



Cornea Day topics range from nomograms to glaucoma

by Michelle Dalton, contributing writer

The 2014 Cornea Day program featured presentations on topics ranging from advances in cataract surgery for the corneal surgeon, to the benefits of using viscosurgical devices and staining materials for better visualization.

Calculating nomograms with femto lasers

With 50% of all patients presenting for cataract surgery having “at least 0.75 D of astigmatism,” choosing how to correct that astigmatism is becoming more of an issue, said **Kendall Donaldson, MD**, Miami. Studies have shown that for astigmatism levels of 2.25 D or higher, toric IOLs are preferred, but at lower levels there’s not much statistical difference in outcomes between toric and limbal relaxing incisions (LRIs).

“We know from the Nichamin nomograms that we need to treat with-the-rule astigmatism differently from against-the-rule,” she said.

Although there are no published nomograms when using the femtosecond laser, “if you’re using the Donnenfeld or Nichamin nomograms, subtract about 33% from your manual nomograms,” she said.

Some tips for success when using the femtosecond laser: patient selection, managing patient expectations, and “select and personalize your nomogram with continual outcome analysis.”

Dry eye and LASIK compatibility

The etiology of dry eye is “not perfectly clear,” and the neurotoxicity of the excimer laser results in a cyclical process of “inflammatory dessication of the ocular surface,” said **Elizabeth Yeu, MD**, Norfolk, Va. Several factors increase the risk of dry eye complica-



Drs. Donaldson and Koch speak at the 2014 Cornea Day.

tions/complaints in the postop LASIK patient, including low Schirmer’s scores, preop contact lens wear, and ocular allergies, among others.

“An older age and female gender may confer a greater risk,” she said. Race may also play a role, as chronic dry eye after 6 months is seen more frequently in Asian eyes than in Caucasian eyes, she added. Postop dry eye will peak between 1 week and 3 months after LASIK, and will be “considerably worse” if preop dry eye exists, she said. She suggests tear film break-up time be more than 8 seconds and preop dry eye be mild before considering LASIK in these eyes.

In general, she suggested treating preop dry eye medically first, then procedurally, which may include thermal pulsation or chalasis cauterization.

“If dry eye does not resolve, these patients will be poor candidates for LASIK,” he said.

Include posterior corneal measurements

Douglas D. Koch, MD, Houston, stressed to attendees here that “if you measure only the anterior cornea,” there will be over- and undercorrection, depending on which IOL is chosen and whether astigmatism is with-the-rule (WTR) or against-the-rule (ATR). If the



Cornea Society

Advancing the treatment of corneal disease

Summer 2014

President's Message

Dear Cornea Society members,

The Cornea Society had a busy but very successful winter and spring, culminating most recently with terrific ASCRS and ARVO meetings. We co-sponsored Cornea Day with the ASCRS Cornea Committee on Friday right before the ASCRS•ASOA Symposium & Congress in Boston. We had more than 1,300 attendees for what many people considered the best Cornea Day in recent memory. This was followed by the Society's networking dinner at the Hard Rock Café and DJ party later that evening at Guilt featuring **Tony Aldave, MD**, and **Terry Kim, MD**. I am constantly amazed how the two of them can get up and function the next day! The Young Physicians Symposium, which we co-sponsor with ASCRS, took place on Saturday morning, and while some attendees straggled in a bit late (perhaps they were at the DJ party), it too was well attended and well received. **Barry Lee, MD**, the Society's scientific program chair, organized a great symposium at ASCRS on corneal ectasia on Sunday, which was also very well attended. **Michael Belin, MD**, and **Sadeer Hannush, MD**, moderated the VISTA dinner at ARVO in Orlando where many younger physicians presented cases to the entire group; an enjoyable time was had by all. The IC3D project spearheaded by **Jayne Weiss, MD**, which we sponsor, also met at ARVO.

The Cornea Society sponsored a current cornea fellow, **Travis Rumery, DO**, from the University of Wisconsin, to attend the AAO Mid-Year Forum in Washington, D.C., in April. Gail Reggio, Travis, **Shahzad Mian, MD**, our AAO councilor, and I had a delightful dinner in D.C. Travis describes his experience at the Mid-Year Forum in this newsletter.

The Society, in conjunction with the Asia Cornea Society, awarded the 2nd Cornea Ed Observership to **Mahshad Darvish, MD**, who completed his observership with Cornea Society Past President **Donald Tan, FRCS**, at the Singapore National Eye Center in April. You can learn more about his experience in his article on page 6 of this newsletter.

We are continuing to work on the Cornea Fellows Educational Summit, which is tentatively planned for this fall. We ran it for the first time last fall, and more than half of the cornea fellows from around the country attended the 2-day meeting that included didactics and wet labs. We have applied for several educational grants to be able to put this program on and are waiting to hear back.

The Society continues to organize Cornea Subspecialty Day and the Cornea Society Symposium at the AAO annual meeting. We co-sponsor the Fall Educational Symposium the Friday before the AAO annual meeting with the EBAA, which will take place October 17 in Chicago—don't miss it! Free paper submissions will open in July at CorneaSociety.org.

Each year at the AAO annual meeting we hold a breakfast for the cornea fellowship directors to get together and discuss topics of shared interest in an informal setting. This year the breakfast will take place at the Westin on Michigan Avenue; a formal invitation will be sent to all directors later this summer. Please check the Society website for more details.

The big project for the Society over the next 11 months is organizing World Cornea Congress VII just prior to the ASCRS•ASOA Symposium & Congress in San Diego on Thursday, April 16, and Friday, April 17, with a welcome reception on the evening of April 15. Hotel reservations are now open on the Cornea Society website (corneasociety.org). The Planning Committee (**Donald Tan, FRCS**, **Marian Macsai, MD**, **Terry Kim, MD**, **Michael Belin, MD**, **Kathy Colby, MD**, **Barry Lee, MD**, **Vincenzo Sarnicola, MD**, and myself) met for more than 3 hours at the ASCRS meeting to select lecture topics, keynote speakers, and invited speakers. We will also have free paper and poster sessions. The call for free paper and poster submissions will be this August. Given the huge amount of work it takes to put on such a meeting, we have appointed a Free Paper/Poster Abstract Review Task Force to help: **Natalie Afshari, MD**, **Esen Akpek, MD**, **Tony Aldave, MD**, **Penny Asbell, MD**, **Robert Feder, MD**, **Sadeer Hannush, MD**, **Bennie Jeng, MD**, **Steve Kaufman, MD**, **Akira Kobayashi, MD**, **Friedrich Kruse, MD**, **Francis Mah, MD**, **Parag Majmudar, MD**, **Shahzad Mian, MD**, **Anjali Pathak, MD**, **William Trattler, MD**, and **Gerald Zaidman, MD**. The Planning Committee has a weekend meeting planned for the fall to finalize the entire program.

One final note: We want to congratulate one of our own, **Dr. Nag Rao**, for recently being elected the president of the Academia Ophthalmologica Internationalis, an incredible honor. Nag was on the Cornea Society Board for many years. The Cornea Society nominated him for the AAO's Outstanding Humanitarian Service Award, which he received in 2013.

Sincerely,
Christopher J. Rapuano, MD
 President



continued from page 1

ATR is on the front cornea, it will be steeper horizontally and will not create much of a change on the back surface, but a WTR astigmatism (steeper on the posterior surface) can result in as much as 0.9 D difference.

“I try to leave patients with 0.4 D of WTR astigmatism. That gives them good uncorrected vision for many years,” he said, adding the importance of accounting for the impact of effective IOL toricity of IOL power and anterior chamber depth. Two nomograms to use are the Holladay II and the Abbott Medical Optics (Santa Ana, Calif.) toric IOL calculator.

“Don’t forget to factor in surgically induced astigmatism,” he said. He has proposed a nomogram that ups the threshold from 1 to 1.7 D of WTR and lowers it by 0.7 D in ATR.

The “holy grail” for perfecting nomograms would be the ability to measure the posterior corneal with either Scheimpflug or optical coherence tomography, he said.

Using femto lasers in glaucoma patients

Surgeons are well aware that IOP spikes occur during phaco, often exceeding 60 mmHg, but advanced phaco machines will address these fluctuations. **Malik Y. Kahook, MD**, Aurora, Colo., said that few publications currently address IOP changes related to femto cataract surgery. “The literature suggests a modest rise in IOP during suction and treatment,” he said.

The potential benefits of femto cataract in pseudoexfoliation patients are that there are “less manipulation of the lens and lens zonules and less phaco energy, so there’s less stress on the zonules,” Dr. Kahook said. “One caveat is that the laser needs a pupil dilation of 4.8 mm and in some cases of pseudoexfoliation, that is not possible.”

Avoid femto cataract in these patients when there is a functioning bleb, or when there is a drainage device and functioning bleb, he said.

“Consider the condition of the bleb and tube position preoperatively,” he said. **CN**

Editors’ note: Dr. Donaldson has no related financial interests. Dr. Koch has financial interests with Abbott Medical Optics and Alcon (Fort Worth, Texas). Dr. Yeu has financial interests with companies including Abbott Medical Optics, Alcon, Allergan (Irvine, Calif.), Bausch + Lomb (Rochester, N.Y.), and TearLab (San Diego).

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Advocacy Ambassador Program and Mid-Year Forum experience

by Travis Rumery, DO



From left to right: Aaron Holtebeck, MD, Travis Rumery, DO, Joseph Schmutz, MD, Senator Tammy Baldwin, John McAllister, MD, Andrew Thliveris, MD, PhD, and Kevin Flaherty, MD

During Academy president Dr. Greg Skuta's address at the American Academy of Ophthalmology opening session, he called Academy members to actively engage in leadership within key medical societies, to accept opportunities to serve or lead, and to advocate for our great specialty. When I received an email from the Cornea Society regarding the Advocacy Ambassador Program, it was clear that I needed to apply. Needless to say, I was more than excited when I was notified that I had been selected as the 2014 Advocacy Ambassador sponsored by the Cornea Society.

The experience offered a unique opportunity to reach out to our elected representatives and their staff on important issues impacting our profession. We were welcomed to

Washington, D.C. at the height of cherry blossom season. We had an Advocacy Ambassador Program briefing on Wednesday evening before heading to Capitol Hill on Thursday morning. This provided us with ample background on the 5 key initiatives we would discuss with our elected representatives. I was struck with the tremendous amount of work that had already been done prior to our arrival to arrange all the events surrounding Congressional Advocacy Day.

Thursday morning came with great anticipation and fervor. Setting foot in the Hart Senate Office Building to meet with Senator Tammy Baldwin of Wisconsin, I could not help but think about those who had walked the halls before me. Our first meeting was a success. Sen. Baldwin was delightful and very receptive to all of our key initia-

tives, as were her staffers. During this meeting, she was kind enough to take a photograph with our team. We felt very lucky to meet the Senator in person as some advocates have never had that opportunity. My team had two additional meetings, both of which felt successful. Gaining insight into the process of lobbying was a great experience. We found the staffers to be very knowledgeable, and they have a tremendous responsibility to take in information, research it, and then present it to their senator or member of Congress.

Thursday evening, there was a post Capitol Hill visits debrief session for the Advocacy Ambassadors involving members of the Young Ophthalmologists (YO) Organization. This was a great time to share our exciting experiences from earlier in the day and learn how to remain enthusiastic about advocacy for ophthalmology after we returned home.

To me, this was the biggest takeaway from my time in Washington, D.C.—to remain highly engaged throughout our careers, seek active involvement in national ophthalmology societies, and become involved at the state level within our state ophthalmology societies.

The remainder of the meeting consisted of the Mid-Year Forum and council meetings. These meetings provided insight into the hard work fellow ophthalmologists put into protecting our profession and making it run well. I cannot thank the Cornea Society, who sponsored me as an Advocacy Ambassador, and my fellowship director, **Neal Barney, MD**, enough for affording me this tremendous opportunity. **CN**

Update from *Cornea*, the journal of the Cornea Society

by Alan Sugar MD, editor in chief

The journal has caught up with the backlog of papers. While this should make acceptance of new manuscripts easier, our acceptance rate is still around 30–35%. Below are some suggestions to increase the chances of acceptance of your paper:

1. Make sure that your studies present new and useful information. Repetition of studies done many times and well in the past clutters the literature and wastes resources.
2. Make sure that studies involving human subjects are approved by an Institutional Review Board or Ethics Committee.
3. When preparing your manuscript, do it right the first time. Consult the “Instructions for Authors” (journals.lww.com/corneajrnl) for details. Poorly written and formatted papers don’t impress reviewers. Improper formatting of references is a frequent problem that requires return to the authors and slows publication.
4. Make sure that ALL authors have read and proofread the manuscript and given their approval. Having all authors review all iterations and make corrections improves the product.
5. If English is not your native language, a fact for about 70% of our authors, seek editing help from a native English speaker when necessary.
6. Respond promptly and thoroughly to requests for revisions.

Thank you for reading the journal, and please continue to submit your best work to *Cornea*. **CN**

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- Eye Banking

Important Dates

- Abstract Submission Opens- December 31, 2013
- Abstract Submission Closes- September 1, 2014
- Notification of Abstract Review Results- September 25, 2014

Cornea Ed observership at SNEC

by Mahshad Darvish, MD



Drs. Tan and Darvish at the Singapore National Eye Center

After finishing my fellowship in cornea and external disease at the Cincinnati Eye Institute, I decided to travel in Asia. In the middle of the trip, I was able to arrange a 3-week observership with **Donald Tan, FRCS**, at the Singapore National Eye Center (SNEC) thanks to a grant from the Cornea Society. My expectation was that I would see similar cases to what I saw during my training in North America and minor variations on their surgical treatment. Instead, I was elated to find a significantly different spectrum of cases as well as new and novel variations on surgical techniques.

From my first cornea clinic with Prof. Tan, I realized that the cases seen in Singapore varied quite differently from those seen at the centers that I had trained in. Due to the warm and humid climate, fungal keratitis is a regular occurrence in Singapore. In any given day, there was usually a new case added to the several cases that were being followed in the clinic. During my

stay, I even saw a case of infectious keratitis due to the fungus-like parasite *Pythium insidiosum*. This was the first time I had been made aware of this pathogen and the fact that it is resistant to conventional anti-fungal medical treatment.

Another pathogen that I gained an appreciation for during my time in Singapore was cytomegalovirus (CMV). Specifically, Prof. Tan explained how CMV endotheliitis with corneal edema could masquerade as other endothelial conditions requiring either Descemet's stripping automated endothelial keratoplasty or Descemet's membrane endothelial keratoplasty. The problem lies in the fact that the primary etiology of the endothelial decompensation has not been addressed and can recur. This can be mistaken for allograft rejection and the cycle perpetuates. As a result, I now have a heightened awareness for this and will do PCR for CMV on an aqueous tap sample in suspicious cases.

After my fellowship with **Edward Holland, MD**, I gained a particular

interest and appreciation for the ocular surface. Therefore, I found it interesting that Prof. Tan's clinics had a significant number of patients with advanced sequelae from Stevens-Johnson syndrome (SJS). While no prospective epidemiological studies have been done to compare the incidence of SJS in Asia to Europe or North America, anecdotally the incidence seems higher. This may be due in part to the higher incidence of HLA-B*1502, which is strongly associated with SJS, in the Asian population. The severity of the cases may also be due to the socioeconomic status of the catchment area of the Singapore National Eye Center, which encompasses all of South East Asia. Many of the patients had not received optimal care during their initial episode, and as a result most had total limbal stem cell deficiency and many had keratinized ocular surfaces.

Interestingly there were several pathologies that were quite common in my previous training, which I found were rare in Prof. Tan's practice. These included what I considered bread and butter corneal diseases such as Fuchs' dystrophy, epithelial basement membrane degeneration, and herpes simplex keratitis. Similarly, ocular surface diseases that I was used to seeing such as mucous membrane pemphigoid (ocular cicatricial pemphigoid) and aniridia were notably scant in his practice.

The spectrum of surgical procedures that I observed with Prof. Tan naturally reflected the pathologies that he encounters in his clinic. I learned how different Asian eyes are compared to Caucasian ones; on average, the anterior chamber is much shallower, making DSEAK and DMEK more difficult in these eyes. Further complicating these procedures is the increased vitreous pressure present in these eyes.

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Therefore, one's surgical techniques have to be modified in order to compensate for these factors.

Prof. Tan is a strong advocate for lamellar surgeries such as deep anterior lamellar keratoplasty (DALK), DMEK, and DSEAK. He uses the latter two quite extensively, even in cases of endothelial failure with stromal scarring. When comparing preoperative photos with the postoperative results that I saw in his clinic, I was routinely surprised at how effective stromal remodeling was in clearing up stromal scars that I would have chosen to treat with a penetrating procedure. Likewise, Prof. Tan prefers to use DALK, using either the manual dissection or big bubble techniques to treat most stromal pathologies. Due to the high prevalence of fungal keratitis, he performs a large number of therapeutic grafts, and I was pleasantly surprised to see that he treats many of them with manual DALK with excellent results.

The most radical procedure that I witnessed at the Singapore National Eye Center was the osteo-odonto-keratoplasty (OOKP). Even though I had read about the procedure and seen videos of it, nothing prepared me to witness the procedure. Given the fact that the majority of the ocular surface disease in Prof. Tan's practice is severe SJS with a keratinized ocular surface and these patients typically do poorly with procedures such as the Boston keratoprosthesis or keratolimbal allografts, the OOKP is an appropriate option.

Finally, I was able to join Prof. Tan for some refractive surgery. In addition to conventional LASIK and PRK procedures, I observed the ReLEX SMILE procedure for the first time. Overall, Asian eyes have a much higher degree of myopia, with the average ablation at the Singapore National Eye Center being around -6 D. Interestingly, I learned that the Asian corneas have a much lower incidence of post-refractive ectasia, and therefore one can be more aggressive in the treatment.

Overall, my time in Singapore was an excellent addition to my corneal training. The ability to observe a procedure and ask questions in real time leads to a far more enriching experience than watching a video or reading an article. I would like to thank the Cornea Society for funding this educational opportunity and encourage all young ophthalmologists to further their training through an international observership. **CN**

Cornea Ed is a joint program sponsored by the Asia Cornea Society and the Cornea Society providing observerships and fellowships to Society members as well as an online database of cornea programs. Please visit the website for more details: www.corneaed.org.

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New concepts in treating corneal ectasia

by Michelle Dalton, contributing writer

When it comes to treatments for keratoconus, 46% of attendees at a symposium on managing corneal ectasias would only consider toric IOLs if the patient did not wear rigid gas permeable lenses (RGP), and 34% would never implant a toric lens in these patients.

In practice, 60% of audience respondents perform corneal crosslinking, and 61% prefer the epi-off technique to epi-on.

In a patient who had severe keratoconus and is contact lens intolerant, 47% of audience respondents at the “What’s New in the Management of Corneal Ectasias” symposium at the 2014 ASCRS•ASOA Symposium & Congress, sponsored by the Cornea Society, would opt to perform big bubble deep anterior lamellar keratoplasty (DALK), 33% would perform penetrating keratoplasty, and 11% would perform femtosecond-assisted DALK.

Thomas Harvey, MD, Eau Claire, Wis., noted that any discussion of lenses in keratoconus patients would be off-label, but when others ask him why he uses a lens to treat the condition, his response is usually, “Why not?”

“As long as there is stability of the corneal shape, and there is a favorable non-corneal anatomy,” he said. Several factors should play a role in the decision-making process, he said, including the cornea (consider the astigmatism, elements of irregularity) and the crystalline lens (consider age, amplitude of accommodation, etc.)

“Implanting phakic IOLs in patients with keratoconus is not for the faint of heart,” he said. “Patients must have a clear lens with good accommodation.”

Some studies have shown the toric ICL (STAAR Surgical, Monrovia, Calif.) has visual results of 20/25 three years after implantation when used in combination with crosslinking. “These are amazing visual results,” Dr. Harvey said, “but there was a cumulative 9% endothelial cell count decrease, which may be a result of crosslinking before lens implantation.”

The literature is full of “small studies, but phakic IOL use in this patient population is a bridge procedure,” he said.

Surgeons should also consider which formula and target they’re using. “The Hoffer Q does not work well in patients with ectasia,” he said.

He recommended surgeons determine if the patient is going to need a contact lens after any procedure, only consider phakic IOLs in those with truly clear lenses, and place sutures in the eye.

Contact lenses are useful for “any corneal ectasia,” said **Deborah Jacobs, MD**, Boston. Conventional treatment of corneal ectatic disorders is typically spectacles, silicone hydrogel lenses, or RGP contact lenses.

“Contact lenses are most effective when the myopia is dominant over the astigmatism,” she said. RGP lenses are the only ones that can also address astigmatism, she said. She considers contact lenses a “new field” in the treatment of corneal ectasia because “U.S. ophthalmologists lost interest in contact lenses” about 20–25 years ago with the advent of the PC IOL.

“In countries where MDs still prescribe lenses, more than 50% use RGP for ectasia,” she said, citing France and Japan, but in countries where ODs prescribe lenses, “it’s under 5%.”

There are several lenses available for keratoconus, Dr. Jacobs said, including piggyback lenses, hybrids, and sclerals.


“There are lenses specifically designed for keratoconus with

innovative base curves,” she said. Surgeons can piggyback “any hard lens over any soft lens” but these have tended to fail because of hypoxia or lens placement.

Hybrid lenses are also not an ideal choice, as they may fail because of juncture breakdown, adherence (suction), or neovascularization.

“Patients see well even when there is a suboptimal fit,” Dr. Jacobs said. **CN**

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2014 Mid-Year Forum and Congressional Advocacy Day

The American Academy of Ophthalmology held its annual Mid-Year Forum and Congressional Advocacy Day on April 9–12 in Washington, D.C. The goal of the Mid-Year Forum is to discuss critical issues facing ophthalmology and to provide input to the AAO's Board. Congressional Advocacy Day involves visiting members of Congress and their staff to deliver key messages impacting ophthalmologists. In conjunction with this meeting, AAO has developed the Advocacy Ambassador Program to engage and educate members-in-training about advocacy early in their careers. The program was a huge success with more than 330 ophthalmologists and 150 residents and fellows participating. The Cornea Society's ambassador this year was **Travis Rumery, OD**, currently a cornea fellow at University of Wisconsin, Madison.

The Congressional Advocacy Day messages included: fair and stable Medicare reimbursement, truth in advertising, funding support for the National Eye Institute and Department of Defense Vision Trauma Research Program and the Electronic Health Records Improvement Act. The sustainable growth rate formula needs to be fixed with a cost of \$116 billion over the next 10 years. Physicians need fair and stable updates in order to function with new systems reforms. The Truth in Marketing Act (HR 1427) clarifies the level of education and training of the providers. The AAO supports funding for the NIH at \$32 billion with \$730 million for the NEI. The Electronic Health Records Improvement Act creates a 3-year hardship exemption for small offices and physicians in and near retirement to avoid shortages. Topics covered at the Mid-Year Forum included finding balance in a changing reimbursement landscape and a discussion on the use of registries for assessing quality of care.

Next year's meeting will be held April 15–18 at the Marriott Marquis in Washington, D.C. **CN**

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

Corneal Effects

Use of topical NSAIDs may result in keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs including ILEVRO™ Suspension and should be closely monitored for corneal health. Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g., dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Postmarketing experience with topical NSAIDs also suggests that use more than 1 day prior to surgery or use beyond 14 days post surgery may increase patient risk and severity of corneal adverse events.

Contact Lens Wear

ILEVRO™ Suspension should not be administered while using contact lenses.

ADVERSE REACTIONS

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

Ocular Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation. These events occurred in approximately 5 to 10% of patients.

Other ocular adverse reactions occurring at an incidence of approximately 1 to 5% included conjunctival edema, corneal edema, dry eye, lid margin crusting, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, photophobia, tearing and vitreous detachment.

Some of these events may be the consequence of the cataract surgical procedure.

Non-Ocular Adverse Reactions

Non-ocular adverse reactions reported at an incidence of 1 to 4% included headache, hypertension, nausea/vomiting, and sinusitis.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects.

Pregnancy Category C: Reproduction studies performed with nepafenac in rabbits and rats at oral doses up to 10 mg/kg/day have revealed no evidence of teratogenicity due to nepafenac, despite the induction of maternal toxicity. At this dose, the animal plasma exposure to nepafenac and amfenac was approximately 70 and 630 times human plasma exposure at the recommended human topical ophthalmic dose for rats and 20 and 180 times human plasma exposure for rabbits, respectively. In rats, maternally toxic doses ≥ 10 mg/kg were associated with dystocia, increased post-implantation loss, reduced fetal weights and growth, and reduced fetal survival.

Nepafenac has been shown to cross the placental barrier in rats. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ILEVRO™ Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Non-teratogenic Effects.

Because of the known effects of prostaglandin biosynthesis inhibiting drugs on the fetal cardiovascular system (closure of the ductus arteriosus), the use of ILEVRO™ Suspension during late pregnancy should be avoided.

Nursing Mothers

ILEVRO™ Suspension is excreted in the milk of lactating rats. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ILEVRO™ Suspension is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of ILEVRO™ Suspension in pediatric patients below the age of 10 years have not been established.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Nepafenac has not been evaluated in long-term carcinogenicity studies. Increased chromosomal aberrations were observed in Chinese hamster ovary cells exposed *in vitro* to nepafenac suspension. Nepafenac was not mutagenic in the Ames assay or in the mouse lymphoma forward mutation assay. Oral doses up to 5,000 mg/kg did not result in an increase in the formation of micronucleated polychromatic erythrocytes *in vivo* in the mouse micronucleus assay in the bone marrow of mice. Nepafenac did not impair fertility when administered orally to male and female rats at 3 mg/kg.

PATIENT COUNSELING INFORMATION

Slow or Delayed Healing

Patients should be informed of the possibility that slow or delayed healing may occur while using nonsteroidal anti-inflammatory drugs (NSAIDs).

Avoiding Contamination of the Product

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Use of the same bottle for both eyes is not recommended with topical eye drops that are used in association with surgery.

Contact Lens Wear

ILEVRO™ Suspension should not be administered while wearing contact lenses.

Intercurrent Ocular Conditions

Patients should be advised that if they develop an intercurrent ocular condition (e.g., trauma, or infection) or have ocular surgery, they should immediately seek their physician's advice concerning the continued use of the multi-dose container.

Concomitant Topical Ocular Therapy

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

Shake Well Before Use

Patients should be instructed to shake well before each use. U.S. Patent Nos. 5,475,034; 6,403,609; and 7,169,767.

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Fort Worth, Texas 76134 USA
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ILEVRO™ Suspension

Designed to put potency
precisely where you need it^{1,2}

ONCE-DAILY POST-OP

One drop should be applied once daily beginning 1 day prior to surgery through 14 days post-surgery, with an additional drop administered 30 to 120 minutes prior to surgery³

Use of ILEVRO™ Suspension more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events³

INDICATIONS AND USAGE

ILEVRO™ Suspension is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract surgery.

Dosage and Administration

One drop of ILEVRO™ Suspension should be applied to the affected eye one-time-daily beginning 1 day prior to cataract surgery, continued on the day of surgery and through the first 2 weeks of the postoperative period. An additional drop should be administered 30 to 120 minutes prior to surgery.

IMPORTANT SAFETY INFORMATION

Contraindications

ILEVRO™ Suspension is contraindicated in patients with previously demonstrated hypersensitivity to any of the ingredients in the formula or to other NSAIDs.

Warnings and Precautions

- Increased Bleeding Time – With some nonsteroidal anti-inflammatory drugs including ILEVRO™ Suspension there exists the potential for increased bleeding time. Ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphema) in conjunction with ocular surgery.
- Delayed Healing – Topical nonsteroidal anti-inflammatory drugs (NSAIDs) including ILEVRO™ Suspension may slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.
- Corneal Effects – Use of topical NSAIDs may result in keratitis. In some patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use.

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

Use more than 1 day prior to surgery or use beyond 14 days post-surgery may increase patient risk and severity of corneal adverse events.

- Contact Lens Wear – ILEVRO™ Suspension should not be administered while using contact lenses.

Adverse Reactions

The most frequently reported ocular adverse reactions following cataract surgery occurring in approximately 5 to 10% of patients were capsular opacity, decreased visual acuity, foreign body sensation, increased intraocular pressure, and sticky sensation.

For additional information about ILEVRO™ Suspension, please refer to the brief summary of prescribing information on adjacent page.

References: 1. Ke T-L, Graff G, Spellman JM, Yanni JM. Nepafenac, a unique nonsteroidal prodrug with potential utility in the treatment of trauma-induced ocular inflammation, II: In vitro bioactivation and permeation of external ocular barriers. *Inflammation*. 2000;24(4):371-384. 2. Data on file. 3. ILEVRO™ Suspension package insert.

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ILEVRO™
**(nepafenac ophthalmic
suspension) 0.3%**