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WARNING: The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician’s microscope view.

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REFERENCE UNIT measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.

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REFERENCE UNIT Surgical Plan can be overlaid on a computer screen or the physician’s microscope view.
IOL system a novel surgical treatment for dry AMD

Intraocular mini-telescope opens pathway for cataract surgery patients with vision loss related to macular disease

By Cheryl Guttman Krader;
Reviewed by Pablo Artal, PhD; Fritz Hengerer, MD, PhD; and Bobby Qureshi, MD

LONDON ::
A NEW INTRAOCULAR mini-telescope (iolAMD, London Eye Hospital Pharma) offers significant surgical and optical advantages compared with previous technology, and its features make it an exciting advance for cataract surgery patients with vision loss related to macular disease.

“The new IOL allows for happy patients, because it is associated with faster visual rehabilitation compared with previous intraocular telescopes and better quality vision,” said Bobby Qureshi, MD, consultant ophthalmic surgeon, and chief medical officer and founder, London Eye Hospital Pharma, London.

“In addition, it makes for happier surgeons,” Dr. Qureshi added. “The implantation procedure is simple and fast, has a short learning curve because it involves existing skills, and it has safety advantages because the lenses are injected through a small incision and situated in the posterior chamber, away from sensitive corneal structures.”

 “[The innovation] is the first patient- and surgeon-friendly procedure to address the symptoms of dry age-related macular degeneration (AMD),” said Rob Hill, chief executive officer, London Eye Hospital Pharma, London.

AMD is the most common cause of blindness in people over age 55 in the developed world, with more than 20 million sufferers in the United States and between 200 million to 300 million worldwide. It is estimated that by 2020, there will be nearly 30 million cases of AMD in the United States alone.

The platform is CE marked and commercially available in some European countries, but not FDA approved. It is the product of a collaboration between Dr. Qureshi and Pablo Artal, PhD. The goals were to create a system that would be easy to implant through a small incision of the cornea.

(Continues on page 24: Mini-telescope)
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Resident Writer's Award

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To watch a treatment for complex tube erosion, go to http://bit.ly/1oRA3gi
(Video courtesy of Davinder Grover, MD, MPH)

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Should ophthalmologists be required to take courses on marijuana?

By Peter J. McDonnell, MD
director of the Wilmer Eye Institute,
Johns Hopkins University School of Medicine, Baltimore, and chief medical editor of Ophthalmology Times.

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

AS EVERYONE KNOWS, there are just not enough hours in the day to do everything—most especially, to read all the various medical journals and textbooks that accumulate on our desks. Earning continuing medical education (CME) credits, learning new electronic medical record systems, and managing various time-intensive requirements to renew board certifications add to the perception of many physicians they are on a treadmill that never slows.

Like all ophthalmologists, I budget copious time to read each and every issue of Ophthalmology Times from cover to cover. Lately, I find that reading a daily newspaper is sometimes too much of a luxury, and typically I simply look at the headlines, skim the first few sentences, and move on the next article. Five minutes max to read the entire newspaper each morning, then out the door to get to my office.

A recent piece in The Baltimore Sun, however, demanded that I spend the time to read it carefully. Entitled, “Doctors Need Marijuana Training,” read the commentary responds to recent legislation passed in my state enabling physicians to prescribe marijuana for medical purposes. It seems little to ask that physicians complete training in addiction and marijuana effects before prescribing it to the citizens of Maryland.” The correspondent is calling for standard courses in which so many physicians in dark rooms are bombarded with PowerPoint slides, with brief breaks in the atrium to consume weak coffee and tasteless Danish pastry.

VALUE TO EYE DISEASE?

The cost-benefit of these newly required courses would be poor for ophthalmologists, as to my eye the data supporting the value of marijuana in the management of eye disease are suspect at best. The California Medical Association, however, lists glaucoma as No. 7 among twelve “serious medical conditions” meriting a medical cannabis card. While that state notes “physicians will have to keep abreast of emerging literature on the subject of medical cannabis,” I do not see it mandating courses as proposed above for Maryland physicians.

No doubt some ill patients benefit from this treatment. A recent study published in JAMA Internal Medicine (http://bit.ly/1pY28Rd) reported that the yearly rate of opioid painkiller overdose deaths in states with medical marijuana laws was about 25% lower, on average, than the rate in states without these laws.

There is an important lesson here for busy ophthalmologists: before rushing to sign up for a class entitled “Marijuana Training,” read the fine print in the course description.

Reference


NOVEMBER 15, 2014 :: Ophthalmology Times

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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Ophthalmology Times’ vision is to be the leading content resource for ophthalmologists. Through its multifaceted content channels, Ophthalmology Times will assist physicians with the tools and knowledge necessary to provide advanced quality patient care in the global world of medicine.
A pharmacological approach to dry eye syndrome in GVHD

Case of graft-versus-host disease often needs multiple available combination of treatments to control symptoms, progression

By Seanna Grob, MD, MAS, and Reza Dana, MD, MPH, MSc

A 65-YEAR-OLD MALE with history of multiple myeloma and acute myeloid leukemia now status post multiple bone marrow transplants (including two allogeneic and 2 autologous transplants) presented for evaluation of dry eye symptoms and photophobia that worsened after stopping oral Tacrolimus, which he was taking for graft-versus-host disease (GVHD) prophylaxis. The patient’s visual acuity was 20/50 in the right eye and 20/100 in the left eye. Schirmer’s test was zero in both eyes. He had corneal fluorescein staining (National Eye Institute grading scale) of 12/15 in the right eye and 10/15 in the left eye with elevated subepithelial opacifications consistent with Salzmann degeneration. The patient was treated with punctal cautery, anakinra 2.5% three times a day, autologous serum tears, and Boston Sight PROSE lenses. The patient also used lubrication eye drops during the day and ointment at night. After close evaluation for a year, with the PROSE lenses in place, his vision improved to 20/25-3 in the right eye and 20/20-3 in the left eye. The treatment of dry eye disease in the setting of GVHD is complicated and requires close monitoring by an experienced cornea specialist and often needs a combination of multiple available treatments to control symptoms and disease progression.

Abstract

A 65-YEAR-OLD MALE with history of multiple myeloma and acute myeloid leukemia now status post multiple bone marrow transplants (including two allogeneic and 2 autologous transplants) presented for evaluation of dry eye symptoms and photophobia that worsened after stopping oral Tacrolimus, which he was taking for graft-versus-host disease (GVHD) prophylaxis. The patient’s visual acuity was 20/50 in the right eye and 20/100 in the left eye. Schirmer’s test was zero in both eyes. He had corneal fluorescein staining (National Eye Institute grading scale) of 12/15 in the right eye and 10/15 in the left eye with elevated subepithelial opacifications consistent with Salzmann degeneration. The patient was treated with punctal cautery, anakinra 2.5% three times a day, autologous serum tears, and Boston Sight PROSE lenses. The patient also used lubrication eye drops during the day and ointment at night. After close evaluation for a year, with the PROSE lenses in place, his vision improved to 20/25-3 in the right eye and 20/20-3 in the left eye. The treatment of dry eye disease in the setting of GVHD is complicated and requires close monitoring by an experienced cornea specialist and often needs a combination of multiple available treatments to control symptoms and disease progression.

Pathophysiology of Acute and Chronic GVHD


BOSTON ::

A 65-YEAR-OLD MALE was referred to the Cornea and Refractive Surgery Clinic at Massachusetts Eye and Ear Infirmary for evaluation of decreased vision, sensitivity to light, and the sensation of dryness in both eyes.

The Pathophysiology Times Resident Writer’s Award Program is a unique recognition opportunity designed to promote excellence in Ocular Surface Disease education. It was created to acknowledge outstanding case identification and written presentation skills in ophthalmology residents.

Bradley Shoss, MD, of Washington University in St. Louis, is the first-place winner of the publication’s 2014 Resident Writer’s Award Program. Dr. Shoss’ winning submission—“Sniffing Up The Wrong Tree”—is featured at http://bit.ly/1xenlzd.

The third-place winner is Evan Warner, MD, of the University of Wisconsin, with his entry, “Not Just Dry Eyes.” Watch for Dr. Warner’s submission in an upcoming issue.

To read all of the case study submissions in this year’s Ophthalmology Times Resident Writer’s Award Program, visit http://bit.ly/1tAgVVy.

Unfortunately, he developed therapy-related acute myeloid leukemia 3 years prior to presentation, but successfully un-


**Approach to Therapy in Ocular GVHD**

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<th>1</th>
<th><strong>Lubrication and tear film preservation</strong></th>
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<tr>
<td>1</td>
<td>Non-preserved phosphate-free AT and ointments</td>
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<td>2</td>
<td>Punctal occlusion or cautery</td>
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<td>3</td>
<td>Mucolytic agents (e.g., Acetylcysteine 5-10%)</td>
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<td>Secretagogues (Pilocarpine or Cevimeline)</td>
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<th><strong>Prevention of tear evaporation</strong></th>
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<td>Warm compresses/Lid hygiene</td>
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<td>Topical ointments (e.g. erythromycin)</td>
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<td>Tetracycline antibiotics (doxycycline or minocycline)</td>
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<td>Macrolides (azithromycin)</td>
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<td>Flax seed oil or fish oils</td>
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<th>3</th>
<th><strong>Reduction in inflammation</strong></th>
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<tr>
<td>1</td>
<td>Topical cyclosporine 0.05% (CsA), consider high frequency</td>
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<td>2</td>
<td>Topical steroids</td>
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<tr>
<td>3</td>
<td>Interleukin-1 receptor antagonist (anakinra) 2.5%</td>
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<td>4</td>
<td>Tacrolimus (systemic and Topical)</td>
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<th><strong>Epithelial support</strong></th>
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<td>Autologous serum eye drops</td>
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<td>2</td>
<td>Bandage soft contact lenses</td>
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<td>3</td>
<td>Sceral lenses</td>
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<td>4</td>
<td>Boston Sight PROSE lenses</td>
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**EXAMINATION**

At this time the patient’s visual acuity was best corrected to 20/20 with pinhole to 20/50 in the right eye and 20/200 with pinhole to 20/100 in the left eye. The patient’s conjunctiva was injected and he had a low tear meniscus and rapid tear break up in both eyes. He had corneal staining (National Eye Institute grading scale) of 12/15 in the right eye and 10/15 in the left eye with elevated subepithelial opacifications consistent with Salzmann degeneration, more on the right than the left eye. Schirmer’s test was zero in both eyes. The patient had intraocular lens implants in both eyes. The pupils, motility, IOP, and dilated fundus exam were unremarkable.

**DIAGNOSIS AND DISCUSSION**

Given the patient’s clinical history and examination, the likely diagnosis was ocular GVHD in the setting of a recent allo-HSCT. GVHD is a common complication after allogeneic transplantation and frequently affects the skin, gastrointestinal tract and the liver.

Approximately 40% to 60% of patients who have received allo-HSCT are affected by ocular GVHD. Both conjunctival (hyperemia, serosanguinous discharge, pseudomembranes, fibrovascular membranes or cicatricial changes in chronic) and corneal (dry eye syndrome, epitheliopathy, corneal epithelial sloughing) findings occur in ocular GVHD.

Pharmacologic agents often used for the prophylactic treatment of systemic GVHD are calcineurin inhibitors, including cyclosporine and tacrolimus, combined with methotrexate. Our patient specifically noticed worsening symptoms of dry eyes after the tacrolimus was discontinued. Fortunately, he never developed systemic symptoms of GVHD. However, if other systemic GVHD findings are present, therapy commonly includes systemic steroids. In contrast, increasing systemic immunosuppression or the cumulative steroid dose is not recommended for the treatment of ocular GVHD. Treatment options focus on lubrication and tear film preservation, prevention of tear evaporation, reduction in inflammation, and epithelial support. Topical lubrication with non-preserved phosphate-free tears is almost always combined with other modalities. Therapies for tear preservation include punctual occlusion or thermal cautery, which can reduce suplemental tear dependence.

Also, the mucolytic properties of Acetylcysteine (5% to 10%) eye drops may be utilized in patients with adherent ocular surface filaments and oral secretagogues (pilocarpine or cevimeline) may contribute to the stimulation of tear flow.

Tear film instability and evaporative dry eye syndrome is closely associated with meibomian gland dysfunction (MGD). Treatments include warm compresses, lid hygiene, topical ointments such as erythromycin, tetracycline antibiotics (doxycycline or minocycline) and macrolides (azithromycin) for their anti-inflammatory effects, and flax seed or fish oil supplements.

Reduction in the inflammatory component of ocular GVHD and dry eye syndrome is also a key component of treatment. Topical cyclosporine (CsA) acts by inhibiting T-cell proliferation and their production and release of lymphokines and has shown some success in refractory ocular GVHD. High frequency (greater than twice daily) 0.05% CsA has shown improved symptoms and clinical signs of ocular disease.

Topical steroids may also be beneficial due to their anti-inflammatory properties, but ocular side effects limit their use, especially in patients with a history (including family history) of ocular hypertension or glaucoma. Short-term, pulse steroids can have therapeutic potential in acute disease, but are not the optimal approach for long-term disease control. Off-label use of topical 2.5% interleukin-1 receptor antagonist (IL-1Ra) (anakinra, formulated by the Massachusetts Eye and Ear Infirmary pharmacy department) has also shown promising results. Systemic tacrolimus (FK506), a calcineurin inhibitor, has a beneficial effect in some cases of ocular GVHD, most likely by improving tear film production.
RESIDENT WRITER

(Continued from page 7)

Topical use is still in its early stages of evaluation, but has shown some clinical evidence of efficacy in dry eye disease. Additionally, several other potential medications with anti-inflammatory properties are in the pipeline for use in dry eye disease.

Epithelial support can be achieved with autologous serum eye drops and special contact lenses. Autologous serum eye drops have shown beneficial effects in the treatment of severe dry eye related to GVHD. The serum contains epitheliopathogenic growth factors and other components essential for the health of the epithelial surface. However, use of serum tears requires specialized centers that can follow the regulations for drugs and blood products.

Contact lenses—including bandage soft contact lenses, scleral lenses, and PROSE (prosthetic replacement of ocular surface ecosystem)—have shown beneficial therapeutic effects in patients with severe dry eye and GVHD and can be an effective addition to the treatment plan.

Our patient was followed closely over the following year. Over this time, the topical steroids were tapered to reduce the cumulative dose of steroid. The upper puncta were cauterized during this period. Topical interleukin-1 receptor antagonist 2.5% three times a day was started in both eyes. Subsequently, the patient was started on autologous serum tears and was also fitted with Boston Sight PROSE lenses (Boston Foundation for Sight) in both eyes due to persistent symptoms of irritation and photophobia.

Currently, the patient is using Boston Sight PROSE lenses, Loteprednol (Bausch + Lomb) every other day, Refresh PM ointment at night, anakinra 2.5% twice a day (before and after the PROSE), autologous serum drops twice a day (before and after PROSE), and Tears Natural (Alcon Laboratories) unmedicated while in PROSE lenses every 2 hours in both eyes. The patient felt that with this regimen, his symptoms and vision had vastly improved. With the PROSE lenses in place, he had vision of 20/25-3 in the right eye and 20/20-3 in the left eye. He was still light sensitive with and without the lenses though. Future plans are to attempt taper of steroids further as tolerated.

C O N C L U S I O N

The treatment of dry eye disease in the setting of GVHD is a complicated condition that can have devastating effects if not diagnosed and treated in a timely fashion. Patients require close monitoring by an experienced cornea specialist and often need a combination of multiple available treatments to control symptoms and disease progression.

References


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**Writings document, express brotherly love in ophthalmology**

Exchange highlights collaboration, respect among three pairs of respected physicians

*Our Ophthalmic Heritage* By Morton F. Goldberg, MD, and David L. Knox, MD

---

**TAKE-HOME**

- This collection of correspondence demonstrates the love and admiration that these distinguished individuals, all of whom are highly respected in the history of ophthalmology, have held for one another.

---

**Extraordinary professional achievement is sometimes characterized by intensely warm and supportive interpersonal relationships.** Such relationships can involve internationally recognized ophthalmic luminaries, as revealed in the following letters and obituaries.

These writings represent examples of brotherhood in medicine and science. In mutually felt platonic love, the donor and the recipient inspire each other in spiritual and intellectual, rather than in physical, ways. These revealing documents demonstrate the love and admiration that these distinguished individuals, all of whom are highly respected in the history of ophthalmology, have held for one another.

In 1958, Frederick Verhoeff, MD, then 84 years of age, and professor of ophthalmic research at Harvard University, wrote his friend, Alan C. Woods, MD, director of the Wilmer Eye Institute at Johns Hopkins University, on the occasion of Dr. Woods’ 70th birthday. Here is his previously unpublished letter (Figure 1):

**November 29, 1958**

Dear Alan,

Gout, the decrepitudes of old age, and the refusal of my better half to permit the trip, prevent me from attending the dinner in honor of your seventieth birthday. I regret this exceedingly because you richly deserve this honor as you have the many others you have received. My regret is heightened by the fact that I feel under obligations to you. For you have praised me more highly, more often, and more publicly than has anyone else alive or dead, and I know you are responsible for my receiving two honors that I value highly. Since you always mean what you say, I am sure that I rank high in your estimation, as you do in mine. Unfortunately for the world, my opinion is not always general opinion, but I am sure that in this instance general opinion accords with my estimation of you even if it does not with your estimation of me.

Our careers have been similar in many respects, but I shall not compare them because comparisons are notoriously odious. However, I cannot refrain from pointing out that as regards physical beauty there is, of course, no comparison between us, and as regards physical prowess I am sure that if we had ever engaged in combat on the tennis courts I should have emerged the victor. As to physical afflictions, I have not yet undergone a cataract operation as you have twice bravely done, but you have not suffered the terrific pains of gout and those of a dislocated lumbar disc, as I have repeatedly had to do.

When, many years ago, I first became aware of your existence I was interested in you for three reasons. First, because of your research work which was attracting wide attention, second, because we were both Hopkins graduates, and a Hopkins graduate who became an ophthalmologist was then still a rare bird, and third, because I knew your father and greatly admired him. I met him often in Baltimore in 1899 and 1900, when you were a mere child and I was a beginner in ophthalmology, and soon discovered that he had a profound knowledge of this subject. He was very kind to me and gave me much encouragement. Afterwards I met him at many meetings of the A.O.S. and was greatly pleased when he was elected...
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president of this society in 1919. He would have been delighted to have known that his son Alan was to receive the same honor thirty-six years later.

Now on your seventieth birthday after the completion of your active services to hospital and medical school, you have many things to give you satisfaction. You know that everywhere these services have been recognized as outstanding. You are now free from your former vexatious responsibilities and obligations. You, your associates and former pupils constitute a mutual admiration society. Whenever you meet, you greet each other with pleasure. You are always welcome at your old haunts. You have the pleasure of having a successor whom you greatly esteem, and who greatly esteems you and always extends to you a warm reception. There are many other things you can contemplate with satisfaction, such as the numerous honors you have received.

You have the intellectual qualities I most admire; intellectual honesty and generosity, logical thought, perseverance against odds, courage to express your convictions even when they are unconventional, a researcher’s spirit uninfluenced by thoughts of personal gain, and a sense of humor that is delightful to all.

Alan, as the years have gone by I have grown to admire you more and more, and, I am almost too bashful to say, have also grown to love you.

Affectionately,

(signed) Fred

In 1956, the same Professor Alan Woods published an obituary about Jonas Friedenwald, MD, a distinguished ophthalmologist at the Wilmer Eye Institute in Baltimore. Dr. Friedenwald had been responsible for much of the knowledge at that time that was related to tonometry, eye pathology, and aqueous humor dynamics. Dr. Woods described him as a “many-faceted genius” . . . an ophthalmologist, physicist, pathologist, physiologist, and chemist.

Woods said that Friedenwald “possessed the sterling qualities of sincerity and tolerance, and these were responsible for the fact that he never excited jealousy or envy in his colleagues when honors were conferred on him. Rather, there was rejoicing that a man so loved should receive just recognition … he was not only my loyal friend, but also my faithful advisor, my colleague and my counselor. During this long association, my respect and my love for him grew. … I think of him as a great scientist, a true investigator, a splendid teacher, an inspiration to his pupils and his colleagues, and, above all, as a dearly loved friend.”

In 1958, Derrick Vail, MD, editor of the American Journal of Ophthalmology and former chairman of ophthalmology at Northwestern University Medical School, published a paean of praise about Sir Stewart Duke-Elder, Director of Research at the Institute of Ophthalmology in London and Surgeon-Oculist to the Kings and Queen of England, on the occasion of Sir Stewart’s 60th birthday. Sir Stewart was the author of the most influential multi-volume textbook in the history of ophthalmology.

Dr. Vail was 60, himself, and described the two of them as “united in age, in war, in work, and in friendship” (unpublished inscription in a privately bound volume). Dr. Vail’s publication ‘reads, in part, as follows:

I have tried to give here some idea of the two Stewart Duke-Elders, the scientist and the man, both of them modest and straightforward, but surprisingly different, for the one, judged from his writings, gives the impression of being very old, articulate, lucid, infinitely wise and learned; the other is youthful, exuberant, a delightful companion, far from austere; hospitable, generous, cosmopolitan, democratic, friendly, intellectual, earthy; a person with whom you get on a first-name basis, no matter what language you speak, straight away. We love both of him.

Sir Stewart replied in a handwritten letter (Figure 2), which is published here for the first time, as follows:

My dear Derrick,

Some men are so full, so rich that they give themselves wholly at each time of meeting. Each time you take leave of them, you feel it is of no importance whether the parting is forever. They come to you brimming over and leave you full overflowing. They live in a universe without boundaries. They do not become all the time they have spent in them. I am one of those very few.

Stewart

Continues on page 14: Writings
For patients with decreased tear production presumed to be due to ocular inflammation associated with Chronic Dry Eye

THE DRY EYE TREATMENT SHE NEEDS TODAY. BECAUSE TOMORROW MATTERS.

RESTASIS® twice a day, every day, helps patients experience increased tear production

Increased tear production was seen at 6 months.¹

Indication and Usage
RESTASIS® (cyclosporine ophthalmic emulsion) 0.05% is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Important Safety Information

Contraindications
RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

Warnings and Precautions
Potential for Eye Injury and Contamination: To avoid the potential for eye injury and contamination, individuals prescribed RESTASIS® should not touch the vial tip to their eye or other surfaces.

Use With Contact Lenses: RESTASIS® should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion.

Adverse Reactions
In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (upon instillation)—17%. Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Please see Brief Summary of the full Prescribing Information on adjacent page.

Reference: 1. RESTASIS® Prescribing information.

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APC23XQ4 141006
RESTASIS® (Cyclopentolate Ophthalmic Emulsion) 0.05% 

BRIEF SUMMARY—PLEASE SEE THE RESTASIS® PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

INDICATION AND USAGE

RESTASIS® ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or punctal plugs.

CONTRAINDICATIONS

RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNINGS AND PRECAUTIONS

Potential for Eye Injury and Contamination

To avoid the potential for eye injury and contamination, be careful to not touch the tip of the vial to any eye or other surfaces.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reininserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

ADVERSE REACTIONS

Clinical Trials Experience

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

In clinical trials, the most common adverse reaction following the use of RESTASIS® was ocular burning (17%). Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, ophthalmia, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurred).

Post-marketing Experience

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

Reported reactions have included: hypersensitivity (including eye swelling, urticaria, rare cases of severe angioedema, face swelling, tongue swelling, pharyngeal edema, and dyspnea), and superficial injury of the eye (from the vial tip touching the eye during administration).

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits, 100 mcg/kg/day), oral cyclosporine, USP, was embryotoxic and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryotoxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 1,000 and 10,000 times greater normalized to body surface area, respectively, than the daily human dose.

In a oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose. Offspring of rats receiving a 45 mg/kg oral dose of cyclosporine from Day 15 of pregnancy until Day 21 postpartum, at a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human dose.

Nursing Mothers

Cyclosporine is known to be excreted in human milk following systemic administration, but excretion in human milk after topical administration has not been investigated. Although blood concentrations are unattainable after topical administration of RESTASIS® ophthalmic emulsion, caution should be exercised when RESTASIS® is administered to a nursing woman.

Pediatric Use

The safety and efficacy of RESTASIS® ophthalmic emulsion have not been established in pediatric patients below the age of 16.

Geriatric Use

No overall difference in safety and effectiveness has been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Systemic carcinogenicity studies were conducted in male and female mice and rats. In the 78-week oral carcinogenicity study, at doses of 1.4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral carcinogenicity study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control value in the low-dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose-related. The low doses in mice and rats are approximately 80 times greater (normalized to body surface area) than the daily human dose of one drop (approximately 28 mcL) of 0.05% RESTASIS® twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Mutagenesis: Cyclosporine has not been found to be mutagenic/genotoxic in the Ames Test, the V79-Hprt test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the Dna repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes in vitro gave indication of a positive effect (i.e., induction of SCE).

Impairment of Fertility: No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 2,000 times the human daily dose of 0.001 mg/kg/day normalized to body surface area) for 9 weeks (male) and 2 weeks (female) prior to mating.

PATIENT COUNSELING INFORMATION

Handling the Container

Advise patients to not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. To avoid the potential for injury to the eye, advise patients not to touch the tip of the vial to the eye.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. Advise patients that if contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reininserted 15 minutes following administration of RESTASIS® ophthalmic emulsion.

Administration

Advise patients that the emulsion from one individual single-use vial is to be used immediately after opening for the administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

Rx Only

Allergan

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NOVEMBER 15, 2014 :: Ophthalmology Times

WRITINGS

(Continued from page 12)

In 2013, Torsten Wiesel, MD, then 89, wrote a eulogy in the form of a letter to David Hubel, MD, his long-term collaborator.1 Drs. Wiesel and Hubel had jointly received the Nobel Prize in 1981 for their research on ocular dominance columns in the brain. Dr. Hubel died in September 2013 at age 87, Torsten Wiesel’s memorial letter, typed near Thanksgiving 2013, reads as follows (Figure 3):

I am writing these words not to say farewell but to point out that you will always remain in my heart and mind as one of the best things that ever happened to me. Even more amazing is that our 20 years working together happened completely by chance. As you well remember, your move to the department of physiology at Hopkins medical school in 1958 was delayed because of lab renovations. Vernon Mountcastle asked Stephen Kuffler at the Wilmer Institute in ophthalmology, where I was a postdoc... if you could be with his group for a year. Steve was delighted, and the three of us met. None of us would have guessed how much that lunch meeting would change everything for us, as you and I over many cups of coffee that day began to carve out our future scientific course.

For inexperienced me, having just arrived from Sweden, you were as if from heaven coming with your famous tungsten microelectrode, which you had successfully used to record single visual neurons in the awake cat, made possible by elegant chambers machined on your lathe and mounted on the animal’s head (a method subsequently copied by colleagues from all over the world). Of course, more than all these technical and inventive skills, you came with a brilliant and creative mind.

Our real bonding was probably established while still at Hopkins when at...
November 15, 2014:: Ophthalmology Times


dawn we would go down through dark tunnels to the animal quarters to pick up a cat or monkey to be anesthetized and later prepared for the experiment. You often liked to tell the story when a spider monkey, to our amazement, skillfully used its long tail to pull the syringe with the anesthetic out of my hand as I tried to make the injection in its abdomen. You were also amused when in late night experiments I resorted to speaking Swedish.

These often more than 24-hour experiments were indeed tiring, but the long hours gave us time to learn to know each other well and above all explore ideas for future experiments and approaches. We were lucky to, over and over again, get exciting leads from our experiments, which in turn led to new questions and answers. Looking back on the years at Hopkins and Harvard, when experiments felt like great adventures with you rushing down the corridors screaming “come and look at this amazing cortical cell responding only to contour of a given orientation,” and again when we found binocular cells, and discovered the columnar organization of the visual cortex. We no doubt will always treasure those days and moments, to which nothing can ever match. You must agree that those were the “golden days.” You used to say that it was like rolling yarn into a big, beautiful ball.

Your ability to write so eloquently is without question that of a true master. This is in part due to your love of the English language—the Fowler and other books on writing were always on your desk. You will remember the press conference after the announcement of the Nobel prize, when I emphasized that from the very beginning your writing was critical for the understanding and acceptance of our papers.

You were always the messenger, and your talks and lectures about our work are still famous for their clarity and brilliance. You, yourself youthful. Many Harvard college students over the years have had the joy to listen and talk with you about science and many other interests.

For so many years, we experienced the absolute wonder and excitement of discovering something that nobody else knew. Now, we must leave it to the next generation, to probe into the secrets of nature yet to be revealed.

Looking back on our years together, you will always remain my much admired and beloved scientific brother.

Thank you,
(signed) Torsten N. Wiesel

LOVE AND ADMIRATION

Verhoeff’s letter to Woods was the result of two able, effective men having interacted in and for American ophthalmology for over forty years. Despite strong and sometimes ascerbic public utterances about all manner of things, their academic experience, authority, leadership and contributions to knowledge were their personally bonding forces.

Dr. Woods’ comments about Dr. Friedenwald are particularly poignant inasmuch as Woods was known to be a crusty individual, not given to public expressions of sentiment or emotion.

Derrick Vail’s comments about Sir Stewart Duke-Elder and his reply are expressions of respect, admiration and affection between two internationally famous ophthalmologists. They met intermittently during World War II and at numerous multinational gatherings. Duke-Elder, who was authoritative and prestigious, and Vail, who was a prominent editor and intellectual leader, admired the merits of each other’s work and thoroughly enjoyed each other’s company.

The length and depth of Torsten Wiesel’s memorial letter to David Hubel is rich in fact and nuance. The two men were research colleagues for more than 20 years and co-Nobel Prize winners. In his later years, Wiesel became a scientific leader, president of the Rockefeller Institute, and a global human rights advocate. Throughout his letter his beautiful memories of Hubel, an able, innovative, and stimulating young man who had original scientific ideas and who had guided peers and younger colleagues with no shred of hunger for personal power. Both men shared their scientific curiosity, their desire for new knowledge, and their affection for each other.

Thinking about these documents has heightened our awareness of the need to appreciate the importance of collaboration in science and medicine: Watson and Crick, Banting and Best, Curie and Curie, Penfield and Jasper, Cogan and Kuwabara, Ryan and Smith, Posner and Schlossman, Blalock and Taussig, along with others.

In many instances, intense and affectionate personal relationships favorably influenced their combined intellectual and clinical output.

Our hope in presenting this collection of documents expressing personal emotions is that more of these special relationships will surface and be published, giving to the world and young scientists evidence of how clinical and research colleagues can work, think, and love, with production of new and useful information for the betterment of all.

References

Join the discussion on how collaboration among ophthalmologists—either past or present—has changed the profession at Facebook.com/OphthalmologyTimes.

MORTON F. GOLDBERG, MD, is the Joseph Green Professor of Ophthalmology and former director, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore.

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NORMAN B. MEDOW, FACS, editor of the Our Ophthalmic Heritage, reviewed this column. He is director, pediatric ophthalmology and strabismus, Monmouth Hospital Medical Center, and professor of ophthalmology and pediatrics, Albert Einstein College of Medicine, Bronx, NY. He did not indicate a financial interest in the subject matter.

OT

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Entering the lion’s cage: ‘Epidemic’ of correcting RK

Second of two-part column addresses lens-based surgeries in eyes with previous RK

Gloves Off with Gulani By Arun C. Gulani, MD

This is the second of a two-part column. In a previous column we discussed addressing the full spectrum of corneal aspects of correcting radial keratotomy (RK) (See “Correcting radial keratotomy: Refractive epidemic of future?”; http://bit.ly/1GMwfYT). This month, we will enter “the lion’s cage” by discussing lens-based surgeries in eyes with previous RK.

—Arun C. Gulani, MD

AS ALWAYS, I want to first set the mindset right. Do not get overwhelmed by the appearance of the cornea, number, or pattern of RK cuts in such patients. Approach them with an attitude of perfecting vision through the “excuse/opportunity” of cataract surgery and do not cut corners in bringing these patients to the end zone of vision (“best vision potential,” or BVP)

Appreciate the attempt of the RK surgeons, who 20 years ago did the best they could in helping these patients. Let us also not forget that many of these patients did in fact enjoy their life with post-RK vision.

Additionally, do not forget that these “Early Adapters” were type A personality then and are Type A today. They still are very well read, well researched, and always wanting and expecting the best possible vision.

Refration is what starts my thought process with every patient. Just like in my corneal scar cases (See “Decoding corneal scars: Straight to 20/20”; http://bit.ly/1ab0UK8), I disregard the RK incisions and focus on the visual capacity of the eye always trying to manipulate the optical elements of the eye in reaching emmetropia/BVP.

So, let’s relieve ourselves of prefabricated myths that premium IOLs don’t work in RK, or that femtosecond laser is difficult to use, or that these eyes are doomed for poor vision. Instead, let’s surprise ourselves and our patients in not only returning back their vision capacity but by further enhancing it with modern technology and dedicated desire to “turn back the clock.”

In this column, I would like to divide the cases into those of most common presentation, i.e., where cataract and refractive error (most usually hyperopia, astigmatism, and presbyopia) are the most common vision culprits.

Even though these eyes have a cataract, if you concentrate on the refractive outcome, the surgery itself it not as daunting as you may think. Follow our 5S system (see sidebar on page 19) to collect the correctable elements of the RK cornea (as we did in our last column) and make a plan to correct the decreased vision resulting from the cataract.

Using our 5S system, in most eyes, the corneal scars (cuts), shape, and thickness are all normal, and the site centrally is clear and okay. It’s the sight that is affected by cataract. Most of these patients present after they’ve become presbyopic, as they’re in their 50s or so. In many cases, they will additionally have hyperopia and astigmatism too. They are frustrated because they have virtually no good vision distance or near. Cataract surgery is our excuse to get back to their good vision.

In this column, I would also like to share my classification system for previous refractive surgery eyes with cataracts to once again outline all factors affected and then plan a line of attack to get them all in one “Strike.”

Continues on page 19: Gloves Off

Figure 1. Previous RK eyes with various implant presentations and possibilities.

Phakic Implant

AC IOL

Accommodative IOL

Piggyback IOL
Meibomian Gland Dysfunction is treatable.

Eliminate the guesswork of dry eye. Identify, diagnose and treat MGD with confidence. Ask us about our new LipiView® II with DMI and learn more about the TearScience® Solution for MGD.

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GLOVES OFF

(Continued from page 16)

**GULANI CLASSIFICATION FOR PREVIOUS REFRACTIVE SURGERY:**

**PRIMARY VISUAL FACTORS:**

**QUANTITATIVE:**
Decreased visual acuity (Myopia, Hyperopia, Astigmatism)

**QUALITATIVE:**
Irregular astigmatism
Small Optic Zone Incisions

**SECONDARY (ASSOCIATED) VISUAL FACTORS:**
Presbyopia
Cataracts
Corneal Scars
Corneal Instability (thin / ectasia / trampoline effect)

Once the above are listed (primary and secondary factors) and determined, the plan simply unfolds in front of your eyes. The seemingly complex eye now provides an opportunity to remove the cataract (bluriness) and optically manipulate the interior using specific lens implants to then fine tune/modify or complete our emmetropic quest toward BVP using the cornea as our “Vision Rehabilitative Platform. This is what I call “Refractive Surgery” to the “Rescue” using the most accurate and elegant way to correct vision components with least intervention.

Do not get too anxious about having to perform cataract surgery on a post-RK eye. I would suggest the following pearls:

1. Select the site of incision (and also your sitting position) based on the axis of astigmatism and available space between two radial incisions. Use clear corneal incisions for patients with under 20 RK incisions, and limbal or scleral tunnel incisions in cases of more than 20 incisions. Sometimes, 16 incisions done irregularly or asymmetrically may also force you to avoid the cornea, so evaluate each case individually.

   In the majority of cataract surgery incisions, normal hydration techniques will need to be slightly modified to ensure the previous RK incisions don’t leak. I use a 3-point technique where I not only hydrate the medial and lateral side of the main incision but also centripetally into the lip of the incision.

   I have also successfully used and propose the recently FDA approved ReSure Sealant. Of course, good ol’ sutures are always a back up. A leaking RK incision is something you do not want but do resist the urge to use sutures without adequate reason as you will induce astigmatism and healing delays. Most corneal incisions seal and heal very well by correct hydration techniques.

   If adjacent RK incisions do come apart, stop surgery, evaluate and suture that incision in a step ladder fashion (minimal sutures with parallel long bites with minimal stress). Resume surgery and your composure without being distracted by these sutures.

2. Gulani Phaco-Feed technique: I use low-flow phacoemulsification or phacochop techniques to keep the pressure in the eye down as you work. Also keep the phaco hand piece stationary in the incision (so as not to torque or cause stress on the adjacent RK incisions) and feed the cataract with your second hand/instrument into it. In other words manipul-
late with the second instrument while staying steady with your phaco handpiece.

Femtosecond lasers can be used with no change in protocol or technique to enhance our consistency in capsulorhexis and lens fragmentation which lead the way to successive, next surgical steps in RK cases.4

3 Always remember that these patients were once myopic in refraction (even though today they may be presenting with hyperopia) and still have the myope’s ocular anatomy, so all the risks of cataract surgery in myopia, such as a deep anterior chamber during surgery, and all risks of retinal implications still apply. Do a thorough preoperative and postoperative check.

Visibility sometimes can be hindered if the RK and AK incision pattern reflects and distorts the microscope lights. Establish landmarks like the edge of your capsulorhexis and corneal anatomy so you don’t get fooled by light reflexes. A blob of Viscoat on the cornea may help in such cases.5

There are numerous sites with formulas and approaches to post RK-IOL calculations and I encourage you to use the one with which you’ve had the most success. Intraoperative devices like the Wavetec ORA can also be used to further ensure the accuracy of lens powers. Always aim between emmetropia and myopia: That will not only combat any hyperopic shift or refractive fluctuation (and also

Continues on page 22 : Correcting RK
THERE’S MORE TO THE IMAGE THAN ANYONE THOUGHT POSSIBLE.
allow these patients to read for the first time in years) but as we’ve discussed before (See “Decoding corneal scars: Straight to 20/20”; http://bit.ly/1wh0JK8), myopic laser ASA allows you to increase optical zone and clear central cornea of irregular astigmatism (both of these additionally help night vision to further enhance patient gratification).

Using the above mentioned pearls, plan for single stage cataract surgery to correct blurry vision (cloudy cataract) and also refractive errors (ie. with toric IOL if needed) or two-staged surgery where you result in myopia and then perform Laser ASA as second stage to correct residual refractive error, expand optical zone and clear central corneal irregularities and scars if present. Additionally, you can use collagen crosslinking procedures to further permancize the corneal result you have so laboriously obtained especially if you have worked on the cornea.

Also, build the cornea or repair it in any of the RK cataract cases with no limits and minimal interventions (Corneoplastique).

Having used these concepts I have also used multifocal lens implants successfully in RK cases and we now have a 10 year follow up...
with these patients who are very appreciative of their vision at distance and near without glasses including night vision.

In summary, do not let the previous RK incisions deter you from today’s premium lens technology, patient expectations or BVP goals. Do keep in mind to establish realistic expectations and explain lower predictability of outcomes compared with virgin eyes in such patients but also don’t forget to still aim for perfection in each of these cases.

Using such mindsets that blur our difficulty levels (RK incisions and associated refractive challenges) and clarify our vision goals (unshakable desire to get to BVP for each patient), we can truly bring “refractive surgery to the rescue” in such cases and “turn back the clock” on this refractive epidemic of the future.

References


Editor’s Note: Watch for the next installment of “Gloves Off With Gulani,” which will explore raising pterygium surgery to cosmetic outcomes.
Incision and reliably provide good quality vision. Using ray-tracing techniques, Dr. Qureshi conceived the idea and refined his concept of an intraocular mini-telescope combining two foldable lenses, one in the ciliary sulcus and the other in the capsular bag.

Then he enlisted the help of Dr. Artal for his optics expertise. Applying wavefront analysis, Dr. Artal optimized the lens optics to improve retinal image quality and allow increased tolerance to variations in relative lens positioning.

The new commercially available platform consists of two hydrophobic acrylic plate haptic IOLs—a high-plus powered lens (+60 D) with a 5-mm optic and asymmetrical haptics placed in the sulcus and a high-minus powered lens (–50 to –60 D) with a 4-mm optic placed in the capsular bag. The asymmetrical haptics of the sulcus IOL result in an offset of 0.85 mm between the two lenses. Together, they create a Galilean telescopic effect with about 1.3× and 3° of foveal displacement.

The amount of magnification provided increases visual acuity without compromising visual field, and therefore enables binocular implantation. The lenses are made of a high refractive index, foldable, glistening-free material and can be easily implanted through a 3-mm incision.

Though modest about his contributions for optimizing the optics, Dr. Artal is genuinely impressed by comments of patients with the intraocular mini-telescope implanted.

“These individuals are very happy and extremely thankful for their improved vision,” said Dr. Artal, professor of physics, University of Murcia, Spain. He added that since the design of the new lens makes intraocular telescope implantation feasible for more surgeons, its benefits will be available to a greater number of patients.

**PATHWAY TO PLATFORM**

Soon after he began to implant intraocular mini-telescopes in 2007 using the IOLVIP, Dr. Qureshi became interested in developing an alternative that would be based on injectable optics and provide good image quality despite the aberrations and distortions associated with high-powered lenses, magnification, and the prismatic effect. Decentering the lenses by 0.85 mm provided the desired 3° of foveal displacement of the image, but also induced astigmatism and coma.

Dr. Artal implemented shape factors and asphericity to correct for those aberrations in order to improve image quality, and further refined the asphericity to improve tolerance to variations in lens positioning.

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**Surgeon shares first clinical experience, results with device**

**FRITZ HENGERER, MD, PHD**, reported outcomes achieved after 4 months of follow-up in 18 eyes implanted by Bobby Qureshi, MD, along with his own initial clinical experience with the intraocular mini-telescope. For the eyes in Dr. Qureshi’s series, mean Snellen preoperative near uncorrected visual acuity (UCVA) (decimal) was worse than 0.14, preoperative distance best-corrected visual acuity (BCVA) was 0.12, and simulated distance BCVA was 0.19. Mean postoperative distance BCVA was 0.2, exceeding the simulation-predicted value, and mean near BCVA improved by 50% to 0.21.

The refractive outcomes were similar to those achieved with monofocal implants. There was a myopic shift in all cases from pre- to postoperative (mean 1.9 D) and a mean of about 0.5 D of induced astigmatism. However, the refractive changes can be neglected, said Dr. Hengerer, assistant professor of ophthalmology, Goethe-University Frankfurt am Main, Frankfurt, Germany.

There were no intraoperative or postoperative complications. Mean IOP was 18 mm Hg preoperatively and 16 mm Hg postoperatively, and mean endothelial cell count showed a decrease of about 18%.

Images from anterior segment OCT demonstrated stable lens positioning, and micropachymetry results confirmed the benefit of the telescopic and prismatic effect for improving threshold sensitivity and fixation stability.

Dr. Hengerer said he performed his first implantation of the device in July 2014 in a patient with stage 3 AMD who had a monofocal IOL in the fellow eye. His next two cases were in the fellow eyes of a second patient with stage 3 AMD. All of the procedures were done through a 3.2-mm superior incision with a 5-mm capsulotomy.

In the first implanted eye, baseline distance BCVA was 0.03. The patient was unable to read with that eye, but the simulation predicted near BCVA would improve to 0.1 after implantation of the intraocular mini-telescope. At 30 days postoperatively, near and distance UCVA were both 0.25, distance BCVA was 0.4 and near BCVA was 0.5.

“With these outcomes, the patient had visual acuity that allowed him to keep his driver’s license,” Dr. Hengerer said.

The results from the second patient who received the intraocular mini-telescope in both eyes suggested outcomes are enhanced with binocular summation.

Preoperatively, distance BCVA was 0.05 in the left eye and 0.16 in the right eye. The patient was unable to read with his right eye and had 0.16 BCVA at near in the left eye.

In binocular testing at 30 days after the second eye surgery, distance UCVA was 0.5, near UCVA was 0.63, and BCVA for both near and distance was 0.8.

“The patient is very happy and particularly pleased because he is able to read stories to his grandchildren, which he could not do before,” Dr. Hengerer said.

Dr. Hengerer also emphasized the importance of completely removing viscoelastic between the two lenses to optimize their relative positioning, and he noted that there is the potential to adjust the orientation of the sulcus lens in a future procedure in order to improve vision for patients when their macular pathology advances.

“The sulcus IOL is not fixed like a toric lens, but can be rotated later according to the patient’s needs, potentially extending vision as the disease progresses,” Dr. Hengerer said.

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**TAKE-HOME**

» A new intraocular mini-telescope is implanted through a small incision and has optimized optics so that it reliably provides good quality vision.
“Image quality is quickly reduced with standard lenses if they are not properly positioned,” Dr. Artal said. “Adding a significant amount of asphericity increases the tolerance in lens position by at least six-fold.

“But, in physics you do not get something for nothing. The tradeoff for the benefit we achieved is a slight decrease in image quality at best focus,” he said. “However, because the patients implanted with the lens have lower visual requirements to begin with, the images that are produced are of sufficient quality for the purpose of enhanced extrafoveal viewing.”

The amount of asphericity present in the lenses makes them suitable for a range of eye sizes. The current device is suitable for patients with a spherical error between –4 D and +4 D and up to 3 D of astigmatism. A larger range encompassing longer and shorter eyes will be available in 2015 as will a version for pseudophakic eyes.

**SIMPLE SURGERY**

Dr. Qureshi said the new device fulfills his goal to create a system that can be implanted by any competent cataract surgeon. The procedure itself just takes a few extra minutes compared with standard IOL implantation.

Preoperatively, a simulation test is performed to assess whether the patient will benefit from the implantation and to allow the surgeon to determine proper orientation of the sulcus lens.

The procedure involves creation of a 5-mm capsulorhexis. After performing routine phaco through a 2-mm incision, Dr. Qureshi extends the entry site to 3 mm and introduces the posterior IOL into the capsular bag with an injector.

“The material has very good memory, centers very nicely with minimal manipulation, and orientation is as per any capsular bag lens,” he said.

The sulcus lens is injected behind the iris and oriented based on the findings of the preoperative simulation to move the image to the chosen area of healthier retina. Due to the haptics design, there is no need for iridotomy or iridectomy.

However, surgeons do need to meticulously remove all viscoelastic from behind the IOL that is in the capsular bag and from between the two lenses. Dr. Qureshi has implanted the intraocular mini-telescope in more than 100 eyes with a variety of macular pathologies, including early to advanced AMD, diabetic maculopathy, macular holes, Stargardt’s disease, and Best’s disease.

In addition, he has performed lens exchange, implanting the mini-telescope after explanting a monofocal IOL. However, he recommended surgeons begin by choosing phakic patients with stable, dry AMD who are undergoing cataract surgery and who have visual acuity ranging from 6/20 to 6/200.

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**REFERENCE**

This article was adapted from an industry-sponsored symposium during the 2014 meeting of the European Society of Cataract and Refractive Surgeons.
TOPICAL IL-1 RECEPTOR BLOCKER MANAGES SIGNS, SYMPTOMS OF DRY EYE

Preclinical findings show substantial improvements in corneal staining, eye pain for these patients

By Lynda Charters; Reviewed by Michael H. Goldstein, MD

Patients with moderate to severe dry eye disease may benefit from the effects of an advanced product candidate. The novel therapy (EBI-005, Eleven Biotherapeutics) blocks interleukin-1 (IL-1), a key player in the initiation and maintenance of the inflammatory response in dry eye disease.

"[The drug] has been validated preclinically to inhibit IL-1, a driver of dry eye disease," said Michael H. Goldstein, MD, MBA, assistant professor of ophthalmology, Tufts University School of Medicine, and co-director, Cornea, External Disease and Cataract Service, New England Eye Center, Boston.

"It is safe and well tolerated, and resulted in a clinically relevant magnitude of improvement in the signs and symptoms of dry eye disease by 6 weeks compared with baseline," he said.

HOW IT WORKS

As an IL-1 inhibitor, the novel therapy works by blocking the signs and symptoms of dry eye.

"[Its] mechanism . . . has demonstrated activity related directly to dry eye signs and symptoms that is a very differentiated approach to development," said Dr. Goldstein, who is also vice president of medical research, Eleven Biotherapeutics. "[The product] has a dual mechanism of blocking both ocular surface damage and hypergesia."

Elevated levels of IL-1 alpha and IL-1 beta drive ocular surface cellular signaling. The proposed mechanism of action is that the product blocks IL-1 alpha and IL-1 beta signaling on inflammatory, epithelial, and nerve cells.

STUDYING THE DRUG

In a phase Ib/IIa double-masked, placebo-controlled trial at eight sites, investigators evaluated its safety and efficacy in 74 patients with moderate to severe dry eye. Patients were randomly assigned to receive either vehicle or one of two doses of the drug: 5 or 20 mg/ml.

Each patient instilled the drug three times daily over 6 weeks. All patients were evaluated for adverse events and underwent ophthalmic examination, corneal esthesiometry and pachymetry, ocular surface microbiology, corneal staining, and eye pain for these patients.

Patients with an OSDI score below 50 had the best response to the drug:

- 39% improvement in corneal staining
- 41% improvement in OSDI score
- 61% improvement in ocular pain

CONTINUES ON PAGE 27: Receptor blocker
Metabolome-wide study explores link between androgen metabolism, dry eye

Emerging research approach focuses on small molecules of biological samples

By Vanessa Caceres; Reviewed by Jelle Vehof, MD

**ANDROGEN METABOLISM** may be an important pathway related to dry eye disease in females.

Researchers—led by Jelle Vehof, MD, of Twin Research and Genetic Epidemiology at St. Thomas’ Hospital, King’s College London, and the Department of Ophthalmology, University Medical Center Groningen, Groningen, Netherlands—studied metabolomics to pinpoint their findings in a metabolome-wide study of dry eye disease.

“Metabolomics is a new emerging field of ‘omics’ research,” Dr. Vehof said. “Next to the genome, the transcriptome, and the proteome, there is the metabolome. A person’s metabolome refers to a snapshot of all the small-molecule metabolites in a biological cell or tissue.”

Dr. Vehof and colleagues believed metabolomics would be valuable to study dry eye disease because they are a measurable direct product of genes and environmental factors.

“The aim of the study was to explore the relationship between dry eye disease and serum metabolites, given the known associations of dry eye with several metabolic dysfunctions,” they said.

Researchers studied 1,622 population-representative female volunteers from the Twins UK Adult Twin Registry, which has been used to study the genetic basis of various cardiovascular, metabolic, musculoskeletal, and ophthalmic disorders.

They performed a non-targeted metabolomics analysis of plasma samples with the use of gas- and liquid-chromatography along with mass spectrometry. This enabled them to measure 390 metabolites in plasma samples.

A dry eye diagnosis was determined with the Short Questionnaire for Dry Eye Syndrome (SQ-DES), administered in 2011 and 2013. The incidence of a dry eye diagnosis was also used as an outcome variable.

**THE DRY EYE FINDINGS**

Researchers found a dry eye prevalence of 16.7% with the SQ-DES.

“A strong and metabolome-wide significant association with dry eye diagnosis was found with the metabolite epiandrosterone,” they noted. “Epiandrosterone and two other steroids that are also involved in androgen metabolism were particularly strongly associated with dryness symptoms on the SQ-DES.”

Researchers also found an association between epiandrosterone and the incidence of dry eye diagnosis. Dehydroepiandrosterone sulfate also seemed associated with a dry eye diagnosis, but it did not reach metabolome-wide significance.

The study suggests that androgen metabolism may be an important pathway in the development of dry eye disease in women, Dr. Vehof and colleagues concluded. Specifically, epiandrosterone may be a biomarker of dry eye because of its association with both the prevalence and incidence of disease.

“The strong association with all androgen metabolites in this large population-representative, hypothesis-free study was actually quite surprising for us, pointing out that androgens are important in this disease, and implicating that further studies on this topic are justified,” Dr. Vehof said.

Dr. Vehof would like to see further randomized, controlled trials that focus on androgen treatment and other studies investigating the role of androgens in dry eye. Researchers in this study are planning a genome-wide association study on dry eye disease.

**RECEPTOR BLOCKER**

(Continued from page 26)

and serum laboratory testing. Other evaluations included corneal fluorescein staining, completion of the Ocular Surface Disease Index (OSDI) questionnaire, and frequency of use of artificial tears.

**TREATMENT RESPONSE**

The therapeutic was found to be safe and well tolerated by patients. No adverse events were reported in association with its instillation.

 “[The drug] resulted in a statistically significant (p < 0.005) reduced use of artificial tears,” he said. “Patients who were treated with the drug used less than half of the amount of artificial tears.”

Further, patients treated with the drug had significant (p < 0.001 for all comparisons) improvements compared with baseline in the total corneal fluorescein staining with a reduction of 33%, a 36% improvement in the OSDI score, and a 46% decrease in ocular pain.

Patients with an OSDI score below 50 had the best response to the drug—specifically, 39% improvement in corneal staining, 41% improvement in the OSDI score, and 61% improvement in ocular pain.
Innovative cyclosporine solution shows excellent safety, tolerability in study

Novel carrier platform delivers immunomodulatory agent without blurring, stinging, or preservatives

By Cheryl Gutman Krader; Reviewed by Philipp Steven, MD, PhD

Cologne, Germany ::

A NOVEL, PATENTED, non-aqueous and preservative-free formulation containing cyclosporine A 0.05% (CyclaSol, Novaliq) demonstrated positive results in a phase I clinical trial.

The product formulates cyclosporine in perfluorobutylpentane (F4H5), a member of Novaliq’s proprietary semi-fluorinated alkanes (SFA) technology (EyeSol), and it is the first clear cyclosporine A solution. Now, additional studies are being planned to further investigate its use in the treatment of dry eye syndrome (DES).

Philipp Steven, MD, PhD, Department of Ophthalmology, Director Ocular Surface Group and Ocular GVHD Competence Center, University of Cologne, Germany, has been involved in the development of the cyclosporine product. He said that the SFA technology has a unique combination of physico-chemical properties that make it an exciting vehicle for formulating ophthalmic products that may overcome most of the challenges facing the ocular drug delivery industry today.

ABOUT THE SFA

The SFAs have excellent spreading behavior, are physically and chemically inert, enable solubility of poorly water-soluble medications, and do not support microbial growth, thus allowing for preservative-free multi-dose units for increased patient convenience. In addition, SFA-based products have a reduced drop volume, which minimizes blinking, contain no surfactants, and unlike emulsions, do not cause blurry vision.

These features would be expected to improve tolerability, and in fact, results of the phase I clinical trial, along with findings from an observational study with the company’s SFA-based ocular lubricant (NovaTears) [See online exclusive], showed the SFAs are extremely well tolerated when applied topically to the eye. In addition, there is also evidence (data on file) indicating that the SFA vehicle enhances cyclosporine bioavailability.

““There is strong rationale for using cyclosporine in the treatment of dry eye disease, and ophthalmologists using the commercially available product (Restasis, Allergan), which is a single unit dose emulsion, or compounded preparations of cyclosporine are familiar with its efficacy,” Dr. Steven said. “However, many patients discontinue treatment with those agents, which are formulated with peanut or mineral oil, for reasons of intolerable stinging, hypersensitivity, or inadequate response.”

Research so far using this cyclosporine formulation with F4H5 as a vehicle suggests that it has potential to overcome the limitations of existing formulations and supports additional studies, he noted.

STUDY RESULTS

Dr. Steven and colleagues have been involved in the development of the SFA-based formulation of cyclosporine, demonstrating initially that it was an excellent vehicle for dissolving cyclosporine, allowing for the formulation of stable preparations containing higher concentrations of the active ingredient.

After initial successful testing in an animal model, a phase I clinical study was initiated to demonstrate safety, local tolerability, and systemic exposure. The study was conducted using a double-blind, randomized, crossover design. In it, 18 subjects without dry eye were assigned to treatment with the cyclosporine 0.05% solution or placebo and then crossed over to the alternate agent.

The phase I results clearly demonstrated that use of the cyclosporine solution caused no signs or symptoms of ocular discomfort or irritation. Nor were there any changes in visual acuity, IOP, or adverse findings on slit-lamp examination. In addition, using a highly sensitive assay to detect cyclosporine in the blood, there was no evidence of systemic absorption.

Dr. Steven noted that results from bioavailability studies in animal eyes demonstrated that cyclosporine concentrations achieved in ocular tissues of interest for dry eye treatment are 5- to 10-fold higher using cyclosporine 0.05% in F4H5 compared with the commercially available cyclosporine 0.05% emulsion.

“Even if it is possible to create a stable topical formulation containing a higher concentration of cyclosporine, efficacy depends on the concentrations achieved in the target tissues,” Dr. Steven said. “The data from bioavailability studies suggest a potential advantage of the SFA-based product, but it remains to be seen if that translates into improved clinical outcomes in terms of faster onset and/or better results.”

PHILIPP STEVEN, MD, PhD
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Dr. Steven receives research funding from Novaliq.
Hyperosmolarity of ocular surface may impact cataract surgery planning

Optimizing ocular surface yields more reliable keratometry for IOL selection, better refractive outcome

By Nancy Groves; Reviewed by Eric D. Donnenfeld, MD

**Take-home**

A recent study demonstrates the importance of evaluating osmolarity during cataract surgery planning in order to ensure that presurgical keratometry readings are not compromised by hyperosmolarity of the ocular surface.

**GROUP DIFFERENCES**

The results showed that the hyperosmolar group demonstrated wider variation in keratometry cylinder between visits \((p < 0.001)\) relative to normal eyes. In normal osmolar subjects \((n = 21)\), the change in keratometry cylinder between visits was \(0.38 \pm 0.26\ D\ (OD)\) and \(0.39 \pm 0.23\ D\ (OS)\); in hyperosmolar subjects \((n = 46)\), the change was \(0.58 \pm 0.46\ D\ (OD)\) and \(0.61 \pm 0.65\ D\ (OS)\).

In the normal osmolar patients, 29% of eyes had a difference between the first and second visits in keratometry cylinder values between 0.5 and 1 D and none had a reading \(\geq 1\ D\). In contrast, 21% of the eyes of hyperosmolar patients had a measurement between 0.5 and 1.0 D but 16% had more than 1 D of change.

The change in osmolarity between visits was \(15.16 \pm 9.64\ (OD)\) and \(14.02 \pm 11.93\ (OS)\) in the hyperosmolar eyes while only \(6.27 \pm 4.45\ (OD)\) and \(6.77 \pm 6.96\ (OS)\) in normal osmolar eyes. The change in osmolarity was not significantly correlated to change in keratometry cylinder.

“The take-home message was that by optimizing the ocular surface, you get more a reliable keratometry for IOL selection, and with a reliable keratometry it’s more likely that you’ll achieve a better refractive outcome,” Dr. Donnenfeld said.

He emphasized that pre-treatment of dry eye improves surgical results.

“The ocular surface is the most important refracting surface of the eye, and with an abnormal ocular surface, which is predicted by osmolarity, you can expect to have suboptimal results because the surface of the cornea creates higher-order aberrations and loss of quality of vision in patients who have irregular corneas,” Dr. Donnenfeld said. “It makes it more difficult to predict the correct IOL power and to effectively treat cylinder with toric IOLs or limbal relaxing incisions.”

**Kit helps manage lid margin disease**

By Nancy Groves

**NEW STUDY FINDINGS** underscore the importance of evaluating osmolarity during surgical planning.

The study demonstrated that hyperosmolar patients had a wider variation in keratometry calculations between visits relative to the normal osmolar group. In the hyperosmolar group, 16% of hyperosmolar eyes had more than 1 D of change in K cylinder values between the first and second visit.

The purpose of the study, sponsored by TearLab, was to investigate the link between dry eye and variance in presurgical calculations in cataract and refractive surgery patients.

Dr. Preeya K. Gupta, MD, assistant professor of ophthalmology, Duke Eye Center, Duke University, Durham, NC. Dr. Gupta has been using the kit since it was released in early fall and has observed that in-office application of the gel and home use of the lid wipes helps reduce inflammation, crusting, and redness along patients’ eyelids. To read more about Dr. Gupta’s experience, go to [http://bit.ly/1umFEjo](http://bit.ly/1umFEjo).

**NEW LID HYGIENE** kit (Cliradex Complete Advanced Lid Hygiene Kit, Bio-Tissue) for lid margin and ocular surface diseases helps manage the symptoms of conditions, such as blepharitis, demodex, meibomian gland dysfunction, rosacea, and dry eye diseases. The comprehensive lid hygiene protocol includes a formulation gel with a stronger concentration of 4-Terpineol than the original Cliradex product.

The gel is well tolerated and effective, said Preeya K. Gupta, MD, assistant professor of ophthalmology, Duke Eye Center, Duke University, Durham, NC. Dr. Gupta has been using the kit since it was released in early fall and has observed that in-office application of the gel and home use of the lid wipes helps reduce inflammation, crusting, and redness along patients’ eyelids. To read more about Dr. Gupta’s experience, go to [http://bit.ly/1umFEjo](http://bit.ly/1umFEjo).
Special Report  |  INTERPRETING TODAY’S PRACTICE GUIDELINES FOR DRY EYE

How 3-step approach eases consult with new chronic dry eye patients

Explore methods to maximize structure for patient visits, treatment plans, education

**By Nancy Groves; Reviewed by Karl Stonecipher, MD**

GREENSBORO, NC :: **IF AT LEAST 20%** of the patients who walk into the typical ophthalmology practice have dry eye disease, then taking them through diagnosis, education, and treatment could consume a substantial part of the day.

Finding an approach that will be beneficial for the patient but not overwhelm the physician’s schedule is essential, according to Karl C. Stonecipher, MD.

At his clinic here, Dr. Stonecipher applies a three-step process of identifying patients with dry eye disease, showing them objective data, educating them and outlining a treatment regimen.

This approach takes advantage of new technology—such as mobile apps—and also overcomes the problem of limited chair time by shifting much of the educational responsibility to the patient. By referring patients to websites known to have reliable information, the physician can devote more time to tasks that can only be done in the office.

“The smartest thing that can help . . . patients is to get them educated about their disease,” Dr. Stonecipher said. “The typical physician doesn’t have the time to do this with their patient load and time constraints, so you have to structure your visits so that the patients walk out with a plan, their questions are answered, and they feel that the doctor cares.”

**IDENTIFY THE PATIENT**

While many whose disease is chronic or severe will have already been to several other physicians and tried multiple over-the-counter products, others will arrive with a list of complaints suggesting dry eye but not a formal diagnosis. Still, others may present for a routine exam then suspect they have dry eye after reading literature in the waiting room or learn their diagnosis only when going over test results with the physician.

The Ocular Surface Disease Index (OSDI) questionnaire is the gold standard for assessing dry eye disease, but Dr. Stonecipher also uses a new instrument—the single-item University of North Carolina Dry Eye Management Scale (UNC DEMS)—to evaluate patients. A recent study (Cornea. 2014;33:1186-1192) demonstrated that it was a valid and reliable questionnaire. The UNC DEMS can be obtained through that article and used as a single-question subjective test.

**SHOW OBJECTIVE DATA**

If a patient’s score on either test suggests dry eye disease, Dr. Stonecipher then uses objective data to confirm the diagnosis and help explain it to the patient. He performs lissamine green staining and then has the patient look in a mirror to see how the staining pattern has highlighted the driest areas of the eye. The other staining option is fluorescein, which can be recorded by the physician after review with the slit lamp exam.

“If fluorescein is the stain of choice, I will additionally record tear break-up time, but my preference is to use lissamine green and allow the patient to see the results,” Dr. Stonecipher said.

**EDUCATE AND IMPLEMENT A TREATMENT PLAN**

One of Dr. Stonecipher’s sources of guidance is the recommendation released in 2006 by the International Task Force Delphi Panel on Dry Eye (revised a year later by the International Dry Eye Workshop), which outline a stepwise treatment based on disease severity levels.

At level 2, for instance, Dr. Stonecipher will usually prescribe a corticosteroid, cyclosporine, or both to reduce inflammation before considering a further step, such as punctal plugs.

**Resources for patients**

1. www.nei.nih.gov/health/dryeye/dryeye
2. www.sjogrens.org
3. www.dryeye.com
4. www.mydryeyes.com

While guidelines and preferred practice patterns are useful, treatment recommendations must also be guided by the patient’s presentation and information about their environment, lifestyle, hobbies, and habits.

“It also has to be reasonable,” Dr. Stonecipher said. “If you send the patient out the door with an astronomically challenging array of things to do, they’re not going to do it.”

‘ . . . You have to structure your visits so that the patients walk out with a plan, their questions are answered, and they feel that the doctor cares.’

— Karl G. Stonecipher, MD

Even after receiving an explanation of dry eye disease and their test results, patients often have many questions, usually arising from Internet searches. Dr. Stonecipher said he usually addresses a few questions at the end of a visit, but he also refers patients to carefully vetted websites where they can learn more about dry eye disease and participate in discussion forums.

**KARL G. STONECIPHER, MD**

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Dr. Stonecipher is a consultant or advisor; lecturer, speaker, and researcher for Alcon Laboratories and Allergan; consultant or advisor, lecturer, and researcher for Nohe, Presbia, and Refocus Group; consultant and lecturer for Bausch + Lomb, Laser A2Z, and STAAR Surgical; an investor in Alphapoint; and an employee of TLC Laser Eye Centers.

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Imaging technology aids in diagnosis of meibomian gland dysfunction

Next-generation tool helps determine lipid deficiency, detect MGD in earliest phases

By Lynda Charters; Reviewed by Eric D. Donnenfeld, MD

ROCKVILLE CENTRE, NY ::

A NEW ITERATION of an imaging technology is in the pipeline to provide more accurate visualization of the meibomian gland structure.

The instrument (LipiView II with Dynamic Meibomian Imaging, TearScience) includes two novel imaging technologies (Dynamic Illumination and Adaptive Transillumination). Both technologies independently generate images of the glands that then are processed, displayed, and combined for improved visualization and more accurate diagnosis.

“Eye-care providers must examine both gland function and structure when diagnosing meibomian gland dysfunction (MGD),” said Eric D. Donnenfeld, MD, founding partner of Ophthalmic Consultants of Long Island and Connecticut, clinical professor of ophthalmology, New York University Medical Center, New York, and a trustee of Dartmouth Medical School.

“The [technology] helps clinicians evaluate gland structure, measure lipid layer thickness, and determine if partial blinking plays a role in the disease,” Dr. Donnenfeld said.

The images are also helpful in patient education. Individuals with dry eye can see the effect of the disease on the glands and understand the importance of instituting treatment before the disease progresses, he said.

In regard to patients with dry eye disease, he described the subsequent morphologic changes that are secondary to obstruction of the meibomian glands. Early obstruction is characterized by decreased gland function with dilation of the central duct. Prolonged gland obstruction results in further duct dilation and the onset of atrophy of acini and shrinkage.

With the new device, however, central dilation, gland truncation, and gland drop out can be clearly visualized in contrast to normal meibomian gland structure.

ABOUT THE TECHNOLOGY

The technology works through the use of surface lighting (Dynamic Illumination) that originates from multiple sources. The multiple light sources eliminate glare. This result is in contrast to traditional meibography in which only one light source is used and glare almost always results.

Another component of the technology (Adaptive Transillumination) changes the intensity of the light across the surface of the illuminator to compensate for variations in the lid thicknesses among patients.

Imaging can be performed by one individual through the use of the keyboard at the top of the device. A lid everter that emits multi-angle light helps to ensure that all of the meibomian glands are visualized, Dr. Donnenfeld noted.

A comparison of images obtained with the new device with those obtained using a traditional meibographer showed the latter technology may not accurately reflect the status of the meibomian glands—possibly resulting in confusion or misdiagnosis of gland dropout and visible glare. Meibomian glands that appear to be dropped out in traditional, static meibography can be seen with dual-mode Dynamic Meibomian Imaging, according to Dr. Donnenfeld.

The technology is intended to be used with other products from the manufacturer—i.e., its Korb Meibomian Gland Evaluator and LipiFlow treatment for the ocular surface that helps restore meibomian gland function.

Eric D. Donnenfeld, MD

Dr. Donnenfeld is a consultant to TearScience. The LipiView II is expected to be commercially available in Europe by early 2015 with upgrade options available for owners of the current technology.
For Products & Services advertising information, contact: Karen Gerome at 800-225-4569, ext 2670 • Fax 440-756-5271 • Email: kgerome@advanstar.com
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Advanced diagnostics measure quality, functional aspects of vision

Objective measurement of subjective complaints can pinpoint diagnosis, guide treatment

By George O. Waring IV, MD, FACS, Special to Ophthalmology Times

CHARLESTON, SC ::

SNELLEN ACUITY—described in the mid-1800s by Herman Snellen—is considered the gold standard for quantifying a patient’s vision. Things have changed since then.

Now, along with visual acuity, ophthalmologists can objectively analyze and improve patients’ quality of vision. Optical aberrations, contrast sensitivity, ocular surface quality, and other formerly subjective assessments can now be objectively quantified, allowing ophthalmologists to identify and address the root cause of patients’ visual dysfunction.

One of the most important determinations is whether a patient seeking surgical vision correction is best served by a corneal- or lens-based procedure. I combine clinical examinations with objective data analysis from an advanced diagnostic/surgical-planning instrument (AcuTarget HD, developed by AcuFocus in collaboration with Visiometrics) to find the best solution for the individual patient.

The ability to evaluate quality of vision by assessing forward light scatter of the dysfunctional lens, measure depth of focus, guide in centration, and functionally evaluate unstable tear film to diagnose dysfunctional tear syndrome have made this tool invaluable in treatment planning in my practice.

OCULAR LIGHT SCATTER

Objective quantification of subjective visual complaints has been of enormous benefit. The instrument essentially sends a low-energy laser beam into the eye and then evaluates the relative intensity of the beam through a double-pass analysis. An Ocular Scatter Index (OSI) is created, which quantitatively describes the amount of scattered light, and the point spread function demonstrates qualitatively the pattern of light scatter distribution. While physicians could previously detect the occurrence of early senile lens changes with careful slit lamp examination—and perhaps contrast sensitivity measurements that may not be widely used in clinical practice—these changes were often overlooked.

Dysfunctional tear syndrome can result in irritation, light sensitivity, and poor visual quality. Awareness of dry eye and ocular surface diseases has intensified over the past couple of years as it directly relates to patient satisfaction following surgery. Being able to generate a series of OSI indices in succession over a 20-second scan period allows ophthalmologists to evaluate—frame by frame—whether image quality becomes distorted in between blinks and if it is restored with a blink.

This helps attribute the scatter to evaporative dry eye. If image quality quickly deteriorates and then restores with every blink, ophthalmologists can easily and objectively see the functional aspect of dry eye, and explain it to patients. Furthermore, this gives the practitioner an objective baseline measurement from which to compare serial exams once ocular surface optimization regimens are established.

Alternatively, if a patient and the OSI show minimal light scatter and an excellent point spread function pattern with subjective visual complaints, a more extensive retinal evaluation may be warranted as these findings suggest a non-optical etiology of visual disturbance.

I use the device for all my patients with dry eye, as it establishes baseline measurements and enables treatment progress to be seen. For complex patients, where diagnosis or complaint is not very straightforward, it is possible to determine if there is a tear film etiology or other subtle optical aberrations resulting in suboptimal image quality.

PRESBYOPIC POPULATION

The general aging of the population means that more and more patients are complaining about the loss of near vision without the aid of spectacles. Being able to measure and document depth of focus is unique and demonstrates for the patient the actual loss of amplitude of accommodation due to presbyopia, as well as what has been regained via treatment, depending on the modality.

Pseudoaccommodation is complex and historically has only been evaluated via subjective patient comments. Ophthalmologists can now evaluate—pre- and postoperatively—the improvement in the defocus curve from various presbyopia-correcting procedures as well as use the point-spread function across a defocus range to educate patients visually.

Determining optimal placement of presbyopia-correcting technologies—like corneal inlays and IOLs—is gaining rapid interest worldwide. By accurately capturing the 1st Purkinje image and pupil center in a patient-fixated, co-axially sighted manner, clinicians now have a diagnostic device that objectively maps out a desired position for centration of refractive treatments.

COURSE OF TREATMENT

When a patient presents for a surgical vision correction consultation, the decision needs to be made whether to perform a corneal- or lens-based procedure. Despite the fact that 20/20 is a benchmark standard for perfect vision, there is excellent quality 20/20 vision and poor quality 20/20 vision.

Advanced diagnostics allow clinicians to objectively measure the quality and functional aspects of patients’ vision. These metrics not only enable ophthalmologists to make proper diagnoses and determine the best treatment, they are also indispensable tools for patient education.
Study: Effect of dry eye products, warm compress for MGD therapy

Functionality better after 2 and 3 months of treatment compared with standard of care

By Lynda Charters; Reviewed by Victor Finnemore, OD, FAAO

BOSTON :: SYMPTOMS of lipid-deficient evaporative dry eye disease can be alleviated with products that increase the number of meibomian glands yielding liquid secretion.

A line of products (Systane Family of Products, Alcon Laboratories) was shown to increase meibomian gland function from baseline compared with the standard of care (warm compresses, with or without saline) in a recent study.

“Meibomian gland dysfunction (MGD) is one of the leading causes of dry eye disease, which is characterized by decreased liquid secretion or a decreased number of meibomian glands yielding liquid secretion and altered gland anatomy,” said Victor Finnemore, OD, partner and clinical researcher at Korb and Associates, Boston.

ABOUT THE STUDY
Dr. Finnemore and colleagues conducted a 3-month, single-center, open-label, investigator-masked, prospective evaluation of patients diagnosed with lipid-deficient evaporative dry eye and six or fewer functioning meibomian glands during screening. Patients completed screening at baseline and examinations at 1, 2, and 3 months of treatment.

The 3-month study included random assignment to either the Systane products (Idid Wipes once daily, Systane Balance eye drops four times daily, and two vitamin omega-3 supplements once daily) or the application of warm, wet compresses to both eyelids for 8 minutes once daily, according to Dr. Finnemore.

The primary endpoint was the functionality of the meibomian glands. The Korb Meibomian Gland Expressor was used to assess the meibomian gland function. The investigators determined the number of meibomian glands yielding liquid secretion at the four time points. Best-corrected visual acuity (BCVA) and adverse events were recorded.

Twenty-six patients (21 women, 5 men; 52 eyes) were included in the study, 13 in each of the two study groups. The mean patient age was 41.7 years (range, 18 to 72 years).

“The meibomian gland functionality was significantly better in the Systane group compared with the warm compresses group at months 2 and 3,” Dr. Finnemore said.

At baseline evaluation, the mean numbers of meibomian glands yielding liquid secretion were similar in the two groups, i.e., 3.5 ± 1.50 in the Systane group and 4.2 ± 1.39 in the warm compresses group. In the Systane group, the mean numbers increased compared with baseline at all time points: 7.0, 6.4, and 9.3 at months 1, 2, and 3 compared with 3.9, 3.5, and 4.7 in the warm compresses group at the same time points. The differences were significant at months 2 and 3 (p = 0.365 and p = 0.0061, respectively).

The safety profile of the products was good and no serious adverse events were reported. One patient reported infectious mononucleosis and sinusitis not related to treatment. BCVA did not change during the study.

Dr. Finnemore also commented on the condition of the eyelids.

“The lid status improved markedly compared with baseline in the Systane group,” he said. “At month 3, 80.8% of eyes in the Systane group had no desquamated debris and collarettes compared with 38.5% of eyes in the standard care group. The investigators observed desquamated debris on the epidermis in two eyes and eyelashes in six eyes and collarettes in 14 eyes in the standard-care group.”

DONALD R. KORB, OD
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This article was adapted from Dr. Finnemore’s presentation at the 2014 meeting of the Association for Research in Vision and Ophthalmology. Dr. Finnemore was joined in this study by Teresa Douglass, AB, COT; Abayomi Ogundele, PharmD; and Donald R. Korb, OD. No author had a financial interest in any aspect of this report. Alcon Research Ltd. sponsored the study.
Approaching ACOs with healthy dose of awareness, acceptance

An overview on accountable care organizations and how they may impact ophthalmology

By Stephanie Skernivitz

Awareness is the first step toward change, an author once said. Acceptance is the second step.

Along those lines, Bruce Maller, president and chief executive officer of BSM Consulting, Incline Village, NV, tested the awareness of an audience of primarily specialists in ophthalmology at a recent conference, by asking whether they were familiar with accountable care organizations (ACOs) forming in their markets? A solid 60% answered affirmatively.

Though awareness of ACOs appears to be on the rise, acceptance is still slow to come. When Maller followed up that question by asking whether any specialists in the audience had signed an agreement to be part of an ACO, only 19% answered “yes.”

However, the real “noise” is not so much about ACOs, but more so about the impact of the Affordable Care Act (ACA) on providers and payers. Maller highlighted what he dubbed a “distillation” of what specialists need to know within the context of their practices and surrounding communities, focusing on key ACA provisions, an ACO overview and their current activity, and how ACOs might impact ophthalmology.

MEDICAID EXPANSION

The big push behind the ACA’s Medicaid expansion is to get more people insured, Maller noted.

“It’s essentially raising the poverty line in a sense for purposes of who’s eligible,” he said.

“Part of the government’s plan is to bring in another 15 million to 20 million people who are currently uninsured. The vehicle to do that is through Medicaid.”

Though not all states are participating in Medicaid expansion, many are, and the impact by state or region can be dramatic, according to Maller. He indicated that 26 states (including Washington, DC) were to implement expansion in 2014: two states were seeking to move forward with expansion post-2014, and the remaining 23 states were not moving forward yet. As an example, he cited New Mexico, which may have close to 500,000 people in the state covered by Medicaid. With the Medicaid expansion, he said that number would essentially double. Such a ripple effect will likely occur in other states.

“This will have a dramatic effect on your marketplace, because the way this is all going to get administered is through managed care,” Maller said. “One theme you’re going to pick up through the ACA is how the ACA empowers managed care to exercise greater leverage in your markets.”

Impact of health insurance benefit exchanges

The second dimension of the ACO discussion is the exchanges, Maller noted.

“Exchanges simply are another vehicle designed to bring more people into the covered insured roles,” he said. “These are not to be ignored. All 50 states have them, it’s just a matter of whether your state is or the feds are administering the benefit exchange.”

As to why ACOs were embedded in the act, Maller said the answer is multifaceted.

“It’s all about the Baby Boomers; it’s all about Medicare; and it’s all about cost,” he said. “The government has a problem on its hands and it needs to figure out how it’s going to manage the cost equation for the Baby Boom generation as it gets older.

“ACOs are the vehicle to achieve that,” Maller said. “They’re being formed by providers (physicians and hospitals).”

How it works is that a Medicare beneficiary is assigned to an ACO based on his or her physician, said. The patient may simply receive a letter. The assignment is based on plurality of care by the primary-care physician. If that primary-care physician is in the ACO, the patient is assigned in-network.

Survey:

Total ACOs by Sponsoring Entity

<table>
<thead>
<tr>
<th>Sponsoring Entity</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<tr>
<td>Physician Group</td>
<td>67</td>
<td>118</td>
<td>150</td>
<td>197</td>
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<tr>
<td>Hospital System</td>
<td>60</td>
<td>145</td>
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<td>Insurer</td>
<td>20</td>
<td>46</td>
<td>35</td>
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</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>11</td>
<td>15</td>
<td>20</td>
</tr>
</tbody>
</table>

Source: “Accountable Care Growth In 2014: A Look Ahead,” David Muhlestein, Jan. 29, 2014; Leavitt Partners Center for Accountable Care Intelligence
“One interesting phenomenon is that patients can choose to opt out (at the time of care) of an ACO to which they have been assigned, similar to out-of-network coverage,” Maller said. “Here we are trying to control costs, but we’re going to allow patients the ability to opt out at the time of care.”

Of import with regard to the opting-out privilege, he noted that this option is part of Phase 1. Do not expect this privilege to continue in the future, he warned.

“There’s going to be pressure to force those primary-care doctors and others to make sure those patients are seen in-network,” he said. Overall, ACOs—if working according to purpose—are designed to improve quality outcomes, improve overall care, and lower costs, Maller explained.

**ACO STRATEGIZING**

(Continued from page 37)

As for which physician are forming ACOs, Maller said, “ACOs are trying to follow the same mantra of encouraging you to a) play and b) play by the rules.”

As for which physician are forming ACOs, he said to look to primary care.

“They’re the ones who are trying to exercise control over market share,” Maller said. “They’re smart enough to figure out if they can aggregate, they have an opportunity to a) be an ACO, b) have a seat at the table, c) control market share, then d) dictate to you all as specialists how this is all going to work.”

In addition to primary-care physicians, don’t forget the payers, who are also intent on determining how to operate effectively in the ACO market, Maller advised.

“In many cases, they’re forming their own or they’re forming a joint venture with provider organizations,” he said.

In aggregate, there are more than 600 Medicare-based (366 or 60.4%) and estimated private and public ACOs (240 or 39.6%). It represents about 18.2 million covered lives today (estimated Medicare-covered beneficiaries, 5.3 million or 29.1%; estimated covered patients through private and public ACOs, 12.9 million or 70.9%).

**ACO STRATEGIZING**

One primary goal of ACOs will likely be to use the network as leverage in negotiations with commercial payers, according to Maller.

“Many will use them as opportunity to participate in expansion of Medicare managed-care programs,” he said. “There’s an attempt to aggregate providers to achieve better care coordination and lower cost. They’re going to have their own products, compete with the same people they’ve been providers for (meaning they’re going to compete with payers). They will market the ‘network’ product direct to consumers and thereby attempt to gain additional market share.”

As for a healthy response to the situation if uncertain where to fit in, Maller advises not to overreact.

“Don’t ignore it either,” he said. “Assess your personal and professional goals. Consider how these changes are likely to impact the practice. Continue to focus on building efficiencies. Get better at tracking and measuring. Focus on building the cash pay service offering. Be a little smarter about how you run your business.”

“If it were me, I am always looking to diversify in things where government does not control what I do,” Maller added. “You have to ask yourself what health-care purchasers really want.”

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This article was adapted from Maller’s presentation at the 2014 meeting of the American Society of Cataract and Refractive Surgery. Maller did not indicate any financial interest in the subject matter.

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“This is the glaucoma meeting to attend.”

–George A. Cioffi, MD
Chairman of Ophthalmology, Columbia University of Physicians and Surgeons
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