



Cornea Day ready for AAO

This year's Cornea Day at the American Academy of Ophthalmology (AAO) annual meeting will take place on Saturday, October 18 from 8:00 a.m. to 5:25 p.m. in Chicago. **W. Barry Lee, MD**, in practice at Eye Consultants of Atlanta, medical director of the Georgia Eye Bank, and scientific program chair of Cornea Day, discussed the program and why it is important to attend.

Dr. Lee said that the mission of the 2014 Cornea Day is "to provide comprehensive ophthalmologists and anterior segment specialists with interests in cornea, glaucoma, refractive surgery, and cataract surgery a multidisciplinary discussion of current and evolving trends and techniques for providing ideal treatments for cornea and anterior segment diseases."

The program for this year will feature case discussions, groundbreaking research, and clinical pearls for treating a variety of ocular surface diseases, infectious and inflammatory diseases, and corneal dystrophies and degenerations.

"Cornea Day will expand on surgical conundrums for the treatment of various corneal diseases with a count/counterpoint session, as well as 'Top Five Tips' for combined anterior segment diseases that must be dealt with during cataract and refractive surgical procedures," Dr. Lee said.

The day will conclude with world-renowned experts discussing some of their most interesting cases of the year, he said.

Some of the hot topics scheduled to be addressed during this year's program include corneal collagen crosslinking and endothelial keratoplasty. The "Top Five Tips" that Dr. Lee referenced



W. Barry Lee, MD

will feature challenging anterior segment surgeries and surgical conundrums; experts will give their opinions on how to handle these challenges.

Not to be missed

There will be a number of new topics covered at this year's Cornea Day. According to Dr. Lee, there will be a new session that deals with combined surgical treatments for conditions such as cataract surgery and glaucoma, cataract surgery with corneal disease, and cataract surgery in challenging situations. "We will also discuss new technology and new diagnostic and treatment paradigms for various ocular surface diseases," he said.

The "Cornea Controversies" session and the "Corneal Surgical Quandaries" session are new this year and will cover different opinions on how to treat common cornea and anterior segment conditions.

"In addition, the case presentation session at the end of the day will have an interactive faculty with lively discussion of some of the most interesting and challenging cases of the year," Dr. Lee said.

The "Cornea Controversies" session moderated by **Elmer Tu, MD**, Chicago, will highlight some of the groundbreaking studies on treatments for infectious keratitis. The session will also discuss preoperative antibiotics, new intracameral combination medications, and whether postoperative antibiotics will be a thing of the past.

Additionally, **Francis Price, MD**, Indianapolis, will speak on the conundrum of cornea disease and glaucoma and which surgeries work best when both conditions need to be treated. **Reay Brown, MD**, Atlanta, will discuss cataract surgery in combination with MIGS.

In the afternoon sessions, **Friedrich Kruse, MD**, Erlangen, Germany, and **Mark Gorovoy, MD**, Fort Myers, Fla., will battle over whether DMEK or DSAEK is better, followed by **Mark Mannis, MD**, Sacramento, Calif., and **Shigeto Shimmura, MD, PhD**, Tokyo, arguing over whether PK or DALK is a better keratoplasty option for patients.

"Cornea Day assembles some of the brightest minds in corneal research, teaching, and clinical experience to provide an action-packed day of learning through one of the most innovative and interesting subspecialty day meetings offered at AAO," Dr. Lee said. "Don't miss it or your cornea toolbox may not be stocked appropriately!" **CN**

Editors' note: Dr. Lee has no financial interests related to his comments.



Cornea Society

Advancing the treatment of corneal disease

Fall 2014



President's Message

Dear Cornea Society members,

I hope everyone had a nice summer and carved out some time to relax. I'd like to update you on several activities the Cornea Society continues to work on. By far, the biggest project for the Society over the next 6 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 the evening of Wednesday, April 15. Hotel reservations are available through the World Cornea Congress website (www.CorneaCongress.org). Meeting registration is scheduled to open November 5.

The confirmed keynote speakers for the invited paper sessions have been selected and are: **Frank W. Price Jr., MD, Elisabeth J. Cohen, MD, Thomas Kohnen, MD, Edward J. Holland, MD, Shigeru Kinoshita, MD, PhD, Ken Nischal, MD, Roberto Pineda, MD, Paul Tambyah, MD, and Charles McGhee, MD.** We will also have free paper and poster sessions. Submissions can be made online at www.CorneaCongress.org from August 13 to September 25.

The Cornea Fellows Educational Summit, which we ran for the first time last year and was hugely successful, is set for September 18–21 in Tampa, Fla. The program chairs, **Barry Lee, MD, Elmer Tu, MD, and Kathy Colby, MD, PhD,** have put together a superb program. Additional faculty will include: **Michael Belin, MD, Deepinder Dhaliwal, MD, Shahzad Mian, MD, Marjan Farid, MD, Bennie Jeng, MD, and Richard Davidson, MD.** Spots are already filling up.

The Society continues to organize Cornea Subspecialty Day and the Cornea Society Symposium at the American Academy of Ophthalmology (AAO) annual meeting. The symposium, titled "Advanced Treatment of Ocular Surface Inflammatory Diseases," will be held on Tuesday, October 21 from 8:30–10:30 a.m. **Mark Mannis, MD,** the 2014 Castroviejo Awardee, will give the Castroviejo Lecture.

We co-sponsor the Fall Educational Symposium the Friday before the AAO annual meeting with the EBAA, which will be on October 17 at the Westin Michigan Ave. Free paper submissions are open at www.corneasociety.org until August 25. We want to congratulate **Fei-fei Huang, MM,** from China, who was awarded the Troutman Award as the first author of the best paper published in the *Cornea* journal over the past year by a young researcher (under age 40), as well as **Dan B. Jones, MD,** who will be receiving the 2014 Claes Dohlman Award. Both awards will be presented during the meeting on Friday, October 17.

The Cornea Society business meeting will occur at the end of the morning session during the Fall Educational Symposium. At that time the membership will elect 2 new members to the Board of Directors. I want to thank **Friedrich Kruse, MD, and Enzo Sarnicola, MD,** who are rotating off the Board, for the tremendous job they both did over the past 4 years. All members with thesis should have received forms to nominate one person to the Board if desired.

Additional activities of the Cornea Society on October 17 include the Fellowship Directors Breakfast at 7:30 a.m. at the Westin Michigan Avenue; the Young Physicians Networking Reception at Studio Paris Nightclub from 6:00–7:30 p.m.; and the DJ Party at Nikki Chicago from 9:00 p.m.–1 a.m. Yes, **Tony Aldave, MD, and Terry Kim, MD,** will be DJ'ing again!

The Society would like to again congratulate Dr. Mannis as the recipient of the Castroviejo Award and Dr. Jones as the recipient of the Dohlman Award.

I look forward to seeing you all at the Cornea Society/EBAA Fall Educational Symposium on October 17 before the AAO meeting and throughout the week. Please feel free to email me (cjrapuano@willseye.org) or speak to me personally in Chicago regarding any Cornea Society issues.

Sincerely,

Christopher J. Rapuano, MD
President

Update on the Cornea journal

Cornea, the Cornea Society journal, is thriving. The number of submissions has increased to a recent rate of 25 per week. This has intensified pressure on the Editorial Board to decrease the acceptance rate, now about 30%. Likewise, this increases the need for submissions to be of ever higher quality to be accepted for publication. An editorial in the Summer 2014 issue of *Cornea Society News* lists some suggestions for authors wishing to publish in *Cornea*.

There are several special upcoming journal projects. A revision of the IC3D, the report of the International Committee for the Classification of Corneal Dystrophies, originally published in 2008, is in preparation. A supplement on global keratoconus will be published in April 2015, and a supplement from the World Cornea Congress VII will be published in the summer of 2015. All will be peer reviewed.

As with all successful journals, we must depend on the work of various experts—in our case those working in corneal and external disease, corneal surgery and corneal science—to review submissions to the journal. This peer-review process is necessary both to judge potential additions to our literature and to improve their science and presentation. Because many invitations to review papers are ignored or declined—often by the same experts who expect others to promptly peer review their submissions—the burden on those willing to voluntarily review submissions increases. I encourage those involved in our subspecialty to participate in this important activity. **CN**

The Cornea Society business meeting will take place on Friday, Oct. 17, during the Cornea Society/Eye Bank Association of America Fall Educational Symposium at the Westin Michigan Avenue, 909 Michigan Avenue, Chicago. All members are invited to attend.

Check the Society website for updates:
www.CorneaSociety.org

2014 ACS

The 4th Biennial Scientific Meeting Asia Cornea Society

TAIPEI

11-12 December 2014
Taipei International Convention Center



www.acs2014.tw

ASIA
CORNEA
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www.asiacorneasociety.org

HIGHLIGHTS OF THE EVENT

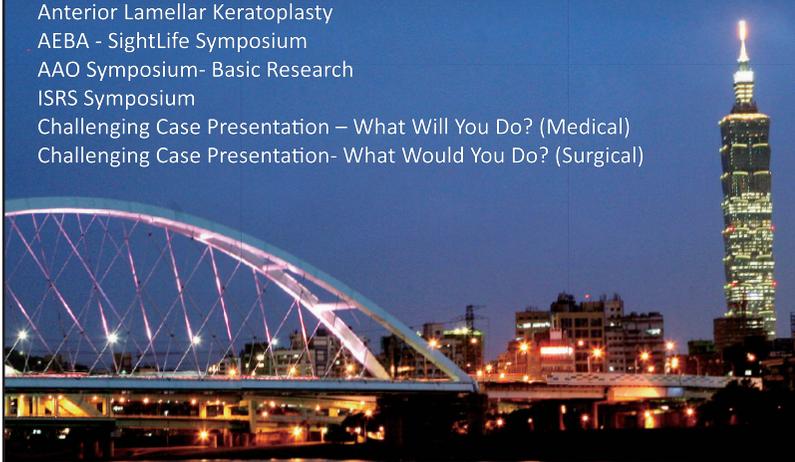
With almost 100 superb invited speakers, this year's ACS Meeting will truly be a remarkable one! We have 16 interesting symposiums with outstanding topics and speakers from all over the world. Participants will indeed benefit from their excellent works! Moreover, ACS 2014 invites many important societies to be our collaborated partners, like: American Academy of Ophthalmology, Cornea Society, International Society of Refractive Surgery, Association of Eye Banks of Asia, and so on.



To know more about our speakers, please visit the official website for detail information at www.acs2014.tw!

SYMPOSIUM TOPICS

- Ocular Surface Disease (Limbal Stem Cell and Cornea NV)
- Corneal Imaging
- Penetrating Keratoplasty/ Complex Graft Complication/ Rejection
- Endothelial Keratoplasty- An Asian Perspective
- Keratoconus and Crosslinking
- Corneal Infection & Inflammation
- Dry Eye/ Allergic Eye Disease/ Blepharitis / Pterygium
- Cornea Society-Endothelial Keratoplasty- An International Perspective
- Ocular Surface Reconstruction/ Stem Cell Therapy/ Keratoprosthesis
- Anterior Lamellar Keratoplasty
- AEBA - SightLife Symposium
- AAO Symposium- Basic Research
- ISRS Symposium
- Challenging Case Presentation – What Will You Do? (Medical)
- Challenging Case Presentation- What Would You Do? (Surgical)



FALL EDUCATIONAL SYMPOSIUM

CHICAGO 2014 WESTIN MICHIGAN AVENUE

Symposium on the Advanced Treatment of Ocular Surface Inflammatory Diseases to Honor the 2014 Castroviejo Awardee

This symposium will feature a combined effort by the Cornea Society and the German Ophthalmological Society (DOG) to discuss a number of immune-mediated and inflammatory conditions that can severely affect the anterior segment of the eye. The various diagnostic strategies and treatment options for some of the most challenging local and systemic inflammatory conditions of the anterior segment will be reviewed. The symposium will conclude with a lecture from the 2014 Castroviejo Lecture awardee, **Professor Mark Mannis, MD, FACS**.

Date and time: Tuesday, October 21, 8:30 a.m.–10:30 a.m.

Location: McCormick Place

Room: Grand Ballroom S100AB

Topic: Cornea, External Disease

Chairs: *William Barry Lee, MD*
Edward J. Holland, MD

8:30 a.m.	Introduction	<i>William Barry Lee, MD</i>
8:32 a.m.	The Itchy Eyes Have It: A Case-Based Approach to Allergic Eye Diseases	<i>Penny A. Asbell, MD, FACS</i>
8:41 a.m.	Atypical Causes of Immune-Mediated Conjunctivitis	<i>Hans E. Grossniklaus, MD</i>
8:50 a.m.	Rosacea and the Ocular Surface: How to Get the Red Out?	<i>Gerd Geerling, MD, PhD</i>
8:59 a.m.	Cicatricial Ocular Surface Diseases: Advances in Treatment Options	<i>Darren G. Gregory, MD</i>
9:08 a.m.	Graft-versus-Host Disease: Treatment Strategies, from Mild to Severe Disease	<i>Claus Cursiefen, MD</i>
9:17 a.m.	Localized Immune-Mediated White Spots of the Cornea	<i>Berthold Seitz, MD</i>
9:26 a.m.	Scleritis: Medical Management Strategies for Scleral Disease	<i>Andrea Y. Ang, MBBS</i>
9:35 a.m.	Stage-Related Therapy for Atopic Ulcerative Keratitis	<i>Walter Lisch, MD</i>
9:44 a.m.	Q&A	
9:57 a.m.	Castroviejo Lecture	
9:57 a.m.	Introduction of the Castroviejo Lecturer	<i>Edward J. Holland, MD</i>
9:59 a.m.	Castroviejo Lecture: Points of Light in the History of Cornea	<i>Mark J. Mannis MD</i>
10:29 a.m.	Conclusion	<i>William Barry Lee, MD</i>
10:30 a.m.	End of Session	

FRIDAY, OCTOBER 17

8:30 AM–4:30 PM

REGISTER TODAY

CorneaSociety.org

RestoreSight.org





WORLD
CORNEA VII
CONGRESS

SAN DIEGO
APRIL 15-17, 2015

ASCRS·ASOA SYMPOSIUM & CONGRESS

2015 SAN DIEGO

APRIL 17-21

ADDITIONAL PROGRAMMING

ASCRS GLAUCOMA DAY
ASOA WORKSHOPS
TECHNICIANS & NURSES PROGRAM

RESERVE HOUSING

BOOK EARLY TO STAY AT YOUR PREFERRED HOTEL.



REGISTRATION OPENS—WEDNESDAY, NOVEMBER 5

AnnualMeeting.ascrs.org

All programming will be held in the San Diego Convention Center.

A joint meeting with



Asociación Latinoamericana de Cirujanos de
Catarata, Segmento Anterior y Refractiva®
Latin American Society of Cataract and Refractive Surgeons®

Members receive access to *Cornea* on the iPad

Your subscription to *Cornea* for the iPad is a benefit of your Cornea Society membership in addition to print and online (www.corneajrnl.com) access to the journal. We hope you are taking advantage of all the great features the app has to offer, including 24/7 access to article content and embedded videos.

To continue (or to start) accessing the journal content via your iPad, **you will be required to sign in using a username and password.** If you already have a username and password for *Cornea's* website, you can use this same information for the iPad app. If you have not set up your account, you will need to create an account using your subscriber ID.



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Where all of ophthalmology meets

Cornea 2014: Restocking the Toolbox: Concepts and Techniques for the Toughest Jobs

In conjunction with The Cornea Society

**Saturday, October 18,
from 8:00 AM to 5:30 PM
Chicago, IL**

Program Directors:
William Barry Lee MD
Elmer Y Tu MD
Stephen C Kaufman MD PhD

Your registration for Cornea Subspecialty Day includes:

- Flexibility to float between all Subspecialty Day meetings on Saturday:

Glaucoma, Ocular Oncology and Pathology, Oculofacial Plastic Surgery, Pediatric Ophthalmology, Refractive Surgery, Retina and Uveitis.

- Access to the AAO 2014 Exhibit Hall on Saturday.

Register in Advance!

- **By September 3** to have your badge mailed
- **By September 24** to pick up your badge onsite



www.aaopt.org/2014

[#aaopt2014](https://twitter.com/aaopt2014)

CME Accreditation

The American Academy of Ophthalmology is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The American Academy of Ophthalmology designates this live activity for a maximum of 7 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ASCRS•ASOA

SIDE **X** **SIDE**

AT THE INTERSECTION OF IDEAS AND IMPLEMENTATION

Formerly known as Winter Update, this new meeting for anterior segment eye surgeons and ophthalmic practice administrators is focused on integrating good ideas into profitable clinical practice.

Top faculty will provide step-by-step instruction on how to take the latest technology and clinical advancements and put them to work for your patients and your practice.

FEBRUARY 12–15, 2015

TURNBERRY ISLE MIAMI
AVENTURA, FLORIDA

**REGISTER TODAY AND
BOOK HOUSING**

sideXside.ascrs.org

Cornea Society presents 2014 Fellowship Educational Summit



The Cornea Society is pleased to present the 2014 Fellowship Educational Summit for current cornea fellows in Fort Worth, Texas. The summit, which takes place September 18–21, is designed in part to meet needs identified from a survey taken at the 2012 Fellowship Director's Breakfast in Chicago. The program directors, **Kathryn A. Colby, MD, PhD**, **William Barry Lee, MD**, and **Elmer Tu, MD**, have assembled a distinguished faculty of dynamic speakers to address advanced concepts in anterior segment surgery and medical management of cornea and external diseases.

Fellows will be introduced to the use and interpretation of anterior segment imaging tools ranging from corneal topography to anterior segment OCT and UBM by **Michael Belin, MD**. Practical applications of these skills will be put to the test as **Deepinder Dhaliwal, MD**, will cover basic and advanced concepts in surface ablation and LASIK surgery. Common and uncommon diseases of the ocular surface including advanced dry eye will be detailed by **Bennie Jeng, MD**. **Shahzad Mian, MD**, will review corneal considerations in cataract

surgery and the management of corneal trauma. All aspects of complex cataract surgery, IOL management, and premium IOLs will be addressed by **Richard Davidson, MD**.

The second full day will feature most of the same speakers sharing their personal pearls and pitfalls in corneal transplantation including full and lamellar corneal surgery. A wet lab will follow to provide the fellows with immediate feedback for lessons learned in corneal transplantation as well as other advanced corneal surgical techniques. All of this will be presented in a wide-ranging format of didactics, roundtables, and case presentations to allow the fellows the opportunity to interact with the faculty during and outside of the program. For this year, the number of program participants was limited to 50 and the response has been tremendous. Please visit fellows.corneasociety.org for further details.

The Cornea Society gratefully acknowledges the unrestricted educational grants and in-kind support received for this program:

Platinum Level

- Alcon Laboratories: Unrestricted monetary grant and in-kind donation of equipment, materials, and personnel
- Lions Eye Institute for Transplant & Research: Donation of meeting and wet lab facilities and equipment

Gold Level

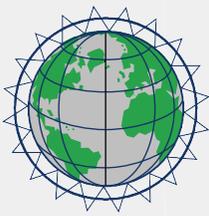
- Moria Surgical: In-kind donation of equipment, supplies, and personnel

Silver Level

- Bausch + Lomb: Unrestricted monetary grant **CN**

2015 dues notice

The 2015 dues notices will be mailed to members in early November. The Society is requesting that members provide a current email address when they renew. The Society is transitioning to an online membership renewal system. **CN**



WORLD CORNEA VII CONGRESS

SAN DIEGO

APRIL 15–17, 2015

EVERY 5 YEARS, CORNEA SPECIALISTS
PRESENT AND REVIEW THE MOST RECENT
MEDICAL ADVANCES.

REGISTRATION OPENS—
WEDNESDAY, NOVEMBER 5

RESERVE HOUSING

BOOK EARLY TO STAY AT YOUR PREFERRED HOTEL.

CorneaCongress.org

PLANNING COMMITTEE

Committee Directors

Marian S. Macsai, MD
Christopher J. Rapuano, MD
Donald TH Tan, FRCS

Committee

Michael W. Belin, MD
Kathryn A. Colby, MD, PhD
Terry Kim, MD
W. Barry Lee, MD
Vincenzo Sarnicola, MD

PROGRAM OUTLINE (subject to change)

Corneal Tissue Engineering, Physiology, and Wound Healing

Moderator: Donald TH Tan, FRCS

Keynote: Future Directions in Corneal Endothelial Cell Biology
Shigeru Kinoshita, MD, PhD

Dystrophies, Degenerations and Genetics

Moderator: Kathryn A. Colby, MD, PhD

**Keynote: Genetics of Congenital Corneal Opacities:
Impact on Diagnosis and Treatment**
Ken Nischal, MD

Infections and Inflammation

Moderator: Christopher J. Rapuano, MD

**Keynote: Management and Prevention of Herpes Zoster
Viral Ocular Disease**
Elisabeth J. Cohen, MD

Keratoconus, Other Ectasias, Deep Anterior Lamellar Keratoplasty, and Other Lamellar Grafts

Moderator: Vincenzo Sarnicola, MD

Keynote: Treatment Paradigms in Keratoconus
Charles McGhee, PhD, FRCS

Keratoprosthesis and Penetrating Keratoplasty

Moderator: Kathryn A. Colby, MD, PhD

**Keynote: Corneal Transplantation in the Developing World:
Lessons Learned**
Roberto Pineda, MD

Ocular Surface Disease

Moderator: W. Barry Lee, MD

**Keynote: Limbal Stem Cell Deficiency: A Historical
Perspective: Past, Present, and Future**
Edward J. Holland, MD

Refractive Surgery

Moderator: Michael W. Belin, MD

**Keynote: Past, Present, and Future Options for the Correction
of Presbyopia**
Thomas Kohlen, MD, PhD

Techniques and Technologies for Endothelial Keratoplasty

Moderator: Terry Kim, MD

**Keynote: The Evolution of Endothelial Keratoplasty:
Where Are We Headed?**
Francis W. Price Jr, MD, PhD

World Health and Eye Banking

Moderator: Marian S. Macsai, MD

Keynote: Emerging Pandemics
Paul Tambyah, MD, PhD

Sponsored by the Cornea Society

 This activity has been approved
for AMA PRA category 1 credit.™

Unique double meeting opportunity



This will be a special year for cornea specialists planning to attend the 2015 ASCRS•ASOA Symposium & Congress this April in San Diego.

The meeting will kick off with the World Cornea Congress VII, a Cornea Society-sponsored event held every 5 years. This cornerstone in the advancement of corneal surgical practices and the treatment of corneal disease will be held April 15–17, immediately preceding the ASCRS•ASOA Symposium & Congress.

But programming for the cornea specialist will not stop there. The ASCRS•ASOA Symposium & Congress, which will be held in the same location

April 17–21, will offer daily meeting programming designed specifically for those focused on advanced corneal disease management and treatment.

The ASCRS•ASOA Symposium & Congress is the largest U.S. meeting that integrates a scientific program dedicated to the needs of the anterior segment specialist with the leading practice management program. Combined with the World Cornea Congress, this is a unique double meeting opportunity.

The World Cornea Congress VII will feature well-known speakers from around the globe, including: **Frank W. Price Jr., MD, Elisabeth J. Cohen, MD, Thomas Kohnen, MD, Edward J. Holland, MD, Shigeru Kinoshita,**

MD, PhD, Ken Nischal, MD, Roberto Pineda, MD, Charles McGhee, MD, and Paul Tambyah, MD.

Those who stay on for the ASCRS•ASOA Symposium & Congress will be able to choose from nearly 1,300 presentations, papers, posters, symposia, and other sessions. Nearly 5,000 eye surgeons are expected to attend.

Continuing education credits are available throughout both programs. ASCRS is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The concurrent ASOA program is entirely accredited for the Certified Ophthalmic Executive (COE). In addition, application has been made for the following continuing education credits: AAPC, ABO, Nursing, JCAHPO/OPS/AOC, and COPE.

Full dates, housing information, and registration details can be found at annualmeeting.ASCRS.org.

The ASCRS•ASOA Symposium & Congress offers:

- Innovative lectures on surgical techniques and technologies
- Scientific discussions and interactive panels
- Unlimited access to roundtables, legislative and regulatory updates, consultations, and ophthalmology's most established practice management program
- Quality clinical and surgical offerings for technicians and nurses
- One price includes crossover access for ASCRS and ASOA sessions (hands-on skills training and ASOA workshops require a separate registration)
- A business track for ophthalmologists
- Hundreds of ophthalmology industry exhibitors **CN**

BRIEF SUMMARY OF PRESCRIBING INFORMATION**INDICATIONS AND USAGE****Ocular Surgery**

DUREZOL[®] (difluprednate ophthalmic emulsion) 0.05%, a topical corticosteroid, is indicated for the treatment of inflammation and pain associated with ocular surgery.

Endogenous Anterior Uveitis

DUREZOL[®] Emulsion is also indicated for the treatment of endogenous anterior uveitis.

DOSAGE AND ADMINISTRATION**Ocular Surgery**

Instill one drop into the conjunctival sac of the affected eye 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.

Endogenous Anterior Uveitis

Instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.

DOSAGE FORMS AND STRENGTHS

DUREZOL[®] Emulsion contains 0.05% difluprednate as a sterile preserved emulsion for topical ophthalmic administration.

CONTRAINDICATIONS

The use of DUREZOL[®] Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures.

WARNINGS AND PRECAUTIONS**IOP Increase**

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, intraocular pressure should be monitored.

Cataracts

Use of corticosteroids may result in posterior subcapsular cataract formation.

Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

Bacterial Infections

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

Viral Infections

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal Infections

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in

any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Topical Ophthalmic Use Only

DUREZOL[®] Emulsion is not indicated for intraocular administration.

Contact Lens Wear

DUREZOL[®] Emulsion should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of DUREZOL[®] Emulsion. The preservative in DUREZOL[®] Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL[®] Emulsion.

ADVERSE REACTIONS

Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects; posterior subcapsular cataract formation; secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Ocular Surgery

Ocular adverse reactions occurring in 5-15% of subjects in clinical studies with DUREZOL[®] Emulsion included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis. Other ocular adverse reactions occurring in 1-5% of subjects included reduced visual acuity, punctate keratitis, eye inflammation, and iritis. Ocular adverse reactions occurring in < 1% of subjects included application site discomfort or irritation, corneal pigmentation and striae, episcleritis, eye pruritus, eyelid irritation and crusting, foreign body sensation, increased lacrimation, macular edema, sclera hyperemia, and uveitis. Most of these reactions may have been the consequence of the surgical procedure.

Endogenous Anterior Uveitis

A total of 200 subjects participated in the clinical trials for endogenous anterior uveitis, of which 106 were exposed to DUREZOL[®] Emulsion. The most common adverse reactions of those exposed to DUREZOL[®] Emulsion occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis. Adverse reactions occurring in 2-5% of subjects included anterior chamber flare, corneal edema, dry eye, iridocyclitis, photophobia, and reduced visual acuity.

USE IN SPECIFIC POPULATIONS**Pregnancy****Teratogenic Effects**

Pregnancy Category C. Difluprednate has been shown to be embryotoxic (decrease in embryonic body weight and a delay in embryonic ossification) and teratogenic (cleft palate and skeletal) anomalies when administered subcutaneously to rabbits during organogenesis at a dose of 1-10 mcg/kg/day. The no-observed-effect-level (NOEL) for these effects was 1 mcg/kg/day, and 10 mcg/kg/day was considered to be a teratogenic dose that was concurrently found in the toxic dose range for fetuses and pregnant females. Treatment of rats with 10 mcg/kg/day subcutaneously during organogenesis did not result in any reproductive toxicity, nor was it maternally toxic. At 100 mcg/kg/day after subcutaneous administration in rats, there was a decrease in fetal weights and delay in ossification, and effects on weight gain in the pregnant females. It is difficult to extrapolate these doses of difluprednate to maximum daily human doses of DUREZOL[®] Emulsion, since DUREZOL[®] Emulsion is administered topically with minimal systemic absorption, and difluprednate blood levels were not measured in the reproductive animal studies. However, since use of difluprednate during human pregnancy has not been evaluated and cannot rule out the possibility of harm, DUREZOL[®] Emulsion should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus.

Nursing Mothers

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when DUREZOL[®] Emulsion is administered to a nursing woman.

Pediatric Use

DUREZOL[®] Emulsion was evaluated in a 3-month, multicenter, double-masked, trial in 79 pediatric patients (39 DUREZOL[®] Emulsion; 40 prednisolone acetate) 0 to 3 years of age for the treatment of inflammation following cataract surgery. A similar safety profile was observed in pediatric patients comparing DUREZOL[®] Emulsion to prednisolone acetate ophthalmic suspension, 1%.

Geriatric Use

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

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

Difluprednate was not genotoxic *in vitro* in the Ames test, and in cultured mammalian cells CHL/IU (a fibroblastic cell line derived from the lungs of newborn female Chinese hamsters). An *in vivo* micronucleus test of difluprednate in mice was also negative. Treatment of male and female rats with subcutaneous difluprednate up to 10 mcg/kg/day prior to and during mating did not impair fertility in either gender. Long term studies have not been conducted to evaluate the carcinogenic potential of difluprednate.

Animal Toxicology and/or Pharmacology

In multiple studies performed in rodents and non-rodents, subchronic and chronic toxicity tests of difluprednate showed systemic effects such as suppression of body weight gain; a decrease in lymphocyte count; atrophy of the lymphatic glands and adrenal gland; and for local effects, thinning of the skin; all of which were due to the pharmacologic action of the molecule and are well known glucocorticosteroid effects. Most, if not all of these effects were reversible after drug withdrawal. The NOEL for the subchronic and chronic toxicity tests were consistent between species and ranged from 1-1.25 mcg/kg/day.

PATIENT COUNSELING INFORMATION**Risk of Contamination**

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the emulsion. Use of the same bottle for both eyes is not recommended with topical eye drops that are used in association with surgery.

Risk of Secondary Infection

If pain develops, or if redness, itching, or inflammation becomes aggravated, the patient should be advised to consult a physician.

Contact Lens Wear

DUREZOL[®] Emulsion should not be instilled while wearing contact lenses. Patients should be advised to remove contact lenses prior to instillation of DUREZOL[®] Emulsion. The preservative in DUREZOL[®] Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL[®] Emulsion.

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Postoperative Inflammation and Pain Can Make a Bad Impression

CHOOSE **DUREZOL® EMULSION** TO HELP RESOLVE INFLAMMATION AND PAIN¹

BROAD MANAGED CARE COVERAGE²



INDICATIONS AND USAGE:

DUREZOL® Emulsion is a topical corticosteroid that is indicated for:

- The treatment of inflammation and pain associated with ocular surgery.
- The treatment of endogenous anterior uveitis.

Dosage and Administration

- For the treatment of inflammation and pain associated with ocular surgery instill one drop into the conjunctival sac of the affected eye 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.
- For the treatment of endogenous anterior uveitis, instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.

IMPORTANT SAFETY INFORMATION

Contraindications: DUREZOL® Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

Warnings and Precautions

- Intraocular pressure (IOP) increase – Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.
- Cataracts – Use of corticosteroids may result in posterior subcapsular cataract formation.
- Delayed healing – The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

- Bacterial infections – Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- Viral infections – Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- Fungal infections – Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.
- Contact lens wear – DUREZOL® Emulsion should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of DUREZOL® Emulsion. The preservative in DUREZOL® Emulsion may be absorbed by soft contact lenses. Lenses may be reinserted after 10 minutes following administration of DUREZOL® Emulsion.

Most Common Adverse Reactions

- Post Operative Ocular Inflammation and Pain – Ocular adverse reactions occurring in 5-15% of subjects included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis.
- In the endogenous anterior uveitis studies, the most common adverse reactions occurring in 5-10% of subjects included blurred vision, eye irritation, eye pain, headache, increased IOP, iritis, limbal and conjunctival hyperemia, punctate keratitis, and uveitis.

For additional information about DUREZOL® Emulsion, please refer to the brief summary of prescribing information on adjacent page.

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

References: 1. DUREZOL® Emulsion prescribing information. 2. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, March 2014.

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DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

THE RESULTS YOU WANT. THE RELIEF THEY NEED.