



Cornea Society and EBAA Fall Educational Symposium wrap-up

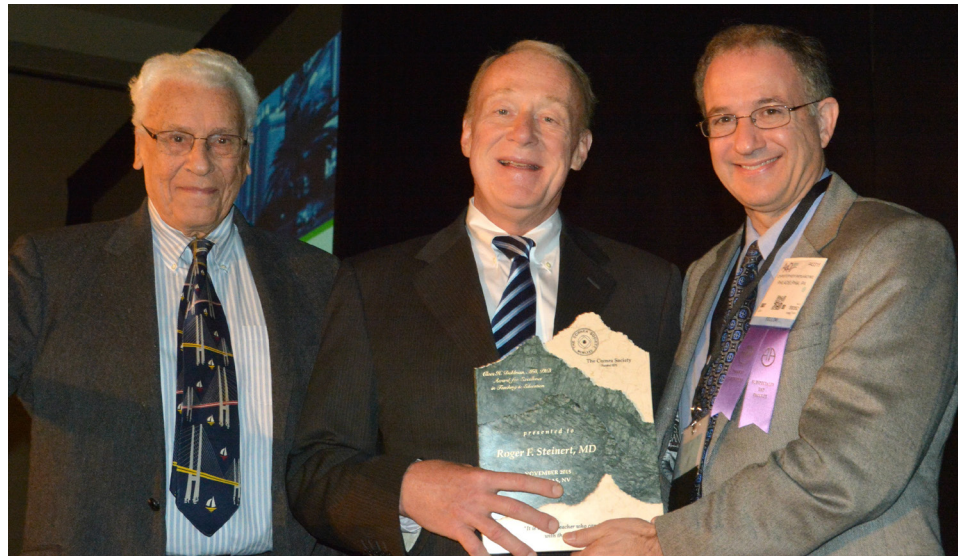
The Cornea Society and Eye Bank Association of America (EBAA) held the Fall Educational Symposium on November 13 at Caesar's Palace in Las Vegas. The full day of programming featured presentations on a number of topics within the cornea subspecialty and included the presentation of the Claes H. Dohlman, MD, PhD, Award to **Roger Steinert, MD**, Irvine, Calif. **Christopher Rapuano, MD**, Philadelphia, presented the award to Dr. Steinert, with Dr. Dohlman in attendance.

The award is presented to someone with a lifetime of teaching excellence in the field of cornea and external disease, according to Dr. Rapuano. Dr. Steinert has had teaching success over the years in a variety of organizations and institutions. What it really comes down to, Dr. Rapuano said, is residents, fellows, and many others regard him as a "superb" teacher. He has taught practicing cornea specialists around the world.

"I can't tell you how much this means to me from all of you and Claes," Dr. Steinert said, accepting the award and noting that Dr. Dohlman has been his mentor since he started in medical school.

During the meeting, **George Rosenwasser, MD**, Hershey, Pa., gave the R. Townley Paton Award Lecture on the topic of "Eye Banking 2015: Where We Came From and Where We're Going." The lecture covered the early history of eye banking, the development of endothelial keratoplasty through the eye of the innovators, and a summary of novel techniques in development.

Dr. Rosenwasser shared the history of the EBAA. In the 1950s, 12 banks got together, but it wasn't until 1961 that the organization was actually formed. Then came the medical standards in the 1980s and the first medical advisory board in the 1990s.



Roger Steinert, MD, receives the 2015 Claes H. Dohlman, MD, PhD Award presented by Christopher Rapuano, MD, and Claes Dohlman, MD, PhD, at the Fall Educational Symposium in Las Vegas.

He spoke about a number of pioneers in the field, including **Charles Tillett, MD**, **Jose Ignacio Barraquer, MD**, **Gerrit Melles, MD**, **Mark Terry, MD**, **Francis Price, MD**, and **Mark Gorovoy, MD**, among others, who contributed to advancements in endothelial grafts and many of the current approaches to corneal transplantation. Dr. Rosenwasser said that some of his life-altering events involved his time with Dr. Terry and **Mike Straike, MD**, working on DLEK, DSEK, and DSAEK procedures.

With current data, it seems as though DMEK and DSAEK are neck and neck, while EK seems to dominate PK, with one possible reason being that it's environmentally friendly. From 2005–2014 about 171,988 EK procedures were performed in the U.S., he said.

So what's new in transplantation? "For the future, you have to think outside the box," Dr. Rosenwasser said. Possible options being studied include using half grafts, ex-vivo expansion, using no graft at all, tissue engineering,

a cell-based approach for the treatment of corneal endothelial dysfunction, and a number of other possible approaches.

Also during the symposium was the Richard C. Troutman, MD, DSc, Prize Lecture given by **Mark Greiner, MD**, Iowa City, Iowa, on "Diabetes Mellitus Increases Risk of Unsuccessful Graft Preparation in Descemet Membrane Endothelial Keratoplasty: A Multicenter Study."

His lecture focused on how diabetes may affect graft preparation in DMEK. Tears can sometimes occur in preparation for DMEK, he said, and if a tear occurs in the central graft, this could then make it unsuitable for transplantation. It has been found that more preparation tears are occurring in tissue from diabetic donors.

In a retrospective review, Dr. Greiner said there was a 15.3% failure rate for diabetic donors, while there was only about a 1.9% rate for non-diabetic donors. This means that there was an almost 9 times greater failure rate in

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Cornea Society

Advancing the treatment of corneal disease



Christopher Rapuano, MD

President's Message

Dear Cornea Society members,

On the east coast these days, the weather is cold and dreary. To help keep me warm, I try and remember the beautiful sunny days of Las Vegas during the American Academy of Ophthalmology (AAO) meeting in November. What a terrific meeting! The Cornea Society was quite busy that week. We started with the Board of Directors meeting Thursday evening during which the following were elected to the Board of Directors: **Eddie Alfonso, MS, Deepinder Dhaliwal, MD, Luigi Fontana, MD, and Shigeto Shimmura, MD.**

Thanks to all members-with-thesis for your nominations. The following officers were also selected to serve on the Executive Committee: **Elmer Tu, MD**, president elect, **Kathryn Colby, MD, PhD**, secretary treasury, **Barry Lee, MD**, vice president of industry relations, and **Bennie Jeng, MD**, vice president of international relations. **Anthony Aldave, MD**, was selected as the scientific program chair. All terms will begin January 1, 2016. I would like to especially thank the following members of the Board of Directors whose terms end December 31, 2015 for their service and hard work on behalf of the Society: **Natalie Afshari, MD, and Sonia Yoo, MD.**

On Friday, we sponsored the Cornea Fellowship Director Breakfast followed by the combined Cornea Society and Eye Bank Association of America Fall Educational Symposium where **Roger Steinert, MD**, was given the Dohlman Teaching Award. It was particularly wonderful to be able to co-present this award with Dr. Dohlman, who is as sharp as ever! That night, **Tony Aldave, MD, and Terry Kim, MD**, reprised their roles as star DJs at the DJ Party at the Hard Rock Hotel. On Saturday, **Stephen Kaufman, MD, Bennie Jeng, MD, and Shahzad Mian, MD**, organized a fabulous Cornea Subspecialty Day, which had a record number of attendees. Later in the week, the Cornea Society Symposium, titled "Glaucoma and the Anterior Segment: Coexistence in Harmony or With Harm?" was a great success and was highlighted by **Elisabeth Cohen, MD's** wonderful Castroviejo Medalist Lecture on "Herpes Zoster."

Last October, we ran our 3rd Cornea Fellows Educational Summit, which was another gigantic success. The Program Chairs were **Barry Lee, MD, Kathryn Colby, MD, and Deepinder Dhaliwal, MD**. The faculty included **Esen Akpek, MD, Tony Aldave, MD, Jessica Ciralsky, MD, Bennie Jeng, MD, Elmer Tu, MD, and myself**. This year we had an expanded wet lab that incorporated creating femtosecond laser LASIK flaps and learning a variety of endothelial keratoplasty insertion techniques. We plan to do it again next fall.

The AAO meeting was my last hurrah as president of the Cornea Society, as my 2-year term ends December 31, 2015. It has been a busy but terrific ride. Needless to say, World Cornea Congress VII was our focus for much of the past few years. However, we were able to accomplish a great deal more, including very successful Cornea Fellows Educational Summits, co-organizing or organizing Cornea Subspecialty Day at the AAO annual meeting and Cornea Day at the ASCRS•ASOA Symposium & Congress, and taking over the VISTA Dinner at the Association for Research in Vision and Ophthalmology (ARVO) meeting. Our presence at international scientific meetings has increased tremendously, almost singlehandedly due to **Michael Belin, MD's** active involvement; this has led to a significant increase in our international membership. The *Cornea Journal*, under **Alan Sugar, MD's** superb leadership, is thriving. Additionally, the *Cornea Journal* published the 2nd Edition of the International Committee for Classification of Corneal Dystrophies (IC3D) and the Global Consensus of Keratoconus and Ectatic Diseases, both of which the Society supported. We continue to work with the AAO, ASCRS, American Board of Ophthalmology, FDA, and Medicare on issues of importance to ophthalmology in general and cornea specifically.

One of our future focuses will be on CorneaEd, which is a comprehensive educational database providing detailed information and web-based links for fellowship training and observership programs in cornea and external disease. Conceived by the Cornea Society and the Asia Cornea Society, CorneaEd offers information on clinical educational opportunities available throughout the U.S. and the Asia-Pacific region, with a view for subsequent expansion to other parts of the world.

I would like to invite all of you to attend Cornea Day 2016 taking place May 6, 2016 in New Orleans preceding the ASCRS•ASOA Symposium & Congress. This meeting is planned in conjunction with the ASCRS Cornea Clinical Committee and promises to be a terrific meeting with engaging panel discussions, interactive talks, and dynamic discussions.

I could not, and did not, accomplish any of this by myself. I had tremendous help from many people throughout my 2 years as president. Although they are too numerous to mention, I would like to especially thank the ASCRS leadership, including David Karcher, Don Bell, and Don Long, and the Cornea Society Executive Committee, **Donald Tan, MD, Marian Macsai, MD, Elmer Tu, MD, Michael Belin, MD, and Terry Kim, MD**, and the entire Board of Directors. Dr. Macsai takes over the reins as president of the Society in January, and I am sure she will do a spectacular job representing and leading our subspecialty. I would encourage all members of the Society to become members-with-thesis so you can rise up through the ranks of this outstanding organization. Lastly, I want to thank Gail Reggio Albert for her ongoing work for and dedication to the Society for more than 10 years.

Thank you again for your support over the past 2 years.

Sincerely,
Christopher J. Rapuano, MD
President

Cornea Subspecialty Day 2015

At the American Academy of Ophthalmology (AAO) Cornea Subspecialty Day 2015, physicians emphasized increasing the evidence-based approach in the subspecialty.

Serious consequences of delayed diagnosis of *Acanthamoeba* keratitis

Despite delayed treatment producing a 10 times greater risk of not seeing well, the vast majority of *Acanthamoeba* keratitis patients are treated “for weeks and often months” for other diagnoses, said **Elmer Tu, MD**, Glenview, Ill. “It is absolutely critical that the clinician understand the risk factors associated with *Acanthamoeba* keratitis because it can look like just about anything else,” Dr. Tu said. Subacute or chronic parasitic infection primarily affecting the cornea

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patients with diabetes. “We are in an epidemic of diabetes in this country,” he said. This means that a reasonable anticipation would be that the donor pool for grafts would be more concentrated with diabetic donors over the coming years.

The study did have a few limitations. Diabetes was defined by a historical method, which is less accurate, and the study was unable to identify undiagnosed diabetics. Premortem data is limited, he said, and there is also no way to stratify diabetes based on severity.

This raises many important questions for the future. “We feel that the most direct way to answer these questions is by a randomized prospective clinical trial of diabetes and keratoplasty,” he said.

In conclusion, Dr. Greiner said DMEK graft preparation may be more likely to fail when the donor has a history of diabetes. Functional differences in diabetic tissue may reflect structural changes. There is a high prevalence of diabetes among donors, and it’s important to use caution with diabetic tissue for DMEK graft preparation. Finally, Dr. Greiner said that further basic and prospective clinical studies are needed to identify tissue at the highest risk. **CN**

masquerades as a non-infectious process. It can appear as other types of subacute infections, including fungi, microsporidia, or herpes. *Acanthamoeba* keratitis is most likely to occur among contact lens wearers and orthokeratology patients, according to the literature. Recognition of the disease is critical because the level of disease was the main prognostic factor to determine patient outcomes, according to a study Dr. Tu co-authored in 2007. “You had a 10 times greater risk of not seeing well if you did not recognize the disease in its early stages,” which makes it very important to understand the risk factors and what the disease looks like in its early stages, Dr. Tu said.

Editors’ note: Dr. Tu has financial interests with Seattle Genetics (Bothell, Wash.).

Early herpes zoster vaccination urged amid timing questions

Vaccination of people at the earliest point allowed by regulators may prove beneficial, according to **Elisabeth Cohen, MD**, New York. Amid a growing incidence of herpes zoster—possibly related to a lack of herd immunity from the varicella (chickenpox) vaccine—the timing of the vaccine for herpes zoster remains very controversial. After first approving the vaccine in 2006, the Food and Drug Administration expanded the approval in 2011 to people in their 50s. The mean age of onset was 52 according to the Centers for Disease Control and Prevention (CDC). However, only about one-quarter of U.S. residents at least 60 years old have received the vaccination.

The CDC recommends providing vaccination to people in their 60s because complications increase with age and the efficacy duration is unknown. However, Dr. Cohen said patients in their 50s may have a longer duration of protection. “Increasing age and not time to vaccination has been found to explain the decrease in efficiency in people age 60 and older,” Dr. Cohen said.

Editors’ note: Dr. Cohen has no related financial interests.

Get to know patients to prevent KPro infections

Preventing infections following Boston Keratoprosthesis (KPro) implantation is closely linked to the level of postop follow-up, said **Kathryn Colby, MD**, Chicago. “Don’t embark on KPro surgeries unless you want to get to know these patients well and not be terribly surprised if they show up in your office unannounced,” Dr. Colby said. It is critical to educate patients to quickly call in if they have problems and regarding the importance of taking their antibiotics. Additionally, diagnosis and management of complications, including persistent epithelial defect and conjunctival erosion, will help reduce the incidence of infectious keratitis and endophthalmitis. “Early diagnosis of infiltrates and aggressive management of keratitis will ensure that these entities do not progress to infectious endophthalmitis,” Dr. Colby said. **CN**

Editors’ note: Dr. Colby has no related financial interests.

2016
CORNEA DAY

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Castroviejo Lecture at the 2015 AAO annual meeting



From left: Christopher Rapuano, MD, Peter Laibson, MD, Deborah Pavan-Langston, MD, Claes Dohlman, MD, PhD, 2015 Castroviejo Medalist Elisabeth Cohen, MD, and William Bourne, MD

Elisabeth Cohen, MD, New York, gave the Castroviejo Lecture on herpes zoster at the 2015 American Academy of Ophthalmology (AAO) annual meeting. According to a PubMed search, in the first 8 months of 2015, 300 articles were published each on herpes zoster and herpes simplex, she said.

There is an increasing incidence of zoster and decreasing age of onset of zoster, Dr. Cohen said. There is an ongoing debate on the role of the varicella vaccine in zoster epidemiology.

There are risk factors before and after zoster to consider, as well as an

ongoing debate relating to efficacy, safety, and timing of the vaccination.

It's estimated that the number of new cases per year in the U.S. is 1.2 million. Among people age 85 and older, there is a 7% mortality that has been reported, Dr. Cohen said. "It is a common misconception to think that healthy people are not at risk for zoster," she said. The rate of zoster goes up with age, and the number of cases is highest for those in their 50s. In Dr. Cohen's opinion, it is better to get the vaccine in your 50s and 60s, but she said that it is never too late.

Worldwide insurance coverage of the zoster vaccine is very limited, Dr. Cohen said. In the U.S., the underusage of the zoster vaccine remains a public health problem. Less than one quarter of eligible people age 60 and up have received it, Dr. Cohen added. Barriers to the vaccine include high cost, complex and partial reimbursement, frozen storage, and lack of strong recommendation from physicians.

Dr. Cohen's lecture covered a new vaccine against zoster, adjuvanted herpes zoster subunit, which is being studied currently. It has shown efficacy in studies, but the adjuvant used is not currently licensed by the FDA in the U.S., and Dr. Cohen said it will take years to become available in the U.S.

To conclude her lecture, Dr. Cohen shared some of the lessons that she has learned from her personal experience with zoster. In terms of being a patient, she said that she learned what it is really like to not see well and that loss of vision in one eye is much worse than she previously thought. Although she had competent and caring doctors, she noted that it's very hard to be a patient.

However, Dr. Cohen said to seize and enjoy opportunities to make contributions. She has found that she's been able to do more research and work more with medical school students. **CN**

Editors' note: Dr. Cohen has no related financial interests.

Society looking for VISTA Dinner hosts

The Cornea Society hosts the Cornea Society VISTA Dinner every year at the Association for Research in Vision and Ophthalmology (ARVO) meeting and is looking for volunteers who would be interested in hosting the event. The dinner takes place on Sunday from 7:00–10:00 p.m. and features a keynote lecture and a variety of free paper presentations.

The hosts/coordinators review the submitted abstracts for inclusion in the

program (usually this is a small number), select those that present, and order the presentations in a logical fashion. The hosts/coordinators also select the guest speaker (named lecture) and communicate with the speaker concerning the lecture, topic, and length. The hosts/coordinators arrive at least 30–45 minutes early for the meeting, and ensure tables, seating, and AV are all adequate; they direct seating to have a good mix of senior to junior physicians at the tables. They

also work as a sergeant-at-arms, in that we do enforce that attendees need to have registered in advance. During the meeting they work as MCs/moderators, direct discussion, and keep the meeting moving on time. The hosts/coordinators make sure discussion is equally distributed around the room and faculty.

Interested parties should email their CV and letter of interest to Gail Albert, executive director, at galbert@corneasociety.org by February 1. **CN**

Cornea Day 2016 set for New Orleans

Christopher Rapuano, MD, Philadelphia, president of the Cornea Society, and Terry Kim, MD, Durham, N.C., chair of the ASCRS Cornea Clinical Committee, discussed their expectations for Cornea Day 2016 in New Orleans before the ASCRS•ASOA Symposium & Congress.

“The Cornea Day program has really evolved over the years,” Dr. Kim said. “We normally get about 1,500 registrants that pack the room.” This year, they expect similar numbers. “As one of the Planning Committee chairs for the last several years, I can say that this year’s committee has worked hard to make the program dynamic and interactive,” Dr. Kim said. Presentations will be given by a number of experts in the field, including young surgeons and international faculty.

The Planning Committee for Cornea Day consists of members of the ASCRS Cornea Clinical Committee and members of the Cornea Society. The day has been divided into a refractive surgery section, a challenging cornea cases section, a corneal and conjunctival surgery section, and corneal cataract issues section, Dr. Rapuano said. This is similar to what we’ve done in the past, he said, but we tackle different aspects of these topics every year.

In the refractive surgery section, Dr. Rapuano said one of the most interesting topics will be the treatment of presbyopia. “That’s becoming a bigger and bigger issue,” he said. There are lenses, the first corneal inlay recently became available in the U.S., and there are other inlays in the pipeline. “People hate presbyopia,” he said. “For almost 30 years, people have been able to get rid of glasses with LASIK and PRK. Now patients are hitting the age of 45–50 and don’t want to go back to glasses.” The last part of the refractive surgery section will cover challenges, such as what to do in cases of epithelial ingrowth, higher order aberrations, and post-LASIK ectasia.

The section on challenging cornea cases will take a case-based approach to relatively common problems that cornea specialists see every day, Dr. Rapuano said. It will also look at corneal

complications of cosmetic procedures, including cosmetic iris implants, cosmetic eye whitening, and conjunctival tattooing.

The third section will cover what’s new in corneal surgery and progress in this field. It will focus on procedures like DALK, DSEK, and DMEK.

The fourth and final section of Cornea Day will highlight cornea and cataract problems, like IOL selection after refractive surgery, managing unhappy patients, and astigmatism management. Some of the sections will be case-based with a panel and some will have the speaker discussing each case, Dr. Rapuano said.

Last year’s 2-day World Cornea Congress VII took the place of Cornea

Day, and so Cornea Day 2016 will be a more compact meeting with a single track and fewer presentations. However, Dr. Rapuano expects Cornea Day 2016 to be a huge success. “Cornea Day works out quite well, and people are generally happy to have a succinct, jam-packed, one-day learning experience,” he said.

Dr. Kim thinks that many people find Cornea Day to be a great precursor to the ASCRS•ASOA Symposium & Congress. “I think people will find that we have the latest and greatest topics discussed in a very dynamic format that will keep them engaged,” he said. **CN**

Editors’ note: Drs. Kim and Rapuano have no financial interests related to this article.

Cornea: Journal news

Wolters Kluwer is pleased to announce the launch of Wolters Kluwer Author Services, a co-branded website that provides Wolters Kluwer authors with access to the leading provider of English-language editing and publication support services, Editage. The site

is intended as an author resource, not as a resource for editors or societies. The purpose of the site is to assist Wolters Kluwer authors in accurately preparing their paper so their research can be published in a journal.

The Wolters Kluwer/Editage website will allow authors to purchase manuscript services directly from Editage. Editors will benefit by having a trusted resource to send authors, particularly authors who are non-native English language writers who need translation services. Editage offers authors:

- Advanced editing: improving sentence structure, grammar, and language usage
- Premium editing: a more advanced assessment of the content and structure of the manuscript
- Translation services
- Journal-specific formatting
- Artwork preparation
- Pre-submission review
- Manuscript revision editing
- Live workshops and online webinars



Report from *Cornea*, journal of the Cornea Society

Submissions to *Cornea* have risen 27% from 2014 to 2015. This means that we are now receiving about 1,200 new papers annually. The acceptance rate for the first three quarters of 2015 was 34.5%. Along with the increased numbers, I think that we are able to accept better quality papers and present more important information from well-conducted clinical trials.

Two “special projects” have been published this year: the second edition of the International Committee for the Classification of Corneal Dystrophies (IC3D) report and the Global Consensus on Keratoconus and Ectatic Diseases. Supplements from the World Cornea Congress VII and the Kyoto Cornea Club provide outstanding updates on various corneal topics.

The journal is busy, growing, a great resource, and a great place to publish the best in our field.

–Alan Sugar, editor-in-chief

Course on Advanced Cornea Surgery to be held March 4–5

The 2016 Course on Advanced Cornea Surgery (CoACS) will be held in Atlanta on March 4–5, 2016. Course organizers **Yousuf Khalifa, MD**, **Barry Lee, MD**, **Brad Randleman, MD**, and **Mohammad Anwar, MD**, invite you to Atlanta for this interactive meeting between attendees, instructors, eye banking experts, and industry to learn advanced techniques in corneal surgery. The course will feature didactic and hands-on wet labs on endothelial keratoplasty (Descemet’s membrane endothelial keratoplasty [DMEK] and Descemet’s stripping endothelial keratoplasty [DSEK]), as well as femtosecond-assisted keratoplasty techniques. The latest state-of-the-art equipment and technology will be available for attendees to learn and perfect the various techniques of keratoplasty. The course will also feature didactic and wet labs covering treatments for corneal ectasia including deep anterior lamellar keratoplasty and collagen crosslinking. Learn from this joint collaboration of leading industry representatives and experienced corneal surgeons and eye banking experts.

Registration for the course will be available at med.emory.edu/cme.

Educational Summit wrap-up

In October, the Cornea Society hosted the 3rd annual Cornea Fellows Educational Summit in Tampa, Fla.—a two-day, intensive educational program that included both classroom and skills transfer lab components. It was designed to complement and reinforce cornea fellowship training.

Developed to address educational challenges identified by cornea fellowship directors, the 2015 Educational Summit provided additional training to improve diagnostic and treatment skills within the clinic setting, instruction on patient selection and surgical techniques for refractive surgery, and technique pearls for routine and complex cataract surgery and corneal transplantation. This year’s Summit included several sessions from the new program Cornea Society University to address large gaps in the guidance of young career development.

Through an integrated training program in both refractive and corneal transplant surgery, the 2015 Educational Summit enhanced current fellowship training and prepared young ophthalmologists for their first years in practice. Led by course directors **Kathryn Colby, MD, PhD**, **Deepinder Dhaliwal, MD**, and **W. Barry Lee, MD**, the small faculty-to-student ratio provided hands-on training and an informal lecture setting. **Esen Akpek, MD**, **Anthony Aldave, MD**, **Jessica Ciralsky, MD**, **Bennie Jeng, MD**, **Christopher Rapuano, MD**, and **Elmer Tu, MD**, served on the Summit faculty.

The Society would like to thank the companies that provided educational grants to make this program possible:

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INDICATIONS AND USAGE

ILEVRO[®] Suspension is indicated for the treatment of pain and inflammation associated with cataract surgery.

DOSAGE AND ADMINISTRATION

Recommended Dosing

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.

Use with Other Topical Ophthalmic Medications

ILEVRO[®] Suspension may be administered in conjunction with other topical ophthalmic medications such as beta-blockers, carbonic anhydrase inhibitors, alpha-agonists, cycloplegics, and mydriatics. If more than one topical ophthalmic medication is being used, the medicines must be administered at least 5 minutes apart.

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 due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. It is recommended that ILEVRO[®] Suspension be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Delayed Healing

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 postimplantation 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.

Alcon[®]
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Broad Managed Care Coverage¹

THE NUMBER OF DAILY DOSES DECLINES, BUT THE EFFICACY DOESN'T

ILEVRO® Suspension dosed once daily post-op has been shown to be noninferior to NEVANAC® (nepafenac ophthalmic suspension) 0.1% dosed three times daily for the resolution of inflammation and pain associated with cataract surgery.^{2,3}

One drop of ILEVRO® Suspension should be applied once daily beginning 1 day prior to cataract surgery through 14 days post-surgery, with an additional drop administered 30 to 120 minutes prior to surgery.²

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 events.²

Available in 1.7 mL and new 3 mL fill sizes

INDICATIONS AND USAGE

ILEVRO® Suspension is a nonsteroidal, anti-inflammatory prodrug indicated for the treatment of pain and inflammation associated with cataract 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. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, June 2014. 2. ILEVRO® Suspension prescribing information. 3. NEVANAC® Suspension prescribing information.

For more resources for eye care professionals, visit MYALCON.COM/ILEVRO