memo about proper preparation.

Heavily armored and with sword in hand, he faced off against a young shepherd armed with a slingshot, the gun equivalent of his day. Apparently these slingshots, with practice, were so accurate that they could be used to shoot down birds in flight. His is a textbook case of bringing the proverbial knife to the proverbial gunfight. Goliath stood there while David loaded his slingshot and fired his rock, then lay unconscious while David sliced off his head.

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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References

Certain principles in ophthalmology are long established and adhered to by surgeons; in some cases, for decades.

Some recent questions regarding two surgical practices—internal limiting membrane (ILM) peeling during vitrectomy and maintaining the facedown position after vitrectomy with gas tamponade—are worth asking, noted Gaetano R. Barile, MD.

The retina subspecialty has enjoyed significant advances resulting in improvements in anatomic and visual outcomes after vitrectomy, said Dr. Barile, professor of ophthalmology, Hofstra Northwell School of Medicine, Manhattan Eye, Ear and Throat Hospital, New York.

For example, instrumentation has improved dramatically because of engineering efforts. Especially in retinal diseases—in which superior visualization is vital—wide-angle viewing has improved the surgeon’s vantage point and dyes facilitate ILM peeling.

Surgical techniques—including the use of pharmacologic adjuvants—have advanced to treat diabetic retinopathy and proliferative vitreoretinopathy among other indications, according to Dr. Barile.

For patients with vitreoretinal diseases is restoration of the retinal anatomy by removing traction from the vitreous and the retinal surface in retinal detachment, vitreomacular traction, macular holes and pucker, and retinal complications associated with longer axial lengths.

In more complex cases, subretinal and intraretinal disease may need to be addressed, he explained.

Dr. Barile questioned if ILM peeling and maintenance of the facedown position after vitrectomy are necessary in order to restore the retinal anatomy.

There are good reasons to stain and peel the ILM, according to Dr. Barile.

“ILM removal might allow for improved anatomic outcomes particularly in retinal surface diseases,” he said. “The retina becomes more compliant and flexible after the ILM is removed, and its removal eliminates the scaffold for reproliferation after the procedure.”

The list goes on—basically, peeling works; macular holes close more consistently; macular pucks recur less often; the macular thickness decreases in diabetic macular edema; there are improvements in myopic foveoschisis, and there is decreased risk of macular pucker in the presence of a primary retinal detachment, he noted.

In support of ILM peeling, Dr. Barile cited a meta-analysis (Retina. 2016;36:679–687) that summarized macular hole data.

“Our success rates with macular hole surgery are very good, well above 90%,” he added. “However, with ILM peeling, the odds of recurrent macular hole formation are considerably less compared with cases in which the ILM is retained.”

Another recent study on macular pucker by Jung et al. (Retina 2016;36:2101–2109) showed that double peeling (versus single peeling of the pucker) to include the ILM ensured complete removal of the membrane in many cases but did not necessarily improve the long-term vision. However, the authors did notice an increased incidence of inner retinal dimpling.

On the flip side of the coin, there might be good reasons to leave the ILM in place, according to Dr. Barile.

Considerations include dye toxicity in the retina, particularly with indocyanine green,

**TAKE-HOME**

› Peeling of the internal limiting membrane has increasingly become a dogma of surgical retina, while maintenance of the face-down positioning may become anachronistic in many cases.

**Surgical Goals**

The intraoperative goal in patients with vitreoretinal diseases is restoration of the retinal anatomy by removing traction from the vitreous and the retinal surface in retinal detachment, vitreomacular traction, macular holes and pucker, and retinal complications associated with longer axial lengths.

(FIGURE 1) Inner retinal dimpling after macular hole closure. (Images courtesy of Gaetano R. Barile, MD)
and physiologic and anatomic effects on the Müller cells and its footplates and other cells of the inner retina, possibly leading to inner retinal dimpling, he noted.

**FACE-DOWN POSITION WITH GAS TAMPOANDES**

A major factor in postoperative care following vitrectomy that surgeons have long adhered to is the face-down position after gas tamponade. Patients are instructed to maintain a face-down position for varying lengths of time postoperatively when a vitreous tamponade is injected at the end of the surgery.

Only two gases have been approved for use as tamponades, perfluoropropane and sulfur hexafluoride, C3F8 and SF6 respectively. In some cases, air is injected. The half-lives of these gases in the eye vary, but they can be long.

‘Prone positioning after vitrectomy is a long-standing dogma in retinal surgery. However, it might be unrealistic and unnecessary in many cases.’

— Gaetano R. Barile, MD

The advantages of using a gas tamponade with the face-down position are the temporary prevention of fluid flow through any retinal breaks and facilitation of permanent retinal adhesion, which might also improve the rate of macular hole closure.

The prone positioning increases the contact by the tamponade with the desired area, Dr. Barile said.

Issues to consider with gas tamponades and prone positioning are patient compliance with the positioning and the location of the area to be tamponaded.

Regarding the latter, when that area is in the inferior retina, studies have shown that inferior retinal breaks and inferior detachments do well despite the absence of contact with a tamponade, Dr. Barile noted.

**SHEAR STRESS**

A study that mathematically modeled the shear stress in the eye, performed by Alyward et al. (*Invest Ophthalmol Vis Sci.* 2011;52:7046–7051), concluded that there is very weak fluid shear stress after the vitreous is removed and this stress is lower than the adhesion strength that occurs immediately after laser retinopexy or cryotherapy. That sheer stress appears to be insufficient to detach the postoperative retina.

This study indicated that in many cases, prone positioning after vitrectomy might not be necessary, Dr. Barile explained.

“In macular hole surgery, we recognize increasingly that prone positioning postoperatively likely is not necessary, especially in cases with small holes (< 400 μm),” he said.

**PROBLEMS IF BUBBLE NOT POSITIONED**

However, there are certain cases in which problems can occur when a gas bubble is not positioned properly, i.e., those with larger tears, superior bullous detachments, residual subretinal fluid, and in eyes that are soft at the end of the surgery.

According to Dr. Barile, this can result in redundancy of the retina with a resultant “tragic” fold in the macular region following a rhegmatogenous retinal detachment that can be extremely difficult to manage.

ILM peeling has established anatomic benefits. However, increasing questions are arising in relation to situations in which peeling should not be performed, Dr. Barile summarized.

“Care is required in cases of advanced glaucoma,” he said. “Testing should be performed in patients who underwent macular surgery or have fairly advanced glaucoma to determine if ILM peeling should be undertaken.

“Prone positioning after vitrectomy is a long-standing dogma in retinal surgery,” Dr. Barile said. “However, it might be unrealistic and unnecessary in many cases; but if a gas bubble is present in the eye, surgeons might use it as needed.”

Some patients choose prone position despite the study results suggesting no benefit, he added. However, prone position remains an essential practice in specific cases.

— Gaetano R. Barile, MD
**INDICATIONS AND IMPORTANT SAFETY INFORMATION**

**INDICATIONS**
- EYLEA® (aflibercept) Injection is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR) in Patients with DME.

**CONTRAINDICATIONS**
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**WARNINGS AND PRECAUTIONS**
- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

**ADVERSE REACTIONS**
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.

- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

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CONTRAINDICATIONS

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Intraocular Pressure

There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. AEs are defined as fatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.8% (93 out of 2450) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the IOVD studies.

ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

• Hypersensitivity [see Contraindications (4.3)]
• Endothelialitis and retinal detachments [see Warnings and Precautions (5.1)]
• Intravitreal hemorrhage [see Warnings and Precautions (5.2)]
• Thromboembolic events [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug may not be directly compared to rates in other clinical trials of the same or another drug and may not reflect the rates observed in practice. A total of 271 patients treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.5% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

Vitreous floaters, retinal detachment, and vitreous hemorrhage are manifestations of the vitreous detachment reaction. The incidence of vitreous detachment was increased in patients treated with EYLEA compared with control patients treated with placebo [see Table 1]. Less common adverse reactions reported in <1% of the patients treated with EYLEA were hypersensitivity, retinal detachment, retinal tear, corneal edema, and injection site hemorrhage.

Eylea is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of: Neovascular (Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); Diabetic Macular Edema (DME); Diabetic Retinopathy (DR) in Patients with DME.

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Table 1: Most Common Adverse Reactions (≥5%) in Wet AMD Studies

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>EYLEA (N=1824)</th>
<th>Active Control (ranibizumab) (N=955)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjunctival hemorrhage</td>
<td>28%</td>
<td>22%</td>
</tr>
<tr>
<td>Eye pain</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>Cataract</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Visceral detachment</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Vitreous floaters</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Intraocular pressure increased</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Occular hypopyon</td>
<td>4%</td>
<td>6%</td>
</tr>
<tr>
<td>Corneal epithelium defect</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Retinal detachment of retinal pigment epithelium</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Foreign body sensation in eyes</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Luminization increased</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Wound healing</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Intravitreal infection</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Retinal pigment epithelium tear</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Injection site hemorrhage</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Cataract</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Less common adverse reactions reported in <1% of the patients treated with EYLEA were retinal edema, retinal tear, vitreous hemorrhage, cataract, episkiasis, vitreous floaters, intraocular inflammation, retinal detachment, retinal pigment epithelium tear, injection site hemorrhage, injection site pain, conjunctival hemorrhage, vitreous floaters, vitreous detachment.

Table 2: Most Common Adverse Reactions (≥5%) inIOVD Studies

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>CRVO (N=218)</th>
<th>Control (N=142)</th>
<th>EYLEA (N=97)</th>
<th>BRVO (N=97)</th>
<th>Control (N=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye pain</td>
<td>18%</td>
<td>5%</td>
<td>4%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>17%</td>
<td>9%</td>
<td>10%</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>Intravitreal pressure increased</td>
<td>8%</td>
<td>6%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal epithelium defect</td>
<td>5%</td>
<td>4%</td>
<td>2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Vitreous floaters</td>
<td>5%</td>
<td>3%</td>
<td>1%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Occular hypopyon</td>
<td>3%</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Foreign body sensation in eyes</td>
<td>3%</td>
<td>5%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visceral detachment</td>
<td>3%</td>
<td>0%</td>
<td>2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Luminization increased</td>
<td>3%</td>
<td>1%</td>
<td>3%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Injection site hemorrhage</td>
<td>3%</td>
<td>1%</td>
<td>5%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Cataract</td>
<td>1%</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

Less common adverse reactions reported in <1% of the patients treated with EYLEA in the CRVO studies were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, vitreous detachment, foreign body sensation in eyes, vitreous detachment, scar formation, injection site hemorrhage, vision blurred, injection site pain, conjunctiva, skin. Less common adverse reactions reported in <1% of the patients treated with EYLEA in the BRVO studies were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, vitreous detachment, foreign body sensation in eyes, vitreous detachment, scar formation, injection site hemorrhage, vision blurred, injection site pain, conjunctiva, skin.
End-stage glaucoma requires outside-of-box management

Provide palliative measures, counseling on resources that may enable reasonable lifestyle

By Cheryl Guttman Krader; Reviewed by Robert L. Stamper, MD

Although the aim of glaucoma management is to maintain visual function, the role of the ophthalmologist does not end once a patient has lost useful vision.

Robert L. Stamper, MD, discussed care for patients with end-stage glaucoma, including provision of palliative measures; counseling on resources that will enable a reasonable lifestyle; compassion, and hope.

“It is important for us not to abandon end-stage glaucoma patients because we feel failure or frustration or because they are blind,” said Dr. Stamper, professor of clinical ophthalmology, director emeritus of the Glaucoma Service, University of California, San Francisco.

OTHER ASSISTANCE

When physicians cannot slow the process toward blindness, they need to be knowledgeable about other assistance they can provide.

“We need to communicate to patients the services that are available,” Dr. Stamper added.

Despite the best of care, up to 11% of glaucoma patients become blind or visually disabled. He suggested that once a patient has lost a considerable amount of vision, it is time to talk about the possibility that significant visual disability may be forthcoming.

“Acknowledge the patient’s feelings of helplessness, isolation, and loss of independence,” Dr. Stamper said. “It is not a bad idea to acknowledge your own feelings of frustration at not having been able to stop the inextricable downhill course.”

Having the patient’s family or friend present for the discussion can help the individual recall and process the information later. The conversation might include a suggestion that the patient seek a second opinion.

“No physician can think of every option for every situation, so offer the patient the idea of seeing another glaucoma specialist or consider discussing the case with a respected colleague,” Dr. Stamper said.

When conversing with these patients, physicians should choose their words carefully, remaining sensitive to cultural differences and the perceptions that blindness may have for a particular individual.

“Help the patient understand that visual disability is not the end of things, but rather the beginning of a different type of life,” he said. “If the patient seems depressed, discuss psychotherapy, and be proactive about finding out whether the patient has thought about hurting himself or herself and thus requires urgent psychiatric referral.”

HOST OF RESOURCES

Dr. Stamper reviewed tools/services for the visually impaired that are available from federal, state, and private organizations. They include groups for emotional support and vocational counseling services for those who are in the workforce.

“It is important to realize that 30% of people who are blind are still employed,” he said. “People who are blind can still enjoy life and many recreational activities that sighted people do.”

There are aids for assisting patients with activities of daily living, including handicapped parking stickers for transportation, products that enable reading if the patient is partially sighted, and products and services for maintaining function and safety at home.

“In California, the Department of Rehabilitation operates a residential center where patients can live for six to nine months to learn skills to function as a partially sighted or blind person,” Dr. Stamper said.

There are also programs that provide training in financial management and financial assistance for the visually impaired. Individuals may be eligible to receive disability or supplemental income payments from Social Security, income tax credits, reduced public transit fares, free prescriptions, free postage for books or other items related to their disability, and coverage by Medicare or Medicaid.

OPHTHALMIC CARE

For glaucoma patients who have lost useful vision, the focus of medical care shifts to palliation. IOP still needs to be controlled at a level that is low enough to prevent pain.

It is also important to manage corneal edema to prevent the development of painful bullae. That may include the use of hypertonic salt solution, bandage soft contact lens wear, keratoplasty, or corneal cautery.

Interventions for pain control include atropine, topical corticosteroids, topical NSAIDs, retrobulbar chlorpromazine, or alcohol—even evisceration or enucleation.

“Some of my happiest patients are the ones who finally agree to evisceration or enucleation after enduring pain for some time in a blind eye,” Dr. Stamper said.

TAKE-HOME

» When treating end-stage glaucoma, physicians need to help these patients understand that visual disability is not the end, but rather the beginning of a different type of life.

HELPING PATIENTS COPE

VIDEO Robert L. Stamper, MD, explains how physicians can help patients by being knowledgeable about available resources. Go to OphthalmologyTimes.com/EndStage

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This article was adapted from Dr. Stamper’s presentation at the Glaucoma Symposium during the 2017 Glaucoma 360 meeting. Dr. Stamper has no relevant financial interests to disclose.
**Novel treatment options for IOP involve range of independent factors**

Effects of lifestyle, systemic factors, body position, alternative therapies can play role

*By Michelle Dalton, ELS; Reviewed by Cynthia Mattox, MD, FACS*

**EDUCATING PATIENTS** about potential lifestyle changes can be an important adjunct to the medication(s) that clinicians prescribe when it comes to managing glaucoma, said Cynthia Mattox, MD, FACS.

Patients ask about lifestyle all the time, said Dr. Mattox, who is director, Glaucoma and Cataract Service, and vice chairman, clinical services for New England Eye Center, Boston, as well as associate professor of ophthalmology, Tufts University School of Medicine, Boston.

“There is evidence supporting what may be beneficial, what may be harmful, and what may not make a difference. For example, consuming dark-green leafy vegetables can reduce glaucoma risk by 30%, and may be even more helpful in those patients who are prone to having paracentral visual field loss.”

A high beta-carotene intake, as well as other sources of retinol equivalents, was shown in the Rotterdam study to be associated with “a two-fold decreased incidence of incident glaucoma,” she said.

Conversely, calcium and iron supplementation “may be harmful to our patients, especially in patients who don’t have a deficiency,” she added, with similar findings for magnesium. The role of antioxidants in food is less clear cut, but Dr. Mattox recommends advocating moderation.

**BENEFICIAL BEHAVIORS**

Regular aerobic exercise is good in general, and may have a moderating effect on IOP levels. However, it is not uncommon to find a slight IOP rise in previously active patients who are newly sedentary (for example, from an injury), according to Dr. Mattox.

“It’s advisable for our glaucoma patients to avoid prolonged Valsalva maneuvers,” she said. Clinicians should advise patients to avoid being upside down for long periods to minimize choroidal expansion. There is some suggestion that in certain patients with certain phenotypes and a paracentral visual defect, that low body mass index may play a role.

“A lot of our patients take herbal supplements,” Dr. Mattox said. “The rationale for some supplements is that they may protect retinal ganglion cells from toxicity or apoptosis.”

They may also reduce caspase 3 and 9, and inhibit gene expression. Some supplements have been reported to reduce IOP in animal models, “but the evidence is soft,” she said.

There is little evidence about the benefits of acupuncture, but the rationale for its incorporation into patients’ lifestyle is that acupuncture stimulates the release of neurochemicals. One study did not find any pressure effect on IOP from patients undergoing acupuncture, nor were the researchers able to study if acupuncture can protect the optic nerve, Dr. Mattox noted.

**TAKE-HOME**

» When exploring novel treatment options for the management of IOP, clinicians should consider a number of independent factors ranging from beneficial behaviors to body position.

**SYSTEMIC FACTORS**

Systemic hypotension, especially nocturnal, could be particularly harmful for patients, she said. Patients with glaucoma should be careful not to be “overtreated with their blood pressure medication,” she said, and recommended that patients avoid nighttime dosing with antihypertensive medications.

Body position during sleep may have an effect on IOP as well, Dr. Mattox said, with the dependent eye having a higher IOP and studies showing a habitual side more prone to worsening optic nerve damage, especially if a patient has a higher IOP.

Sleeping with a wedge pillow may help mitigate supine IOP elevations, “which can be helpful if our patients do have an autoregulatory problem while they’re sleeping in a supine position,” she said.

Caution patients not to flex or extend their necks as IOP can be aggravated. For side-sleeping patients, recommend that they alternate sides when possible to minimize the pressure on the pillow-facing side, she added.

Finally, retinal ganglion cells are known to express estrogen receptors, and “there does appear to be some increased risk in patients who have an early onset menopause or have prolonged oral contraceptive use,” she said.

Some studies have looked at reduced risk of developing glaucoma in patients who have postmenopausal estrogen hormone replacement therapy. In one study—using data from a large, nationwide healthcare claims database with medical records for more than 150,000 women—estrogen hormone therapy “may reduce the risk of primary open-angle glaucoma.”

Dr. Mattox said this is an active area of research that may help us understand the mechanisms of glaucoma.

**References**


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This article was adapted from Dr. Mattox’s presentation during Glaucoma Subspecialty Day at the 2016 meeting of the American Academy of Ophthalmology. Dr. Mattox is a consultant to and/or has received lecture fees or grant support from Aerie Pharmaceuticals, Alcon Laboratories, Allergan, the National Eye Institute, Ocular Therapeutics, and Transcend Medical.
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Residual astigmatism is not uncommon after toric IOL implantation. Depending on its cause and magnitude, lens reorientation may be a good solution.

Patients choosing a toric IOL are hoping for good uncorrected distance vision. When this goal is not achieved because implant misalignment is causing significant residual astigmatism, IOL rotation planned using a free online back-calculation tool (astigmatismfix.com, Ocular Surgical Data LLC) can be a safe, effective, and preferred solution, said John P. Berdahl, MD.

“Patients who choose a toric IOL have usually paid a price out of pocket, and surgeons should get them the refractive outcome they need to function without glasses,” said Dr. Berdahl, assistant clinical professor of ophthalmology, University of South Dakota, and private practice, Vance Thompson Vision, Sioux Falls, SD.

“Residual astigmatism that is present because the IOL is not in the intended location can often be addressed by excimer laser vision correction or IOL rotation,” he said. “Many surgeons do not have access to an excimer laser, however, and even if they do, rotating the IOL is an easier and safer approach assuming it can solve the problem and as long as the patient has an intact posterior capsule.”

The website (astigmatismfix.com) was created by Dr. Berdahl and David R. Hardten, MD, of Minneapolis, MN. Surgeons enter the patient’s manifest refraction with cylinder in plus power, the toric IOL model, and the magnitude of astigmatism and axis of the toric lens. The back-calculation determines the ideal position of the toric IOL for minimizing the residual refractive error, the magnitude and direction of rotation needed, and the expected residual refraction. Surgeons can decide if the spherical equivalent outcome is acceptable so that they want to go forward and rotate the lens.

“Laser vision correction creates competing axes where the axis of the refraction is at one location, the axis of corneal astigmatism is at another, and the axis of the toric IOL is at a third location,” Dr. Berdahl said. “In contrast, IOL rotation neutralizes the corneal astigmatism with lenticular astigmatism and avoids putting a different ablative pattern on the cornea.

“Some people think that if you can induce less astigmatism by rotating a toric IOL off axis, but that is not true,” he added. “The best location for a toric lens is always in the axis of the astigmatism of the cornea.”

When evaluating a toric IOL orientation, there are three axes of interest.

The first is the intended axis, derived from whatever preoperative calculator is used. It may consider posterior corneal astigmatism and/or surgically induced astigmatism (SIA). This “Intended Axis” is the target for the surgeon.

The second axis of interest, the actual orientation of the toric IOL, is determined after surgery. This can be directly measured in a variety of ways. It may or may not be the same as the intended axis.

Finally, if the patient’s postoperative refraction is known, then vector mathematics can be used to derive the best orientation of the given toric IOL. Again, this may be the same as the intended axis and/or the same as the actual axis.

(Figure courtesy of John P. Berdahl, MD)
Study finds advantages using trifocal IOL to correct presbyopia

Lens provided effective visual improvements at near, intermediate, far distances

By Vanessa Caceres; Reviewed by Matteo Piovella, MD

A 4-YEAR STUDY following trifocal IOL implantation (AT LISA tri 839MP, Carl Zeiss Meditec) found that the lens provided good distance, near, and intermediate visual acuity. The lens also improved patient quality of vision with better diffraction and less reduction in contrast sensitivity, said Matteo Piovella, MD, medical director, Centro Microchirurgia Ambulatoriale-CMA in Monza, Milan, Italy.

Their study, starting in 2012, included 111 eyes of 67 patients who had phacoemulsification and trifocal IOL implantation of the AT LISA lens. All surgeries were uncomplicated. Distance (5 m), near (40 cm), and intermediate (80 cm) visual acuity were measured after surgery, as well as corneal topography, contrast sensitivity and defocus curve. The follow up period was 4 years.

The study included 111 eyes from 67 patients, with a mean age of 67 years. The preoperative distance uncorrected visual acuity was 20/125 (0.8 logMAR), compared with 20/20 at 4 years postoperatively.

The monocular and binocular uncorrected near vision was respectively 0.06 and 0.02 logMAR. Monocular and binocular intermediate vision was 0.13 and 0.09 logMAR, respectively. Nearly 8% of patients still wear glasses occasionally.

By the year 2015, 73% of patients having cataract surgery at CMA surgical center received the trifocal technology.

“Ninety-four percent of eyes achieved postoperative refractive results within ± 0.50 D,” he said.

“In practice, intermediate vision is the most important vision because of iPad, smartphone, and computer use,” Dr. Piovella said.

He was surprised that the trifocal is the only technology submitted and approved to provide effective far, intermediate, and near vision.

Although extended depth-of-focus IOLs are available, their strengths are only far and intermediate vision, he said.

Regarding trifocal IOLs, “if you learn to improve your preoperative organization to provide plano refractive results by doing a perfect biometry analysis, then every patient is happy,” Dr. Piovella said.

However, surgeons using the trifocal must provide dry eye therapy to ensure optimal ocular surface health, he said. His study found that over 16% of patients required pre- and postoperative dry eye management.

Dr. Piovella himself was implanted binocularly with the trifocal IOL.

Dr. Piovella added he is involved in a study on a trifocal toric IOL based on the same platform that should be in press soon.

ASTIGMATISM

(Continued from page 14)

While ideally it may be better to do the procedure sooner than later to reduce the patient wait time to have good uncorrected vision, patience may pay off because it may decrease the likelihood that the lens will re-rotate.

To perform the rotation, surgeons should mark the current and ideal axis, instill viscoelastic to inflate and protect the capsular bag, and place viscoelastic under the IOL to free the implant from the cul de sac. Using a Sinskey hook, they should then make sure the haptic is freed from the posterior capsule and use the instrument to rotate the IOL into the desired position. Viscoelastic is then removed.

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This article was adapted from Dr. Berdahl’s presentation at the 2017 meeting of the American Society of Cataract and Refractive Surgery. Dr. Berdahl is a consultant for Acufocus, Carl Zeiss Meditec, Johnson & Johnson Vision, and TearLab.
Preoperative considerations with extended depth-of-focus lenses
Invest in successful outcomes with careful patient selection, preoperative measurements

By Sumit “Sam” Garg, MD; Special to Ophthalmology Times

EXTENDED depth-of-focus (EDOF) IOLs are an exciting new option for presbyopic patients. Though these lenses tend to be more forgiving of residual refractive error and mild decentration than other presbyopia-correcting IOLs, it is still important to select patients carefully and follow good preoperative protocols to maximize the chance of a successful outcome.

PATIENT SELECTION AND COUNSELING
When introducing EDOF lenses to the surgical regimen, I recommend selecting uncomplicated cases (e.g., no concomitant ocular disease or prior surgery) at first, with the aim of building confidence in the lens. Choose patients with bilateral cataracts so that you can give them the same optics in both eyes. Certainly, EDOF lenses can still be a good option for a patient with unilateral cataract or for a post-LASIK eye—but save those cases for later, if possible.

EDOF lenses provide a very functional range of vision for patients who still have active lives and want to be less dependent on spectacles for their daily activities. However, it is important not to mislead patients that their vision will be perfect.

I tell patients to expect they will still need glasses for some tasks, such as small print or prolonged reading. I also talk about glare, halo, and starbursts. I explain that the incidence is lower and the symptoms seem to be less bothersome than with multifocal IOLs, but they may still experience some night-vision symptoms. Patients who seem like they will not be able to tolerate any night-vision symptoms at all might be better served with a monofocal IOL.

Early on, I implanted an EDOF lens (Syntec Symfony, Johnson & Johnson Vision) in a 95-year-old patient who had cataract surgery bilaterally. The patient was very happy with the results and reported that she could see well enough to drive and enjoy her daughter’s wedding. She was able to watch the wedding without glasses.

Tolerance to Astigmatism

In the New Zealand Duet study, subjects with the IOL (Tecnis Symfony, Johnson & Johnson Vision) implanted could tolerate up to 1.5 D of astigmatism without loss of distance visual acuity.

Unlike the distinct foci of a multifocal IOL, extended depth-of-focus (EDOF) lenses elongate the focus, giving patients a more natural continuous range of vision.

Take-home

» Though extended depth-of-focus lenses tend to be more forgiving of residual refractive error and mild decentration than other presbyopia-correcting IOLs, it is important to select patients carefully and follow good preoperative protocols for a successful outcome.
Satisfaction
(Continued from page 1)

Refractive error is the most common cause of patient dissatisfaction with vision after presbyopia-correcting IOL implantation, but before addressing residual astigmatism or spherical error, cataract surgeons should look for and manage dry eye.

“This is a situation where listening to the patient’s complaints is very helpful for directing your care,” Dr. Berdahl explained. “If the patient reports having visual fluctuations, then dryness of the ocular surface is a problem, and treatment of residual ametropia will address the refractive error as it is measured at one point in time.”

Treatment for dry eye will depend on the cause and its severity. It may include lubricants, topical and oral anti-inflammatory medications, thermal pulsation, environmental and behavioral modifications, punctal plugs, and omega-3 fatty acid supplementation.

Because refractive error is a common cause for dissatisfaction among presbyopia-correcting IOL patients, surgeons who are offering this technology should be prepared to perform excimer laser enhancement procedures. Dr. Berdahl noted that in his practice, all patients are counseled preoperatively about the possibility of having another procedure, and the cost of a refractive touchup is included in the premium package.

Positive dysphotopsia, i.e., glare and halos, is another issue that patients may complain about after presbyopia-correcting IOL surgery. Dr. Berdahl said that even though the risk can be mitigated by making sure that dry eye is adequately treated and by excluding patients who have high levels of corneal higher-order aberrations or irregular astigmatism, all patients receiving a multifocal or extended depth of focus IOL should be counseled about the potential for these visual symptoms.

“I tell my patients that by choosing these lenses, they are trading some visual quality for an increase in flexibility through decreased dependence on glasses,” he said. “I say they will likely have some glare and some halos and that the brain usually learns to adapt to these issues, just as it learns to filter out the shadow created by the edge of their frames or their nose when they look through their glasses.”

At the same time, however, he counsels patients that there is a small chance that they will find the problems persistently bothersome to the point where management would involve removing the presbyopia-correcting IOL and replacing it with a standard monofocal lens.

Dr. Berdahl said the cost of an exchange procedure also is included in the surgical package.

“It is hard to predict when an exchange will be needed, and we do not want to make these patients unhappy by charging them more for another procedure,” he said.

Some patients who choose a presbyopia-correcting IOL may be unhappy with the result if their best near point is not consistent with their visual needs. The best management for this problem is prevention, and that involves listening to the patient before the surgery.

Patients who want good uncorrected vision to do detailed near tasks, such as needlework, are good candidates for a higher add multifocal IOL, whereas someone whose needs are more for intermediate and far distances would be happier with an extended depth of focus or accommodating IOL, Dr. Berdahl said.

“Knowing the best near points for the different presbyopia-correcting IOLs is useful for recommending a lens that will match each patient’s visual goals,” he said. “In some cases, different lenses can be implanted in fellow eyes to give a patient a range of vision that will make them independent of glasses all of the time.

“However, I don’t ever promise freedom from glasses,” Dr. Berdahl said. “That may be my internal goal, but I always make sure patients accept the possibility that they may need to wear glasses some of the time.”

The “visually demanding” individual represents another scenario for patient dissatisfaction after presbyopia-correcting IOL surgery. Dr. Berdahl described this group as people who want ultra-crisp distance vision.

To screen for them preoperatively, he asks: “Are you visually picky?”

“Usually patients say they don’t know what I mean, and then I ask if when they got new glasses, they would return multiple times for adjustments,” he said. “If they say ‘yes,’ I explain that I am not sure they will be happy with a presbyopia-correcting IOL because I cannot make adjustments for them the way it was done with their glasses.

“I remind them that they have to decide if they are interested in increasing their visual freedom and flexibility in exchange for some decrease in visual quality,” Dr. Berdahl added.

“Then, a presbyopia-correcting IOL might be a good fit for them.”

Patients who are unhappy postoperatively with their distance vision are asked to look through a pair of +3.0 D glasses to show them the benefit they have with their presbyopia-correcting IOL.

Dr. Berdahl tells them that the lens can be exchanged to provide better distance vision, but that they will lose their ability to see without correction at near and intermediate distances.

“This demonstration reminds patients in a very tangible way of what they got with the IOL they chose,” Dr. Berdahl said. “Then I explain how time can be our friend before discussing an IOL exchange.”

‘I always make sure patients accept the possibility that they may need to wear glasses some of the time.’ — John P. Berdahl, MD

Posterior capsule opacification (PCO) is another common issue underlying vision complaints among patients with a presbyopia-correcting IOL. Because IOL exchange is much more difficult once the posterior capsule is open, surgeons should be absolutely certain that PCO is a patient’s problem and that treating it is likely to make the patient happier with his or her vision.

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This article was adapted from Dr. Berdahl’s presentation at the 2017 meeting of the American Society of Cataract and Refractive Surgery. He is a consultant to and/or receives lecture fees from companies that market presbyopia-correcting IOLs.
EDOF LENSES
(Continued from page 16)

Sulcus refractive IOLs solid option for presbyopia, other refractive errors

implantation of a sulcus-supported, pseudophakic supplementary IOL can be a safe, effective method for improving vision in eyes with residual refractive error after cataract extraction, refractive lens exchange, or keratoplasty, said Thomas Kohnen, MD, PhD. It also can be used to provide reversible presbyopia correction.

“Sulcus refractive IOLs can be considered as an alternative to spectacle, contact lenses, incisional techniques, and laser-based corneal surgical procedures to correct residual refractive error that is having a negative impact on visual quality,” said Dr. Kohnen, professor and chairman, Department of Ophthalmology, Goethe University, Frankfurt, Germany.

In the literature and in his experience, complications with add-on IOLs are rare, he noted. “Antero-posterior and rotational movement of the IOL can occur,” he added. “Because of how these lenses are designed, we almost never see interlenticular opacification or pigment dispersion . . . associated with piggyback lenses.”

Pseudophakic supplementary IOLs were introduced in Europe about 10 years ago, and are available from two manufacturers in aspheric, toric, and multifocal versions. HumanOptics (Erlangen, Germany) was the first company in the market with its add-on IOLs. The lenses have a 7-mm silicone optic and PMMA haptics with a 0° angulation. The lenses have an overall diameter of 14 mm, and the multifocal version is based on diffractive technology. Sulcoflex IOLs from Rayner (Hove, United Kingdom) are another option. These lenses are made of a hydrophilic acrylic material and have specially designed waved haptics with a 10° angulation. The optic has a 6.5-mm diameter with a convex-concave structure, and the overall lens diameter is 13.3 mm. The multifocal IOL has a refractive design.

“All of the supplementary IOLs are relatively thin because they are designed to correct lower amounts of residual refractive error,” Dr. Kohnen said.

Papers reporting on the use of an add-on multifocal IOL include a prospective study by Gerten et al. that included 56 eyes of 30 cataract patients who received an aspheric silicone monofocal IOL in the capsular bag, followed by sulcus placement of the add-on multifocal lens [J Cataract Refract Surg. 2009;35:2136-2143]. Results from follow-up to 3 months showed the dual IOL implantation led to improved distance, intermediate, and near UCVA, and there were no major complications. Liekfeld et al. reported a study comparing groups of cataract surgery patients who had bilateral implantation of a diffractive multifocal IOL in the capsular bag or a monofocal IOL in the bag followed by sulcus placement of an add-on diffractive multifocal IOL. The study included 26 patients and found the two techniques were associated with equivalent visual performance, and there were no significant differences in patient satisfaction between groups.

I recommend waiting a few weeks after implanting your first EDOF lenses to evaluate the initial outcomes. In my early cases, the day 1 outcomes were slightly myopic, which at first led me to believe my power calculations might be off. However, I found that patients settled toward emmetropia within 2 weeks. As with any other premium lens, patient counseling and good measurements are critical to good outcomes with EDOF lenses. In order to really embrace this technology, it is important to have a good early experience, so choose your cases wisely and invest the time to take a careful approach preoperatively.

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IOL selection important in patients with concurrent retinal disease

Additional considerations must be made to allow for potential, future procedures

By Steve Lenier; Reviewed by Timothy W. Olsen, MD

IN PATIENTS WITH retinal disease, or a risk of retinal detachment, certain IOLs should be avoided due to their potential complications, said Timothy W. Olsen, MD, professor of ophthalmology, chairman emeritus, Emory University, Atlanta.

In routine cases with no retinal disease, or in low-risk eyes, surgeons should choose the lens they feel best meets the patient’s need. However, when risks of retinal disease, retinal detachment (such as in high myopia with extensive lattice degeneration), macular disease, or a strong family history of macular disease, certain types of IOLs can cause complications.

IOLS TO AVOID

IOLs that should be avoided include silicone, multifocal, or hydrophilic acrylic lenses. In general, plate-style lenses are more likely to dislocate into the posterior segment.

Silicone lenses are not optimal if the patient may need retina surgery in the future, Dr. Olsen said. These lenses can make vitreous surgery difficult by limiting visibility, and the lens may need to be explanted. Further, silicone oil adheres to these lenses and diminishes the patient’s quality of vision.

In patients with maculopathy, or potential for macular disease, multifocal IOLs are a concern. These IOLs can make vitreous surgery difficult by limiting visibility, and the lens may need to be explanted. Further, silicone oil adheres to these lenses and diminishes the patient’s quality of vision.

In patients with maculopathy, or potential for macular disease, multifocal IOLs are a concern. These IOLs carry a higher risk of being unhappy with the quality of their vision. The reason for this is not yet known.

“It may be due to a reduced level of contrast sensitivity in some cases and exaggerated metamorphopsia in cases of epiretinal membranes or with macular edema,” Dr. Olsen suggested.

Hydrophilic acrylic lenses have a risk of opacities from calcification, which may necessitate lens replacement. If a patient receives an anterior or posterior segment gas bubble in the future, it can induce a calcification process and opacification in these lenses.

Another point to consider is whether to use blue-blocking IOLs. These IOLs reduce the amount of blue and violet (shorter wavelength) light in the eye. However, there is no consensus on the value of using these lenses.

Mainster and Turner provided a comprehensive discussion about this topic. They concluded that most age-related macular degeneration (AMD) occurs in phakic adults, 60 years and older, despite crystalline lens photoprotection that is greater than that of blue-blocking IOLs.

If light is involved in AMD pathogenesis, they explained, senescent crystalline lenses—and blue-blocking IOLs—cannot prevent it.

Considering the patient’s current and future eye health will provide the best information for proper IOL selection. There are clear reasons why certain lenses should not be used in some patients, and these should be discussed with the patient to allow them to be involved in the decision.

Reference


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This article was adapted from Dr. Olsen’s presentation at the 2017 meeting of the American Society of Cataract and Refractive Surgery. Dr. Olsen has no financial disclosures relevant to this topic.
Small-aperture IOL offers extended depth of focus, high satisfaction

Lens yields excellent visual performance, safety, tolerance to residual astigmatism at 6 months

**By Laird Harrison; Reviewed by Prof. H. Burkhard Dick, MD, PhD**

**A NOVEL** small-aperture IOL extends patients’ depth of focus as well as multifocal IOLs with fewer dysphotopsias, according to researchers.

In a prospective, open-label trial, the device (IC-8, AcuFocus) improved patients’ uncorrected distance visual acuity to 20/23, uncorrected intermediate visual acuity to 20/24, and near visual acuity to 20/30 in the implanted eyes.

“The IC-8 IOL is a great lens that is highly versatile,” said Prof. H. Burkhard Dick, MD, PhD, chairman of the University Eye Hospital Bochum, Germany, and principal investigator of a prospective, open-label trial of the AcuFocus product published in the July issue of the *Journal of Cataract & Refractive Surgery.*

“The pinhole only allows central focused light to reach the retina and blocks peripheral defocused light that degrades image quality,” Dr. Dick said. “This results in a high quality, extended depth of focus without blurry transition zones.”

**ABOUT THE DEVICE**

The IC-8 is a 1-piece hydrophobic acrylic posterior chamber IOL with an optic that contains an embedded mask with a 1.36-mm central aperture. The dimensions of the mask and aperture contained within the optic are based on that of the corneal diameter (Kamra, AcuFocus), with a smaller diameter and flatter radius of curvature to account for its more posterior placement within the eye.

It is CE marked and currently available in some European and Asia Pacific markets. The company plans to start a U.S. clinical trial in 2018.

The small-aperture lens will compete with multifocal and trifocal IOLs. These lenses provide good functional vision, but with the drawbacks of reduced contrast, visual disturbances and noncontinuous range of vision. Dr. Dick and his colleagues implanted the device in 1 eye each of 114 patients while implanting the fellow eyes with a variety of aspheric monofocal IOLs.

**TESTING SMALL-APERTURE LENS**

At 6 months, 105 patients were available for follow-up. Their mean age was 67.5 years and 57.1% were women. The mean uncorrected distance visual acuity in eyes with the small-aperture lens implanted improved from 0.57 to 0.06 logMAR. Mean uncorrected intermediate distance visual acuity improved from 0.66 to 0.08 logMAR. Mean uncorrected near visual acuity improved from 0.75 to 0.18 logMAR.

By comparison, the uncorrected distance visual acuity in the eyes implanted with the monofocal lenses improved from 0.61 to 0.03 logMAR. Uncorrected intermediate visual acuity in these eyes improved from 0.64 to 0.30 logMAR and uncorrected near visual acuity improved from 0.71 to 0.51 logMAR.

Binocular uncorrected distance visual acuity at 6 months was -0.056 logMAR, uncorrected intermediate vision was 0.043 logMAR and near vision was 0.160 logMAR.

By blocking peripheral defocused light rays, the small-aperture lens not only provides depth of focus, it also reduces dysphotopsias, particularly for patients with aberrated corneas like post-refractive or keratoconic patients, Dr. Dick said.

It also provides tolerance to corneal astigmatism up to 1.50 D and a functional range of vision even if the refractive target is missed by as much as 1.00 D MRSE, he said.

“Thus, it would be inaccurate to say that there are zero complaints of glare or halo, but the incidence and severity seem to be by far much less than other multifocal IOLs based on my personal experience,” Dr. Dick said.

In the study, patients rated their visual symptoms on a scale of 0 to 5 where 0 was no symp-

toms, 1 was very mild and 5 was very severe. They rated blurry vision a mean of 1.09, fluctuating vision 1.0, dry eye 1.4, glare 1.4, halo 1.1, double vision 0.2, and ghost images 0.1.

The researchers performed mesopic contrast sensitivity testing in a subgroup of 36 patients. The eyes with the monofocal IOL had significantly better contrast sensitivity than the eyes with the small-aperture IOL at 1.5 cpd, 3.0 cpd, 6.0 cpd, and 12.0 cpd.

Binocular contrast sensitivity without glare in eyes with the small-aperture IOL was similar to that in eyes with the monofocal IOL at all spatial frequencies.

Eyes with the monofocal IOL had significantly better monocular mesopic contrast sensitivity with glare than eyes with the small-aperture IOL eyes at 1.5 cpd, 3.0 cpd, and 6.0 cpd. At 12.0 cpd, the difference in contrast sensitiv-
ity between eyes with the small-aperture IOL and eyes with a monocular IOL was not statistically significant.

The 114 enrolled patients experienced 14 ocular adverse events: 9 in eyes with the small-aperture IOL and 5 in eyes with the monocofocal IOL. The only serious adverse event was 1 case of persistent macular edema in an eye with the small-aperture IOL, but researchers did not consider it to be related to the device.

Overall 88.5% of patients said they were satisfied, 5.5% were neutral and 5.8% were dissatisfied.

ADVANTAGES OF LENS
The small-aperture IOL appears to offer some advantages over other IOLs designed to correct for presbyopia, Dr. Dick said.

With multifocal lenses, the patient has to interpret in-focus images on top of out-of-focus images as the various optical zones focus light to different focal points, he explained.

“As a result, these lenses can achieve good vision at specific foci, however with the determent of visual symptoms,” he said. “The IC-8 IOL, with its small aperture, provides a continuous extended depth of focus that doesn’t overlay in-focus and out-of-focus images.”

The small-aperture IOL also provides a more complete range of vision than bifocal lenses, he said.

“Compared with trifocal IOLs the near focal point with the IC-8 IOL may not be quite as close, however the quality of vision with the IC-8 IOL is better,” Dr. Dick said.

In addition to cataract patients who do not want to use reading glasses, the lens is increasingly being used for patients who have undergone refractive surgery and in challenging eyes like iris trauma and keratoconic patients, and in complex cataract cases to decrease dysphotopsias, he noted.

“The lens can truly benefit a broad spectrum of patients,” Dr. Dick said.

CONTRAINDICATIONS
However, he cautioned that it is contraindicated in patients with untreated ocular surface disease, macular diseases or proliferative retinal disease.

Before surgery, he points out to patients that the lens is used monocularly and is paired with a high quality monofocal IOL in the fellow eye.

“If patients cover one eye and then the other to compare the different lenses, they may notice some differences in dimness between eyes,” he said. “Patients should be encouraged not to compare eyes as this will delay their natural adaption.”

Dr. Dick added that researchers are now evaluating the potential for bilateral implantation with the lens.

REFERENCE

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The study was supported by Acufocus. Dr. Dick is a member of the Acufocus Inc. medical advisory board.

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Centroid value, posterior cornea input adds game for toric calculators

Advances reconsider surgically induced astigmatism: mean versus median versus centroid

By Vanessa Caceres; Reviewed by Warren E. Hill, MD

CATARACT SURGEONS USING toric IOL calculators are more likely to have better outcomes when using a centroid value for surgically induced astigmatism (SIA), rather than a mean or a median value.

Warren E. Hill, MD, in private practice, Mesa, AZ, provided a comparison of toric IOL calculators and also how they differ.

He addressed the value that Douglas Koch, MD, of Houston, added to toric IOL calculations when he recommended the inclusion of posterior corneal astigmatism.

In addition, Dr. Hill noted that Graham Barrett, MD, of Perth, Australia, took this insight a step further by adding an algorithm to automatically calculate both the magnitude and the orientation of posterior corneal astigmatism as part of his popular Barrett toric calculator. Subsequently, other toric calculators are adopting this approach.

Dr. Hill provided an example of a series of toric IOL outcomes with the original Alcon Laboratories toric calculator and the Holladay toric calculator that did not include the posterior cornea.

“These calculations typically produced outcomes that were skewed in the same way,” he said. “The moment we added posterior cornea, toric IOL outcomes began to normalize.”

For SIA, it was previously popular to calculate the mean, or a median value, for a series of patients.

“Contrary to conventional wisdom, both the magnitude and the orientation of SIA is not always predictable from one patient to the next,” Dr. Hill explained. “For individual patients, the amount of SIA might be as low as 0.00 D to as high as 1.50 D. In addition, the orientation of SIA produced by the corneal incision is not always orthogonal. That was a surprise.”

The results depend in part on precise IOL alignment because there is a 3.3% loss of cylindrical power correction for every degree that the IOL is off-axis.

The Barrett toric calculator is currently the most advanced one we have,” Dr. Hill said. “[Dr.] Koch gave us the gift of the posterior cornea and [Dr.] Barrett made it practical for all of us.”

Dr. Hill also highlighted the currently available toric calculators in the United States, including the Bausch + Lomb Trulign, the Holladay IOL Consultant calculator, the Abbott Medical Optics calculator (Johnson & Johnson Vision Care), the updated Alcon calculator, and the Barrett toric calculator, available on the American Society of Cataract and Refractive Surgery website (www.ascrs.org/barrett-toric-calculator).

“The Barrett toric calculator is currently the most advanced one we have,” Dr. Hill said. “[Dr.] Koch gave us the gift of the posterior cornea and [Dr.] Barrett made it practical for all of us.”

CONTRARY TO CONVENTIONAL WISDOM, BOTH THE MAGNITUDE AND THE ORIENTATION OF SIA IS NOT ALWAYS PREDICTABLE FROM ONE PATIENT TO THE NEXT.’ — Warren E. Hill, MD

Warren E. Hill, MD

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This article was adapted from Dr. Hill’s presentation during Refractive Subspecialty Day at the 2016 meeting of the American Academy of Ophthalmology. Dr. Hill is a consultant for Alcon Laboratories.

TRANSITIONAL CONIC TORIC IOL ENHANCES TOLERANCE TO MISALIGNMENT

A NEW ABERRATION-FREE, transitional conic toric IOL (Precizon, Ophtec) with good rotational stability and tolerance to misalignment is providing excellent visual and refractive outcomes for patients with pre-existing regular corneal astigmatism undergoing cataract surgery in Europe.

“As little as 0.5 D of astigmatism can have a significant effect on the quality of vision after cataract surgery,” said José L. Güell, MD. “Toric IOLs are an option for accurate correction of pre-existing astigmatism.”

The results depend in part on precise IOL alignment because there is a 3.3% loss of cylindrical power correction for every degree that the IOL is off-axis.

Go to OphthalmologyTimes.com/ToricCone

CENTROID VALUE

Recently, surgeons have found that using a centroid value gives improved outcomes, Dr. Hill noted. A centroid value is the two-dimensional mean of SIA for a series of patients.

Using data from a large physician database of more than 35,000 cases, Dr. Hill observed that for the typical temporal clear corneal incision, the calculated centroid value generally ranges from 0.08 D to 0.14 D.

If a surgeon has not yet calculated a centroid value for a cataract surgery incision, he advised beginning with a centroid value of 0.12 D when using toric calculators. A centroid calculation can be carried out using a free tool (www.SIA-calculator.com).

take-home

Surgeons should use a centroid value for surgically induced astigmatism rather than a mean or median value when working with toric IOL calculators.
Exploring wider role for premium IOL implantation in glaucoma patients

Patient selection is key to both surgical success, satisfaction in this populace

By Fred Gebhart; Reviewed by Richard A. Lewis, MD

PATIENTS WITH glaucoma who need cataract surgery are no different than similar patients without glaucoma: Both groups expect a full range of vision after cataract surgery; neither group wants to be dependent on glasses, and both groups should be offered the most appropriate range of premium IOLs to meet those expectations.

“From the patient’s perspective, it’s all about the outcome,” said Richard A. Lewis, MD, co-founder of Sacramento Eye Consultants, Sacramento, CA.

“For the surgeon, managing all aspects of their refractive needs should be the obvious course,” Dr. Lewis said. “The premium lens—the right premium lens—has tremendous value in glaucoma.”

PREMIUM IOLs IN GLAUCOMA

Cataract surgery is the most common surgical procedure used in patients with glaucoma, as well as the safest and most effective procedure for restoring vision, Dr. Lewis noted.

The surprise, he said, is just how few glaucoma specialists complete cataract surgery by implanting a premium IOL.

When it comes to recommending an IOL, the status of the patient’s glaucoma is only one factor to consider. Just like any other patient planning cataract surgery, visual needs and preferences for or against glasses are the most important factors.

ASK THE RIGHT QUESTIONS

All of the usual questions about work and lifestyle apply regardless of the presence or absence of glaucoma. Always ask patients what they do for a living and what they do for fun, Dr. Lewis advised.

Also, ask if they do close-up detail work, such as needlework. It is just as important to explore their attitudes and preferences for glasses. Do they mind wearing glasses? Do they hate taking glasses on and off? The answers help shape IOL recommendations.

Traditional spherical IOLs offer monofocal vision. While traditional IOLs are less expensive than premium lenses, traditional lenses also provide less satisfactory visual outcomes compared with premium choices.

Too many glaucoma specialists forget that the premium IOL category includes several types of lenses. Each type of IOL offers a different combination of advantages and disadvantages that can make it more—or less—suitable for specific patients.

CANDIDATE SELECTION IS VITAL

Good patient selection is the key to both surgical success and patient satisfaction.

“For some ophthalmologists, ‘premium lens’ just means one thing, a multifocal lens,” Dr. Lewis said. “The premium lens category also includes aspheric lenses, accommodating lenses, and toric lenses. The bottom line is doing what is best and safest for the patient.”

Simply moving from a spherical IOL to an aspheric lens can improve contrast sensitivity by 25%. The improvement is especially notable in nighttime situations where high contrast is the norm.

Multifocal IOLs cause a decrease in contrast sensitivity, especially for refractive—rather than diffractive—lenses. Multifocal IOLs also degrade the visual image by solidifying multiple focal points.

Patients often ask for multifocal lenses to maximize their freedom from glasses after surgery. As long as the visual field is intact, multifocal image degradation is no more of a problem in the setting of glaucoma than in non-glaucomatous eyes.

For patients with more advanced glaucoma and who have already suffered visual field loss, multifocal lenses are probably not the ideal choice, Dr. Lewis said.

Patients with intraocular hypertension but no field loss may be candidates for a multifocal IOL, but multifocal IOLs should generally be avoided in patients with glaucoma who have cupping and/or visual field loss.

Toric and accommodative IOLs do not induce a loss of contrast sensitivity, Dr. Lewis noted, which gives them an advantage in visual acuity over multifocal lenses. For most patients with glaucoma, a toric IOL is probably the best overall choice to maximize the refractive correction.

“The toric lens manages astigmatic needs,” Dr. Lewis explained. “Glaucoma patients may have astigmatism naturally or from a previous glaucoma surgery. There are a few contraindications, but the vast majority of patients with glaucoma are good candidates for a toric lens.”

WHO MIGHT BE POOR CANDIDATES?

Pseudoexfoliation is the most common contraindication to a toric IOL, he continued.

Patients with zonular weakness are also poor candidates for a toric IOL because the lens is more likely to rotate after implantation. For patients with less than 1 D of astigmatism, astigmatic keratotomy—with or without a femtosecond laser—may be a viable alternative to a toric lens.

“Premium IOLs, especially toric IOLs, offer significant advantages for patients with glaucoma,” Dr. Lewis said. “But as with any lens, patient selection is key to achieving the best possible outcome.

“At the end of the day, our real job is to get patients the best possible vision we can,” he added. “For the vast majority of patients, a premium IOL is the most effective way to deliver on that promise.”

RICHARD A. LEWIS, MD

This article was adapted from Dr. Lewis’ presentation during Glaucoma Day at the 2017 meeting of the American Society of Cataract and Refractive Surgery. He is a consultant to Advanced Visual Science, Allergan, Alcon Laboratories, Allergan, CenterVue, Glaukos, and Ivantis.
Scleral tunnel-glued fixation advantageous for slipped IOLs

Technique provides short-term stability via tissue glue; long-term stability via compression

By Laird Harrison; Reviewed by Sumit “Sam” Garg, MD

A SCLERAL TUNNEL, “GLUED”

fixation technique works better than alternative fixation techniques in cases where IOLs cannot be placed in capsular bag or in the sulcus, according to Sumit “Sam” Garg, MD.

“It’s easier than suture fixation because you don’t have to deal with the spaghetti of the sutures and it will turn out to be more stable long-term,” said Dr. Garg, associate professor of ophthalmology, University of California, Irvine.

Popularized by Amar Agarwal, FRCOphth, Chennai, India, scleral tunnel fixation avoids the problem of long-term suture degradation, provides good short-term stability through the use of tissue glue, and creates long-term stability through compression of the haptics.

Running through the alternatives, Dr. Garg said iris fixation offers the advantages of avoiding scleral or conjunctival surgery, a small, self-sealing incision, and foldable IOLs with small-incision insertions. But iris fixation requires sealing incision, and foldable IOLs with small-incision insertions. But iris fixation requires normal iris anatomy and can chafe the iris, causing pupil ovaling, pseudophakodonesis, and/or increased risk of cystoid macular edema.

TECHNIQUE PROVIDES SEPARATION

Suturing the IOL to the sulcus provides the maximum separation from sensitive iris tissue and the corneal endothelium. There is no angle or trabecular involvement and no distortion of the pupil.

But scleral suturing is time consuming and demanding, and it can require a large incision. Potential suture exposure can lead to endophthalmitis, and late suture breakage can lead to IOL dislocation, Dr. Garg said.

He cited a recent study of 82 patients with scleral sutures. In a mean follow-up time of 83 months, 30.5% had ocular hypertension, 6.1% had suture breakage, 11% had suture exposure, 4.9% had retinal detachment (RD), 7.3% had cystoid macular edema (CME), and 3.17% had persistent elevated IOP.

“There have been a number of studies showing that sutures last 7-10 years and then have a higher chance of breaking,” Dr. Garg said. “In a 40- to 50-year-old patient, you’re pretty much assuring they’re going to need another surgery. If you’re not depending on the longevity of the suture, you have a better chance of a once-and-done surgery.”

The keys to Dr. Garg’s acceptance of scleral tunnel fixation are the low rate of complications and the tunnel—not the glue—that are responsible for long-term stability. Studies with high-speed videography have shown that unlike iris- and scleral-sutured IOLs, scleral-tunnel IOLs have minimal phacoedonesis, he said.

But scleral suturing is time consuming and demanding, and it can require a large incision. Potential suture exposure can lead to endophthalmitis, and late suture breakage can lead to IOL dislocation, Dr. Garg said.

A current or future bleb, previous surgery, a thin sclera, or insufficient vitrectomy can pose significant problems.

“Any procedure where you have disrupted the anterior hyaloid face, you have to be careful to do as complete a vitrectomy as possible,” Dr. Garg said. “You don’t want traction on the vitreous to cause cystoids macular edema and risk of infection.”

He also advised caution in conjunctivitis with extensive scarring.

“If the conjunctiva is scarred down, this procedure becomes more difficult because the conjunctiva has to be lifted up,” said Dr. Garg.

“If someone has really scarred down, that’s where an alternative may be the better choice.”

Other relative contraindications include corneal decompensation or atrophic scleromalacia.

“Make sure the sclera is healthy and you have enough to tunnel the haptic in,” Dr. Garg advised. “We are limited by the length of the haptics, so you have to make sure it’s not a huge eye.”

AGARWAL STUDY

Dr. Agarwal and colleagues followed 208 eyes in 185 patients for 17 months and recorded a low incidence of complications. Early on, 6% had corneal edema, 2% had epithelial defects, and 2.5% had grade 2 anterior chamber reactions. Later, 0.4% had hyphema, 0.4% of haptics broke, and 1% of haptics were deformed.

Another 4.3% had optic capture, 3.3% IOL decentration, 2% haptic extrusion, 1.4% subconjunctival haptics, 2% macular edema, and 2% pigment dispersion. Re-operation was required in 7.7% of patients.

Best-corrected visual acuity (BCVA) was 20/40 or better in 40% of this group and 20/60 or better in 49%.

In a second cohort of 60 eyes with a fol-
low-up of 5 years, Dr. Agarwal and colleagues reported that 35% had optic tilt of roughly 3º between the IOL and the iris. The mean residual cylinder was 0.5 D (±0.5 D). There was no correlation with BCVA.

“We don’t have really long-term data on the technique,” Dr. Garg said. “You can get migration of the haptics out of the tunnel, which on occasion has to be retunneled, or a patch graft has to be placed to make sure it doesn’t extrude through the conjunctiva. But by and large, it’s a really stable method of fixation.”

He described a recent case of an IOL that stayed intact even though the penetrating keratoplasty wound dehisced after a patient bumped his eye against the ledge of a table. “The scleral fixation of the haptics actually prevented dislocation of the IOL,” Dr. Garg said.

**PROCEDURE POINTS**

Scleral tunnel fixation is easiest done with an assistant and it requires coaxial micro instruments, including a micro-forceps for the anterior segment, an anterior chamber maintainer, and fibrin glue. The procedure will not work with every IOL, Dr. Garg added. “You want something with a relatively resistant haptic, something that can be bent and maintains its shape,” he said.

He recommended an acrylic optic, polyvinylidene fluoride haptic IOL (Aaren EC-3 PAL, Carl Zeiss Meditec). Dr. Garg advised making sure the haptics are 180º apart. Grab the haptic during insertion and try not to lose it once it is externalized. The sclerostomy should only be about 23-gauge, he said. Dr. Garg uses a scleral scale ruler. In the case of a large, white-to-white measurement, he recommended orienting the haptics vertically.

“Even though this is called a ‘glued’ IOL, it’s not really glued long-term,” Dr. Garg explained. “The glue is meant for initial fixation and healing. The fixation is because of the haptic in the scleral tunnel. “The glue will dissolve over the first week to two,” he said. “You could do it without glue if you have to. I use a vicryl suture to fixate the haptic just to provide short-term fixation while the haptic secures itself long-term.”

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**NEW IOL OFFERS FULL-DISTANCE, GOOD INTERMEDIATE DISTANCE**

**PRESBYOPIA PATIENTS HAVE CHANGED.** They are younger than ever, more active than ever before, and they have more treatment options than ever before.

“There is an intense amount of interest in helping our patients who have cataract surgery to lessen their dependence on glasses postoperatively,” said Bret L. Fisher, MD, medical director, Eye Center of North Florida, Panama City. “As practicing ophthalmologists, we have been looking for lenses that offer solutions for our patients without too much compromise and that allow them a full range of vision without causing other problems.”

Dr. Fisher helped introduce the first in a new family of ActiveFocus IOLs (AcrySof IQ ReStor +2.5 D IOL, Alcon Laboratories) during the 2017 meeting of the American Society of Cataract and Refractive Surgery. This new lens design offers patients full-distance vision plus intermediate vision as close as 21 inches.

“This is the first multifocal lens implant that is truly distance-dominant with 100% distance vision in its center portion,” Dr. Fisher explained.

Go to OphthalmologyTimes.com/DistanceIOL
Managing nonresponsive bacterial keratitis cases

Better diagnosis can lead to better treatment; new therapies continually in development

By Vanessa Caceres; Reviewed by Eduardo C. Alfonso, MD

Nonresponsive bacterial keratitis requires an accurate diagnosis so clinicians know how to treat it. New treatment possibilities are continually in development, including molecular-targeted therapy, the cautious use of topical corticosteroids, corneal crosslinking for superficial keratitis, and biologicals, said Eduardo C. Alfonso, MD.

Regarding the public health problem associated with bacterial keratitis, “information from the Centers for Disease Control shows that there are 1 million [visits] for keratitis and other contact lens-related problems [seen annually],” said Dr. Alfonso, the Kathleen and Stanley J. Glaser Chair in Ophthalmology; professor and chairman, Department of Ophthalmology; and director, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine.

An analysis of nonresponsive bacterial keratitis at Bascom Palmer between 2011 to 2015 found that 75% of cases were bacterial; 43% were gram-negative; 31% were gram-positive; and 1% was mycobacteria. The remaining 25% were nonbacterial.

“The bacterial species isolated were Pseudomonas and Staphylococcus, with a variety of gram-positive and negative species,” he added.

When considering why bacterial keratitis may be nonresponsive, it is important to remember that in only 50% of cases will clinicians identify an organism, Dr. Alfonso said.

“Consider that 80% will be treated empirically without any microbiologic studies,” he said. “It’s in this group where we’ll find most cases of poorly responsive presumed bacterial keratitis.”

Looking at treatment, fluoroquinolones are the choice for bacterial keratitis, Dr. Alfonso said. However, aminoglycosides and fortified antibiotics also continue to play a role.

Research at Bascom Palmer has found that when culturing patients on prior treatment, those on monotherapy were more likely to have gram-positive and gram-negative isolates. There was a higher incidence of cultural-positive results if two or three antibiotics were used.

“There’s also a greater chance that the reason [the bacterial keratitis] didn’t respond is because it was a nonbacterial ulcer, most likely caused by fungi,” Dr. Alfonso said. “It needs to be pointed out that these are trends and are not statistically significant.”

Vancomycin is often the treatment of choice for gram-positives and cases of in vitro resistance. For mycobacteria, which are not seen that often, clarithromycin and amikacin are the drugs of choice, Dr. Alfonso said.

WHAT CAN BE DONE

By Vanessa Caceres

Eduardo C. Alfonso, MD, discusses what to do about antibiotic resistance with nonresponsive bacterial keratitis. Go to OphthalmologyTimes.com/Nonresponsive

Top Ten Bacterial Keratitis Pathogens

<table>
<thead>
<tr>
<th>RANK</th>
<th>PATHOGEN</th>
<th>NUMBER</th>
<th>PERCENTAGE (ALL ISOLATES, N = 1495)</th>
<th>PERCENTAGE (BACTERIA ISOLATES, N = 1119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pseudomonas aeruginosa</td>
<td>405</td>
<td>27%</td>
<td>36.2%</td>
</tr>
<tr>
<td>2</td>
<td>Staphylococcus aureus</td>
<td>234</td>
<td>15.6%</td>
<td>20.9%</td>
</tr>
<tr>
<td>3</td>
<td>Serratia marcescens</td>
<td>78</td>
<td>5.2%</td>
<td>7.0%</td>
</tr>
<tr>
<td>4</td>
<td>Streptococcus viridans group</td>
<td>76</td>
<td>5.1%</td>
<td>6.8%</td>
</tr>
<tr>
<td>5</td>
<td>Coagulase Negative Staphylococci (S. epidermidis-58%)</td>
<td>67</td>
<td>4.5%</td>
<td>6.0%</td>
</tr>
<tr>
<td>6</td>
<td>Enterobacteriaceae, other</td>
<td>61</td>
<td>4.1%</td>
<td>5.4%</td>
</tr>
<tr>
<td>7</td>
<td>Gram-Negative Bacilli, other (S. maltophilia, Achromobacter, etc.)</td>
<td>57</td>
<td>3.8%</td>
<td>5.1%</td>
</tr>
<tr>
<td>8</td>
<td>Streptococcus pneumoniae</td>
<td>39</td>
<td>2.6%</td>
<td>3.5%</td>
</tr>
<tr>
<td>9</td>
<td>Moraxella species</td>
<td>33</td>
<td>2.2%</td>
<td>2.9%</td>
</tr>
<tr>
<td>10</td>
<td>Mycobacterium species other than Mtb-MOTT</td>
<td>21</td>
<td>1.4%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

(Source: Bascom Palmer Eye Institute 2011-2015; Chart courtesy of Eduardo C. Alfonso, MD)
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*Ophthalmology Times*
Considering PDGF treatment prior to anti-VEGF therapy for AMD patients

Anti-platelet-derived growth factor therapy may lead to better results in AMD patients

By Vanessa Caceres; Reviewed by Pravin U. Dugel, MD

**Pre-treatment with** an anti-platelet-derived growth factor (PDGF) prior to anti-vascular endothelial growth factor (VEGF) therapy is being explored as a novel approach in a pilot study.

The pre-treatment strategy led to better visual acuity outcomes in patients with treatment-resistant neovascular age-related macular degeneration (AMD) after 18 months in a 24-month pilot study, said Pravin U. Dugel, MD.

Every time an anti-VEGF is injected, PDGF is upregulated, explained Dr. Dugel, managing partner, Retinal Consultants of Arizona, Phoenix, and clinical professor, USC Eye Institute, Keck School of Medicine, Los Angeles.

“This PDGF upregulation will allow for a protective armor of pericytes to cover the neovascular complex, making it more resistant to further anti-VEGF therapy,” Dr. Dugel said. “It makes sense to consider pre-treatment [with an anti-PDGF] to render the neovascular complex more sensitive and vulnerable to further VEGF therapy.”

**Improvements in visual acuity**

This is what prompted the study done at Dr. Dugel’s practice, which involved 30 patients with AMD, 27 of whom were treatment-resistant and who had persistent or recurrent fluid and no improvement in visual acuity.

The average patient age was 80 years old. Patients had an average of 25 prior injections, and the treatment interval was less than 6 weeks in almost 90% of patients.

Dr. Dugel previously reported a 6-month visual acuity improvement of 3.7 letters of vision for patients with no pre-treatment compared with 15.1 letters of vision for patients who did receive pre-treatment.

The 18-month results showed a mean improvement of 1.6 letters of vision for no pre-treatment compared with a mean of 20.3 letters of vision for the group that did receive pre-treatment.

**Multi-modal imaging as predictor**

The best predictor of response was multi-modal imaging, said Dr. Dugel, noting that patients were analyzed based on optical coherence tomography (OCT), fluorescein angiography, and optical coherence angiography.

The patients who fared best tended to be dry by conventional OCT and had no leakage by fluorescein angiography, but they did show flow by optical coherence angiography.

“There appears to be an OCT and vision disconnect,” Dr. Dugel said.

Normalized vessels may be necessary for this wound-healing response after the pruning of immature vessels, and there may be a “Goldilocks” principle of flow—where neither too little nor too much is ideal.

“We do have a large structure and function disconnect,” Dr. Dugel said, “but we’re in the precipice of an imaging revolution that will bridge the disconnect and force us to reconsider our goals in patients with macular degeneration.”

**PRAVIN U. DUGEL, MD**

e: pdugel@gmail.com

This article was adapted from Dr. Dugel’s presentation during Retina Subspecialty Day at the 2015 meeting of the American Academy of Ophthalmology. Dr. Dugel reports financial interest with Abbott Medical Optics, Aeolus, Alcon Laboratories, Alimera Sciences, Allergan, Dighyst, Genentech, Novartis, Ophthotech, Ono, Regeneron, and ThromboGenics.
Topical cetirizine latest therapy to treat allergic conjunctivitis

Agent offers rapid onset of action for reduced ocular itching

By Cheryl Guttman Krader

ORAL CETIRIZINE IS ONE of the most used oral medications for treatment of allergic rhinitis. In May 2017, the FDA approved the first ophthalmic formulation of the second-generation histamine-1 (H1) receptor antagonist for use in treating ocular itching associated with allergic conjunctivitis.

The approval was based on an NDA package that included data demonstrating the efficacy, safety, and tolerability of cetirizine ophthalmic solution 0.24% (Zerviate, Nicox) in 3 phase III randomized, double-masked, vehicle-controlled clinical trials using the conjunctival antigen challenge (CAC) model.

The results showed that cetirizine had a rapid onset of action for mitigating allergen-induced conjunctival itching and prolonged activity, demonstrating statistically and clinically significant superiority to vehicle at evaluations performed 15 minutes and 8 hours after instillation of the topical drop.

Cetirizine is recommended for twice daily dosing, and its safety and effectiveness were established in pediatric patients 2 years of age and older.

“We are excited to bring this product to market because it is the only topical ocular antihistamine containing cetirizine, an active ingredient with a long track record of safe and effective oral use,” said Michele Garufi, chairman and CEO, Nicox, Valbonne, France. “Cetirizine has been available for oral use for over 20 years. The compound is well known to ophthalmologists, allergists, pediatricians, and other primary care providers.”

PHASE III STUDIES

Participants in the phase III CAC studies had a history of allergic conjunctivitis. They were treated with vehicle or cetirizine, challenged with the allergen 15 minutes and 8 hours later, and evaluated for signs and symptoms of an allergic response at various intervals post-allergen challenge.

Ocular itching, the primary efficacy endpoint, was evaluated using a 5-point severity rating scale at 3-, 5-, and 7-minute, post-allergen challenge. Evaluation of secondary endpoints showed that cetirizine demonstrated statistical superiority to vehicle at 15 minutes and 8 hours after administration for chemosis, eyelid swelling, and ear or palate itching.

In total, topical cetirizine was evaluated in 7 clinical trials in which 840 patients with allergic conjunctivitis or at risk of developing allergic conjunctivitis received the active medication or vehicle. The most commonly reported adverse reactions, which occurred in about 1% to 7% of subjects treated with either topical cetirizine or vehicle, were ocular hyperemia, instillation site pain, and reduced visual acuity.

Animal models show that cetirizine is selective for H1 receptors and has negligible anticholinergic and antiserotonergic activity.

The ophthalmic formulation of cetirizine was developed by Aciex Therapeutics, a company founded by Ora (Andover, MA). Nicox (Paris, France) acquired Aciex Therapeutics in 2014. The company intends to partner the commercialization rights to cetirizine in the United States.

in case you missed it

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- **Novel treatment options for IOP involve range of independent factors** [Page 12](#)
- **Which IOLs to avoid using in patients with retinal disease** [Page 19](#)
- **Small-aperture IOL offers high patient satisfaction** [Page 20](#)

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