



Cornea Subspecialty Day back at AAO

This year's Cornea Subspecialty Day at AAO, titled, "Through the Looking Glass – Where We Are, Where We're Headed," aims to give participants a look at the past, present, and future of the field. Program directors **Kathryn A. Colby, MD, PhD**, Massachusetts Eye and Ear Infirmary, Boston; **Elmer Y. Tu, MD**, University of Illinois College of Medicine at Chicago; and **William Barry Lee, MD**, Eye Consultants of Atlanta, and co-medical director, Georgia Eye Bank, expect an impressive program with a variety of speakers and interesting topics.

Cornea Subspecialty Day, which will take place on Saturday, Nov. 16, aims to give attendees an updated and comprehensive review of anterior segment topics by utilizing a number of national and international faculty, Dr. Lee said. The hope is that the attendees "can apply many of the lessons learned from this educational day to their everyday practices for prevention of corneal blindness."

"Cornea Subspecialty Day will be filled with anterior segment pearls from experts around the world," Dr. Lee said. "We have an action-packed day of lectures including case studies, reviews, and groundbreaking research in cornea, external diseases, and refractive surgery."

"The goal of Cornea Subspecialty Day is to give participants a taste of where the field was in the past, where it is now, and where it's going to be in 10 years," Dr. Colby said.

Dr. Tu said that one of the main goals of the day is "not only to introduce drugs and practical new techniques but also how best to use them as described by the experts that developed them."

This year's Cornea Subspecialty Day will be divided into six sessions, three in the morning and three in the afternoon. The first session will explore medical treatment of corneal diseases. That will be followed by a look at infectious diseases of the cornea and possible management strategies. The final morning session will focus on Fuchs' endothelial corneal dystrophy and will include medical and surgical treatments for the condition.

Following a break for lunch, the first afternoon session will feature an update on corneal surgery, including pearls for traditional penetrating keratoplasty, anterior lamellar keratoplasty, endothelial keratoplasty, and artificial corneal transplantation. The second afternoon session will look at corneal crosslinking, with discussions on epithelium-on and epithelium-off techniques. The final session of the day will be titled "Cornea Grand Rounds" and will feature short case presentations of challenging medical and surgical cases of the anterior segment.

Dr. Colby said this year's format is a bit different from previous years. Among the changes are an entire session focused on a single topic, Fuchs' endothelial corneal dystrophy. She said there is a lot currently going on with the topic, especially with surgery and potential medical treatments.

"The other thing that's new that will be interesting and help keep people's attention at the end of the day is the 'Cornea Grand Rounds' where we'll have short, focused case presentations by people who we've chosen for their excellent speaking abilities," Dr. Colby said. Presenters will discuss challenging cases from their practices, followed by an interactive group discussion with the presenters and program directors.

"This year's program is an exciting one," Dr. Tu said. "The highlight will be a keynote lecture by **Claes Dohlman, MD**, on the past, present, and future of keratoprosthesis, a life's work, which has brought the gift of sight to so many people around the world." Other topics will look at the value of testing and surgical prophylaxis for MRSA, epithelial-on vs. epithelial-off collagen crosslinking, and the importance of the availability of compounded drugs over commercially available medications.

The schedule and topics for Cornea Subspecialty Day are designed to appeal to cornea specialists as well as general ophthalmologists. "We have tried to create a vast overview of topics for the comprehensive ophthalmologist to learn a variety of anterior segment pearls from the meeting while also providing some focused talks in each session to stimulate the curiosity and interest of the pure cornea subspecialist," Dr. Lee said.

"This Cornea Subspecialty Day will provide the same great content and knowledge that has been characteristic of all the previous Subspecialty Days, but this will without question be a more dynamic program than in past years," Dr. Tu said. "We believe that we have enlisted the very best minds and most engaging speakers and given them challenging topics for which they can provide nuances and preferences that can only be gained through their research and experience." **CN**

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Cornea Society
Advancing the treatment of corneal disease

Fall 2013

President's Message

Dear Colleagues and Members,

For the first time, the annual meeting of the Asia-Pacific Association of Cataract and Refractive Surgeons, now into its 26th meeting, kicked off with Cornea Day jointly organized by the Cornea Society and Asia Cornea Society on July 11, 2013 in Singapore. The Cornea Society has long been organizing Cornea Days at the annual American Society of Cataract & Refractive Surgery/American Society of Ophthalmic Administrators (ASCRS•ASOA) Symposium & Congress, and this was the Society's first Cornea Day outside the United States, a culmination of the strong relationship fostered with the Asia Cornea Society. Cornea Day was applauded for its stimulating scientific program, which provided an attendance of more than 800 corneal surgeons with high-level subspecialty information from clinical and basic research to the latest advances in surgical and clinical management of cornea and external eye diseases.



Another first was the presentation of the CorneaEd International Training Grant (Observership) – Asia Cornea Society to **Vanissa WS Chow, MD**, from the Chinese University of Hong Kong. CorneaEd is an educational initiative collaboratively developed by the Cornea Society and Asia Cornea Society awarding international training grants to remarkable young corneal clinicians/surgeons to undertake observership or fellowship training programs in an ophthalmic institution listed in the CorneaEd registry. I strongly encourage Cornea Society members to apply for the CorneaEd International Training Grant (Observership) to undertake observership attachment in any of the U.S. or Asian ophthalmic institutions listed on the CorneaEd website.

Moving on, you can look forward to yet another remarkable AAO Castroviejo Symposium co-sponsored by the Cornea Society and the American Academy of Ophthalmology (AAO) this coming November. The theme for this upcoming Castroviejo Symposium addresses the changing trends in keratoplasty surgery, identifies various keratoplasty advances, and discusses their outcomes. The AAO Cornea Subspecialty Day follows with an exhilarating theme of "Through the Looking Glass – Where We Are, Where We're Headed," aimed at keeping delegates apprised of surgical management of corneal diseases, evidence-based treatments for challenging medical disorders of the cornea including corneal infections, as well as advances in the understanding and treatment of Fuchs' corneal dystrophy. This will be given in various formats including didactic lectures, panel discussions, and case presentations. Don't miss out on the opportunity to find out where the corneal community is headed.

Sincerely,
Donald TH Tan, FRCS
President

ASCRS•ASOA Symposium & Congress: Wide range of education for the cornea specialist

Cornea specialists from around the globe will be in Boston for the 2014 ASCRS•ASOA Symposium & Congress, April 25–29. Now in its 40th year, the ASCRS•ASOA Symposium & Congress is the only U.S. meeting that integrates a scientific program dedicated to the needs of the anterior segment specialist with the leading practice management program for comprehensive ophthalmology and subspecialties.

In addition to daily meeting programming dedicated to advances in corneal surgical practices, those in Boston can choose to attend Cornea Day (April 25), which is presented through a partnership with the Cornea Society and the ASCRS Cornea Clinical Committee. More than 1,400 physicians attend Cornea Day each year to focus on corneal innovations and challenges in anterior segment surgery and disease management. Together, the ASCRS•ASOA Symposium & Congress

and Cornea Day offer a wide range of education geared toward the advanced cornea specialist.

Continuing education credits are available throughout the entire meeting. ASCRS is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The concurrent ASOA Congress 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.

The ASCRS•ASOA Symposium & Congress is unique as it brings together a wide range of anterior segment specialists and ophthalmology's thought leaders in one place for a dynamic five days of education. Full dates, housing information, and registration details can be found at www.ASCRs.org.

- One price includes crossover access to more than 1,300 ASCRS and ASOA presentations, post-meeting resources, and the MediaCenter (hands-on skills training, Cornea Day, ASCRS Glaucoma Day, and the ASOA Workshops require separate registrations)
- Innovative lectures on surgical techniques and technologies
- 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
- A business track designed for ophthalmologists
- Scientific discussions and interactive panels
- Access to hundreds of ophthalmology industry exhibitors **CN**

2014 DUES NOTICE

The 2014 Dues Notices will be mailed to members in early November. The Society is requesting members provide a current email address when they renew their dues. The Society is transitioning to an online membership renewal system.



Eye Bank Association of America update

The Eye Bank Association of America has recently undertaken a number of initiatives to help advance the profession of eye banking and corneal transplantation. A few of these efforts are detailed below.

Vision: EBAA – In November 2012, the Board of Directors approved a new strategic plan, titled *Vision: EBAA*, which will shape the association's direction and efforts through 2015. The plan was structured along five categories: advocacy, member value, international outreach, governance, and future considerations.

Each of these initiatives has a number of specific goals and action items that, taken together, will help us fulfill our mission. Each has been scheduled within a specific time of year for completion, thus helping to maintain accountability and coordinate efforts across categories. A copy of *Vision: EBAA* is available on our website.

More assertive advocacy – EBAA initiated a comprehensive, sustained campaign to educate legislators about how eye banking and corneal transplantation benefit their constituents and the country as a whole. Two committees in the House (Ways and Means and Energy and Commerce) and two in

the Senate (Finance and Health, Education, Labor and Pensions) have the most immediate effect on eye banking's future, and each has a healthcare subcommittee. Since the start of the year, we have met with almost all of the members of these committees and with many other members of Congress.

Our message is simple: This is who we are, this is what we do, and this is how we serve your constituents. We don't ask for anything, we just inform them about eye banking. The response from legislators' offices has been universally positive, and we have established relationships we can call upon when needed.

We have also begun a grassroots campaign to facilitate members' visits with their own legislators in the district; a number of eye banks have scheduled these meetings, which help to strengthen lawmakers' understanding of how our work affects their constituents.

Societal value of corneal transplantation – EBAA commissioned a study to determine the net value of corneal transplantation to recipients and to society as a whole. While the final report is not expected until later this year, preliminary calculations suggest that cornea transplants performed

in 2012 alone will result in a net benefit of more than \$6 billion. This data will be shared with legislators and regulators to illustrate the profound effect that eye banking and corneal transplantation have on individuals and our country.

Research grants – This year, our EBAA/Richard Lindstrom Research Grants provided funding for the following projects:

- **Gene Therapy to Protect Cornea During Storage after Transplantation**
Thomas Fuchsluger, MD, FEBO, Lions Eye Bank North Rhine-Westphalia
- **Nanoparticle Based Targeted Therapy of Corneal Inflammation**
Quingguo Xu, PhD, Wilmer Eye Institute, Johns Hopkins University
- **Role of Integrins MAdCAM-1 in Corneal Transplantation**
Hamidreza Moein, MD, Schepens Eye Research Institute
- **Erythropoietin for Re-innervation After Transplantation**
Shruti Aggarwal, MD, Massachusetts Eye and Ear Infirmary
- **In Vivo Imaging-Guided Risk Assessment for Corneal Graft Rejection in Dry Eye Disease**
Jing Hua, MD, Schepens Eye Research Institute
- **The Use of Rapamycin as an Additive to Corneal Storage Media**
Behard Milani, MD, University of Illinois at Chicago

International growth – This June, EBAA welcomed two new international members—the Daqing Eye Bank at Daqing Hospital in China and the Hospital Authority Lions Eye Bank in Hong Kong. We are working with the Daqing Eye Bank to translate our Medical Standards and other governing documents into Chinese for use by these eye banks and others that are interested in EBAA membership and accreditation.

For more information about these and other projects being undertaken by EBAA, please refer to our 2012-13 Year in Review report, which is available on our website, www.restoreight.org. **CN**

Cornea journal highlights

A recent paper in *Ophthalmology* (Chen H, Chen CH, Jhanji V. *Ophthalmology* 2013;120:1697–701), the journal of the American Academy of Ophthalmology, studied the times from submission and acceptance to publication of papers in ophthalmic journals in 2010.

The median time from submission to publication for *Cornea* was then very long, about 18 months. I am pleased to report that through the great efforts of the Cornea Society, the editorial board, our reviewers, and our authors, we have eliminated our backlog of papers. In August the median time from submission to final acceptance with revisions was 10 weeks and to print was 7.5 months. We are trying to improve this further. As the dedicated journal of our subspecialty, *Cornea* in 2013 is the appropriate site for prompt publication of our best clinical and laboratory science.

Alan Sugar, MD, editor-in-chief

Edward Holland, MD, to give Castroviejo Lecture at Cornea Society Symposium at AAO

We have seen a variety of advances in keratoplasty for the surgical treatment of corneal blindness in all age groups, young to elderly. Understanding both keratoplasty trends and the adoption of new techniques, including lamellar surgery, artificial corneal transplants, and stem cell transplants, and new devices, such as implementation of femtosecond laser technology, is crucial for ophthalmology in the 21st century. This symposium will feature surgical management strategies for diverse forms of corneal blindness. The symposium will conclude with the Castroviejo Lecture by **Edward Holland, MD**, discussing advances in limbal stem cell disease.

Date and time: Monday, Nov. 18, 2013, 8:15 AM – 10:15 AM

Location: Morial Convention Center

Room: LA NOUVELLE ORLEANS C

Chairs: *William Barry Lee, MD*

James P. McCulley, MD, FACS, FRCOPHTH

8:15 AM	Introduction	<i>William Barry Lee, MD</i>
8:17 AM	Keratoplasty Trends in the United States	<i>Woodford S. Van Meter, MD, FACS</i>
8:27 AM	Update on Pediatric Keratoplasty: Success or Distress?	<i>Gerald W. Zaidman, MD, FACS</i>
8:37 AM	Endothelial Keratoplasty: What the Future Holds	<i>Francis W. Price Jr., MD</i>
8:47 AM	Advances in Deep Anterior Lamellar Keratoplasty: Don't Burst the Bubble	<i>Rajesh Fogla, MD, FRCS</i>
8:57 AM	Advances in Femtosecond-Assisted Keratoplasty: Is It Worthwhile?	<i>Marjan Farid, MD</i>
9:07 AM	Therapeutic Keratoplasty: Tips for Success	<i>Clara C. Chan, MD</i>
9:17 AM	Management of the Failed Graft: Repeat Tissue Transplantation is Better	<i>Deepinder K. Dhaliwal, MD</i>
9:27 AM	Management of the Failed Graft: Counterpoint – Keratoprosthesis is Better	<i>Victor L. Perez, MD</i>
9:37 AM	Castroviejo Lecture	
9:37 AM	Introduction of the Castroviejo Lecturer	<i>James P. McCulley, MD, FACS, FRCOPHTH</i>
9:39 AM	Castroviejo Lecture: The Evolution of Lamellar Keratoplasty	<i>Edward J. Holland, MD</i>
10:11 AM	Conclusion	<i>William Barry Lee, MD</i>
10:15 AM	End of Session	

EyeWorld

CME Education

New Orleans 2013

This activity has been approved for
AMA PRA Category 1 Credit™

Register Now

Saturday, November 16

Incorporating Advanced Tear Film Testing into the Point of Care to Drive Evidence-Based Dry Eye and Red Eye Treatment Protocols

Astor Crowne Plaza (739 Canal Street) – Grand Ballroom (2nd Floor)

6:30 – 7:00 AM Registration (and breakfast)
7:00 – 8:00 AM Program

Program Chair Eric D. Donnenfeld, MD

Supported by unrestricted educational grants from:
Gold Level – TearLab and TearScience
Silver Level – Nicox

Register Now!

www.EyeWorld.org/meetings

Cornea journal app now available



The *Cornea: The Journal of Cornea and External Disease* app is now available for download in the App Store. Downloading the app is free, and access to the full text content is included in your membership. This app is an exciting development for *Cornea*.

Cornea for the iPad delivers the full contents of each issue, enhanced with the convenience of iPad functionality. With this app, your *Cornea* subscription goes wherever you go.

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- **Easy-to-read, full text articles** that you can share via email or social media
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- **Quick scrolling** through abstract summaries
- **Notification** when a new issue is available
- **Link to www.corneajrnl.com** to view supplemental content, browse the archives, and more **CN**

2014 **ACS**

The 4th Biennial Scientific Meeting

Asia Cornea Society

TAIPEI

11-12 December 2014

Important Dates:

Abstract Submission Opens

On-line Registration Opens

Abstract Submission Closes

Notification of Abstract Review Results

Early-bird Registration Closes

Last Day for Cancellation of Registration with 75% Refund

On-line Registration Closes

December 2, 2013

December 2, 2013

September 01, 2014

September 25, 2014

October 15, 2014

October 15, 2014

November 12, 2014

ASIA
CORNEA
SOCIETY
www.asiacorneasociety.org

**Taipei International
Convention Center**

www.acs2014.tw



NEW ORLEANS

Astor Crowne Plaza Hotel



FALL EDUCATIONAL SYMPOSIUM

Friday, November 15, 2013
8:30 AM–4:30 PM

Register Today

www.CorneaSociety.org

www.RestoreSight.org



Cornea Society
Advancing the treatment of corneal disease



**EYE BANK
ASSOCIATION
of AMERICA**

Cornea Society presents 2013 Fellowship Educational Summit

For the first time, the Cornea Society is pleased to present the 2013 Fellowship Educational Summit for current cornea fellows in Fort Worth, Texas. The summit, which takes place Oct. 11–13, is designed, in part, to meet needs identi-

fied from a survey taken at the 2012 Fellowship Director's Breakfast in Chicago. The program directors, **William Barry Lee, MD, Nathalie Afshari, 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 **Charles "Chaz" Reilly, 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 management, ocular surface reconstruction, and ocular surface neoplasia will be detailed by **Christopher Rapuano, MD, Bennie Jeng, MD, and Shahzad Mian, MD**. All aspects of complex cataract surgery, IOL management, and premium IOLs will be addressed by **Terry Kim, 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, round tables, 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 grant and donation of the use of wet lab facilities received from Alcon Laboratories Inc. in support of this program. Additional educational grants in support of the program are being sought. **CN**



ASCRS·ASOA SYMPOSIUM & CONGRESS 2014 APRIL 25-29 BOSTON

Additional Programming

Cornea Day
ASCRS Glaucoma Day
ASOA Workshops
Technicians & Nurses Program



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to the Anterior Segment Specialist
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2014 CORNEA DAY

Sponsored by the Cornea Society and ASCRS

Friday, April 25
Boston Convention & Exhibition Center

Register Today!
www.CorneaDay.org



"Cornea Day is an excellent overview of corneal innovations and challenges in anterior segment surgery and disease management."

Program Outline (Subject to Change)
8:00 AM–4:30 PM

- Current Management of External Ocular Infections: What Works, What Doesn't & What Might
- Surgical Pearls in Corneal Surgery
- Refractive Surgery Success: Screening, Surgery & Beyond
- Recent Advances in Cataract Surgery for the Corneal Surgeon

Planning Committee

Terry Kim, MD Planning Committee Co-Chair
Donald TH Tan, FRCS Planning Committee Co-Chair

Natalie Afshari, MD
Richard Davidson, MD
John Hovanesian, MD
Francis Mah, MD
Christopher Starr, MD
Christopher Rapuano, MD
Elmer Tu, MD
Sonia Yoo, MD

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



WORLD CORNEA CONGRESS VII

Sponsored by the Cornea Society

APRIL 15–17, 2015

Immediately prior to the annual ASCRS•ASOA
Symposium & Congress, April 18–21

SAN DIEGO

Sneak preview: The Asia Cornea Society Infectious Keratitis Study

The Asia Cornea Society Infectious Keratitis Study (ACSIKS) is a multinational, prospective, observational study on all infectious keratitis cases over a one-year period involving 12 Study Centers across eight major Asian countries. There are two Study Centers in China and India, three in Japan, and one each in Korea, Taiwan, Thailand, Philippines, and Singapore, with some Study Centers coordinating cases accrued from more than one participating institution. The largest study of its kind to date, ACSIKS was conceptualized with the ultimate objective of improved strategies for the prevention and treatment of infectious keratitis, a significant cause of corneal morbidity and corneal blindness in Asia.

Preliminary data from a total of 5,843 cases recruited from 26 ACSIKS participating hospitals and eye departments suggest that both fungal and bacterial infections remain the main causes of infectious keratitis. Detailed analyses upon conclusion of the study will enhance existing knowledge and information regarding risk factors, organisms and microbial resistance relating to infectious keratitis for better clinical management in different types of microbial infection and disease causation.

Plans to expand the study to include more Asian countries or sites, including Vietnam, Indonesia, Hong Kong, and New Delhi, are in the pipeline. Also in discussion are further microbiological studies involving microbial isolates collected at the various Study Centers. **CN**

**The Cornea Society Business Meeting
will take place on Friday, November 15,
at the Astor Crowne Plaza Hotel during
the Cornea Society EBAA Fall
Educational Symposium.**

All members are invited to attend.

Submissions Open Summer 2014

www.CorneaSociety.org



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 pruritis, 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.

Revised: May 2013

U.S. Patent 6,114,319

Manufactured For:

Alcon[®]
a Novartis company

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Fort Worth, Texas 76134 USA
1-800-757-9195
Manufactured By:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134 USA
or
Catalent Pharma Solutions
Woodstock, IL 60098

If only you could predict how ocular inflammation will behave.

DUREZOL® Emulsion has head-to-head data vs prednisolone acetate in patients with endogenous anterior uveitis.¹



Scan the QR code with your smartphone or log on to www.inflammationhappens.com to see the results for yourself.



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.



DUREZOL®
(difluprednate ophthalmic emulsion) 0.05%

The results you want. The relief they need.

Alcon®
a Novartis company

Reference: 1. DUREZOL® Emulsion package insert.

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